# NEW FORCES YET UNDETERMINED: THE CHALLENGE OF BIODEFENSE

by

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ABSTRACT

This dissertation finds that the full implementation of the traditional security approaches of prevention, deterrence and defense would not be effective at protecting the United States from a catastrophic biological attack. The traditional approaches would not merely fail but would be counterproductive. Most of the relevant literature – in both the policy and academic worlds – urges the application of traditional strategies to combat the risk of catastrophic biological attack.

The traditional strategies are undercut by two broad changes in the strategic environment: 21st century biotechnologies and the emergence of serious non-state adversaries. This dissertation proposes refinements to the traditional strategies of prevention, deterrence, and defense. Prevention seeks to stop an adversary or a potential adversary from acquiring a capability that could be used to decisive effect in an attack. Deterrence seeks to dissuade an adversary from launching an attack by making it plain in advance that the costs would significantly outweigh the benefits. Defense is protecting against an adversary's attack so as to minimize its effects.

Traditional prevention strategy should shift from emphasizing export controls and inspections to norm-building. It should use international technical elites to build and enforce norms. These strengthened norms would, in turn, strengthen existing prohibitions. Traditional deterrence strategies should shift from post-attack retaliation to a declaratory strategy more tailored to the biological threat, underscoring the risk of failure for a terrorist group and the resulting exposure and destruction of their key operational assets.

Defense must strengthen both traditional defense and medical response. Traditional defense of the homeland would be overwhelmed by the greater scale, speed and technical complexity of a catastrophic biological attack. There would be a new requirement for strategic decisions, as well as a need for federal supplements to state and local tactical and logistical capabilities. The medical countermeasure strategy needs both substantive and structural improvements. Substantively, it needs a continuum of activities seeking to exploit the defensive potential of new technologies, even as adversaries may exploit their offensive potential. The structure that would be most useful would be an international scientific exchange, where the additional technical and fiscal contributions would likely speed needed progress.

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**New Forces Yet Undetermined: The Challenge of Biodefense**

Carol R. Kuntz[1]

*Table of Contents*



[1] The views expressed in this dissertation represent the personal opinion of the author and not the position of the United States Department of Defense or any of its components. The author is a civil service employee of the US Department of Defense.

*[T]he new American [born since 1900]—the child of incalculable coal-power, chemical power, electric power, and radiating energy, as well as of new forces yet undetermined—must be a sort of God compared with any former creation of nature. At the rate of progress since 1800, every American who lived into the year 2000 would know how to control unlimited power.*

*--Henry Adams, 1918*[2]

[2] The phrase "new forces yet undetermined" used in the title of this dissertation is from Henry Adams, *The Education of Henry Adams: An Autobiography* (Boston: Houghton Mifflin Company, 1918), page 496. Adams was insightful, as always, but was certainly wrong at least in his view that Americans would uniquely wield this "unlimited power."

# Chapter 1

## Overview of the Dissertation

This dissertation assesses whether the full implementation of the traditional security approaches of prevention, deterrence and defense could be effective at protecting the United States from a catastrophic biological attack. Virtually all the relevant literature urges redoubled efforts to implement traditional approaches, often generalizing from related but critically different security challenges.

The dissertation finds that the traditional strategies would not work effectively in the case of catastrophic biological attack and indeed would likely prove to be counterproductive. The traditional strategies are undercut by two broad changes in the strategic environment: 21st century biotechnologies and the emergence of serious non-state adversaries. The dissertation proposes refinements to the traditional strategies.

The dissertation is organized by these traditional strategies – prevention, deterrence, and defense. These are the three basic approaches that can be used to deal with any emerging threat to security. Prevention seeks to stop an adversary or a potential adversary from acquiring a capability that could be used to decisive effect in an attack. Deterrence seeks to dissuade an adversary from launching an attack by making it plain in advance that the costs would significantly outweigh the benefits. Defense is protecting against an adversary's attack so as to minimize its effects.

*Significance of Question*

Most writers on the issue of biodefense urge redoubled efforts to implement traditional strategies, with more liberal analysts emphasizing traditional prevention strategies and more realist analysts emphasizing traditional defense strategies. Liberals and realists are the traditional protagonists in the study and practice of foreign policy. Liberals generally believe that conflict grows out of misunderstanding and that cooperation often can find an outcome acceptable to all parties. Realists generally believe that outcomes are determined by relative power.

In the case of catastrophic biological attack, liberal analysts tend to argue that a non-state actor probably could not launch a catastrophic attack in the near future. They are troubled by growing US government programs to strengthen defenses against a biological attack. They fear the defensive programs will increase the risk of a biological attack because the programs will weaken non-proliferation norms, fuel defensive arms races and make the pathogens easier to obtain by proliferating them through many more government laboratories. They instead urge the implementation of prevention strategies with inspections and export controls similar to those used in various existing arms control regimes.[3]

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[3] For example, Benjamin Friedman, "Homeland Security," *Foreign Policy,* No. 149 (Jul – Aug, 2005) pages 22-29; Milton Leitenberg, "Assessing the Biological Weapons and Bioterrorism Threat," Strategic Studies Institute, US Army War College, August 2005; Hillel W. Cohen, Robert M. Gould and Victor W. Sidel, "The Pitfalls of Bioterrorism Preparedness: the Anthrax and Smallpox Experiences," *American Journal of Public Health,* 2004 October; 94(10): 1667-1671. Elisa D. Harris, "Bioweapons Treaty: Still a Good Idea," *Christian Science Monitor,* dated 08/24/2001, Center for International and Security Studies at Maryland website (http://www.cissm.umd.edu/papers/display accessed 2/14/2008). Andrew Lawler, " Biosafety: Boston Weighs a Ban on Biodefense Studies," *Science,* 30 April 2004, Vol 304, no. 5671, 665. Even some realists appear to doubt that a catastrophic attack is within at least the current capability of terrorist groups. See Barry R. Posen, "The Struggle Against Terrorism: Grand Strategy, Strategy, and Tactics," *International Security*, Volume 26, Number 3 (Winter 2001/02), pages 39-55; see page 41: "The ability to make chemical agents and biological poisons is more widespread than ever, through turning the basic ingredients into useful weapons and delivering them effectively on a large scale and thus far not proven easy for small clandestine groups."

Realists fear a catastrophic attack by a non-state actor, pointing to the broad diffusion of technologies needed to construct such a capability. They doubt the efficacy of prevention strategies in light of this diffusion and hence urge strengthened defensive programs, believing that effective defenses might deter an attack by reducing its benefits to an attacker. These authors warn that hundreds of thousands of innocent civilians could be vulnerable in a catastrophic biological attack. They are deeply troubled by the extent to which biodefense is offense dominant, with the attacker being favored by a significant margin over the defender.[4] Theorists have warned that offense dominance creates incentives for wars of preemption, arms races and other destabilizing behaviors.[5] In short, both liberals and realists warn of dire consequences, but have essentially completely different assessments of the core problem and the most promising solution.

These two different assessments probably turn most fundamentally on another critical insight – the fundamental role played by the spiral model or the deterrence model as an explanation of basic cause and effect in international relations.[6] Spiral model effects can occur when a state takes measures it judges necessary to strengthen its defenses. Other states, though, often cannot distinguish between measures that have defensive as opposed to offensive effects. These other states, confronted by measures that could be interpreted as offensive, in turn judge that they must take measures to strengthen their defenses, continuing the spiral of military preparations and sometimes leading to defensive arms races, miscalculation and war. This series

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[4] For example, Richard Danzig, "Catastrophic Bioterrorism – What is to be Done?" Center for Technology and National Security Policy. National Defense University. August 2003. Richard Danzig and Pamela B. Berkowsky, "Why Should We Be Concerned About Biological Warfare?" in Joshua Lederberg, ed., *Biological Weapons: Limiting the Threat"* (Cambridge, MA: The MIT Press, 1999).

[5]Robert Jervis, "Cooperation Under the Security Dilemma," *World Politics*, Vol 30, No. 2. (Jan., 1978) , pp.167-214.

[6] Jervis, "Cooperation under the Security Dilemma," This phenomena is called the "security dilemma: many of the means by which a state tries to increase its security decrease the security of others."

of reasonable calculations by basically status quo powers can lead to conflicts that neither sought and each would have avoided if their security fears could have been alleviated through more benign means. In the biological case, the US defensive program may be interpreted by other states to demonstrate US doubts that the non-proliferation norms will prevent a biological attack and hence increase the doubts of other states.

Realists generally believe the dominant explanation of international relations is the deterrence model. If states see a significant benefit and little risk from an attack, they may be tempted to launch that attack. Hence, policy efforts must focus on reducing the benefit and increasing the risks to a potential adversary. A core objective of this strategy must be deterring potential adversaries through demonstrating strength and resolve.

This classic division between the concerns of the spiral model and the deterrence model can be seen in liberal and realist explanations of the biodefense threat. Generally, there is an unavoidable tension between avoiding spiral model effects and strengthening deterrence effects. The spiral model and the deterrence model each are focused on their audiences of principal concern. Generally, the audience is the same – other nation-states. An interesting and possibly unique element of the catastrophic biological attack problem is that the audiences are different – the principal sources of an attack are serious non-state adversaries, while the principal sources of unhelpful spiral model effects are other status quo states. The posited peaceful tendencies of status quo states are reinforced by the reality that the United States has a reasonably effective deterrent against an overt state-launched catastrophic biological attack. The refinements to the traditional strategies outlined here seek to exploit this dichotomy – complicating acquisition and use by a non-state adversary, while working with other status quo states to strengthen the full range of strategies against this shared threat.

*Structure of Sections*

Despite their many advocates, these traditional approaches of prevention, deterrence, and defense generally have been poorly specified. This dissertation specifies these traditional strategies. It outlines the enabling conditions that were necessary to make these approaches work in the past. For both of these tasks, the dissertation uses historical case work, relying on an analysis of political and institutional factors to help interpret the results of those cases. The dissertation then considers the extent to which the enabling conditions are present today or expected in the near-term in the biological area given two significant changes in independent variables – 21st century biotechnologies and the rise of serious non-state adversaries. Where the enabling conditions are not expected to be present, the dissertation recommends refinements to repair the traditional strategy.

The dissertation is organized into three broad sections – prevention, deterrence, and defense. Prevention seeks to stop an adversary or a potential adversary from acquiring a capability that could be used to decisive effect in an attack. The prevention section has one chapter on each of the four tools used in traditional prevention strategies: (1) export controls; (2) peaceful use limitations; (3) norms, sanctions and benefits; and (4) prohibitions. Deterrence seeks to dissuade an adversary from launching an attack by making it plain in advance that the costs will significantly outweigh the benefits. The deterrence chapter demonstrates the weakness of Cold War-style deterrence (post-attack retaliation) when applied to non-state actors and proposes an alternative deterrence strategy tailored to catastrophic biological attack by a non-state actor.

Defense is protecting against an adversary's attack so as to minimize its effects. The defense section has two parts. The first part, which consists of four chapters, outlines traditional defense of the US homeland. It then assesses the extent to which these traditional defense methods would be overwhelmed in any catastrophic terrorist attack because of the greater scale, speed and technical complexity of such an attack. It focuses on the need for swift strategic decisions in a catastrophic biological attack and develops proposed decision tools to enable officials to make such decisions on the necessary timeline. The second part, which consists of two chapters, discusses the medical elements unique to responding to a catastrophic biological attack, particularly the medical countermeasure strategy and public health response.

In each of the sections, the dissertation finds that the application of traditional strategies to the challenge of biological attack would not merely fail but would prove counterproductive. The traditional approaches ultimately would be defeated by a changed world. It is a world still organized by nation-states but one with a much more diffuse international distribution of technical excellence and one where important non-state actors – with both economic and security ambitions – constrain some state choices. The following findings are distilled from the longer, supporting chapters. The concluding chapter restates these findings and then considers their possible broader application in two areas: in other emerging technologies, like the biotechnologies, where technological advances are fueled by advances originating in the civilian sector as opposed to the security sector; and in other forms of catastrophic terrorism.

*Prevention*

Prevention seeks to stop an adversary or a potential adversary from acquiring a capability that could be used to decisive effect in an attack. The traditional prevention strategy combines

four, mutually-supportive tools: (1) export controls; (2) peaceful use limitations; (3) norms, sanctions and benefits; and (4) prohibitions. Export controls can prevent or at least slow the diffusion of worrisome technology. Inspections can assure peaceful use of worrisome technology. Norms define good behavior so worrisome behaviors are more noticeable and can be shamed or punished. Prohibitions are particularly useful if coupled with effective inspections that can assure others are not creating threatening capabilities and hence reduce spiral model incentives.

*Export Controls*

Export controls can be an effective tool to prevent the diffusion of dangerous technology. Effective export controls are possible if worrisome technology has not significantly diffused beyond states that share a political desire to control it. Effective export controls are vastly easier to enforce if the entry costs to the new technology are relatively high. Export controls work best when states are the most significant actors.

Many post-World War II supplier regimes – including the Coordinating Committee for Multilateral Export Controls (CoCom), the Nuclear Supplier's Group, and the Australia Group – demonstrate the potential for effective export controls as long as the technology has not diffused beyond states that share a political desire to control it. The political agreement of the technically-ascendant Western states to counter the Soviet threat in the early decades of the Cold War made CoCom a useful if imperfect tool to control technology diffusion. Two things eventually changed with the passage of time: the political agreement among the Western states weakened with the easing of the Cold War threat from the Soviet Union, and the extent to which the Western states were technically-ascendant and hence effectively controlled access to the

relevant technology was reduced. As these two changes altered the broader context, the relative effectiveness of the post-World War II CoCom export-control regime similarly eased. CoCom was replaced by the vastly less effective Wassenaar arrangement in 1996.

High entry costs – such as characterized nuclear technology in the immediate post-World War II period – slow technology diffusion and facilitate controls. Low entry costs – technical or fiscal – undercut the effectiveness of export controls, as the struggles in the 1990s over computer encryption technology illustrate. Implementation of export controls is vastly complicated by the emergence of significant non-state actors – whether economic or terrorist. Multi-national corporations often can readily move research and assets between corporate labs in different countries. They often do so based on small differences in the relative favorability of host business climates, an ability that can render unilateral control efforts not merely ineffective but counterproductive. Terrorist groups – whether domestic or foreign – often can elude entirely the state-centered, border-focus of traditional export controls, either because basic materials are available within most states or they can be acquired through the pretense of legitimate business.

*Inspections*

Inspections can assure that worrisome technology is only used for peaceful purposes. This assurance can strengthen related norms and prohibitions because they assure countries that another state will not benefit from a military capability they have foresworn.

Inspections to assure enforcement of peaceful use limitations require meaningful technical differences between military and civilian programs. Inspections also require confidence that states will self-declare program sites for inspection and that these self-declarations will be reasonably accurate because of the deterrent effect of the well-known

technical ability of other states or the international community to remotely identify likely program sites for challenge inspections. The technical ability to remotely identify program sites is also critical to identify the facilities of non-state actors. The importance of these characteristics can be seen in the early successes of the International Atomic Energy Agency (IAEA). The significant difficulties in the absence of these characteristics can be seen in the debates about chemical and biological inspection regimes.

*Norms, Sanctions and Benefits*

Norms can define good behaviors, thereby reducing the incidence of worrisome behaviors and making continued worrisome behaviors more noticeable and therefore more easily shamed or punished. International technical elites are often a promising place to build and enforce norms, particularly when the objective of the norm is consistent with the values of the technical elite. Observance of norms can be strengthened through the use of sanctions or benefits. Sanctions work best in the national context or in the international context for issues perceived to be non-zero sum. Sanctions are more difficult to make work in issues perceived to be zero-sum, like security in the anarchic international security environment. Benefits often work best as an inducement to observe norms in the security realm. Norms can be violated and still be useful as long as they play a meaningful culling role: sorting problematic and potentially dangerous cases from standard cases. This culling should reduce the number of potentially dangerous cases to a number that can be more thoroughly examined through targeted diplomatic, law enforcement or intelligence assets.

The potential role of international technical elites can be seen in post-World War II institution building in Europe, where central bankers and financiers facilitated the construction of the European Union and, eventually, the euro zone, to advance their own norms of the relative

importance of orderly markets. The Ansilomar conference that established norms for recombinant DNA research in the 1970s similarly illustrates the potential usefulness of technical elites, particularly when the goal of the norms is consistent with the core values of the technical elite.

*Prohibitions*

Prohibitions, particularly if coupled with effective confidence-building measures, can reduce spiral model tendencies. They can yield more stable security outcomes at lower costs and force levels than could have been otherwise achieved. Confidence-building measures have often been inspections to assure peaceful-use of worrisome technology.[7] Such inspections have been useful for nuclear weapons under the IAEA, as well as conventional and nuclear forces under treaty regimes like the Conventional Forces in Europe treaty and the START treaties. Prohibitions are not, though, invariably a boon to peace and security. Poorly crafted prohibitions – particularly if the benefits of cheating are significant, if they principally accrue to the offense, and if verification or transparency is poor – could worsen spiral model effects and cause deterrence failures.[8]

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[7] For a discussion of these dynamics, see Robert Jervis, *Perception and Misperception in International Politics* (Princeton, NJ: Princeton University Press, 1976), particularly chapter 3, "Deterrence, the Spiral Model and Intentions of the Adversary." Treaties in the early 20th century include the ill-fated Kellogg-Briand Pact of 1928 and the Washington Naval Treaty of 1922. The period also includes the Geneva Protocol on chemical and biological weapons in 1925. Cold War and post-Cold War treaties – easily the most numerous -- include treaties on strategic nuclear weapons (SALT I & II, START and SORT), intermediate-range nuclear weapons (1987), conventional weapons in Europe (1992), nuclear weapon-proliferation (1957 creation of the IAEA and the 1968 agreement of the Nuclear Non-Proliferation Treaty) and the biological and chemical weapon conventions (1972 and 1993). These treaties were all motivated by a desire to better manage spiral model dynamics and the desire to achieve a stable force balance at lower cost. The only outlier arms control treaty is the 1997 Land Mines Treaty (of which the United States is not a signatory) which seems motivated by pure humanitarian concerns, more similar to the motivation for some of the initial 11th and 12th century agreements on basic norms for the conduct of war and the treatment of non-combatants and prisoners. Author interviews with former government arms control experts.

[8] This set of assertions is worthy of a few good dissertations and books in its own right. The complicated dynamics are probably best considered in the Jervis chapter cited in the previous footnote (Chapter 3 of *Perception and Misperception*) and in the classic book on the interwar period, Edward Hallett Carr, *The Twenty Years' Crisis, 1919-1939* (London: Macmillan and Company, 1939).

Liberals tend to assume that spiral model effects are dominant, while realists tend to assume that deterrence model effects are dominant. Most liberals and realists believe, however, that both models operate and can be found in history: World War I is generally considered a spiral model failure, while World War II is generally considered a deterrence failure. The intentions (not the capabilities) of the potential adversary are considered the single most significant factor in determining which model of cause and effect applies.[9] Thus, most analysts focus on the dyad or bilateral relationship between the two states of interest and strive to deduce their intentions. More complex analyses examine the dyads among multiple states and the interaction effects of these dyads on more complex arrangements like alliance formation, balancing behaviors or band-wagoning among nation-states. The literature on the catastrophic biological attack problem is sharply divided between those focused on minimizing spiral model effects and those focused on strengthening deterrence effects.

*Likely Presence of Enabling Conditions*

This dissertation finds that the enabling conditions needed to make the traditional prevention strategy effective would not be present in the case of biodefense. The traditional strategy is undercut by technical characteristics unique to 21st century biotechnologies, including its extensive diffusion and the emergence of serious non-state adversaries. Implementation of the classic prevention strategy would not merely fail, but would be counterproductive. This assessment is at odds with most of the literature, which assumes that the classic prevention tools should be applied to the biological case and would yield meaningful security benefits.

[9] This is Jervis's formulation, still considered the seminal distillation of concepts that appear throughout writings on international relations. Jervis, *Perception and Misperception.*

Export controls would be undercut by the diffusion of technology, lack of political consensus on controls, and emergence of significant non-state actors, both economic and security, with interest and expertise in the biotechnologies. Knowledge and materials needed for catastrophic biological weapons attack are widely diffused abroad. Entry costs for biological weapons are low (defined in terms of both costs and technical knowledge).

Inspections to enforce peaceful use limitations would not work because there are no meaningful technical distinctions between a civilian and military program in the general pre-attack stage. They are further undercut because there would be no reliable external indicators of a biological program site, to check the declarations of a state actor or to discover the facilities of a non-state actor.

Lack of effective export controls or inspections undercuts the effectiveness of norms and prohibitions that already exist in the case of biological weapons. The lack of meaningful confidence-building measures raises reasonable doubts about whether the norms and prohibitions are being observed. These reasonable doubts can fuel spiral model dynamics, where countries judge they must take reasonable defensive measures but other nations interpret these measures as offensive and hence are spurred to take ever more significant actions.

*Recommendations for Refinements*

Traditional export controls and inspections to assure peaceful use should not be pursued in the biological case because of the low probability they would have any beneficial effect. Work should focus instead on catalyzing efforts by the relevant international technical elite – the life sciences research community – to develop and implement meaningful international norms on biosafety, biosecurity and worrisome dual use research. Establishing norms (which most people want to observe) helps reduce ambiguous behaviors and this culling helps identify remaining

worrisome behaviors. Diplomatic, investigative, or intelligence assets should be used to further investigate these remaining worrisome cases.

While there are many articles that call for better control of access to dangerous pathogens[10] none are very specific about the mechanism by which this should be achieved and none warn sufficiently of the importance that the norms be established in the international as opposed to the national context. This dissertation validates the extreme importance of strengthened norms but emphasizes this importance because of the fatal weaknesses of the traditional strategies in the biotechnologies case. Drawing on functionalist case studies and literature, it identifies the international life sciences community as the most promising venue for the construction and adoption of these norms. After considering the relative success of sanctions and benefits to strengthen norms, it urges that the adoption of norms be catalyzed by the prospect of benefits. It identifies a potential source of these benefits – participation in an international scientific exchange to develop defensive medical countermeasures. Current US policy instead focuses on constructing a national unilateral system of norms enforced by sanctions. This US policy provides a limited security benefit, but imposes broader security, economic and technological costs. An international system of norms would be vastly better from a security, economic and technological point of view for both the United States in particular and international security in general.

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[10]See, for example, Christopher F. Chyba, "Toward Biological Security," *Foreign Affairs,* May/Jun 2002, Vol 81 Issue 3, p. 122-136, see page 127: "....Washington should act to improve international control of dangerous pathogens, either within the BWC framework (perhaps by supporting the proposal of a like-minded ally) or in a new forum." See also Gregory Koblentz, "Pathogens as Weapons: The International Security Implications of Biological Warfare," *International Security,* Vol 28, No 3 (Winter 2003/04), pages 84-122: see page 121, "[T]he barrier to the acquisition of biological weapons should be raised by limiting access to dangerous pathogens, techniques, and research results applicable to the development of biological weapons." Reynolds M. Salerno and Lauren T. Hickok, "Strengthening Bioterrorism Prevention: Global Biological Materials Management," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science,* Jun 2007, Vol 5, No. 2: 107-116, see page 107: "Global biological materials management, which would focus on identifying and protecting those biological materials at the greatest risk of being used maliciously, is one potential solution."

In a case like catastrophic biological attack, the classic argument between realists and liberals about whether spiral model or deterrence model effects dominate seems odd. Yet this is precisely the argument that pervades most of the literature on catastrophic biological attack.[11] This dissertation argues that there are enough actors with enough different interests that both effects are likely to be present in the broad problem of catastrophic biological attack. Spiral model effects seem most dangerous on other status quo states. Preserving and strengthening the international norm against biological weapons acquisition and use provides valuable benefits, as long as no significant policy-maker forgets that the norm is not verifiable in any meaningful sense. Deterrence effects seem most significant with non-state actors, who, because of the characteristics of the biotechnologies, could launch a catastrophic biological attack. This dissertation urges that policy should seek to minimize spiral model effects on other status quo states, but strengthen deterrence and defense against non-state actors.

Prevention remains a worthy goal but, despite their many advocates, classic strategies would fail. There is a clear alignment between the interests of the technical elite in the life sciences and the broader prevention objective. The technical elite in the life sciences community should be encouraged to develop and implement international norms on biosafety, biosecurity and worrisome dual use research even as policy-makers should manage programs so as to minimize spiral model effects on status quo states, but strengthen deterrence on the non-state actors of greatest concern.

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[11]Milton Leitenberg, "Biological Weapons in the Twentieth Century: A Review and Analysis," *Critical Reviews in Microbiology,* 27(4): 267-320 (2001). Milton Leitenberg, "Assessing the Biological Weapons and Bioterrorism Threat."

*Deterrence*

Deterrence seeks to dissuade an adversary from launching an attack by making it plain in advance that the costs will significantly outweigh the benefits. Deterrence, of different sorts, always has been part of conflict. Deterrence of a strategic nuclear exchange between the United States and the Soviet Union during the Cold War was based on the threat of severe retaliation after a successful attack. Strategic deterrence during the Cold War threatened to swiftly and reflexively destroy much of the attacker's civilian population in response to a successful nuclear first strike.

This declaratory policy with its threat to punish in retaliation was perceived to have worked with acceptable confidence during the Cold War because of its persistent plausibility: the attacker could be identified and located, and the defender would retain sufficient capabilities after absorbing the attack to implement a massive retaliatory blow. And, while largely unremarked upon at the time, the attacker on balance preferred to avoid his own demise and his state's devastation. [12]

A strategic nuclear exchange never occurred between the United States and the Soviet Union during the Cold War. The threat of post-attack retaliation appears to have worked, although the extent to which the credit goes to US declaratory policy, as opposed to luck or other factors, remains a point of debate for historians and political scientists.[13] Deterrence is a worthy but invariably uncertain enterprise.

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[12] Steven E. Miller, ed., *Strategy and Nuclear Deterrence: An International Security Reader* (Princeton: Princeton University Press, 1984).

[13] Ward Wilson, "The Myth of Nuclear Deterrence," *Nonproliferation Review,* Vol 15, No. 3, November 2008, 1746-1766.

*Likely Presence of Enabling Conditions*

The threat of post-attack retaliation is not a solid basis for deterrence against a non-state adversary contemplating a catastrophic biological attack. The limits on post-attack retaliation grow out of broad concerns that the threat of retaliation is weak against groups that could not be identified and located and may not, on balance, prefer to avoid their own devastation.[14] A determined and talented non-state actor probably could develop a biological weapons capability while generating few if any external indicators that could be used to locate the weapons facility.[15] Destruction of the leadership team of the attacking organization may not matter – either to them or to the long-term health of the terrorist organization.[16] Post-attack retaliation would not merely fail to deter a non-state adversary but would likely prove counterproductive. The terrorism literature warns that it is precisely such undifferentiated retaliation that proves a boon to the recruiting efforts of most terrorist groups.[17]

Post-attack retaliation is a more potent threat to a nation-state. Post-attack retaliation probably would be sufficient to deter an overt biological attack by a nation-state. There are two remaining concerns: deterring covert assistance from a nation-state to a non-state actor or deterring a covert attack by a nation-state itself. These risks could be reduced through

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[14] For an example from the policy world, see The White House, The National Security Strategy, March 2006, White House web-site (http://www.whitehouse.gov/nsc/nss/2006 accessed 3/29/08), see page 8: "The United States can no longer simply rely on deterrence to keep the terrorists at bay or defensive measures to thwart them at the last moment." For an academic assessment, see Gregory D. Koblentz, *Pathogens as Weapons: The International Security Implications of Biological Warfare* (PhD diss., Massachusetts Institute of Technology, 2004), see page 84: "Biological weapons undermine deterrence as a security strategy…"

[15] Donald A. Henderson, MD, MPH, e-mail communication with the author, February 7, 2008. See, also, Koblentz, *Pathogens as Weapons*, see page 89.

[16] Historical case studies show a mixed record for decapitation as a counterrorism strategy. Robert J. Art and Louise Richardson, eds., *Democracy and Counterterrorism: Lessons from the Past* (Washington, DC: *The United States Institute of Peace, 2007)* pages 590-591.

[17] Art and Richardson, eds., *Democracy and Counterterrorism,* see page 571: "Terrorist strategists have long been aware of the value of provoking governmental overreactions that play back into the terrorists' hands."

declaratory policy and strengthened attribution capabilities but probably never eliminated entirely.

*Recommendations for Refinements*

Narrowing deterrence to only post-attack retaliation is fueling tremendous despondency in the academic and policy literature about deterring biological attack. Declaratory policy instead should underscore the risk the attack would fail and expose the attackers' valuable operational cells to destruction. Neither the United States government nor the academic literature has articulated a coherent declaratory policy against catastrophic biological attack by a non-state actor.[18] US declaratory policy remains limited to a set of related but not directly germane observations that are largely unhelpful to the problem of deterring a non-state adversary.

This proposed shift from the Cold War's model of post-attack retaliation is significant. In the biological case, the declaratory policy should warn that the attack could fail and in that failure would almost inevitably expose the attackers' most valuable operational assets to destruction. The attacker's operational cells deploying the biological pathogen would very likely be caught by the defender's law enforcement forces, regardless of the ultimate effectiveness of the attack. These operational cells – like the 19 hijackers in the United States who launched the 9/11 attacks – may be the non-state actor's most valuable assets: skilled, loyal operatives successfully concealed in the United States. However the leaders of the terrorist group may feel about their own destiny, they are likely to accept only so much risk that these operational assets would be destroyed in an attack mode with a meaningful risk of complete failure. The terrorist

[18] The most significant exception is suggestions that strengthened defenses would reduce the incentives to attack, a piece of the recommendation here. See, for example, Chyba, "Toward Biological Security."

group may prefer to shift to a different attack mode, with a higher rate of operational success but a lower rate of death in the defender's population.

The biological attack could fail for one of three reasons: (1) the delivery mode fails because the attackers decide to avoid detection by foregoing testing (detection and disruption); (2) the attack would work but the defender effectively defends against its effects (tactical denial); (3) the attack works but fails to secure the attacker's strategic and tactical goals (strategic denial). These three outcomes are plausible, as is the argument that launching the attack would almost certainly expose the operational cells. Unhappily, as has been the focus of most of the rest of the dissertation, a plausible outcome also is that the attack is successful from the attacker's point of view. The declaratory policy cannot pretend that failure for the attacker is inevitable, but it should paint the starkest possible picture of the risk the attacker would be running with its very precious and limited operational assets.

To deter attack, this declaratory policy would require the non-state actor to be "rational". He does not need to be rational in the sense that his objectives or chosen means seem rational to others, but that he pursues them in a way that seeks to maximize the probability of success and reduce the risk of failure to him, as he defines it. Even if the attacker wishes only to inflict pain and suffering on the defender's civilian population, he might rationally assess that the risks of failure in a biological attack were too great and decide to use his operational cells in a different attack mode with a lower risk of complete failure from the perspective of the attacker.

The literature on the motivation and efficacy of terrorism is large and growing. It has three major parts, of which the largest is the "rational terrorist" school – the weak pursue

terrorism because it has proven to be an effective strategy to exact concessions from the strong.[19] A smaller school argues that terrorists are "non-rational" in the sense that they are not seeking strategies to maximize the achievement of specific political or territorial goals. This school argues that terrorism has not been an effective strategy overall and that terrorists are motivated by "non-rational" goals like the affective benefits of belonging to a purpose-filled group.[20] An emerging literature talks about what might be called "situational terrorists." This literature observes that how an issue is defined has a big effect on whether specific terrorist actions can be deterred or pacified through limited concessions.[21] This literature is particularly interesting when considering catastrophic terrorism and the many sub-groups with particular expertise that would be necessary to build a catastrophic biological capability. Targeting some of these sub-groups may be an effective strategy because some sub-groups, like financiers or technical experts, might be much more sensitive to both threats and opportunities than the leaders of the core terrorist group.

Currently, the United States does not have a declaratory policy against non-state adversaries contemplating a catastrophic biological attack. It has made two somewhat relevant observations, but these observations probably hurt overall with the audience of particular interest here. The two observations are: (1) obliquely warning states that the use of unconventional weapons in an otherwise conventional conflict with the United States risks nuclear retaliation;

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[19] Robert A. Pape, "The Strategic Logic of Suicide Terrorism," *American Political Science Review,* Vol. 97, No. 3 August 200, 20:32.

[20] Max Abrahms, "Why Terrorism Does Not Work," *International Security,* Fall 2006, Vol 31, No 2, pages 42-78. Max Abrahms, "What Terrorists Really Want: Terrorist Motives and Counterrorism Strategy," *International Security,* Spring 2008, Vol 32, No 4, pages 78-105.

[21] Robert F. Trager and Dessislava P. Zagorcheva, "Deterring Terrorism: It Can Be Done," *International Security,* Winter 2005/06 Vol 30 No 3, pages 87-123; see page 96: "To produce a large-scale attack, terrorists must constitute a system of actors fulfilling specific functional roles."

and (2) warning domestic political elites of the potential gravity of a catastrophic biological attack by a non-state adversary.

The underlying capacity of the defender to cause the three deterrence outcomes – deterrence through detection and disruption, through tactical denial, and through strategic denial -- should be strengthened. Deterrence through detection and disruption largely relies on intelligence and law enforcement assets, like the technical capacity to observe the testing of aerosol delivery capabilities even in relatively remote parts of the world. Aerosol delivery systems are relatively easy to build but notoriously tricky to optimize and hence, for example, both the early US and Soviet systems found testing to be essential. Deterrence through tactical denial relies on continued improvement to the nation's ability to respond to a biological attack in a timely and effective manner with needed medical countermeasures and supportive care. Deterrence through strategic denial – seeking to assure that the adversary does not achieve the sought political or territorial ambitions -- would be achieved through a variety of tools, including strengthened and updated non-proliferation norms robustly supported by the international community.

Deterrence would be greatly strengthened by shifting declaratory policy from post-attack retaliation to the real risk of failure and the almost inevitable exposure and destruction of key operational assets. This proposed declaratory policy would help with "rational terrorists" and with at least some "situational terrorists." It should neither hurt nor help with "non-rational terrorists." But while worthy, deterrence will remain somewhat weak and uncertain. An attacker may decide they are prepared to risk failure. Risking it, they may well instead succeed, causing unprecedented deaths and strategic reversal for the United States. Deterrence strategy should be

updated and strengthened as suggested here, but its inherent weakness in the case of catastrophic biological attacks must be recognized.

*Defense*

Defense is protecting against an adversary's attack so as to minimize its effects. In traditional defense of the US homeland, state and local governments have taken principal responsibility for responding to the threats that have confronted the homeland -- disasters, accidents and epidemics. This generally has made sense and worked well because two enabling conditions were present. First, the nature of the threats was limited to relatively small disasters, accidents and epidemics whose response could be (and generally was) well-managed by state and local public safety officials, with their inherent ability to get to the scene first, generally high professional skills, and significant local expertise. Second, for the larger disasters or epidemics that inevitably did occur occasionally, the federal government had little unique assistance to offer, particularly in the time-sensitive early phases of the crisis.

*Likely Presence of Enabling Conditions*

Neither of these enabling conditions would be present in a catastrophic biological attack on the homeland. Most disasters and accidents in the homeland have killed fewer than 100 people. Only three episodes in the US homeland have caused more than 10,000 deaths, the number assumed in a catastrophic biological attack.[22] Traditional defense approaches would be overwhelmed by the greater scale, speed and technical complexity of a catastrophic biological

[22]The top three single events in US history causing the greatest number of deaths were the Influenza Epidemic, 1918-1919 (700,000 individuals died); the US Civil War, 1861-1865 (620,000 died); and the Yellow Fever Epidemic, 1878 (20,000 individuals died). All other single events caused less than 10,000 deaths and the numbers drop rapidly. See discussion in Chapter 7.

attack. With the advent of targeted medical countermeasures, there would at least be the prospect that federal expertise and materials could significantly improve the response in the very early hours and days of a possible biological event, long before the federal government generally gets involved in the detailed response to a homeland security event.

The reality that traditional approaches would be overwhelmed creates two problems: (1) additional capabilities are needed to respond effectively to these larger, catastrophic attacks, and (2) there is significant ambiguity in the US federal system about who would be responsible for handling the response to these larger events. This ambiguity complicates the development of the needed additional capabilities and their efficient use in an actual crisis.

*Recommendations for Refinements*

This dissertation makes two specific recommendations: (1) the president should explicitly have responsibility for making the needed strategic decisions to shape the response to a biological event and decision aids should be constructed to assist him; and (2) additional "modular" federal capabilities should be created to supplement state and local capabilities in a catastrophic crisis and a clear and agreed leadership structure, consistent with US federal values, should be created to assure its effective use in a crisis.

An effective response to a catastrophic biological attack would require that complex and highly-contested strategic decisions be made and made quickly. There does not appear to be explicit recognition that these decisions would need to be made, appropriate analytical means to support them, or explicit authority or agreement on who should make them. This situation creates significant risk that in a catastrophic biological attack needed strategic decisions would not be made swiftly enough to be implemented. Traditional defense of the homeland usually

does not require any official to make strategic decisions. The public safety objective is generally unstated but straightforward – maximize lives saved and minimize property damage. This dissertation urges that the president explicitly have responsibility for strategic decisions in a biological event and that an appropriate set of analytical tools be developed to support him.

The dissertation has a lengthy discussion of the type of analytical tools that should be developed. The challenge of decision-making in a catastrophic biological attack has too often been ignored. The focus instead has been on getting accurate data about each diagnosis to enable accurate case management and comprehensive post-event review and assessment. In those cases where the challenge of decision-making has been seriously considered, the posited solution has generally been to get the data about each case more quickly to a central point and then swiftly aggregate it. This dissertation argues that in a possible catastrophic biological attack an alternative approach is needed: robust extrapolations using the limited data available early in the crisis. The extrapolations should be robust in their recognition of what is known (for example, speed of symptoms emerging after exposure for a particular pathogen) and what is not known (for example, maybe it's a catastrophic biological attack or maybe it's just a single, benign case from innocent exposure to an infected animal skin). Given the tight timelines, this absence of a serious debate in the literature and in the policy world about how these decisions would be made analytically and who would make them vastly reduces the probability of an effective response to a catastrophic biological attack.

State and local emergency response is usually effective at the tactical and logistical elements of a response. This dissertation urges the development of "modular" federal capabilities that can appropriately supplement state and local capabilities in a catastrophic event in the homeland. A variety of leadership models, consistent with US federal values, could work

and should be evaluated. The capabilities are described as "modular" because they would not constitute a stand-alone, unique response structure for catastrophic events, but rather would be additional types or increments of capability to supplement existing capabilities. These "modular" federal capabilities make the integrated effort effective given the greater scale, speed and complexity of a catastrophic attack. The needed capabilities for these new "modular" pieces and how they would work with existing state and local assets have not been articulated, much less agreed or implemented between local, state and federal officials. There do not appear to be authorities, agreements or expectations that allow either the president or the governor to lead an integrated set of federal, state and local assets such as would be needed to respond effectively to a catastrophic event.

Much like the United States, most countries put local or regional governments in charge of the initial response to a disaster, accident or epidemic. In unitary governments, these local and regional emergency responders generally work for a national disaster agency. While local staff are expected to respond promptly to the disasters that do emerge – usually fires, floods or earthquakes – the national agency retains clear authority to direct the incident response should it grow unexpectedly in complexity or scope. Even other federal systems have much clearer divisions of responsibility than the US federal system, often, like Germany, with the regional government being responsible for protecting the population in peacetime and the national government being responsible in wartime.

*Medical Aspects of Defense*

A catastrophic biological attack would pose some unique medical challenges. Public health was significantly transformed in the mid-1900s as targeted medical countermeasures

became widely available for the first time. The enabling conditions for an effective public health response in this post-drug age are two-fold: one scientific and one societal. First, the bug must be relatively slow in evolving to defeat the countermeasure; and second, the broader public health infrastructure must be sufficiently committed and coherent that it can provide supportive, ongoing care in an appropriate environment.

Several examples illustrate the interaction effects within and between these scientific and societal factors. The speed with which the bug can defeat the medicine depends on the interaction of two qualities: the ease with which the bug mutates and the range of the medicine's effectiveness. This can be seen in cases where the inherent rate at which the pathogen naturally mutates is very rapid. Influenza, for example, has a genetic structure that facilitates rapid and significant natural mutations that defeat the flu vaccine with such predictability that the vaccine is reformulated annually. Smallpox, in contrast, mutated much more slowly and the traditional smallpox vaccine had a broad range of effectiveness. Hence, the traditional smallpox vaccine remained effective across time and across the globe and was used to successfully eradicate naturally-occurring smallpox. The importance of a robust societal public health infrastructure is illustrated by comparing the ongoing incidence in poorer countries of diseases that are treatable and have been limited or effectively eliminated in more wealthy countries. There are vastly different survival rates for HIV-AIDs in the West as compared to Africa, for example, and there has been a virtual elimination of malaria in the West while it continues to cause death at a significant rate in Africa.

*Likely Presence of Enabling Conditions*

Neither enabling condition would be expected to be present in the case of a catastrophic biological attack. The first enabling condition -- the bug must be relatively slow in evolving to defeat the countermeasure – would be defeated by adversaries exploiting natural mutation or mutation facilitated by 21st century biotechnologies. A characteristic of the biotechnologies is that for the foreseeable future it is expected to be vastly easier to modify a pathogen than to modify the medical countermeasure needed to defeat the new pathogen. This characteristic of the biotechnologies favors the attacker over the defender. A situation where the attacker is favored over the defender is called offense dominant. Offense dominant situations are considered to be highly vulnerable to a host of destabilizing behaviors, including wars of preemption and defensive arms races.

There is valuable research underway and significant progress to report in the development of useful medical countermeasures. Overall, however, the pace and nature of technological progress appears to continue to favor the attacker, not the defender. The evolution of the defensive strategy is poorly aligned with the likely evolution of the threat. Laboratory advances are poorly linked to needed progress in related capabilities, like production capacity. The long-term strategic objective of shifting this area of warfare from offense dominant to defense dominant remains well beyond the reach of the resources applied to this objective.

The second enabling condition – that the broader public health infrastructure must be sufficiently committed and coherent that it can provide supportive, ongoing care in an appropriate environment -- also would not be expected to be met in a catastrophic biological attack. A catastrophic biological attack would stress the medical infrastructure in any country

and, while cross national comparisons are difficult, the United States is probably as well prepared as any other country. There is a broadly held view, though, that the current public health infrastructure in the United States would be overwhelmed by a bioattack of any significant size.[23]

This dissertation argues that the necessary planning for an effective public health response has not been done because of the ambiguity about who would be responsible for executing such a response. This case is similar to, but even worse than, the ambiguity about responsibilities for traditional defense of the homeland. Like the traditional homeland defense challenge, there would be significant ambiguity about who was responsible for responding to a catastrophic attack. First, there is extreme ambiguity among local, state and federal officials about who would be responsible in the US federal system for leading the response to a catastrophic attack. Second, there also is ambiguity among federal departments, including particularly the Departments of Health and Human Services and Homeland Security.

In addition, there is a third source of ambiguity which uniquely complicates planning for the public health response. The third source of ambiguity is that one professional community is worried about and responsible for mitigating the problem of bioattack (the security community) while a different community (the public health community) would need to sacrifice its time, energy and scarce assets to solve the problem. Public health response is a capability largely implemented by state and local public health officials who confront more illness than they can

[23]This view is widely held among those who believe there is any meaningful risk of an attack occurring. See, for example, Thomas V. Inglesby, MD, "Observations from the Top Off Exercise," *Public Health Reports,* 2001 Supplement 2, Volume 116, pages 64 - 68, see page 67: "Not unexpectedly, the logistics of antibiotic distribution proved quite complex....the ensuing local distribution process did not go smoothly." Richard A. Falkenrath, Robert D. Newman, and Bradley A. Thayer, *America's Achilles' Heel: Nuclear, Biological, and Chemical Terrorism and Covert Attack* (Cambridge, Massachusetts: The MIT Press, 1998), see page 311: "...local medical services could easily be overwhelmed after a large attack...."

treat within current and foreseeable assets and understandably don't feel the need to plan against theoretical threats, however potentially devastating. While officials of the federal public health agencies can and have devoted significant efforts to strengthening biodefense response capabilities, there remains a disconnect between their rhetorical calls for greater exertions and the reality that most public health assets in the United States are state and local. Authority is sufficiently diffuse in the national public health system that there really is no one actor who could force the public health community to participate in the type of detailed planning that would be essential to an effective response.

The recommendations in this dissertation seek to align the incentives of various relevant actors -- life science researchers, non-state actors, and public health officials, among others – with broader national and international security interests. Non-state actors contemplating a biological attack need to be deterred or defeated, while states need to be reassured that wars of preemption, arms races or other destabilizing behaviors are not warranted to protect their citizens from the risk of biological attack.

*Recommendations for Refinements*

This dissertation has four broad recommendations, two each for medical countermeasure strategy and for public health response. In each category, one recommendation focuses on the substance and one focuses on the structure needed to enable achievement of the substance. The two recommendations for defensive medical countermeasures urge that: (1) the substance of the strategy should be a continuum of activities focused on providing capabilities over time, as both the likely nature of the threat and of the possible defensive capabilities evolve, focusing on a strategy of stockpiling, and then of rapid adaptation, and then of transformative strategies; and

(2) the institutional structure for pursuing a medical countermeasure strategy should be an international scientific exchange. This strategy would best align incentives and resources, both technical and fiscal, with broader strategic objectives. These strategic objectives include the long-term goal of shifting bioattack from offense-dominant to defense-dominant, as well as minimizing spiral model effects and strengthening deterrence model effects.

The dissertation also makes two recommendations for strengthening the public health response: (1) detailed, integrated planning on how to execute a response to a catastrophic biological attack should be undertaken, with an initial focus on how stockpiled countermeasures could be distributed on the needed timeline; and (2) this planning should be embedded in a forum with legitimacy in the public health community, possibly the international scientific exchange recommended above, to strive to build greater agreement from the bottom up in the public health community on the potential challenge posed by bioattack. This call for integrated planning and technical analyses accepts the diffuse structure of the public health community but attempts to make it work effectively to solve this problem in the near and mid-term.

*Medical Countermeasure Strategies*

The substance of the needed research program for defensive medical countermeasures is very complicated. This dissertation recommends that the program seek to align the evolution of the defensive medical countermeasures with the likely pace of technological advances on the part of the adversary. The substantive content should include a continuum of activities focused on providing capabilities over time, as both the likely nature of the threat and of the possible defensive capabilities advance. Specifically, the chapter urges that a continuum of activities be pursued. On one end of this conceptual continuum would be stockpiled medical

countermeasures against known pathogens. The continuum would progress through rapid adaptation, a strategy that seeks to strengthen the ability to craft a countermeasure tailored to an adversary's modified pathogen after the adversary launched an attack. The end-point of the continuum would be transformative strategies, a category that includes the broad spectrum countermeasures and other revolutionary approaches that rapid advances in the biotechnologies may make possible over time. All the parts of this strategy would need to be pursued simultaneously, although perhaps not with equal emphasis, as some protect against near-term threats and others offer the long-term prospect of eventually diminishing if not effectively blunting the biological threat altogether.

The second recommendation focuses on how to structure such a medical research strategy. The dissertation recommends that a defensive countermeasure program be pursued as part of an international scientific exchange. There could be significant benefits to such an international approach – including reduced spiral model effects and strengthened deterrence model effects. The dissertation's earlier discussion on norms focused on another possible benefit: that the prospect of participating in the scientific exchange could catalyze the broadest possible international adoption of norms on biosafety, biosecurity and worrisome dual use research.

This dissertation's recommendation that the medical countermeasure strategy be pursued in the context of an international scientific exchange appears to be in direct contradiction to emerging US policy. The United States appears to be constructing a national, unilateral system to enforce norms in this area. A national, unilateral system would provide a security benefit but would impose security, economic and technological costs.

The decision about whether to pursue an international program is very complex. It turns on many assumptions, including about the evolution of the relevant technology, assumptions that are not known or cannot be known. There are eight areas of concern. As a presentational device, they are stated as propositions in favor of the proposal but each rests on complicated judgment calls and can be legitimately questioned and rejected. There are eight propositions:

(1) Requiring the adoption of norms for biosafety, biosecurity and worrisome dual use research as the price of admission to an international scientific exchange on defensive medical countermeasures would catalyze the broadest possible international adoption of these norms;

(2) The process of developing and implementing international norms and pursuing a shared defensive medical countermeasure program would cause a broader effect in the relevant technical communities of status quo states, reducing spiral model effects because of the vastly greater – although not necessarily complete – transparency it would create;

(3) Given the global distribution of research excellence in the biotechnologies, creating an international research program is the only strategy that could assure the US defensive medical countermeasure program remains at the cutting edge of technology;

(4) Given the inevitable limitations on national resources and the enormity of the technical challenge, an international scientific exchange would be the only strategy that has any prospect of applying sufficient resources to the challenge of developing a full suite of defensive countermeasures quickly enough that the scientific effort could achieve a core strategic objective -- moving

biodefense from offense dominant to defense dominant in the foreseeable future;

(5) The benefits of secrecy are limited (but not zero) in a defensive medical countermeasure program and these benefits would be expected to go down over time as the program transitions from a strategy of stockpiling (or "one bug, one drug") to a strategy of rapid adaptation;

(6) Strengthening the defensive medical countermeasures available to the United States and to its partners through an international scientific exchange would greatly strengthen deterrence because it would increase the effectiveness and distribution of medical countermeasures;

(7) Because of various characteristics of the technology and the security environment, these norms and the countermeasure program would be best implemented through an informal scientific exchange instead of the institutionalized structure used more traditionally, like the IAEA and the OPCW; and

(8) An historical vulnerability of international agreements – an inappropriate surrender of domestic autonomy – would be avoided in this case and the United States would properly retain and exercise autonomy in pursuing any needed classified medical countermeasure programs and diplomatic, intelligence and law enforcement initiatives.

Clearly some of these propositions strain credulity more than others. Each is discussed in more detail in the chapter on medical countermeasures and the complex and sometimes uncertain pros

and cons are weighed. Taking these considerations together, the dissertation recommends that an international scientific exchange be pursued.

*A Strengthened Public Health Response*

The recommendations on public health strive to overcome the great difficulty in the highly diffuse US public health system of catalyzing appropriately detailed, integrated planning. Experience with public health response in other countries and in the United States, both today and historically, indicates that an effective response is possible but would need to be planned in advance. With some isolated exceptions, this type of detailed planning is not underway. There is probably no way to catalyze the needed planning other than securing broader support from all segments of the highly diffuse public health community.

The dissertation makes two recommendations to strengthen the public health response: (1) detailed, integrated planning on how to execute a response to a catastrophic biological attack should be undertaken, with an initial focus on how stockpiled countermeasures could be distributed on the needed timeline; and (2) this planning should be embedded in a forum with legitimacy in the public health community, possibly the international scientific exchange recommended above, to strive to build greater agreement from the bottom up in the public health community on the potential challenge posed by bioattack.

In addition to all of the normal constraints to change or innovation that organizations face, the challenge would be complicated by the reality that the public health community does not constitute an "organization." It is made up of a community of public health professionals who are employed by local, state or federal organizations with weak ability by any one actor to set shared objectives. The diffuse organizational structure of the public health community

probably requires more of a broad cultural change in favor of greater emphasis on developing capabilities to respond to catastrophic bioattack.

The needed planning would be very different from the strategic decision aids to support decision-making by the president. Those decision aids sought to inform the early, strategic decisions about whether medical countermeasures should be administered and, if so, to which segment of the population. The detailed planning called for here would focus on the tactical and logistical implementation of those decisions. It would, for example, work through the staffing details of how, for example, to set up and staff sites to provide countermeasures quickly enough to all members of a community.

Additional resources almost certainly would be needed to implement the plans, but sound plans have not yet been developed much less implemented to swiftly distribute medical countermeasures. Similarly, detailed, robust technical analyses of how to maximize the technical benefits of non-pharmacological means to slow the spread of an infectious disease – like wearing masks or closing schools – have not been developed and vetted in a process that gives them meaningful standing in the public health community.

*Summary*

The risk of catastrophic biological attack demands significant changes to traditional defense of the homeland. Traditional defense techniques have served the nation well overall. Traditional defense of the homeland challenges – accidents, disasters, and most epidemics – should continue to be handled by state and local emergency responders, consistent with national tradition. When confronted by a catastrophic biological threat, however, these techniques would be overwhelmed. They would be overwhelmed by the new requirement to swiftly make complex

strategic decisions and by the tactical and logistical demands of responding to an attack of this vastly greater scale, speed, and technical complexity.

Needed substantive progress on medical aspects of a response to a catastrophic biological attack can be defined. It has, though, proven remarkably difficult to catalyze for a variety of reasons. Setting the medical aspects in the context of a broader international effort that included significantly strengthened norms might break various logjams that are complicating progress. An international effort would, though, have significant vulnerabilities.

The challenges of updating traditional defense of the US homeland are significant, but surmountable. Unhappily, the same can be said about the challenge confronted by a talented and determined adversary seeking to develop a catastrophic weapons capability. History may record which party stays most tightly focused on their objectives and makes best use of available time and resources.

*Conclusion*

Even as the emerging biotechnologies of the 21st century make plain the mechanism of age-old human diseases, they are making murky indeed the proper security response to the growing risk of catastrophic biological attack. This dissertation argues that the traditional security approach to prevention, deterrence and defense, if applied to this new problem, would not merely fail, but would prove counterproductive. New security approaches must be devised and implemented, as new, not yet fully understood threats emerge.

## Section I

## Prevention

### Overview of the Prevention Section

Prevention strategies seek to stop an adversary or a potential adversary from acquiring a capability that could be used to decisive effect in an attack. Prevention strategies have been used from the dawn of history, with more technically ascendant empires striving to control the craft knowledge that enabled a decisive military advantage. These efforts often worked for at least a short period, enabling military victories or staving off defeat. But these prevention strategies eventually failed in one of two ways: the technology of interest became more widely available (either through diffusion or independent development) or a countermeasure was developed, rendering the controlled technology unimportant.[24]

In the 19th and 20th centuries, and particularly after World War II, these control strategies were supplemented with inspections, norms and prohibitions that worked together to control technology with military uses yet minimize the economic costs of the controls and maximize the benefits to stability. Norms and prohibitions, when strengthened by inspections, transparency, or other confidence-building measures, could minimize spiral model dynamics and enable a stable security equilibrium at a lower and less dangerous force level.

The traditional prevention strategy discussed here is the post-World War II effort that combines four, often mutually-supportive tools: (1) export controls; (2) peaceful use limitations; (3) norms, sanctions and benefits; and (4) prohibitions. Export controls can prevent or at least

[24] Ernest Volkman, *Science Goes to War: The Search for the Ultimate Weapon, from Greek Fire to Star Wars* (New York: John Wiley & Sons, Inc, 2002). Stephen Peter Rosen, *Innovation and the Modern Military: Winning the Next War* (Ithaca, NY: Cornell University Press, 1991).

slow the diffusion of worrisome technology. Inspections can assure peaceful use of worrisome technology. Norms can define good behavior so worrisome behaviors are more noticeable and can be shamed or punished. Sanctions or benefits can encourage the observance of norms. Prohibitions can be useful if coupled with effective inspections or other verification measures that can assure others are not creating threatening capabilities and hence reduce spiral model incentives.

*Needed Enabling Conditions*

Each of these tools requires certain enabling conditions to work effectively. These enabling conditions and the case studies from which they are derived are outlined in the detailed chapters on each of the four tools.

Export controls can be an effective tool to prevent the diffusion of dangerous technology. Effective export controls are possible if worrisome technology has not significantly diffused beyond states that share a political desire to control it. Effective export controls are vastly easier to enforce if the entry costs to the new technology are relatively high. Implementation of export controls are complicated by the emergence of significant non-state actors – whether economic or terrorist. Multi-national corporations often move research and assets between corporate labs in different countries based on small differences in the relative favorability of host business climates. Terrorist groups – whether domestic or foreign – can elude entirely the state-centered, border-focus of traditional export controls, either because basic materials are available within most states or they can be acquired through the pretense of legitimate business.

Inspections can assure that worrisome technology is only used for peaceful purposes. Inspections seek to assure enforcement of peaceful use limitations require meaningful technical

differences between military and civilian programs. Inspections also require confidence that states will self-declare program sites for inspection and that these self-declarations will be reasonably accurate because of the deterrent effect of the well-known technical ability of other states or the international community to remotely identify likely program sites for challenge inspections. The technical ability to remotely identify program sites also is critical to identify the facilities of non-state actors.

Norms can define good behaviors, thereby reducing the incidence of worrisome behaviors and making continued worrisome behaviors more noticeable and therefore more easily shamed or punished. International technical elites are often a promising place to build and enforce norms, particularly when the objective of the norm is consistent with the values of the technical elite. Observance of norms can be strengthened by the use of sanctions or benefits. Norms can be violated and still be useful as long as they play a meaningful culling role: sorting problematic and potentially dangerous cases from standard cases. This culling should reduce the number of potentially dangerous cases to a number that could be more thoroughly examined through targeted diplomatic, law enforcement or intelligence assets.

Prohibitions, if coupled with effective inspections or other verification measures, can reduce spiral model tendencies and other destabilizing behaviors. They can yield more stable security outcomes, at least for a time, than could have been achieved otherwise. Helpful prohibitions are harder to build in cases where significant benefits accrue to a cheater and where those benefits strongly favor the offense.

*Likely Presence of Enabling Conditions*

Needed enabling conditions are not expected to be present in the case of 21st biotechnologies, particularly for export controls and inspections to assure peaceful-use. Implementation of the traditional prevention strategy would not merely fail but would be counterproductive. This assessment is at odds with most of the literature, which assumes that the classic prevention tools should be applied to the biological case and would yield meaningful security benefits.[25]

Export controls would be undercut by the diffusion of technology, lack of political consensus on controls, and emergence of significant non-state actors, both economic and security, with interest and expertise in the biotechnologies. Knowledge and materials needed for catastrophic biological weapons attack are widely diffused abroad. Entry costs for biological weapons are low (defined in terms of both costs and technical knowledge).

Inspections to enforce peaceful use limitations would not work because there are no meaningful technical distinctions between a civilian and military program in the general pre-attack stage. They are further undercut because there would be no reliable external indicators of

[25] These come in different flavors and with different levels of nuance. For the view that verification provisions should be added to the BWC, see (1) Harris, "Bioweapons Treaty: Still a Good Idea;" (2) Graham S. Pearson and Marie Isabelle Chevrier, "An Effective Prohibition of Biological Weapons," in Joshua Lederberg, ed., *Biological Weapons: Limiting the Threat* (Cambridge, MA: The MIT Press, 1999), pages 113-134; and (3) Leitenberg, "Biological Weapons in the Twentieth Century," page 309. For the view that verification measures should be added but they should be significantly different in nature, see, for example (1) Robert P. Kadlec, Allan P. Zelicoff, and Ann M Vrtis, "Biological Weapons Control: Prospects and Implications for the Future," in Joshua Lederberg, ed., *Biological Weapons: Limiting the Threat* (Cambridge, MA: The MIT Press, 1999) which calls for investigation of unusual disease outbreaks as a deterrent against having offensive programs; and (2) Koblentz, "Pathogens as Weapons;" see page 122, which calls for making "development, production, transfer, and use of biological weapons...a crime against humanity and that perpetrators would be subject to international arrest and prosecution." For calls to better control export of and access to dangerous pathogens see, for example, Chyba, "Toward Biological Security," see page 127: "....Washington should act to improve international control of dangerous pathogens, either within the BWC framework (perhaps by supporting the proposal of a like-minded ally) or in a new forum." Chyba overall provides a nuanced call for more of the same with a reasonably pragmatic recognition of the limits on likely success.

a biological program site, to check the declarations of a state actor or to discover the facilities of a non-state actor.

Lack of effective export controls or inspections undercuts the effectiveness of norms and prohibitions that already exist in the case of biological weapons. The lack of meaningful confidence-building measures raises reasonable doubts about whether the norms and prohibitions are being observed. These reasonable doubts can fuel spiral model dynamics, where countries judge they must take reasonable defensive measures but other nations consider these measures to be troubling and hence are spurred to take ever more significant defensive actions.

*Recommendations for Refinements*

Traditional export controls and inspections to assure peaceful use should not be pursued in the biological case because of the low probability they would have any beneficial effect. Work should focus instead on catalyzing efforts by the relevant international technical elite – the life sciences research community – to develop and implement meaningful international norms on biosafety, biosecurity and worrisome dual use research. Functionalist literature and case studies indicate that it is promising to attempt to root norms in the relevant international technical elite particularly when those norms are consistent with core values of the elite. Establishing norms (which most people want to observe) helps reduce ambiguous behaviors and this culling helps identify remaining worrisome behaviors. Diplomatic, investigative, or intelligence assets should be used to further investigate these remaining worrisome cases.

The section discusses the use of sanctions and benefits to strengthen the observance of norms. Sanctions can work domestically and, at least imperfectly, in international regimes that are not perceived to be zero-sum. Sanctions are more difficult to implement in the security area

in the anarchic international environment. For security issues, attention tends to be focused on relative standing and hence outcomes are zero-sum. The dissertation considers cases where benefits were used to catalyze desired behavior on security problems in the international environment. The dissertation proposes the use of benefits as a source of leverage for the broad international adoption of norms on biosafety, biosecurity and worrisome dual use research. The proposal is that adoption of such norms would be the price of admission to an international scientific effort to develop needed defensive medical countermeasures. Such an effort would have many benefits and possible risks, which are discussed in a later chapter on a medical countermeasure strategy.

Current US policy instead focuses on constructing a national unilateral system of norms enforced by sanctions. This unilateral system provides a limited security benefit, but also imposes broader security, economic and technological costs. An international system of norms would be vastly better from a security, economic and technological point of view for both the United States and international security more broadly.

Prohibitions could convey meaningful benefits to security and stability.[26] Prohibitions are not, though, invariably a boon to peace and security. Poorly crafted prohibitions – particularly if the benefits of cheating were significant, if they principally accrued to the offense,

[26] For a discussion of these dynamics, see Jervis, *Perception and Misperception*, particularly chapter 3, "Deterrence, the Spiral Model and Intentions of the Adversary." An overview of treaties follows: Treaties in the early 20th century include the ill-fated Kellogg-Briand Pact of 1928 and the Washington Naval Treaty of 1922. The period also includes the Geneva Protocol on chemical and biological weapons in 1925. Cold War and post-Cold War treaties – easily the most numerous -- include treaties on strategic nuclear weapons (SALT I & II, START and SORT), intermediate-range nuclear weapons (1987), conventional weapons in Europe (1992), nuclear weapon non-proliferation (1957 creation of the IAEA and the 1968 agreement of the Nuclear Non-Proliferation Treaty) and the biological and chemical weapon conventions (1972 and 1993). These treaties were all motivated by a desire to better manage spiral model dynamics and the desire to achieve a stable force balance at lower cost. The only outlier arms control treaty is the 1997 Land Mines Treaty (of which the United States is not a signatory) which seems to have been motivated by pure humanitarian concerns, more similar to the motivation for some of the initial 11th and 12th century agreements on basic norms for the conduct of war and the treatment of non-combatants and prisoners. Author interviews with former government arms control experts.

and if verification or transparency was poor – could worsen spiral model effects and cause deterrence failures.[27] In a case like catastrophic biological attack, the classic argument between realists and liberals about whether spiral model or deterrence model effects dominate seems singularly odd. Yet this is precisely the argument that pervades most of the literature on catastrophic biological attack.[28] This dissertation argues that there are enough actors with enough different interests that both effects are likely to be present. Spiral model effects seem most dangerous on other status quo states. Preserving the international norm against biological weapons acquisition and use provides valuable benefits, as long as no policy-maker forgets that the norm is not verifiable in any meaningful sense. Deterrence effects seem most significant with non-state actors, who, because of characteristics of the biotechnologies, could launch a catastrophic biological attack. This dissertation urges that policy should seek to minimize spiral model effects on other status quo states, but strengthen deterrence and defense against non-state actors.

This paper does not closely focus on preemption, or military action to destroy an adversary's biological assets before they could be launched in an attack. The paper is focused on broad, long-term strategies to reduce the risk of catastrophic biological attack. Preemption is a highly-scenario dependent tactic that is focused on a particular situation in a time delimited period.

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[27]This set of assertions is worthy of a few good dissertations and books in its own right. The complicated dynamics are probably best considered in the Jervis discussions (Chapter 3 of *Perception and Misperception* and "Cooperation under the Security Dilemma") and in the classic book on the interwar period, E.H. Carr, *The Twenty Years' Crisis.*

[28] For the danger of spiral model failures, see Leitenberg, "Assessing the Biological Weapons and Bioterrorism Threat," see page 68: "the greatly increased magnitude of the U.S. biodefense R&D program will promote a BW arms race, and, at least in the part of others, perhaps not all of it of a defensive nature.....That arms race, at least in its initial stages, is more likely to be with developments in our own BW research program than against developments in the programs of other states or nonstate actors." For the danger of deterrence failures, see Koblentz, "Pathogens as Weapons" *International Security,* see page 107: "The accessibility of biological weapons to a diverse set of actors and the ease of covert attacks complicate efforts to deter their use. The proliferation of biological weapons to nondeterrable actors and the prospect of anonymous attacks could undermine reliance on deterrence as a security strategy and lead states to adopt preventive or preemptive strategies."

*Conclusion*

Prevention remains a worthy goal but the classic strategies would fail, despite their many advocates. There is a clear alignment between the interests of the technical elites in the life sciences and the broader prevention objective. This alignment should be strengthened and used as the basis for the development and adoption of norms that could greatly strengthen national and international security. Policy should be configured to minimize spiral model effects on status-quo states and maximize deterrence effects on non-state actors. Using old tools to control profoundly new technology would fail, undercut by the diffusion and characteristics of new technologies and the emergence of significant non-state actors in the biotechnology sector.

## Prevention: Chapter 2

## Export Controls

Export controls can be an effective tool to prevent the diffusion of dangerous technology. Effective export controls are possible if worrisome technology has not significantly diffused beyond states that share a political desire to control it. Effective export controls are easier to enforce if the entry costs to the new technology are high. Implementation of export controls are complicated by the emergence of significant non-state actors – whether economic or terrorist. Multi-national corporations often move research and assets between corporate labs in different countries based on small differences in the relative favorability of host business climates. Non-state terrorist actors – whether domestic or foreign – can elude entirely the state-centered, border-focus of traditional export controls, either because basic materials are available within most states or they can be acquired through the pretense of legitimate business.

In the case of the biotechnologies, export controls would be undercut by the diffusion of technology, lack of political consensus on controls, and the emergence of significant non-state actors, both economic and security, with interest and expertise in the biotechnologies. Knowledge and materials needed for catastrophic biological weapons attack are widely diffused abroad. Entry costs for biological weapons are low (defined in terms of both costs and technical knowledge).

This chapter on export controls has three objectives: (1) it uses historical cases to distill the enabling conditions needed for effective export controls; (2) it outlines the capabilities needed for an effective catastrophic biological attack capability, a necessary precursor for an

assessment of whether export controls could control these capabilities; and (3) it demonstrates that there are limited prospects for effective export controls. It concludes with the assessment that the most promising strategy is building and adopting international norms on biosafety, biosecurity and worrisome dual-use research. Diplomatic, law enforcement or intelligence assets should be used to pursue further investigation of programs that fail to observe these international norms.

*(1)* *Needed Enabling Conditions*

Export controls can work if the states with the technology share the political desire to control it. Export controls are easier if the entry costs to the new technology are high. The emergence of non-state actors with either economic or security ambitions greatly complicate effective export controls.

Many post-World War II supplier regimes – including the Coordinating Committee for Multilateral Export Controls (CoCom), the Nuclear Supplier's Group, and the Australia Group – demonstrate the potential for effective export controls as long as the technology has not diffused beyond states that share a political desire to control it. The broader control regimes required stronger political agreement. CoCom, formed in 1947, was built on the strong perception of a shared security threat. There was strong political agreement that the diffusion of technology to the Soviet Union and the Warsaw Pact could swiftly constitute a security threat to the Western states that were members of CoCom and controlled most relevant technology. CoCom had three lists of controlled items: the International Atomic Energy List (IAEL), the International Munitions List (IML), and the Industrial List.

The political agreement of the technically-ascendant Western states to counter the Soviet threat in the early decades of the Cold War made CoCom a useful if imperfect tool to control technology diffusion. Consensus was strongest around the nuclear-related exports, strong around the weapons-focused Munitions List, and weakest around the Industrial List with its dual use elements. Two things eventually changed with the passage of time: the political agreement among the Western states weakened with the easing of the Cold War threat from the Soviet Union, and the extent to which the Western states were technically-ascendant and hence effectively controlled access to the relevant technology was reduced. As these two changes altered the broader context, the relative effectiveness of and political commitment to the post-World War II CoCom export-control regime similarly eased. CoCom was eventually replaced by the less effective Wassenaar arrangement in 1996. The Wassenaar arrangement tries to focus on nonproliferation concerns but the lack of political agreement about the nonproliferation target has limited its effectiveness.

The control of exports of nuclear-related items, covered initially by CoCom's International Atomic Energy List and, since 1974, the Nuclear Suppliers Group, had the strongest support because the items were clearly needed only for nuclear-related purposes and the peaceful use of the items for civilian nuclear purposes was assured by the inspections conducted by the International Atomic Energy Agency. Nuclear-related equipment was expensive, difficult to acquire and complex to construct indigenously.[29] The consensus to control these nuclear-related exports and to monitor those that go forward to assure their peaceful

[29]Steve Fetter, "Ballistic Missiles and Weapons of Mass Destruction: What is the Threat? What Should be Done?" *International Security,* Vol. 16, No. 1. (Summer 1991), pages 5-42. See page 41: "Nuclear weapons are by far the most difficult to acquire; the requisite technologies to produce nuclear materials are expensive and export controls are relatively effective."

use has been strong. The Nuclear Suppliers Group, for example, unlike CoCom, survived the end of the Cold War.

High entry costs – such as characterized nuclear technology in the immediate post-World War II period – slow technology diffusion and facilitate export controls. Low entry costs – technical or fiscal – undercut the effectiveness of export controls, particularly if there is some motive for actors to acquire and use the technology. This effect can be seen in the case of computer encryption technology. After more than three decades of government efforts to slow and control the availability of "strong" computer encryption, the entry costs for the technology became extremely low. Ultimately, it was downloadable for free off the Internet. Strong public key encryption could be used to assure secure transmission of computer-based financial transactions and other communications. This strong public key encryption, though, complicated the ability of US law enforcement and national security agencies to monitor communications. The United States placed export controls on strong public key encryption in the 1970s to preserve this capability.[30] But the academic literature indicates that as the technology was emerging, the National Security Agency sought to work with the relevant portions of the research community to help them understand the risks and slow down the pace at which the new technology emerged.[31] One author speculates that the NSA policy did have the effect of slowing

[30] Shirley K. Hung, "Managing Uncertainty: Foresight and Flexibility in Cryptography and Voice Over IP Policy," (PhD diss., Massachusetts Institute of Technology, 2009).

[31] Bobby Inman played a critical role in shaping the policy of the National Security Agency in this issue. See "Cryptography: A New Clash Between Academic Freedom and National Security," News and Comment, *Science,* Vol. 209, 29 August 1980, page 995: "At the National Security Agency's (NSA) prodding, the National Science Foundation (NSF) last week told a computer scientist that it would withhold funds on certain parts of his cryptography research grant because they impinge on national security....Inman, however, thinks the agency is being entirely reasonable and that the NSA's funding of cryptographic research will work. 'We just need two or three people who aren't scared to death of us. I really am dealing with sociological problems on both sides,' he says." B.R. Inman, "Letters: Cryptography Research Funding," *Science*, Vol. 210, No. 4466 (Oct. 10, 1980), pages 134-136: "I anticipate that the results of most of the research funded by NSA will raise no direct questions of national security and could be published and otherwise publicly released. On occasion, because of the nature of cryptographic materials and of the work done by NSA, it may be necessary to classify resulting publications because

down the pace at which strong encryption became widely available and that this delay was valuable to the NSA because it enabled them to build their own capabilities to preserve their mission despite the emergence of the new technology.[32] By the 1990s, there was significant demand from consumers and businesses for strong encryption. Strong encryption became available from multiple international sources and even downloadable for free off the Internet. The economic opportunity costs of the export controls increased sharply as this policy reduced the ability of US companies to compete in the burgeoning computer sector and affected their market-share. The US policy was abandoned in the 1990s.[33] Computer encryption technology in the 1970s, 1980s and 1990s provides an ideal example of the impact of low entry costs, both technical and fiscal, for wide adoption of a new technology, despite government efforts to prevent that adoption.

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of their impact on national security." I. Peterson, "Science News of the Week: Silencing Science for Security," Science News, Volume 121, January 16, 1982, No. 3, see page 35: "As a model of a 'reasonable and fair' approach to the problem, Inman gave the example of the voluntary review of cryptologic research that was established while he was director of the National Security Agency (NSA). Researchers working in the area of cryptology send manuscripts to the NSA for prepublication review. So far, 25 papers have been submitted, and none has caused the NSA any security concerns." Some of Inman's later views can be seen in B.R. Inman and Daniel F. Burton, Jr., "Technology and Competitiveness: The New Policy Frontier," *Foreign Affairs*, Spring, 1990, Council on Foreign Relations website (http://www.foreignaffairs.com/articles/45444 accessed 4/13/2009), see the abstract: "....when it comes to advanced technology, national security can no longer be viewed in purely military terms; economic security is also a vital consideration. Moreover, just as it is increasingly difficult to make a meaningful policy distinction between military and commercial technologies, so is it difficult to determine how to manage international relationships, since important political allies in military technology are often hard-nosed economic competitors in commercial technology."

[32] Hung, "Managing Uncertainty: Foresight and Flexibility in Cryptography and Voice Over IP Policy," see page 30: "Although the Clipper Chip initiative was ultimately unsuccessful, and export controls on encryption were loosened considerably in 1999, the efforts were arguably quite effective in terms of delaying development and deployment of other forms of cryptography. It is impossible to quantify how many years' delay resulted or how much more encryption and of what strength or quality would otherwise be used today. However, the fact that the NSA bought itself time by throwing what seemed like the kitchen sink at commercial cryptography is undeniable. This would not have been possible without the existence of and willingness of key members of the Agency to formulate and pursue a rather sophisticated and unspoken long-term strategy for managing mass market encryption. While to the casual observer it may have seemed that the NSA sought to eliminate strong commercial encryption altogether, the agency most likely never expected such a strategy to work. Instead, it used a variety of tactics as stalling devices, never expecting for them to actually succeed, to buy time to increase and solidify its existing technological advantages."

[33] Hung, "Managing Uncertainty: Foresight and Flexibility in Cryptography and Voice Over IP Policy."

Implementation of export controls are vastly complicated by the emergence of significant non-state actors – whether economic or terrorist. Multi-national corporations often can readily move research and assets between corporate labs in different countries. They often do so based on small differences in the relative favorability of host business climates, an ability that can render unilateral control efforts not merely ineffective but counterproductive. Non-state terrorist actors – whether domestic or foreign – can elude entirely the state-centered, border-focus of traditional export controls, either because many items are available within the state or can be acquired through trade using legitimate businesses.

*(2) A Catastrophic Offensive Biological Capability*

This section discusses the knowledge and materials needed to mount an effective catastrophic biological attack. This discussion is necessary to inform the next section's consideration of whether any of these capabilities could be effectively controlled through export controls.

There are legitimate debates about how soon a non-state actor could launch an effective catastrophic biological attack. These debates generally are about whether or how swiftly a non-state actor could surmount various technical and operational challenges to launching an effective catastrophic attack. Unhappily, there is little debate that a well-executed, well-conceived biological attack would be devastating against an undefended civilian population: "a millionth of a gram of anthrax constitutes a lethal inhalation dose. A kilogram, depending on meteorological conditions and means of delivery, has the potential to kill hundreds of thousands of people in a metropolitan area."[34]

[34]Danzig and Berkowsky, "Why Should We Be Concerned About Biological Warfare?", page 9-10. There are many examples of posited catastrophes to choose from. See also Jeffrey D. Simon, "Biological Terrorism: Preparing to

There are two very broad requirements for an attacker: (1) getting a deadly biological agent; and (2) delivering it effectively. There are many subparts to both of these broad objectives[35] and many excellent published discussions of the technical details.[36] The chapter walks through each of these two broad objectives.

*Getting a Deadly Biological Agent*

The first requirement for a catastrophic biological weapons capability would be acquiring a deadly biological agent and growing it in quantity. There are a range of pathogens that could be used in an attack. Anthrax and smallpox have many of the characteristics most useful to the offense:[37] they are relatively robust in the environment (surviving relatively well the stresses,

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Meet the Threat," in Joshua Lederberg, ed., *Biological Weapons: Limiting the Threat*, see page 236: "BW terrorism could result in hundreds of thousands or millions of casualties." Also see Koblentz, "Pathogens as Weapons," MIT diss., see page 15-16: "The ability of biological weapons to cause mass casualties has been documented by the Stockholm International Peace Research Institute (SIPRI), World Health Organization (WHO), and OTA.....The most significant result of these studies is that the potential of biological weapons to cover large areas and cause large numbers of casualties are comparable to nuclear weapons." See also Fetter, "Ballistic Missiles and Weapons of Mass Destruction"; see page 26: "To illustrate the magnitude of the casualties that could be produced by biological weapons, consider a missile armed with 30 kilograms of anthrax spores. Lethal doses to unprotected adults would result over an area of 6 to 80 square kilometers, depending on the weather conditions and assumptions about the release...." There are many legitimate detailed arguments about biological attack scenarios. The implications of these arguments tend to be about how hard a particular task would be to accomplish technically, not how many people would die if the attack were executed as posited in the scenario.

[35] Many authors have proposed more detailed and very useful taxonomies for the characteristics that optimize an agent for biological attack. See, for example, Raymond A. Zilinskas, *Possible Terrorist Use of Modern Biotechnology Techniques,* Conference Paper, Conference on Biosecurity and Bioterrorism, Instituto Diplomatico "Mario Toscano" Villa Madema, Rome, Italy, September 18-19, 2000, page 2. Zilinskas structures his paper around five attributes of a "perfect" military biological weapon: (1) high virulence coupled with high host specificity; (2) high degree of controllability; (3) high degree of resistance to adverse environmental forces; (4) lack of timely countermeasures to the attacked population; (5) ability to camouflage the BW agent with relative ease. A taxonomy from a medical perspective would be, for example Ross H. Pastel, et al, "Clinical Laboratories, the Select Agent Program, and Biological Surety (Biosurety)," *Clinics in Laboratory Medicine,* Volume 26, Issue 2 (June 2006), see page 2: "Biological agents are not equivalent to biological weapons. For a biological agent to become a biological weapon, it must be processed further for environmental stability, particle size, and dispersability. Following processing, the biological agent must be kept in a container (munition) that will maintain viability, delivered by a delivery system (eg, aircraft, truck, or missile), and then be dispersed by some mechanism (eg, explosion or spray device). These four components (biological agent, munition, delivery system, dispersal mechanism) form a biological weapon."

[36] Two of the best general reference works are Richard F. Pilch and Raymond A. Zilinskas, eds., *Encyclopedia of Bioterrorism Defense* (Hoboken, NJ: John Wiley & Sons, Inc., 2005) and Luther E. Lindler, Frank J. Lebeda, and George W. Korch, eds., *Biological Weapons Defense: Infectious Diseases and Counterbioterrorism* (Totowa, New Jersey: Humana Press, 2005).

[37] Donald A. Henderson, "The Looming Threat of Bioterrorism," *Science,* 283, 1279 (1999).

for example, of sunlight and wind); are relatively lethal (in the absence of timely medical intervention they both could be expected to exact deaths on the order of 50 percent or so of an exposed population); and are relatively easy to grow, store and deliver effectively. A catastrophic attack is defined here as one causing at least 10,000 deaths.[38]

There are, of course, other more unusual agents that could be used effectively for a catastrophic attack. Other agents, though, tend to pose more advanced but plausibly surmountable technical problems of one sort or another. For example, plague – the black death of medieval history – has high lethality but is somewhat more fragile and hence would require more technical skill to store, grow and deliver it in sufficient quantity to get large enough numbers of individuals sick enough, fast enough to cause catastrophic effects.[39] Other agents could be used but again would pose a higher technical challenge of one sort or another to the attacker. For example, ricin has the advantages to an attacker of being made from the easily acquired castor bean and generating very high rates of death. Ricin, though, is very difficult to weaponize and hence would pose a significant challenge to an adversary trying to optimize it for effective catastrophic delivery. It would be well-suited from the attacker's point-of-view for an assassination weapon.[40]

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[38]Fetter, "Ballistic Missiles and Weapons of Mass Destruction;" See page 24: "In particular, *bacillus anthracis*, the bacteria that causes anthrax, seems especially well suited for dissemination by missiles or bombs because of its ability to form spores that can survive violent dissemination methods and exposure to sun, air, and rain.....Left untreated, anthrax kills nearly all who contract it within a few days."

[39] Norman F. Cantor, *In the Wake of the Plague: The Black Death and the World It Made* (New York, NY: The Free Press, 2001). National Institute of Allergy and Infectious Disease (NIAID), "NIAID Biodefense Research Agenda for CDC Category A Agents," February 2002, U.S. Department of Health and Human Services, National Institutes of Health, NIAID, see page 20: Plague's "potential for use as a biological weapon is based on methods that were developed to produce and aerosolize large amounts of bacteria and on its transmissibility from person to person in certain forms....Infection by inhalation of even small numbers of virulent aerosolized *Y. pestis* bacilli can lead to pneumonic plague, a highly lethal form of plague that can be spread from person to person. Natural epidemics of plague have been primarily bubonic plague, which is transmitted by fleas from infected rodents....If untreated, pneumonic plague has a mortality rate that approaches 100 percent. Antibiotics are effective against plague, but an effective vaccine is not widely available."

[40] U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), "USAMRIID's Medical Management of Biological Casualties Handbook," USAMRIID, Fort Detrick, Frederick, Maryland, February 2001, See page 132:

The most widely-cited listing of biological pathogens of concern is the "Category A" list identified by the US Centers for Disease Prevention and Control. The CDC defines agents as "Category A" because, among other characteristics, they "can be easily disseminated or transmitted from person to person; [and] result in high mortality rates and have the potential for major public health impact." The six CDC Category A agents are the classic biological agents of anthrax, botulism, plague, smallpox, tularemia, and the viral hemorrhagic fevers.[41]

Over time, technical advances in the biotechnologies are likely to ease the technical challenges to an adversary of using an unusual or modified pathogen. An unusual pathogen is one of these pathogens that exists in nature but has qualities, like relative fragility or low infectiousness, which would make it less attractive to an attacker. Advances in technology, though, may make it easier for the attacker to overcome the weakness and deploy the unusual pathogen to catastrophic effect. For example, new encapsulation technology might be used to

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"Ricin's significance as a potential biological warfare toxin relates in part to its wide availability. Worldwide, one million tons of castor beans are processed annually....The toxin is also quite stable and extremely toxic by several routes of exposure, including the respiratory route. Ricin was apparently used in the assassination of Bulgarian exile Georgi Markov in London in 1978. Markov was attacked with a specially engineered weapon disguised as an umbrella, which implanted a ricin-containing pellet into his body." See a similar discussion on botulinum toxin and biological delivery in general in Fetter, "Ballistic Missiles and Weapons of Mass Destruction"; See page 24 where Fetter discusses the extreme lethality of botulinum toxin but some of the technical difficulties of using it for catastrophic delivery.

[41]The category A agents and their characteristics are from U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. Emergency Preparedness and Response, Bioterrorism Agents/Diseases. Category A. CDC Website (http://emergency.cdc.gov/agent/agentlist-category.asp accessed 11/ 8/2007). There is a burgeoning effort to rank biological pathogens and assess the threat they pose. Many institutions, even within the US government, have their own lists. The CDC list is the most commonly used and hence is referenced here. The intellectual complexities of conducting a biological threat assessment are significant. Many papers discuss these complexities. Two very different treatments can be found, for example, in the following articles. For a thoughtful but skeptical discussion that seems to argue that only demonstrated, extant capabilities be considered see Leitenberg, "Biological Weapons in the Twentieth Century." For a more classic discussion of how defense professionals would tend to think about the threat, see Grapham S. Pearson, "The Essentials of Biological Threat Assessment," in Raymond A. Zilinskas. ed., *Biological Warfare: Modern Offense and Defense* (Boulder, Colorado: Lynne Rienner Publishers, Inc., 2000), pages 55-84.

overcome plague's inherent fragility and make it useful for a catastrophic attack from an adversary's point of view.[42]

Using an unusual or modified pathogen would complicate the defense. This is because stockpiled medical countermeasures in general need to be targeted to a particular pathogen. Resources to purchase defensive countermeasures are finite and so there is a risk that stockpiled countermeasures would not include countermeasures against an unusual pathogen. The implications for the defense of this interactive struggle between the offense and the defense are developed in the dissertation's later chapter on a medical countermeasure strategy. The current chapter is focused more directly on the attacker and her requirements to launch a catastrophic biological attack.

Modified pathogens also would become more likely over time.[43] Modified pathogens are pathogens whose genetic structure was purposefully modified in some way to increase its effectiveness from an adversary's point of view. The pathogen may be modified so as to be able to defeat extant medical countermeasures or have greater lethality, for example.[44] Modifications can range from the relatively straightforward (introducing antibiotic resistance) to the exotic. State programs could – and apparently have particularly in the Soviet Union – modified

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[42] For the general point about microencapsulation, see Raymond A. Zilinskas and Malcom Dando, "Biotechnology and Bioterrorism," in Richard F. Pilch and Raymond A. Zilinskas, eds., *Encyclopedia of Bioterrorism Defense* (Hoboken, NJ: John Wiley & Sons, Inc., 2005), page 63.

[43] Chyba, "Toward Biological Security," see page 126: "Genetic modification of biological agents (to make them resistant to vaccines or antimicrobial drugs, for instance) probably remains beyond the capabilities of terrorist groups for the time being – although the illicit Soviet program did carry out such work and scientists have in effect done the same in research contexts. This sort of biological know-how is spreading quickly."

[44] National Research Council of the National Academies, *Biotechnology Research in an Age of Terrorism,* (Washington DC: National Academies of Science, 2004). This report is sometimes called the "Fink Report" after its chairman, Gerald Fink, Professor of Genetics, Whitehead Institute for Biomedical Research, Massachusetts Institute of Technology. See pages 114-115: This report outlined seven "Experiments of Concern" that would be of particular concern. These are modifications that: "(1) Would demonstrate how to render a vaccine ineffective....(2) Would confer resistance to therapeutically useful antibiotics or antiviral agents....(3) Would enhance the virulence of a pathogen or render a nonpathogen virulent....(4) Would increase transmissibility of a pathogen....(5) Would alter the host range of a pathogen....(6) Would enable the evasion of diagnostic/detection modalities....(7) Would enable the weaponization of a biological agent or toxin."

pathogens in the lab and the testing range.[45] There is legitimate debate about how quickly technical advances could be incorporated into most adversaries' programs, particularly into non-state programs. There is little debate that the pace of progress in the biotechnologies is rapid, widely-distributed geographically and unpredictable.[46]

This section will be organized by the four theoretical routes for acquiring biological agents: (1) from nature; (2) from a civilian research laboratory; (3) from a state offensive or defensive research program; and (4) from de novo construction in a laboratory, often using parts purchased through mail order or over the internet.

From Nature

The first route to acquire a dangerous pathogen is from nature. Many dangerous pathogens occur in nature and could be isolated from naturally occurring cases and then grown in

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[45]It appears that the Soviets did conduct efforts to genetically modify pathogens. See, for example, Chyba, "Toward Biological Security;" see page 127: "Genetic modification of biological agents (to make them resistant to vaccines or antimicrobial drugs, for instance) probably remains beyond the capabilities of terrorist groups for the time being – although the illicit Soviet program did carry out such work and scientists have in effect done the same in research contexts. This sort of biotechnical know-how is spreading quickly." See also Kadlec, et al, "Biological Weapons Control," in Lederberg, ed., *Biological Weapons;* see page 104: "In 1992, Boris Yeltsin admitted that the former Soviet Union had violated the BWC by developing an offensive biological weapons program....In addition, unconfirmed published reports from Russian defectors who were formerly involved in the biological weapons program suggest that they were researching and developing new classes of biological weapons agents. These defectors disclosed that they were developing viral hemorrhagic fevers and genetically engineered biological weapons agents. They specifically mentioned creating a strain of *Yersina pestis* that was resistant to multiple antibiotics and engineered to overcome the protection of available vaccines." See Jonathan B. Tucker and Raymond A. Zilinskas, "Introduction," in Jonathan B. Tucker and Raymond A. Zilinskas, eds., *The 1971 Smallpox Epidemic in Aralsk, Kazakhstan, and the Soviet Biological Warfare Program* (Monterey, CA: Center for Nonproliferation Studies, Monterey Institute of International Studies, 2002), see: Tucker and Zilinskas state according to information provided by two former Soviet officials "a variety of BW agents were tested on [the then-Soviet] Vozrozhdeniye Island, including the microbial pathogens that cause plague, anthrax, Q-fever, smallpox, tularemia, and Venezuelan equine encephalitis, as well as botulinum toxin. Some of the pathogens tested in aerosol form were genetically modified strains that produce atypical disease processes and are resistant to existing medications, potentially complicating diagnosis and treatment." See also Ken Alibek with Stephen Handelman, *Biohazard: The Chilling True Story of the Largest Covert Biological Weapons Program in the World – Told From the Inside by the Man Who Ran It* (New York, NY: Dell Publishing, 1999), see page 41: Ken Alibek, the 1992 Soviet defector, stated that the Soviets were hard at work at genetic modification of various sorts and produced large volumes of these modified pathogens. "Launched by a secret Brezhnev decree in 1973, the [Enzyme] program aimed to modernize existing biological weapons and to develop genetically altered pathogens resistant to antibiotics and vaccines, which could be turned into powerful weapons for use in intercontinental warfare."

[46] *Globalization, Biosecurity and the Future of the Life Sciences.* National Research Council of the National Academies, (Washington DC: National Academies of Science) page 25.

a laboratory.[47] These include all of the CDC Category A agents except for smallpox -- anthrax, botulism, plague, tularemia, and the viral hemorrhagic fevers. Some – like anthrax – are relatively common in nature. Isolation of a lethal agent from a naturally occurring case probably could be done with easily acquired materials and the training possessed by an experienced technician or a research assistant.[48] It would not, though, be technically trivial and at least one group tried and failed.[49] The more widespread a disease outbreak, the easier it would be technically to isolate an agent from the outbreak.[50]

Anthrax, for example, is a naturally occurring disease that affects animals like cows and sheep. It continues to occur, including in the Western part of the United States and Canada. For example, in 2007 "anthrax has been diagnosed on five farms in Manitoba with about 25 [cattle] deaths, on two farms in Minnesota with about 15 deaths and in 17 North Dakota herds with approximately 100 deaths. Other deaths have been recently reported in South Dakota and

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[47]See Dominique M. Missiakas and Olaf Schneewind, "*Bacillus anthracis* and the Pathogensis of Anthrax," in Lindler, Luther E., Frank J. Lebeda, and George W. Korch, eds., *Biological Weapons Defense: Infectious Diseases and Counterbioterrorism.* (Totowa, New Jersey: Humana Press, 2005), see page 79: "*B. anthracis* [anthrax] can be obtained from infected animals or soil and anthrax spores are easily prepared."

[48] Zilinskas and Dando, "Biotechnology and Bioterrorism," in Pilch and Zilinskas, see page 71: "A graduate from a four-year college biology program with an emphasis on microbiology [or a technician with five or more years of experience] should have good knowledge of all aspects of basic bacteriology, including the metabolism and growth characteristics of common bacteria, host-parasite interactions, and endotoxin and exotoxin production. He or she will have been exposed to virology and mycology, will have learned about many advanced biotechnology techniques, and will have practiced them in laboratory work. Thus, he or she can follow directions in published protocols that provide detailed and frequently updated instructions of basic sequencing, genetic manipulation, and so on."

[49] Salerno and Hickok, "Strengthening Bioterrorism Prevention" in *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Volume 5, Number 2 (2007), see page 110: "Although almost every biological agent may be isolated from nature, this procedure can be technically difficult and the necessary skills are often much different from those required to culture a pathogen in the laboratory." See page 113, where Salerno and Hickok note that members of Aum Shinrikyo traveled to an ebola outbreak but were not able to acquire a sample. Also on Aum Shinrikyo, see Leitenberg, "Biological Weapons," see page 294: "Despite the expenditure of substantial time, effort, money and some requisite talent, their efforts [to develop offensive BW capabilities] totally failed." The precise source of the group's difficulties has not been well explained in the literature and hence it seems difficult to speculate on its general implications.

[50] Salerno and Hickok, page 113.

Nebraska."[51] More cases would be expected abroad where both animal vaccination and reporting programs would be less comprehensive.

Other naturally-occurring diseases vary significantly in their utility as a catastrophic biological weapon. Ebola, for example, is naturally-occurring, generally in non-human primate populations in Africa. It is transferred to humans under an unusual set of circumstances. Once in humans, it has a high fatality rate but is relatively hard to transmit.[52]

Smallpox, one of the most deadly diseases in human history, is no longer naturally-occurring. Naturally-occurring smallpox was eliminated through a remarkable eradication effort led by the World Health Organization. The last naturally-occurring case of smallpox occurred in 1977.[53]

From a Civilian Research Laboratory

A second source for a deadly pathogen would be from agent collections in civilian biological laboratories.[54] These pathogens would have been acquired and retained with benign intentions. Research laboratories are at present very poorly regulated, particularly outside of the United States. The extent of lethal pathogens in private agent collections is poorly understood but appears to be extensive, probably numbering in the thousands of agent collections.[55] A recent description of a highly–regarded and relatively well-secured laboratory underscores the challenge:

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[51]John Kirk and Heidi Hamlen, "*Anthrax*" Veterinary Medicine Extension, School of Veterinary Medicine, University of Calafornia Davis, Tulare, CA, website (http://www.vetmed.ucdavis.edu/vetext/inf-da/inf-da_anthrax.html accessed 11/14/2007).

[52]"Questions and Answers about Ebola Hemorrhagic Fever," Centers for Disease Control and Prevention website (http://www.cdc.gov/ncidod/dvrd/srp/mnpages/dispages/ebola/qa.htm accessed 5/20/2009).

[53]"Smallpox," The World Health Organization website (http://www.who.int/mediacentre/factsheets/smallpox accessed 4/3/2009).

[54]Chyba, "Toward Biological Security," see page 127: "Hundreds of culture collections containing dangerous organisms also exist around the world. Although terrorists can acquire pathogens from natural disease outbreaks, existing collections offer the easiest sources."

[55] Salerno and Estes, "Biosecurity: Protecting High Consequence Pathogens and Toxins Against Theft and Diversion," in Pilch and Zilinskas, see page 57: "Thousands of bioscience facilities around the world conduct critical research on pathogens and toxins that could be used as biological weapons."

> Thierry Heidmann's office, adjacent to the laboratory he runs at the Institute Gustav Roussy, on the southern edge of Paris, could pass for a museum of genetic catastrophe. Files devoted to the world's most horrifying infectious diseases fill the cabinets and line the shelves. There are thick folders for smallpox, Ebola virus, and various forms of influenza. SARS is accounted for, as are more obscure pathogens, such as feline leukemia virus, Mason-Pfizer monkey virus, and simian foamy virus, which is endemic in African apes. H.I.V., the best-known and most insidious of the viruses at work today, has its own shelf of files. The lab's beakers, vials, and refrigerator, secured behind locked doors with double-paned windows, all teem with viruses.[56]

Even smallpox may have been inadvertently retained in some old laboratory freezer somewhere. Only two avowed stockpiles of smallpox remain – one at the US CDC in Atlanta and one at the State Center for Research on Virology and Biotechnology in Novosibirsk, Siberia. Most analysts assume there are other, unacknowledged stocks of smallpox.[57] Virologists active in the smallpox elimination effort warn that the elimination of smallpox holdings at sites in the 1970s was simply requested but there were no practical measures that could reliably certify that all stocks had actually been destroyed. Virologists have warned that it was common practice for a virologist to preserve virus isolates from diagnostic specimens which they had processed. Smallpox virus was grown on the allantoic membrane of a fertile chicken egg. After examination of the membrane, it was a simple matter to place the membrane in a small vial and

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[56] Michael Spector, "Darwin's Surprise: Why Are Evolutionary Biologists Bringing Back Extinct Deadly Viruses?" *The New Yorker*, December 3, 2007, page 64. Civilian research labs have done an enormous amount of good, but have previously been the source of infection. See Jill Lepore, "It's Spreading: Outbreaks, media scares, and the parrot panic of 1930," *The New Yorker,* June 1, 2009, see page 50: In a "Parrot Fever" or psittacosis outbreak in 1930, the largest single source of infection was the laboratory leading the epidemiological investigation: "In February and early March of 1930, while Armstrong was still recovering, nine other people at the Hygienic Laboratory became sick. Psittacosis seemed to have contaminated the whole building. On March 15th, McCoy ordered the building evacuated. Alone, he walked down the stairs to Armstrong's basement laboratory. He killed with chloroform, every parrot, mouse, pigeon, guinea pig, rat and monkey that had been used in the psittacosis experiments....He burned the bodies in the building's incinerator. He sealed all the windows. The fumigation squad arrived at 2 P.M. and began spraying the building with cyanide. Sparrows flying fifty feet over the building froze, mid-flight, and fell to earth....Two months later, on May 26, 1930, Congress rewarded the Hygienic Laboratory by expanding it and granting it a new name: the National Institute of Health."

[57] Robert G. Darling, Timothy H. Burgess, James V. Lawlwe, and Timothy P. Endy, "Virologic and Pathogenic Aspects of the *Variola* Virus (Smallpox) as a Bioweapon," in Lindler, Luther E., Frank J. Lebeda, and George W. Korch, eds., *Biological Weapons Defense: Infectious Diseases and Counterbioterrorism.* Totowa, New Jersey: Humana Press, 2005; see page 102: "In short, most authorities agree that the likelihood of smallpox virus existing outside the WHO-sanctioned laboratories is high."

store it in a freezer. Many different virus specimens were preserved in this manner for possible comparison with apparently similar viruses isolated at a later date. Virologists have observed that it was common to put such vials in the back of a freezer and for old-fashioned-style labels to sometimes fall-off. Small-pox scabs that had remained frozen would remain lethal indefinitely.[58]

From a State Offensive or Defensive Research Program

The third source of a deadly pathogen would be from a state offensive or defensive research program. The leakage could either be inadvertent or malicious on the part of the state.[59] It would be extremely difficult but not entirely impossible to identify the source of the pathogen, because different variants of diseases can be identified under certain conditions. Attribution and its possible utility for deterrence are discussed in the deterrence chapter. Leakage from a state program probably would speed a non-state program's acquisition of a pathogen with unusual or modified characteristics favorable to an attacker. Once a terrorist group had acquired the seed stock, the pathogen could be grown in essentially unlimited quantity with few constraints using easily available materials. This lack of a meaningful quantity constraint is one of the great difficulties of the biological threat.[60]

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[58] Donald A. Henderson, M.D., e-mail communication with the author dated May 26, 2009. Dr. Henderson led the WHO effort that eradicated naturally-occurring smallpox.

[59] In an example of an inadvertent leak that didn't happen, one is reminded of the 1989 case of monkeys infected with Ebola that were identified in a laboratory in Reston, Virginia. See Richard Preston, *The Hot Zone: A Terrifying True Story* (New York: NY: First Anchor Books, 1995).

[60]The ease of growing larger stocks from a stable seed stock is widely held. See, for example, Zilinskas and Dando, in Pilch and Zilinskas, page 71: "A graduate from a four-year college biology program with an emphasis on microbiology [or a technician with five or more years of experience] should have good knowledge of all aspects of basic bacteriology, including the metabolism and growth characteristics of common bacteria, host-parasite interactions, and endotoxin and exotoxin production. He or she will have been exposed to virology and mycology, will have learned about many advanced biotechnology techniques, and will have practiced them in laboratory work. Thus, he or she can follow directions in published protocols that provide detailed and frequently updated instructions of basic sequencing, genetic manipulation, and so on." It should be noted that some analysts warn the ease of this step is greatly exaggerated; see, for example, Leitenberg, "Biological Weapons," see page 308: "Contrary to a massive amount of disinformation purveyed in recent years, it is not a simple matter either to obtain or to prepare human pathogens for use as BW agents."

Diversion from the former Soviet program is a particular concern for many in the security field. Ken Alibek, who defected from a leadership role in the Soviet offensive biological weapons program, has warned that very large quantities of smallpox and other deadly pathogens were produced and weaponized in the Soviet program.[61] It appears that the Soviets did conduct efforts to genetically modify pathogens.[62] The precise disposition of the Soviet stores has never been fully established.[63]

The recent case in the United States of the 2001 anthrax letter attacks which killed five people provide further warning about the vulnerability of materials in state defensive programs. The FBI has said that Bruce Ivins, a scientist in the biodefense program at USAMRIID, was uniquely and personally responsible for the anthrax attacks. Ivins committed suicide before he

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[61]It appears that the Soviets did conduct efforts to genetically modify pathogens. See Tucker and Zilinskas, "Introduction," in Tucker and Zilinskas, eds., The report states that according to information provided by two former Soviet officials "a variety of BW agents were tested on [the then-Soviet] Vozrozhdeniye Island, including the microbial pathogens that cause plague, anthrax, Q-fever, smallpox, tularemia, and Venezuelan equine encephalitis, as well as botulinum toxin. Some of the pathogens tested in aerosol form were genetically modified strains that produce atypical disease processes and are resistant to existing medications, potentially complicating diagnosis and treatment." See also Alibek with Handelman, *Biohazard*, see page 41: Ken Alibek, the 1992 Soviet defector, stated that the Soviets were hard at work at genetic modification of various sorts and produced large volumes of these modified pathogens; "Launched by a secret Brezhnev decree in 1973, the [Enzyme] program aimed to modernize existing biological weapons and to develop genetically altered pathogens resistant to antibiotics and vaccines, which could be turned into powerful weapons for use in intercontinental warfare."

[62]See, for example, Kadlec, et al, in Lederberg, ed., *Biological Weapons*, see page 104: "In 1992, Boris Yeltsin admitted that the former Soviet Union had violated the BWC by developing an offensive biological weapons program....In addition, unconfirmed published reports from Russian defectors who were formerly involved in the biological weapons program suggest that they were researching and developing new classes of biological weapons agents. These defectors disclosed that they were developing viral hemorrhagic fevers and genetically engineered biological weapons agents. They specifically mentioned creating a strain of *Yersina pestis* that was resistant to multiple antibiotics and engineered to overcome the protection of available vaccines." See also Alibek with Handelman, *Biohazard.* See page x: "[W]e stockpiled hundreds of tons of anthrax and dozens of tons of plague and smallpox near Moscow and other Russian cities for use against the United States and its Western allies." See also page 121-122: "We calculated that the production line in the newly constructed Building 15 at Koltsovo was capable of manufacturing between eighty and one hundred tons of smallpox a year."

[63] Kadlec, et al., in Lederberg, ed., *Biological Weapons*, see page 104: "[D]espite bilateral agreements between the U.S. and Russian governments to resolve concerns about the biological weapons capabilities inherited by the Russian government, concerns still persist about the veracity and completeness of Russian assurances and statements."

could be charged and prosecuted, thus leaving some lack of closure about the case.[64] The case does, though, provide evidence for those who argue that the defensive programs are a likely source of these pathogens.[65] There is a more extensive discussion of the potential spiral model implications of these defensive programs in the chapter on prohibitions. For the purposes of this chapter, it is sufficient to use the case to demonstrate that even programs with defensive intent can inadvertently be the source of pathogens used for offensive purposes.

From de novo Construction in a Laboratory

The fourth route to acquire a deadly pathogen is through de novo construction in a laboratory. This is by far the most demanding route technically. The rate of progress here is interrelated with the extent to which the sale of parts through mail-order and the internet is well-regulated.

The polio virus has been sequenced de novo in the lab[66] as has the influenza strain that caused the 1918 Influenza epidemic.[67] Smallpox is a much longer and more complex virus and its sequencing would be expected to be correspondingly difficult. The capability to sequence and recreate pathogens will surely improve over time, although how quickly is uncertain and the capability would likely spread first to state programs and only later to non-state actors.

The speed of progress in de novo construction is closely related to the ability to acquire pieces through mail-order and internet purchases. The purchase of items clearly related to deadly pathogens is better regulated, particularly in the United States, than it was even a few

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[64] See newspaper accounts, including, for example, Carrie Johnson, Del Quentin Wilber, and Dan Eggen, "Government Asserts Ivins Acted Alone: Officials Detail Evidence, but Questions Linger, *The Washington Post*, Thursday, August 7, 2008, Page A01.

[65] See, for example, Hillel W. Cohen, Robert M. Gould, and Victor W. Sidel, "The Pitfalls of Bioterrorism Preparedness: the Anthrax and Smallpox Experiences," *American Journal of Public Health,* 2004 October; 94(10): 1667-1671.

[66] The relatively-simple polio virus was built from scratch five years ago. Jocelyn Kaiser, "Proposed Biosecurity Review Plan Endorses Self-Regulation," *Science,* Vol 316, 27 April 2007, page 529.

[67] Brian Handwerk, "'Bird Flu' Similar to Deadly 1918 Flu, Gene Study Finds," National Geographic website (http://news.nationalgeographic.com/news/2005 accessed 5/19/2009).

years ago. These controls need to be further strengthened. A related problem, though, is that the sophistication and multi-use elements of materials that can be ordered from these mail-order facilities is growing rapidly. The norms governing the sale of these items should be covered by the norms on biosafety, biosecurity, and worrisome dual-use research discussed later in this section.

*Effective Delivery*

Once an adversary had a lethal pathogen in sufficient quantity, she would need to weaponize it for effective delivery. While this would not be particularly complicated if the objective was to cause a small numbers of deaths, it becomes vastly more complicated for a catastrophic attack. There are three theoretical routes to infect a human being: (1) through the skin and into the blood stream; (2) through consumed water or food and into the digestive track; or (3) through the air and into the lungs. The routes selected by an adversary and the particular tactic selected within these routes would have very different effects on the number of potential causalities. Virtually all analysts agree that the most efficient technique to cause catastrophic numbers of casualties would be through an aerosol attack on a densely-populated area. There is folk-wisdom that the food and water route would not be effective for a catastrophic attack. The degree of analysis supporting this view should be improved.

Through the Skin

The first route – through the skin and into the blood stream – can be used and unhappily has been used as an effective assassination technique.[68] No one in the literature, though, appears to have come up with a technique by which this route could be used to inflict catastrophic effects.

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[68] George W. Christopher, Theodore J. Cieslak, Julie A. Pavlin, and Edward M. Eitzen, Jr., "Biological Warfare: A Historical Perspective," in Joshua Lederberg, ed., *Biological Weapons: Limiting the Threat* (Cambridge, MA: The MIT Press, 1999), page 30.

Through Food and Water

The second possible delivery technique is through the consumption of food and water and then infection of the individual through the digestive track. The daily news, unhappily, demonstrates that innocent but still significant contamination through the food and water systems is possible.[69] Several acts of purposeful contamination of food supplies have occurred, largely resulting in illness, not deaths.[70] It seems likely that at least small successful attacks could be launched through the food and water system by an attacker.[71] What is somewhat less clear is the extent to which purposeful and even very highly-skilled attacks on the food and water system could generate catastrophic effects. There does not appear to be a robust consensus in the technical literature about whether food and water attacks could have catastrophic effects. Based on the current level of knowledge, it does not appear that either the attacker or the defender could confidently rule it in or out. An attacker could try this route and might have success from their perspective in that they could cause widespread illness, possibly some deaths, and significant panic and economic dislocation. Any attacker, though, would face considerable uncertainty

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[69] In the fall of 2007, for example, there were significant multi-state outbreaks in the United States of food-borne E. coli 0157 infections linked to ground beef, salmonella in pot pies, and botulism in canned hot dog chili sauce. There is no indication that any of these cases had hostile intent but occurred, rather, because of errors in food handling, preservation and storage. CDC website (http://www.cdc.gov accessed 11/14/ 2007).

[70] In 1984, an Indian cult, the Rajneeshee, contaminated salad bars in the town of The Dalles, Oregon with Salmonella typhimurium. Over 750 individuals were poisoned and 40 were hospitalized. The Rajneeshee sought to influence the outcome of a local election through discouraging individuals from voting. The poisoning was only discovered after members of the cult reported the incident to local authorities almost a year later. Leitenberg, "Biological Weapons," see page 291: "The salmonella was obtained from a type-culture collection, and a trained technician who belonged to the group carried out the culturing." See also W. Seth Carus, "The Rajneeshees (1984)," in Jonathan B. Tucker, ed., *Assessing Terrorist Use of Chemical and Biological Weapons* (Cambridge, MA: The MIT Press, 2000), pages 115-137. USAMRIID's Medical Management of Biological Casualties Handbook, page 133: There have been attempts to use biological agents administered through food to commit murder.

[71] Zygmunt F. Dembek, "Modeling for Bioterrorism Incidents" in Lindler, Lebeda, and Korch, see pages 24-25: "An outbreak in Minnesota in 1985 affecting more than 16,000 [individuals and causing the deaths of 14] with antimicrobial-resistant salmonellosis was eventually hypothesized to have been caused by cross-contamination of raw milk into a pasteurized milk product sold to the public....This outbreak and many others demonstrate that food-borne bioterrorism has perhaps greater chances of success closer to the table that contamination occurs, thus circumventing issues of dilution of the pathogen and destruction by cooking/pasteurization. Water-borne contamination is perhaps more difficult for a terrorist to achieve, ....However, a determined enemy could overcome the purification process."

about the scope and effectiveness of a prospective attack. Additional studies should be launched to better understand this route of attack and to close particularly vulnerable junctures.

Through Inhalation

The third route -- through the air and into the lungs -- could be actualized through a couple of techniques, some of which would cause a small number of infected individuals and others which could produce catastrophic effects. For example, an adversary could use either the tactic of "human vectors" or of wide-area aerosol release. The first tactic (human vectors) would probably only result in a relatively small number of deaths, while the second, depending on a number of variables, could cause catastrophic effects.

The first tactic – the use of human vectors -- would generate some but only a small number of deaths, assuming there was not a thorough collapse of the defender's decision-making and public health system. "Human vectors" means that an adversary would infect a handful of willing individuals with smallpox or a different contagious pathogen and then send them to the defender's territory to infect people with whom they came into contact. While the ranges for contagious diseases vary significantly, most individuals with smallpox, for example, infect from one to three other individuals.[72] The use of human vectors infected with smallpox hence would probably "work" from an adversary's point of view in that it would result in some sick people, about half of whom would probably die.[73] But the rate at which people got infected would probably be too slow to cause catastrophic effects unless there were serious mistakes in the defender's response. Even one confirmed case of human smallpox should provoke widespread

[72] This is a reasonable estimate for contagious diseases but the actual number in any particular outbreak would, of course, vary widely. See discussion in "Smallpox," World Health Organization fact sheet, WHO website (http://www.who.int/mediacemtre/factsheets/smallpox accessed 4/3/2009).

[73] Estimates of death rates for unvaccinated populations newly exposed to smallpox vary significantly but are probably about 50 percent of the exposed population with the remainder having extensive scars and other lingering non-fatal effects. Historically, in populations that had been exposed to smallpox epidemics, the death rate was generally about 30 percent. See discussion in "Smallpox," World Health Organization fact sheet, WHO website (http://www.who.int/mediacemtre/factsheets/smallpox accessed 4/3/2009).

vaccinations and the rate of spread of the disease from a handful of human vectors should not outpace the rate of vaccinations unless the decision-making and public health delivery systems operated even more inefficiently than is generally expected by even relatively pessimistic analysts.[74] By 2006, the United States had more than enough smallpox vaccine for its citizens and some to share abroad. Vaccine shortages would certainly occur in a global epidemic and the available vaccine is far from optimal.[75]

In contrast, effective delivery via the aerosol route – through spray containing the pathogen – could theoretically generate a large exposed population very quickly.[76] Several technical hurdles would need to be overcome to have an effective attack from the adversary's point of view. The pathogen contained in the spray would need to be the right particle size to be inhaled and retained in the lungs. Asthma inhalers and nebulizers, for example, take liquid

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[74]The US public health response is expected to be overwhelmed in an attack of any significant size. This view is widely held among those who believe there is any meaningful risk of an attack occurring. See, for example, Thomas V. Inglesby, MD, "Observations from the Top Off Exercise," *Public Health Reports,* 2001 Supplement 2, Volume 116, pages 64- 68, see page 67: "Not unexpectedly, the logistics of antibiotic distribution proved quite complex....the ensuing local distribution process did not go smoothly." Falkenrath, et al., *America's Achilles' Heel*, page 311, "...local medical services could easily be overwhelmed after a large attack...." For an attack launched using human vectors, however, the number of cases should be much smaller – assuming 20 individuals serving as human vectors, you might expect the first generation of infected individuals to be about 60 individuals, the second generation about 180 individuals and so on until the process of infection was stopped. As long as the public health community began aggressively vaccinating all contacts, they should be able to keep up with an exposure of this size. The longer the delays of reporting and properly diagnosing the "index" or initial case and then in launching an aggressive ring vaccination program, the worse the death rate would be and the larger the size of the total infected population. But, analogizing from the response to the recent swine flu case, the public health community could plausibly respond to an attack of this size as long as none of the early decisions (properly report and diagnose index case, aggressively vaccinate contacts and plausible contacts) were poorly managed. There have been about 2,500 cases of the novel H1N1 virus in the United States, with 61 pediatric deaths. See, on statistics for novel H1N1 influenza response, CDC Influenza (Flu) – Weekly Report: Influenza Summary Update Week 19, CDC website (http://www.cdc.gov/flu/weekly/ accessed 5/23/2009).

[75] "Vaccine Overview," Smallpox Fact Sheet, Centers for Disease Control and Prevention, US Department of Health and Human Services, CDC website (http://www.bt.cdc.gov/agent/smallpox/vaccination/facts.asp accessed 4/3/2009).

[76] Richard F. Pilch, "Delivery Methodologies," in Pilch, Richard F. and Raymond A. Zilinskas, eds., *Encyclopedia of Bioterrorism Defense* (Hoboken, NJ: John Wiley & Sons, Inc., 2005), see page 149: "In a 1950 simulation, U.S. Army officials dispersed BG [a simulant for anthrax] and monitored its spread to assess the potential impact of a comparable release of *B. anthracis* spores (Fothergill, 1958). The test employed off-the-shelf technology that has improved tremendously in the last half-century. Despite this limitation, a 2-mile dissemination line yielded a highly infectious area approximately 6 miles in length, with simulant traveling a maximum distance of 23 miles. In all, the release covered approximately 100 square miles, with an infectious area large enough to cover the entire metropolitan Washington, DC, area. The simulation lasted only 29 min."

medicine and convert it into the appropriate micron size for retention in the lungs and hence remediation of the asthma-related symptoms. Similarly, a pathogen would need to be the right micron size to be inhaled and retained in the lungs. Transforming the pathogen into the correct particle size remains a meaningful technical challenge.[77]

The particles of pathogen would then need to be disseminated, either through a point source (a container like a test-tube or a cluster bomb) or a line source (where there is a continual release of the agent while moving, generally using something like an aerosol sprayer or crop duster). The equipment and expertise required for successfully developing and delivering biological weapons through the aerosol route would require significant technical skills.[78] It is not, though, out of the reach of most states or at least some non-state actors. The US achieved this capability during WWII.[79]

The technical challenge of making, storing and delivering large quantities of pathogen of the appropriate micron-size would be a meaningful but not insurmountable challenge. Most authors suggest the possible use of crop dusters or aerosol sprayers such as are used to spray insecticides through neighborhoods fighting mosquito infestation:

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[77] The implication of most published accounts is that Aum Shinrikyo was able to get the right micron size particle, but did not acquire a virulent strain of a biological pathogens and failed to have an effective delivery device. See, for example, the discussion in Pilch, "Delivery Methodologies," in Pilch and Zilinskas, page 147. The challenge of getting the right micron size for effective aerosol delivery is generally considered among the hardest if not the hardest technical step. See the discussion of the literature in Leitenberg, "Biological Weapons," page 309. While most analysts characterize the other technical steps as easy but concede that the micron-size step is hard, Leitenberg says that all the technical steps are hard.

[78] Pilch, "Delivery Methodologies," in Pilch and Zilinskas, page 146-149. See also Centers for Disease Control and Prevention, "Key Facts about Tuleramia," CDC website (http://www.cdc.gov assessed on 11/14/07). CDC assesses that "manufacturing an effective aerosol weapon would require considerable sophistication." Others argue aerosol delivery is more straightforward. See Danzig and Berkowsky, "Why Should We Be Concerned About Biological Warfare?" see page 10: "Since aerosolization is the predominant method of dissemination, extraordinarily low-technology methods, including agricultural crop dusters, backpack sprayers, and even purse-size perfume atomizers will suffice. Small groups of people with modest finances and basic training in biology and engineering can develop an effective biological weapons capability."

[79] Leitenberg, Biological Weapons, see page 272: "[T]he most significant development in all of the WWII programs was the US achievement of small particle size aerosol dissemination of wet or dry preparations of pathogens. It is clear that two or three of the programs of other states were moving toward similar technologies for dissemination mechanisms, but the technological accomplishment was made in the course of the US program."

> The classic line source dispersal is a crop duster, ideally flown crosswind upwind of a target so that the stream of released agent is carried by the wind over the target area .... The goal with this approach, and generally with the use of any type of spray device, is to generate an aerosol cloud of the ideal particle size range of 1 to 5 um in a high enough concentration to cover a broad area.[80]

If an adversary could surmount the technical challenges, he could launch a catastrophic attack through wide-area aerosol delivery either outside in a densely-populated area or inside a large venue like a sports stadium.

It is also worth noting that the US and Soviet offensive biological programs had sufficient problems actually making an aerosol system work that they conducted outdoor tests of their aerosol delivery capabilities and learned a great deal that helped optimize these systems from an attacker's perspective. An adversary – particularly a non-state adversary – would face a difficult trade-off. However sophisticated their laboratory-based program, they naturally would have significant uncertainty about how well an aerosol delivery system would actually work.[81] Field trials would be extremely helpful to optimize the system from the attacker's point of view. Yet field trials of aerosol delivery systems would be reasonably noticeable if the group was operating in an area where surveillance was taking place by a defender. The attacker would face a difficult tradeoff between accepting vulnerability from detection of field trials or accepting significant risk that the delivery system would not work or at least would not work particularly well in an actual operation. Defenders should optimize their surveillance efforts to increase the probability that field trials of adversary aerosol delivery systems would be detected.[82] This and other factors

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[80] Pilch, "Delivery Methodologies," in Pilch and Zilinskas, page 148.

[81] Jonathan B. Tucker, "Bioterrorism: Threats and Responses," in Joshua Lederberg, ed., *Biological Weapons: Limiting the Threat* (Cambridge, MA: The MIT Press, 1999), page 290.

[82] Detecting sustained outdoor aerosol tests seems like a reasonable ambition. It may be interesting, though, to note an historical assessment that the US was not always successful in this type of effort: "[I]t appears that the U.S. intelligence community had no firm evidence during this time that the Soviet Union possessed an offensive BW program. This lack of information is remarkable considering that the Soviet program had been active since approximately 1928 and had conducted a sizeable open-air testing program since the early 1950s...." Tucker and Zilinskas, "Introduction," in Tucker and Zilinskas, eds., *The 1971 Smallpox Epidemic,* page 11.

contributing to uncertainty on the part of the attacker and the potential role of this uncertainty as an element of strengthened deterrence will be more fully developed in the deterrence section.

It should be recognized that technical trends over the near and mid-term are likely to ease the challenge of successfully delivering a biological agent from an adversary's point of view:[83] Microencapsulation, for example, is expected to greatly ease an adversary's challenge of stabilizing a biological agent during delivery. While the rate at which actors, and particularly non-state actors, could identify and incorporate these innovations into delivery techniques is difficult to assess, it could certainly happen eventually and would be speeded by rapid advances in the civilian pharmaceutical industry.

*The Tactical Complexity of a Catastrophic Attack*

The benefit of field testing an aerosol capability illustrates a related, proposed access control point – whether the knowledge to put together a sufficiently integrated, broad-based attack would be within the capabilities of a non-state actor. To really drive up the size of the exposed population, there would need to be multiple, perhaps simultaneous attacks. Richard Danzig has particularly written about the problem of "reload" or repeat attacks where an adversary attempts to drive up the number of exposed individuals and the degree of panic as high as possible.[84] In addition to having the materials needed for an attack of that magnitude, an adversary would need to combine such attacks so that multiple attacks were launched by multiple

[83] Zilinskas and Dando, "Biotechnology and Bioterrorism", in Pilch and Zilinskas, see page 63: "[R]ecently developed techniques to administer vaccines to animals by aerosol dispersal might be adapted to effectively disperse living pathogens over a target population; and sophisticated meteorological maps of major urban centers commonly available on the Internet could guide terrorists in dispersing aerosols for maximum effect. Furthermore, discussion of the letters containing Bacillus anthracis spores [or anthrax] sent to public figures in the United States during September/October 2001 served to focus attention on the key problems of drying, milling, and formulating agents so that they are of the right particle size when dispersed and are able to survive environmental stresses. Anyone with access to the Internet will have little difficulty discovering the enormous effort within commercial companies to find more effective technologies for the dry aerosolized vaccines, as well as the much-improved large-scale spraying systems used in agricultural biocontrol."

[84] See particularly Richard Danzig, "Proliferation of Biological Weapons into Terrorist Hands," *The Challenge of Proliferation*, Aspen Institute Website (http://www.AspenInstitute assessed 11/18/2007), pages 67-68.

teams simultaneously or nearly simultaneously to cause catastrophic effects. This greater operational sophistication would require more individuals and more teams. But, of course, the more individuals and the more teams involved, the more complexity in the operation and the more risk to the attacker of mistakes and leaks. Authors seem conflicted internally on the point of whether non-state actors could manage the complexity of such an attack, both noting the difficulty of effectively delivering biological weapons, while admiring the remarkable operational efficiency and elegance of the 9/11 terrorist attacks.[85]

*Summary*

An adversary seeking the capacity to launch a catastrophic biological attack would need to acquire a dangerous pathogen and then deliver it effectively. This section discussed the four routes for acquiring a dangerous pathogen: (1) from nature; (2) from civilian research laboratories; (3) from diversion from state defensive or offensive research programs; (4) from de novo construction in a laboratory, often using parts purchased through mail order or over the internet. While on balance a non-state actor would most likely use one of the classic biological agents, there is some risk even today that they would use an unusual or modified pathogen and that risk should increase over time as the biotechnologies continue to advance. There are three theoretical routes for delivery – through the skin, through food and water, or through inhalation. There is broad agreement that aerosol delivery in a densely-populated space would be the most effective route for an adversary to cause large numbers of casualties. A catastrophic attack also

[85]The seeming contradiction probably is the technical difficulty of making a biological agent robust and deliverable, but it is interesting to contrast the differences between the two observations, one focused on operational limitations and one focused on operational excellence: (1) "The ability to make chemical agents and biological poisons is more widespread than ever, though turning the basic ingredients into useful weapons and delivering them effectively on a large scale has thus far not proven easy for small clandestine groups." And (2) "The hijackings of all four airliners [on 9/11] were carefully synchronized. If this had been a Western commando raid, it would be considered nothing short of brilliant. Given the demonstrated motivation and organizational and technical skills of its members, al-Qaeda will likely attempt further large-scale attacks on the United States or its citizens and soldiers abroad, or both." Posen, "The Struggle Against Terrorism," quotes from pages 41, 40, respectively.

would require a certain operational sophistication – including the complexity of launching multiple simultaneous or near-simultaneous attacks.

*(3) Prospects for Export Controls*

The previous section outlined in general terms what would be needed to launch a catastrophic biological attack. This section assesses the implications of those requirements for the efficacy of export controls. Three different types of export controls are considered: (1) general controls; (2) targeted controls on specific items that are difficult to develop independently and critical to a deadly and robust pathogen; and (3) targeted controls on specific items needed for catastrophic delivery. This consideration of possible export controls tries to consider both current technology and technology likely to emerge over time.

The core finding is that the relevant knowledge and technologies are too widely diffused for general export controls to help.[86] This knowledge and technology is diffused well beyond states who share a political desire to control them. The entry costs are low, in both fiscal and technical terms. There are significant non-state actors with both economic and security ambitions that have significant knowledge of the relevant biotechnologies.[87]

The study finds no valuable items for targeted controls, either for the pathogens or for delivery. As technology evolves, there may be controls or licensing schemes that would be valuable. Some examples of these are discussed but all would needed additional vetting by a technical group before implementation. Over time, there plausibly would be high-leverage ways to shape innovations in the mid and long-term.

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[86] "Globalization, Biosecurity, and the Future of the Life Sciences," National Academy of Sciences, see page 4: "To a considerable extent, new advances in the life sciences and related technologies are being generated not just domestically but also internationally."

[87] Fetter, "Ballistic Missiles and Weapons of Mass Destruction;" see page 36: "The power of export controls by the industrialized nations is waning."

*Efficacy of General Controls*

A recent report warned that it not only was impossible to predict the nature of the next technological advance but where geographically such an advance would emerge. Production of equipment is widely diffuse, with the production of fermentors, growth media, and incubators being global. Only the most sophisticated equipment is produced in small number and there is strong debate about whether any meaningful controls could be imposed on these items. Knowledge is widely diffused as well.[88] Significant numbers of the most advanced students in the life-sciences in the United States are foreign-born and the quality of academic training abroad is increasing.[89]

A recent US National Academy of Sciences report on biotechnologies was blunt and direct: "The techniques, reagents, and information that could be used for offensive purposes are readily available and accessible. Moreover, the expertise and know-how to use or misuse them is distributed across the globe."[90]

A separate, more recent National Academy of Sciences report further validated the international extent of the diffusion of this technology: "To a considerable extent, new advances in the life sciences and related technologies are being generated not just domestically but also internationally....The increasing pace of scientific discovery abroad and the fact that the United

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[88] Joshua Lederberg, "Introduction," in Joshua Lederberg, ed., *Biological Weapons: Limiting the Threat* (Cambridge, MA: The MIT Press, 1999), see page 7: "The facilities required for producing and dispensing BW agents are modest, easily concealable, and almost indistinguishable from licit production of pharmaceuticals and vaccines. The same holds true for the underlying technical knowledge, which is part and parcel of medical research and education. The potential for grave enhancement of virulence and the intractability of pathogens for BW use go hand in hand with the advances in biotechnology for human life enhancement."

[89] Doug Lederman, "More Doctors of Philosophy (and Science)," Inside Higher Ed website (http://www.Insidehighered.com accessed 11/21/2007) see: "[F]oreign born researchers accounted for nearly 35 percent of all doctorates granted in 2006 (15,947 of 45,596), and for 43 percent of the Ph.D.'s awarded in scientific and engineering fields (12,775 of 29,854). Non-citizens accounted for more than 70 percent of doctorate recipients in electrical, civil and industrial/mechanical engineering, and more than half of Ph.D. recipients in all other engineering fields, computer sciences, math and physics."

[90] National Academy of Science, *Biotechnology Research in an Age of Terrorism,* see page 2.

States may no longer hold a monopoly on these leading technologies means that this country is, as never before, dependent on international collaboration...."[91] A more detailed US government study of the distribution of specific technologies of concern outlined how widely diffused throughout the globe many, although not all, of these capabilities have become.[92]

The biotechnology sector is burgeoning: there are significant numbers of actors both in the United States and abroad. By 2003, there were more than 2,500 biotechnology firms worldwide[93] in addition to the work in university laboratories and the major pharmaceutical companies. There were 419 biotech companies traded on the stock exchange in 2006, with total biotech financing reaching $48.3 billion.[94]

The great rapidity in the pace at which the technology is advancing is such that a recent National Academy of Sciences report warned against the attempt to predict future breakthroughs, both their substantive nature and their country of origin, because previous efforts to predict trends had proven so inaccurate: "About the only thing one can predict is that the life sciences will continue to advance quickly, in a variety of directions, and that new and previously unanticipated paradigm shifts are very likely to occur in the future ....[and] as difficult as it is to

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[91] National Academy of Sciences, *Globalization, Biosecurity, and the Future of the Life Sciences,* see page 4.

[92] National Security Advisory Board for Biosecurity, U.S. Department of Health and Human Services, *Addressing Biosecurity Concerns Related to Synthesis of Select Agents,* Washington, D.C.: NSABB Staff Report, December 2006. See page 6: "Reagents and equipment for synthesizing DNA are readily available around the world; Synthesizing oligonucleotides accurately up to 120 base pairs (bp) in length is routine and common although synthesizing oligonucleotides of more than 180 bp remains somewhat of an art; Complete genomes of some viruses can be synthesized at the present time, but not all DNA synthesis providers have this capability; It is possible and routine in some laboratories, to recover/reconstruct infectious virus from DNA for certain Select Agents; however, successful use of such reverse genetic systems currently require that one be "skilled in the art"; and some researchers create infectious chimeric viruses on a routine basis using combinations of genomic material from various select agents; these novel organisms do not fit into traditional classification schemes."

[93] Tom Abate, *The Biotech Investor: How to Profit from the Coming Boom in Biotechnology* (New York: Henry Holt, 2003), page 8.

[94] Riku Lahteenmaki and Stacy Lawrence, "Public Biotech 2006 – The Numbers," *Nature Biotechnology,* Volume 25, Number 7 (July 2007) page 729.

predict what kind of technological or scientific breakthroughs might occur next, it is practically impossible to know where in the world these breakthroughs might happen."[95]

*Possible Targeted Controls on Pathogens*

There do not appear to be any good prospects for targeted controls on specific items available now that are difficult to develop independently and critical to acquiring or growing a deadly and robust pathogen. There may be some high-leverage strategies to pursue as the biotechnologies evolve. These should be monitored, likely by the group that the paper recommends more broadly be created to develop norms governing biosafety, biosecurity and worrisome dual-use research. There is also benefit in embedding in these broader norms appropriate controls on the sale of parts via mail order or the internet that can be used to construct pathogens de novo in the lab. As the paper discussed, there are four ways to get a dangerous pathogen: (1) from nature; (2) from a civilian research laboratory; (3) from a state offensive or defensive research program; (4) from de novo construction in a laboratory, often using parts purchased through mail order or over the internet. None of these routes seem amenable to targeted controls, although a technically-proficient group should be vested with responsibility for continuing to assess this problem.

Emerging Technology

Two possible candidates for targeted control points have been identified in the literature. A prominent biologist has argued that some of the equipment necessary for the genetic manipulation needed to produce a pathogen able to defeat extant medical countermeasures is sufficiently unusual that it could offer a promising control point. Specifically, George Church of

[95] National Academy of Sciences, *Globalization, Biosecurity and the Future of the Life Sciences*, page 25.

Harvard Medical School has recommended that advanced genetic machines and be licensed and available only to licensed non-profit, government and for-profit entities.[96] Other scientists were more skeptical this approach could work. Strategies such as Church proposed should be closely examined for their net effectiveness.

Another example is in the field of synthetic biology. Synthetic biology has as its ambition building interchangeable biological parts so that genetic manipulation becomes much more routinized and less of an "art." A standard element of a modified cell is a suicide vector that assures the modified cell stops replicating at a certain point. As interchangeable synthetic biological parts are increasingly built, it would be a valuable policy to direct that the "suicide vector" component not just be a separate component (that could be easily cut out of an engineered pathogen) but somehow be integral to the newly-engineered pathogen.[97] While this is a useful policy insight, there appears to be technical disagreement about whether this actually could be implemented. This question should be closely examined by technical experts. Some argue that synthetic biology would allow interchangeable parts to be placed on a common platform. The common platform (one might think of standardizing electric sockets so that a variety of electrical devices could be plugged into any socket) could contain elements like a suicide vector. Altering a characteristic within the common platform would require a

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[96]George M. Church, "A Synthetic Biohazard Non-proliferation Proposal," private paper for distribution, Harvard Medical School, 77 Ave Louis Pasteur, Boston, MA 02115, 18 June 2004, updated 6 August 2004, see: "Sales and maintenance of oligo synthesis machines and supplies would be restricted to licensed non-profit, government and for-profit entities. All use of reagents and oligos would be automatically tracked and accountable (as is done for nuclear regulations). This licensing would initially be voluntary, then expanded by economic incentives (e.g. via government grant restrictions, and awarding "seals of approval"), then international agreements.....Manufacturers would tag each new machine with an IIN (Instrument Identification Number like VIN numbers used in cars). A non-profit or government DNA Instrument & Reagent Registry (DIRR) database and web site would allow manufacturers and customers to register their instruments. Reagent vendors would be required to check that a customer had registered prior to shipping phosphoramidites to them. The registry would also supply IINs for existing machines, the resale of used machines and confirmed destruction of machines. Additional "discovery" would be achieved by methods analogous to current Drug Enforcement Agency (DEA) chemical monitoring."

[97] This insight came from MIT researcher Gautam Mukunda.

significantly higher degree of technical abilities. Other scientists argued that the difference between altering the envisioned "common platform" and the slicing of genes that is inherent in rDNA efforts is overstated and that slicing out a suicide vector would require only very standard abilities. No obvious export control opportunities on emerging technologies present themselves but an international group of outstanding scientists should systematically consider opportunities to shape emerging technology to complicate catastrophic attack.

Possible Controls on Delivery Capabilities

There do not appear to be useful targeted export controls for catastrophic delivery. There are two delivery routes that could possibly cause catastrophic effects. Additional analysis of the food and water route should be undertaken and dangerous junctures should be closed. For aerosol delivery, the needed materials were widely available for legitimate purposes. No control scheme seemed likely to work effectively for catastrophic aerosol delivery.

The best protection seems very simplistic but would likely be effective: aerosol spraying is a reasonably visible activity outside and can be secured against inside large venues. Law enforcement should take vigilant steps to secure against both inside and outside delivery of lethal biological agents through the aerosol route. A discussion of these activities would be a lengthy argument in its own right but there are two broad strategies: detection and suppression. Detectors can measure air either indoor or outdoor for dangerous biological pathogens. Some detectors of this type have been deployed. There are ongoing efforts to improve them technically and deploy them more broadly. The issue of detection and acting on the resulting tactical warning is discussed at length in the chapter on strategic decisions.

"Suppression" is more of a general category of efforts to swiftly identify and then stop efficient aerosol delivery. These can range from the prosaic (quality HFAC filters in air-handling systems of big buildings) to the traditional law enforcement (rigorously checking credentials of anyone spraying in public areas). None of these measures is a silver bullet but taken together they would vastly reduce the probability of an adversary executing a sustained, effective catastrophic attack.

*Conclusion*

This chapter reviewed whether export controls were a promising strategy to control the biotechnologies relevant for bioweapons. The needed materials and knowledge are so widely diffused internationally that general access controls could not work. It then considered whether there were any promising candidates for targeted access controls. It judged, in the end, that there did not appear to be any. The low probability of success for classic export controls makes the importance of seeking strengthened and broadly adopted international norms even more important. Norms should be adopted on biosafety and biosecurity: "biosafety aims to protect people from dangerous pathogens, while biosecurity aims to protect pathogens from dangerous people."[98] There should also be norms on worrisome dual-use research.

[98] Salerno and Estes in Pilch and Zilinskas, page 58.

## Prevention: Chapter 3

### Peaceful Use Limitations

Inspections can assure that worrisome technology is used only for peaceful purposes. This assurance can strengthen related norms and prohibitions because the inspections can assure countries that another state will not benefit from a military capability they have foresworn. This strategy appears to be exclusively a Cold War and post-Cold War creature. These peaceful use restrictions generally are implemented through international arms control treaties such as the Nuclear Non-Proliferation Treaty and the Chemical Weapons Convention. Under such treaties, states agree to a variety of measures, including declarations of facilities covered by the treaties' provisions and inspections to assure that the materials only are used for approved, peaceful purposes.

Inspections to assure enforcement of peaceful use limitations require meaningful technical differences between military and civilian programs and access by neutral inspectors to the program site. Inspections also require confidence that states will self-declare program sites for inspection and that these self-declarations will be reasonably accurate because of the deterrent effect of the well-known technical ability of other states or the international community to remotely identify likely program sites for challenge inspections. The technical ability to remotely identify program sites and then gain access to those sites also would be critical to identify the facilities of non-state actors.[99]

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[99] Chyba, "Toward Biological Security," see page 125.

The nuclear regime provides an example of the ideal case for inspections to assure peaceful use limitations. There are clear and immutable differences between the type of fissile material needed for a civilian and a military nuclear program and these differences can be assessed by inspectors with access to the program site. There is at least some reasonable basis for believing that the lists of program sites provided by a state will be accurate because of the deterrent effect of the well-known ability of the international community to remotely identify likely reprocessing facilities. This ability for remote detection gives some assurance that non-state actors could not construct reprocessing facilities, if the technical complexity and expense were not sufficient bars in their own right.

There is now an inspection regime for chemical weapons but it provides a more complex picture, because the military and civilian technologies are more tightly intertwined and the distinctions between military and civilian technologies are being rendered less important as the technology evolves. There remain some meaningful distinctions, particularly between a civilian and a traditional military chemical program. The lethal dose of a chemical weapon is relatively large and, under current technology, cannot be produced de novo in a lab, so building a stockpile large enough for a catastrophic attack would be difficult to conceal. A serious weakness in the chemical regime is that the treaty remains focused on monitoring for traditional World War II chemical weapons produced in a traditional fashion, even as the chemical technologies evolve rapidly.

*Likely Presence of Enabling Conditions*

Inspections to enforce peaceful use limitations would not work in the biotechnologies because there are no meaningful technical distinctions between a civilian and military program in

the general pre-attack stage.[100] Inspections are further undercut because there would be no reliable remote indicators of a biological program site to check the declarations of a state actor or to discover the facilities of a non-state actor. [101]

*Recommendations for Refinements*

Inspections to assure the peaceful use of biotechnologies should not be pursued. They would consume more diplomatic energy and goodwill than the security benefit they could confer. This dissertation urges instead that the diplomatic energy be invested in the development and adoption of international norms on biosafety, biosecurity and worrisome dual use research, as discussed elsewhere.

The dissertation does note that there would be meaningful technical distinctions between a civilian and a military program in the immediate pre-attack stage. There may be unique situations where the international community or the United States may wish to conduct inspections as part of a broader set of diplomatic measures in a particular crisis where a biological attack is feared to be imminent.

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[100] Kadlec, et al., "Biological Weapons Control" in Lederberg, ed., *Biological Weapons*, see page 96: "UNSCOM's experience in Iraq challenges the conventional wisdom that intrusive inspections can provide convincing proof of violations and resolve suspicions" and also page 105: "The experience of UNSCOM in Iraq has important lessons for negotiators seeking to strengthen the BWC. Iraq successfully deceived, denied, and hid information from UNSCOM inspectors concerning its biological weapons program for four years after the Persian Gulf War. Despite comprehensive mandatory declarations, numerous intrusive routine and challenge inspections to eighty biocapable facilities, including breweries, food production plants, pharmaceutical plants, and medical laboratories, UNSCOM found "no incriminating evidence that would identify any of the sites as linked to a proscribed biological weapons program." Yet, based on Kamel Hassan's detailed technical analysis of materials taken from the Al Hakam single-cell protein and biopesticide facility, Iraq developed and maintained a standby biological weapons capability under the constant scrutiny of UN routine and no-notice inspections."

[101] On the extreme difficulty of remote detection of a biological site, see Henderson e-mail to author, February7, 2008. See also Lederberg, "Introduction," in Lederberg, ed., *Biological Weapons,* page 7: "The facilities required for producing and dispensing BW agents are modest, easily concealable, and almost indistinguishable from licit production of pharmaceuticals and vaccines."

This chapter has three objectives: it (1) develops the necessary enabling conditions through a close examination of the leading example of inspections to assure observance of peaceful use limitations -- the "Atoms for Peace" trade that sits at the core of the broader nuclear non-proliferation regime; (2) shows the persistence of these needed enabling conditions in the Chemical Weapons Convention and the difficulties introduced for an inspection regime by a technology is changing rapidly; and (3) demonstrates that the biotechnologies lack the enabling characteristics needed for the successful implementation of an inspection regime. The section on biological inspections also makes two subordinate points: (a) It discusses and ultimately rejects the argument that, whatever the technical limitations of inspections, they would deter cheaters, particularly non-state cheaters; [102] and (b) It notes that the international community or the United States may wish to retain some technical capacity to conduct inspections as a confidence building measure in unique situations where an imminent attack is feared. There would be meaningful technical distinctions between a civilian and a military program in the immediate pre-attack phase.

(1) *The Nuclear Case: "Atoms for Peace" and its Progeny*

The greatest success story of peaceful use limitations is the "Atoms for Peace" trade that lies at the heart of the nuclear non-proliferation structure. Initially proposed by President Dwight D. Eisenhower, the system was created in 1957. Countries agreed to forego the option to develop nuclear weapons in exchange for technical assistance to exploit nuclear technology for the purpose of power generation. To reassure the broader international community that they were keeping their pledge to use nuclear technology exclusively for peaceful purposes, countries

[102] Harris, "Bioweapons Treaty," 08/24/2001, see: "The Bush team argues that because the equipment and materials used to make bioweapons are also used for legitimate civilian purposes, the convention's ban can't be verified. Therefore, no additional measures could detect violations with high confidence. The Clinton administration agreed that verification in this narrow sense was not possible....Rather than verification, our goal was deterrence: to make it more costly and risky for cheaters to keep cheating."

agreed to intrusive inspections conducted by the International Atomic Energy Association or IAEA. [103] There were significant entry costs – both fiscal and technological -- to nuclear technology, particularly in the 1950s and 1960s. Plants for enriching or reprocessing uranium are very large and noticeable from the outside, even from remote locations. There are meaningful technical distinctions between a civilian and a military nuclear program which inspections at the reprocessing sites are able to assess. While the nuclear non-proliferation structure is a little ragged around the edges these days and needs to be updated, it probably slowed the rate of new nuclear powers.[104]

*What do you need for a nuclear weapon?*

Most analysts judge that a program needs two basic items for a workable nuclear weapon – a firing device and a sufficient quantity of fissile material. Most technical experts agree that the most primitive type of firing device – a gun device – is hard but not insurmountable technically. Its basic technical elements have been well understood for decades. A "gun type" firing device was considered sufficiently straightforward technically that the "gun type" firing devices used in the US nuclear weapons dropped on Japan at the end of World War II were not tested before use. A gun device probably limits the net yield of the weapon to about 10 kiloton of destructive force. But this is still easily strong enough to destroy large areas of a city. The bombs used on Hiroshima and Nagasaki were on this rough order of magnitude. [105]

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[103] International Atomic Energy Agency, "About the IAEA: The 'Atoms for Peace' Agency," and "Mission Statement," IAEA website (http://www.iaea.org?ABout/index.html accessed 4/20/2009).
[104] See, for example, Peter R. Lavoy, "The Enduring Effects of Atoms for Peace," Arms Control Association website (http://www.armscontrol.org/act/2003_12/Lavoy accessed 4/29/2009).
[105] Federation of American Scientists, "Nuclear Weapons Design,", FAS website (http:://www.fas.org.nuke/intro/nuke/design.htm accessed 5/30/2009) .

More sophisticated weapons, like those used by the two superpowers during the Cold War, tend to use the more complicated "implosion" firing device. These firing devices are more complicated to build and would tend to need testing or at least extensive and sophisticated simulation to have confidence in their effectiveness. The implosion firing device can generate larger yields overall and a larger yield per volume of fissile material.[106]

The second thing needed for a nuclear weapon is fissile material. There are two types of fissile material – highly enriched uranium and plutonium. Getting enough fissile material is still considered to be hard. There are technical challenges to enrichment or separation itself and the material is highly radioactive and thus requires facilities and handling equipment with heavy shielding. Much of the needed equipment is unique to the purpose of enrichment or separation to acquire weapons grade material.

Gun devices use highly-enriched uranium. A simple gun-type nuclear weapon would need about 90-110 pounds of weapons grade uranium. Natural uranium consists overwhelming of uranium 238; only 0.7 percent of natural uranium is uranium 235 – the uranium isotope needed for a nuclear weapon. Highly enriched uranium or HEU contains at least 20 percent of uranium-235, while "weapons grade" uranium is generally 90 percent or more uranium-235. The two types of uranium isotopes are sufficiently similar that separating them is a challenging task technically and requires expensive and specialized equipment.[107]

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[106] Federation of American Scientists, "Nuclear Weapons Design," FAS website (http://www.fas.org.nuke/intro/nuke/design.htm accessed 5/30/2009).

[107] Union of Concerned Scientists, "Fissile Material Basics," UCS website (http://www.ucsusa.org accessed 12/17/2007), page 1-2: "Uranium occurs naturally, but fortunately not in a form that is directly usable for nuclear weapons. Natural uranium consists mostly of two different "isotopes" – atoms of the same element that differ only in their number of neutrons and thus have slightly different weights. Natural uranium contains approximately 0.7 percent uranium-235 (the isotope essential for nuclear weapons) and 99.3 percent uranium-238. To convert natural uranium into a form that can be used in nuclear weapons, it must be "enriched" to increase the concentration of

Plutonium also can be used for a nuclear weapon. Plutonium is acquired by separating the different elements in the fuel produced as a byproduct of a nuclear power plant. The spent reactor fuel is reprocessed to separate the plutonium from the rest of the fuel. While technically easier than separating the highly similar uranium isotopes, the process is still highly radioactive and would require special, shielded facilities and equipment.[108] There is no civilian requirement for fissile material and there is no requirement for the specialized equipment in the needed quantity or configuration that creates this material.

Concerns about a non-state actor focus on them acquiring either a complete device or enough fissile material either covertly or overtly from a national source. This is because building a plant to reprocess or enrich fissile material is still considered hard overall for a non-state actor and difficult to conceal. From the public record, it is hard to assess the full proliferation implications of the efforts of Pakistani nuclear scientist A.Q. Kahn. From public statements, it appears that his contributions are considered to have speeded the efforts of state programs – particularly Iran and North Korea – but there does not appear to be the implication he eased the challenge to a non-state actor.[109]

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uranium-235. Enriching uranium is both technically difficult and expensive, as it requires separating isotopes that have very similar chemical and physical properties. The enrichment process is thus the main barrier to producing uranium suitable for use in nuclear weapons."

[108] Union of Concerned Scientists, "Fissile Material Basics," UCS website (http://www.ucsusa.org accessed 12/17/2007), page 2: "Plutonium separation is easier than uranium enrichment because it involves separating different elements rather than different isotopes of the same element, and it uses well-known chemical separation techniques. However, since the spent fuel is highly radioactive, this process requires heavily shielded facilities with remote handling equipment."

[109] Bobby Ghosh, "The U.S. Sees Dangers in Khan's Release," *Time,* Friday Feb 6, 2009: "State Department spokesman Gordon Duguid said Khan "remains a serious proliferation risk." He added, "The proliferation support that Khan and his associates provided to Iran and North Korea has had a harmful impact on the international – on international security, and will for years to come."

*Weaknesses of the Nuclear Non-Proliferation Regime*

Prevention strategies do not work forever. The nuclear regime is showing significant weaknesses and should be strengthened and updated. Several states that were members of the IAEA inspection regime -- Iraq, North Korea, and Iran -- have pursued nuclear weapons capabilities through exploiting various loopholes in the IAEA regime. Access to "peaceful" technology from the IAEA probably did speed the sophistication of nuclear programs in several countries of concern.[110]

Israel, India and Pakistan are not signatories of the NPT and hence do not come under the coverage of the IAEA. Most analysts assess, however, they each have nuclear weapons capabilities of various sizes and sophistication.[111] A durable system-wide way to reconcile these de facto nuclear weapons states with the prohibition on new nuclear weapons states in international law has yet to be conceived much less implemented. Russia, with US technical assistance and funding, continues to try to identify and secure its extensive fissile material stockpiles left over from the Soviet era. There are broad concerns about the increasing ease of an adversary, either state or non-state, acquiring fissile material.[112]

(2) *The Chemical Regime – Strengths and Stasis*

Both the nuclear and chemical regimes can claim significant successes and confront significant weaknesses. The CWC is a much younger regime – having been in operation for only about a decade. Negotiation of the CWC was begun in the 1980s and completed in 1993, with

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[110] See, for example, Peter R. Lavoy, "The Enduring Effects of Atoms for Peace."
[111] Arms Control Association, "The Nuclear Non-Proliferation Treaty (NPT) at a Glance," Arms Control Association Fact Sheet, Arms Control Association web site, (http://www.armscontrol.org/factsheets/nptfact accessed 5/30/2009).
[112] Graham Allison, Ashton B. Carter, Steven E. Miller and Philip Zelikow, eds., *Cooperative Denuclearization: From Pledges to Deeds,* Harvard Project on Cooperative Denuclearization (Cambridge, MA: Harvard University, 1993).

the treaty entering into force in 1997. A great success of the CWC is the supervised destruction of the extant stockpiles of acknowledged chemical weapons. Both the United States and the Russian Federation have very large stockpiles of chemical weapons that are very expensive to destroy but are far better off being destroyed than decomposing in volume in stockpiles. The CWC also provides greater transparency into the disposition and trade of precursor ingredients for the very lethal chemical weapons developed for use in World War I and World War II. These would prove no less lethal against a civilian population today. The CWC requires declarations of holdings of chemicals of particular concern and allows routine and challenge inspections of certain state and private facilities to clarify information in state declarations and raise the costs of cheating in the declarations. The chemical regime is hampered by the reality that protecting against traditional, World War II chemical weapons produced by traditional, World War II techniques will cease at some point to be a sufficient solution to the real chemical challenge posed by a rapidly evolving technology.

*Chemical Inspection Regime*

Two broad differences between chemical and biological weapons are relevant to the question of the relative efficacy of inspections. First, the lethal dose of a chemical agent generally is significantly larger than the lethal dose of a biological agent. Hence, the volume of chemical agent required for a catastrophic attack would be extremely large and, in most contexts, observable.[113] A lethal dose of the chemical agent VX would be 15 ug per kg of body weight,

[113] This difference is widely recognized in the technical community. See, for example, Jonathan B. Tucker, "Introduction," in Jonathan B. Tucker, ed., *Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons"* (Cambridge, MA: The MIT Press, 2000), see page 5: "At least in theory, germ weapons are much more potent on a weight-for-weight basis than even the most lethal chemical weapons. Nerve agents such as sarin can kill in tiny doses if inhaled, but they must be delivered in massive quantities to produce lethal concentrations over large areas. For example, a chemical attack that caused 50 percent casualties over a square kilometer would require about a metric ton of sarin. In contrast, microorganisms infect people in minute doses and then multiply within the host to cause disease. For example, a mere 8,000 anthrax bacteria – an amount smaller than a speck of dust – are sufficient in infect a human being. As a result, a biological attack with a few kilograms of anthrax could inflict the same level

while a lethal dose of the chemical agent sarin would be about 100 ug per kg of body weight. In contrast, lethal doses of biological agents – assuming the technical issues about micron size and delivery have been surmounted – are much smaller. For anthrax or smallpox exposure through the inhalation route, it would take as few as 10-15 particles. For a biological agent like botulinum toxin, the lethal dose is 0.001 ug per kg of body weight. [114]

Hence, for a catastrophic attack (10,000 dead), the volume required of chemical agents would be on the order of 1,000-fold greater than for a biological attack. The chemicals themselves are flammable and dangerous to handle and, once released, can be a little unpredictable unless close attention has been paid to the prevailing winds and other meteorological conditions. Chemical weapons are more amenable to inspection regimes than biological weapons because of the larger volumes necessary for a catastrophic attack.

The second significant difference between biological and chemical weapons is that under current technology, a chemical stock is not self-generating. Securing larger quantities requires securing more precursor chemicals.[115] Under current technology, the building blocks for

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of casualties over a square kilometer as a metric ton of sarin – provided that the anthrax was efficiently disseminated." Also, the chemical agent phosgene oxime causes severe burning to the eyes at about 200 mg for a minute, with death at about 3,200 mg, a density of exposure hard to sustain in an open area. While used in World War I as a chemical agent, phosgene is now used widely for a variety of industrial purposes and retains its ability to inflict injuries.

[114] There are significant substantive disagreements about the toxicity data. The estimates are generally extrapolated from small amounts of animal data. The numbers cited here are what is called "LD50" or amounts where 50 percent of the people exposed to this amount would have received a Lethal Dose (aka: "LD50"). This data is drawn from the standard reference books on this subject, Medical Management of Biological Casualties Handbook, page I-1 and the US Army Medical Research Institute of Chemical Defense (USAMRICD), Medical Management of Chemical Casualties Handbook, Chemical Casualty Care Division, Aberdeen Proving Ground, Maryland, Third Edition, July 2000, page 266. There are two reasonable criticisms: the difficulty of extrapolating (1) human effects from animal data; and (2) general effects from small "n" tests.

[115] For the technical aficionado, it could be noted that the third significant difference between chemical and biological weapons (which does not affect the relative usefulness of inspections) is the period of time between exposure to lethal dose and death. Classic chemical weapons, when administered in lethal dose, cause death very quickly, often in minutes. Military professionals can be equipped and trained to self-administer medical countermeasures against most classic chemical agents on an effective timeline. But given the short timelines between exposure and death, civilian populations could only be saved through timely administration of medical

chemical weapons either have to be purchased or their precursor ingredients have to be purchased. These chemicals, at least in large quantity, have to be reported under the CWC. The CWC thus does complicate the production through traditional techniques of large stocks of dangerous WWI and WWII chemical weapons. This is in contrast to biological weapons which do not confront a meaningful quantity constraint. Once an adversary has acquired the needed seed stock for a dangerous pathogen, further volumes can be grown using biological growth media that is used so widely in legitimate research that it probably could be acquired without triggering suspicion.

*Details of the Chemical Treaty*

The chemical weapons treaty requires states to declare and eventually destroy all chemical weapons stockpiles and production facilities.[116] It also requires the declaration of chemical industry facilities that produce or use chemicals of concern. These chemicals are organized into three "schedules" or lists of chemicals that pose a high, significant or low risk. The accuracy of the declarations is checked through the use of "routine" inspections, with most facilities only being inspected every couple of years.

While there are certainly troubling aspects to the treaty, the interaction effect that the precursor chemicals cannot be created de novo and that large quantities are required for a catastrophic attack do have the effect of meaning that the diversion of the quantities of precursor chemicals needed for catastrophic attack using World War I or II era chemical weapons would

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countermeasures in a very unusual set of circumstances. Biological agents, even when administered in lethal dose, have various periods between exposure and death but this period tends to be at least about 48 hours.

[116] Chemical weapons related materials are organized into categories in the treaty, with category one being the most dangerous (VX and sarin); category 2 being somewhat less dangerous (phosgene); and category 3 being even less dangerous (munitions and equipment unique to chemical weapons).

be difficult. Diversion on that magnitude would certainly be complicated by the reporting provisions required under the treaty.

The treaty also allows states to request that challenge inspections be conducted at a site in another state if there are grounds to believe that the site is in "fundamental" as opposed to "technical" violation of the treaty. Despite this provision, though, no challenge inspections have ever been formally requested or launched under the Chemical treaty.[117] The timelines between a state levying the request for a challenge inspection and the team actually securing admittance to the site would vary but unless the challenged country waived all rights, the challenged country would have at least 157 hours or about a week of warning.[118] A week is a remarkable amount of time, easily long enough to hide biological seed stocks, destroy stockpiles, and thoroughly clean fermentors and other key equipment. The verification provisions of the CWC are considered a high point for arms control. Even the most ardent arms controller appears to hope only to replicate them in a BWC inspection regime, not improve significantly upon them.

[117] John Hart, "Political and Technical Aspects of Challenge Inspections under the Chemical Weapons Convention," Presented at "EU Seminar on 'Challenge Inspections' in the framework of the CWC" Austrian Federal Ministry for Foreign Affairs, 24-25 June 2004, Vienna, Austria, SIPRI website (http:/www.sipri.org/ accessed on 11-17-07).
[118] Hart, "Challenge Inspections," page 3-4.

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|---|---|
| State requests challenge inspection | S |
| Director-General confirms request meets criteria | S+1 |
| Director-General must inform challenged state party at least 12 hours before team arrival | S+13 |
| EC Meeting can't occur in less than 3 hours, EC empowered to stop inspection if ¾ votes charge to be "frivolous" | Embedded |
| Inspection team readies itself, and then travels to point of entry in challenged country (Having the team on this short of a tether seems unlikely; even US military forces considered to be on alert are often on a tether of at least 24 hours) | Embedded |
| Inspection Team arrives in country and informs challenged country of the site of interest, range of travel time to perimeter of site (12 to 36 hours) | S+49 |
| Team enters inspection site (108) | S+157 hours |

*Weaknesses of the CWC*

As the CWC moves into its second decade, there are three questions that will help determine its ongoing relevance. First, how and to what extent can the treaty update its methods to deal with new chemicals or new ways of producing old chemicals? The treaty is vulnerable to staying focused on traditional techniques to produce World War I and II weapons. This is a worthy but somewhat limited goal.

Second is the inherent problem of relying so extensively on self-declarations about dangerous stocks. While the treaty permits challenge inspections, none have yet been launched. While current technology does not permit the creation de novo of particularly dangerous chemicals used in WWI and WWII, there is always a risk of diversion. This weakness in the treaty is all the more worrisome because export controls were eliminated on chemicals covered by the treaty as a quid pro quo for chemical industry acquiescence with the inspection protocols.

The third weakness in the treaty is that the inspection protocols necessarily have been shaped fundamentally not merely by what is lethal but by what is easiest to inspect with the smallest inconvenience to industry. Chemicals that are lethal but have legitimate commercial purposes are much more easily acquired in quantity. An example of this is phosgene, which was used in World War I. Chlorine, the first chemical agent used in war in the modern era (by the Germans in World War I), is not on the list at all given its extensive use in water systems. The transport of large quantities of these chemicals into populated areas for peaceful purposes could provide an adversary with an opportunity. These "Schedule III" and other chemicals, if the containers were breached by an accident or an adversary and the weather conditions were

favorable from an adversary's perspective, could produce large plumes that could harm populations in the immediate area.

*(3) The Biological Case*

The Geneva Convention signed in 1925 forbids the use of biological weapons in warfare. The Biological and Toxins Weapons Convention (BWC), negotiated and signed in the early 1970s, forbids possession of these weapons except for certain, narrow defensive purposes. The BWC contains no meaningful verification provisions. It does require states to provide declarations about facilities with certain characteristics, including particularly those facilities with particular research and development capabilities.[119]

*Ease of Shrouding Offensive Biological Program*

There is a significant literature outlining the ease of shrouding an offensive biological weapons capability in the general pre-attack stage within a legitimate pharmaceutical program. The ease was acknowledged during the initial crafting of the BWC. The British, who were advocating development of the treaty in July 1968, recognized internally that the difficulty of distinguishing an offensive program from legitimate efforts was "insurmountable.'"[120] And "insurmountable" it has remained with the challenge only becoming greater since 1968 with the growing sophistication and diffusion of the biotechnologies.

The fermentors, incubators, freeze-dryers, and growth media, for example, that an offensive program would use to isolate, modify or grow agent would be exactly the same as the equipment a legitimate program would require to do research, diagnostics, or develop vaccines. The equipment can be thoroughly decontaminated so as to conceal evidence that the equipment

[119] Kadlec, et al in Lederberg, ed., *Biological Weapons.*
[120] Quoted in Koblentz, "Pathogens as Weapons," PhD diss., page 45.

was used to grow or otherwise manipulate a dangerous pathogen.[121] In the general pre-attack stage there would only be limited reasons to actually use a dangerous pathogen – related, but benign organisms would provide most of the needed insights, pose less of a risk to technicians and look entirely legitimate to any lab visitor. The ease of shrouding an offensive program in a legitimate program is widely acknowledged:

> Scientists with the expertise necessary to misuse biology can be found internationally in nearly all areas of the life sciences. Important advances in the biosciences, many of which could be exploited to cause harm, are published almost every day in scientific journals, research publications, patents, and on the internet. Modern biotechnology, including the tools necessary to develop and disseminate a low-grade biological weapon, is also ubiquitous in the international pharmaceutical, agricultural, and microbiological communities. And viable and virulent organisms—almost all of which occur naturally – are stored and used in legitimate bioscience facilities around the globe. The fundamentally "dual-use" nature of all the technical building blocks of biological weapons – materials, technology and expertise – not only provide ample opportunities for terrorists to exploit but also make imposing controls extremely difficult.[122]

The relative ease of shrouding an offensive program in a legitimate program can be demonstrated by the very unique context within which the United Nations inspections occurred in Iraq in the period between the two Persian Gulf wars. The UN's experience indicates that a sustained, highly intrusive (anytime, anyplace challenge inspection regime) technically proficient inspection effort cannot really find unambiguous evidence of a program in the general pre-attack phase. [123] An inspection effort like the UN in Iraq from 1992-2002 was probably helpful in establishing the past efforts by an adversary and also in complicating an adversary's current efforts on weapons programs. As the summary indicates, though, it was not fully successful at either objective.

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[121] Reynolds Salerno, Manager, International Biological Threat Reduction, Sandia National Laboratory, e-mail message to author, December 6, 2007.
[122] Salerno and Hickok, "Strengthening Biological Prevention," page 108.
[123] Drawn from Koblintz, *Pathogens as Weapons,* PhD diss., pages 48-83.

Some of the UNSCOM triumphs are remarkable. One of the most impressive was its ability to piece together the total quantity of growth media imported into Iraq between 1987-1990 and demonstrate the incoherence of Iraq's explanations of how the growth media had been used. This technical example helped shore up support in the UN Security Council for tougher pressure on Iraq because it illustrated the probability that Iraq was still lying about a large production program in the late 1980s. But UNSCOM also shows the profound difficulty of such inspections, even under these most favorable of circumstances. For example, there were persistent disagreements among UNSCOM's technical staff about the real purpose of various Iraq facilities. Even with complete physical access to the facilities, UNSCOM was unable to either identify concealed locations or, more commonly, to prove that unapproved activities had occurred at known locations. [124]

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[124] Kadlec, et al., in Lederberg, *Biological Weapons,* see page 105: "Iraq successfully deceived, denied, and hid information from UNSCOM inspectors concerning its biological weapons program for four years after the Persian Gulf War. Despite comprehensive mandatory declarations, numerous intrusive routine and challenge inspections to eighty biocapable facilities, including breweries, food production plants, pharmaceutical plants, and medical laboratories, UNSCOM found "no incriminating evidence that would identify any of the sites as linked to a proscribed biological weapons program." Yet, based on Kamel Hassan's detailed technical analysis of materials taken from the Al Hakam single-cell protein and biopesticide facility, Iraq developed and maintained a standby biological weapons capability under the constant scrutiny of UN routine and no-notice inspections." See also Koblintz, *Pathogens as Weapons*, PhD diss., see page 81: "A net assessment of UNSCOM's investigation of Iraq's biological weapons program does not yield a simple clear-cut review. UNSCOM's success was neither swift nor complete, but was significant. Between 1991 and 1994, UNSCOM visited several dual-capable sites in Iraq including Al Hakam, Dawrah, Taji, and Fudaliyah and failed to find any incriminating evidence that linked them with biological weapon activities. As a result, until 1995, Iraq was able to retain the facilities, equipment, growth media and personnel at Al Hakam to restart production of biological weapons. UNSCOM's investigation, supported by information from foreign suppliers and national intelligence agencies, eventually led to the collection of a large amount of compelling yet circumstantial evidence that indicated that Iraq was hiding an offensive program. UNSCOM was also able to refute Iraq's claims to the contrary or demonstrate the implausibility of Iraq's alternative explanations. Although UNSCOM's detective work forced Iraq to admit to an offensive program and the production of biological warfare agents at Al Hakam, it took the defection of Hussein Kamal for Iraq to reveal a more complete history of the program, scope of research and production activities, and the extent of weaponization. This disclosure allowed UNSCOM to destroy the production equipment, facilities, and growth media that Iraq had used in its offensive program. UNSCOM, however, was unable to satisfactorily verify Iraq's newest accounts of the program. Although this failure was due to Iraqi obstruction, it illustrates the limits of UNSCOM's independent capabilities and its reliance on Iraqi cooperation. Furthermore, Iraq was able to conduct biological weapons-related research and development under UNSCOM's nose: first at al Hakam and later in the secret laboratory network established by the Iraqi intelligence service."

*Immediate Pre-Attack Stage*

There is an important distinction to be made between "general pre-attack" and "immediate pre-attack." In the general pre-attack stage, only small quantities of a lethal agent would be needed by an adversary. Much of the research could be conducted using related, benign organisms. Work on delivery vehicles could occur in a separate facility and could use simulents to test dispersion techniques. International law specialists, microbiologists and fervent advocates of arms control have agreed "that offensive and defensive research were distinguished only by intent, and not by substance."[125] The facilities needed to grow large quantities of agent could be configured so as to give few if any external indications of volume production of a pathogen: "pathogen production facilities can be extremely identical to a pharmaceutical facility and even be a pharmaceutical facility."[126]

There are, though, reasonably clear indications of an offensive intent in the immediate pre-attack stage – large quantities of agent with large numbers of delivery vehicles optimized for release of pathogens against civilian populations. Most experts agree filling numerous delivery vehicles with large quantities of agent would be signs of an offensive program but need not occur much before an attack and need not generate many, if any, externally observable indicators. The window would be small in time, and not necessarily observable unless one was inside or close to the facility in question.[127]

It would be useful for some organization, possibly an element of the United Nations, to harvest, sustain and extend available expertise to conduct inspections to identify an offensive

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[125]Leitenberg, "Distinguishing Offensive from Defensive Biological Weapons Research," *Critical Reviews in Microbiology*, Volume 29, Number 3/July-September 2003, pages 223-257, see page 224.
[126] Koblintz, *Pathogens as Weapons*, PhD diss., page 42.
[127] Koblintz, *Pathogens as Weapons*, PhD diss., pages 42-43. See also Leitenberg, "Distinguishing Offensive from Defensive Biological Weapons Research," page 246.

biological weapons capability in the immediate pre-attack phase. The range of situations where this type of program could be helpful is relatively small (and would require a very unusual political context) and the limits on the confidence of its findings would be extensive. It is probably, though, worth the small investment to nourish a community of individuals expert in these techniques.

*Inspections and Non-State Actors*

These arms control regimes are built on a structure of declared sites and holdings of sensitive items and then inspections, of varying aggressiveness, to validate or invalidate the declarations. They founder because of the ease of concealment – either of dangerous sites or of dangerous holdings within declared sites. The nuclear and chemical regimes work – to the extent that they do work -- because concealment is hard, or at least it is hard enough if there is some risk an inspector could be visiting the facility.

This section focused on the issue of whether one could distinguish between an offensive or legitimate program. For a non-state actor, the challenge is more whether the site itself could be entirely concealed. It would be difficult for a group to entirely conceal a site used to enrich uranium. Few expect a non-state actor to enrich their own uranium, but rather fear they would get the fissile material from some other source. It would not be as difficult to conceal a site used for an offensive biological program. There would be two strategies for a non-state actor. One would be to create an open, putatively peaceful biological program and embed the offensive work inside of that program. This paper has already discussed the relative ease of doing so. The vulnerability to a non-state actor would be establishing and maintaining the providence of the putatively peaceful program. Whatever the technical ease of shrouding an offensive program,

other indicators – like sources of funding or histories of personnel – could reveal the real ownership and objective for the facility.

The second strategy for a non-state actor would be to conceal the program site entirely. This would be a tricky, but probably not impossible effort. The aspects of a program directly related to agent manipulation would be the easiest to control. Many of the most observable elements of a lab for biological weapons purposes – like the air handling systems or the overhead hoods – could be avoided by a non-state actor inclined to cut corners and accept greater personal risk for lab personnel. One of the buildings in Iraq later established to have been involved in its offensive weapons program was given a clear assessment by very talented UNSCOM inspectors because it lacked safety features that would have been required in a Western lab.[128] The delivery aspects, as has been discussed, could be the most easily observed. Concealment probably would require separate locations for pursuing various aspects of the planned delivery technique.

*Deterrence, Transparency and Other Putative Benefits*

Some security analysts argue that the addition of an inspection regime to the BWC would add a strong deterrent against countries having inappropriate biological weapons programs. State parties to the BWC already have to provide declarations about all facilities with specific characteristics. These experts argue that, under a rigorous inspection regime, states considering whether to pursue an offensive biological weapons capability, faced with the prospect of a possible challenge inspection at a secret facility, would be deterred. These analysts argue the state would face a stark choice: It would have to either include the secret, offensive facility on its list of declared sites and face the prospect of routine inspections to clarify or confirm the report data, or leave the secret, offensive facility off the list and run the risk of being confronted with a

[128] Koblintz. *Pathogens as Weapons*, PhD diss.

"smoking gun" should a challenge inspection be demanded for the secret facility. The inspection, in this theory, would show clearly that the state had offensive biological programs underway at the site. The risk that either a routine or a challenge inspection would reveal the offensive site would prevent states from having these sites in the first place, according to this argument.[129] There is logic to this argument. The force of the argument turns fundamentally, though, on the strength of two assumptions: (1) that an undeclared offensive site runs real risk of being discovered; and (2) that an inspection, either routine or challenge, would reveal the weapons-related elements of an offensive program in a general pre-attack stage.

These assumptions are extremely weak in the case of biological weapons and significantly weaker in the biological case than either the chemical or particularly the nuclear case. In the chemical and nuclear case, these inspection regimes rest, however imperfectly, on very small but meaningful and durable technical differences between a civilian and a military program. Yet even these small technical differences cannot be found in a biological program in the general pre-attack stage. The absence of these small differences undercuts the two assumptions upon which arguments for a biological inspection regime would rest. The weakness of these assumptions in the biological case is why securing these types of inspections would not, on balance, increase the confidence of the biological regime.

*Conclusion*

The prior sections argue that because of the technology of biology neither of the assumptions inherent in arguments in favor of inspections hold: (1) that an undeclared offensive biological site runs real risk of being discovered; and (2) that an inspection, either routine or challenge, would reveal the offensive elements of an offensive biological program in the general

[129] See, for example, the comments of Meselson, "Reducing the Threat."

pre-attack stage. Securing the inspections, hence, would not yield net security benefits against state programs. In addition, the largest threat is from non-state as opposed to state programs. These types of inspection regimes would yield even less benefit against non-state programs because of the low probability that either a host or non-host country could remotely detect a program site.

## Prevention: Chapter 4

### Norms, Sanctions and Benefits

Norms on biosafety, biosecurity and worrisome dual-use research would enhance national and international security. Functionalist literature and case studies indicate that it is promising to attempt to build norms within an international technical elite whose shared, core values and interests are consistent with the norms. Norms can be violated and still be useful as long as they play a meaningful culling role, sorting problematic and potentially dangerous cases from standard cases. This culling should reduce the number of potentially dangerous cases to a number that are then more thoroughly examined through targeted diplomatic, law enforcement or intelligence efforts.

Observance of norms can be strengthened through the use of sanctions or benefits. Sanctions are easiest to establish in the national context or for issues that are perceived to be non-zero sum in the international environment (like trade). Benefits, while quite imperfect, have been made to work for at least a time in the security realm as demonstrated by some alliance relations and the "Atoms for Peace" trade that lies at the heart of the international nuclear non-proliferation regime.

Current US policy appears to be to construct and impose a national unilateral system of norms using sanctions, including criminal and civil penalties and denial of federal funding and licensure. This approach has a security benefit, but also imposes security, economic and technological costs. An international system of norms would be vastly better from a security perspective, as well as an economic and technological perspective.

This chapter recommends that the United States should root norms on biosafety, biosecurity and worrisome dual use research in the relevant international technical elite – the international life sciences community. While there are many articles that call for better control of access to dangerous pathogens, none[130] are very specific about the mechanism by which this should be achieved and none warn sufficiently of the importance that the norms be established in the international as opposed to the national context. Observance of the norms should be catalyzed through the use of benefits, specifically participation in an international scientific effort to develop defensive medical countermeasures. There are a variety of additional benefits to such an approach, which are discussed more systematically in the later chapter on medical countermeasures.

This chapter stays more narrowly focused on norms, specifically how to catalyze their development and broad observance. The chapter (1) reviews neofunctionalist theory and case studies to demonstrate the argument that international technical elites are a good place to root norms, particularly if those norms are consistent with the core values of the international technical elite; (2) demonstrates that the current US policy appears to be to construct a national unilateral system of norms enforced through sanctions; and (3) outlines the limited security benefit of such a system but also its significant security, economic and technological costs.

[130]See, for example, Chyba, "Toward Biological Security," see page 127: "....Washington should act to improve international control of dangerous pathogens, either within the BWC framework (perhaps by supporting the proposal of a like-minded ally) or in a new forum." See also Koblentz, "Pathogens as Weapons" *International Security,* see page 121: "[T]he barrier to the acquisition of biological weapons should be raised by limiting access to dangerous pathogens, techniques, and research results applicable to the development of biological weapons." And see Salerno and Hickok, "Strengthening Bioterrorism Prevention," see page 107: "Global biological materials management, which would focus on identifying and protecting those biological materials at the greatest risk of being used maliciously, is one potential solution."

*(1) Norms: Their Creation, Persistence, and Enforcement*

There was tremendous interest in the academic study of international relations, particularly starting in the 1970s, about "norms" and "international regimes." Both realists and liberals, the traditional protagonists in the study of international relations, recognized that interactions between individuals who were citizens of different states and between the states themselves were increasingly mediated by "international regimes" or "principles, norms, rules, and decision-making procedures around which actor expectations converge in a given issue-area."[131] The existence and effects of "international regimes" have been quite evident in the post-World War II period and particularly after the early 1970s.

*Useful Role of Technical Elites*

International technical elites are often a promising place to build and enforce norms, particularly when the objective of the norm is consistent with the values of the technical elite. The core motivation for regime construction is the mutual recognition that individual behavior will yield an outcome that is less desirable to both parties, or, in the terms of microeconomics, the uncoordinated outcome will not be "pareto-optimal." The leading explanation for what causes the construction of regimes is "functionalism." While the theory of "functionalism" has evolved, its core assumption is that the growing complexity of issues in the 20th century demands that international communities of technical experts work together to resolve common issues. Examples of this sort of technical issue include trade policy, maritime and airline norms, and environmental issues. These are all issues where it is at least theoretically possible that cooperation could yield a better outcome for everyone. Technical experts in these issue areas are

[131]Stephen D. Krasner, "Structural Causes and Regime Consequences: Regimes as Intervening Variables," *International Regimes* (Ithaca and London: Cornell University Press, 1983), page 1.

able to step outside of their national affiliation because of the shared norms of their professional community: "By emphasizing cooperation to find solutions according to a specific need or function, the basis would be created for a thickening web of cooperation leading to the formation and strengthening of international regimes and institutions."[132] As one example, international elites generally believed that free trade benefited everyone and hence were generally prepared to negotiate and implement rules that strengthened and enhanced free trade in the post-World War II period. Regimes are recognized to be less common and more difficult to construct for security issues because of the focus on relative standing generally inherent in security calculations. The security area "more closely approximates zero-sum games than do most economic issue-areas" hence complicating the construction of regimes.[133]

There is a generally held view among cooperation theorists that positive experiences in cooperating in one issue area can fuel a readiness to deepen the cooperation in that issue area or extend cooperation to a related issue. Beyond that general observation, there are different views about the mechanisms by which the cooperation can be extended. David Mitrany, an earlier writer on functionalism, called this process "ramification" because successful cooperation in one technical area would validate or "ramify" the usefulness of cooperation in a broadening set of issues, ideally eventually encompassing essentially all issue areas and hence reducing the risk of war and the relevance of the nation-state.

More recent work, often based on the process of European integration, has been somewhat more qualified in its eventual expectations and somewhat less altruistic in its core source of motivation. Neofunctionalists like Ernst Haas have agreed with Mitrany that groups of

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[132] James E. Dougherty and Robert L. Pfaltzgraff, Jr, *Contending Theories of International Relations: A Comprehensive Survey* (New York: Addison Wesley Longman Inc., 2001), page 512.
[133] Krasner, page 8.

technical experts are a sound place to start cooperation, but have underscored that the technical experts are most likely to be successful if they represent their functionally specific national bureaucracies. Haas agreed that successful cooperation in one issue area was likely to have a positive "spill-over" effect on the state's readiness to cooperate in a related area. Eventually, cooperation must move beyond technical issues to a more political commitment if it is to persist and broaden.[134]

*Persistence of Norms*

There also has been significant attention to the question of whether norms have persistence, particularly as the underlying distribution of power changes in the international environment. This issue was highlighted by whether the "regimes" or agreed norms, particularly those that managed international economics and had enabled the remarkable period of international economic growth experienced after World War II, could be sustained even as the relative economic power of the United States, the principal shaper and enforcer of these regimes, declined. Authors distinguished between the greater demands of "regime creation" as opposed to "regime maintenance." Liberals believe it is vastly easier to create norms or cooperative structures than realists, but both agree that the demands for "regime maintenance" would likely be lower than "regime creation."

While disagreement persists about whether the unique security conditions of the post-World War II environment were necessary for the creation of the various norms and regimes, even realists could agree that the structures could "assume a life of their own" and continue even as the relative power of the United States declined. Realists though remain "skeptical of the

[134] Ernst B. Haas, *Beyond the Nation-State: Functionalism and International Organization* (Stanford, CA: Stanford University Press, 1964).

extent to which regimes can persist in the face of alterations in the underlying national power capabilities."[135] The more liberal authors were somewhat more optimistic that the regimes had a persistence that would enable them to continue and perhaps extend their ability to manage certain areas, despite a decline in relative power.

*Norm Against Biological Weapons*

The strength and persistence of the norm against biological weapon acquisition and use is highly ambiguous. It certainly appears today to be a relatively strong norm. Some analysts assume it will persist and grow. Others argue it was unique to the historical period of the Cold War and will not persist in the changed strategic environment. For example, Samuel Huntington has argued that it was unique to the Cold War era and will not durably extend beyond that era. Huntington argues that viewed through the lens of civilizational conflict, arms control and non-proliferation efforts in the post-Cold War period do not advance universal norms, as is often claimed by their proponents. They instead represent attempts by the West to prevent other countries from acquiring weapons which are probably the other countries only viable strategy for challenging the military supremacy of the United States. Foreign militaries generally prefer to avoid confronting the United States in a classic conventional war. States outside the traditional anti-Soviet alliance increasingly have been, particularly since the first Persian Gulf War, turning to asymmetric modes of attack, with a particular focus on nuclear, biological and missile capabilities.[136]

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[135] Krasner, page viii.
[136] Samuel P. Huntington, "The Clash of Civilizations?" *Foreign Affairs*; Summer 1993; and *The Clash of Civilizations and the Remaking of the World Order* (New York: Simon & Schuster, 1996).

*Enforcing Norms: Sanctions or Benefits*

Regimes are recognized to be less common and more difficult to construct for security issues because of the focus on relative standing generally inherent in security calculations. The security area "more closely approximates zero-sum games than do most economic issue-areas" hence complicating the construction of regimes.[137] Sanctions – or punishments – are inherent in national governance. Crimes can be punished by civil and criminal penalties. Taxes can be levied or funding can be withheld for projects. Sanctions can be created and implemented in the international environment for issues where cooperation is judged to be in all the participants' interests or, in other words, the issue is perceived to be non-zero sum. Jervis has noted that international issues in the security area tend to lack regimes or norms because of the emphasis on relative standing. Norms or regimes based on sanctions are very difficult to construct and enforce in the security arena because of the anarchic international environment.

In the security sphere, benefits can work effectively, at least for a time. This can be seen in alliance relations and the "Atoms for Peace" trade at the core of the nuclear non-proliferation regime. In the "Atoms for Peace" trade, countries agreed to forego the option to develop nuclear weapons in exchange for technical assistance to exploit nuclear technology for the purpose of power generation. To reassure the broader international community that they were keeping their pledge to use nuclear technology exclusively for peaceful purposes, countries agreed to intrusive inspections conducted by the International Atomic Energy Association or IAEA. [138]

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[137] Krasner, page 8.
[138] International Atomic Energy Agency, "About the IAEA: The 'Atoms for Peace' Agency," and "Mission Statement," IAEA website (http://www.iaea.org?ABout/index.html accessed 4/20/2009).

*Summary on Norms*

There is broad agreement that norms exist and that they can alter behavior. Communities of technical experts are a promising place to build norms, consistent with the core finding of functionalism. There is a reasonable basis to believe that international norms could shape the behavior of the average biologist in the average biology laboratory. Not even the most fervent advocate of norms, though, would claim that norms could alter the behavior of every single individual. The low entry costs of offensive biological weapons combined with their potential military effect would give a cheater significant incentive to act in violation of the most durable possible norm. Norms can increase the difficulty for an adversary of acquiring these weapons, and can increase the costs to him (if caught) of using these weapons. Norms could reduce the number of worrisome cases and facilitate the targeting of assets to investigate those cases – through diplomacy, law enforcement, or intelligence. Through these measures, norms could make a significant contribution to security, even with their many gaps and weaknesses.

*The Example of Ansilomar*

As the life sciences community struggles with the risk that the fruits of life sciences research could be used to launch a catastrophic biological attack, they turn, somewhat naturally, to Ansilomar. It stands for the life sciences community as the touchstone of prudent, self-initiated self-regulation. The Ansilomar resort in California was used in 1974 for a meeting of leading members of the life sciences community and a small number of reporters, lawyers and ethicists. The meeting was catalyzed by the recent, dramatic advances in recombinant DNA research. Scientists feared this research could create organisms that would threaten both the scientists and the technicians exposed to them in the course of their research and, if the organisms were not contained in the laboratory, the general public.

At Ansilomar, basic rules governing recombinant DNA research were formulated. The basic elements of the now-canonical biosafety level I, II, III and IV system were formulated which establish rules for the physical protection of the researcher (masks, gloves, breathing apparatus) and the laboratory (hood, showers, overpressure, separate water and sewage systems) at the different levels of risk. Other rules provided broad guidance on what experiments could and could not be conducted. These rules then informed and shaped the work of a previously-created National Institutes of Health committee, the Recombinant DNA Advisory Committee or the "RAC."[139]

These rules have been considered a great success. They are required for all government-funded research and often required by universities and pharmaceutical companies for non-government funded research. The US Food and Drug Administration has said that only items developed using the RAC guidelines will be licensed, providing the strongest possible motivation for companies to clearly stay in compliance with them. The Ansilomar norms reflect the scientific value on free and open communication of findings. Classification, or control of information, generally is anathema to this community.

These rules have been a great success when judged by the criteria outlined for them. This success should be qualified by three observations. First, recombinant DNA research – or at least the first few decades of recombinant DNA research -- has turned out to be vastly less dangerous inherently than was feared in 1974. Hence, one might say that the Ansilomar guidelines have done well on an "easy" test. Second, they were formulated in a context that had fewer self-interested parties. The economic potential of the biotechnologies had not yet been recognized

[139] For background on the Ansilomar conference, see, for example, Paul Berg, "Ansilomar and Recombinant DNA," Remarks of 26 August 2004, located on the nobelprize.org website; Marcia Barinaga, "Ansilomar Revisited: Lessons for Today?," *Science*, Volume 287, Number 5458, pages 1584-1585, March 3, 2000. "Biotech@25: The Founders, UC Berkeley Library, on the website at bancroft,berkeley.edu.

and so the issue existed more in the realm of pure science than in pubic policy. US dominance in this area of technology was sufficiently great that most other countries have modeled their own programs of bio lab safety on the American model developed at Ansilomar. Third, it should be noted explicitly that, as positive as they have been for many purposes, the Ansilomar guidelines have no meaningful way to influence an adversary who doesn't need government funding, doesn't want tenure or publications, and doesn't want his product eventually licensed by the FDA.

*(2) Current Unilateral US Policy*

The current US policy on biosafety, biosecurity and worrisome dual-use research appears to be constructing a national unilateral system of norms enforced by sanctions. The emerging system does not appear to be the result of a conscious decision to seek such a national, unilateral system but more the accumulation of outcomes, with the greater control over decision-processes in the domestic sphere yielding success, but lesser influence in the foreign sphere yielding lack of progress. Hence the emerging structure has concrete sanctions on the behavior of domestic actors, and rhetorical calls on the behavior of international actors. This national, unilateral system should provide a security benefit, but also imposes security, economic and technological costs. An international system of norms would be vastly better for international peace and security both from the perspective of the United States and the international community.[140]

[140] The value of these controls, without the focus on the relative utility of national and international controls, is discussed in Salerno and Hickok, "Strengthening Bioterrorism Prevention." Another author who expresses concern about the vulnerability posed by the growing number of domestic programs in the United States is Laura H. Kahn, "Biodefense Research: Can Secrecy and Safety Coexist?," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science,* Volume 2, Number 2, 2004.

*The Emerging US-based System*

The sanctions-based aspects of US policy are emerging in a piecemeal fashion. Research on select agents is shaped by the USA Patriot Act of 2001 and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. "Select Agents" are biological agents or toxins identified by the CDC as having particular security and health risks. These laws make possession of "select agents" both a civil and criminal offense unless the possession is for legitimate research and the select agents are properly registered with the government. It also prohibits access to select agents by restricted persons, which include foreign nationals of terrorist countries or a convicted felon. There also are strict security requirements for labs used for research on Select Agents.[141] There have been concerns expressed about these rules, both that they are inadequate[142] and that they are difficult to implement because of their ambiguity.[143]

A national system with sanctions is recommended by the federal committee in charge of worrisome dual-use research and appears to be the implied policy of prestigious National

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[141] Lauren K. Schoenthaler, "The Impact of 9/11 Legislation on Fundamental Research," Briefing charts presented June 3, 2004, Committee on Research Public meeting, Office of the General Counsel, Stanford University, Stanford website. See also National Academy of Science, Biotechnology Research in an age of Terrorism, see page 2: "In the United States, the USA PATRIOT Act of 2001 and the Bioterrorism and Response Act of 2002 already establish the statutory and regulatory basis for protecting biological materials from inadvertent misuse. Once fully implemented, the mandated registration for possession of certain pathogens (the "select agents"), designation of restricted individuals who may not possess select agents, and a regulatory system for the physical security of the most dangerous pathogens within the United States will provide a useful accounting of domestic laboratories engaged in legitimate research and some reduction in the risk of pathogens acquired from designated facilities falling into the hands of terrorists."

[142] Edward Hammond, Director, The Sunshine Project, Austin, Texas, Written Testimony submitted to the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce. US House of Representatives, October 4, 2007. The Sunshine Project, News Release of 26 June 2007, "Bioweapons Infections Hit Texas A&M University Again (Q Fever Cluster)" Sunshine Project website (http://www.sunshine-project.org/publications/pr/pr260607.html accessed 4/13/2009).

[143] Eddie J. Davis, Interim President, Texas A&M University at College Station, Testimony before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, US House of Representatives, October 4, 2007.

Academy of Science reports.[144] These proposals have not yet been formally adopted. The structure recommended by the federal advisory committee is an extension of the model used for recombinant DNA (rDNA) and human subject research.

These review boards currently oversee research on human subjects and recombinant DNA. Approval of the review boards is required for federal funding and is often used in other contexts to assure the research is sound. Under the proposal, researchers would need to self-identify their projects as having potential dual-use implications. The dual-use implications of particular concern were first articulated by the National Academy of Sciences report chaired by MIT biologist Gerald Fink and are sometimes referred to as the "Fink Deadly Seven" or more blandly as "experiments of concern." The "deadly seven" include experiments to alter a pathogen so as to make it deadly even against an otherwise effective medical countermeasure.[145] Once a project was self-identified, it would be subjected to review by institutional review boards.

The research community has fairly pointed out that a critical difference is the ambiguity of what constitutes dual-use research. It is, after all, clear when an experiment involves human subjects or recombinant DNA techniques. Whether research will affect one of the "deadly seven" is much more ambiguous. The Ansilomar guidelines are implemented through the requirement that they be met for all experiments conducted with federal funding. They are now

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[144]National Science Advisory Board for Biosecurity, US Department of Health and Human Services, "Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information," June 2007. NSABB website (accessed 4/13/09). The basic approach could be seen in the terms of reference creating the NSABB and the National Academy of Science report that catalyzed the creation of the NSABB, "Biotechnology Research in an Age of Terrorism, Gerald R. Fink, chair of the Committee on Research Standards and Practices to prevent the Destructive Application of Biotechnology, National Research Council.

[145] The "Experiments of Concern" would be those that: "(1) Would demonstrate how to render a vaccine ineffective....(2) Would confer resistance to therapeutically useful antibiotics or antiviral agents....(3) Would enhance the virulence of a pathogen or render a nonpathogen virulent....(4) Would increase transmissibility of a pathogen....(5) Would alter the host range of a pathogen....(6) Would enable the evasion of diagnostic/detection modalities....(7) Would enable the weaponization of a biological agent or toxin." *Biotechnology Research in an Age of Terrorism*, pages 114-115.

commonly required even for university or private-sector based research not paid for by federal funds. The FDA also has said it will not license a product that was not developed using RAC guidelines. There is every indication that the NSABB is focusing on similar sorts of sanctions for violating the broad guidelines it envisions creating for biodefense. These enforcement mechanisms are national.

*(3) Limited Benefits and Extensive Costs of US Unilateral System*

The national, unilateral system being constructed will provide an important but limited security benefit because these measures should strengthen biosafety, biosecurity and oversight of dual-use research in the United States. Given the assessment of the FBI that the 2001 anthrax attacks were launched using pathogens from a biotechonology lab located within the United States,[146] the security benefit of strongly controlling these capabilities in the United States are clear and should be pursued with thoroughness. A unilateral, national system imposed by sanctions is not, however, the only technique that could achieve this important goal.

*Security Costs*

This national, unilateral system will impose security, economic and technological costs. The security costs will be twofold. First, this strategy will have no effect on increasing the control of dangerous pathogens abroad, a plausible source for a pathogen used in an attack in the United States. While the United States remains dominant in the biotechnologies, it is implausible to assume, particularly over time, that the United States would be the only source for sophisticated materials and knowledge. Foreign universities and labs, absent strong biosafety and biosecurity norms, would be vulnerable to exploitation by adversaries. Overtime, non-state

[146] See newspaper accounts, including, for example, Johnson, Wilber, and Eggen, "Government Asserts Ivins Acted Alone."

actors will grow increasingly sophisticated in their own unilateral efforts which generally can be easily concealed.

Rhetorical agreement that nations should strengthen enforcement of these types of norms has been secured but little corresponding progress has been made. A multilateral effort to strengthen biosecurity was undertaken in the United Nations Security Council under the auspices of Security Council Resolution 1540 in April 2004. This resolution requires states to implement national legislation to assure that materials necessary for weapons of mass destruction have adequate security. This resolution "has direct consequences for all states' domestic legal structures, imposing upon each country the requirement to criminalize WMD proliferation by and among non-state actors and to implement effective controls."[147] While the SR 1540 approach seemed promising and may yet prove useful, implementation has proceeded slowly and unevenly.[148]

The second security cost of the national, unilateral system will be the loss of domestic expertise critical to responding effectively to a biological attack, particularly an attack using an unusual or modified pathogen. Multinational corporations in the biotechnologies are highly sensitive to small differences in the relative favorability of national business climates. These recent rules have driven research and facilities abroad[149] and raised further concerns that will probably drive more research abroad in the future. [150]

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[147]Peter Van Ham and Olivia Bosch, "Global Non-Proliferation and Counter-Terrorism: The Role of Resolution 1540 and Its Implications," in Olivia Bosch and Peter Van Ham, eds., *Global Non-Proliferation and Counter-Terrorism: The Impact of UNSCR 1540,* (London: Chatham, 2007), page 5.

[148] Van Ham and Bosch, "Global Non-Proliferation and Counter-Terrorism" in Bosch and Van Ham, eds, *Global Non-Proliferation and Counter-Terrorism,* page 5.

[149] See Kendall Hoyt and Stephen G. Brooks, "A Doubled-Edged Sword: Globalization and Biosecurity," *International Security* (Winter 2003-2004), see especially pages 141-143. See also Jorge Niosi and Bertrand Bellon, "The Global Interdependence of National Innovation Systems: Evidence, Limits, and Implications," *Technology in Society,* Vol. 16, No. 2, pp. 173-197, 1994, page 179: "The pharmaceutical industry, like the biotechnology industry,

There are other examples that illustrate that global pharmaceuticals are highly sensitive to the relative favorability of national business environments. There is, for example, evidence that global pharmaceuticals moved at least some activities out of the United States and into European subsidiaries in response to the additional requirements imposed by the new Sarbanes-Oxley requirements, the increased accounting requirements in the wake of the Enron and other corporate scandals in the United States. [151]

*Economic Costs*

This tendency of the pharmaceutical industry to move pathogen-related research out of the United States in response to unilateral rules could be expected to have an economic impact on US businesses over time. The computer encryption case demonstrates the direct economic costs of unilateral controls. During the 1990s, the United States sought to impose unilateral controls on public key encryption technology. Over time, the entry costs to this technology became essentially zero. "Strong" public key encryption capability was posted on the internet and was available for free down-load, despite US export controls against the diffusion of such capability. The estimates of the economic costs of the unilateral US controls on "strong" public key encryption have a number of methodological weaknesses but are acknowledged to be large:

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is one in which the valuable asset of a research laboratory is its personnel, and the role of economies of scale is not significant. Company strategies include moves toward large talent pools in countries with favorable legal, commercial, and political environments." The same point is made more diplomatically in a National Academy of Science report. The report does not focus on the critical point (ill effects of Select Agent legislation) but instead argues the affirmative point very strongly – that the web of controls must be international in nature if they are to be effective because of the extent of the global diffusion of relevant expertise. *Biotechnology Research in an Age of Terrorism*, pages 12-13.

[150] Hoyt and Brooks, "A Double-Edged Sword," also Schoenthaler briefing, "The Impact of 9/11 Legislation," which notes that "Effects of Legislation [include] diminishing interest in research on select agents because: must undergo background check process; there is the potential for severe civil and criminal consequences stemming from benign administrative errors; there is a real concern that results of research may not be published due to security concerns."

[151] Lahteenmaki and Lawrence, see page 731: "Three US companies chose to launch on Euronext instead of on their home markets....The increasing costs of listing on US markets due to Sarbanes Oxley compliance, as well as the relative ease of listing on Euronext helped to pull these companies across the pond."

about $100 billion over five years and they put at risk the market share of US computer companies.[152] The unilateral controls were eventually allowed to lapse.

*Technological Costs*

This type of national, unilateral control system also could impose technological costs on the US biotechnology sector. Several studies indicate that, given the distribution of excellence throughout the globe, the biotechnologies sector is increasingly advancing as a web of activity where scientists from many countries participate in scientific advances but the benefits flow differentially depending on the ability of the home country to absorb the benefits.[153] These unilateral controls would reduce the ability of the United States to absorb the benefits. Integration increasingly is required to be at the cutting edge of these types of technologies but having a uniquely unfavorable climate for the conduct of this research would harm US researchers.[154] There is growing international collaboration, particularly in the production of basic scientific knowledge.[155]

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[152] Staci I. Levin, "Who are We Protecting? A Critical Evaluation of United States Encryption Technology Export Controls," *Law and Policy in International Business,* Spring, 1999, see page 6: Numbers cited included putting at risk "$60 billion and over 200,000 American jobs" and up to $96 billion over the next five years," and "foreign competitors have begun to surface, filling the vacuum in the international encryption market left open by American companies' inability to compete overseas."

[153] Noisi and Bellon, "The Global Interdependence of National Innovation Systems." A broad point about the importance of the "public supply of infrastructures to make a country attractive for the deployment of S&T activities" is made in Daniele Archibugi and Jonathan Michie, "Technological Globalisation or National Systems of Innovation?" *Futures,* Vol. 29, No. 2, pp. 121-137, 1997, page 133. The evidence "seems to point uniformly to increasing interdependence of innovation systems in various countries....each of the authors also emphasizes the importance of national policies and institutions." Bo Carlsson, "Internationalization of innovation systems: A survey of the literature," *Research Policy*, 35 (2006) 56-67, see page 60: A study that focused exclusively on the biotechnology sector found, similarly, that "'forming cross-border alliances may thus be one of the most important means for firms to enhance their innovative capability in biotechnology'" but that the efficacy of these cross-border alliances rested on unique national systems. See discussion of Bartholomew in Carlsson, page 69.

[154] For example, Richard R. Drake, Yuping Deng, E. Ellen Schwegler and Stefan Gravenstein, "Proteomics for biodefense applications: progress and opportunities," *Future Drugs,* April 2005, Vol. 2, No. 2, pages 203-213, see on page 203: "...translating these proteomic discoveries to useful counter-bioterrorism products will require large collaborative research efforts across multiple basic science and clinical disciplines."

[155] This can be seen in an "increase in the number of published articles coauthored by scientists in different countries, the number of countries that participate in international copublication, and the number of multiauthored

*Conclusion*

Norms on biosafety, biosecurity and worrisome dual-use research would enhance national and international security. Functionalist literature and case studies indicate that it is promising to attempt to build norms within an international technical elite whose shared, core values and interests are consistent with the norms. Norms can be violated and still be useful as long as they play a meaningful culling role: sorting problematic and potentially dangerous cases from standard cases. This culling should reduce the number of potentially dangerous cases to a number that are then more thoroughly examined through targeted diplomatic, law enforcement or intelligence efforts.

Observance of norms can be strengthened through the use of sanctions or benefits. Sanctions are easiest to establish in the national context or for issues that are perceived to be non-zero sum in the international environment (like trade). Benefits, while quite imperfect, have been made to work for at least a time in the security realm as demonstrated by some alliance relations and the "Atoms for Peace" trade that lies at the heart of the international nuclear non-proliferation regime.

Current US policy appears to be to construct and impose a national unilateral system of norms using sanctions. This approach has a security benefit, but also imposes security, economic and technological costs. An international system of norms would be vastly better from a security perspective, as well as an economic and technological perspective.

This chapter recommends that instead the United States should strive to root norms on biosafety, biosecurity and worrisome dual use research in the relevant international technical

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articles." Noisi and Bellon, "The Global Interdependence of National Innovation Systems," page 182. Caroline S. Wagner, "The Elusive Partnership: Science and Foreign Policy," *Science and Foreign Policy,* volume 29, number 6, December 2002, pages 409-417.

elite – the international life sciences community. Observance of the norms should be catalyzed through the use of benefits, specifically participation in an international scientific effort to develop defensive medical countermeasures. There are a variety of additional benefits to such an approach, which are discussed in the later chapter on Medical Countermeasures.

## Prevention: Chapter 5

### Prohibitions

The fourth tool used to control technologies and the weapons they can spawn focuses on prohibitions on the resulting weapons type. These prohibitions usually are grounded in international treaties and were most common during the Cold War, although there were some agreements limiting major conventional weapons during the 19th and early 20th century and several treaties in the post-Cold War period. Some prohibitions call for the elimination of a weapons-type,[156] while others impose numerical or deployment limits.[157]

Prohibitions, when strengthened by inspections, transparency, or other confidence-building measures, can minimize spiral model dynamics and enable a stable security equilibrium at a lower and hence less expensive and dangerous force level. These efforts can convey meaningful benefits to security and stability but often are of limited duration and effectiveness.[158] Prohibitions are not, though, invariably a boon to peace and security. Poorly crafted prohibitions – particularly if the benefits of cheating are significant, if they accrue mostly

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[156] The major treaties that eliminate weapons-types are the Biological Weapons Convention, the Intermediate Nuclear Weapons Treaty, the Chemical Weapons Convention, and the Landmines Treaty. Author's interview with former government arms control experts.

[157] Most treaties impose numerical or deployment limits, like the nuclear weapons treaties like START or SORT, or the Conventional Forces in Europe (CFE) treaty. Author's interview with former government arms control experts.

[158] For a discussion of these dynamics, see Jervis (*Perception and Misperception,* particularly chapter 3, "Deterrence, the Spiral Model and Intentions of the Adversary" and "Cooperation Under the Security Dilemma"). Treaties in the early 20th century include the ill-fated Kellogg-Briand Pact of 1928 and the Washington Naval Treaty of 1922. The period also includes the Geneva Protocol on chemical and biological weapons in 1925. Cold War and post-Cold War treaties – easily the most numerous -- include treaties on strategic nuclear weapons (SALT I & II, START and SORT), intermediate-range nuclear weapons (1987), conventional weapons in Europe (1992), nuclear weapon-proliferation (1957 creation of the IAEA and the 1968 agreement of the Nuclear Non-Proliferation Treaty) and the biological and chemical weapon conventions (1972 and 1993). These treaties were all motivated by a desire to better manage spiral model dynamics and the desire to achieve a stable force balance at lower cost. The only outlier arms control treaty is the 1997 Land Mines Treaty (of which the United States is not a signatory) which seems motivated by pure humanitarian concerns, more similar to the motivation for some of the initial 11th and 12th century agreements on basic norms for the conduct of war and the treatment of non-combatants and prisoners. Author interviews with former government arms control experts.

to the offense, and if verification or transparency is poor – can worsen spiral model effects and cause deterrence failures.[159]

Prohibitions function in an interesting way in the biological area. There, after all, is an existing prohibition on biological weapons. The Geneva Protocol in 1925 outlawed the use of biological weapons in war. The Biological and Toxin Weapons Convention in 1972 outlawed the possession of these weapons. While there are some reporting requirements, these conventions lack any sort of meaningful verification measures.[160]

The dissertation has discussed two alternative models used in international relations theory to explain cause and effect: the spiral model and the deterrence model. Liberals tend to assume that spiral model effects are dominant, while realists tend to assume that deterrence model effects are dominant. Most analysts concede, though, that both phenomena can be found in history: World War I is generally considered a spiral model failure, while World War II is generally considered a deterrence failure. The intentions (not the capabilities) of the potential adversary are considered the single most significant factor in determining which model of cause and effect applies.[161] Thus, most analysts focus on the dyad or bilateral relationship between the two states of interest and strive to deduce their intentions. More complex analyses examine the dyads between multiple states and the interaction effects of these dyads on more complex

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[159]The complicated dynamics are probably best considered in the Jervis pieces (*Perception and Misperception,* particularly chapter 3, "Deterrence, the Spiral Model and Intentions of the Adversary" and the journal article "Cooperation Under the Security Dilemma") and in the classic book on the interwar period, Carr, *The Twenty Years' Crisis*.

[160] Kadlec, et al., "Biological Weapons Control," in Lederberg, ed., *Biological Weapons,* see page 100-103. Jonathan B. Tucker, "A Farewell to Germs: The U.S. Renunciation of Biological and Toxin Warfare, 1969-70," *International Security*, Vol. 27, No 1, (Summer 2002), pages 107 - 148.

[161] This is Jervis's formulation, still considered the seminal distillation of concepts that appear throughout writings in international relations (*Perception and Misperception,* particularly chapter 3, "Deterrence, the Spiral Model and Intentions of the Adversary" and the journal article "Cooperation Under the Security Dilemma").

arrangements like alliance formation, balancing behaviors or bandwagoning between nation-states.

In a case like catastrophic biological attack, the classic argument about whether spiral model or deterrence model effects dominate seems singularly odd. Yet this is precisely the argument that pervades most of the literature on catastrophic biological attack. This dissertation argues that there are enough actors with enough different interests that both effects are likely to be present. Spiral model effects seem most dangerous on other status quo states. Preserving the international norm against biological weapons acquisition and use provides valuable benefits, as long as no policy-maker forgets that the norm is not verifiable in any meaningful sense. Deterrence effects seem most significant with non-state actors, who, because of the characteristics of the biotechnologies, could launch a catastrophic biological attack. Very few other attack modes could even theoretically enable a non-state actor to launch a catastrophic attack against a nation-state.

There remain disputes about how much time, luck, skill and money a non-state actor would need to launch such an attack, with significant differences between liberals and realists. But, as a hypothetical case, even most liberal analysts would concede that generous allotments of each of those variables would eventually yield a catastrophic biological attack capability on the part of a non-state actor. This dissertation urges that policy should seek to minimize spiral model effects on other status quo states, but strengthen deterrence and defense against non-state actors.

This chapter has three objectives: it (1) provides additional detail on the spiral model and the deterrence model; (2) gives an overview on the recent increases in the US defensive program; and (3) reviews the perspective of liberal and realists analysts on the dangers and benefits of

these defensive programs. The chapter concludes that given the range of actors and motivations both spiral model and deterrence model effects will be present in the biological attack problem. Policy should be crafted to minimize unwanted spiral model effects, but strengthen deterrence.

*(1) The Spiral Model and the Deterrence Model*

Robert Jervis outlined two alternative models to explain cause and effect in international relations – the deterrence model and the spiral model. His discussion is the best distillation of concerns and assumptions that have shaped the classic liberal and realist intellectual traditions throughout history. Both phenomenon – wars caused by spiral model effects and wars caused by deterrence failure – can be found in history: World War I generally is considered a spiral model failure, while World War II generally is considered a deterrence failure. [162]

The deterrence model is embedded in the classic realist tradition: "[G]reat dangers arise if an aggressor believes that the status quo powers are weak in capability or resolve."[163] Under this model, states tend to expand until they are stopped by countervailing power. Jervis is careful to explain that even in the context of a world where cause and effect is predicated on the assumptions of the deterrence model, war need not occur to resolve every point of contention: "Legitimate grievances can be identified and rectified, although care must be taken to ensure that the other side understands the basis on which the state is acting....the other's friendship cannot be won by gratuitous concessions."[164] An important assumption of the deterrence model is "that

[162] Jervis, *Perception and Misperception,* page 94.
[163] Jervis, *Perception and Misperception*, page 58: "This belief will lead the former to test its opponents, usually starting with a small and apparently unimportant issue. If the status quo powers retreat, they will not only lose the specific value at stake but, more important in the long run, will encourage the aggressor to press harder. Even if the defenders later recognize their plight and are willing to pay a higher price to prevent further retreats, they will find it increasingly difficult to convince the aggressor of their new-found resolve. The choice will then be between continuing to retreat and thereby sacrificing basic values or fighting."
[164] Jervis, *Perception*, page 60.

the world is tightly interconnected."[165] States and other international actors are closely watching how matters across the globe and across the issue spectrum are being handled. Lack of resolve in one matter will be generalized to a general irresoluteness unless the state clearly articulates reasonable boundaries on the implications of any seeming concession.

In contrast, the spiral model holds that cause and effect in international relations is fundamentally shaped by a state's recognition of its own vulnerability: "The lack of a sovereign in international politics permits wars to occur and makes security expensive."[166] In this model, states want to assure their security but are acutely aware of their vulnerability: "[T]he central theme of international relations is not evil but tragedy. States often share a common interest, but the structure of the situation prevents them from bringing about the mutually desired situation."[167] Reaching a mutually-agreeable outcome is complicated by the security dilemma – the reality that reasonable measures to enhance one's own security often are perceived to threaten another state's security.[168] Many measures to increase a state's defensive capabilities can be reasonably judged to also increase its offensive capability. The security dilemma is particularly acute in areas of warfare that favor the offense. If attacking first essentially assures victory and waiting until an attack is launched assures defeat, even decision-makers inclined toward peace will be under tremendous pressure to act first and ask questions later.

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[165] Jervis, *Perception,* page 61.

[166] Jervis, *Perception.* The bracketed text appears as footnote 12 in Jervis's article on page 63. The unbracketed text is from page 67. " [For this reason, whether anarchy produces the unfortunate effects we are discussing is strongly influenced by two variables: the extent to which the weapons and strategies that are useful for defending oneself are also useful for threatening and attacking others, and the relative advantage of the offense over the defense.]....If technology and strategy are such that each side believes that the side that strikes first will have a decisive advantage, even a state that is fully satisfied with the status quo may start a war out of fear that the alternative to doing so is not peace, but an attack by its adversary. And, of course, if each side knows that the other side is aware of the advantage of striking first, even mild crises are likely to end in war."

[167] Jervis, *Perception*, page 66.

[168] Jervis, *Perception*, page 68: "[D]ecision-makers frequently assume ... that the arms of others indicate aggressive intention. So an increase in the other's military forces makes the state doubly insecure – first, because the other has an increased capability to do harm and, second, because this behavior is taken to show that the other is not only hostile but is actively contemplating hostile action."

Jervis explains that the key distinction for assessing which model applies is the intentions of the adversary. Assessing the intentions of one's adversary has been a challenge throughout history and those intentions are, of course, always subject to change, both in response to the bargaining in a particular situation and in response to other, unrelated situations. ~[169] What then should be the dominant strategy for a thoughtful, status quo decision-maker? What strategy yields the best outcome when a decision-maker makes the right assumption about the intentions of the adversary and costs the least when the decision-maker makes the wrong assumption? Jervis probes the question with insight and precision but ultimately provides no answer.[170]

*(2) Increases in US Defensive Program*

Consistent with its treaty obligations under the Biological Weapons Convention, the United States dismantled its offensive biological weapons program in the 1970s.[171] The adoption of the BWC, though, apparently spurred the Soviet Union to increase its own secret offensive biological weapons program. The Iraqi program proceeded with the West having little understanding of its extent until after the end of the first Gulf War in 1992. Several non-state

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[169] The most interesting meditations on assessing the intentions of an adversary probably can be found in Carl von Clausewitz, *On War*, edited and translated by Michael Howard and Peter Paret (Princeton: Princeton University Press, 1984), page 89. Clausewitz, as the title of his book makes clear, was looking at intentions in war but his observations inform the complexity of the enterprise even in peacetime: "War is more than a true chameleon that slightly adapts its characteristics to the given case. As a total phenomenon its dominant tendencies always make war a paradoxical trinity – composed of primordial violence, hatred, and enmity, which are to be regarded as a blind natural force; of the play of chance and probability within which the creative spirit is free to roam; and of its element of subordination, as an instrument of policy, which makes it subject to reason alone."

[170] Jervis, *Perception,* page 84: "In summary, both the spiral and the deterrence theorists are deeply concerned with the danger of misunderstandings and the consequent importance of states' making their intentions clear. But the deterrers worry that aggressors will underestimate the resolve of the defenders, while the spiral theorists believe that each side will overestimate the hostility of the other. Policies that flow from deterrence theory (e.g. development of potent and flexible armed forces; a willingness to fight for issues of low intrinsic value; avoidance of any appearance of weakness) are just those that, according to the spiral model, are most apt to heighten tensions and create illusory incompatability. And the behavior advocated by the spiral theorists (attempts to reassure the other side of one's nonaggressiveness, the avoidance of provocations, the undertaking of unilateral initiatives) would, according to deterrence theory, be likely to lead an aggressor to doubt the state's willingness to resist." Jervis, *Perception,* page 100: "These calculations are difficult to make and therefore often yield bad policies."

[171] See Tucker, "A Farewell to Germs," see particularly pages 143-146 on some of the complexities of implementation.

groups have pursued and some have acquired relatively primitive biological weapons capability.[172]

These revelations in the 1990s prompted an increase of concern about the biological threat throughout the security community.[173] The United States Executive Branch took some initial steps to strengthen response capabilities in the 1990s. Secretary of Defense Les Aspin announced the "Counterproliferation Initiative" in October, 1993 which sought to strengthen the ability of the US military to fight effectively against a military opponent using weapons of mass destruction. The Defense Department led efforts at NATO to similarly strengthen the alliance's military capabilities. Toward the end of the 1990s, there was growing concern within the Executive Branch about the threat of attack against the US civilian population and efforts taken to clarify responsibilities and strengthen response capabilities. These efforts were accompanied by only relatively small increases in funding.[174]

Spending on US biological countermeasures has increased forty-five-fold since 1997. In FY1996 and FY1997, US biodefense expenditures were about $150 million per year. They had increased to about $400 million by FY2001. Estimates for FY2005 range variously between $6 to $8 billion.[175] The number of organizations involved in defensive biological research also has increased significantly. Prior to 1969, when President Nixon unilaterally halted work on

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[172] Kadlec, et al., "Biological Weapons Control," in Lederberg, ed., *Biological Weapons.*

[173] See, for example, the assessment of Koblentz, page 9, "The security studies community began paying closer attention to the threat posed by these weapons in the 1990s." See also Henderson, "The Looming Threat of Bioterrorism." See also Kadlec, et al., "Biological Weapons Control" in Lederberg, ed., *Biological Weapons.*

[174] Henderson, "The Looming Threat of Bioterrorism."

[175] The numbers are from Leitenberg, Assessing, page 65. He puts the FY2005 number at $7.5 billion. There has been a significant increase in the resources devoted to biodefense in the United States over the past ten years. The total amount of USG civilian biodefense funding has increased from $576 million in FY2001 to a request of $5, 421 million in FY2008, an order of magnitude increase. The size of the program from FY2001 through FY2008 request is estimated at $40 billion. The level hit about $8 billion in FY 2005 and saw relatively small decreases in subsequent years. For the overall biodefense numbers, see Table 1in Crystal Franco and Shana Deitch, "Billions for Biodefense: Federal Agency Biodefense Funding, FY 2007-FY2008," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science,* Volume 5, Number 2, 2007.

offensive biological programs, the work was focused in the Department of Defense and specifically in the US Army Medical Research Institute for Infectious Disease (USAMRIID). After the 1969 decision, USAMRIID stopped doing any classified work on biological issues although it continued to conduct unclassified research to develop vaccines and other countermeasures to protect military personnel on the battlefield.

In more recent years, as the threat has been perceived to more directly affect the US civilian population, defensive work has spread to the US Department of Health and Human Services, including particularly the National Institutes of Health (which now receive about $1.4 billion annually to conduct unclassified research on biological threat agents) and the Centers for Disease Control and Prevention (which has significantly expanded the size of the stockpile of medical countermeasures available for the civilian population and sought to work with state and local public health providers to strengthen the public health response to an attack).

With the creation of the Department of Homeland Security in 2002, that department has also gotten involved in strengthening biodefenses, playing a particular role in detection (with the placement of aerosol detectors under the Bioshield program) and the creation of a research institute, the National Biodefense Analysis and Countermeasures Center (NBACC), co-located with USAMRIID on Fort Detrick in Maryland. DHS officials have stated that the NBACC will strengthen the nation's ability to conduct post-attack forensic analysis (critical for attribution and prosecution) and will conduct classified assessments of threat and vulnerability.[176]

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[176] See lengthy, critical discussion of the proposed DHS program in Leitenberg, Assessing, pages 69-75. See a short, DHS description of the programs in Department of Homeland Security, "Fact Sheet: National Biodefense Analysis and Countermeasures Center," Release date of 02/24/2005. DHS website (http:/www.dhs.gov assessed on 1/8/2008).

*(3) The Perspective of Liberals and Realists*

Liberals and realists ghave very different perspectives on what constitutes the main risk in national programs to develop defensive medical countermeasures. Liberals worry that the programs will cause spiral model problems; realists worry that the programs will fail to move swiftly enough to develop countermeasures to deter or defeat an adversary.

*Liberals and Spiral Model Effects*

Most liberals focus on the effect of spiral model dynamics on the calculations of status quo nation-states and how those resulting calculations are likely to degrade the international norm against biological weapons. Different analysts make the argument in different ways, but the broad elements of the argument from liberals can be aggregated and summarized as including the propositions that (1) the leakage of a pathogen from the burgeoning US biodefense complex poses a much more likely threat to US citizens than an attack by a foreign adversary and hence the programs should be kept as small as possible or ideally eliminated; (2) nation-states can be fully deterred from launching a catastrophic biological attack against the United States and non-state actors are not plausibly able to launch a catastrophic biological attack for the foreseeable future because of the technical complexity of such an attack; (3) the growing US defensive program indicates the US doubts the efficacy of the BWC and these evident doubts weaken it, as these US doubts incline other states to doubt it also; (4) the growing US program in general and the classified portion in particular could raise concerns in the minds of some that the US is violating its obligations under the BWC and these concerns could further weaken the biological nonproliferation norm; (5) the strong characterization of the biological threat in the US public debate to stimulate domestic investments in defensive countermeasures is stimulating the interest of non-state actors in biological attack modes and hence worsening the very problem it is meant

to redress; and (6) taking these considerations together, the US government should invest these funds in public health efforts, like pandemic influenza, instead of biodefense.[177] In sum, these authors warn that the US biodefense program, with its associated public discussion of the threat and publications of research in scientific journals, probably is making the biodefense problem worse, not better.[178]

Leitenberg, for example, judges that threat assessments that assert non-state actors could execute an effective catastrophic offensive biological weapons program in the foreseeable future are inflated. He does not contest that two groups have made sustained attempts to develop such capabilities – Aum Shinrikyo and al Qaida. He simply outlines that based on the best material available to him their efforts have been unsuccessful to date.[179]

The apparent lack of technical success to date reported by Leitenberg is striking and does provide evidence for his implicit, broader argument that both agent acquisition and effective catastrophic delivery are complicated technical problems. He identifies some factual errors and some differences in judgment between himself and authors more troubled by the biological threat.[180] His argument does not, though, seem to generalize systematically from what is known publicly about the specific historical experiences of these two groups. This lack of

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[177] For example, Friedman, "Homeland Security." Leitenberg, "Assessing the Biological Weapons and Bioterrorism Threat." Cohen, Gould and Sidel, "The Pitfalls of Bioterrorism Preparedness." Harris, "Bioweapons Treaty: Still a Good Idea." Lawler, "Biosafety: Boston Weighs a Ban on Biodefense Studies." Even some realists appear to doubt that a catastrophic attack is within at least the current capability of terrorist groups. See Posen, "The Struggle Against Terrorism."

[178] For example, Friedman, "Homeland Security;" Leitenberg, "Assessing the Biological Weapons and Bioterrorism Threat;" Cohen, Gould and Sidel, "The Pitfalls of Bioterrorism Preparedness."

[179] Leitenberg, "Assessing," page 88: "The Rajneesh group (1984) succeeded in culturing Salmonella. The Japanese Aum Shinrikyo group failed to obtain, produce or disperse anthrax and botulinum toxin. The steps taken by the al-Qaida group in efforts to develop a BW program were more advanced than the United States understood prior to its occupation of Afghanistan in November-December 2001. Nevertheless, publicly available information, including the somewhat ambiguous details that appeared in the March 31, 2005, report of the Commission on Intelligence Capabilities, indicates that the group failed to obtain and work with pathogens..... No serious military threat assessment imputes to opponents capabilities that they do not have. There is no justification for imputing to real world terrorist groups capabilities in the biological sciences that they do not possess."

[180] Leitenberg, "Assessing," see pages 43-64.

generalization fails to demonstrate more broadly that a non-state actor could never develop a catastrophic biological attack capability in the foreseeable future. He also does not seem to systematically identify the major technical constraints affecting a non-state actor. One can, after all, responsibly puzzle about how generally and durably applicable are the experiences of two groups in a delimited time period.

Leitenberg also rejects the proposition that defensive planning should be based on an expectation of trends in adversary capabilities over time rather than a static assessment of them based on the information publicly available at one point in time. He asserts that biological threat assessments are unique in strategic planning in that they try to anticipate the trajectory of adversary capabilities over time rather than assessing only the sophistication of extant capabilities: "A threat assessment of the potential for the use of biological agents by terrorist groups is a very different exercise than that customarily faced in providing military threat assessments....The range of possible assumptions is enormous, the utilization of extreme worst-case assumptions is the rule, and these universally depend on the projection of capabilities into the future rather than their existence at the present time."[181] The tendency of defense planners to focus on worst-case assumptions is well-recognized, as is the reality that their projections for the future are often wrong, sometimes tragically so.[182] Leitenberg can make a compelling case that defense planners sometimes are wrong when they make projections about adversary capabilities into the future, but he cannot really sustain a case that biological threat assessments are the only place where these projections are made. Projecting future trends in the sophistication of

[181] Leitenberg, "Assessing," page 9.
[182] Jervis, *Perception*, see page 62: "And so we find that decision-makers, and especially military leaders, worry about the most implausible threats," Jervis observes. He goes on to note, though, as a small caveat that "lest we are too quick to laugh, it should be noted that for years historians confidently concluded that Frederick the Great of Prussia was paranoiac to have believed that the Seven Years' War was preceded by a foreign conspiracy aimed at his state. But the opening of the most secret archives revealed that Frederick's fears were actually justified."

adversary capabilities is standard for all types of military threat assessments because of the long-lead time necessary to prepare defenses.[183]

Leitenberg points explicitly at the spiral model effects of these defense projections and warns of these effects not merely on status quo states but on non-state actors: "The inflated predictions that were common were certainly *not* realistic. Much worse, in addition to being wrong, inflated predictions were counterproductive. They induced interest in BW in the wrong audience."[184] Leitenberg argues that al Qaida's interest in biological weapons was stoked by US official statements about the potential effectiveness of a biological attack against the United States. He warns specifically against two spiral model effects of the US defensive program: the additional scientific knowledge and publications it generates will be available to groups developing a clandestine capability, and the public debate about the risks posed by a biological attack will fuel further interest in and creation of such programs by potential adversaries.[185]

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[183] This is a bipartisan tenet of government defense planning. See, for example, a Republican perspective (Secretary of Defense Dick Cheney, "Defense Strategy for the 1990s: The Regional Defense Strategy, January, 1993, page 5): "An unavoidable challenge for defense planners is that we must start development today of forces to counter threats still so distant into the future that they cannot be confidently predicted....The military capabilities we have today and the ones we will have for the next few years are largely the product of decisions made a decade or more ago." A Democratic statement of this view (Hillary Rodham Clinton, "Security and Opportunity for the Twenty-first Century," Foreign Affairs, November-December 2007, page 8-9) implicitly agrees with the proposition that such future projections are necessary but argues explicitly that the Republican projections have been wrong: "To help our forces recover from Iraq and prepare them to confront the full range of twenty-first-century threats, I will work to expand and modernize the military....As the only senator serving on the Transformation Advisory Group established by the Joint Forces Command, I have had the chance to explore these issues in detail. Ongoing military innovation is essential but the Bush administration has undermined this goal by focusing obsessively on expensive and unproven missile defense technology while making the tragically misguided assumption that light invasion forces could not only conquer the Taliban and Saddam Hussein but also stabilize Afghanistan and Iraq."

[184] Italics in the original. Leitenberg, "Assessing," page 43.

[185] Leitenberg, "Assessing," pages 68-69. The Tucker materials are from Jonathan Tucker, "Biological Threat Assessment: Is the Cure Worse than the Disease?" Arms Control Today, Vol 34, No. 8, October 2004, page 13-19. See, from the Leirenberg text: "Tucker makes two major points. The first concerns proliferation, and it is that "The most serious risk associated with science-based threat assessment is that the novel pathogens and information it generates could leak out to rougue states and terrorists." The risk may be less a "leak" in a classic sense than simply the accelerated accretion of relevant science and publications, and the substantial overall push that the field is now getting and which will continue in the coming years. Both Aum Shinrikyo and the al-Qaida groups went back to look at professional literature of previous decades. It is the same procedure that new or expanding state programs followed, whether it was Russia in the 1950s and 1960s, or Iraq in the 1980s. Tucker's second main point is that the greatly increased magnitude of the U.S. biodefense program will promote a BW arms race, and, at least in its initial stages, is more likely to be with developments in our own BW research program than against developments in the

Because at least some liberals judge the threat of catastrophic biological attack to be small – state programs are deterred and non-state programs are not sufficiently proficient technically -- they fear the spiral model effects of the US defensive program more than an attack itself. From this liberal perspective, adversaries would not have sought biological weapons if the weapon's value had not been underscored by US policy makers in an attempt to build domestic political support for defensive countermeasure programs. The liberals seem to argue that those prone to peace would have judged that the biological non-proliferation norm durably protected them; those prone to aggression would have failed to recognize the potential opportunities inherent in biotechnologies when applied to warfare.

Several authors who have deep concerns about spiral model effects warn that these effects are significantly worsened when the program has classified elements. They argue that classified programs make assurances that the program is purely defensive less persuasive.[186] Some authors also argue that classified programs complicate the ability even of legitimate national leaders to oversee and rein-in the scope of these programs: "The intense secrecy that shrouds biological warfare programs obstructs civilian oversight and distorts decision-making by military and political leaders."[187] Another author similarly warns that "a national-level oversight system" is needed to assure proper oversight of all US defensive programs.[188] Liberals worry that classified programs in particular will amplify the risk of spiral model dynamics.

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programs of other states or nonstate actors.....Overall, the outcome [very likely will be] the stimulation of parallel programs in other states."

[186] Tucker, "A Farewell to Germs;" see particularly pages 144-148.

[187] Koblintz, *Pathogens As Weapons*, PhD diss., page 94. He looks at three cases – the Soviet Union, Russia and South Africa. See page 94: "In addition, secrecy allows biological warfare organizations to achieve a high degree of autonomy. This autonomy increases the risk of corruption, insubordination, and proliferation. Although all weapons programs are subject to some level of secrecy to prevent adversaries from learning about capabilities and vulnerabilities, the secrecy surrounding biological weapons programs has been unusually high."

[188] Leitenberg, "A national-level oversight system to see that the BWC compliance is maintained by all projects of the U.S. biodefense program – unclassified, classified, and perhaps yet other "black" projects – does not exist.

*Realists and the challenge of deterring and defending against attack*

Realists, in contrast, believe that the threat of bioattack is real. They judge that (1) a skilled, operationally sophisticated biological attack could kill tens or hundreds of thousands of innocent civilians; (2) strong defensive capabilities are essential to deter an attack or to reduce its effectiveness should one occur; (3) non-state actors plausibly can acquire the means to launch a catastrophic biological attack, with a skilled, determined adversary able to do so now or soon; (4) deterrence of non-state actors will be hard because some of these actors might not care if they are destroyed by retaliation and others might judge they could elude retribution by concealing their location. Deterrence of state actors may be hard because they may judge that they can conceal their participation in an attack and hence avoid post-attack retaliation. (5) bioattack favors the offense – it is much easier for an attacker to launch an effective catastrophic attack than it is for the defender to defend against the attack or to deter the attack. Victory goes to the first to strike. No one analyst necessarily holds all of these assumptions but these assumptions represent a responsible composite of the view of security analysts who believe there is a threat of bioattack.

*Offense Dominance*

Security analysts appear to be united in their assessment that biological weapons are offense-dominant because "developing and using biological weapons to cause casualties is significantly easier and cheaper than developing and fielding defenses against them."[189]

Jervis underscored that spiral model dynamics are particularly strong in weapons types that are offense dominant and where it is particularly hard to distinguish between offensive and

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Should the BWC be weakened further and if other state programs go down the same research path as the U.S. biodefense program, together with any eventual resort to BW by nonstate actors, the international regime against the development of biological weapons may be irrevocably damaged."

[189] Koblentz, *Pathogens as Weapons,* PhD diss., see page 13-14: A footnote at this point states "This feature of biological warfare has been recognized for more than fifty years." It then cites extensive literature. He explains that "Four factors help to determine the attacker's advantage in biological warfare: (1) the diversity of threat agents, (2) the potency of biological weapons, (3) the ease of surprise, and (4) the difficulty in defending against such an attack."

defensive weapons. This paper has already walked through the difficulty of distinguishing between an offensive and a defensive biological program, particularly when that program is in the general pre-attack phase. Jervis warns that the risk of preemptive wars is directly correlated to the extent that the current weapons balance favors the offense over the defense.[190]

*Conclusion*

In a case like catastrophic biological attack, the classic argument about whether spiral model or deterrence model effects dominate seems singularly odd. Yet this is precisely the argument that pervades most of the literature on catastrophic biological attack. This dissertation argues that there are enough actors with enough different interests that both effects seem likely to be present. Spiral model effects seem most dangerous on other status quo states. Preserving the international norm against biological weapons acquisition and use provides valuable benefits, as long as no policy-maker forgets that the norm is not verifiable in any meaningful sense. Deterrence effects seem most significant with non-state actors, who, because of the characteristics of the biotechnologies, could launch a catastrophic biological attack. Very few other attack modes could even theoretically enable a non-state actor to launch a catastrophic attack against a nation-state.

There remain disputes about how much time, luck, skill and money a non-state actor would need, with significant differences between liberals and realists. But, as a hypothetical case, even most liberal analysts would concede that generous allotments of each of those

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[190] Jervis, "Cooperation Under the Security Dilemma," see pages 188-190: "When the offense has the advantage, a state's reaction to international tension will increase the chances of war. The incentives for pre-emption and the "reciprocal fear of surprise attack" in this situation have been made clear by analyses of the dangers that exist when two countries have first-strike capabilities.....because wars are expected to be both frequent and short, there will be incentives for high levels of arms and quick and strong reaction to the other's increases in arms. The state cannot afford to wait until there is unambiguous evidence that the other is building new weapons. Even large states that have faith in their economic strength cannot wait, because wars will be over before their products can reach the army....Thus, there will be more cases of status quo powers arming against each other in the incorrect belief that the other is hostile."

variables would eventually yield a catastrophic biological attack capability on the part of a non-state actor. This dissertation urges that policy seek to minimize spiral model effects on other status quo states, but strengthen deterrence and defense against non-state actors.

## Section I

## Prevention

### Conclusion of the Prevention Section

This section has sought to explicate the traditional prevention strategy and assess its applicability to the biodefense problem. Prevention seeks to stop an adversary or a potential adversary from acquiring a capability that could be used to decisive effect in an attack. The traditional prevention strategy used four mutually-supportive tools: (1) export controls; (2) peaceful use limitations; (3) norms, sanctions and benefits; and (4) prohibitions.

This section finds that the traditional strategy would fail because of characteristics of the biotechnologies and the emergence of non-state adversaries. Export controls would fail because of the extensive global diffusion of the technology and its low entry costs, in terms of both technology and materials. Inspections to assure peaceful use would not work, because there are no meaningful distinctions between civilian and military programs in the general pre-attack stage and there is no confident ability to remotely detect program sites. These two prevention tools should not be pursued in the biotechnology case. The effort would consume diplomatic energy and goodwill without providing meaningful security benefits.

That energy and goodwill should instead be devoted to securing the broadest possible acceptance of international norms on biosafety, biosecurity and worrisome dual use research. Current US policy appears to be constructing a unilateral, national set of norms enforced by sanctions. Such a unilateral set of norms will provide a limited security benefit but impose significant security, economic and technological costs. Neofunctionalist theory teaches that norms have the best chance of broad international adoption if they are firmly rooted in the relevant international technical elite and are consistent with the core values of that technical elite.

The proposed international norms should be firmly rooted in the international life sciences research community.

The dissertation also observes that sanctions work best in national contexts or non-zero sum issues in the international environment. Benefits tend to work best for security issues in the anarchic international security environment. This dissertation urges that the benefit of participation in an international scientific research effort to develop defensive medical countermeasures be used to catalyze the broadest possible international adoption of the norms.

The dissertation also urges that strong efforts to deter and defend against catastrophic biological attack by a non-state actor be pursued, but in a manner sensitive to the danger of catalyzing spiral model effects on status quo states. The transparency and strengthened defensive capabilities likely to emerge from an international research effort to develop defensive medical countermeasures would likely help reduce spiral model problems.

## Section II

## Deterrence: Chapter 6

## Deterrence of a Catastrophic Biological Attack

Deterrence, of different sorts, always has been part of conflict. Deterrence of a strategic nuclear exchange between the United States and the Soviet Union during the Cold War was based on the threat of severe retaliation after a successful attack. Strategic deterrence during the Cold War threatened to swiftly and reflexively destroy much of the attacker's civilian population in response to a successful nuclear first strike.

This declaratory policy with its threat to punish in retaliation was perceived to have worked with acceptable confidence during the Cold War because of its persistent plausibility: the attacker could be identified and located, and the defender would retain sufficient capabilities after absorbing the attack to implement a massive retaliatory blow. And, while largely unremarked upon at the time, the attacker on balance preferred to avoid his own and his state's devastation.[191]

A strategic nuclear exchange never occurred between the United States and the Soviet Union during the Cold War. Deterrence appears to have worked, although the extent to which the credit goes to the well-calibrated US declaratory policy, as opposed to luck or other factors,

[191] While this central tenet was agreed and long-held, it contained many nuances, doubts and caveats that were highly contested and much discussed in the literature. For some of the breadth of the debate, see Miller, ed., *Strategy and Nuclear Deterrence.*

remains a point of debate for historians and political scientists.[192] Deterrence is a worthy but invariably uncertain enterprise.

*Likely Presence of Enabling Conditions*

The threat of post-attack retaliation is not a solid basis for deterrence against a non-state adversary contemplating a catastrophic biological attack. The limits on post-attack retaliation grow out of broad concerns that the threat of retaliation is weak against groups that could not be identified and located and may not, on balance, prefer to avoid their own devastation.[193] A determined and talented non-state actor probably could develop a biological weapons capability while generating few if any external indicators that could be used to locate the weapons facility.[194] Destruction of the leadership of the attacking organization may not matter – either to them or to the long-term health of the terrorist organization.[195] Post-attack retaliation would not merely fail to deter a non-state adversary but would likely prove counterproductive. The

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[192] Wilson, "The Myth of Nuclear Deterrence," see: "And a review of the practical record of nuclear deterrence shows more obvious failures than obvious successes. Given this, the record of nuclear deterrence is far more problematic than most people assume."

[193] For examples of the many security analysts, both inside and outside of government who share this view, see The White House, *The National Security Strategy*, March 2006, see page 8: "The United States can no longer simply rely on deterrence to keep the terrorists at bay or defensive measures to thwart them at the last moment." For an outside academic assessment see Koblentz, *Pathogens as Weapons*, PhD diss., page 84: "Biological weapons undermine deterrence as a security strategy…"

[194] Henderson, e-mail communication with the author, February 7, 2008: "[A] clandestine laboratory might be no larger than an ordinary 2 car garage. It would be impossible to detect from external appearance or odor. There are unlikely to be any purchases that would call attention to the fact of an operation. The costs for a reasonably well-equipped operation could be in the range of $200,000 but my guess is that one could do the necessary at expenditures far less than this. The less that was spent, however, the greater the risks to the producers." Henderson's e-mail previously expressed the view that a "catastrophic" bioattack such as this paper focuses upon (with thousands of deaths) is the wrong metric. He argues that "only 3 or 4 small releases strategically released being all that one would need to throw the country into chaos – and such small releases are far more likely than one requiring 2 to 3 kilos of dried spores of anthrax." Hence, his description of the size of the necessary laboratory cited above and its ease of concealment is characterizing facilities needed for a smaller attack than that described in this paper as "catastrophic." See, also, Koblentz, *Pathogens as Weapon,* PhD diss., see page 89: "Biological weapons are relatively easy to develop in secret, are well-suited for covert delivery, and do not provide signatures that can be used to identify the attacker."

[195] Historical case studies show a mixed record for decapitation as a counterrorism strategy. Art and Richardson, pages 590-591.

terrorism literature warns that it is precisely such undifferentiated retaliation that proves a boon to the recruiting efforts of most terrorist groups.[196]

Post-attack retaliation is a more potent threat to a nation-state. Post-attack retaliation probably would be sufficient to deter an overt attack by a nation-state.[197] There are two remaining concerns: deterring covert assistance from a nation-state to a non-state actor or deterring a covert attack by a nation-state itself.[198] These risks could be reduced through declaratory policy and strengthened attribution capabilities but probably never eliminated entirely.

*Recommendations for Refinements*

Declaratory policy should underscore the risk the attack would fail and would expose the attackers' valuable operational cells to destruction. A coherent deterrence policy for catastrophic biological attack by a non-state actor has neither been adopted by the United States nor emerged in the academic literature.[199] US declaratory policy remains limited to a set of related but not directly germane observations that are largely unhelpful to the problem of deterring a non-state adversary. Declaratory policy had two objectives. First, it focused on warning nation-states

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[196]Art and Richardson, eds., *Democracy and Counterterrorism*, see page 571: "Terrorist strategists have long been aware of the value of provoking governmental overreactions that play back into the terrorists' hands."

[197] Posen, "The Struggle against Terrorism," see page 44: "Particularly in the age of weapons of mass destruction, the United States cannot allow any state to participate in catastrophic attacks on its homeland with impunity. Mote intensive defensive precautions can reduce but not eliminate U.S. vulnerability to mass destruction attacks, so deterrence must be the first line of defense. For these reasons, the Taliban regime in Afghanistan had to be destroyed."

[198] There is a debate about whether this deterrence should and could be achieved through a declaratory policy that exclusively relied on conventional capabilities or if possible resort to nuclear weapons should be left, at least obliquely, as an option. This debate is beyond the scope of this dissertation. An interesting exchange on the issue can be found in Scott D. Sagan, "The Commitment Trap: Why the United States Should Not Use Nuclear Threats to Deter Biological and Chemical Weapons Attacks," *International Security,* 24 no 4 pages 85-115, Spring 2000; and the response from Susan B. Martin, "Correspondence: Responding to Chemical and Biological Threats," *International Security,* Vol 25 No 4 (Spring 2001), pages 193-198.

[199] The most significant exception is suggestions that strengthened defenses would reduce the incentives to attack, a piece of the recommendation here. See, for example, Chyba, *Toward Biological Security*.

believed to have a chemical or biological capability and expected to soon be in an otherwise conventional war with the United States that there was significant ambiguity about how the United States would respond to the use of biological or chemical weapons, including the possible risk of the use of nuclear weapons.[200]

Second, the declaratory policy focused on domestic political elites and sought to underscore to them the real risk of a catastrophic biological attack. Shaping the perception of these domestic political elites was critical to securing fiscal and other support needed to catalyze needed defensive programs. This domestic debate was important and necessary.[201] These messages should be supplemented by a more targeted declaratory policy for non-state actors contemplating launching a catastrophic biological attack.

In the biological case, the declaratory policy should warn that the attack could fail and in that failure would almost inevitably expose the attackers' most valuable operational assets to destruction. The attacker's operational cells deploying the biological pathogen would very likely be caught by the defender's law enforcement forces, regardless of the ultimate effectiveness of the attack. These operational cells – like the 19 hijackers in the US who launched the 9/11 attacks – may be the non-state actor's most valuable assets: skilled, loyal operatives successfully

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[200] Sagan, "The Commitment Trap:" see page 85: "Should the United States threaten to use nuclear weapons in retaliation for an adversary's use of chemical or biological weapons? The U.S. government has a clear policy on this matter: it is deliberately unclear about its plans. In March 1996, Secretary of Defense William Perry explained: 'For obvious reasons, we choose not to specify in detail what responses we would make to a chemical attack. However, as we stated during the Gulf War, if any country were foolish enough to use chemical weapons against the United States, the response will be 'absolutely overwhelming' and 'devastating.' The purpose of this U.S. policy – which has become known as the 'calculated ambiguity' doctrine – was underscored by Secretary of Defense William Cohen in November 1998: 'We think the ambiguity involved in the issue of nuclear weapons contributes to our own security, keeping any potential adversary who might use either chemical or biological [weapons] unsure of what our response would be.'"

[201] This focus has been lauded and criticized. An author who believes the threat has been exaggerated includes Leitenberg, "Assessing the Biological Weapons and Bioterrorism Threat," see page 1: "Speaking at the World Economic Forum in Davos, Switzerland, on January 27, 2005, U.S. Senate Majority Leader William Frist stated that "The greatest existential threat we have in the world today is biological." He added the prediction that "an inevitable bio-terror attack" would come "at some time in the next 10 years." Frist was seconded by Dr. Tara O'Toole, head of the Center for Biosecurity at the University of Pittsburgh, who underscored: "'This [bioterrorism] is one of the most pressing problems we have on the planet today.'"

concealed in the United States.[202] The biological attack could fail for one of three reasons: (1) the attack just wouldn't work technically (detection and disruption); (2) the attack would work but the defender effectively defends against its effects (tactical denial); (3) the attack works but fails to secure the attacker's strategic and tactical goals (strategic denial). These three outcomes are plausible, as is the argument that deploying the pathogen would expose the operational cells.

Deterrence would be greatly strengthened by shifting declaratory policy from post-attack retaliation to the real risk of failure and exposure and destruction of key operational assets. But while worthy, deterrence will remain somewhat weak and uncertain. An attacker may decide they are prepared to risk failure. Risking it, they may well instead succeed, causing unprecedented deaths and strategic reversal for the United States. Deterrence strategy should be updated and strengthened as suggested here, but its inherent weakness in the case of catastrophic biological attacks must be recognized.

This chapter has four objectives: (1) it discusses how advanced technologies eliminates many of the elements that used to moderate post-attack retaliation; (2) it proposes a new declaratory policy tailored for non-state actors contemplating launching a catastrophic biological attack; (3) it reviews the literature on the efficacy and motivations of terrorists; (4) it considers how to strengthen deterrence against covert action by other states; and (5) it discusses the need to strengthen the underlying capacity to cause the threatened deterrence effects.

[202] Posen, "The Struggle Against Terrorism," see page 40: "The hijackings of all four airliners were carefully synchronized. If this had been a Western commando raid, it would be considered nothing short of brilliant."

*(1) Technology and Post-Attack Retaliation*

War has often resulted in severe pain being inflicted on innocent civilians, sometimes in anger, sometimes in error, and sometimes with the explicit objective of deterring or coercing them or their government through the threat of its infliction. Nuclear weapons, particularly large arsenals of nuclear weapons, though, changed one critical element of post-attack retaliation. The speed[203] and machine-like efficiency[204] with which such an exchange could occur in the nuclear era might eliminate some of the traditional constraints on civilian destruction: the time for reflection, moderation or sheer human weariness. Thomas Schelling observed that "It is not 'overkill' that is new [in the strategic nuclear balance during the Cold War]; the American army surely had enough 30 caliber bullets to kill everybody in the world in 1945."[205] It was the speed and efficiency with which 'overkill' could be inflicted with new technologies.

The speed with which a strategic nuclear exchange could be launched essentially eliminated the opportunity to clarify miscalculation. Miscalculation, often a cause of war, could

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[203] Thomas C. Schelling, *Arms and Influence* (New Haven, CT: Yale University Press, 1966), see page 20: "Nuclear weapons can do it quickly. That makes a difference. When the Crusaders breached the walls of Jerusalem [in 1099] they sacked the city while the mood was on them. They burned things that they might, with time to reflect, have carried away instead and raped women that, with time to think about it, they might have married instead. To compress a catastrophic war within the span of time that a man can stay awake drastically changes the politics of war, the process of decision, the possibility of central control and restraint, the motivations of people in charge, and the capacity to think and reflect while the war is in progress."

[204] The ability to exercise command and control of nuclear forces in an actual conflict deeply troubled Cold War nuclear analysts, who feared pre-set codes would push a nuclear exchange beyond the point humans would accept, if they only had time to think about it. The danger in a biological event is similarly that the dynamic, once loosed, would be uncontrollable. The accelerant wouldn't be pre-set launch codes but a particularly robust and virulent pathogen. On the nuclear command and control issue, see Bruce G. Blair, *Strategic Command and Control: Redefining the Nuclear Threat,* (Washington, D.C.: The Brookings Institution, 1985), see page 5: "But the ability of Soviet forces to deliver a crippling blow to U.S. C3I systems long ago created strong incentives on both sides for launching a first strike or for launching a U.S. second strike on warning, incentives that have undermined crisis stability."

[205] Schelling, *Arms and Influence*, page 23. More famous probably is Schelling's observation, on page 16, that "Against defenseless people there is not much that nuclear weapons can do that cannot be done with an ice pick."

here be a cause of catastrophe.[206] Declaratory policy was carefully nuanced during the Cold War, seeking to eliminate miscalculation.[207]

The speed with which such a biological attack could be launched, and if things unfolded most favorably for the adversary, spread across the nation and perhaps even the globe causes many of the same vulnerabilities that troubled analysts during the Cold War: it eliminates the period of probing and reassessment immediately prior to the outbreak of conflict that could reduce miscalculation. It reduces the opportunity for moderation or sheer weariness that sometimes limits civilian damage in a conflict.

*(2) Declaratory Policy*

Declaratory policy should draw attention to three issues: (1) there are real technical risks from the attacker's point of view that an attack would fail but that their intentions and operational cells would be revealed and destroyed (deterrence by detection and disruption); (2) the attack might be successfully launched but would fail to harm many civilians because of the effectiveness of the defense (deterrence by tactical denial); and (3) even if the attack succeeded there would be significant risk that the attackers would fail to achieve their political or territorial objectives (deterrence by strategic denial).

*Deterrence by Detection and Disruption*

Declaratory policy should be refined to underscore the unavoidable tension that confronts a non-state adversary and warn of the most severe consequences should they miscalculate. The

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[206] Geoffrey Blainey, *The Causes of War* (New York, NY: The Free Press, 1973), see page 293: "Wars usually begin when two nations disagree on their relative strength, and wars usually cease when the fighting nations agree on their relative strength."

[207] The literature on Cold War strategic deterrence is extensive. A nice overview and summary is Fred Kaplan, *The Wizards of Armageddon* (New York: A Touchstone Book, 1983).

unavoidable tension is that actions to increase the probability their delivery mode would work effectively have the effect of increasing the probability their attack would be detected by the defender before it is launched. The attacker at some level has to gamble: don't test the delivery mode and maintain operational secrecy or test the delivery mode and risk operational exposure. A launched attack, even if it fails because of a technical glitch, probably would expose the operational cells that conducted the attack. These operational cells would be one of the most valuable assets of the terrorist group and one they probably would be loath to waste. A fizzled but unambiguous biological attack would probably generate great international sympathy for the US, effectively granting the US a free hand in cleaning out whatever nest of terrorists could be found or even plausibly posited.[208]

The delivery mode most likely to cause catastrophic deaths is aerosol delivery in a densely-populated area or inside in a large space, like a sports stadium or shopping mall. While the technology needed to construct an effective aerosol delivery system is not particularly hard for a trained engineer, such a system benefits greatly from testing. Not testing would run a significant risk of the delivery mode not working quite right and hence possibly causing the worst outcome from the attacker's point of view: the attack fails but the intentions and operational teams of the terrorists are exposed to the full opprobrium of the defender and the international community. The operational teams for effective deployment may be among the most valuable assets of the attacker. They have to be identified, trained, and then smuggled into position in the United States.

[208] This tradeoff for an adversary – risking failure or detection – is discussed in Pearson, "The Essentials of Biological Threat Assessment," in Zilinskas, ed., page 69.

Food and water contamination is less well understood from both the attackers' and the defenders' perspective but holds at least the prospect for a catastrophic attack. Steps by an adversary to reduce that uncertainty – through trial runs of contaminating food or water systems – run the risk of revealing their plans to US authorities and hence losing surprise.

Failing to test the delivery mode would increase the risk that the attack would fizzle. A fizzled but unambiguous biological attack would probably generate great international sympathy for the US, effectively granting the US a free hand in cleaning out whatever nest of terrorists could be found or even plausibly posited. In the immediate pre-attack mode, the signatures of an offensive biological program could be identifiable so the attacker could be caught with a smoking gun – in this case, probably aerosol systems optimized for delivery of biological agent and loaded with large quantities of dangerous pathogens.

US declaratory policy should be crafted to highlight the virtually unavoidable uncertainties that would accompany a non-state adversary's efforts to launch a catastrophic attack on the United States. Launching what was intended to be a catastrophic attack and then having it fizzle from the adversary's point of view would probably still create a terrible situation for many, many individual Americans – some deaths, many illnesses, widespread panic, and significant economic losses. But under most scenarios, such an attack, using disease as an offensive weapon against civilians, also would brand the attacker in the eyes (and resolutions) of the international community as being a legitimate object of US military operations and probably would secure the ability for the United States to undertake extensive conventional military operations previously constrained by political realities. Whatever the longer-term history of US intervention in Afghanistan, the fall of 2001 was not a good period for the Taliban or for al Qaeda. While many other steps also should be taken to strengthen US biodefense policy, one

step should be to carefully craft US declaratory policy to exploit this uncertainty to maximally strengthen deterrence. The potential deterrent effect of this uncertainty on adversaries should not be overestimated, but, whatever deterrent benefit could be derived, should be derived.

Several writers in the security literature have observed that there is this tension between testing to optimize an attack and risking detection.[209] They have not generally linked this observation to its potential utility for deterrence.

*Deterrence by Tactical Denial*

The second outcome, that the attack would be launched and would be effectively mitigated by defensive measures, hopefully will become more likely with each passing year as US defensive capabilities are improved.

For example, the US national stockpile already contains more than enough smallpox vaccine for the US population. While there are plenty of reasons for the defender to be concerned about a smallpox attack, an attacker also would have to fear that the response could be improvised with sufficient skill that deaths in the United States would be minimized.

Many authors in the security literature point to this "deterrence by denial" as the most promising deterrence strategy.[210]

*Deterrence by Strategic Denial*

The third outcome is that the attack would be launched and would succeed tactically from the perspective of the attacker. The declaratory policy could underscore that even in this case the

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[209] See Pearson, "The Essentials of Biological Threat Assessment," in Zilinskas, ed., page 69.

[210] See for example Chyba, "Toward Biological Security," see page 6: "In addition to the difficulties of attribution, some terrorist groups may also believe themselves to be invulnerable to retaliation, may be unconcerned by it, or may even intend to provoke it. Such groups are obviously poor candidates for deterrence through the threat of retaliation. However, deterrence by denial – deterring enemies by convincing them that biological defenses are credible and that therefore an attack would be unlikely to succeed – may be more useful tool for biological security than it was for nuclear weapons. Of course, warning and prevention are preferable to coping with the consequences of an attack, so intelligence remains vital."

terrorist might not achieve their political or territorial objectives. Declaratory policy could point to many cases where there were limited effects from some previous cases of terrorism. The terrorists may have a specific territorial or political objective. The stronger the international nonproliferation norms, the more likely these types of objectives could be foiled.

The terrorists would probably have one of three objectives (1) just to cause pain; (2) to deter the defender from taking some action; or (3) to compel the defender to take some action. Deterrence or coercion is likely to be accompanied by the warning that more attacks will follow if some desired behavior is not forthcoming. Deterrence generally is considered easier than compellence.

The course of negotiations between a non-state adversary and a country having suffered catastrophic losses is difficult to predict. The academic literature underscores the limits on suicide terrorism to achieve strategic goals. This literature, though, seems to assume implicit limits on the extent of damage that could be inflicted through suicide terrorism.

*(3) Terrorist Literature*

To deter attack, this declaratory policy would require the non-state actor to be "rational". He does not need to be rational in the sense that his objectives or chosen means seem rational to others, but that he pursues them in a way that seeks to maximize the probability of success and reduce the risk of failure to him, as he defines it. This proposed declaratory policy assumes that terrorists are making a rational calculation that a catastrophic biological attack would be the best way to achieve a specific political or territorial goal. Whether terrorists are likely to make decisions based on this type of calculation is a point of significant dispute in the academic literature. Even if the attacker wishes only to inflict pain and suffering on the defender's civilian population, he might rationally assess that the risks of failure in a biological attack were too great

and decide to use his operational cells in a different attack mode with a lower risk of complete failure from the perspective of the attacker.

*"Rational Terrorists"*

The literature on the motivation and efficacy of terrorism is large and growing. It has three major parts, of which the largest is the "rational terrorist" school – the weak pursue terrorism because it has proven to be an effective strategy to exact concessions from the strong.[211] The dominant strand in the literature is that terrorists are "rational" in this utility-maximizing sense: they make a cost-benefit assessment of the likelihood that acts of terrorism will advance some specific and somewhat limited objective. More acts of terrorism are occurring in recent years, according to this perspective, because experience has shown that it is the most effective way for small groups to exact certain, limited concessions from nation-states.

Terrorists are just the weak, trying to maximize their influence in a world that favors strong powers even more disproportionately than usual. The most elegant exposition of this view argues that terrorists have a demonstrated track record in expunging occupiers from their homeland. They have failed to cause great powers to make more strategic concessions. In this model of "rational actor" the terrorist could be deterred by the proposed declaratory policy.

*"Non-Rational Terrorists"*

There is an emerging school of the "non-rational" terrorist. This position argues that only a very small sample of unrepresentative cases are visited again and again to demonstrate that "terrorism works." By looking at a more complete listing of terrorist groups (groups listed on the US State Department's Foreign Terrorist Organization list) over a sustained but longer period

[211] Pape, "The Strategic Logic of Suicide Terrorism."

of time (since 2001) Max Abrahms makes an interesting argument case that terrorist groups generally did not achieve their strategic objectives, either territorial or political, and that their rate of failure was highest when their targets were civilian targets.[212] Guerilla groups – loose, non-state actors that attack traditional militaries – have a significantly higher rate of success.

If terrorists are not motivated by the achievement of specific political or territorial goals, then what are they motivated by? The new "non-rational" literature is struggling with an answer to this question. Abrahms argues that members of terrorist groups are motivated by a need for "affective membership," that they are isolated, somewhat lonely individuals who join a group led by a charismatic individual excited about a common purpose.[213] This would mean that the proposed declaratory policy – showing that an attack would not advance their territorial or political ambitions – would not affect their interest in pursuing the attack.

This literature explains that terrorism fails partly because while the terrorist may articulate limited goals that might be acceptable to the defender, the attacks are interpreted by the defender as threatening their most fundamental national values. Hence, whatever the terrorists may have articulated as an objective is lost in the defender's perception that any attack in the homeland that kills large numbers of innocent civilians must be categorically resisted.

*"Situational Terrorists"*

An emerging literature talks about what might be called "situational terrorists." This literature observes that how an issue is defined has a big effect on whether specific terrorist

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[212] Abrahms, "Why Terrorism Does Not Work," see page 43: "First, the groups accomplished their forty-two policy objectives only 7 percent of the time. Second, although the groups achieved certain types of policy objectives more than others, the key variable for terrorist success was a tactical one: target selection. Groups whose attacks on civilian targets outnumbered attacks on military targets systematically failed to achieve their policy objectives, regardless of their nature."

[213] Abrahms, "What Terrorists Really Want."

actions can be deterred or pacified through limited concessions.[214] These analysts argue, for example, that there are ways to define the political struggle such that splinter groups would choose not to support al Qaeda in its global struggle against the United States. This literature is particularly interesting when considering catastrophic terrorism and the many sub-groups with particular expertise that would be necessary to build a catastrophic biological capability. Targeting some of these sub-groups may be an effective strategy because some sub-groups, like financiers or technical experts, might be much more sensitive to both threats and opportunities than the leaders of the core terrorist group.

Deterrence policy should consider closely strategies targeting communities with the needed skill sets. It may be that one subset or another subset of this group is particularly amenable to "rational" deterrence.[215] For example, the stronger the message of professional codes of conduct are developed in the life sciences community, the stronger the probability that some member might come forward, fearing professional ostracism if they participated. This would include suppliers, technical experts, and financiers. Professional ostracism (for scientists who collaborate); freezing of assets (for financiers); and other targeted measures may work for some of these sub-populations. Government efforts in the post-9/11 world have sought to increase these capabilities. They need to be further advanced, and refined.[216] For example, tracing financial flows is often relatively straightforward and the tools to do so are relatively well

[214] Trager and Zagorcheva, "Deterring Terrorism: It Can Be Done," see page 96, "To produce a large-scale attack, terrorists must constitute a system of actors fulfilling specific functional roles."
[215] Trager andZagorcheva, "Deterring Terrorism: It Can Be Done," see page 96: "To produce a large-scale attack, terrorists must constitute a system of actors fulfilling specific functional roles."
[216] A significant number of new government agencies with the objective of integrating terrorist-related intelligence has have been created including the National Counterterrorism Center (NCTC), the Terrorist Screening Center, and the Intelligence Analysis branch of the Department of Homeland Security.

developed.[217] Identifying and targeting these sub-populations will be a significant intelligence challenge – many writers have been correct in their calls for greatly enhanced intelligence capabilities.[218]

*Broader Concessions and Broader Considerations*

The terrorism literature generally contains a presumption, though, that terrorists cannot cause significant concessions from large states. Even the dominant literature warns that only specific, somewhat limited types of goals could be achieved by terrorism (for example, expelling foreign forces from land perceived to be a homeland) but more sweeping adjustments in type of government cannot be achieved.[219] Only a few articles on nuclear terrorism have considered the use of these capabilities to deter or coerce a large state through the infliction of pain and then the threat of more pain against their civilians. It is possible that these much more devastating attacks could affect a nation-state's calculations in more fundamental ways than predicted by the extant terrorism literature.

It is also the case that there could reasonably be expected to be a wide range of terrorist organizations and motivations. A wider variation of motivations could be expected from terrorist groups than, for example, nation-states. International relations theory argues that the

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[217] See, for example, Department of the Treasury, Terrorism and Financial Intelligence, Mission Statement, Treasury website (http://www.treas.gov/offices/enforcement accessed 3/29/08).
There are useful but still imperfect government efforts, including those of the Office of Terrorism and Financial Intelligence in the US Department of Treasury toward "combating rogue nations, terrorist facilitators, weapons of mass destruction (WMD) proliferators, money launderers, drug kingpins, and other security threats."
[218]This observation has been widely and correctly made. See, for example, Art and Richardson, page 565-568; and Falkenrath, et al., *America's Achilles' Heel.*
[219] Pape, "The Strategic Logic of Suicide Terrorism," see pages 3, 9, 13, respectively: "The main purpose of suicide terrorism is to use the threat of punishment to coerce a target government to change policy, especially to cause democratic states to withdraw forces from territory terrorists view as their homeland...Perhaps the most striking aspect of recent suicide terrorist campaigns is that they are associated with gains for the terrorists' political cause about half the time....Coercive success is so rare that even a 50% success rate is significant, because international military and economic coercion, using the same standards as above, generally works less than a third of the time.....While suicide terrorism has achieved modest or very limited goals, it has so far failed to compel target democracies to abandon goals central to national wealth or security."

international state system functions effectively to discipline states that violate core norms too significantly so that some useful generalizations can be made about state behavior. There is no particular reason to believe that the international state system or any other systemic force would exercise a similar sort of discipline on terrorist groups, which are vastly smaller and can emerge much more quickly.

*(4) Strengthening Deterrence Against Covert State Action*

Post-attack retaliation probably would be sufficient to deter an overt attack by a nation-state. There are two remaining concerns: deterring covert assistance from a nation-state to a non-state actor or deterring a covert attack by a nation-state itself.[220] These risks could be reduced through declaratory policy and strengthened attribution capabilities but probably never eliminated entirely.

Host nations are often pointed to by security authors as a good point of leverage over a covert, non-state biological weapons program.[221] There are certainly scenarios where a host nation can and should be asked to eliminate the sanctuary allowing the covert non-state program to proceed. The number of scenarios where this is actually likely is probably far smaller than the security analysts seem to assume. A hypothesis for why security analysts tend to overestimate the likely utility of host-nation leverage is that the security community overestimates the ease with which a covert program can be identified in a fashion sufficiently compelling to persuade a host-nation to act.

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[220] There is a debate about whether this deterrence should and could be achieved through a declaratory policy that exclusively relied on conventional capabilities or if possible resort to nuclear weapons should be left, at least obliquely, as an option. This debate is beyond the scope of this dissertation. An interesting exchange on the issue can be found in Sagan, "The Commitment Trap," and the response from Martin, "Correspondence: Responding to Chemical and Biological Threats."

[221] See for example, Barry R. Posen, "The Struggle Against Terrorism: Grand Strategy, Strategy, and Tactics," *International Security*, Volume 26, Number 3 (Winter 2001/02); Phillip B. Heymann, "Dealing with Terrorism: An Overview," *International Security*, Vol. 26, No. 3 (Winter 2001/02), pages 24-38, see page 33.

Post-attack retaliation is a more potent threat to a nation-state. Post-attack retaliation probably would be sufficient to deter an overt attack by a nation-state.[222] There are two remaining concerns: deterring covert assistance from a nation-state to a non-state actor or deterring a covert attack by a nation-state itself.[223] There is in addition the ambition to exact maximum help from other nation-states to deal with the catastrophic biological attack problem.

*How could other states help?*

First, this paper considers how other nation-states could help. These possible ways to help take two forms: specific and general. Specific means that they are somehow directly involved in a non-state actor's development of a catastrophic capability, most likely because they are the host country for a non-state actor's program site. The paper discussed in the inspection chapter the difficulty of remote detection of these types of facilities. The chances that the host country could detect the pathogen-handling facility are possible but limited. More likely is that they would observe – or could observe if they knew what to look for – the testing of an aerosol delivery device. The security literature arguably overestimates the technical likelihood that the host country could locate the facility.[224]

The second way a nation-state could help is as a general member of the international community. There are three roles. First, tools in a diplomatic crisis are generally hard to come by and a possible tool is to demand inspections. There is no concrete right for such inspections.

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[222] Posen, "The Struggle against Terrorism," see page 44: "Particularly in the age of weapons of mass destruction, the United States cannot allow any state to participate in catastrophic attacks on its homeland with impunity. Mote intensive defensive precautions can reduce but not eliminate U.S. vulnerability to mass destruction attacks, so deterrence must be the first line of defense. For these reasons, the Taliban regime in Afghanistan had to be destroyed."

[223] There is a debate about whether this deterrence should and could be achieved through a declaratory policy that exclusively relied on conventional capabilities or if possible resort to nuclear weapons should be left, at least obliquely, as an option. This debate is beyond the scope of this dissertation. An interesting exchange on the issue can be found in Sagan, "The Commitment Trap," and the response from Susan B. Martin, "Correspondence."

[224] See Posen, "The Struggle Against Terrorism," and Heymann, "Dealing with Terrorism."

They were acquired in Iraq as part of the peace agreement at the end of the first Persian Gulf War in 1992. Such inspections certainly have their weaknesses but they could be a useful tool in a particular scenario.

Second, they can assist in the orderly investigation of worrisome cases that emerge from the hoped-for broad observance of norms. The discussion of possible international norms on biosafety, biosecurity and worrisome dual-use research underscored their role as a culling device. Norms can be violated and still be useful as long as they play a meaningful culling role: sorting problematic and potentially dangerous cases from standard cases. This culling should reduce the number of potentially dangerous cases to a number that can be more thoroughly examined through targeted diplomatic, law enforcement or intelligence assets. The more countries that can help with these tasks of targeting these broader set of assets and then share information, the more likely the system will work.

Third, they can help assure that strategic denial is a strong, plausible threat before an attack and a diplomatic reality after an attack. These roles are why preserving and strengthening the international norm against biological weapons acquisition and use provides valuable benefits.

*How could other states hurt?*

Nation-states could either conduct a covert attack or provide covert assistance to a non-state actor. These risks could be reduced through declaratory policy and strengthened attribution capabilities but probably never eliminated entirely.

Covert attack by a nation-state might be relatively easy technically but it is difficult to construct a situation where the motivation makes sense. Nation-states seem less likely to simply want to impose pain and suffering. It is hard to construct a scenario where a threat is levied (do

x or else we will strike you again) that does not preferentially benefit a particular nation-state. The preferentially benefited nation-state would then be under significant suspicion that they had participated in the attack in some, as yet identified, fashion. While the precise characteristics of the scenario are hard to play out, it would be a risky gambit for a nation-state to have an angry super power.

Covert assistance of a nation-state to a non-state actor could take two forms – malicious or innocent. Declaratory policy could state that countries that even unwittingly aided terrorist attacks would be held responsible. This type of threat is more usefully made once a standard set of norms for biosafety, biosecurity and worrisome dual-use research has been promulgated. While the dissertation argues that benefits should be the fundamental catalytic force for the widespread adoption of the norms, a few countries judged to be lagging in implementation could be warned that poor implementation of these international norms followed by some sort of leakage would carry heavy sanctions in the eyes of the international community.

Strong attribution capabilities would strengthen deterrence. Attribution capabilities would enable the technical characteristics of the pathogen or the growth media within in which the pathogen grew to be traced to a particular source. There are significant regional variations in naturally-occurring diseases. Better understanding of the geographic distribution of these variants would help strengthen attribution after an attack and, in turn, potentially deterrence. Newspaper reports indicate that this type of attribution techniques was used to construct the FBI case against Bruce Ivins. Broadening the library of regional or other variants would doubtless

speed the evolution of these capabilities.[225] Attribution would be valuable tool to strengthen deterrence.

*(5) Build Underlying Deterrence Capacity*

The underlying capacity of the defender to cause these three outcomes – deterrence through detection and disruption, through tactical denial, and through strategic denial -- should be strengthened. Strengthening these capabilities requires some new elements and many others discussed elsewhere in this dissertation.

Deterrence through detection and disruption largely relies on intelligence and law enforcement assets, focused on strengthening the capacity to detect dangerous modes of delivery at home and abroad. First, there needs to be a strengthened capacity to observe the testing of aerosol delivery capabilities even in relatively remote parts of the world. Working with the police and national security apparatus of host countries to strengthen their ability to recognize the often subtle clues would be valuable. Remote means to monitor this type of testing and other indications of a biological capability would be valuable. Second, there needs to be every measure taken to assure that law enforcement will recognize, detect, apprehend and suppress efforts to deploy pathogens, particularly through the aerosol route. The role of detectors in this objective is discussed in a later section but classic police measures are a valuable part of the strategy. This is the part of strategy that would have the effect of increasing the probability that operational teams launching even a failed attack would be apprehended.

Deterrence through tactical denial relies on continued improvement to the nation's ability to respond to a biological attack in a timely and effective manner with needed medical

[225]Salerno and Hickok, "Strengthening Biological Protections," see page 110 "Scattered throughout these foci [across the globe] are many different strains that exhibit tremendous genotypic and phenotypic diversity."

countermeasures and supportive care. The dissertation includes a number of recommendations to strengthen these capabilities. An associated benefit of the proposed international strategy on defensive medical countermeasures is that it should speed the development of more advanced countermeasures and spread their availability much more widely throughout the globe. The discussion has focused on an international medical countermeasure strategy as a benefit to catalyze broad observance of international norms on biosafety, biosecurity and worrisome dual use research. The deterrence benefits of strengthening defensive capabilities throughout the broader international community would be a meaningful benefit, also.

Deterrence through strategic denial – seeking to assure that the adversary does not achieve the sought political or territorial ambitions -- would be achieved through a variety of tools, including strengthened and updated non-proliferation norms robustly supported by the international community. The discussion about minimizing spiral model effects should have the effect of maintaining cooperation between the various countries. These measures are transparency to the full extent consistent with a responsible national defensive program, a transparent and responsible civilian management system for classified programs and renewed international role in establishing and assuring the broad adoption of norms in the international environment.

*Conclusion*

Declaratory policy should warn explicitly of the low probability that an attack will succeed and that it will expose and destroy valuable operational assets.[226] This could help deter

[226] Strengthening US post-attack attribution capabilities could reduce this risk. If post-attack analysis could help identify either the source of the pathogen or the place of purchase of component parts, deterrence would be strengthened. The US government recently created a program to strengthen post-attack biological forensic programs at the National Biodefense Analysis and Countermeasure Center (NBACC). This is valuable. Attribution for

"rational" terrorists but probably not "non-rational" terrorists. Targeted policies, looking at sub-groups with skill sets needed to construct a catastrophic weapons capability, need to be developed and fully implemented to affect "situational terrorists." The great difficulty of fully developing and implementing these tools, though, should be recognized and the implications of that difficulty accepted. One could never be confident of deterring all possible determined, talented non-state adversaries.

Deterrence would be greatly strengthened by shifting declaratory policy from post-attack retaliation to the real risk of failure and operational exposure and destruction. It would help with "rational terrorists" and with at least some "situational terrorists." It should neither hurt nor help with "non-rational terrorists." But while worthy, deterrence will remain somewhat weak and uncertain. An attacker may decide they are prepared to risk failure. Risking it, they may well succeed, causing unprecedented deaths and strategic reversal for the United States. Deterrence strategy should be updated and strengthened, but its inherent weakness in the case of catastrophic biological attacks must be recognized.

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biological weapons, though, turns out to be a difficult technical problem. Libraries of regional variants of common disease might help focus follow-up investigations, but are unlikely to provide conclusive evidence. These efforts should be investigated and pursued, but current capabilities do not offer confidence that in every plausible scenario they would support post-attack attribution.

## Section III

## Defense of the US Homeland

### Overview of the Defense Section

In traditional defense of the US homeland, state and local governments have taken principal responsibility for responding to the threats that have confronted the homeland -- disasters, accidents and epidemics. This generally has made sense and worked well because two enabling conditions were present. First, the nature of the threats was limited to relatively small disasters, accidents and epidemics whose response could be (and generally was) well-managed by state and local public safety officials, with their inherent ability to get to the scene first, generally high professional skills, and significant local expertise. Second, for the larger disasters or epidemics that inevitably did occur occasionally, the federal government had little unique assistance to offer, particularly in the time-sensitive early phases of the crisis.

*Likely Presence of Enabling Conditions*

Neither of these enabling conditions would be present in a catastrophic biological attack on the homeland. Most disasters and accidents in the homeland have killed fewer than 100 people. Only three episodes in the US homeland have caused more than 10,000 deaths, the number assumed in a catastrophic biological attack. Traditional defense approaches would be overwhelmed by the greater scale, speed and technical complexity of a catastrophic biological attack. With the advent of targeted medical countermeasures, there would at least be the prospect that federal expertise and materials could significantly improve the response in the very early hours and days of a possible biological event, long before the federal government generally gets involved in the detailed response to a homeland security event.

The reality that traditional approaches would be overwhelmed creates two problems: (1) additional capabilities are needed to respond effectively to these larger, catastrophic attacks, and (2) there is significant ambiguity in the US federal system about who would be responsible for handling the response to these larger events. This ambiguity complicates the development of the needed additional capabilities and their efficient use in an actual crisis.

*Recommendations for Refinements*

This dissertation makes two specific recommendations: (1) the president should explicitly have responsibility for making the needed strategic decisions to shape the response to a biological event and decision aids should be constructed to assist him; and (2) additional "modular" federal capabilities should be created to supplement state and local capabilities in a catastrophic crisis and a clear and agreed leadership structure should be created to assure its effective use in a crisis, consistent with US federal values.

An effective response to a catastrophic biological attack would require that complex and highly-contested strategic decisions be made and made quickly. There does not appear to be explicit recognition that these decisions would need to be made, appropriate analytical means to support them, or explicit authority or agreement on who should make them. This situation creates significant risk that in a catastrophic biological attack needed strategic decisions would not be made swiftly enough to be implemented. Traditional defense of the homeland usually does not require any official to make strategic decisions. The public safety objective is generally unstated but straightforward – maximize lives saved and minimize property damage. This dissertation urges that the president explicitly have responsibility for strategic decisions in a biological event and that an appropriate set of analytical tools and authorities be developed to

support him. The dissertation describes the type of analysis that should be used to support these decisions given the very limited information that would be available in an actual crisis. Given the tight timelines, this absence of a serious debate in the literature and in the policy world about how these decisions would be made and who would make them makes an effective response to a catastrophic biological attack unlikely.

State and local emergency response is usually effective at the tactical and logistical elements of a response. This dissertation urges the development of "modular" federal capabilities that can appropriately supplement state and local capabilities in a catastrophic event in the homeland. A variety of leadership models, consistent with US federal values, could work and should be evaluated. The capabilities are described as "modular" because they would not constitute a stand-alone, unique response structure for catastrophic events, but rather would be additional types or increments of capability to supplement existing capabilities. These "modular" federal capabilities make the integrated effort effective given the greater scale, speed and complexity of a catastrophic attack. The needed capabilities for these new "modular" pieces and how they would work with existing state and local assets has not been articulated, much less agreed or implemented between local, state and federal officials. There do not appear to be authorities, agreements or expectations that allow either the president or the governor to lead an integrated set of federal, state and local assets such as would be needed to respond effectively to a catastrophic event.

*Medical Aspects of Defense*

A catastrophic biological attack would pose some unique medical challenges. Public health was significantly transformed in the mid-1900s as targeted medical countermeasures

became widely available for the first time. The enabling conditions for an effective public health response in this post-drug age are two-fold: one scientific and one societal. First, the bug must be relatively slow in evolving to defeat the countermeasure; and second, the broader public health infrastructure must be sufficiently committed and coherent that it can provide supportive, ongoing care in an appropriate environment.

*Likely Presence of Enabling Conditions*

Neither enabling condition would be expected to be present in the case of a catastrophic biological attack. The first enabling condition -- the bug must be relatively slow in evolving to defeat the countermeasure – would be defeated by adversaries exploiting natural mutation or mutation facilitated by 21st century biotechnologies. A characteristic of the biotechnologies is that for the foreseeable future it is expected to be vastly easier to modify a pathogen than to modify the medical countermeasure needed to defeat the new pathogen. This characteristic of the biotechnologies favors the attacker over the defender. A situation where the attacker is favored over the defender is called offense dominant. Offense dominant situations are considered to be highly vulnerable to a host of destabilizing behaviors, including wars of preemption and defensive arms races.

The second enabling condition – that the broader public health infrastructure must be sufficiently committed and coherent that it can provide supportive, ongoing care in an appropriate environment -- also would not be expected to be met in a catastrophic biological attack. A catastrophic biological attack would stress the medical infrastructure in any country and, while cross national comparisons are difficult, the United States is probably as well prepared as any other country. There is a broadly held view, though, that the current public

health infrastructure in the United States would be overwhelmed by a bioattack of any significant size.

*Recommendations for Refinements*

This dissertation has four broad recommendations, two each for medical countermeasure strategy and for public health response. In each category, one recommendation focuses on the substance and one focuses on the structure needed to enable achievement of the substance. The two recommendations for defensive medical countermeasures urge that: (1) the substance of the strategy should be a continuum of activities focused on providing capabilities over time, as both the likely nature of the threat and of the possible defensive capabilities evolve, focusing on a strategy of stockpiling, and then of rapid adaptation, and then of transformative strategies; and (2) the institutional structure for pursuing a medical countermeasure strategy should be an international scientific exchange. This strategy would best align incentives and resources, both technical and fiscal, with broader strategic objectives. These strategic objectives include the long-term goal of shifting bioattack from offense-dominant to defense-dominant, as well as minimizing spiral model effects and strengthening deterrence model effects.

The dissertation also makes two recommendations for strengthening the public health response: (1) detailed, integrated planning on how to execute a response to a catastrophic biological attack should be undertaken, with an initial focus on how stockpiled countermeasures could be distributed on the needed timeline; and (2) this planning should be embedded in a forum considered legitimate by the broader public health community, possibly embedding it in the international scientific exchange recommended above. This proposal strives to overcome the

great difficulty in the highly diffuse US public health system of catalyzing appropriately detailed, integrated planning.

The challenges of updating traditional defense of the US homeland are significant, but surmountable. Unhappily, the same can be said about the challenge confronted by a talented and determined adversary seeking to develop a catastrophic weapons capability. History may record which party stays most tightly focused on their objectives and makes best use of available time and resources.

## Defense: Chapter 7

### Traditional Defense of the US Homeland

Traditional defense of the US homeland was fashioned in an unusual crucible. During much of the 19th and virtually all of the 20th century, the United States enjoyed the strategic luxury of being able to defend itself forward – to fight conventional wars on the territory of other states, defeating or deterring an adversary before fighting occurred on the US homeland itself.[227] No other modern society has pushed its dangers so far away for so long.[228] The risks to the US homeland basically were limited to natural disasters, accidents and epidemics. State and local governments historically have managed the response to these risks. The magnitude of these events, the speed with which they unfolded, and their technical complexity generally meant they could be managed effectively by state and local public safety and health officials, augmented, as needed, by counterparts from surrounding communities. Even the response to military threats to the homeland was generally organized and implemented by local communities, although often

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[227] There are obviously exceptions to this statement, including the attack by the Japanese against the US Naval Base at Pearl Harbor in the territory of Hawaii in 1941 and, most fundamentally, the ability of the Soviet Union to threaten the United States homeland with strategic nuclear weapons during the Cold War from the 1950s through the 1990s. At least Russia and China retain the ability to this day to threaten the US homeland with strategic nuclear weapons. The "much of" caveat for the 19th century is meant to start the period after the War of 1812, during which the British occupied territory in the continental United States and burned much of Washington DC, including most of the White House. The Civil War from 1861-1865 was a conventional war that took place entirely in the continental United States. At least 620,000 American soldiers died in the Civil War, nearly as many as in all other wars fought by the country combined. It destroyed significant proportions of Southern livestock, farm machinery, factories, railroads and wealth. The US army conducted ongoing operations against the Native American populations in the 19th century, ending in the Native Americans' extermination or relocation on reservations. Overall US foreign policy: Thomas G. Paterson, J. Garry Clifford and Kenneth J. Hagan, *American Foreign Policy: A History* (Lexington, Massachusetts: D.C. Heath and Company, 1977); Chinese and Russian nuclear and delivery capabilities: Arms Control Association, Fact Sheets, World Wide Ballistic Missile Inventories, September 2007 ACA website (http://www.armscontrol.org/factsheets/missiles.asp assessed 7-11-08); Extent of damage wrecked by US Civil War: James M. McPherson, *Battle Cry of Freedom: The Era of the Civil War* (New York: Oxford University Press, 1988).

[228] China and Japan prior to their "openings" by the West in the middle of the 19th century may be the best modern examples of other societies that "pushed away" conventional attacks, but their strategy was self-imposed isolation in security, economic and cultural terms rather than the almost ahistorical safety offered by the US continental position after the Mexicans and Native Americans had been defeated and before intercontinental missiles had been incorporated into foreign militaries. The US could pursue economic interests abroad but have significant confidence in the security of its homeland. Paterson, et al, *American Foreign Policy: A History*.

based on "best practices" provided by the federal government. A few threats to the homeland did overwhelm the capacity of local and state responders. These threats generally were severe epidemics and the rare hurricane that hit a particularly densely-populated area with great intensity and then was followed by a large storm-surge of flooding.

Traditional defense of the US homeland, with its reliance on local and state public safety and health officials, has, by and large, worked well. There are two significant exceptions to the pattern that state and local governments lead the response to threats to the homeland. First, there is broad agreement that the federal government would be responsible for repelling an invasion by a foreign military. Second, the federal government has consistently led the response to the threat, or the perceived threat, from within. The federal law enforcement community – generally the Federal Bureau of Investigation -- has led the recurring efforts to root out real or imagined spies, saboteurs, or terrorists.

This chapter has three specific objectives: it demonstrates (1) that the vast number of threats to the homeland historically have been small events in which a limited number of individuals died; (2) that the authorities are quite clear that the federal government is responsible in cases where there is an invasion by a foreign military or a threat from within by spies, saboteurs, and terrorists; and (3) that the significant difference in scale, speed and technical complexity between a traditional homeland security event and a catastrophic biological attack would render traditional approaches ineffective.

*(1) Disasters, Accidents, Epidemics and Other Bad Days*

Not a lot happens in the United States. Or, more precisely, not a lot happens that is outside the set of problems broadly agreed to be within the province and capabilities of state and

local public safety and health professionals. Most disasters and accidents are small in scale, resulting in a handful of fatalities and mostly requiring post-event restoration. While broad long-

**Table 1: Deaths from most-deadly single events in the United States homeland**

| | |
|---|---|
| Influenza Epidemic, 1918-1919 | 700,000 |
| Civil War, 1861-1865 | 620,000 |
| Yellow Fever Epidemic, 1878 | 20,000 |
| Galveston Hurricane, 1900 | 8,000 |
| Terrorist Aircraft Attacks, 2001 | 2,744 |
| Southeast Florida Hurricane, 1928 | 2,500 |
| Attack on Pearl Harbor, 1941 | 2,333 |
| Gulf Coast Hurricane, 2005 | 1,500 |
| Ohio Flood, 1913 | 467 |

term public policy changes perhaps could have altered these outcomes (strengthened levees, better airbags, better community policing), there is little to do immediately before the disaster and the tasks that could be done tend not to be manpower intensive. These disasters and accidents present local public safety officials with a daily and critical challenge but one profoundly different in nature from a large attack, with many deaths and injuries occurring

almost simultaneously. This section walks though historical trends on how Americans die. It demonstrates that single events in which more than a hundred Americans die have been few and far between. It further shows that for most events causing large numbers of deaths, there were only a limited set of measures that could have been taken in the time-sensitive period before the devastating event hit to further reduce deaths.

The vast majority of Americans die of natural diseases, particularly heart disease and cancer. Of natural disasters, accidents, and epidemics, most result in small numbers of deaths. These statistics are not cited to argue that big natural disasters or epidemics will not occur (they will) or that the scale and frequency of natural disasters in the past is necessarily a good predictor of what they will be in the future (they might not be).[229] The recounting of historical trends here simply demonstrates the core finding of this section: the vast number of threats to the homeland historically has been small events in which a limited number of individuals died.

The effectiveness with which state and local emergency preparedness capabilities generally handle these events is a tribute to the professionalism of these forces. But the vast difference between the demands of these routine events, even the routine disasters, and a catastrophic biological attack must be recognized and its implications for planning assessed. This review demonstrates that less than a handful of events (the 1918-1919 Influenza, the 1861-1865 Civil War, and the Yellow Fever Epidemic of 1878) had more than the number of deaths (at 10,000) that this paper defines as being a "catastrophic biological attack." This demonstrates the paper's point that such an attack would be unprecedented in the experience of any serving

[229] A recent paper argued that the effects of global warming will increase severe weather events in the United States. Robert J. Trapp, Noah S. Diffenbaugh, Harold E. Brooks, Michael E. Baldwin, Eric D. Robinson, and Jeremy S. Pal, Changes in Severe Thunderstorm Environment Frequency during the 21st Century Caused by Anthropogenically Enhanced Global Radiative Forcing; Press Release from Purdue University Dated December 3, 2007. Purdue University Website (http://news.uns.purdue.edu/x/2007b/0712303TrappStorms.html accessed 7/2/2008).

public official and in the experience of the American public.[230] Number of total deaths provides a rough measure of the intensity of an attack and hence usefully demonstrates that a catastrophic biological attack would have few if any meaningful precedents in the entire history of the United States.[231]

*Death in Small Numbers*

In 2005, about 2.5 million people died in the United States. Almost half of these deaths were from heart disease or cancer. About 175,000 people died from injuries of various sorts, the vast majority of which were unintentional (118,000). Other medical conditions account for all of the other deaths in the United States. These unintentional injuries largely were motor vehicle accidents (44,000), followed closely by unintentional poisonings (24,000) and falls (20,000).[232] While these trends change somewhat year to year, the pattern holds that in the United States few people – proportionally -- die due to disasters and accidents and the disasters that do occur each affect a relatively small number of individuals.[233]

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[230] The National Weather Service observed as an aside in a paper that they believe the public has about a seven-year memory – for about seven-years after a severe storm hits an area, people carefully follow the advice in all the weather advisories. But as the memory of the severe storm fades, so does compliance with their recommendations. See Eric S. Blake, Edward N. Rappaport, and Christopher W. Landsea, "The Deadliest, Costliest, and Most Intense United States Tropical Cyclones From 1851 to 2006 (And Other Frequently Requested Hurricane Facts)," National Weather Service, National Hurricane Center, Miami, Florida, April 2007.

[231] It should be noted that events with low numbers of deaths can injure many individuals and cause vast property damage, leading to profound societal change and great human tragedy. The Jamestown Flood of 1927, for example, caused a number of deaths that are variously estimated from a handful to somewhere in the low hundreds. But each of those deaths mattered profoundly to someone and the flood's other effects caused profound and lasting changes in American politics and society. John M. Barry, *Rising Tide: The Great Mississippi Flood of 1927 and How It Changed America* (New York: Simon and Schuster, 1998). Barry estimates a few hundred died in the flood. He tells a moving story of the profound impact of the loss of almost a million homes and the resulting relocation of sub-populations.

[232] Kung HC, Hoyert DL, Xu JQ, Murphy SL. *Deaths: Final Data for 2005*. National vital statistics reports; vol 56 no 10. Hyattsville, MD: National Center for Health Statistics. 2008. Page 1, Page 9, and Table 18. The unintentional deaths from injuries were homicide, suicide or deaths in warfare or law enforcement.

[233] There was, for example, a significant increase in the number of deaths due to cataclysmic storms between 2004 and 2005, an increase traceable directly to Hurricane Katrina, Hurricane Rita and a single tornado. Kung, et al., *Deaths*.

Deaths due to severe weather – including hurricanes, tornados and floods – have averaged about 650 for each of the past ten years. The largest single component each year are heat fatalities (170 fatalities), with hurricanes coming in second (117 fatalities). Floods and tornados are third and fourth (74 and 62 fatalities annually, respectively).[234] The following section walks through these data in more detail. Three things are striking about the data: first, few of these disasters cause more than a hundred deaths; for most of these types of disasters, the actions needed in advance tend to be straightforward and well within the abilities of state and local officials; and third, the Federal government had little to contribute in terms of specialized capabilities to mitigate the initial effects of these disasters.

*Background Data*

For the entire period 1851-2006, only 51 hurricanes caused deaths of more than 25 people in the United States. The top three in terms of deaths were in 1900 in Galveston, Texas (8,000); in 1928 in southeast Florida (2,500); and in 2005 in Louisiana and the Gulf Coast (1,500). Hurricane Katrina, that hit Louisiana and the Gulf Coast in 2005, also caused at least $81 billion dollars of property damage and is by far the most expensive hurricane ever to hit the United States, even when property damage costs are normalized across time.[235]

The average number of fatalities each year from tornados for the period from 1977 to 2006 is 54. Since 1940, the worst single year was 1953 with 515 deaths. But these 515 deaths came from nine separate tornados in nine states, with the most severe in terms of deaths being in

[234]Tornados have caused more than 200 deaths in only four years since 1940. National Weather Service, National Oceanic and Atmospheric Administration, Office of Climate, Water and Weather Services, *67-year List of Severe Weather Fatalities,* NOAA website (http://www.nws.noaa.gov/om/hazstats/images/67-years/pdf accessed 6/23/08).
[235] Blake, et al., "The Deadliest, Costliest, and Most Intense United States Hurricanes."

Michigan with 115 deaths. Years with high death tolls generally had multiple tornados, with the death tolls from a single tornado rarely exceeding a hundred deaths.[236]

Floods are similar, with 99 deaths per year on average since 1977. The worst years for deaths from floods since the 1940s include 1972 (555 deaths); 1969 (445 deaths); 1955 (302 deaths); 1977 (210 deaths) and 1983 (204 deaths). All other years since 1940 had less than 200 deaths.[237] The high number of deaths in the worst year --- 1972 -- came from at least three separate floods, in three separate areas, of which the largest was 237 deaths in Rapid City, South Dakota.[238]

Technical advances in recent years have increased the probability that there would be tactical warning of a big hurricane headed toward a populated area. Large numbers of deaths from a hurricane tend to be correlated with failing to evacuate a densely-populated area that receives a storm surge of 10 feet or more after the passage of the hurricane.[239] Less risk of a hurricane directly hitting a densely populated area should be accepted in a city that lies below sea-level (like New Orleans or Galveston) than in a city less vulnerable to this post-storm surge. Flood response consists of tactical warning (if available), carefully calibrated evacuation versus shelter-in-place decisions, and sand-bagging and other measures to protect vulnerable properties. These early phases can be critical but they tend not to exceed the capacity of traditional state and local emergency response capabilities, with its routinized procedures to augment forces with

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[236] National Weather Service, *67-year list of Severe Weather Fatalities,* Some of the most fine-grained data was extracted from "Worst Tornadoes" derived from the book "Significant Tornadoes" by Thomas P. Grazulis, director of the Tornando Project. Contained on his website. "The Tornando Project," Website accessed 7/2/2008.
[237] National Weather Service, *67-Year List of Severe Weather Fatalities.*
[238] Charles A. Perry, United States Geological Service, Fact Sheet 024-00. March 2000, *Significant Floods in the United States During the 20th Century – USGS Measures a Century of Floods, Floods*, US Geological Website, accessed 7/2/2008. See particularly the chart on page 4. The largest single loss of life was due to the Ohio Flood of 1913 in which 467 people died. The flood was due to excess regional rainfall.
[239] See discussion of this in both (1) Perry, *Significant Floods in the United States,* page 5; and (2) Blake, et al., *The Deadliest, Costliest, and Most Intense United States Hurricanes.*

counterparts from surrounding areas. For both hurricanes and floods, the federal government provides assistance and funding after the crisis to aid the clean-up and reconstruction of the affected community.

A large earthquake affecting a populated area – such as is feared along the San Andreas fault in California -- would certainly overwhelm state and local responders but, again, the federal role would probably be limited largely to providing tactical warning, if available, and aiding search and rescue; and then helping with the provision of food, water and shelter; and then reconstruction.

Other severe but relatively frequent weather conditions – like heat fatalities and tornadoes – cause more deaths in most years than the relatively infrequent large hurricane or epidemic. Heat fatalities and tornadoes tend to focus requirements on personal or small group response to tactical warning ("get out of your mobile home"; "get in your basement") and on public safety efforts to assist at-risk populations (taking poor or elderly individuals to air conditioned shelters during the day). Local and state public safety officials perform a profound role – but it is many small decisions, combined, to reduce the number of deaths from many events that each threatened a relatively small number of people.

*Epidemics*

Epidemics have most often overwhelmed the response capability of state and local officials. Epidemics are not he diseases that cause the largest incidence of sickness or death in any particular period. Communities somehow discount for the expected level of auto accidents

(today) and measles and scarlet fever (prior to the development of targeted vaccines.)[240] But a contagious disease, sweeping through a community without inherent immunity, causes a degree of destruction and panic that is unique. The Influenza Epidemic of 1918 – 1919 killed 700,000 Americans and at least 20 million individuals worldwide over the course of about a year and a half.[241] Local public health officers struggled against the epidemic, using the classic public health tools of isolation and quarantine and some new insights about sterilization. They closed the public schools and encouraged hand-washing, and needed (and received) little help from Washington to do either.[242] There were efforts to develop a vaccine and other countermeasures using various national institutes (although largely private institutions -- like the Rockefeller foundation) but these worthy efforts probably had a limited net effect on quelling the epidemic. The influenza largely burned through the available population.

Other notable acute public health crises have been smallpox, yellow fever and polio outbreaks. The Yellow fever outbreak in the Mississippi Valley of 1878 killed 20,000. Memphis lost 5,000 individuals or nearly a third of its population. Its story is emblematic of how the functioning of a city can fall apart in a raging epidemic of a contagious disease. The

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[240] Susan B. Carter, Scott Sigmund Gartner, Michael R. Haines, Alan L. Olmstead, Richard Sutch, and Gavin Wright, *Historical Statistics of the United States: Earliest Times to the Present.* Millennial Edition, Volume 2, Part B Work and Welfare, (Cambridge, UK: Cambridge University press) 2006. Incidence of Disease, Richard H. Steckel, Table Bd448-462. Incidence rates of selected reportable diseases: 1912 – 1998.

[241] It could be argued that these nascent capabilities have never been tested in anything of the scale and speed of the 1918 Influenza Epidemic. The general stride in vaccine development did, though, moderate the death rate from the polio outbreaks of the first half of the 20th century and the HIV/AIDs pandemic. Both the polio and HIV/AIDS epidemics have had devastating and tragic effects on the population but the respective routes of transmission meant that the speed of these pandemic's progression was slower than the type of easily-transmitted disease like was at the root of the 1918 Influenza pandemic or the Yellow Fever epidemics in the late 1800s. John M. Barry, *The Great Influenza: The Story of the Deadliest Pandemic in History* (New York: The Penguin Group, 2004); Molly Caldwell Crosby, *The American Plague: The Untold Story of Yellow Fever, the Epidemic that Shaped Our History* (New York: Penguin Group, 2006); David M. Oshinsky, *Polio: An American Story* (New York City: Oxford University Press, 2005).

[242] Local public health officials took different stances on these issues during the 1918 influenza pandemic, for example, with public health officials in Philadelphia taking a relatively draconian position of limiting funerals to no more than 15 minutes and forbidding public gatherings of more than three people. Officials in some towns tried to isolate the entire town. Barry, *The Great Influenza.*

descriptions of the 1878 yellow fever epidemic are dispiritingly similar to the descriptions of the 1918-1919 influenza epidemic and even the bubonic plague in 1340 in Europe – the dead cast aside in the streets because there is no capacity to bury them; very limited nursing care for the sick; and little provision of food and water for the living.[243] A second element that is dispiriting is that the death rates are generally percentages – 30 percent die, 50 percent die, 10 percent die. The conclusion seems to be that for a contagious disease in the era before targeted countermeasures the size of the population without inherent immunity is the limiting factor.

Federal capacity to assist with epidemics has been enhanced in recent decades both because of strides in medical science and in the capacity of the relevant federal agencies. Medical science in general has made great strides in its technical capacity to develop targeted medical countermeasures. The U.S. Centers for Disease Control and Prevention have strengthened their disease surveillance capabilities, particularly domestically, and increasingly provide technical and other assistance to state and local public health officials. The National Institutes of Health are strengthening and speeding their ability to develop targeted vaccines.

Despite this valuable progress, an epidemic could still be very difficult to manage. As the current Federal Influenza response plan makes plain, the federal government would still look to state and local public health officials to play a leading role, particularly in the application of traditional, community-based means for managing an epidemic.[244]

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[243] Crosby, *The American Plague,* see page 75 and see quote on page 65: A minister in Memphis in the midst of the epidemic wrote a friend: "'People constantly send to us, saying, 'Telegraph the situation.' It is impossible. Go and turn the destroying Angel loose upon a defenseless city; let him smite whom he will, young and old, rich and poor, the feeble and the strong, and as he will, silent, unseen, and unfelt, until his deadly blow is struck… and then you can form some idea of what Memphis and all this Valley is …" See also Barry, *The Great Influenza*; Cantor, *In the Wake of the Plague.*

[244] Department of Health and Human Services, HHS Pandemic Influenza Plan, November 2005, asks regional governments to develop plans for "how health departments and other agencies of state and local government and

*(2) Clear Federal Responsibility in Two Situations*

While state and local emergency responders are expected to lead a response to a traditional defense of the homeland event, the federal government is clearly expected to lead in two areas – in responding to an actual invasion of the homeland by a foreign military and in investigating and prosecuting spies, saboteurs, and terrorists.

Congress has provided extensive authorities to the federal government to protect against the threat from within.[245] The President and the Congress also have used expansive techniques to extend their authorities in wartime to protect against the threat from within. At the time of their initial use, these expansive definitions of authority generally have been upheld by the Supreme Court or otherwise accepted.

The FBI has investigated and prosecuted sabotage inside the United States. There were significant fears of and limited cases of German sabotage prior to and after US entry into World War I.[246] There also were significant fears prior to World War II, although the threat in that

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tribal nations will prevent, mitigate, respond, and recover from an influenza pandemic." It is, one must admit, a reasonably through-going tasking for flu response.

[245] Legislation strengthening federal control of threats from within includes the Alien and Sedition Acts of 1798, which, among other things, prohibited assembly "'with intent to oppose any measure ... of the government'" and the Smith Act of 1940 which prohibited the "'teaching and advocating'" of subversive doctrines. Japanese-American interment was implemented through executive orders that were upheld, initially, by the Supreme Court. Eric Foner and John A. Garraty, eds., *The Reader's Companion to American History (Boston: Houghton Mifflin Company, 1991)* pages 27, 38, 386, 588-589, 709-710.

[246] The United States has had essentially no conventional military attacks since the British invasion that destroyed much of Washington D.C. in the War of 1812. There is, of course, the significant exception of the Japanese air attack against the then-territory of Hawaii in 1941 which killed 2,388 and catalyzed formal US entry into World War II. The most significant act of sabotage ascribed to the Germans prior to World War I was the explosion at the Black Tom Munitions Factory. While the United States was technically neutral at the outset of World War I, British control of the high seas meant that US munitions effectively only got to the UK. Germany struck back by trying to destroy this supply of munitions at the source – the plant in New Jersey. Federal Bureau of Investigation, Headline Archives, "1916 'Black Tom' Bombing Propels Bureau Into National Security Arena," FBI website (http://www.fbi.gov/page2/july04/blacktom accessed 02/21/2009); George H. Quester, *"American Deterrence Theory and Homeland Defense," October 22, 2000, Journal of Homeland Security,* page 6 of 20.

conflict came on both the Atlantic and Pacific coasts of the continental United States, from both Germany and Japan.[247]

The FBI similarly investigated and prosecuted cases of terrorism occurring in the United States. Almost 250 terrorist events have occurred in the United States since 1980. Of this, only the 9/11 terrorist attacks could be described as having a response in which the FBI played only a supporting role. Otherwise, the FBI has played the leadership role in investigating and prosecuting those responsible. Only four terrorist events since 1980 in the United States caused the deaths of more than two individuals -- the 1993 car bombing at the World Trade Center (which killed 6 individuals); the 1995 truck bombing of the Murrah Federal Office building in Oklahoma City (which killed 168 individuals); the 2001 aircraft attacks against the World Trade Center, the Pentagon, and a third, unknown target (which killed 2,972 individuals); and the anthrax mailings in the fall of 2001 (which killed 5 individuals).[248]

There is broad agreement that the federal government would respond to the actual invasion of the homeland by a foreign military. But history shows that if the invasion is only feared, state and local governments play the leading role. Local and state officials generally organized the patrols to watch for German submarines off the Eastern shore of the United States

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[247] There is an interesting history of attacks on the continental United States during World War II. The attacks had essentially no operational effect but they did help fan the sense of vulnerability in the homeland. The attacks on the Pacific coast by the Japanese included two cases of a Japanese submarine shelling the continental United States and one bombing by a seaplane launched by a submarine. There were several German attacks. There was the conviction of 33 German spies in the Duquesne Spy Ring and eight saboteurs captured before launching any of their attacks. German U-boats sank 348 US supply ships very close to the East Coast of the US in the early stages of US entry to World War II. Various sources, including The White House, Fact Sheet: Confronting the Emerging Dangers of a New Century, Wednesday, Aug 20, 2008. White House Website (www.whitehouse.gov accessed 11/28/08); The California State Military Museum, "California and the Second World War." California State Military Museum website (www.military museum.org/HistoryWWII.html accessed 11/25/2008); Federal Bureau of Investigation, FBI History, Famous Cases: The Duquesne Spy Ring, FBI website (www.fbi.gov/libref/historic/famcases/spyring/spyring.html accessed 11/25/2008)

[248] Federal Bureau of Investigation, *Terrorism, 2002-2005,* FBI website, Reports and Publications (http://www.fbi.gov/publications/terror/terrorism 2002-2005.pdf accessed 6/23/08. Chart: Chronological Summary of Terrorist Incidents in the United States 1980-2005, pages: 57-66.

or to assure compliance with "black-out" rules to complicate targeting by a German pilot during World War II.[249] Cold War-era "duck and cover" training and shelter programs were locally implemented based on "best practices" issued by the federal government.[250]

*(3) Greater Scale, Speed and Technical Complexity*

A catastrophic biological attack predictably would overwhelm state and local assets because of its vastly greater scale, speed and technical complexity. The scale would be greater both in terms of the number of individuals needing assistance and the number of individuals needed to help in the response. Getting the number of individuals needed to help in the response would require accessing sources of personnel generally little used by state and local officials and hence unfamiliar. Speed would be vastly greater in a catastrophic biological attack, with critical decisions needing to be made and centrally implemented very swiftly. A catastrophic biological

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[249] Thomas Tulenko, Bradley Chase, Trevor N. Dupuy and Grace P. Hayes, *US Home Defense Forces Study,* A study prepared for the Assistant Secretary of Defense by the Historical Evaluation and Research Organization of T.N. Dupuy Associates Inc. Defense Technical Information Center. Pentagon Library, April 1981. World War I: page 7-8; World War II: page 34-35. The state and localities often had to improvise to find forces for these internal security missions because the federal government swiftly and sometimes unexpectedly federalized state National Guard troops. The same finding applies to deployments of naval vessels. While the Navy would sometimes deploy forces to protect the US coastline, they would do so only when the Navy judged there were no pressing needs for the vessels elsewhere: "Japanese seizure of the Aleutians [during World War II] and some uncertainty about Japanese intentions did not deflect important U.S. Navy elements from participation in the pivotal Battle of Midway despite considerable concern over the possibility of Japanese strikes against California." Adam B. Siegel, *The Wartime Diversion of U.S. Navy Forces in Response to Public Demands for Augmented Coastal Defense,* Center for Naval Analyses, Professional Paper 472, November 1989. Pentagon Library, page 1.

[250] Laura McEnaney, *Civil Defense Begins at Home: Militarization Meets Everyday Life in the Fifties,* (Princeton, NJ: Princeton University Press, 2000). McEnaney describes how the policy for Cold War civil defense programs was set by a federal agency, the Federal Civil Defense Administration, and advanced by a mixture of state, local and private organizations. She underscores, though, that such programs were implemented by the individual American family. The emphasis on local groups implementing civil defense can also be seen in "Appendix A: A Civil Defense Chronology" which notes that during World War I "A Field Division...was created under the Council of National Defense to coordinate the activities of thousands of state, local, and community "local defense" units that had sprung up during the war." It also notes that in 1958, "PL-606...was signed, making civil defense a joint responsibility of the Federal Government and State and local governments...." See Robert A. Gessert, Nehemiah Jordan, and John E. Tashjean, "Federal Civil Defense Organization: The Rationale of Its Development," Institute for Defense Analyses, Economic and Political Studies Division, January 1965, Report for the Office of Civil Defense, Pentagon Library.

attack would require very different technical knowledge than that used in the types of accidents, disasters or epidemics generally confronted by state and local response officials.

*Scale*

The scale of both the effects and the needed response forces would be greatly larger in a biological catastrophic biological attack. The vast number of traditional defense of the homeland events caused less than one hundred deaths. A catastrophic event is defined as more than 10,000 deaths, a number of deaths caused by only three events in the history of the United States.

Scale also would be profoundly different in the size of the needed response force – it would need to be much bigger than the force used for routine events, even "routine" disasters. Managing such a big force would be a challenge in its own right as would be managing across the disparate organizational seams that would be unavoidable in pulling together such a large group. Once the scale of the response requires moving beyond sharing counterparts from surrounding communities, the response necessarily would use personnel unfamiliar to many state and local officials.

Sources of Response Personnel

There are only so many public safety or public health officials in a community. The vast majority of public safety officials work for the local government (more than 90 percent) while a smaller percentage but still a majority of public health personnel work for the local government (56%). These local experts often have very high professional skills and naturally look to their local leaders in a crisis.[251] There are about 45 public safety officers (local, state and federal) for

[251] Census Bureau; Federal, State and Local Government; Public Employment and Payroll; State and Local Government; *Compendium of Public Employment,2002;* Table 7: Employment and Payrolls of State and Local

every 10,000-person increment of population in the United States. There are about 56 public health officers per 10,000-person increment.[252]

There are several standard strategies to grow the public safety force to cope with a larger disaster. First, a community could deploy all its own public safety officials, pulling individuals off of vacation, training, and administrative jobs. An interesting study found, however, that many first responders hold "multiple, and often conflicting, critical jobs." The study found that in 16 fire departments, an average of 22.2 percent of employees hold two (or more) public safety positions. Hence, mobilizing the full force of public safety officials in a community would leave many gaps because many individuals are on two sets of roosters. The same problem plays out in a mobilization of the National Guard – either for a federal war-fighting mission abroad or in an activation for use at home. The same study found that in one law enforcement agency, 13 percent of their personnel also had military obligations.[253]

Second, communities have long-standing and often-used agreements to share public safety personnel in a crisis. There are a variety of these types of agreements, but the most prominent example is probably the Emergency Management Assistance Compact (EMAC) which is activated by the governor. These agreements facilitate the sharing of public safety personnel. For example, during the 2004 hurricane season, more than 800 people deployed

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Governments by Type of Government and Function: 1957 to 2002. "Public safety officers" is calculated by adding "police protection" and "fire protection." "Public health officials" is calculated by adding "Hospitals" and "Health." The percentage is calculated by dividing the local total by the state plus local total.

[252] Census Bureau; Federal, State and Local Government; Public Employment and Payroll; State and Local Government; *Compendium of Public Employment,2002;* Table 3: Summary of Public Employment and Payrolls by Function: March 2002. "Public safety officers" is calculated by adding "police protection" and "fire protection." "Public health officials" is calculated by adding "Hospitals" and "Health."

[253] Rebecca F. Denlinger with Kristen Gonzenback, "The Two Hat Syndrome: Determining Response Capabilities and Mutual Aid Limitations, in Juliette N. Kayyem and Robyn l. Pangi, eds., *First to Arrive: State and Local Responses to Terrorism,* (Cambridge, MA: The MIT Press, 2003).

under EMAC from 38 member states to assist after four hurricanes hit the Gulf Coast.[254] These agreements provide a framework that is very flexible and could theoretically increase the size of the relevant public safety force significantly. These formal agreements have only existed for a few decades and hence post-date episodes of severe infectious disease outbreaks. The sharing is generally implemented in a situation where it is clear that only the requesting community is threatened (the hurricane has come and gone) and when forces are needed to help with post-crisis security and restoration. One question is whether these agreements would function in an event like a biological attack where the persistent vulnerability of surrounding communities to reattack by a biological pathogen might make them loathe to denude their community of public safety personnel.

The history of epidemics shows that while individual doctors, nurses, and spiritual advisors are prepared to enter a threatened city for humanitarian reasons, the political leadership of surrounding communities is inclined to retain assets in case their own communities are threatened. The risk a community with an infectious disease outbreak poses to another, as-yet uncontaminated community was reasonably well understood by the late 1800s, with officials in Memphis complaining bitterly that officials in New Orleans, the port of entry, were so lax in allowing seamen sick with yellow fever to enter the port and contaminate others.[255]

The third source of additional personnel to supplement local and state public safety responders probably would be the National Guard. The National Guard can be used by the governor for state missions, often supplementing local police in fighting fires or aiding in hurricane relief efforts, or it can be federalized by the president and used as an element of the US

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[254]International Association of Chiefs of Police, State and Provincial Division, *The Role of State and Provincial Law Enforcement Agencies in a Post-9/11 Era: The Demands and Capacities of Protecting and Policing the Homeland,"* International Association of Chiefs of Police website (http:///www.iacp accessed 6/27/08).
[255] Colby, *American Plague.*

Armed Forces. The FY2007 National Guard end-strength was 367,000 distributed across the fifty states and the territories, including about 40,000 commissioned and warrant officers.[256] Hurricane Katrina, that hit the Gulf Coast of the United States in August of 2005, caused the largest stateside deployment of the Guard in history, with more than 50,000 soldiers and airmen aiding in the search and rescue and stabilization efforts. This deployment exceeded the previous record for a stateside deployment of the National Guard – 30,000 for the 1906 San Francisco earthquake and fire. It should be noted that a significant proportion of the National Guard are currently deployed abroad in Iraq or Afghanistan and so any sizeable deployment for homeland duty would put a significant, additional strain on overall assets.

Active duty military probably would be the fourth available pool of personnel assets. The active duty military numbers about one and a half million individuals. Large portions of it are forward deployed and it is under significant operational strain now because of its multiple and extended war-fighting requirements. Using the active duty military in the homeland can be important and useful; on the other hand, its use comes laden with legal and cultural restrictions, including particularly the Posse Comitatus act that imposes restrictions on the use of the Armed forces for law enforcement functions in the homeland. Some observers judge that the use of the active duty military in a catastrophic event in the homeland would be unavoidable[257] while most would avoid it to the maximum extent possible and only permit it to go forward under clear civilian leadership below the level of the President and the Secretary of Defense.

The fifth source of additional personnel probably would be various relatively small teams of federal personnel with specific, technical expertise. On the one hand, they would bring

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[256] Army National Guard website, "Recruiting," (http://www.arng.army.mil/PostureStatement/97-99/page 16.html accessed 07/10/2008).

[257] Arnold S. Punaro, chairman, Commission on the National Guard and Reserves, *Transforming the National Guard and Reserves into a 21st Century Operational Force.* See particularly pages 11-15.

outstanding technical assistance and professionalism. On the other, it is possible that a decision-maker, particularly a state or local decision-maker, would be hard pressed to sort out the conflicting perceptions of responsibility, authority and recommended next steps from these different groups. Federal response forces could include individuals from the 6,000 member commissioned Public Health Service (PHS), whose members include the full-range of health professionals. The PHS does not have standing forces waiting to deploy into a newly-emerged crisis: they all have day-jobs and it would take some time to configure and ready them for deployment.[258] A surprisingly large number of other federal agencies also have teams of emergency responders to deploy to a crisis and offer subject matter expertise. See, for example, the Environmental Protection Agency, with its 13 regional response teams, and the Department of Energy's emergency response teams. [259]

It is possible, of course, particularly in a catastrophic event, that the public safety officials in a community would not be available because they were injured in the disaster or were otherwise rendered unable to function. Some of this effect could be seen in Hurricane Katrina, where the communications and even the operational effectiveness of the police and public safety personnel were knocked out in New Orleans because of a combination of the force of the storm and poor decisions about whether and where to shelter in place. The sheer complexity of the incident, with the scale of the population that needed to be sheltered in place, also overwhelmed the capacity of the denuded local and state response capabilities.

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[258] Centers for Disease Control and Prevention, US Department of Health and Human Services, Public Health Service, "About Us," PHS website (http://www.usphs.gov/aboutus/questions.aspx#whatis accessed 07/10/2008).
[259] Environmental Protection Agency, 13 Regional Response Teams, EPA website (http://www.wpa.gov/superfund/programs/er/nrs/nrsrrt.htm assessed 07/10/2008) ; US Department of Energy, Emergency Response Teams, DoE website (http://doe.gov accessed 07/10/2008).

A good, but very rough estimate would be that the inherent emergency response force in a community would need to be duplicated. There are many variables and certainly a wide range of plausible estimates. This rough estimate is derived by assuming that most of the public safety force will be needed to perform public safety functions in a city under the extreme stress of an attack. Additional personnel would be needed for a variety of functions and again their ultimate number would vary widely, including countermeasure distribution, food and water resupply, and medical supportive care.

As will be discussed in more detail, there are three broad modes for distributing countermeasures (1) classic Points of Dispensing or PODs; (2) postal or in-home delivery; and (3) home kits. The issue of how medical countermeasures would be provided to such a large number of individuals on these short timelines will require a section in its own right. For the argument's purposes here, it is sufficient to observe that almost every theory that has been put forward would require that a significant number of additional personnel arrive in the affected region very quickly to provide medical services.[260]

Although these assumptions are highly scenario-dependent, it seems likely that the stress of an emerging pandemic would put significant pressure on local law enforcement and hence only small numbers, if any, of these personnel would be available to help with countermeasure

[260] The time requirements for the arrival of additional personnel would be less demanding in a scenario where "med-kits" containing antibiotics had been pre-distributed to the general population with the understanding that they would only be opened upon the direction of national health officials in the event of a biological attack. Even if "med-kits" were used, there would still be a requirement for PODs to open a few days later to provide follow-on medication. Antibiotics would only work for anthrax and some other contagious diseases, like many strains of plague. Smallpox, which requires a vaccine, could not be treated through a self-administered "medkit," CDC has conducted some pilot programs to assess the viability of "med-kits." HHS is conducting further feasibility studies on medkits and, pending the findings of these studies, no decision about whether to pursue "med-kits" is expected until at least 2010. Centers for Disease Control and Prevention, Coordinating Office for Terrorism Preparedness and Emergency Response, *CDC's Division of Strategic National Stockpile Emergency MedKit Evaluation Study Summary: Background, Key Results, and Next Steps*, As of November 15, 2007, CDC website (http://emergency.cdc.gov/agent/anthrax/prep/pdf_medkit_evaluation_2007.pdf accessed 07/10/2008).

distribution or the provision of other needed medical services. While the estimates vary widely, one could guess on a rough order of magnitude that an additional force on the order of the extant (but already busy) emergency response personnel would be needed, or about 100 public safety and health personnel per 10,000.

Surrounding jurisdictions might be loath to share their law enforcement personnel, the traditional source of additional personnel in a crisis. Unlike a hurricane, smallpox or plague is contagious and so surrounding communities would be understandably concerned about the vulnerability of their own population.

Managing across the organizational seams necessary to acquire and then use the needed response force would be complicated and an unusual skill set for anyone. The scale of a catastrophic biological attack hence would be vastly greater than all but a handful of disasters confronted by the US in its history – both in terms of the size of the injured and dying population and the size and disparate organizational sources of the needed responders.

*Speed*

Speed also acts differently in a big disaster as opposed to a small disaster. Certainly, time is of the essence in many public safety actions – getting a fire truck to the scene of a big fire, sending an ambulance to a traffic accident, or dispatching a police officer to the scene of a crime. These are issues of time-sensitive prioritization: how many assets to send, or which call to answer first. How well these time-sensitive decisions are made affects the life or death of many individuals, but again, one at a time or a small group at a time. These are the hundreds of small decisions that add up to policing well or badly done in a community and to lives lost or saved.

For the big disasters, there tend to be one or two time-sensitive decisions early on that have a big impact on overall fatality rates. For Hurricane Katrina in 2005, the early decision was whether to order an evacuation early enough that it could be meaningfully implemented and then whether to facilitate that implementation through providing transportation for those who could not provide it for themselves.[261] Public officials in low-lying cities like New Orleans or Galveston should be much quicker to order evacuations because most hurricane-related fatalities occur in the post-storm surge of 10 feet or more.

With the greatly enhanced technical ability to predict hurricanes and hence order the evacuation of threatened areas, hopefully the death tolls of the 1900 Galveston hurricane (8,000 dead) and the 1928 Southwest Florida hurricane (2,500) will never be approached, even as the size of the population at risk from hurricanes increases. Fully 90 percent of deaths from hurricanes come from drowning in a subsequent storm surge of 10 feet or more.[262] Once it becomes too late to evacuate, there are few effective strategies to avoid the storm surge, as was illustrated in the aftermath of Katrina. For tornados and lightning, warnings and advice from local officials can greatly improve the quality of individual decisions, but it is the small group decisions – to leave a car or mobile home, to go into the basement -- that make all the difference.

The greatest needs for help by a local community before most severe weather incidents are for tactical warning – a function the National Weather Service generally performs well and is

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[261] US House of Representatives, Select Bipartisan Committee to Investigate the Preparation for and Response to Hurricane Katrina, Tom Davis, Chairman, *A Failure of Initiative: The Final Report,* February 15, 2006. US House of Representatives website (Accessed 07/22/2008), page 2, "The failure of complete evacuations led to preventable deaths, great suffering, and further delays in relief; Evacuations of general populations went relatively well in all three states; Despite adequate warning 56 hours before landfall, Governor Blanco and Mayor Nagin delayed ordering a mandatory evacuation in New Orleans until 19 hours before landfall; The failure to order timely mandatory evacuations, Mayor Nagin's decision to shelter but not evacuate the remaining population, and decisions of individuals led to an incomplete evacuation; The incomplete pre-landfall evacuation led to deaths, thousands of dangerous rescues, and horrible conditions for those who remained."

[262] See discussion of this in Perry, *Significant Floods in the United States,* page 5; and Blake, et al., *The Deadliest, Costliest, and Most Intense United States Hurricanes.*

seeking to improve further. The greatest need for federal help tends to be after an event, when the time-pressure is somewhat eased. Critical decisions can remain time sensitive, of course, like moving swiftly to impose a curfew or a security cordon to reduce looting in damaged areas. But most of these post-event decisions have to do with minimizing the extent of property damage, not reducing fatalities.

As will be discussed later, in a catastrophic biological attack, there will be a small number of decisions that need to be made very early in the attack, probably based on highly imperfect information. The caliber of these few, early decisions will have an enormous effect on the number of deaths from the attack. For example, the timeline on which exposed individuals would need to get medical countermeasures vary pathogen to pathogen but are in all cases very demanding. Individuals, for example, should start receiving antibiotics within 48-96 hours of showing symptoms of anthrax poisoning. The "gold standard" lab tests to confirm the disease generally take somewhat longer to complete. Waiting too long to move the national stock of antibiotics could render its effect meaningless, because its arrival would be too late to help most infected individuals.

Speed would be different because not only does a decision need to be taken, but a large response needs to be implemented by the government, not self-implemented as would be the case with most of the response to an evacuation order. The decision to order an evacuation of low-lying areas in the face of a strong hurricane is an important one, with life and death consequences. But generally the hurricane has been threatening the city for at least several days. Once the local or state officials order an evacuation, most members of the population implement the decision themselves – driving to higher ground in their own vehicles. Local and state officials must provide transportation for special needs populations, as Hurricane Katrina

demonstrated. But the evacuation of the special needs population generally is within the capacity of the traditional homeland security strategy if state and local governments have done their planning in advance and execute those plans competently. The overwhelming demands – the ones well beyond the inherent capacity of the state and local governments – come after a hurricane has hit. If it is a bad hit and either an evacuation was not ordered or significant numbers of citizens did not or could not abide by that evacuation order, there would be immediate requirements for search and rescue, and provisioning and shelter. In any case, there will be requirements for help with clean-up and ultimately rebuilding of the affected community.

In contrast, in a biological event, the decision would need to be taken and response measures fully implemented for the entire population before the biological equivalent of the hurricane hitting. The "biological equivalent" would be the point where the administration of medical countermeasures could contain the incident and limit deaths. While the length of this period varies significantly pathogen to pathogen, it is often about 48-96 hours.

*Technical Complexity*

An effective response to a catastrophic biological threat also would be more complex than traditional defense of the homeland. These elements of technical complexity are basically the reasons why this paper argues that the president should be the official vested with responsibility to make the needed strategic decisions. First, the technical expertise needed to support such decisions would be complex to build, maintain and use and probably could not be constructed at each state or local level. It seems implausible that the needed subject matter expertise either could or should be cultivated and actively sustained separately in every state or locality. There are a variety of models that could be adopted, but the federal government needs to

cultivate a cadre of individuals who have been trained, perhaps as an adjunct to other duties, to think about and manage a catastrophic biological attack in the United States.[263] Building an infrastructure able to acquire these technical variables and meld them into usable decisions has not yet been constructed but its complexity augers for it only being plausible to construct and maintain at the national level.

Second, the specialized assets and capabilities needed to respond would be expensive and complex and hence probably could only be constructed and sustained at the national level. In an attack using a standard pathogen, the Federal Strategic National Stockpile (SNS), with its contents including smallpox vaccine and antibiotics, would be critical. The federal government has spent about $500 million dollars annually since FY2001 on medical countermeasures to build up the SNS.[264] In an attack using an unusual pathogen, federal assets probably would be critical to develop and produce targeted countermeasure.

Third, these assets and capabilities would be quantity constrained and thus difficult allocation decisions would have to be made among different communities during all but the smallest attacks. Unlike a hurricane or tornado, smallpox is contagious. How the local community chooses to manage the event could affect the risk posed to other communities. Similarly, if scarce medical assets are being used, there could be some difficult allocation decisions. Formal efforts by the government to prioritize the allocation of medical countermeasures in advance of a crisis have been highly contentious and have generally ended up with a remarkable emphasis on the need to keep government functioning (and hence the high

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[263] Creation and exercising of one possible model for such teams in discussed in Danzig, "Catastrophic Bioterrorism – What is to be Done?"

[264] France and Deitch, "Billions for Biodefense: Federal Agency *B*iodefense Funding, FY2007-FY2008," See Table 2: Annual expenditures for the National Strategic Stockpile are more than $7 billion from FY2001 through FY2008. Annual stockpile expenditures now average a half billion dollars. Annual expenditures prior to FY2001 were less than $100 million.

relative priority of government officials at all levels to receive vaccine, as opposed to members of the general public). Whether these prioritization lists would be observed in an actual crisis is a separate question.

Should smallpox be released, for example, the government would have to make difficult decisions about where to allocate the various vaccines. The government has more than enough vaccine for all people in the United States. The older, traditional vaccine (which is possessed in greatest quantity) causes significantly more adverse reactions, including about one death per million vaccinations.[265] Allocating the vaccine, and particularly allocating the newer vaccine with its significantly lower risk and smaller stockpile, would be a difficult and controversial decision in a crisis.

Fourth, a catastrophic biological attack would be "policy by other means" and hence the diplomatic or military response would have to be integrated with the overall foreign policy of the United States government. The prospect of "reattack" or "reload" and the possible bargaining associated with that threat would need to be considered.[266] Deterrence of reattacks would be strengthened through the swiftest condemnation of the attacks by the international community, including not only rhetoric but diplomatic blessing for the United States to track down the culprits and clearly limit the political gains to the attacker. Foreign policy traditionally has been the province of the federal branch of government.

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[265] Centers for Disease Control and Prevention, Emergency Preparedness and Response, Smallpox Fact Sheet, "Side Effects of Smallpox Vaccination, CDC website (http://www.bt.cdc.gov/agent/smallpox/vaccination accessed 02/21/2009); Joanne Cono, M.D., Christine G. Casey, M.D., David M. Bell, M.D., "Smallpox Vaccination and Adverse reactions: Guidance for Clinicians," *Mortality and Morbidity Weekly Report: Recommendations and Reports,* February 21, 2003/52(RR04); 1-28. Centers for Disease Control and Prevention website (http://www.cdc.gov/mmwr/preview/mmwrhtml accessed 02/21/2009.

[266] "Policy by other means" is from the famous Clausewitz quote that "war is policy by other means. "Reload" is a term coined by Richard Danzig.

*Conclusion*

Traditional defense of the US homeland, with its reliance on local and state public safety and health officials, has, by and large, worked well. The federal government has clear responsibility to lead in two types of threats to the homeland: in responding to an invasion by a foreign military and to the risk posed by spies, saboteurs and terrorists. A catastrophic biological attack would overwhelm traditional defense methods because of its vastly greater demands in terms of scale, speed and technical complexity.

## Defense: Chapter 8

### Responsibility for Strategy, Tactics and Logistics

Traditional methods of responding to a homeland security event would be overwhelmed by the vastly greater speed, scale and technical complexity of a catastrophic biological event. The reality that traditional approaches would be overwhelmed creates two problems: (1) additional capabilities are needed to respond effectively to these larger, catastrophic attacks, and (2) there is significant ambiguity in the US federal system about who would be responsible for handling the response to these larger, catastrophic events. This ambiguity complicates both the development of these needed additional capabilities and their effective use in an actual crisis.

Refinements would require strengthening strategic, tactical and logistical capabilities to respond to a larger, catastrophic attack. An effective response to a catastrophic biological attack would require that complex and highly-contested strategic decisions be made and made quickly. There does not appear to be explicit recognition that these decisions would need to be made, appropriate analytical means to support them, or explicit authority or agreement on who should make them. This situation creates significant risk that in a catastrophic biological attack needed strategic decisions would not be made swiftly enough to be implemented. Traditional defense of the homeland usually does not require any official to make strategic decisions. The public safety objective is generally unstated but straightforward – most often to maximize lives saved and minimize property damage. This dissertation urges that the president explicitly have responsibility for strategic decisions in a biological event and that an appropriate set of analytical tools and authorities be developed to support him.

State and local emergency response is usually effective at the tactical and logistical elements of a response. This dissertation urges the development of "modular" federal capabilities that can appropriately supplement state and local capabilities in a catastrophic event in the homeland. A variety of leadership models, consistent with US federal values, could work and should be evaluated. The capabilities are described as "modular" because they would not constitute a stand-alone, unique response structure for catastrophic events, but rather would be additional types or increments of capability to supplement existing capabilities as needed. The needed capabilities for these new "modular" pieces and how they would work with existing state and local assets has not been articulated, much less agreed or implemented between local, state and federal officials. There do not appear to be authorities, agreements or expectations that allow either the president or the governor to take leadership of an integrated set of federal, state and local assets such as would be needed to respond effectively to a catastrophic event.

Thus, this dissertation makes two specific recommendations: (1) the president should explicitly have responsibility for making the needed strategic decisions to shape the response to a biological event and decision aids should be constructed to assist him; and (2) additional "modular" federal capabilities should be created to supplement state and local capabilities in a catastrophic crisis and a clear and agreed leadership structure should be created to assure their effective use in a crisis, consistent with US federal values.

This chapter has three objectives: to demonstrate (1) that for a larger, catastrophic homeland security event there is significant ambiguity about who would be in charge. This is demonstrated through reference to authorities, perceptions and the relevant literature; (2) that strategic decision-making would be a new challenge in a larger, catastrophic event and that the president should be vested with the responsibility for strategic decision-making in a biological

event; and (3) that federal "modular" capabilities should be developed to work effectively with extant state and local capabilities and an effective command and control structure should be developed and agreed.

*(1) Ambiguity of Responsibility for Catastrophic Threats*

Essentially all emergency response officials agree that a routine traffic accident should be handled by the local police and an all-out conventional invasion should be handled by the Department of Defense. Most everything in between is marked by a remarkable tangle of conflicting authorities, responsibilities and perceptions.[267]

The avowed, reigning philosophy is that the local level of government would play the leadership role in responding to a crisis in its community, informally drawing on counterparts and other assets, until the city judges that its capabilities have been overwhelmed. The local government would then seek assistance from the state, which would add additional assets and assess the severity of the incident. Based on these assessments, the governor could seek additional assistance, through more formally drawing on mutual assistance pacts with surrounding jurisdictions, activating the National Guard in its state role, and seeking federal assistance through a variety of venues, including a Presidential disaster declaration. Such a disaster declaration would free up federal funding to reimburse state and local crisis response expenses and help communities and individuals with rebuilding after the crisis has passed.[268]

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[267] There is a nice summary of US emergency preparedness and response activities in Richard A. Falkenrath, "Problems of Preparedness: US Readiness for a Domestic Terrorist Attack," *International Security,* Vol 25, No 4 (Spring 2001), pp. 147-186: Published in 2001, the summary does not reflect the implications of the creation of the Department of Homeland Security. It notes, page 185) consistent with the argument here, that "„there is great uncertainty about how an actual response to a WMD incident will or should unfold."

[268] A Presidential Disaster Declaration frees up funding under the Robert T. Stafford Disaster Relief and Emergency Assistance Act to assist individuals and the state and local government to pay for disaster-related expenses. Federal

In practice, the process is marked by much more simultaneity. State and federal officials would be monitoring predictions of a natural disaster or early reports of an accident or epidemic, calling local counterparts, and offering help or suggesting response measures. For a disaster with the potential to be significant, federal or state officials might be prepositioning assets in the area, informing the local and state emergency operations center of their actions. Non-governmental organizations, which play a critical role particularly in providing temporary shelter and other assistance to evacuees, also probably would be prepositioning assets if the crisis looked like it might be significant. In general, this process works well.

Traditional defense of the homeland generally is handled entirely by the relevant public safety organization (the local fire department or police department). Teams from other organizations or jurisdictions may informally help, in their established areas of expertise. For larger responses, a system called the Incident Command System is used. The Incident Commander is the first on the scene commander and this individual remains the commander until a superior official arrives on the scene and takes command. The ICS system strives to assure unified command, common terminology and integrated communications. Units contributing to an incident response tend to be modular: a fire unit from a neighboring city supports the fire chief and his units in extinguishing a particularly large blaze. The tasks assigned to the units are familiar, as are the procedures that enable them to work together effectively.

Three qualities make this hybrid system generally work well. First, there generally is no ambiguity about the strategic objective. It is most often unstated but generally is to maximize lives saved and minimize property damage. The second quality is that the leader is often obvious

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Emergency Management Agency, "Robert T. Stafford Disaster relief and Emergency Assistance Act (Public Law 93-288) as amended, FEMA website (http://www.fema.gov/about/stafact.shtm accessed 02/21/2009).

and has credibility with the teams. It is often a senior official in the local police or fire department. Third, the teams are modular (a fire unit is added, not a fireman). The teams implementing the tactical and logistical aspects of the response generally have worked together or at least are constructed of modular units performing well-understood and well-practiced roles.[269]

These qualities would not be present in a catastrophic biological attack. First, the strategic objectives would not be relatively obvious and widely-shared. A catastrophic biological attack would pose a new, time-sensitive requirement for highly contested strategic decisions to shape the response. The ICS system has no background of making these types of decisions, probably no expectation or recognition that they would need to be made, and no adequate technical support. Second, the scale of the needed response would be much greater and would require the use of units whose skill sets and approaches are not well-understood by each other and that are not used to working together. Third, there is significant ambiguity about who would be responsible for responding to a catastrophic biological attack. Some practitioners profess that there is no ambiguity: they personally are certain how a response would unfold. The problem is that other relevant actors do not share the same expectation. The controlling documents and broader elite discussion reveals starkly different views on the question of how a response would be managed.

In marked contrast to clear delineations of federal authority to deal with, for example, the threat from spies, saboteurs and terrorists, there is no clear controlling legislation that clarifies

[269] The ICS systems emerged formally in the 1970s in California. See California's Standardized Emergency Management System (SEMS), codified at Section 8607(a) of the California Government Code. See also 29 CFR Part 1910.120 for the federal requirement to use ICS for state and local emergency response if the organizational entity receives federal funding. See also US Department of Homeland Security, National Incident Management System, March 1, 2004, DHS website (http://www.dhs.gov.xlibrary/assets/NIMS-90-web.pdf accessed 02/21/2009), page 7.

the responsibility of federal emergency responders as opposed to state or local officials. There are relevant constitutional and legislative issues aplenty and many learned discussions of their net implications.[270] The actual balance of power in a crisis would be hard to predict in advance because the situation is genuinely unprecedented and probably would be shaped by more than legal calculations. In a catastrophic biological attack, no one actor – local, state or federal – is likely to have sufficient assets to mount an effective response. Hence, whoever leads will need to invest significant time and energy into assuring that other key actors are following.

*Federal Perspective*

The White House Homeland Security Strategy issued in 2007 explains that responsibility for homeland security is "shared" among federal, state and local governments and private citizens and the private sector. There is even sharing among federal departments, with ambiguity about the relative roles of the Departments of Homeland Security and Health and Human Services, for example. While DHS possesses the federal expertise on disaster response (principally in its component organizations of FEMA and the Coast Guard), HHS possesses the

[270] Several of the blue-ribbon commission reports discussed previously warn, either implicitly or explicitly, that the legal authorities for a response to a catastrophic attack in the homeland are confusing or absent and should be reviewed systematically and revised appropriately. See the Bremer Commission report; the Gilmore Commission report; the Hart-Rudman Commission report; the CSIS report. The first set of issues are constitutional and appear to cut both ways, with the relative implications of the Tenth amendment to the Constitution which reserves unenumerated rights to the states, and the fourth article of the Constitution where the United States shall protect each state "against invasion." Federal legal authority to act can be increased by a presidential declaration of a disaster under the Stafford Act but such declarations can only be made at the request of a governor, except in unusual circumstances. Such declarations generally are sought not because of the additional federal authorities they activate but because they open access for the state and its citizens to additional sources of federal funding. For example, the Secretary of HHS has authority to enforce quarantine or isolation at the international borders of the US or at the borders between states. He has no evident authority to enforce quarantine within a state, unless it was tied somehow to his broader authorities to save lives available to him under a Presidential disaster declaration. Federal involvement is further complicated by the issue of the Posse Comitatus law covering the use of active duty military forces and National Guard forces when operating under the command of the President. The Posse Comitatus law prohibits the use of these federal forces for law enforcement uses in the homeland. The President can avoid these restrictions by invoking the insurrection act. The Navy and Marine Corp are not covered by the Posse Comitatus act, but the norm behind the act would complicate their use and their inherent capabilities would be less well-suited to being used in most homeland contingencies. There is a cut-out permitting the use of the military for law enforcement purposes in a catastrophic biological event.

subject matter expertise to deal with a public health crisis, including one caused by human intent. The National Strategy for Homeland Security, issued by the White House on October 5, 2007, is quite explicit:

> Throughout the evolution of our homeland security paradigm, one feature most essential to our success has endured: the notion that homeland security is a shared responsibility built upon a foundation of partnerships. Federal, State, local, and Tribal governments, the private and non-profit sectors, communities, and individual citizens all share common goals and responsibilities – as well as accountability – for protecting and defending the Homeland."[271]

While all of these actors doubtless share the goal of being non-dead at the end of any particular terrorist or homeland security event, it is somewhat remarkable to imagine they would completely share all other goals, responsibilities and, especially when things go bad, accountability.

One is somewhat unhappily reminded of the experience during the week after Hurricane Katrina. The Hurricane hit the Gulf Coast of the United States on August 29, 2005. The Hurricane devastated 90,000 square miles and caused the deaths of almost 1,000 people.[272] The collective national memory recalls the devastation of the initial hurricane and storm surge, and then the slow flooding of New Orleans as the levees, holding water back on three sides from a city that largely lies below sea-level, slowly gave way and the water flooded the low-lying portions of the city. Late in the week after the initial hurricane hit, the President, the governor of Louisiana and the mayor of New Orleans reportedly discussed the issue of "sharing" goals, responsibilities and accountability in a meeting on Air Force One. The "sharing" in that meeting

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[271] The White House, National Strategy for Homeland Security, October 5, 2007, White House website (http://www.whitehouse.gov/infocus/homeland/nshs/2007 accessed 07/24/2008)

[272] Douglas Brinkley, *The Great Deluge: Hurricane Katrina, New Orleans, and the Mississippi Gulf Coast* (New York: Harper Perennial, 2006), page xx.

was apparently sufficiently hostile that one observer described it as "as blunt as you can get without the Secret Service intervening."[273]

The National Response Framework (NRF), the DHS-issued and White House approved document that putatively clarifies these matters, contains basically a carefully-crafted delineation of this problem. The document was developed in consultation with state and local emergency responders but was strongly criticized by many state and local when it was formally issued.[274] The NRF affirms that both mayors and governors are responsible for the welfare of the individuals who live in their respective (and overlapping) jurisdictions. It acknowledges that most crises should be handled at the lowest jurisdictional level possible and that local or state officials should assess when their assets would be overwhelmed and need to be supplemented by Federal assets. It appears to claim little if any independent role for the federal government in assessing when a state or local government may become overwhelmed, nor delimit any technique by which disagreements might be adjudicated in a crisis situation. Disputes among federal agencies can be resolved by the President, but the document acknowledges that states are "sovereign entities" and governors have responsibility for their citizens' public safety and welfare.[275]

The National Response Framework, issued in early 2008, notes that the federal government reserves the right to undertake a proactive response to a catastrophic incident. These

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[273] Quoted in Brinkley, page 521.

[274] See for example, Michael D. Selves, "National Response Framework Unveiled Amid Heavy Criticism," National Association of Counties, NACO website (http://www.naco.org/Template accessed 02/21/2009). "Overall, the NRF has engendered significant criticism from stakeholder groups, academics, Congress, the media, and state and local officials. Perhaps the most compelling indictment came in a Sept. 13 editorial by the *New York Times*, which stated that "the homeland security policy – the already overdue 'national response framework' – amounts to a failing paper. It not only ignores Congress's vital mandate, but it breezes past a range of valuable state and local disaster managers and first responders."

[275] Department of Homeland Security, National Response Framework, January 2008, DHS website, http://www.dhs.gov).

proactive deployments would be for cases where it can easily be anticipated that state and local governments would be overwhelmed by the crisis.[276] The DHS "Catastrophic Incident" Annex has conceptual strengths.[277] It does not, though, appear to have any authority or even conceptual support from anyone other than its authors in DHS. The document's incomplete implementation is demonstrated rather conclusively by the reality that the annex was issued in December 2004 but had no discernable effect on the response to Hurricane Katrina in August 2005. Arguably in that case the point where a more aggressive federal role could have saved the most lives – the evacuation period – passed without the federal government apparently realizing that the window was closing for a successful evacuation. Any struggle over jurisdiction for the search and rescue phase was too late to limit deaths significantly however the fight was ultimately resolved.

*State and Local Perspective*

Governors apparently are less of a mind to "share" goals, responsibilities and accountability when the issue under consideration is a disaster of some sort in their state. For example, a "Governor's Guide to Homeland Security" prepared by the National Governors' Association is vastly more blunt than the White House's National Strategy: "As the chief executive of their states, governors are responsible for overseeing the state's response to any emergency or disaster."[278] The federal role is limited, in the worldview captured by this NGA document, to receiving specific requests from the state and responding to them, and writing checks to compensate the state for expenses it absorbed in responding to what eventually

[276] National Response Framework, January 2008, page 42; and the Catastrophic Incident Annex, December 2004. The Catastrophic Annex had not been widely vetted by the time of Hurricane Katrina. Some argue that the document is not flawed, only the training was flawed and that could be fixed for the next catastrophic event in the homeland.

[277] The Congressional Report on Hurricane Katrina, *A Failure of Initiative*, notes that the Catastrophic Annex was not activated by DHS during the response to Hurricane Katrina but expresses the view that it probably would not have helped if it had been activated.

[278] NGA Center for Best Practices, A Governor's Guide to Homeland Security, http://www.nga.org/portal/site/nga accessed 3/24/08.

becomes a federally-declared disaster. As DHS acknowledges, states are sovereign entities in the US federal system of government.[279]

Mayors, local emergency managers and police chiefs also seem to believe that they are responsible for the welfare of their citizens at all times, including during a catastrophic event in their city. Most cities publish on their websites the view that they develop the plans for all types of emergencies in their cities, manmade or natural. They underscore that they coordinate with the full panoply of counterpart organizations, at all levels of government.[280] The International Association of Police Chiefs underscored in a post-9/11 report that "Local, not federal, authorities have primary responsibility for preventing, responding to, and recovering from terrorist attacks.....Because of their day-to-day work, state and local law enforcement officers are uniquely situated to identify, investigate, and apprehend suspected terrorists." The Police Chief's report made a useful distinction between "national" and "federal" planning, calling for all levels of government to participate in planning homeland security strategies "as full and equal partners" in contrast, it said, to the federal government's tendency to include them only on advisory panels with little actual impact on policy.[281]

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[279]Department of Homeland Security, National Response Framework.

[280] District of Columbia, Homeland Security and Emergency Management Agency, About HSEMA, DC website (http://hsema.dc.gov/dcema/cwp/view,a,3,q,531996,dcemaNav_GID,1531,dcemaNAV, %7C.... accessed 7/18/2008) Just as one example, the Washington DC Homeland Security and Emergency Management Agency explains its role as "developing plans and procedures to ensure emergency response and recovery capabilities for all emergencies and disasters....In carrying out its mission the agency works closely with other emergency response agencies, including the Metropolitan Police Department, the District of Columbia Department of Fire and Emergency Medical services, the District of Columbia Department of Health and other District and federal agencies, as well as with the major utility companies and non-profit and volunteer organizations such as the Red Cross and the Salvation Army."

[281]IACP, State and Provincial, page 11-12. "During disasters, the process for acquiring federal assistance begins with the recognition by local authorities that they need the states to assist them with an occurring disaster. The state will respond with resources and conduct damage assessments....Once assessments are completed, the governor decides whether to pursue a request for a presidential disaster declaration." Page 32. IACP, *The Role of State and Provincial Law Enforcement Agencies in a Post 9/11 Era.*

*Public Health Officials*

Much as there is significant ambiguity about the relative roles of the local, state and federal emergency response officials, there is significant ambiguity among local, state and federal public health officials. In a biological attack, it would be critical to swiftly administer a medical countermeasure or otherwise implement public health measures. It is not clear who could direct such action.[282] Current plans assume that there would be consensus in terms of what actions should be taken among public health officials at all levels of government. Local public health officials (which are 56% of state and local public health officials) work for the mayor, while state public health officials work for the governor.

The federal Centers for Disease Control and Prevention (CDC) based in Atlanta is a highly respected repository of public health expertise. It does not have, in either perception or law, a command and control relationship with state and local public health departments.[283] The views of the CDC would carry important weight about the appropriate nature of a response to a national health crisis but those views would not necessarily dominate the public health debate. Indeed, the federal government has directed that state, country and local health authorities should develop plans that they could implement to provide mass prophylaxis to their civilian

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[282] See, for example, Thomas B. Cole, MD, MPH, "When a Bioweapon Strikes, Who Will Be in Charge?" JAMA. 2000; 284(8): 944-948 (doi:10.1001/jama.284.8.944) www.jama.com accessed on 10/9/2008. From Cole, page 944: "Unfortunately, said Lawrence O. Gostin, JD, LLD, of the Georgetown University Law Center, in a recent interview, the authority for carrying out these recommendations [for vaccination, treatment, isolation, and hospital infection control after a biological attack] is not clear. Until recently, said Gostin, lawmakers never examined the legal authority for a response to bioterrorism. When the authors of the US Constitution were reserving public health powers to the states, all epidemics were local. Today, he said, 'laws are so antiquated and unclear that no one even knows what our powers and duties are.'"

[283] Cole, "When a Bioweapon Strikes, Who Will Be in Charge? see page 947: The CDC has organized a collaboration of "public health practitioners, researchers, legal advisors, and policymakers. The impetus for this, said Goodman, was the CDC's awareness that existing legal authority may be insufficient to respond to an emergency resulting from terrorist use of biological and chemical weapons."

populations in a crisis. The federal government's role in this planning is limited, even in the federal government's perception, to providing financial and technical support.[284]

The public health community in the United States is a loose collection of individuals whose opinion leaders include the Director of the CDC and some of her top staff, the US Surgeon General, and some senior officials at the National Institutes of Health. Public health opinion leaders also would include highly regarded state public health directors, leaders of professional associations like the Association of State and Territorial Health Officials (ASTHO), and highly-regarded physicians and scientists at universities and in various research labs. Which individual emerged as the most influential spokesperson would depend on several factors, including the personal credibility of the individual with the broader public health community. During the anthrax attacks in the fall of 2001, the government officials, including the government physicians, were important voices but hardly dominated the public discussion.

*Public Health Authorities*

The Department of Health and Human Services has some authority but these authorities have significant limits and overlaps with the authority of states.[285] How a crisis would actually play out is hard to anticipate because HHS has some grounds for shaping the response but not clear or uncontested authority to do so. It also does not, under any scenario, have directive power over the medical decisions of state and local public health officials. Indeed, the federal

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[284] Nathaniel Hupert, M.D., M.P.H., et al., "Community-Based Mass Prophylaxis: A Planning Guide for Public Health Preparedness, Bioterrorism and Other Public Health Emergencies: Tool and Models for Planning and Preparedness, Prepared for: Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, AHRQ Pub No. 04-0044, August 2004. Contract No. 290-02-0013-3. Prepared by Weill Medical College of Cornell University, Department of Public Health, see page vi.

[285] See the discussion of these issues from a decidedly federal perspective in the Bremer Commission Report, page 37-38. It notes the lack of federal authority to order vaccinations, to conduct autopsies or to impose quarantine within a state.

pandemic plan makes clear that the expected norm is for local leadership on many critical public health decisions during a crisis.[286]

This is a conceptually sound strategy when dealing with a naturally occurring epidemic. The spread of such epidemics tends to be marked by waves as the epidemic moves through communities, not hitting all communities at the same time or with the same intensity. The waves for the 1918-1919 influenza pandemic were spaced by about six weeks, meaning that new communities were affected by the epidemic at intervals spaced by about six weeks. It makes sense that the most useful tools for managing that epidemic – including hand-washing and isolation -- should be locally implemented depending on when the epidemic is proceeding in a particular community. Each individual with an infectious disease passes the disease to a small number of individuals with whom they have close contact. The mechanism varies but often is through coughing and sneezing (influenza) or through vectors like mosquitoes (yellow fever and malaria). The number of people infected in the next generation of illness varies significantly but is larger. For example, each smallpox patient infects on average about one to three people. Individuals move through the cycle of infection, symptoms, onset of complications, and death or recovery at different rates because their initial infection was at different times. The "index" cases or initial cases which inform the clinical diagnosis often have the worst clinical outcome overall, but the insights from their diagnosis and treatment often enable improved care for subsequent generations of patients.

The significant difference with a catastrophic biological attack is that at least 10,000 individuals would have received a lethal dose at about the same time. While there would be some individual variation, this large group of infected individuals would basically move through

[286]HHS, "The National Plan for Pandemic Influenza."

the disease presentation cycle together. As horrible as historic epidemics have been, a catastrophic biological attack would unfold much more quickly, benefiting much less from local decisions on when it was best to close the local schools, and more from the swift decision and ability to medicate appropriately.

HHS does not have significant directive authority over state and local public health officials. Its authorities relevant to immediately responding to a biological attack could be crudely sorted into four baskets: imposing isolation or quarantine at international or interstate borders; and, after the HHS Secretary declares a public health emergency, conducting and supporting investigations into the cause, treatment, or prevention of the specific disease or disorder; activating (but not evidently deploying) public health surge teams, including particularly the US Health Service Commissioned Corp and the National Disaster Medical System; and spending money, including through grants to state and local agencies.

To illustrate some of the problems, one can examine the HHS secretary's authority to order isolation or quarantine. The president by executive order can add a disease to the list of diseases for which federal isolation and quarantine are authorized. States, as part of their inherent police powers, can enforce isolation and quarantine within their states. The HHS Secretary by statute has responsibility to prevent communicable diseases from coming into the United States from foreign countries and from moving from one state into another. He does not appear to have authority to impose isolation or quarantine within a state, unless such imposition could be tied to his broader responsibilities for interstate or international transmission of the disease or his assistance is requested by the state or local governments. There could be cases where both state and federal authorities applied to a single event – like an aircraft from abroad

landing in the United States.[287] HHS has broad authorities to distribute food, medicine and supplies and to provide services to save lives, but these authorities only come into play in a situation the president has declared to be a major disaster. Except for a small set of cases, these declarations can only be issued at the request of the governor.[288]

CDC does have authority if it makes a ruling that the measures taken by any state are ineffective to prevent the spread of a communicable disease to another state. This authority, though, has never been invoked. If invoked, it would give the CDC the right to intervene, but the reality would remain that the national government does not readily have the assets – in terms of personnel or physical assets – to effectively act in any but a small situation. CDC would need to invoke this authority, but then effectively build a coalition to lead the local, state and private sector public health assets to formulate and then implement a more effective response.

HHS has three authorities that probably would not help particularly in the crisis period, but could be useful over the mid or long-term. First, the Congress has given CDC responsibility for defining and managing access to "select agents" that could be used as biological agents.[289] Second, CDC is able to link the provision of federal funds to state and local public health departments to certain policy goals. A significant amount of funding in recent years has been tied to construction of state and local plans to respond to a catastrophic biological attack. The

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[287] The diseases currently listed in the Executive Order are cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers and severe acute respiratory syndrome. Centers for Disease Control and Prevention. Department of Health and Human Services. Fact Sheet, "Legal Authorities for Isolation/Quarantine." CDC Website (http://www.cdc.gov/ncidod/sars/factsheetlegal.htm accessed 7/22/20008).
[288]Centers for Disease Control and Prevention. Department of Health and Human Services. Fact Sheet, "Legal Authority for Implementation of a Federal Public health and Medical Services Response," HHS website (http://www.hhh.gov/disasters/discussion/planners/legalauthority.html accessed 7/23/08)
[289] In 1996, the Congress "established the framework for a comprehensive regulatory regime to control the domestic use of hazardous toxins and infectious agents, Under this regime, the centers for Disease Control and Prevention (CDC) regulate the transfer and use of more than thirty toxins, bacteria and viruses posing significant risks to public health and safety." James R. Ferguson, "Biological Weapons and US Law," in Joshua Lederberg, *Biological Weapons: Limiting the Threat* (Cambridge, MA: The MIT Press, 2001), page 82. The Legislation is the Anti-Terrorism and Effective Death Penalty Act of 1996, Public Law 104-132, April 24, 1996.

effectiveness of the resulting plans, though, has been questioned. CDC's ability to vet, validate and exercise these plans is highly contested.[290] Third, CDC does serve as a "bully pulpit" for public health issues. It sets standards of care. This is illustrated by the many panels it convenes to set standards, like the Advisory Committee on Immunization Policy that sets policy on vaccination for the general population. While CDC does not have authority to require these vaccinations, they generally are adopted by school districts and other governmental entities as the standard for care. This system of advisory panels is effective for issues like school vaccinations. If there is not an obvious sanction like not being allowed to register for school, though, people ignore CDC advice regularly, as the annual struggle and eventual failure to get all members of the indicated population a flu shot every winter.

*Ambiguity Among Federal Departments*

Even within the Federal government, the accountability and responsibility for homeland security appears to be shared among federal departments. The National Strategy states that "The Federal Government as a united whole – and not simply one or two departments or agencies – has a critical role in homeland security and leads in those areas where it has a constitutional mandate or where it possesses the unique capabilities to address the most catastrophic or consequential scenarios."[291] This statement seems somewhat problematic. One need not even be a particularly close student of Graham Allison to observe that the Federal Government does not always act "as a united whole."[292]

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[290] Gregory D. Koblentz, "Biological Terrorism: Understanding the Threat and America's Response," in Arnold M. Howitt and Robyn L. Pangi, eds., *Countering Terrorism: Dimensions of Preparedness* (Cambridge, MA: The MIT Press, 2003.) see, for example, pages 44-45.
[291] White House, *National Strategy for Homeland Security*, page 4.
[292] Graham T. Allison and Philip Zelikow, *Essence of Decision: Explaining the Cuban Missile Crisis,* Second Edition, (Reading, MA: Longman, 1999). Allison outlines the now-famous three models for explaining foreign

The Homeland Security Act of 2002, the legislation creating the department, grants the Department of Homeland Security broad responsibilities but is more ambiguous about whether it is also granting real authority to the new department.[293] There are at least three sources of ambiguity: (1) whether the new department can provide direction to other federal departments and agencies within its area of jurisdiction; (2) what actually constitutes its area of jurisdiction; and (3) what type of value it will add to the federal response. The Department's area of jurisdiction rhetorically is most clearly "terrorism" and "homeland security" but these are both complicated terms. "Terrorism" implies the nature of the attacker: a non-state actor seeking to use attacks against civilian populations to advance a political agenda. "Homeland Security" implies a theater of attack: the territory of the United States. What if a state attacked the territory of the United States? Is the Department of Defense now responsible solely for the indirect protection of American citizens? The Department of Homeland Security has clear responsibility to "prevent [and] minimize the vulnerability to terrorist attacks." But the top priority of the FBI is to "protect against terrorist attacks"[294] and, at least to an outsider, the lines are very hard to draw between these two sets of responsibilities.

There is significant ambiguity about the relative roles of the Departments of Homeland Security and Health and Human Services, even in a naturally-occurring public health crisis like

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policy outcomes: rational actor; organizational process; and governmental politics. His work underscored that "palace politics" was a critical component to explaining foreign policy outcomes. See also Morton H. Halperin with the assistance of Priscilla Clapp and Arnold Kanter, *Bureaucratic Politics & Foreign Policy* (Washington D.C.: The Brookings Institution, 1974) which observes that "A government is not, in fact, a single individual with a single purpose and an ability to control completely his actions. Rather each government consists of numerous individuals [with]... very different interests, very different priorities, and ... very different questions." Page 311-312.

[293] Department of Homeland Security Act of 2002, P.L. 107-296. Section 101 "The primary mission of the Department is to (A) prevent terrorist attacks within the United States; (b) reduce the vulnerability of the United States to terrorism; [and] (c) minimize the damage, and assist in the recovery from terrorist attacks that so occur in within the United States;" The relationship between DHS's responsibility for terrorism and the ongoing responsibility of other agencies for terrorism-related tasks remains an ambiguity.

[294] The number one FBI priority is to "protect the United States from terrorist attacks." FBI webpage (www.fbi/priorities accessed 3/24/08).

pandemic influenza and even more so in a man-made attack. For example, as noted previously, the Secretary of HHS has authority to prevent communicable diseases from entering the United States from a foreign country or across the borders of the several states. By statute, US Customs and Coast Guard officers are required to aid in the enforcement of quarantine rules and regulations. US Customs and Coast Guard officers normally work for the Secretary of Homeland Security. Which Secretary would decide when to close the borders is ambiguous from the authorities.[295] The Congressional report on the response to Hurricane Katrina somewhat delicately observes that top officials at HHS and DHS did "not share an understanding" of their relative roles in the medical aspects of a response.[296]

National Guard

There is similar ambiguity about how the National Guard would contribute to a response in the homeland. There is a broadly shared view that the National Guard could play a helpful role in a homeland defense attack. The views on how it will play that role are vastly more disparate, including the extent to which it will play a leadership role, and whether it will act under the command of the president or the governor. These issues should be clearly framed, if not resolved, in advance of a crisis.

Under congressional direction and funding, the National Guard has developed and deployed two sets of capabilities targeted at strengthening the expertise available to state and local officials in a biological attack. First, there are 55 Civil Support Teams distributed throughout the states and territories that have training and equipment to enter a contaminated site and identify common pathogens. Second, there are 12 "response forces" focused on helping

[295] CDC Fact Sheet on Legal Authorities for Isolation/Quarantine.
[296] *A Failure of Initiative*, Executive Summary, page 5.

triage the injured from a biological or other unconventional (chemical, radiological or nuclear) attack.[297] While these units are useful, they would not, as presently constituted, provide the core analytical or technical support needed by a governor in a crisis. They meet only a handful of the requirements. Their size would be too small and the speed with which they could get to an affected community would probably be too slow. The National Guard is likely to be an important part of the solution to this problem, but only a part in the absence of a significant national decision to fundamentally reorient their structure, expertise and equipment. Some articles urge that the National Guard be given a prominent role in domestic response, because their structure weaves successfully between two imperatives for an effective disaster response capability in the homeland.[298] They combine centralized equipping (and, hence, at least theoretically low per-unit cost and technical sophistication) by the Defense Department but command by the state. There is certainly merit to this argument.[299]

A complication of using the National Guard is the status under which it would be used. The National Guard, a part of the US military largely staffed by individuals who work only part-time as military personnel and who hold regular jobs in the private sector, can be called to active duty in two ways: by the governor or by the president. Governors frequently activate their National Guard units to help with wildfires, or disaster response in the state. The president frequently activates the National Guard to supplement the active duty military abroad, including most prominently in recent years the wars in Iraq and Afghanistan. Using the National Guard in federal status in the United States is complicated by the Posse Comitatus Act of 1878. The act

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[297] National Guard Bureau, "National Guard Homeland Defense White Paper: September 11, 2001, Hurricane Katrina, and Beyond," October 11, 2005, National Guard Website (http://www.arng.army.mil/Publications/HLD%10White%20 Paper_11Oct05_Final_Version.pdf accessed 7-10-08). Page 4; page 10, and page 9.
[298] Punaro Commission Report.
[299] Hart-Rudman said National Guard should "be given homeland security as a primary mission, as the U.S. Constitution itself ordains." See page ix.

limits the president's ability to use the US military within the United States for law enforcement purposes unless that use is separately authorized.[300] The President has separate authorities enabling the use of the military for law enforcement purposes in a biological event, as well as in a chemical or nuclear event or in an insurrection.

There are sharp debates within the legal community about exactly how restrictive the Posse Comitatus laws really are, at least partly because there are sharp debates about what most narrowly constitutes a "law enforcement" function. Whatever the legal parsing, the Posse Comitatus law certainly speaks to a deep and abiding preference in the United States to avoid the use of the US Armed Forces in the homeland.[301]

*Relevant Literature*

There is a significant literature on aspects of the problem of responding to a catastrophic biological attack, including blue ribbon commission reports on terrorist attacks in the homeland, both before and after the 9/11 terrorist attacks, as well as lessons learned reports from the response to Hurricane Katrina, the life sciences and public health literature and the security literature. Some, but only very little, of this literature focuses on the confusion of responsibility, capabilities and authority for catastrophic response.

Blue Ribbon Commission Reports

Three broad sets of blue-ribbon commission reports look at the general issue of homeland defense, including a focus on terrorist events in the homeland: (1) reports on reducing the

[300]The Coast Guard, normally a part of the Department of Homeland Security, is not covered by Posse Comitatus except in those rare cases, usually only during wartime, when it has been activated to serve as part of the Department of Defense.
[301]That deep and abiding preference appears to work both ways. Government lawyers responsible for interpreting Posse Comitatus sometimes explain that the Latin means "We don't want to do that."

vulnerability to terrorism in the United States published prior to the terrorist attacks of 9/11; (2) lessons learned reports after the 9/11 attacks; and (3) lessons learned reports after the Hurricane Katrina response in August of 2005.

Many of the blue-ribbon commission reports on terrorism issued prior to 9/11 proved prescient, [302] with many warning that poor coordination between federal, state and local governments would complicate a response.[303] In contrast, the assessments conducted after the 9/11 terrorist attacks tend to focus on poor federal unity of effort. The focus is on "connecting the dots" between foreign and domestic intelligence collection.[304]

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[302] See, for example, the report of the National Commission on Terrorism, chaired by Paul Bremer. It focuses significantly on strengthening federal unity of effort, particularly between domestic and foreign intelligence collection, although it does note the need for federal, state and local governments to work together in a catastrophic event. The Bremer report was decidedly not angling for creation of a Department of Homeland Security; it sees DoD as playing the organizing role for catastrophic scenarios. Paul Bremer, chairman, National Commission on Terrorism (the Bremer Commission), *Countering the Changing Threat of International Terrorism,* June 7, 2000. GPO website (http://w3.access.gpo.gov/nct/ accessed 7/23/08). See also the Hart-Rudman Commission report. It does recommend a new Homeland Security Agency to integrate homeland defense and particularly border security, with the new agency containing the Customs agency and the Coast Guard. It urges significant realignments in the structure of the Departments of State and Defense and sweeping changes in their personnel systems. It does not discuss the balance of roles between local, state and federal government. Gary Hart and Warren B. Rudman, co-chairs, U.S. Commission on National Security/21st Century (the Hart-Rudman Commission Report); *Road Map for National Security: Imperative for Change,* Phase III Report, Washington, D.C., February, 2001. The Gilmore Commission report similarly focused on intelligence-sharing, but did note the added complication of including state and local governments at least to some extent, in that sharing. It similarly called for strong preparedness across State and local governments to meet criteria set by the federal government and underscored the need to reconcile the persistent questions about the appropriate role of the military in responding to crises in the homeland. James S. Gilmore, Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction (the Gilmore Commission reports) first through fifth annual reports to the President and the Congress, Washington D.C., Fifth annual report issued December 15, 2003. RAND website (www.rand.org/nrsd/terrpanel/ accessed 7/23/08). A very helpful overview of these and several other homeland-security related reports issued in the decade surrounding the September 11, 2001 terrorist attacks is John V. Parachini, Lynn E. Davis, Timothy Liston, *Homeland Security: A Compendium of Public and Private Organization's Policy Recommendations,* RAND Corporation website (http://www.rand.org/ accessed 7/23/08).

[303] The Bremer Commission and Gilmore Commission reports both note this issue but only in passing.

[304] While "connecting the dots" is the principal message, there are strong calls for increased effectiveness of domestic and foreign intelligence collection and a host of other issues. The reports do not focus on the complexitieis of tying together local, state and federal efforts in the context of a catastrophic attack. See Thomas H. Kean, chair, *The 9/11 Commission Final Report,* National Commission on Terrorist Attacks Upon the United States, Washington D.C. Also principally focused on problems with federal unity of effort, particularly in intelligence collection and analyses, is the WMD Commission report. Charles S. Robb and Laurence H. Silberman, co-chairman, Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass, Report to the President of the United States, March 31, 2005.

The lessons-learned from the Hurricane Katrina assessments generally include the insights that (1) the author was not responsible for the tragedy that played across the lives of the citizens of the Gulf Coast region and the television screens of all citizens; (2) response to a catastrophic event, where local and state governments are swiftly overwhelmed, is mighty complicated and something needs to be figured out to handle it better; and (3) someone other than the report's author should figure it out, preferably later.

A notable exception is contained in a more recent blue ribbon commission report, not on Katrina but on a possible nuclear detonation in an American city, authored by a group co-chaired by William Perry and Ashton Carter. That report urged that the response to a nuclear detonation in an American city be characterized as "federal from the outset." This is a broader recommendation than advocated here, because it puts responsibility for strategic, tactical, and logistical challenges with the federal government.[305] This recommendation would work only if the "federal from the outset" response pulled together the full participation of state and local personnel, who because of sheer numbers will be critically important to an effective response. Precedent, experience, and authorities all warn that this will not work easily – absent a blunt public discussion.

The White House report on Hurricane Katrina states unambiguously that federal agencies must be able to perform their "response roles" but then fails to clarify what those roles might be.

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[305] The view is expressed that nuclear detonations should be considered "federal" from the outset in Ashton B. Carter. Michael M. May, and William J. Perry, *The Day After: Action in the 24 Hours Following a Nuclear Blast in an American City,* A Report Based on a Workshop hosted by The Preventive Defense Project, Harvard and Stanford Universities, May 31, 2007. "**The federal government should stop pretending that state and local officials will be able to control the situation on the Day After** [a nuclear detonation in an American city.] [bold in original] The pretense persists in Washington planning for the Day After that its role is to "support" governors and mayors, who will retain authority and responsibility in the affected area. While this is a reasonable application of our federal system to small and medium-sized emergencies, it is not appropriate for large disasters like a nuclear detonation. ...state and local government guard their supposed "authorities" under the federal system, and Washington seeks to evade responsibility. The result is a failure to plan realistically." Page 10.

It does note that in catastrophic events, the federal government may need to perform "inherently state or local roles" until the state and local officials can recover from the "initial impact" of a catastrophic event. It notes that this "necessarily" will require "collaborative planning" among local, state and federal officials.[306]

The Congressional report on Hurricane Katrina shares something of the view expressed in this dissertation:

> Leadership requires decisions to be made even when based on flawed and incomplete information. Too often during the immediate response to Katrina, sparse or conflicting information was used as an excuse for inaction rather than an imperative to step in and fill an obvious vacuum. Information passed through the maze of departmental operations centers and ironically named "coordinating" committees, losing timeliness and relevance as it was managed and interpreted for internal audiences.
>
> Summaries and situation reports describing the gross totals of relief supplies directed to affected areas did not say when or how or to whom those desperately needed supplies would be delivered. And apparently no one asked.

The congressional report also criticizes the failure of DHS to activate the plan for catastrophic events but notes that it is unlikely that the plan would have worked even if it had been activated.[307]

A recent report on the future of the National Guard underscored that governors have "primary responsibility" for the lives and property of their citizens and stressed that state and local emergency preparedness officials, including the National Guard in state status, would provide the "bulk" of any response to an attack on the homeland. The report also underscored the ambiguity surrounding how a response to a catastrophic attack would actually be handled, noting that far from seeking responsibility for such a mission, DoD officials are "reluctant" to discuss such a role for the Defense Department. The National Guard report asserted that it was

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[306] White House, *The Federal Response to Hurricane Katrina: Lessons Learned.*
[307] House of Representatives, *A Failure of Initiative.*

obvious to every observer who did not work for the Defense Department that DoD would need to play a significant role in responding to any catastrophic attack.[308]

Life Sciences and Public Health Literature

The academic articles on biodefense in the life sciences and the public health community tend to focus on broader questions about the probability of a bioattack or the broad characteristics of a response. They have little if any discussion of who should be making the decisions shaping that response. The small slice of the life sciences and public health literature concerned with biodefense contains four strands. The first strand warns that the risk of bioattack is real. The second strand argues that the risk of bioattack is false, that the "dual use" argument of broader public health benefits from biopreparedness is false, and that biopreparedness increases the risk of bioattack both by proliferating pathogens in defensive research programs and undercutting non-proliferation norms. The third strand is descriptive, outlining how a response to a biological attack is expected to unfold but not critically evaluating the plausibility or robustness of these plans. The fourth strand warns that the authorities and capabilities to respond are flawed.

The first strand is a core group of public health opinion leaders who warn that the threat of bioattack is real: "A bioterrorism attack against the civilian population in the United States is inevitable in the 21st century. The only question is which agent(s) will be used and under what circumstances will the attack(s) occur."[309] Most of these statements came after the fall of 2001,

[308] The extreme ambiguity, both in perception and legal authority, that surrounds a response to a catastrophic attack in the homeland is a strong theme of the Punaro Commission Report, see particularly pages 11-15.
[309] Anthony S. Fauci, "Infectious Diseases: Considerations for the 21st Century," *Clinical Infectious Diseases*, 2001;32:675-85; see page 678. See also National Academy of Sciences, *Biotechnology Research in an Age of Terrorism*.

with the terrorist aircraft attacks on the United States and the anthrax letter attacks, but at least some of the warnings significantly predate the 9/11 attacks.[310]

The second strand of the life sciences and public health literature takes a very different stance. It argues that the risk of bioattack is false or greatly overstated,[311] that the "dual use" argument of broader public health benefits from biopreparedness is false, and that biopreparedness increases the risk of bioattack both by proliferating pathogens in defensive research programs and undercutting non-proliferation norms. Several articles argue that the purported "dual use" benefits from biopreparedness have been oversold, undemonstrated or the effect is to harm, not help, public health efforts in general.[312] One article even interestingly traces the creation of the Epidemic Intelligence Service, the "disease detectives" of the CDC, to the Cold War fears of a bioattack. The article warns that the early focus on biodefense narrowed the appropriate focus of the CDC and that the funding increases left no sustainable benefits. The article clearly warns that the current pledges of "dual use" benefits from biopreparedness will similarly be in vain and the biodefense focus will similarly misshape the focus of current public health efforts.[313] This strand also warns that biodefense programs will increase the risk of bioattack to Americans through two routes. The first route is that the proliferation of dangerous

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[310]Henderson, "The Looming Threat of Bioterrorism," page 1279.

[311] Leitenberg, "Assessing Biological Weapons and Bioterrorism Threat," see page 9: "Threat estimation of potential bioterrororism is as different as possibly can be from the assessment of a real operational system. It is almost purely hypothetical, and rarely, if ever, is predicated on a specific identifiable group and its capabilities. The range of possible assumptions is enormous, the utilization of extreme worst-case assumptions is the rule, and these universally depend on the projections of capabilities into the future rather than their existence at the present time."

[312] Cohen, et al., "The Pitfalls of Bioterrorism Preparedness."

[313] Elizabeth Fee, PhD, and Theodore M. Brown, PhD, "Preemptive Biopreparedness: Can We Learn Anything From History?" *American Journal of Public Health*, May 2001, Vol 91, No. 5, 721-726. From the article: "The Centers for Disease Control and Prevention grew substantially during the Cold War era in large part because Alexander Langmuir, Chief Epidemiologist of the CDC, used an earlier generation's anxieties to revitalize the CDC, create an Epidemic Intelligence Service and promote epidemiologic "surveillance" as part of the nation's defense....Given clear historical parallels, it is appropriate to ask, What was gained and what was lost by Langmuir's central role in that first instance of American biopreparedness? Among the conclusions drawn is that biopreparedness efforts fed the Cold War climate, narrowed the scope of public health activities, and failed to achieve sustained benefits for public health programs across the country."

pathogens housed in the laboratories of the US defensive program is the most likely source for contamination. This argument has certainly gotten useful supporting evidence from the case of Bruce Ivins, a biodefense researcher at USAMRIID, who has been accused of being personally responsible for the anthrax letter attacks in the United States in the fall of 2001.[314] The second route, these authors argue, is through the damage to the non-proliferation norms caused by the US defensive programs. These authors warn that while the US defensive programs are growing because of understandable US doubts that the biological non-proliferation norms are a sufficient protection against attack against the United States. Other nations may then ponder their own vulnerability and respond by also developing defensive programs. The United States has foresworn the use of biological weapons and would derive no military benefit from their use it could not more easily achieve through conventional military techniques.[315]

The third strand of the life sciences and public health community is descriptive, outlining how a response to a biological attack is expected to unfold but not critically evaluating the plausibility or robustness of the plans. These articles are factual and substantive discussions of the threat posed by the agents and the proper medical response. The fact that the articles have been researched and published in the leading medical journals demonstrates that bioterorrorism is a concern of the community, but the articles adopt a neutral, just the facts, approach to the topic.[316]

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[314]See newspaper accounts, including Johnson, Wilber, and Eggen, "Government Asserts Ivins Acted Alone: Officials Detail Evidence, but Questions Linger."
[315] Tucker, "A Farewell to Germs."
[316]There is a growing and helpful literature. See Thomas V. Inglesby, MD, et al., "Anthrax as a Biological Weapon: Medical and Public Health Management," *Journal of the American Medical Association,* May 12, 1999, Vol 281, No 18, pages 1735-1745. Joanne Cono MD and et al., "Smallpox Vaccination and Adverse Reactions," *MMWR: Recommendations and Reports,* February 21, 2003. Centers for Disease Control and Prevention website (http://www.cdc.gov/mmwr/preview accessed 02/21/2009).

The fourth strand – a handful of articles – warns that the authorities and capabilities to respond are flawed. A handful of articles warn that the authorities for public health response are fatally flawed.[317] A second handful warns that traditional response methods will not work because of time pressures and other execution problems. They do not tend to trace the source of the problems to ambiguity about authorities.[318]

Security Literature

Most of the security literature is focused on much broader questions and does not get into the issue of the deleterious effects of the ambiguity.[319] Some of the emerging literature on domestic preparedness in the post-9/11 world speaks either implicitly or explicitly to the issue of the division of responsibility among local, state and federal levels of government. This is valuable but the articles generally can be sorted into one of two categories: they either (1) acknowledge that there is confusion and urge that the confusion be eliminated through dialogue;[320] or (2) assume which level of government will take the lead without acknowledging the lack of consensus on the point.[321] The articles interestingly note the lack of knowledge at state and local emergency response levels about federal capabilities that could be useful.[322]

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[317] Cole, "When a Bioweapon Strikes, Who Will Be in Charge?"
[318]See Koblentz, "Biological Terrorism" in Howitt and Pangi, eds., *Countering Terrorism.* See also Falkenrath, et al., *America's Achilles' Heel.*
[319] For example, many important issues are discussed but the balance of authority between various levels of government in a response is not discussed in an influential article on biosecurity such as Chyba, "Toward Biological Security."
[320] Most helpful is probably David Grannis, "Sustaining Domestic Preparedness: Challenges in a Post-9/11 World," in Juliette N. Kayyem and Robyn L. Pangi, eds., *First to Arrive: State and Local Responses to Terrorism* (Cambridge, MA: The MIT Press, 2003); see page 217: "[T]he Homeland Security Council, in conjunction with the Office of Management and Budget, the Department of Homeland Security, the National Governor's Association, city and country organizations, and first responder associations must delineate federal responsibilities for domestic preparedness and state and local responsibilities."
[321] See, for example, the presumption of state (and National Guard) leadership in Paul D. Monroe, Jr., "Homeland Security and War-Fighting: Two Pillars of National Guard Responsibility," in Kayyem and Pangi, eds.
[322]See Monroe in Kayyem and Pangi, eds. He notes that a survey found 43 percent of first responders were unaware of available, relevant federal capabilities.

*(2) The Need for Strategic Decisions*

There is significant risk that in a catastrophic biological attack needed strategic decisions would not be made swiftly enough to be implemented. Traditional defense of the homeland usually does not require any official to make strategic decisions. The public safety objective is generally unstated but straightforward – most often to maximize lives saved and minimize property damage. In contrast, an effective response to a catastrophic biological attack would require that complex and highly-contested decisions be made and made quickly. There does not appear to be explicit recognition that these decisions would need to be made, appropriate analytical means to support them, or explicit authority or agreement on who should make them. This dissertation urges that the president explicitly have responsibility for these decisions and that an appropriate set of analytical tools and authorities be developed to support him.

The argument for putting the president in charge of the strategic decisions for any biological event seems very strong. There are four elements. First, the challenge of overcoming the technical complexity of the decisions is too difficult to overcome at the local and state level – not because the political officials at the federal level would be more technically proficient but because the support structure to empower them would be expensive to build and would much more easily support one federal official than 50 plus state and territorial leaders. Second, the needed assets and capabilities to respond would be expensive and complex and hence probably could only be built at the national level. Third, particularly in the case of a contagious bioagent, the policies best for the nation may be particularly hard for a mayor or governor to select and implement.[323] They may require difficult allocation decisions among different communities of

[323] This was illustrated dramatically by the Dark Winter wargame conducted on the summer of 2001 by the Center for Strategic and International Studies in Washington, DC. The game assumed a catastrophic attack using smallpox occurred in the US homeland. At the time the game was played, the United States had a stockpile of about 14,000

limited medical countermeasures. Fourth, only the Executive Branch can assure that the foreign policy and security component of the crisis is well integrated with the nation's overall policy abroad.

There are two very different challenges in implementing this recommendation. The first is analytical. Chapter 10 develops more thoroughly the types of decision aids that should be developed to support the president in making strategic decisions for a possible catastrophic biological event. The second is political and legal. Developing agreement across local, state and federal bureaucracies that a catastrophic biological event would require strategic decisions and that the president should make these decisions would be difficult. Two theoretical paths present themselves – building broad consensus or passing legislation. Having a broad and honest discussion in the national emergency response community about the unique challenges posed by a catastrophic biological attack is probably long overdue. On-the-ground emergency responders are eminently practical and it is possible broad agreement could emerge that any biological event should be promptly reported to the president and managed in accordance with his direction. Various analysts also have proposed legislation that would give the president this authority, generally grounding it in his powers as commander in chief. The strengths of the federal system need not be sacrificed to achieve a workable solution in this area.

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doses of smallpox vaccine. Many of the assumptions of the wargame can be challenged and some of the basic facts on the ground have changed from the time the game was conducted (most significantly, the nation now has more than enough smallpox vaccine to vaccinate the entire population). But the game nevertheless provides a warning that in a large, contagious bioattack, governors may take actions they judge to be in the unilateral interests of their own states and not in the interests of the nation as a whole. Center for Biosecurity, University of Pittsburgh Medical Center, "Dark Winter: Exercise Overview," Center for Biosecurity website (http://www.upmc-biosecurity.org/website/events/2001_darkwinter/index.html accessed 04/14/2008).

*(3) Strengthening Tactical and Logistical Decision-Making*

The tactical and logistical demands of a catastrophic biological event would overwhelm traditional methods. An alternative method of handling a catastrophic event has not been articulated, much less agreed or implemented between local, state and federal officials. In most countries, the central government retains the authority to decide when it will directly lead a response and when it will delegate the response to regional or local staff, all of whom generally work for the federal government. The United States does not have to replicate this centralized response structure but should confront much more explicitly the implications of its federal structure for catastrophic emergency response. In the United States, most of the personnel with the relevant skills work for state and local governments. State and local officials welcome federal cash but generally are not otherwise looking for help: their statements are clear that they are in charge of responding to disasters in their area, regardless of whether those disasters are catastrophic. Federal documents, particularly in the aftermath of Hurricane Katrina, observe that there are problems with catastrophic response and focus on developing norms for "sharing" responsibility.

This dissertation urges the development of "modular" federal capabilities that can appropriately supplement state and local capabilities in a catastrophic event in the homeland. A variety of leadership models, consistent with US federal values, could work and should be evaluated. The capabilities are described as "modular" because they should not constitute a stand-alone, unique response structure for catastrophic events, but rather provide additional types or increments of capability to supplement existing state and local capabilities. There do not appear to be planning processes or discussions to clarify what capabilities uniquely are needed

for a catastrophic event, or frank discussions about the authorities, agreements or expectations needed to use them in an effective fashion in a catastrophic event.

Constructing a useful set of modular capabilities requires significant planning. "Planning" in this sense means three different functions: (1) identifying the needed increments of capability and assigning the responsibility for developing those capabilities to someone, including local, state or federal actors; (2) conceptually constructing different packages of capabilities to deal with different types of scenarios as a planning exercise in advance of a crisis; and (3) building the capacity to rapidly assess an emerging crisis and identify the needed combination of force elements necessary to respond in real-time to an actual crisis. Training and exercising would strengthen the ability of the different pieces – federal, state and local – to come together quickly and put together an effective response force.

Some examples of force increments would be federal capabilities to move very swiftly at the outset of a catastrophic attack, taking immediate action in those cases where state and local capabilities are destroyed in the initial phases of an attack. An example of this occurring is the initial phase of Hurricane Katrina in New Orleans in August of 2005 when the command centers were flooded and at least temporarily unavailable to direct operations. Some force elements need to be constructed to manage the reality of the high variance in the quality of state and local response capabilities across the United States.

The only example of this type of planning is the military. The military is quite practiced at building units with certain capabilities and then making them modular so that they can be put together in different ways for different sizes and types of missions. The military analogy is very

helpful but imperfect because the homeland security challenge is even more complex – the range of actors is larger, the relationships more ambiguous, and the range of tasks more dissimilar.

*Conclusion*

The previous chapter described traditional defense of the US homeland, explaining that the response to disasters, accidents and epidemics was led by local and state emergency responders. It showed that most threats to the homeland were small events, with those killing more than 100 Americans being few and far between. These traditional response methods, sound for most events, would be overwhelmed by the greater speed, scale and technical complexity of a catastrophic biological attack.

The reality that traditional approaches would be overwhelmed creates two problems: (1) additional capabilities are needed to respond effectively to these larger, catastrophic attacks, and (2) there is significant ambiguity in the US federal system about who would be responsible for handling the response to these larger events. This ambiguity complicates the development of the needed additional capabilities and their efficient use in an actual crisis.

This dissertation makes two specific recommendations to strengthen response capability for a catastrophic biological attack: (1) the president should explicitly have responsibility for making the needed strategic decisions to shape the response to a biological event and decision aids should be constructed to assist him; and (2) additional "modular" federal capabilities should be created to supplement state and local capabilities in a catastrophic crisis and a clear and agreed leadership structure should be created to assure its effective use in a crisis, consistent with US federal values.

## Defense: Chapter 9

### Comparative Models for Defense of a Homeland

Unique characteristics of the US system can be seen best when set in contrast to the structure of other national systems for defense of the homeland. Two broad observations can be made. First, this dissertation has argued that there is significant ambiguity about the division of responsibilities and authorities among federal, state and local emergency response personnel and among federal, state and local public health officials in the United States. A comparison with other systems does appear to confirm that there is greater ambiguity in the United States than in other countries. Most other countries similarly rely on local and regional emergency response personnel to handle disasters in the homeland. In these unitary systems, however, the central government retains clear authority to centralize all or portions of a response or to direct the actions of their local or regional staff. Even other nations with a federal system for disaster response, like Germany, have the responsibilities and authorities between the regional and the federal government clearly and explicitly divided, in marked contrast to the situation in the United States.[324]

Second, this dissertation has argued that there is significant ambiguity about the division of responsibilities among departments at the national level in the US system. This ambiguity also can be found in most other national systems. It is inherently difficult to create governmental structures to deal with events that have not happened yet or happen very infrequently.

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[324] There is literature arguing that the clear German demarcation of responsibilities between wartime (federal government) and peacetime (regional government) would not function in an era of catastrophic terrorism. There is some merit to this broader argument. The dissertation here is only making the narrower point that the authorities between national and regional governments are very clearly specified in the German case in contrast to the ambiguity that characterizes state and federal responsibilities in the United States. See Gerhard J. Klose, "The Weight of History: Germany's Military and Domestic Security," in John L. Clarke, ed., *Armies in Homeland Security: American and European Perspectives* (Washington, DC: National Defense University Press, 2006).

Responsibility for the various homeland defense related functions are divided in different ways between various ministries in other countries. Structures created to deal with natural disasters are being reformed to deal with the risk of catastrophic terrorism, or links, sometimes tenuous, are being developed to combine capabilities in one ministry with those in another ministry during a crisis. No structure has yet emerged that clearly is superior at unifying disparate activities swiftly and effectively in the event of a catastrophic terrorist event.

The homeland security-related functions that would need to be integrated include immigration and border security; disaster preparedness, particularly against fires, earthquakes, and floods; CBRN mitigation and response; standard law enforcement functions; law enforcement functions in a crisis like enforcing a security cordon or a curfew; the provisioning of shelter, food and medical care; and domestic intelligence collection and analysis.

*Standard Model*

This paragraph describes the "standard" or average model for organizing these functions in an industrialized country. This description is just a heuristic device to organize the following discussion of national variations on this model. It is not an endorsement that the "standard model" is somehow ideal. The standard model is that there is a separate national agency for disaster response, with local and regional employees. The envisioned disasters are principally fires, floods, and earthquakes. The local employees of both the disaster agency and the police are expected to respond promptly to disasters and accidents in their community, drawing both on their proximity and local expertise. The national disaster agency retains the right to centralize some or all portions of a response and tends to do so for serious or catastrophic crises. The disaster agency is part of a larger interior ministry, which often has responsibility for police

functions and border or immigration security. The interior ministry has some expertise in chemical, radiological, and nuclear (CBRN) issues, but responsibility and knowledge is diffused and often confused among various agencies, usually including the health ministry, the defense ministry, and possibly a science agency.

The health expertise and personnel necessary for effective response to a catastrophic biological attack is resident in a separate health ministry, which has national, regional and local employees. Many countries have nationalized a significant proportion of their health care industry and so the national health ministry (or, often, an independent agency that reports to the health ministry) may have effective control of many if not most hospitals and physicians in the country. There are few if any linkages between the interior ministry and the health ministry. In many cases, the health ministry would have leadership of the nation's response to a naturally-occurring pandemic like influenza, while the interior ministry would have leadership of the response to a terrorist event, presumably including a catastrophic biological event.

Involvement in homeland defense by the military tends to be limited, focused on the military provision of unique, often CBRN, capabilities and mediated by the interior ministry. Most countries have a disinclination to use their armed forces in the homeland for law enforcement purposes, although there is a mixture of precedent and legal prohibition for this disinclination. Cross-ministry coordination is achieved through a coordinating committee chaired in the office of the head of government, generally convened only to manage an extant emergency, not to shape policies or capabilities in advance of an emergency.

No country matches this standard model exactly but close approximations can be found in the United Kingdom, Japan, and France. Differences will be noted explicitly. Germany and

Switzerland are closer to a federal system in peacetime when the regional governments have responsibility to protect the population. In wartime, responsibility for protecting the population reverts back to the national government. Switzerland and Israel have pursued different but extensive programs of individual civil defense. These systems technically could protect against biological attack but both are vulnerable to being stymied by the unusual characteristics of a terrorist or covert biological attack – the lack of tactical warning. Their citizens probably would not know to use the protective materials until after extensive contamination had occurred. Israel, with its relatively small population and relatively large, well-organized reserve forces, could plausibly administer medical countermeasures even after contamination on a timeline to be effective, if medical countermeasures were available in the necessary volume.

The standard model is similar to the United States in the following ways. The United States has a separate disaster agency (the Federal Emergency Management Agency) which resides in the Department of Homeland Security (DHS). In contrast to the standard model, the Department of Homeland Security has responsibility for border and immigration security but not for police functions (which are limited at the federal level in the US system and largely reside in the Federal Bureau of Investigation in the Department of Justice). Consistent with the standard model, CBRN expertise is scattered and unfocused, with some residing in DHS and more expertise residing in the Departments of Health and Human Services, Defense and Energy. There are few linkages between departments under the level of committees chaired by the staff of the National Security Council/Homeland Security Council located within the Executive Office of the President. These committees do meet regularly, striving to shape policy in advance of a crisis in addition to trying to manage a crisis when one emerges.

A small note on terms is worthwhile. Most countries use "disaster preparedness" to include preparation and response to all natural disasters, most commonly fires, earthquakes and floods. "Civil defense" is the term used, particularly during the Cold War, for efforts to protect the civilian population from either conventional or nuclear war. Current usage of "homeland defense" or "homeland security" generally is unique to the post-9/11 United States. For the aficionado, it is worth noting that the broad US enterprise is called "homeland security" (as in the Department of Homeland Security) while the US Department of Defense conducts "homeland defense" – a term never clearly defined as being either smaller or larger than homeland security.

*Observations*

The next section will walk through specific national homeland defense structures in additional detail, seeking to highlight commonalities and differences. There is significant national variation. Detailed comparative studies would be interesting because all major industrialized countries have confronted the challenge of somehow growing their organic disaster response capabilities to deal with the prospect of catastrophic terrorism. Detailed case studies theoretically could indicate which of these models work best although few have been tested by an actual crisis. On paper, none of these structures appear inherently more logical than another. The one exception may be Israel, but the efficiency of its structure was demanded by the unique severity of its strategic risk.

The following detailed discussion will illustrate several points:

- Most countries have national, regional and local layers of disaster response personnel and rely on local personnel to respond immediately and completely to most disasters

in the homeland. The difference between the United States and unitary governments is that the central government retains the clear authority to centralize all or parts of a response when it judges it to be necessary. Even other federal systems for disaster preparedness have clear demarcations of when the local and regional governments are in charge of protecting the civilian population and when that responsibility shifts to the central government, as compared to the ambiguity that characterizes the US federal system.

- These clear demarcations of authority in other federal countries are often based on the distinction between peacetime and wartime. In both Germany and Switzerland, the regional governments are responsible for protecting the population in peacetime and the central government is responsible in wartime. The clear distinction between wartime and peacetime arguably would be one of the first causalities of an era of catastrophic terrorism. The United Kingdom in 2004 codified an interesting set of authorities, making it clear that local and regional authorities were responsible for protecting the civilian population in all cases except those where the central government has invoked emergency powers. The criteria for invoking these powers are broad and explicitly include the use of weapons of mass destruction or terrorist attack. The authority is unilateral, with the prime minister having to explain the reasons to Parliament as soon as practicable.
- Organizing the central government for catastrophic terrorism is troublesome because of the cross-cutting nature of the needed capabilities and the inherent characteristic of unusual events like catastrophic terrorism, which is that they don't happen very often. Most governments adopt one of two broad strategies to organize these responses: by

cause or by effect. Examples of organization by cause are the UK, where a naturally-occurring pandemic like Influenza would be handled by the Ministry of Health, a terrorist event would be handled by the Ministry of Interior, an invasion by a foreign military would be handled by the Ministry of Defense and a natural disaster would be handled by the regional government, with oversight from a staff in the Office of the Prime Minister. In contrast, in France, it is organized by effect: any attack on the civilian population would be handled by the Ministry of Interior with the authority to task other departments to provide needed capabilities. It's neither clear which of these broad organizational devices characterizes the US system, nor which device works better overall. Systems organized by cause, though, are highly vulnerable to an unusual characteristic of a catastrophic biological attack: in the early days, such an attack would look like a small disease outbreak. Once it is evident the cause of the illness was a catastrophic biological attack, it may be too late to do much but bury the dead.

- All industrialized countries have had to confront at least analytically the vastly greater technical complexity of CBRN defense as compared to more classic disaster response, like fire fighting or earthquake response. In many countries the effect of CBRN and catastrophic terrorism has been to strengthen the central disaster response bureaucracy at the expense of its regional and local offices. In Japan, for example, while formal control for disaster response has always resided with an agency of the central government, the regional offices of that agency were relatively strong and independent because of the severity of floods and earthquakes that regularly plagued the country and generally could be handled best by regionally executed responses. In

recent years, though, the central structure appears to have grown significantly, at least in part because of the recognition that the technical complexity of CBRN response made it difficult to devolve to regional offices. This bureaucratic response may have been affected by the Japanese experience of the Aum Shinrikyo attacks using sarin in the Tokyo subways in 1995.[325]

- All countries have separate health departments and the links between the health departments and the disaster response agency generally are weak or non-existent. Coordination generally would occur through central coordinating structures managed in the office of the head of government, consistent with the US model. Unitary governments, and particularly unitary governments with a high degree of control of the national health sector, probably could implement central directives on medical countermeasures or public health measures with more clarity and speed than federal systems.
- There is an interesting phenomenon in European defense ministries. At the end of the Cold War, the armed forces were down-sized and refashioned for expeditionary roles, such as peacekeeping under NATO, EU or UN auspices. The emergence of catastrophic terrorism in the 21st century has caused a reappraisal of this focus, although not invariably a reorientation.

*United Kingdom*

More than most countries, the United Kingdom has assessed the implications of catastrophic terrorism and made explicit changes in authorities and governmental structure to

[325] Robyn L. Pangi, "Consequence Management in the 1995 Sarin Attacks on the Japanese Subway System, in Arnold M. Howitt and Robyn L. Pangi, eds., *Countering Terrorism: Dimensions of Preparedness,* (Cambridge, MA: The MIT Press, 2003).

accommodate it. In 2004, the United Kingdom passed legislation that explicitly put local and regional governments in charge of responses to disasters, accidents and epidemics in the homeland. The legislation also codified the right of the national government to unilaterally use "emergency powers" and take control of the response if an exceptionally serious event "is occurring, has occurred or is about to occur." The use of emergency powers by the national government must be ratified by the Parliament as soon as "reasonably practicable." This is consistent with the standard model in that the response for disasters is assumed to reside with local and regional authorities unless the central government decides to take control of all or part of a response. The UK authorities for shifting control are unusually clear, efficient (unilateral decision by the national government), and applicable in an era of catastrophic terrorism (the shift from local and regional control to national control in many other systems requires a shift from "peacetime" to "wartime" – a shift likely to be blurry in a terrorist attack). They also are consistent with representative government because of the requirement to secure the agreement of Parliament.

In 2007, the United Kingdom also clarified the responsibilities of government departments. The Home Office was put in charge of national security and counterterrorism, policing, borders and immigration, and identity management, including a national ID card. This is consistent with the standard model, although often border security is in a different department. A significant difference with the standard model, though, is that the Home Office has the lead only for terrorism – not for disasters or accidents that occur in the homeland for other causes. For non-terrorism national emergencies, the lead department is selected by the Prime Minister based on subject matter expertise relevant to the cause of the emergency. For example, the Ministry of Health would be the lead department in the event of an influenza pandemic. The

Ministry of Agriculture was put in charge of the response in 2003 against foot and mouth disease in cattle.

The UK does not have a separate disaster preparedness agency at the national level. Disaster preparedness is handled at the local and regional levels. The Civil Contingencies Secretariat, a policy staff in the Office of the Prime Minister, monitors local and regional response, deciding when it is necessary to supplement local and regional efforts with additional personnel or equipment, designate a lead national department or invoke the emergency powers. The secretariat also seeks to identify "best practices" for adoption by local disaster preparedness agencies and runs a college on disaster preparedness issues.[326]

The UK has a unique structure to deal with domestic intelligence collection – the MI5. MI5's focus includes terrorism and the proliferation of weapons of mass destruction. Its governance is complicated, as is its relationship to the counterterrorism activities handled in the immediate office of the Prime Minister and the office of the Home Secretary.[327]

The UK does not have explicit legal barriers to the use of the armed forces in the homeland, analogous to the prohibitions in the German Basic Law or the US Posse Comitatus statute. Use outside of Northern Ireland has been very infrequent in the modern era, though, and generally highly criticized by the Parliament and the public. Since the end of the Cold War, the

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[326] Frank Gregory, "National Governance Structures to Manage the Response to Terrorist Threats and Attacks: A cross-national comparative analysis with special reference to the UK 'lead department' response structure and UK counter-terrorism strategy," in Paul Wilkinson, ed., *Homeland Security in the UK: Future Preparedness for terrorist attack since 9/11* (London: Routledge, 2007) pages 117-140; Government of the United Kingdom, UK Resilience Program, particularly on Civil Contingencies Act, Civil Contingencies Secretariat, Emergency Powers, Management and Co-ordination of Local Operations, UK Resilience website (http://www.ukresilience.gov.uk accessed 02/18/2009); Government of the United Kingdom, Newsroom: "A Refocused Home Office and a New Ministry of Justice," published Wednesday, 9 May 2007, Directgov website (http://www.direct.gov.uk/en/N11/Newsroom accessed 02/18/2009).

[327] "The Service operates under the statutory authority of the Home secretary, but it is not part of the Home Office." Government of the United Kingdom, Security Service: MI5, MI5 website (http://www.mi5.gov.uk/output/organization.html accessed 02/18/2009).

military has focused on refining its capabilities for expeditionary missions. As catastrophic terrorism has emerged as a concern, though, there has been an increasing debate about how to fill gaps in law enforcement capacity in a catastrophic event perceived to be filled in France by the *Gendarmie* and in the United States by the National Guard.[328]

The UK has a separate health ministry. Much of the health sector in the United Kingdom has been nationalized and so the government arguably would be in a stronger position to order the implementation of particular response measures in a catastrophic biological event. There is ambiguity about whether in a catastrophic terrorism attack using an infectious disease agent the lead agency would be the Home Office or the Health Ministry. There is significant diffusion of CBRN expertise, with the Home Office, the Defense Ministry and the Health ministry all having some expertise.[329]

*France*

France is consistent with the broad characteristics of the standard model. Compared to the UK system, there are two particularly notable differences. First, the UK system is organized by the cause of the disaster, so the UK Home Office has responsibility only for terrorist incidents. In the French system, the Ministry of Interior has responsibility for all events in the homeland that threaten the population, not just events caused by terrorism.

The French Ministry of Interior has a Civil Defense and Protection Directorate (DDSC) which is the "central structure responsible for risk management in France, whether daily life

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[328] Jonathan Stevenson, "The Role of the Armed Forces if the United Kingdom in Securing the State against Terrorism," in John L. Clarke, ed., *Armies in Homeland Security: American and European Perspectives,* (Washington, D.C.: National Defense University Press, 2006), pages 21-36.
[329] Government of the United Kingdom, Department of Health, National Health Service website (http://www.dh.gov.uk/en/About us accessed 02/18/2009).

accidents or major disasters." There is an extensive network of DDSC employees at the local and regional level and these local officials are expected to respond to smaller disasters and accidents in their communities. In 2004, legislation was passed clarifying that the civil defense actors were under the sole direction of the prefects, representatives of the state at the regional or prefectural level who work for the Ministry of Interior.

The Ministry of the Interior controls the law enforcement forces (both the police and the *Gendarmerie*), identity documents, and relations between the central government and local governments (including the prefects). One of the peculiarities of the French system is the existence of components of the armed forces that have as their main mission classic policing and fire-fighting roles. The *Gendarmie Nationale* is in charge of public security in 95 percent of French territory and provides the fire fighting units in Paris and Marseille, the two largest French cities. They also provide more general units for the use of the civilian protection agency. While the *Gendarmie* are formally part of the Ministry of Defense, they are under the day-to-day direction of the Ministry of the Interior.

The Ministry of the Interior has broad authorities for planning and coordination of responses with other ministries for civil defense against all types of threats. The role of the Office of the Prime Minister is minimized, at least in formal descriptions of the process. This minimal role seems particularly striking when compared to a system like the UK where much of the staff responsibility resides in the Prime Minister's Office. While the Ministry of Interior has broad responsibilities for planning in advance of a wide variety of civil disturbances, their linkages to the Ministry of Health seem limited.

There is no formal bar to the use of the armed forces in homeland defense, although since the end of the Cold War the traditional military has focused on shaping its forces to conduct expeditionary missions, like the UK and most other EU states. [330]

*Japan*

Japan has a unitary system of government. It has a stand-alone National Police Agency and a Fire and Disaster Management Agency located within the Ministry of Internal Affairs and Communications. Both agencies have extensive local and regional staffs expected to respond to events in their communities, but both agencies retain the right to centralize the response to a serious or catastrophic event. Under legislation passed in 2004, the national government is responsible for assuring the protection of the people against all threats in all conditions – wartime or peacetime.

Japan is one of the few countries to have experienced a CBRN attack since World War II. The religious cult Aum Shinrikyo released sarin gas in a small village in 1994 (to influence a judicial proceeding) and then in the Tokyo subway in 1995. [331] As a result of this experience, Japan seems to have strengthened the central component of its disaster response effort and to significantly have increased the training of all levels of emergency responders, national, regional and local, particularly in the response to an attack using CBRN agents. [332]

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[330] Denis Vaultier, "The Military's Role in Homeland Security in France," in John L. Clarke, ed., *Armies in Homeland Security: American and European Perspectives,* (Washington, DC: National Defense University Press: 2006), pages 203-231; Government of the Republic of France, the Ministry of the Interior, including Civil Defense in France, Ministry of the Interior website (http://www.interieur.gouv.fr accessed 02/09/2009).

[331] Robyn L. Pangi, "Consequence Management in the 1995 Sarin Attacks on the Japanese Subway System," in Arnold M. Howitt and Robyn L. Pangi, eds., *Countering Terrorism: Dimensions of Preparedness,* (Cambridge, MA: The MIT Press, 2003).

[332] Fire and Disaster Management Agency, Ministry of Internal Affairs and Communications, Government of Japan. Government of Japan website (http://www.mhlw.go.jp/english/org/detail/index.html accessed 2/12/2009). Prime

*Germany*

There are strong parallels between the US and the German systems. Unlike the standard unitary model, the German regional governments have clear responsibility for the protection of the population in peacetime. The regional governments are responsible not only for execution of emergency response but for emergency planning and operational preparation for peacetime. The federal government is responsible for the protection of the population only in wartime or when the parliament has determined that a state of tension, defined as a stage preliminary to war, exists. Even in wartime, the regional governments would be the technique by which federal direction for civil defense was implemented.

After the 9/11 terrorist attacks in the United States and catastrophic floods in Germany in 2002, the federal government developed additional capacity to coordinate the activities of the regional governments. A new federal office, the Office for Civil Protection and Disaster Response, was created to facilitate this coordination role. The underlying laws were not, however, changed. One specific task of the newly created office seemed to recognize the greater technical complexity of CBRN defense: "coordinating the protection of people against weapons of mass destruction." The federal government also can provide regional governments with specialized equipment, like CBRN detectors. The federal office would initiate an overall coordinating function for incident response in those cases when a catastrophe exceeds the ability of the regional government to cope or has spread beyond its territorial boundaries. The standard model is that these national coordinating functions are run directly out of the office of the head

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Minister or Japan and his Cabinet, The Cabinet, the Ministry of Internal Affairs and Communications; Prime Minister of Japan website (http:///www.kantei.go.jp/foreign/link/links_e.html. accessed 02/21/2009).

of government. In Germany, as in France, the formal responsibility for this national coordination role is devolved to the Ministry of Interior.

There are significant constraints in the German Basic Law on the use of the German military in peacetime in the German homeland. The federal Ministry of Interior would manage interactions with the armed forces to request specific, needed capabilities if that became necessary.[333]

The German health care system is very different from the United States but is not centralized and hence in the absence of extensive planning, which has not yet occurred, does not seem likely to be inherently more responsive than the US system during a catastrophic biological attack. The health system in Germany is a mixture of public and private. Slightly more than half of hospital beds are in the public sector, while about 38 percent were run by private, non-profit organizations and some 8 percent were run by private, for- profit institutions. Physicians generally are not employees of the state – they are paid on a fee for service basis. It is unclear that this medical structure would provide much greater leverage in executing centralized direction.[334]

*Israel*

Israel varies significantly from the standard model described above, largely because the greater extent of its strategic risk. Israel does have the standard police and national fire and

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[333] Gregory, "National Governance structures," in Paul Wilkinson, ed., *Homeland Security in the UK: Future preparedness for terrorist attack since 9/11.* Government of Germany, Federal Office for Civil Protection and Disaster Response, International Civil Defence Directory, Government of Germany website (www.http//germany accessed 2/11/09). Klose, "The Weight of History," in Clarke, ed., *American and European Perspectives.*

[334] David G. Green, Ben Irvine and Ben Cackett, "Health Care in Germany," *Civatas: The Institute for the Study of Civil Society* website (http://www.civitas.org.uk.pubs/bb3Germany.php accessed 2/16/2009). National Coalition on Health Care, "Health Care in Germany," National Coalition on health Care website (http://www.nchc.org accessed 2/16/2009).

rescue agency to respond to events, including terrorist events, in their local communities. The Ministry of Defense and other offices are notified of all events and, if additional capabilities are needed, the Homeland Defense Command, part of the Ministry of Defense, efficiently supplements local responders. For significant terrorist events, the Defense Forces themselves often are involved.

The technical capacity to respond to a CBRN attack is within the Ministry of Defense and specifically the Homeland Defense Command. Israel has done more to protect its citizens against unconventional attacks than any other country, distributing masks and requiring since the end of the 1991 Gulf War that all houses and apartment buildings have shelters with reinforced concrete and filtration systems capable of protecting against chemical and biological pathogens. Israel is a relatively small society with a very well organized and relatively large civilian reserve force. It is plausible that medical countermeasures against a biological attack could be distributed in time to be effective. The population size is small enough that the antibiotics for anthrax or the vaccine for smallpox probably is possessed by Israel or could be acquired within the necessary timelines.

The issue would be the tactical warning. Israel, also uniquely, has a system of sirens and detectors that enable it to warn of incoming missiles from surrounding countries. In a period of heightened tension, it's plausible that the warning provided by these sirens would be enough to get most individuals to protective shelters or into their masks. For a terrorist attack launched from inside its territory, like 90 percent of the terrorist attacks on Israel since 1970, there would not be the type of detection of a delivery vehicle that would cause the sirens to go off. Israel may or may not have regularly deployed detectors for biological or chemical agents. But in the

absence of such detectors, it is not clear that the available masks and shelters would work because of the lack of tactical warning. [335]

The scale and rate of terrorist attacks in Israel probably necessitates this unique structure. As a contrast, in the German case of occasional terrorist attacks by the Red Army Faction, responses even to terrorist attacks were handled by the regional governments vested with defending the population in peacetime.[336]

*Switzerland*

Switzerland is a very interesting case. It is a federal system with highly independent regional governments that are responsible for classic disaster response, like the response to fires, floods and earthquakes. The distinction between wartime and peacetime is critical here, as the federal government has responsibility for assuring the protection of the population in wartime. Switzerland's history as an armed neutral power in the center of Europe prompted it to launch a remarkable program of civil defense construction in the Cold War years that ultimately yielded space in shelters for every person in the country. While the shelters could not have provided protection from a direct nuclear hit, the probability even in the darkest days of the Cold War was not that Berne would sustain a direct hit but rather that the country would be threatened by the fall-out of an attack directed elsewhere. For this purpose, the public documents certainly make the shelters appear adequate.

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[335] Ariel Merari, "Israel's Preparedness for High Consequence Terrorism," in Arnold M. Howitt and Robyn L. Pangi, eds., *Countering Terrorism: Dimensions of Preparedness,"* (Cambridge, Massachusetts: The MIT Press, 2003); Ministry of Interior, Israel Fire and Rescue Services, "Aims," Fire and Rescue Services website (http://www.102.co.il/en/aims accessed 02/21/09); Israel Homeowner, Glossary of Terms, "Mamad: a room that is blastproof and impermeable to chemical and biological substances, required in all Israeli homes following the Gulf War in 1991. Israel Homeowner website (http://www.israelhomeowner.com/Glossery.asp accessed 02/21/1991).
[336] Klose, "The Weight of History," page 53.

In a dissertation with much discussion of offense and defense dominance it is interesting to observe that such an ambitious shelter program by Switzerland – because of its neutrality and its renunciation of the possession of nuclear weapons – was viewed by all as defensive. Had the United States or the Soviet Union engaged in a similarly thorough shelter program, the program could have been perceived by the adversary as offensive and possibly provoked preemptive war. This is because it could have been judged as a strategy to reduce the impact of a retaliatory strike and hence reduce deterrence against launching a first strike.

The Swiss shelters probably are or could be made effective against a biological attack. Public descriptions of the shelters indicate that they have air filtration systems. The air handling systems probably have or could be retro-fitted with the fine-grained filters needed to keep dangerous biological pathogens out. Like Israel, the problem would be the tactical warning. If the biological pathogen was delivered through classic military means – like a long-range missile attack after a period of heightened tension – the country might be able to get people into the shelters and close the shelter doors before the pathogen was released upon impact of the missile. If a biological pathogen was released through covert means, people would be contaminated before anyone realized an attack had occurred. The best detectors warn of the presence of a pathogen; they don't warn that one is coming. If the pathogen is infectious and the shelter doors were closed with even one infected individual inside, everyone inside would probably become infected. With most diseases, people are infectious before they are symptomatic.[337]

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[337] Lawrence J. Vale, *The Limits of Civil Defense in the USA, Switzerland, Britain and the Soviet Union: The Evolution of Policies since 1945,* (New York: St. Martin's Press, 1987); The Federal Office for Civil Protection, Government of the Swiss Confederation; "Civil Protection," website (http://www.bevoelkerungsscchutz.admin.ch/internet/bs/en/home.htm accessed 02/09/2009); Suburban Emergency Management Project, "Civil Defense: The Swiss Approach," website (http://www.semp.us/publications/biot_reader.php?BiotID+245 accessed 02/09/2009)

*Conclusion*

National responses to the emerging risk of catastrophic terrorism provide a fascinating window into the enduring effects of history and national culture. Much more detailed work could and should be done on this question. This very initial review provides some context for the two broad observations made about the US case. The responsibilities and authorities of local, regional and national responders in the case of a catastrophic terrorist attack are more ambiguous in the United States than in other industrialized countries. Most countries are unitary so the central government can pull control of a response to the center when they judge it to be necessary. Even federal systems – like Germany and Switzerland – have much clearer demarcations between the responsibilities of the national and regional governments for protection of the civilian population.

The second observation about the US system – that there is significant ambiguity about the roles of the various national departments in a catastrophic terrorist event – could be made about most of these other national systems. Each system has some strengths and some weaknesses and all would be vulnerable to problems in a catastrophic event.

## Defense: Chapter 10

### Improving Strategic Decisions

The previous three chapters have outlined and assessed the techniques used for traditional defense of the US homeland. The chapters have argued that while the techniques in the United States are sound for the purposes for which they were designed, they would be ineffective when confronted with the vastly greater scale, speed and technical complexity of a catastrophic biological attack. Specifically, the previous chapters argued that the implicit consensus about strategic objectives would not be present. In traditional defense of the homeland, the shared but often unstated strategic objectives are to maximize lives saved and minimize property damage. How to achieve that strategic objective in a large fire or a chemical spill turns on many complicated decisions, but ones that generally would be considered tactical (because they are about how to do something most effectively) instead of strategic (which tend to be about what should be done).[338]

A catastrophic biological attack would require significant strategic decisions. These strategic decisions would be complex, highly contested and very time-sensitive. The previous chapters argued that under current circumstances the need for these decisions might go unrecognized and, in any case, there would be no agreement about who should make them. The previous chapters urged that the president have responsibility for making strategic decisions in a biological event and that an appropriate set of decision aids be developed to support him.

[338] The line between strategic and tactical decisions is imperfect and highly contested. In government, they are both often defined, prospectively, as whatever the definer is responsible for doing and, retrospectively, especially after a disaster, as whatever the other person should have been doing.

These aids would help assess, for example, the relative probability that a few human cases of anthrax exposure came from a naturally-occurring benign source as opposed to being the leading edge of a large underlying exposed population from a catastrophic attack. These aids also could help use the initial, quickly-available data to identify the likely members of the underlying exposed population in a large attack. This identification could enable medical countermeasures to be administered on a timeline where they would be much more likely to be effective. These probabilistic tools are an extension of classic public health methods that seek to identify all contacts of an individual identified as having an infectious disease of concern. Because of the risk in a catastrophic biological attack that tens or hundreds of individuals are infected simultaneously, this model substitutes probability based assessments of who likely was in the area of contamination for the laborious and time-consuming interviews and contact-tracing inherent in classic public health epidemiology.[339]

The issue discussed in this chapter -- who would make what decisions based on what information in a possible biological attack -- is poorly developed in either public government documents or in the academic literature. Generally ignored, the issue is treated by the public health community as a mere extension of techniques suited to the response to a naturally developing epidemic (with an infected individual infecting a few people, who each in turn infect

[339] There would be an almost inevitable delay in clinical diagnosis of a biological attack if there is no reason to suspect such an attack from an external source like a positive detection on a detector or an explicit and detailed threat from a terrorist group. Inglesby, et al. "Anthrax as a Biological Weapon," see 1739: "If only small numbers of cases present contemporaneously, the clinical similarity of early inhalational anthrax to other respiratory tract infections may delay initial diagnoses for some days. ...A widened mediastinum on chest radiograph in a previously healthy patient with evidence of overwhelming flulike illness is essentially pathognomonic of advanced inhalational anthrax and should prompt immediate action. Although treatment at this stage would be unlikely to alter the outcome of illness in the patient concerned, it might lead to earlier diagnosis in others." See also Z.F. Dember, M.G. Kortepeter and J.A. Pavlin, "Review Article: Discernment between deliberate and natural infectious disease outbreaks," *Epidemiol. Infect.* (2007) 135, 353-371, see page 353: The same danger would be present in a smallpox attack: "One simulation study of a smallpox outbreak showed that the more rapid the intervention, including quarantine and vaccination, the greater the chances of halting disease spread. It is unlikely that a bioterrorism event would be considered initially by medical professionals, especially if the disease presentation is similar to other diseases that might be expected to occur, such as seasonal influenza."

a few people) without incorporating the implications of the very different scenario when tens of thousands of people are simultaneously infected. The security community – which has more experience planning for catastrophic events in a systematic fashion – has thus far successfully avoided responsibility for thinking systematically about this particular catastrophe.

This chapter has five objectives: (1) it explains the extremely tight time pressure that would confront a decision-maker in a biological event; (2) it explains "tactical warning" and argues that such warning would come from either detectors or clinical diagnosis. It expresses skepticism that computer-based systems could speed initial warning; (3) it explains "characterization" and describes the technical characteristics of the recommended decisions aids for this phase; (4) it describes "assessment" and why strategic tradeoffs would need to be made; and (5) it reviews the relevant literature and finds it would either support or be neutral on the development of aids such as described here.

*(1) Tight Time Pressure*

The probabilistic tools recommended here should fully incorporate various risks, including that (1) the initial cases are actual cases of anthrax, for example, but they arise from limited, benign sources and are not indicative of any sort of purposeful attack; (2) an attack could be small and limited, not catastrophic; (3) some responses could be worse than the attack. Overreacting and overmedicating could cause unjustified panic, reduced confidence in government, loss of valuable stockpiles, and adverse medical reactions to the administration of unneeded countermeasures.

The probabilistic decision aids would formalize and extend what public health response to an epidemic has always done – tried to figure out who is likely to be sick from a contagious

disease based on their proximity to someone diagnosed with a dangerous infectious disease. In a naturally-occurring epidemic, this has been through identifying and vaccinating household and other contacts of the sick individual (or "contact tracing"). The people around the sick individual would be vaccinated (or "ring vaccination"). It should be noted explicitly that traditional public health methods often did not wait until each individual showed symptoms of infection. Once a reasonable case had been established (they live in the same house as someone with smallpox), the public health community would proceed to vaccinate in the case of a dangerous pathogen like smallpox. The analytics behind these decision aids argue that a catastrophic attack would demand the logical extension of this traditional public health method. The prospect of tens or hundreds of thousands of individuals being contaminated at the same time makes it unworkable to proceed using traditional contact tracing and ring vaccination.

The decision-making literature is reviewed and while the literature agrees on little it would either support or be neutral on such decision aids, with one caveat. The literature would warn against the development of decision aids that were primed to cause actions that other nations could interpret as offensive. This could inadvertently set off a spiral of reactions, inadvertently leading to war. The measures provoked by these decision aids do not seem likely to be interpreted as offensive, but it is a worthy caution should the aids be developed.

The core challenge is that the period of time between when the nation plausibly would get warning that a catastrophic biological attack had occurred and when medical countermeasures would need to be administered generally is extremely small.[340] The size of this period varies pathogen to pathogen (and, to a lesser extent, individual to individual) but generally

[340] Hupert, M.D., M.P.H., et al., "Community-Based Mass Prophylaxis," see page 33: "Since the 2001 U.S. anthrax attacks, a number of scientific studies have underscored the importance of rapid mass prophylaxis of civilian populations to prevent casualties in real-life and hypothetical disease outbreak scenarios."

is about two to four days. For example, individuals exposed to anthrax generally show symptoms sometime from two to about 60 days after exposure. Once symptoms emerge, the disease progresses very rapidly. Antibiotics probably would have little effect in controlling the disease if administered more than 48 hours after the emergence of symptoms. Antibiotics kill anthrax spores, but any surviving spores produce a toxin that is impervious to antibiotics. It is the toxin that causes the rapid onset of acute flu-like symptoms and very high mortality rates, historically more than 80 percent. Confident diagnosis probably would occur only after it is too late to help the initial patient, but still early enough to inform the treatment of others who may have been exposed at the same time.[341] The statistical reality is that if the underlying exposed population is sufficiently large, the disease presentation would follow a standard deviation, with some individuals presenting with disease earlier than others, even though they were both exposed in the same attack. There could be additional staggering in terms of presentation if there were multiple attacks, separated in both time and distance.[342]

Hence, in the event of a catastrophic biological attack, the nation often would have about four days to ascertain an attack has occurred (tactical warning); identify the likely affected population (characterization); and decide how to respond, balancing this situation against broader strategic calculations (assessment). These issues are the ones contained in this chapter. The four days, though, also would have to contain time enough to transport the stockpile of appropriate

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[341] Inglesby, et al., "Anthrax as a Biological Weapon," Journal of the American Medical Association, 1999; 281 (18) 1735-1745. This article has a significant amount of valuable information. See page 1740: One point, particularly, reinforces a significant theme of this paper: "Given the rapid course of symptomatic inhalational anthrax, early antibiotic administration is essential. A delay of antibiotic treatment for patients with anthrax infection even by hours may substantially lessen chances for survival."

[342] Smallpox unfolds differently in epidemiological terms, but similarly from a response point of view in that symptoms emerge too late for standard medical countermeasures to be effective. The traditional smallpox vaccine is effective if administered within four days of exposure to the smallpox virus. Symptoms, though, only emerge much later – at about ten days post-exposure and hence much too late for post-exposure vaccination at that point to be confidently effective. USAMRIID, "Medical Management of Biological Casualties Handbook," pages 79-89.

medical countermeasure to the area and distribute it to the affected population. The next chapters consider the challenges in developing, over time, the "right" medical countermeasure. They also consider how to distribute the available countermeasures to the population in a timely fashion and non-pharmacological techniques to mitigate the spread of infectious disease, such as the wearing of masks, closing of schools and other gathering places, and imposing isolation.

The phases of strategic decision-making would be tactical warning, characterization and assessment. The decision aids should particularly be constructed to aid the characterization phase, but all of the stages will be discussed to explain how the pieces fit together.

*(2) Tactical Warning*

The first step would be tactical warning of a large attack. Tactical warning has three steps: detection, verification and reporting. Progress has been made in each area in recent years, but more progress needs to be made.

The first step is detecting an attack. The country probably would get initial detection of a large attack from one of two sources: clinical diagnosis or detectors. Clinical diagnosis basically means a healthcare practitioner examines a patient and diagnoses the disease. There would usually be a lag of a couple of days before it is plausible that a clinician would diagnose exposure to a biological pathogen. This is because early symptoms for most biological pathogens are non-specific.[343] For anthrax, for example, early symptoms look like any upper

[343] As another example, tularemia would be difficult to distinguish from a naturally occurring disease. David T. Dennis, Thomas V. Inglesby, Donald A. Henderson, et al., "Tularemia as a Biological Weapon: Medical and Public Health Management," Journal of the American Medical Association, June 6, 2001, 285 (21): 2763-2773 (doi:10.1001/jama.285.21.2763), see page 2765: "Release [of aerolozied tularemia] in a densely populated area would be expected to result in ana abrupt onset of large numbers of cases of acute, nonspecific febrile illness beginning 3 to 5 days later (incubation range, 1-14 days), with pleuropneumonitis developing in a significant proportion of cases during the ensuing days and weeks. Public health authorities would most likely become aware of an outbreak of unusual respiratory disease in it early stages, but this could be difficult to distinguish from a

respiratory infection. Diagnosis would be speeded if there was some non-medical reason to suspect exposure to a biological pathogen, like an explicit, public threat from the attacker or a positive reading from a detector.

Anthrax, while still naturally occurring in parts of the United States, is not common and so is not likely to be the first posited diagnosis of even the most acute clinician. While it varies pathogen to pathogen, there will always be at least a short lag between exposure and symptom presentation and then finally settling on the correct diagnosis.

Aerosol detectors for biological attack were initially deployed in 2001 and have been improved in the subsequent period. Their precise characteristics are not widely publicized.[344] There would be at least two theoretical vulnerabilities to an aerosol detection system. The first is that the density could be poor – there could be too few detectors deployed to cover all of the major population centers so an attack might occur in a covered area or it might not. Second, the lag between the release of the pathogen and the detection being picked up might be too long.[345] Over time, one would expect that the detector system would get better in terms of density of coverage and speed of reporting.

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natural outbreak of community-acquired infection, especially influenza or various atypical pneumonias....tularemia would be expected to have a slower progression of illness and a lower case-fatality rate than either inhalational plague or anthrax."

[344] Department of Homeland Security, The Office of Weapons of Mass Destruction of Biodefense, Biowatch "provides a bio-aerosol environmental monitoring system to our Nation's largest cities for early detection of biological attacks. Biowatch operates with the inclusion of public and private health personnel at all levels of government and is currently running in over 30 cities around the country." DHS web site (http://www.dhs.gov/xabout/structure accessed 11/12/2008). Spencer S. Hu, "Modest Gains Against Ever-present Bioterrorism Threat," The Washington Post, Sunday, August 3, 2008. Page A10: "Early detection is critical because the impact of a bioweapons attack can spiral out of control in the hours or days it takes to discover it. Administration defenders have praised BioWatch, a five-year-old, $400 million effort to install sensors in more than 30 U.S. cities to detect the airborne release of biological warfare agents such as anthrax spores, plague bacteria and smallpox virus."

[345] Hu, "Modest Gains Against Ever-present Bioterrorism Threat," see "Critics say big gaps remain. BioWatch remains of limited use, because it takes 10 to 34 hours for samples taken by the machines to be analyzed. A new generation of sensors that can detect lethal agents within four to six hours was scheduled for pilot deployment in 2008 but now is not expected until 2010 or 2011."

As discussed previously, there are three theoretical routes for biological attack: consumed in food or water; absorbed through the skin; and inhaled through the lungs. Of these routes, aerosol is probably the best from an adversary's point of view in terms of causing the largest number of causalities. The risks from water or food borne attack are poorly understood. Recent food outbreaks demonstrate that the warning systems in these areas appear to be after the fact – using the incidence of disease to backtrack to the source of the disease and then prevent its further distribution through recalling other possibly contaminated food. Absorption through the skin could be an effective assassination technique but probably could not be used to cause a catastrophic attack with its assumed 10,000 deaths.

While detectors or clinical diagnosis are the most likely routes for detection, it is also possible that the nation could get initial warning from a much more traditional technique – a threatening letter, an abandoned car with spraying equipment, or the capture of the terrorists in the act of spraying. Theoretically, if the law enforcement agencies had some reason to suspect an attack might be looming, police and other officials could watch for behaviors that are likely indications of the most dangerous attacks. Since an aerosol attack is the worst, close attention could be paid to all forms of spraying equipment in populated areas. Police, for example, could closely check the credentials of all trucks spraying in a neighborhood.

Once officials had initially detected an attack, the second step would be verification or rapid vetting of the initial finding. There are always potential sources of error in any diagnosis so some vetting makes sense. There are two particularly likely sources of error. The first is that the original detection was accurate but the cause of the infection is benign and limited. In the case of a clinical diagnosis, someone could have traveled to and gotten infected in an area with

naturally occurring anthrax, for example.[346] Thus, the case is from a unique cause and is not the first case presenting in a larger, underlying exposed population.[347] In the case of a detector, a true but benign positive could come from the reality that several biological pathogens of concern are naturally occurring. These include, for example, anthrax (in the Western United States), hanta virus (in New Mexico), and tularemia (in Texas). A few naturally-occurring spores could have hit the detector but that accurate detection would not be indicative of a broader attack. These might be called true but benign positives.

The second source of error could be a false positive, where the detector or a laboratory test gave a positive finding for a pathogen that in fact was not present, or a false negative, where there was release of a pathogen but the detectors failed to register it. Essentially any detection system or test developed for any purpose is vulnerable to false positives and false negatives – reporting an event occurred when it had not in fact occurred (false positive), or failing to report an event that did occur (false negative). With most detectors or tests, increasing the sensitivity (and hence reducing the risk of missing a release, in other words, reducing the risk of having a false negative) increases the dangers of false positives (a more sensitive system will more often wrongly believe the pathogen has been detected). Over generations of development, detectors generally improve and have greater discrimination (avoiding false positives) even as they have greater sensitivity (avoiding false negatives). Striking the right balance for the degree of

[346]A New York City man got inhalational anthrax in February 2006 as a result of using African animal skins to make drums. Anthrax can be found naturally occurring in livestock. Center for Infectious Disease Research and Policy, University of Minnesota, "New York Man has First US Anthrax Case Since 2001," February 22, 2006. CIDRAP website (http://www.cidrap.umn.edu/cidrap/content/bt/anthrax/news/feb220 accessed 9/30/2008).

[347]One of the best examples of the type of analytics that should be further developed can be seen in Stanley L. Wiener, "Biological Warfare Defense," in Richard F. Pilch and Raymond A. Zilinskas, eds., *Encyclopedia of Bioterrorism Defense.* Hoboken, NJ: John Wiley & Sons, Inc., 2005; see pages 146-148: Wiener has three simple decision trees that outline, for example, a diagnostic algorithm for infectious agents. Such decision-trees are extremely useful and should be extended. They would need to be crafted with a slightly different perspective to aid macro-level crisis decision-making, as opposed to individual diagnosis.

confidence an attack has occurred at the end of the verification phase is a little tricky. There must be some vetting of initial detections because they are notoriously unreliable. A too thorough vetting is vulnerable, though, to consuming too much time.

The third step – reporting – seems like it should be straightforward but given the current muddle of responsibilities it remains a source of problems.[348] If a positive detection comes from a detector or another source, there could be time lost as individuals report the finding up their reporting chain. But their reporting chain could be local, state or federal depending on where the initial detection occurs. Progress has been made to standardize these reporting measures but they remain a potential weakness. The pathogens of concern are all "reportable" illnesses under the CDC system. So, under the rules, a clinical diagnosis should be reported swiftly to CDC. Even if this occurs, though, CDC must assure their internal processes don't consume too much time rechecking the data before passing it forward to the Department of Health and Human Services and onward to the White House. Establishing a clear decision-maker for the strategic decisions in the event of any biological event should help solve these problems and speed notifications.

*"Decision Aids" as compared to "Surveillance"*

The two agreed sources of initial detection of a biological attack are clinical diagnosis and detectors. There is a broad and complex debate about whether there might be a third source of initial detection of a catastrophic biological attack: integration of computer-based information from emergency room reports and other public health sources to provide initial detection of an attack through computer-based syndromic surveillance. Some analysts argue that by sorting through significant amounts of data using sophisticated computer algorithms, patterns could

[348] Cole, "When a Bioweapon Strikes, Who Will Be in Charge?" see page 948: "Unfortunately, unless the legal authorities for a public health response to bioterrorism can be sorted out before bioterrorists strike, something is likely to go wrong in a big way."

emerge faster than through the other two, more traditional techniques for initial detection of an attack.[349] Other analysts argue that the accretion of data will not alter the reality that the data is ambiguous about whether, for example, the illness is an upper respiratory infection or an anthrax attack. These analysts are dubious that the aggregation of data that shows there is an outbreak of some disease with certain characteristics could provide the initial insight that the source of the disease was anthrax as opposed to an upper respiratory infection.[350] While there is a complex and unresolved argument about whether computer-based algorithms could provide initial detection of a biological attack, there is general agreement that better integration of reporting systems would help with the management of the response. There needs to be some clarity about which purpose – initial detection or response management – various systems are trying to serve.

Several initiatives have been announced to integrate the findings from various detection sources into a more coherent picture of the risk of bioattack. Most recently, the Congress has directed that more attention be paid to a nascent DHS effort called the National Biointelligence

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[349] The case has been made by some analysts but is not fully accepted. Julie A. Pavlin, et al., "[I]nnovative Surveillance Methods for Rapid Detection of Disease Outbreaks and Bioterrorism: Results of an Interagency Workshop on Health Indicator Surveillance," *American Journal of Public Health*, August 2003, Vol 93, No. 8, 1230-1235. See page 1232: "Simultaneous small and unexpected but concordant variations in multiple data sets may suggest an actual disease outbreak." Pavlin et al. also cite the argument that "Measurable alterations in personal behaviors within the first hours or days of illness, including work or school absenteeism and purchase of over-the-counter remedies, can assist in the early detection of an event or epidemic." They cite the article of Goldenberg A., Shmueli G., Caruana RA, Fienberg SE. "Early statistical detection of anthrax outbreaks by tracking over-the-counter medication sales." Proceedings of the National Academy of Sciences. 2002;99:5237-5240. Another argument that detection could be speeded through sophisticated analysis of "pre-diagnostic data such as emergency department chief complaints and over-the-counter (OTC) drug sales to detect bioterrorism events in a timely manner....[Preliminary evaluation] shows that our method outperforms benchmark methods in terms of outbreak detection speed and detection sensitivity at given level of false alarm rates." Hsin-Min Lu; Daniel Zeng, Hsinchun Chen, "Bioterrorism event detection based on the Markov switching model: A simulated anthrax outbreak study," *Intelligence and Security Informatics*, 2008, ISI 2008. IEEE International Conference, 17-20 June Pages 76-81.

[350] Kirsty Hope, David N. Durrheim, Edward Tursan d'Espaignet, Craig Dalton, "Syndromic surveillance: Is it a useful tool for local outbreak detection?" Journal of Epidemiological Community Health 2006; 60: 374-375: [D]emonstrated utility in detecting localized disease clusters has remained an elusive goal for syndromic surveillance systems. In this respect, the review [of the relevant medical literature] identified important limitations, particularly relatively low specificity and positive predictive value, with a considerable burden of false alarms, and an inability to distinguish between signals and background noise."

Center (NBIC).[351] The avowed objective of the NBIC is to integrate all of the data from all sources (private, local, state, and federal, including the Departments of Health and Human Services and Agriculture) to provide warning of a biological attack.[352] This statement of the goal again raises the question of whether the NBIC has waded through the technical argument about whether the integration of this data can realistically provide initial warning of an attack. NBIC's second objective -- "integration" -- seems too amorphous an ambition. Is the proposition that the integration could provide initial detection of an attack? If so, there needs to be some careful explanation of how the pattern analysis would be able to indicate an anthrax attack without any prior specific diagnosis or detection of anthrax through other means. There is a complex technical debate on the topic and the answer seems far from obvious based on the state of the literature in the medical journals. "Integration" also could be focused on helping to manage the response to an attack after the initial detection had come from another source. Both NBIC and the related CDC effort "Biosense" need to be very specific about whether their objective is providing initial detection of an event (in which case they need to wade into the very technical argument about the plausibility of such an approach) or assisting with the management of the response through consolidating information about case presentation subsequent to initial queing from one of the two traditional sources.

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[351] Spencer S, Hsu, "Modest Gains Against Ever-present Bioterrorism Threat," *The Washington Post*, Sunday, August 3, 2008, A10. "At Congress's direction, DHS this year is developing a new National Biosurveillance Integration Center to coordinate federal efforts, but faces 'big challenges' to being operational [in September 2008]."

[352] Department of Homeland Security, The Office of Weapons of Mass Destruction and Biodefense, The National Biosurveillance Integration Center. DHS website (http://www.dhs.gov/xabout/structure accessed 11/12/2008). The National Biosurveillance Integration Center "integrates bio-monitoring activities of executive branch Departments to provide a biological common operating picture and facilitate earlier detection of adverse events and trends [and] provides seamless integration of information through an interagency effort to fuse intelligence from more than 12 Federal agencies with biosurveillance information on human, animal, plant, and environmental health measures to provide early warnings of a possible biological attack."

These systems – even if they could be made to provide initial detection – are different from the decision aids recommended in this chapter. The decision aids recommended here attempt to answer questions based on probabilistic assessments of the very limited data that would be available in the very early phases of an attack. They do not attempt to acquire needed data more quickly. They accept it won't be available quickly enough and instead make probabilistic predictions based on the data that would be available. This chapter urges the use of this type of prospective, probabilistic analysis because at least for the foreseeable future, any response system that waits for retrospective data will distribute countermeasures too late to be of genuine use to most of the exposed population.

Some authors have developed qualitative as opposed to quantitative techniques to assess whether an event is a biological attack as opposed to a naturally-occurring event. These tools are valuable but are principally useful for retrospective analysis of data. They are unlikely, in the foreseeable future, to provide a decision to act quickly enough.[353]

*(3) Characterization*

Characterization, the step after tactical warning, would be the process of making educated guesses about the underlying exposed population based on the limited data about the attack that would be available. The decision-maker needs to decide whether to direct that a certain population be offered medical countermeasures. In most cases, the precise contours of that

[353] Z. F. Dembek, et al., "Review Article: Discernment Between Deliberate and Natural Infectious Disease Outbreaks," see page 358-359: Outlines 11 "clues" that could help indicate a bioterrorism event has occurred: "[1] A highly unusual event with large number of casualties…[2] Higher morbidity or mortality than is expected….[3] Uncommon disease….[4] Point-source outbreak….[5] Multiple epidemics….[6] Lower attack rates in protected individuals….[7] Dead animals….[8] Reverse spread….[9] Unusual disease manifestation….[10] Downwind plume pattern….[11] Direct evidence. They also discuss the qualitative criteria recommended by Grunow and Finke to distinguish between an intentional and a natural release. Both of these are valuable, but again are most useful for retrospective assessments. They would be more problematic to implement in a forward-looking context.

population are going to be very difficult to calculate and, based on a variety of factors, the size of the population could be estimated to be larger or smaller.

Traditional epidemics go tragically bad, tragically quickly. But while naturally-occurring epidemics can break out very quickly, they are still characterized by a string of infectious encounters. One person infects a few more people, each of whom infects a few more people. In that string, each individual moves through the stages of the disease on their own timeline, staggering at least somewhat the infection, presentation of symptoms, and the time when medical countermeasures could be administered and still be effective. In a catastrophic bioattack, in contrast, tens of thousands of individuals would be exposed simultaneously or near-simultaneously and hence move through those stages at roughly the same time. For infectious diseases, classic public health measures tend to emphasize identifying the individual who caused the infection and then treating that individual and all of the people they came into contact with and hence could have plausibly infected. Such "contact-tracing" coupled with "ring vaccination" of those contacts around the infected individual has been extremely effective in managing countless epidemics. It was a key element of the strategy that led to the eradication of naturally-occurring smallpox. In a catastrophic biological attack, such a ring vaccination strategy would be overwhelmed by the simultaneous presentation of thousands or tens of thousands of individuals. Mass vaccination would be the only viable approach.[354]

This topic gets one into various lengthy debates in the security community about "plume modeling" or models showing where the plume of the aerosol release traveled based on its

[354] Henderson, "The Looming Threat of Bioterrorism," see page 1282: "With mounting numbers of cases, contacts, and involved areas, mass vaccination would soon be the only practical approach." Inglesby et al., "Management of Anthrax as a Biological Weapon." See page 1740: "Given the difficulty in achieving rapid, microbiologic diagnosis of anthrax, all persons with fever or evidence of systemic disease in an area where anthrax cases are occurring should be treated for anthrax until the disease is excluded."

direction and volume at the time of release and the intervening effects of weather patterns. To train the cadre of government and academic experts in biodefense, many institutions develop "scenarios" of how a bioattack could be conducted. These scenarios often make detailed assumptions about the specific equipment an attacker would use (the nozzle size of the sprayer, the volume of the canisters, the route of the trucks or other delivery vehicles, the prevailing weather conditions, and the specific characteristics of the pathogen, including whether it is a dry preparation or a wet slurry of a particular concentration, for example). These scenarios then generate findings about where the pathogen would be distributed in lethal doses. Based on data about the population density and distribution in those areas, the scenarios then make estimates about the number of people exposed to a lethal dose.[355] These models are very useful for the purpose for which they were designed: as a training tool for the cadre of public and private experts in biodefense and to provide insight into more or less dangerous types of attacks.

For decision-making, in a crisis, one would need very different sorts of models, integrating insights from both the public health and the defense worlds. In an actual attack, the decision-maker probably would have very little data. None of the painstaking arguments in the technical literature about the size of the nozzle sprayers would be particularly helpful because the nation probably would not know what size nozzle sprayer an attacker had used.[356] The type of

[355] These scenarios are very useful as a heuristic device but invariably engender significant arguments about the various assumptions. Often, the data is very poor and not because of the intellectual weaknesses of any of the authors but simply because the data is very poor. For example, while there is published lethal dose data that is used pretty consistently in these models, the authors of the lethal dose data are the first to admit it is based on very small numbers of animal challenges (or experiments where animals were exposed to a certain dosage of pathogen and their reactions observed over time), and so is vulnerable to both all the statistical weaknesses of extrapolating from a small sample size and all the biomedical challenges of extrapolating human effects from animal data. USAMRIID "Medical Management of Biological Casualties Handbook."

[356] One could certainly posit a situation where an abandoned sprayer truck is found along the roadside by the police after a biological attack has been launched and the equipment inside could be used to make vastly refined estimates about the extent and lethality of the attack. As a general rule, though, it is not wise to have the plan be getting lucky. There is no reason for the defender to expect to have precise information about the nature of the attacker's delivery vehicle in the immediate aftermath of the attack being launched. Detailed technical work on the size of nozzle

information that would probably be available would be a few hits on a few detectors perhaps of varying intensity, and the presentation of a small number of individuals with symptoms to various hospitals or clinics in the area. Particularly if there were positive hits on detectors, reasonably good estimates could be made about the approximate time of release and so records of relevant weather patterns could be examined. These records could inform estimates about where a plume would have traveled.

Based on this limited data, what would be most helpful to a decision-maker is a variety of plausible plume models showing the geographic areas likely to have been affected by the attack. Probably something like a small, medium and large plot of possible attacks should be developed. By looking at a map of deployed detectors, for example, and comparing them to which detectors were triggered in the release, some guess could be made about the smallest and largest possible size of the attack. One could judge that the underlying attack had to be at least this size to trigger the detectors it did trigger, but could not be any larger than this size or it would have triggered more detectors.

Similarly, the presentation of cases at local hospitals and clinics should be modeled to provide maximum insight into the likely size of the underlying exposed population. Like most phenomenon when it occurs in sufficiently high number, disease presentation would be expected to follow a standard statistical distribution if the underlying exposed population was large enough. Assuming that an underlying population of 500,000 had been exposed at essentially the same time to anthrax, a few individuals would be expected to show symptoms at the early end of the expected disease presentation timeline. These individuals might have the weakest underlying

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sprayers done well in advance of an actual attack would be helpful during an actual attack to the extent it helped the defender bound the plausible size of the sprayers used by the attackers.

immune system or might have gotten a relatively high exposure to the pathogen. Statistical modeling should be able to assess, pathogen by pathogen, what various rates of presentation and their geographic distribution predict, with what degree of confidence, about the nature of the underlying exposed population, both its size (which theoretically could be zero or millions) and its geographic distribution. These statistical models would be slightly different if the initial triggering information came from clinical diagnosis (relatively longer after the exposure) or a confirmed hit on a detector (relatively earlier after the exposure).

There should be strong pressures against presenting one solution unless the data were unusually robust and one solution actually could be calculated confidently. The tendency in government would be for every agency to develop one favored plume model and for the different models to be argued about in lengthy interagency meetings. One model would then emerge as the winner of this process, based on criteria possibly the same as technical coherence but possibly also the presentational skills of the representative of its host agency. The decision-maker would be best served by being told that the available data made it impossible to plot the attack exactly and be shown the range of possibilities as clearly as possible and the uncertainties that characterized the alternatives.

Once the range of plausible affected populations had been calculated, several factors relevant to the available countermeasure need to be factored into the calculation. The first and most significant in this phase would be the expected rate of adverse reactions to the countermeasure, particularly with limited screening. Given that the decision-maker is only making educated guesses about the size of the underlying, exposed population, the more adverse reactions caused by the medical countermeasure, the smaller the population that should be assumed, other factors being held constant. Some medical countermeasures have very few

adverse reaction rates and even the adverse events consist largely of hospitalization but not death. This largely describes common antibiotics like ciprofloxine, which causes adverse reactions in less than one percent of the population and even those events tend not to be fatal. With such a countermeasure, the model would probably want to err on the side of the largest plausible exposed population. In contrast, the traditional smallpox vaccine caused one death in a million vaccinations when it was widely used prior to the 1970s.[357] A newer vaccine has fewer adverse events but is available in a significantly smaller quantity. Particularly for the traditional vaccine, with its dangerous adverse reaction profile, more conservative assumptions probably should be used in the identification of the relevant population.

It is worth noting that the individual interest in vaccination decisions, particularly prior to a significant disease outbreak, often would be different from the societal interest in the case of infectious disease. Every medical countermeasure causes some adverse events. One could imagine, particularly for a contagious disease that the best outcome for any particular individual would be for everyone else to get vaccinated and for them and their family not to be vaccinated.[358] These phenomena are strongest, though, in contexts where the risk of the contagious disease has disappeared (because of the success of the vaccination policy over time)

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[357] Centers for Disease Control and Prevention, Emergency Preparedness and Response, Smallpox Fact Sheet, "Side Effects of Smallpox Vaccination, CDC website (http://www.bt.cdc.gov/agent/smallpox/vaccination accessed 02/21/2009); Cono, et al., "Smallpox Vaccination and Adverse Reactions."

[358] Paul E. M. Fine and Jacqueline A. Clarkson, "Individual Versus Public Priorities in the Determination of Optimal Vaccination Policies," *American Journal of Epidemiology*, Vol 124, No 6, page 1012 – 1020, see page 1012: "There is a tendency for governments to decide whether or not to offer routine vaccination on the basis of arguments of financial cost, whereas individuals decide whether or not to accept vaccination on the basis of their perception of the risks involved. Furthermore, some vaccines impart, or appear to impart, a degree of indirect protection to nonvaccinated individuals in the community. For both of these reasons, public motives concerning vaccination differ from those of the individual. The quantitative implications of these differences are explored in this paper. It is found that, under a broad range of conditions rational informed individuals would "choose" a lower vaccine uptake than would the community if it acted as a whole."

and the real and present risk is from the adverse events from the vaccination.[359] These phenomena would probably be much less present in a raging epidemic in the aftermath of a catastrophic attack. For cases where the vaccination was recommended in advance of an attack, there would be stronger opposition based on the reality that society in general benefits from vaccination but individuals bear the cost, in the form of the generally rare but sometimes serious adverse events.

The second consideration is that while all of the timelines for responding to a biological attack are compressed, some are more compressed than others. If immediate response is necessary to have any real prospect of saving lives, more should be favored to receive countermeasures. If there is a little more time, the time should be used to further refine the estimates and see whether additional cases with the disease present themselves. Most countermeasures provide only a few days between exposure and administration of medical countermeasures to be effective.

It is these inherent uncertainties about the size of the underlying exposed population when there is a single case of biological disease that makes this dissertation argue that the responsibility for strategic decisions be vested in the President regardless of the size of the incident. In the first few days it will be ambiguous if the cases of anthrax, for example, are isolated cases that arise from natural causes or whether they are leading cases of a large, underlying exposed population. If responsibility transfers to the President only when it has been demonstrated that there is, indeed, a large, underlying exposed population than all of the useful time has been spent learning that fact. The time could have been used to transport the stockpile

[359] C. Feudtner and E.K. Marcuse, "Ethics and Immunization Policy: Promoting Dialogue to Sustain Consensus," *Pediatrics*, Volume 107, Issue 5, May 2001, pages 1158-1164.

and begin setting up distribution networks for the medical countermeasures. Much of the benefit of rapid response will be lost if every case of biological exposure is not immediately treated as a possible catastrophic biological attack that needs to be subjected to through substantive assessment. That substantive assessment should not be skewed to assume that every case of anthrax, for example, is the leading edge of a large, underlying exposed population. The analysis should assure the question is informed by the best possible integration of public health and security insights. As the biodefense community learned in 2006, some cases of naturally occurring disease are just naturally occurring. They have no strategic requirements beyond getting the individual in question the best possible medical treatment.[360]

*(3) Assessment*

Once the best possible assessment has been made of tactical warning and characterization of the attack, the decision-maker would need to stand back and judge how to respond given the broader strategic context. The previous two sections – tactical warning and characterization – have dealt with issues that were basically technical. This section deals with more strategic calculations. There would be a broader set of issues, including, for example, the allocation of scarce medical assets in a crisis, and the use of technical capacity to build an international coalition.

If an appropriate medical countermeasure was available in the strategic stockpile, there are arguments on both sides of the question of whether the relevant population should be flooded with the countermeasure. On the one hand, using the countermeasure widely to staunch the epidemic and minimize deaths would be very wise. It would save the maximum number of lives,

[360] A New York City man got inhalational anthrax in February 2006 as a result of using African animal skins to make drums. Anthrax can be found naturally occurring in livestock. Center for Infectious Disease Research and Policy, University of Minnesota, "New York Man has First US Anthrax Case Since 2001."

reassure the public, and discomfort the enemy. On the other hand, while these calculations are scenario-dependent, there would probably be no particular reason to assume that an attacker would be quantity-constrained in terms of the amount of biological pathogen he possessed.[361] If the risk of reattack by the attacker using the pathogen seemed significant, the policy-maker might want to hedge by retaining stores of the medical countermeasure and so use the countermeasure as sparingly as possible.

Particularly for a contagious disease like smallpox, there would significant and not unjustified fears that at least some contagion would be spread abroad even if the initial attack was in the United States. The international community would likely want some pledge of access to countermeasures, particularly if they were not available abroad. The United States would have a significant interest in working closely with the international community. Deterrence against reattack would be strengthened if the initial attack was condemned by the international community in the strongest possible terms; if the political goals of the attacker were harmed, not helped, in international forums; and if the United States was given a freer hand in pursuing suspicious actors or investigating suspicious sites, including, for example, across international boundaries. These would be core US interests in the aftermath of an attack that would be strengthened by building and maintaining international condemnation of the attack. That international condemnation likely would be strengthened by having the capacity and protocols in place to share at least the recipes for if not the medical countermeasures themselves. That national value would have to be balanced against the stark reality that these countermeasures likely would be exceptionally limited in quantity.

[361]Biological agents are not meaningfully quantity-constrained. Acquiring the seed stock for a pathogen can be more or less straightforward. Once the seed stock has been obtained, the only constraint in getting more of the pathogen is acquiring growth media (a common supply in a biological laboratory used for many, benign purposes) and having time and laboratory space. Fissile material, in constraint is quantity constrained in the sense that processing the second gram of fissile material is only slightly easier than processing first gram.

*(4) Relevant Literature*

The need for these types of decision aids has not been discussed in the literature. These decision aids fall between the natural interests of the two relevant communities – the public health literature and the security literature. The strength of the public health literature is the great sophistication of its knowledge of the progress of the diseases and the likely adverse effects of the various medical countermeasures. The weakness is its failure to focus on the implications of the simultaneous or near-simultaneous exposure of thousands, tens of thousands or hundreds of thousands of individuals to the disease. In the public health literature, the factual limits on timelines are noted but the implications for response are generally not fully developed. The public health community has developed some decision aids to speed individual diagnosis of exposure to a dangerous pathogen, but not to speed decision-making about whether and to what extent a large underlying population has been exposed.[362]

The small security literature on biodefense has focused on strategies to speed delivery of needed medical countermeasures, but not on the challenges of the characterization and assessment period. The challenges of the characterization and assessment period analytically are similar to classic security work on indications and warning, but that intellectual community thus far seems to have successfully avoided the intellectual challenge of catastrophic biological attack.

The security literature has long puzzled over the intellectual challenge of decision-making under extreme uncertainty and severe time pressure. Theater commanders have to decide

[362] One of the best examples of the type of analytics that should be further developed can be seen in Wiener, "Biological Warfare Defense" in Pilch and Zilinskas, eds., *Encyclopedia of Bioterrorism Defense,* see pages 146-148: Wiener has three simple decision trees that outline, for example, a diagnostic algorithm for infectious agents. Such decision-trees are extremely useful and should be extended. They would need to be crafted with a slightly different perspective to aid macro-level crisis decision-making, as opposed to individual diagnosis.

whether and when to start moving forces in one direction. If they do move the forces in one direction, the forces are mal-positioned to move in the other direction if that is where the war starts first. While many military aphorisms deal with the limits on information in war, the most elegant discussion is in Clausewitz: "The textbooks agree, of course, that we should only believe reliable intelligence, and should never cease to be suspicious, but what is the use of such feeble maxims? They belong to that wisdom which for want of anything better scribblers of systems and compendia resort to when they run out of ideas."[363] The intertwining of planning with uncertainty can be seen in the best conceptual defense planning: if a particular step has to be taken well in advance of a particular military risk to be effective and is relatively inexpensive, the step is often taken as a hedge even when the indications that the risk is looming are relatively small. The decision to take the hedging step gets harder, of course, if the step is very expensive.

*Decision-Making Literature*

There is an extensive literature on decision-making that underscores the many potential sources of miscalculation and hence misstep in a crisis. While the literature is large and agrees on little, the various theories of decision-making would either support the development of decision aids such as are described in this chapter or at least be neutral about them.

The literature does offer a caution against creating pre-determined sets of behavior to be undertaken in a crisis that possibly could appear to an opponent to be offensive. Jervis has interestingly outlined the risks associated with situations where it is difficult to tell offensive and

[363] Clausewitz, *On War,* see page 117: See the probably even more famous: "Many intelligence reports in war are contradictory; even more are false, and most are uncertain....[An officer] should be guided by the laws of probability. These are difficult enough to apply when plans are drafted in an office, far from the sphere of action; the task becomes infinitely harder in the thick of fighting itself, with reports streaming in."

defensive actions from one another.[364] The general danger of a defensive action being perceived as offensive is real, as is the risk that defensive measures may in fact have offensive effects. The most famous case is the launching of defensive operations that involved conducting offensive measures, like seizing neutral territories at the outset of World War I.[365]

The decision aids recommended here do not seem likely to appear to be offensive, even to an observer inclined to assume the worst about the United States. These aids would try to inform a decision about whether to administer a medical countermeasure to a portion of the US domestic population. The decision-maker would have very limited information – perhaps a few positive readings on detectors or a few patients presenting to emergency rooms with unusual although probably still somewhat ambiguous symptoms. The administration of medical countermeasures or other palliative measures to members of the civilian population in the US homeland does not seem likely to appear to be offensive. It seems clearly to increase defense-dominance, in other words, making the US population less vulnerable to bioattack and hence perhaps making the US more inclined to further investigate a suspicious set of events instead of

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[364] Jervis, "Cooperation Under the Security Dilemma," see page 186-187: "Another approach starts with the central point of the security dilemma—that an increase in one state's security decreases the security of others—and examines the conditions under which this proposition holds. Two crucial variables are involved: whether defensive weapons and policies can be distinguished from offensive ones, and whether the defense or the offense has the advantage. The definitions are not always clear, and many cases are difficult to judge, but these two variables shed a great deal of light on the question of whether status-quo powers will adopt compatible security policies." Offense has a very powerful advantage in the case of bioattack and hence the security dilemma would be expected to operate powerfully. For the argument that the offense has the advantage in a biological attack, see Koblintz, *Pathogens as Weapons*, PhD diss.

[365] Steven E. Miller, "Introduction: Sarajevo after Seventy Years," in Steven E. Miller, ed., *Military Strategy and the Origins of the First World War,* (Princeton, NJ: Princeton University Press, 1985), see page 3: "[T]he wellspring of disaster in 1914 resided in the unwavering and wholehearted commitment of all the major European militaries to offensive doctrines – despite the overwhelming defensive advantages afforded by prevailing technologies. It was this profound belief in the primacy of the offensive that linked the mobilization plans of the major powers, one to another, that made speed necessary and preemption desirable, that limited the opportunities for diplomacy while creating an irresistible dynamic of escalation, that took policy from the hands of the political leaders and put it in those of the generals. By the summer of 1914, all the major continental powers – in particular, France, Germany, and Russia – had adopted offensive military doctrines and in the July crisis this collective offensive-mindedness resulted in such severe political-military instability that a single murder in Serbia triggered a world war."

immediately launching a military attack against the assumed attacker. The US ability to launch an attack would not be commensurately increased by the administration of medical countermeasures to the civilian population.

With that caveat, the extensive literature on decision-making would either agree that these decision aids would be useful or would be neutral about their development. The aids could have the effect of mitigating various problems, including the effects of complexity, time pressure and stress, that many explanations of decision-making point to as the fundamental cause of strategic miscalculations.

There is no comprehensive theory of decision-making. The literature on decision-making probably is best understood if divided into what the various authors believe is the fundamental determinant of outcomes in the international environment or in more academic terms, their "unit of analysis": the international state system, the state, or individual decision-makers.[366] There are various theories about how the decision-making process works at each of these units of analysis and these theories would accord decisions aids greater or lesser utility.

The traditional perspective is to look at the largest unit of analysis, the traditional state system. In this perspective, the nation-state is judged to be a unified actor within the international state system that rationally seeks to maximize utility in all decisions. Realists, structural realists and even neo-functionalists all basically use this perspective in their work,

[366] Kenneth Waltz provided probably the most elegant summary of this debate in *Man, the State and War*, (New York: Columbia University Press, 1954): "Where are the major causes of war to be found?...[Are they] within man, within the structure of the separate states, [or] within the state system." Waltz points out that both realist and liberal explanations can be found in each of these "units of analysis" or, as he calls them, first, second and third images of the structure of international relations. One can argue that within the international state system, for example, lies either the opportunity for peace, through international organizations or even world government, or the inevitability of conflict because of the unavoidable competition between nation states. Similarly, the various explanations of decision-making can be sorted into characteristics of individuals, of the state, or of the state system.

while recognizing some of the constraints in its pure application.[367] Since this model assumes rational behavior by the nation-state, it would expect the state to have both the desire and the capacity to automatically conduct the kind of cost-benefit analysis called for here. These theories would support development of analytically-based tools to aid rational decision-making.

The second unit of analysis is the state itself, with all of the competition and conflicting interests that come together to create the modern state. The focus on the state as the appropriate level of analysis has been a more recent perspective. There are two basic theories of the state as the unit of analysis. First, that the "right" answer exists not for the nation state but for a particular bureaucratic entity and the "national policy" that emerges is the victor of the tugging and hauling inherent in the inevitable conflict among these different bureaucratic entities.[368] The second basic theory is the observation that process affects outputs. There are several variants on this central insight. One is that the process of working together yields a group dynamic,[369] while another argues that the standard operating procedures of the government affect the outcomes.[370] These theories would have no objection to the construction of decision aids, but would doubt their effect, unless their advocates were for non-substantive reasons somehow bureaucratically favored.

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[367] For representative examples of these perspectives and the core role of a unitary, rational-actor state in their calculations (however much that role is constrained, caveated, or regretted), see Kenneth N. Waltz, *Theory of International Politics* (New York: Random House, 1979); Robert Gilpin, *War and Change in World Politics* (Cambridge,UK: Cambridge University Press, 1981); Robert O. Keohane, *After Hegemony: Cooperation and Discord in the World Political Economy* (Princeton, NJ: Princeton University Press, 1984); Joseph S. Nye Jr., *Bound to Lead: The Changing Nature of American Power* (New York: Basic Books, 1990).

[368] This refers most directly to Allison's Model III or governmental politics. Allison and Zelikow, *Essence of Decision.* Allison outlines the now-famous three models for explaining foreign policy outcomes: rational actor; organizational process; and governmental politics. His work underscored that "palace politics" was a critical component to explaining foreign policy outcomes. See also Halperin et al., *Bureaucratic Politics & Foreign Policy,* see page 311-312: "A government is not, in fact, a single individual with a single purpose and an ability to control completely his actions. Rather each government consists of numerous individuals [with]... very different interests, very different priorities, and ... very different questions."

[369] Irving L. Janus, *Groupthink,* (Boston: Houghton Mifflin Company.1982).

[370] This is best captured by Allison's Model II or "organizational politics." See Allison, *Essence of Decision.*

The third level of analysis is the individual. Many decision-making theories place the core of the decision process here – either in the common errors to which all individuals are prone or the unique perspective of a particular individual. The classic rational model of decision-making implicitly believed all theoretical courses of action were outlined and weighed for their strengths and weaknesses and the option was selected that maximizes utility. Most analysts now judge that this classic, rational model called for analytical efforts that were too complex for an individual to perform, particularly under severe time-pressure and stress. Most analysts have accepted an alternative theory that argues that instead of maximizing utility, officials tend to satisfice or identify an option that is acceptable and then stop searching for alternatives.[371]

Perception has been seen as a significant problem, with individuals tending to see hostile intent even where none was meant.[372] Incrementalism was underscored, with cybernetic theories of decision-making describing how individuals watch their feedback from a few key variables and adjust their next round of behavior to maximize these variables.[373] The mistake of selecting the wrong key variables would obviously be a serious problem. Stress further corrodes decision making skills.

More recent decision-making theories focused on the individual have used experimentation, close process-tracing or quantitative coding of large numbers of foreign policy interactions to identify characteristics of the individuals and correlate decisions with those characteristics. Prospect theory has emerged from this work and divides decision-making into two categories: editing and evaluation. This work stresses the great importance of framing

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[371] Herbert A. Simon, *Models of Bounded Rationality* (Cambridge, MA: MIT Press, 1982).
[372] This is a principal insight of Jervis's security dilemma, "Cooperation Under the Security Dilemma." The issue of perception is further developed in Jervis, *Perception and Misperception in International Politics.*
[373] John D. Steinbruner, *The Cybernetic Theory of Decision: New Dimensions of Political Analysis* (Princeton, NJ: Princeton University Press, 1974).

decisions carefully, demonstrating that even "trivial aspects of framing options can consistently exert profound impacts on the substance of choice." It also warns that most individuals are risk adverse in ways that are not consistent with a "rational" model for decision-making, fearing downside risk more than upside risk.[374] In a biological event, this would be consistent with the behavior often observed in exercises such as TOPOFF: policymakers greatly fear the risk associated with the decision to administer medical countermeasures by mistake (and causing adverse medical reactions to the countermeasure) but tend to minimize the risk that a catastrophic biological attack has occurred and thousands could die if nothing is done. The vast and disparate literature on individual decision-making would strongly support well-crafted decision aids to correct these various human analytical weaknesses.

For the purposes of the present paper, an interesting finding is that while there is a lively debate within the decision-making literature over the appropriate "unit" of analysis and, even once one has agreed on the unit, a lively debate about causes, all of the decision-making theories either would support the development of decision aids such as are called for in this chapter or would be neutral about them. For those who root the cause of outcomes in the individual or the state, these types of analytics would mitigate against the various perversities that are vulnerable to emerging. Those who root the causes in the state system itself would either support these analytics or would be neutral to them. For the realists, these aids would strengthen the probability that the nation would act in a way consistent with its national interest and prestige, thus reducing the benefit of the initial attack and increasing deterrence against a subsequent attack. The only caution would be if the measures the decisions aids would cause could be

[374] Rose McDermott, "Experimental Methods in Political Science," *Annual Review of Political Science,* 2002, Volume 5, pages 31-61. Quote from pages 49-50.

perceived by an opponent to be offensive and hence to catalyze spiral model dynamics. These measures seem unlikely to be perceived as offensive, even by a skeptical observer.

*Conclusion*

The previous chapter focused on clarifying who was in charge of the response to a catastrophic biological attack on the homeland. It argued that the president should immediately take responsibility for making the strategic decisions shaping the response to any biological event. The disasters, accidents and epidemics that have historically characterized traditional defense of the homeland generally have not required strategic decisions. The public safety objective of traditional defense events has generally been straightforward. This chapter outlines the types of strategic decisions that would be needed in a biological event. It recommends the development of probabilistic decision aids to assist in making these judgments and discusses the substantive content of those decision aids. The chapter reviews the academic literature on decision-making and finds that writers of all perspectives would support or be neutral about the development of these types of aids.

The strategic decisions for a potential catastrophic biological attack would be complex – deciding, for example, on relatively scant data to medicate a specific, largely unscreened population with a medical countermeasure. The "decision aids" would attempt to inform questions like the probability that one or two human cases of anthrax exposure were from a naturally-occurring benign cause, as opposed to being the leading edge of a large population exposed in a simultaneous or near-simultaneous catastrophic attack.

These types of aids have not been developed because they integrate intellectual concerns from two different but very distinguished intellectual traditions – the public health literature with

its concern for saving lives but minimizing adverse events from medical countermeasures, and the security literature with its acceptance of the need to act swiftly in a crisis on imperfect information. Unifying the complex, technical insights from these intellectual traditions in advance of a crisis seems wise. As the decision-making theories warn, even the most talented individuals can stumble under time pressure and stress. Stumbling analytically in the initial hours or days of a catastrophic biological attack would yield a poor response and a poor response would yield more deaths.

## Defense: Chapter 11

### A Defensive Medical Countermeasure Strategy

In addition to the general challenge posed by any catastrophic attack on the homeland, a biological attack would pose some unique medical challenges. Public health was significantly transformed in the mid-1900s as targeted medical countermeasures became widely available for the first time. The enabling conditions for an effective public health response in this post-drug age are two-fold: one scientific and one societal. First, the bug must be relatively slow in evolving to defeat the countermeasure; and second, the broader public health infrastructure must be sufficiently committed and coherent that it can provide supportive, ongoing care in an appropriate environment.

Several examples illustrate the interaction effects within and between these scientific and societal factors. The speed with which the bug can defeat the medicine depends on the interaction of two qualities: the ease with which the bug mutates and the range of the medicine's effectiveness. This can be seen in cases where the inherent rate at which the pathogen naturally mutates is very rapid. Influenza, for example, has a genetic structure that facilitates rapid and significant natural mutations that defeat the flu vaccine with such predictability that the vaccine is reformulated annually.[375] Smallpox, in contrast, evolved slowly and the traditional smallpox vaccine had a broad range of effectiveness. The traditional smallpox vaccine remained effective across time and across geography. These and other factors, like the absence of an animal reservoir, enabled naturally occurring smallpox to be eradicated.[376] The importance of a robust

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[375] Centers for Disease Control and Prevention, "Key Facts About Seasonal Flu Vaccine," CDC website (http://www.cdc.gov/FLU/protect/keyfacts.htm accessed 4/3/2009).
[376] News-Medical Net, "Smallpox Evolved Earlier Than Believed," News-Medical Net website (http://www.news-medical.net accessed 4/3/2009). World Health Organization, "Smallpox," WHO website. Bruce Aylward, Karen A.

societal public health infrastructure is illustrated by comparing the ongoing incidence in poorer countries of diseases that are treatable and have been limited or effectively eliminated in more wealthy countries. There are vastly different survival rates for HIV-AIDs in the West as compared to Africa, for example, and there has been a virtual elimination of malaria in the West while it continues to cause death at a significant rate in Africa.[377]

*Likely Presence of Enabling Conditions*

Neither enabling condition would be expected to be present in the case of a catastrophic biological attack. The first enabling condition -- the bug must be relatively slow in evolving to defeat the countermeasure – would be defeated by adversaries exploiting natural mutation or mutation facilitated by 21st century biotechnologies. A characteristic of the biotechnologies is that for the foreseeable future it is expected to be vastly easier to modify a pathogen than to modify the medical countermeasure needed to defeat the new pathogen. This characteristic of the biotechnologies favors the attacker over the defender.[378] A situation where the attacker is favored over the defender is called offense dominant. Offense dominant situations are considered to be highly vulnerable to a host of destabilizing behaviors, including wars of preemption and defensive arms races.[379]

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Hennessey, Nevio Zagaria, Jean-Marc Olive, and Stephen Cochi, "When is a disease eradicable? 100 years of lessons learned," *American Journal of Public Health,* Washington: Oct 2000. Vol 90, Iss 10; page 1515, 6 pages.

[377]David M Morens, Gregory K. Folkerts and Anthony S. Fauci, "The challenge of emerging and re-emerging infectious diseases," *Nature,* Vol 430, 8 July 2004, pages 242-249. See page 242: "The burden of morbidity (ill health) and mortality associated with infectious diseases falls most heavily on people in developing countries, and particularly on infants and children ...." For a specific example, see Tom Smith, "Commentary: Malaria death rates remain highly pertinent," *International Journal of Epidemiology,* 2006 35(3): 704-705: There was an "estimated number of just over 800,000 deaths in children <5 years of age, for the year 2000" in Africa from malaria. In contrast, the CDC estimates there were 6 deaths in the United States from malaria in 2005, see Kung, et al., "Deaths," page 31.

[378] See for example, Koblentz, "Pathogens as Weapons" *International Security,* see page 13.

[379] Fetter, "Missiles and Weapons of Mass Destruction," see page 37: "The war against Iraq was a preventive war in the minds of many Americans. A primary goal of the war was to destroy Iraq's potential to make and deliver nuclear, chemical, and biological weapons – to make war now, rather than later when Iraq might be armed with

There is valuable research underway on defensive medical countermeasures and significant progress to report.[380] Overall, however, advances in the biotechnologies in the near and mid-term generally are expected to favor the attacker, not the defender.[381] The evolution of the defensive strategy is poorly aligned with the likely evolution of the threat, with insufficient focus on responding to the growing risk over time that an adversary would use a modified or unusual pathogen. Laboratory advances are poorly linked to needed progress in related capabilities, like increased and speeded production capacity. The long-term strategic objective of shifting this area of warfare from offense dominant to defense dominant remains well beyond the reach of the resources currently applied to this objective.[382] This chapter discusses the proposed substance and structure of a medical research program to develop needed defensive medical countermeasures.

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long-range weapons of mass destruction. The destruction of the Iraqi Osiraq reactor by Israel is another example of a preventive use of force."

[380] H. Clifford Lane, John La Montagne and Anthony S. Fauci, "Bioterrorism: A clear and present danger," *Nature Medicine,* Volume 7, Number 12, December 2001, pages 1271-1273. Anthony S. Fauci, M.D., "Statement on Biodefense," National Institute of Allergy and Infectious Diseases website (http://www3.niaid.nih.gov/topics/Biodefense Related/Biodefense/about/directorsstatement.htm accessed 6/3/2008). National Institute of Allergy and Infectious Disease, Progress Report, "NIAID Biodefense Research Agenda for CDC Category A Agents, August 2003, National Institutes of Health, NIAID.

[381] Authors agree this characterizes the current situation and the foreseeable future, the near and mid-term. Authors argue that the net effect of technical trends in the mid and long-term is impossible to predict. Mid and long-term innovations that favor the defender are what gives at least hope to the category called here "transformative strategies." The ambiguity about the net effect of technological trends in the mid and long-term is acknowledged in Koblentz, *Pathogens as Weapons*, see page 13: "Whether the biotechnology revolution will strengthen the defender or allow attackers to maintain their edge in this competition is unknown." And the National Academy of Sciences, *Biotechnology Research in an Age of Terrorism.*

[382] There has been a significant increase in the resources devoted to biodefense in the United States over the past ten years. The total amount of USG civilian biodefense funding has increased from $576 million in FY2001 to a request of $5, 421 million in FY2008, an order of magnitude increase. The size of the program from FY2001 through FY2008 request is estimated at $40 billion. The level hit about $8 billion in FY 2005 and saw relatively small decreases in subsequent years. The Obama administration appears likely to only further reduce amounts. They identified the procurement fund for defensive medical countermeasures (Bioshield) as a source of reprogramming should additional funds be needed for H1N1 purchases. For the overall biodefense numbers, see Table 1in Franco and Deitch, "Billions for Biodefense," For the Obama administration request on reprogramming the Bioshield monies, see Spencer S. Hsu, "Bipartisan WMD Panel Criticizes Obama Plan to Fund Flu Vaccine," *The Washington Post,* Monday, June 8, 2009.

The next chapter discusses the second enabling condition – that the broader public health infrastructure must be sufficiently committed and coherent that it can provide supportive, ongoing care in an appropriate environment. This second enabling condition also would not be expected to be met in a catastrophic biological attack. A catastrophic biological attack would stress the medical infrastructure anywhere and, while cross national comparisons are difficult, the United States is probably as well prepared as any other country. There is a broadly held view, though, that the current public health infrastructure in the United States would be overwhelmed by a bioattack of any significant size.[383]

While there are a variety of activities underway to strengthen all of these medical capabilities, there is neither an academic nor a policy literature that explains how the various activities fit together to form a complete national capability.[384] Solutions, when proposed, have an odd quality of disconnect from the institutional context within which they would need to be implemented. The literature is plagued by the limits of the various professional disciplines that produce it, with the life sciences literature focused on particular technical issues and the security literature analogizing from other security problems to the highly dissimilar biological problem. This paper seeks to align the incentives of various relevant actors -- life science researchers, non-state actors, and public health officials, among others – with broader national and international security interests. Non-state actors contemplating a biological attack need to be deterred or defeated, while states need to be reassured that wars of preemption, arms races or other

[383]This view is widely held among those who believe there is any meaningful risk of an attack occurring. See, for example, Inglesby, "Observations from the Top Off Exercise," see page 67: "Not unexpectedly, the logistics of antibiotic distribution proved quite complex....the ensuing local distribution process did not go smoothly." Falkenrath,et al., see page 311: "...local medical services could easily be overwhelmed after a large attack...."

[384] The bureaucratic division of responsibility between DHS and HHS remains ambiguous. See, for example, the discussion in the Congressional report on the response to Hurricane Katrina somewhat delicately observes that top officials at HHS and DHS did "not share an understanding" of their relative roles in the medical aspects of a response. See House of Representatives, *A Failure of Initiative*.

destabilizing behaviors are not warranted to protect their citizens from the risk of biological attack.

*Recommendations for Refinements*

This dissertation makes two recommendations. First, it outlines the proposed substance for a defensive medical countermeasure strategy. Second, it urges that these efforts to strengthen medical countermeasures be placed in the context of an open international scientific exchange. These strategies would best align incentives and resources, both technical and fiscal, with the broader strategic objectives.

The first recommendation focuses on the substance of the research strategy. The medical countermeasure strategy that needs to be conducted is very complicated. It should seek to align the evolution of the defenses with the likely pace of technological advances on the part of the adversary. The substantive content of a complete medical countermeasure strategy should include a continuum of activities focused on providing capabilities over time, as both the likely nature of the threat and of the possible defensive capabilities advance. On one end of this conceptual continuum would be stockpiled medical countermeasures against known pathogens. The continuum would progress through rapid adaptation, a strategy that seeks to strengthen the ability to craft a countermeasure tailored to an adversary's modified pathogen after the adversary launched an attack. The end-point of the continuum would be transformative strategies, a category that includes the broad spectrum countermeasures and other revolutionary approaches that rapid advances in the biotechnologies may make possible over time. All three parts of this strategy – stockpiling, rapid adaptation, and transformative strategies -- would need to be pursued simultaneously, although perhaps not with equal emphasis, as some protect against near-

term threats and others offer the long-term prospect of eventually diminishing if not effectively blunting the biological threat altogether.

The second recommendation focuses on how to structure such a medical research strategy. The dissertation recommends that a defensive countermeasure program be pursued as part of an international scientific exchange. There could be significant benefits to such an international approach, including reduced spiral model effects and strengthened deterrence model effects. The dissertation's earlier discussion on norms focused on another possible benefit: that the prospect of participating in the scientific exchange could catalyze the broadest possible international adoption of norms on biosafety, biosecurity and worrisome dual use research. Adopting the norms nationally would be the price of admission to the international exchange. There also would be significant benefits to the United States from the participation of other countries in the scientific exchange – these benefits would be the direct benefits of the technical and fiscal contributions by other nations and the indirect benefits of the synergy of international research efforts in a cutting edge field like the biotechnologies.

This dissertation's recommendation that the medical countermeasure strategy be pursued in the context of an international scientific exchange appears to be in direct contradiction to emerging US policy. The United States appears to be constructing a national, unilateral system to enforce norms in this area. A national, unilateral system would provide a security benefit but would impose security, economic and technological costs. This benefit and the associated costs are discussed in the chapter on norms.

The decision about whether to pursue an international program would be very complex. It turns on many assumptions, including about the evolution of the relevant technology. There

are eight areas of concern. As a presentational device, they are stated as propositions in favor of the proposal but each rests on complicated judgment calls and can be legitimately questioned and rejected. There are eight propositions:

(1) Requiring the adoption of norms on biosafety, biosecurity and worrisome dual-use research as the price of admission to an international scientific exchange on defensive medical countermeasures would catalyze the broadest possible international adoption of these norms;

(2) The process of developing and implementing international norms and pursuing a shared defensive medical countermeasure program would cause a broader effect in the relevant technical communities of status quo states, reducing spiral model effects because of the vastly greater – although not necessarily complete – transparency it would create;

(3) Given the global distribution of research excellence in the biotechnologies, creating an open international research program would be the only strategy that could assure the US defensive medical countermeasure program remained at the cutting edge of technology;

(4) Given the inevitable limitations on national resources and the enormity of the technical challenge, an open international scientific exchange would be the only strategy that had any prospect of applying sufficient resources to the challenge of developing a full suite of defensive countermeasures quickly enough that the scientific effort could achieve a core strategic objective -- moving biodefense from offense dominant to defense dominant in the foreseeable future;

(5) The benefits of secrecy are limited (but not zero) in a defensive medical countermeasure program and these benefits would be expected to go down over time as the program transitions from a strategy of stockpiling (or "one bug, one drug") to a strategy of rapid adaptation;

(6) Strengthening the defensive medical countermeasures available to the United States and its international partners through an international scientific exchange would greatly strengthen deterrence because it would increase the probability that a bioattack would fail because of effective defenses and hence increase deterrence;

(7) Because of various characteristics of the technology and the security environment, these norms and the countermeasure program would be best implemented through an informal scientific exchange instead of the institutionalized structures used more traditionally, like the IAEA and the OPCW; and

(8) An historical vulnerability of international agreements – an inappropriate surrender of domestic autonomy – would be avoided in this case and the United States would properly retain and exercise autonomy in pursuing any needed classified medical countermeasure programs and diplomatic, intelligence and law enforcement initiatives.

Clearly some of these propositions strain credulity more than others. Each is discussed in more detail and the complex and sometimes uncertain pros and cons are weighed. Taking these considerations together, the dissertation recommends that an international scientific exchange be pursued.

This chapter has two objectives: (1) it outlines the proposed substantive content for a defensive medical countermeasure program; and (2) it considers the benefits and risks of an internationalized defensive medical countermeasure program.

(1) *Substantive Content of a Medical Countermeasure Strategy*

The substantive content of a complete medical countermeasure strategy should include a continuum of activities focused on providing capabilities over time, as both the likely nature of the threat and of the possible defensive capabilities advance. Specifically, the chapter urges that a continuum of activities be pursued. On one end of this conceptual continuum would be stockpiled medical countermeasures against known pathogens. The continuum would progress through rapid adaptation, a strategy that would speed the defense's ability to develop a tailored countermeasure in response to an adversary's unusual or modified pathogen after the adversary had launched an attack. The end-point of the continuum would be transformative strategies, a category that includes the broad spectrum countermeasures and other revolutionary approaches that rapid advances in the biotechnologies may make possible over time.

Points along this continuum represent both the likely progression of the nature of the threat and the possible progression in defensive capabilities. Put more simply, a near-term attack most likely would use a naturally-occurring pathogen and the response strategy that would bear benefits most immediately would be stockpiling known countermeasures, particularly against anthrax and smallpox. If the broad spectrum countermeasures that are one ambition of the long-term transformative strategy were available today, it would be better to buy them instead of smallpox vaccine. But broad spectrum countermeasures are not available today and, while the nation should start investing in the basic research needed to develop them as quickly as possible,

they are not likely to be available for purchase and use any time particularly soon. The progress through the continuum from stockpiling known countermeasures to transformative strategies, thus, integrates both the likely progression over time of the threat and the likely progression in defensive capabilities that could be extracted from the expected rapid advances in the biotechnologies.

Characterizing this progression as a continuum is not to imply that funds should be invested equally along that continuum. Policy-makers must assess the best information about the threat and decide whether a near-term attack is likely (in which case the stockpiles should be relatively larger and perhaps contain a wider set of antibiotics). If, on balance, the assessment was made that a near-term attack was not likely but one in the mid-term was likely, then funds should be preferentially invested in a strategy of rapid adaptation. The next three sections walk through the three strategies: stockpiling, rapid adaptation, and transformative strategies.

*Stockpiling*

Stockpiling known medical countermeasures against the most serious biological threats is a necessary component of a biodefense strategy. Anthrax and smallpox top almost every list of biological threats.[385] Both of these pathogens have high lethality and great robustness to survive in the environment. Nature makes more robust and deadly pathogens than could be produced confidently in just any lab, particularly in the near-term.

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[385] See, for example, Henderson, "The Looming Threat of Bioterrorism," see page 1281: "A Russian panel of bioweapons experts reviewed the microbial agents [in 1994] and concluded that there were 11 that that were 'very likely to be used.' The top four were smallpox, plague, anthrax and botulism. ... Each of the four top-rated agents is associated with high case fatality rates when dispersed as an aerosol. The rates range upward from 30% for smallpox to more than 80% for anthrax. Smallpox and anthrax have other advantages in that they can be grown reasonably easily and in large quantities and are sturdy organisms that are resistant to destruction. They are thus especially suited to aerosol delivery dissemination to reach large areas and numbers of people. Plague and botulinum toxin are less likely prospects. From experience in the now defunct U.S. bioweapons development program, producing and dispensing substantial quantities of plague organisms or botulinum toxin pose virtually insurmountable problems. Thus, smallpox and anthrax effectively stand alone at the top of the list among potential agents."

Smallpox kills a third of most unprotected populations. In populations that have not seen the disease before, more than two-thirds can be killed, effectively destroying the society.[386] Given that smallpox vaccination was generally stopped during the 1970s, much of the current population has not seen the disease before. Smallpox, from an adversary's point of view, is a great pathogen – tough and resilient in the environment and highly contagious. Many analysts believe there are stores of smallpox outside the two avowed and highly-secure stockpiles in Atlanta and Novosibirsk, Siberia.[387] After the world wide eradication of smallpox, the WHO requested that all stocks of smallpox except for these two be destroyed but there was no practicable way to assure compliance with that request.[388] The ability to construct even a complex virus like smallpox de novo in the lab likely will become more widely available over time.[389]

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[386] Ann Marie Nelson, "The Cost of Disease Eradication: Smallpox and Bovine Tuberculosis," *Annals of the New York Academy of Sciences*, pages 83-91. See page 86: "The potential for mass casualty and significant spread from a point source is exemplified by the history of smallpox spread in the New World during the age of exploration. Twenty-six years before the first contact of the Stolo society and European explorers, more than two-thirds of the tribe was wiped out by smallpox. The disease was introduced into the indigenous population of Mexico in 1779, more than 2,000 miles from the Stolo villages in British Columbia. Historians suspect that the epidemic spread up the river trading routes through the plains, the mountains and finally into the woodland and coastal tribes. The disease resulted in the loss of more than 60% of the population—corpses were piled in huts and burned. Because most deaths occurred during the peak of hunting and gathering season, many more were affected by starvation during the winter months. Not only was the population devastated, but the death of tribal elders also resulted in a tremendous loss of the oral traditions and culture of these people."

[387]NIAID Biodefense Research Agenda for CDC Category A Agents. Progress Report. August 2003, see page 13: "Although a worldwide immunization program eradicated smallpox disease in 1977, small quantities of smallpox virus still exist in two secure facilities in the United States and Russia. However, it is likely that unrecognized stores of smallpox virus exist elsewhere in the world."

[388]Henderson, M.D., e-mail communication with the author dated May 26, 2009.

[389] Viruses and bacteria vary significantly in their complexity. Smallpox is relatively complex. A more simple virus like the polio virus was built from scratch five years ago. Kaiser, "Proposed Biosecurity Review Plan Endorses Self-Regulation."

Anthrax, similarly, is well-suited to an attack, from an adversary's point of view. It is naturally-occurring in nature and is a tough, resilient pathogen when released into the environment. Inhalational anthrax historically kills about 80 percent of those infected.[390]

Other naturally-occurring pathogens available today could be used in a catastrophic attack. Most experts judge that, on balance, launching a catastrophic attack with a pathogen other than smallpox or anthrax would require greater technical competence on the part of the adversary. This is because the other pathogens have some vulnerability and hence would require more sophisticated manipulation to be deployed to catastrophic effect. An example might be the hemorrhagic fever viruses, many of which are very deadly but which would be difficult to deliver effectively in aerosol form to cause catastrophic effect.[391] Another example is plague which also is very deadly but fragile and thus requires sophisticated weaponization to cause a catastrophic attack.[392]

Stockpiled countermeasures are critical. Coupled with a plausible distribution and deterrence strategy, they make it less likely that an adversary would launch a smallpox or anthrax attack because they reduce the likelihood the attack could succeed. The United States has

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[390] Henderson, "The Looming Threat of Bioterrorism," see page 1281. The lower death rates after the 2001 exposures give some hope that modern medicine can achieve better outcomes although the intensive medical attention given to each of the five people who were sickened would probably be unattainable in the aftermath of a catastrophic attack.

[391] Luciana Borio, MD et al, "Hemorrhagic Fever Viruses as Biological Weapons: Medical and Public Health Management," *Journal of the American Medical Association,* May 8, 2002 Vol 287, No 18, page 2391 – 2405. See page 2392: the article notes, for example, that dengue would be very difficult to transmit through small-particle aerosol (the most likely mode for catastrophic attak) and Crimean-Congo hemorrhagic fever and the agents of HFRS "do not readily replicate to high concentrations in cell culture...."

[392] Recall Henderson, "The Looming Threat of Bioterrorism," see page 1281: "From experience in the now defunct U.S. bioweapons development program, producing and dispensing substantial quantities of plague organisms or botulinum toxin pose virtually insurmountable problems." Technical advances since the end of the US bioweapons program in the 1970s, though, of course, may have made these previously "virtually insurmountable problems" somewhat more surmountable.

stockpiled "antibiotics, chemical antidotes, antitoxins" and other medical supplies.[393] Naturally occurring anthrax, for example, can be treated, in the initial 48-hour window of symptoms, by a broad range of antibiotics. In a crisis, once the contents of the national stockpile had been used, the government has arranged for follow-on stocks of medical materials through something called the "vendor managed inventory." Communities would then turn to the inherent stocks of antibiotics in the economy.

For most terrorist groups, particularly in the near-term, these standard pathogens would probably be the weapons of choice. For some groups, though, and for increasing numbers of groups over time, it would probably become increasingly likely that an attack would use a modified or unusual pathogen. Stockpiling known countermeasures is critical. But, particularly as time passes, a stockpiling strategy is something of a self-limiting strategy. Stockpiles of medical countermeasures are expensive.[394] They have a limited shelf-life and so, at some point, if they are not used, they have to be thrown away and replaced. Stockpiling is necessary but not sufficient, particularly as the technical sophistication of the adversary is expected to increase over time. A more flexible defensive strategy must be put in place for the mid and long-time given the expected progress in the technology and the resulting ease of delivering effectively an unusual or modified pathogen.

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[393] These items are contained the "Strategic National Stockpile" managed by the Centers for Disease Control and Prevention, Department of Health and Human Services. Emergency Preparedness & Response, Strategic National Stockpile, A National Repository of Life-Saving Pharmaceuticals and Medical Material. CDC website (http://emergency .cdc.gov/stockpile/index.asp assessed 3/26/08).

[394] Chyba, "Toward Biological Security," see page 128: "The BPRP created the National Pharmaceutical Stockpile (NPS) of antibiotics and other drugs that could be rapidly deployed to counter domestic outbreaks. The BPRP also funded pilot projects to bolster disease surveillance, improved capacity at the state and local levels, and sponsored research. In fiscal year 2000, the BPRP budget stood at $155 million, an amount that some experts viewed as only one-tenth the funding needed for the tasks required." Spending for medical countermeasures has increased from $81 million in FY2001 to a high of $1,157 million in FY2002, drawing back to about $500 million annually thereafter. Franco and Deitch, "Billions for Biodefense."

*Rapid Adaptation*

For the mid-term, a strategy of rapid adaptation would strengthen the ability to swiftly craft a tailored countermeasure after an adversary has delivered an unusual or modified pathogen. Over time, the number of possible modifications that could be made by an adversary is theoretically infinite. Even a large stockpile is finite. Based on current technical trends, an adversary is likely to be able to modify a pathogen sooner than the defender could field an effective broad spectrum countermeasure.[395] Hence a strategy of rapid adaptation seeks to build defensive capability against unusual or modified pathogens for which stockpiled countermeasures would not be available.

Building defensive capability against a modified or unusual pathogen would be very hard. In the mid-term, such a response would need to be built around the ability to adapt rapidly. Rapid adaptation means refining a tailored countermeasure after the adversary has launched an attack using an unusual or modified pathogen. The tailored countermeasure would be refined after the attack from a set of countermeasures whose "recipe" was developed prior to the attack but the countermeasure was not produced in quantity. The set of countermeasures developed in advance would need to collectively provide protection against the full range of modifications, as well as a set of platforms or other generic vehicles for packaging and administering the medicine. A defensive strategy of rapid adaptation would require three capabilities: rapid characterization of a suspect pathogen; screening and refinement of a set or pre-developed medical countermeasures; and rapid production.

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[395] A discussion of medical treatment options outlines that "penicillins are not recommended for the monotherapy of anthrax....[for a variety of reasons including] reports that scientists in the former Soviet Union had engineered penicillin- and tetracycline-resistant *B anthracis.*" See Robert A. Greenfield and Michael S. Bronze, "Current therapy and the development of therapeutic options for the treatment of diseases due to bacterial agents of potential biowarfare and bioterrorism," *Current Opinion in Investigational Drugs*, 2004 52): 135-140.

Pieces of this strategy are being pursued but the efforts are far from what is needed. The first piece -- rapid characterization of a suspect pathogen – is the most advanced. NIAID and its sister agencies are sequencing all major threat pathogens.[396] The second piece – screening and refinement of a set of pre-developed medical countermeasures – is not really underway. While interesting work is underway on medical countermeasures, it has three gaps. First, while valuable medical countermeasures are being developed, they are not being developed with an eye to yielding a set of countermeasures developed in advance that would need to collectively provide protection against the full range of modifications. There are several strategies that can be pursued to develop such a set of comprehensive countermeasures that are discussed in more detail. Second, the strategy should be developing more generic platforms or other generic vehicles for packaging and administering the medicine. Third, the process of tailoring a countermeasure in the crisis after an attack using an unusual or modified has not been refined. The organizations and their responsibilities in such a crisis have not been well-organized. Groups who would step into the breech with competancre exist but their efforts would be strengthened by a conscious delineation of authorities and refinement of capabilities well in advance of a crisis. The analytics of how the pieces fit together have not been outlined, pieces are missing and programs should be initiated to fill them, and efforts are needed to connect and

[396]These pathogens are more formally called "Category A-C priority pathogens." NIAID Biodefense Research Agenda for CDC Category A Agents. Progress Report. August 2003; see page 5: "NIAID has made a significant investment in the genome sequencing of microorganisms considered agents of bioterrorism. As a result of a coordinated federal effort with the department of Energy (DoE), CDC, the United States Department of Agriculture (USDA), and the National Science Foundation (NSF), and international partners including the Sanger Center, genome sequencing projects are ongoing for at least one strain of every virus or protozoan on the list of Category A-C priority pathogens. To date there is a completed or near completed genome sequence for every bacteria on the list, including *Bacillus anthracis, Clostridium botulinum, Yersinia pestis,* and *Francisella tularensis.* In addition, the coordinated federal effort has expanded the sequencing and annotation of variola major viruses. These sequences will be used for identifying potential microbial genetic signatures and targets for the development of drugs and vaccines against these agents."

rationalize the various pieces that do exist.[397] Absent a coherent, integrated and well-articulated strategy and supporting programs, a strategy of rapid adaptation probably could not work swiftly enough to be useful in a real crisis. Even with such a strategy, the timeline are very tight and demanding.

Rapid Characterization

The first step would be speeding the ability to characterize a threat pathogen in a crisis. Current capabilities should be able to recognize an unusual but natural pathogen. The technical challenge would be identifying the unique characteristics of a genetically modified pathogen.

Two routes might be taken by an adversary: (1) taking a known pathogen – like anthrax -- and then altering it genetically to heighten a desirable quality from the adversary's point of view, like lethality or its ability to defeat stockpiled medical countermeasures,[398] or (2) perhaps combining two pathogens with the ambition of getting the best qualities of each pathogen from an adversary's point of view, like combining a highly lethal pathogen with a highly infectious one.[399]

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[397] Such a strategy is called for in David A. Relman, M.D., "Bioterrorism – Preparing to Fight the Next War," *The New England Journal of Medicine,* Volume 354:113-115, January 12, 2006. Number 2: "A robust biodefense plan must be anticipatory, flexible, and rapidly responsive. It should exploit crosscutting technologies and cross-disciplinary scientific insights and use broadly applicable platforms and methods that offer substantial scalability. Examples include the use of "lab-on-a-chip" technology, based on advances in microfluidics, for rapid, sensitive, point-of-care diagnostics; computational approaches for predicting drug-ligand interactions; genomic tools such as microarrays and genome-wide screening for protective antigens; and automated robotic systems for rapid, high-throughput drug screening and the scale-up of vaccine production. Efforts to understand microbial virulence should emphasize the study of mechanisms and structures that are shared by a variety of agents."

[398] NIAID Biodefense Research Agenda for CDC Category A Agents." "Progress Report." August 2003, see page 14: "Australian scientists showed that introducing the murine IL-4 gene into ectromelia (mousepox) virus increased the virus's pathogenicity to the extent that standard vaccines were no longer protective."

[399] Zilinskas, "Possible Terrorist Use of Modern Biotechnology Techniques," see page 6: These tend to be called "chimeras" by the technical literature and are judged by at least some authors to be well-within standard capabilities. For a non-biological example, consider: "recently scientists were able to insert genes, and appropriate promoters, that code for scorpion neurotoxins into a virus used for insect control to improve their insecticidal effectiveness."

There is a largely implicit debate in the life sciences literature about how easy it would be to make such a modification. At least some biologists warn that a cell is not entirely like a lego set and making an alteration in one characteristic (like increasing lethality) sometimes has unexpected effects in other characteristics (like decreasing infectiousness).[400] The net effect of a particular alteration on the total organism apparently is sometimes difficult to predict. Other biologists argue that any such difficulties would be quickly swept aside by the rapidly advancing progress in the biotechnologies.[401]

The National Institutes of Health and its partners are working on sequencing the strains of all pathogens identified by the CDC as being of particular concern. Other researchers have identified novel techniques to speed the process of comparing a standard pathogen and the threat pathogen and identifying the differences.[402]

Screening and Refining Countermeasures

The first step in a rapid adaptation strategy is speeding the ability to characterize a threat pathogen in a crisis. The second step – screening and refinement of a set of pre-developed medical countermeasures – is not really underway. While interesting work is underway on medical countermeasures, it has three gaps. First, while valuable medical countermeasures are

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[400]Zilinskas, "Possible Terrorist Use of Modern Biotechnology Techniques," see page 4: "Imbuing a bacterial strain with antibiotic resistance is no longer a substantial scientific challenge. Many plasmids with resistance markers are available in ordinary bacterial strains; these may be moved into new hosts using either classical or molecular biology techniques. Having stated this, it must also be made clear that although the development of antibiotic resistant bacterial strains is technically not so difficult, this does not guarantee that the altered strains will be better suited for weapons use than their less antibiotic-resistant relatives. The reason is that the newly developed antibiotic resistant strains may evidence pleiotropic effects (unwanted and unplanned characteristics); i.e., the newly engineered strains will possess not only the desired characteristic of antibiotic resistance, it also will manifest additional but unwanted characteristics that will make it unsuitable for weapons purposes, such as less virulence or hardiness (or both)."

[401] See, for example, comments by Craig Ventor, a DNA researcher, in Ed Pilkington, "I am creating artificial life, declares US gene pioneer," *The Guardian,* Saturday, October 6, 2007, Guardian website (http://www.guardian.co.uk/science/2007/oct/06/genetics accessed 10/2/2008).

[402] Science News, "On the Trail of Rogue Genetically Modified Pathogens," *Science Daily* website (http://www.sciencedaily.com/releases/2008/03 accessed 10/2/2008).

being developed, they are not being developed with an eye to yielding a set of countermeasures developed in advance that would need to collectively provide protection against the full range of modifications. There are several strategies that can be pursued to develop such a set of comprehensive countermeasures that are discussed in more detail. Second, the strategy should be developing more generic platforms or other generic vehicles for packaging and administering the medicine. Third, the process of tailoring a countermeasure in the crisis after an attack using an unusual or modified has not been refined. The organizations and their responsibilities in such a crisis have not been well-organized. Groups who would step into the breech with competancre exist but their efforts would be strengthened by a conscious delineation of authorities and refinement of capabilities well in advance of a crisis. Each of these three weaknesses should be corrected.

The first weakness is the need for a strategy to develop the "recipes" for a comprehensive set of countermeasures should be developed. Second, there should be comprehensive strategies identified and implemented to develop the recipes for a set of countermeasures, at least one of which could reasonably be expected to be identified and implemented and effective against the modified or unusual pathogen that is actually used by an attacker. There are a variety of strategies that could be used to shape such a research program. An example would be to develop countermeasures that use different mechanisms to defeat the pathogen. Some biologists posit that even a successful modification of a pathogen from the adversary's point of view would only alter one of the mechanisms of action for one of the medical countermeasures. Having the "recipes" for several countermeasures against a pathogen, using different mechanisms of action – vaccine, antibiotics, anti-toxin, for example – would make it likely that there was at least one countermeasure that would be effective even against a modified pathogen.

For example, for anthrax there is a vaccine (pre-exposure); antibiotics (first 24-48 hours after symptoms emerging) and anti-toxins (that somewhat imperfectly attack the toxins after they proliferate in the blood stream). A genetic modification of the anthrax pathogen probably would only have the effect, even if fully successful, of rendering one of these countermeasure mechanisms ineffective. It is unlikely that a modification could render a full suite of different mechanisms ineffective.

For smallpox, the nation has about 300 million doses of the traditional vaccine. There also is a "next-generation, safer smallpox vaccine called modified vaccinia Ankara (MVA) in clinical testing, and other vaccines under preclinical development. In addition, two new antiviral drugs, ST-246 and oral cidofovir, are in advanced product development. Both hold promise for use in the event of a smallpox attack, as well as to treat the rare but serious complications of the classic smallpox vaccine." The smallpox vaccines can be administered after exposure but before the emergence of symptoms, while the therapeutics could be administered after the emergence of symptoms and still have effect. [403]

A second systematic strategy for drug development could focus on strengthening and speeding the ability for purposeful drug development informed by the genetic differences between the standard and modified pathogen. These differences would be identified in the rapid characterization phase. The usefulness of understanding is still imperfect but advancing rapidly. For example, the sequencing of a few naturally occurring pathogens has provided insights into the genetic basis for their resistance to commonly used medical treatments and has informed strategies to develop treatments that overcome the resistance.[404] Second, advances in functional

[403] Anthony S. Fauci, M.D., NIAID Director, "Statement on Biodefense."
[404] David M. Morens et al., "The challenge of emerging and re-emerging infectious diseases." See: "The recent sequencing of the genomes of important pathogens will provide novel opportunities to delineate more precisely the

genomics have enabled the construction of a targeted countermeasure in a few cases where the genetic cause of a disease was very precise.[405] Further advances in functional genomics may enable the speeded construction of more such therapies.

These are only two examples of the systematic strategies that should be pursued. Advances in both generic and specific strategies are needed. The objective would be developed "recipes" that would speed the construction of a tailored countermeasure.

The second weakness is that a speeded program to develop platforms and other generic vehicles to develop the drugs needs to be implemented. An example of a generic strategy would be platforms used annually for the reformulated flu vaccine that are preapproved by the FDA. The flu vaccine is modified every year because the flu virus tends to drift genetically. Generic inputs are strategies that would speed development or production of any tailored countermeasure. An example of a generic strategy would be the platforms used annually for the reformulated flu vaccine that are preapproved by the FDA. The flu vaccine is modified every year because the flu virus tends to drift genetically. The "platform" for the vaccine is standardized and readied in advance each year, so that the process of producing the vaccine itself and filling the platform can proceed swiftly once a decision is made about the vaccines precise contents. A variety of these types of standardized generic platforms should be developed, pre-approved by the FDA, and produced in quantity. There are efforts underway to develop common platforms.[406] These

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genetic basis for resistance, as has been accomplished with *P. falciparum* and chloroquine resistance. Such information will greatly facilitate the development of alternative therapies against resistant strains of microbes."

[405] For example, a cancer medication made by Novartis, imatinib mesylate, "works by targeting, and turning off, specific proteins in cancer cells that cause the cancer cells to grow and multiply." "How Gleevec Works," Novartis website (http://www.gleevec.com/info/ag/index.jsp accessed 5/1/2009).

[406] NIAID, "Strategic Plan for Biodefense Research," 2007 Update, see page 5: "Broad spectrum platforms are standardized methods that can be used to significantly reduce the time and cost required to bring medical countermeasures to market. For example, a proven monoclonal antibody fermentation and purification method can be applied to rapidly develop any therapeutic monoclonal antibody, avoiding lengthy development work. Other examples of platform technologies include screening systems, in vitro safety testing, expression modules,

efforts should be speeded and extended technically. A procurement strategy should be developed and implemented, which includes prior approvals by the FDA.

The third weakness is the weakness of the process for tailoring a countermeasure in the crisis after an attack using an unusual or modified. The organizations and their responsibilities in such a crisis have not been well-organized. Groups who would step into the breach with competance exist but their efforts would be strengthened by a conscious delineation of authorities and refinement of capabilities well in advance of a crisis.

Speeded Volume Production

The third phase of a rapid adaptation strategy would be swift volume production of the tailored medical countermeasure. Rapid characterization would precisely identify the characteristics of a modified pathogen. The second phase, screening and refinement, would identify an effective countermeasure from a systematic set of pre-developed countermeasure recipes. Once an effective countermeasure was identified, it would need to be produced in sufficient quantity to protect the vulnerable civilian population.

Production capacity for vaccines and other medical therapeutics is currently very limited worldwide and particularly limited in the United States. Various market forces have led most companies to locate production capacity abroad. Various government policies – tax-breaks or subsidies, intellectual property rights, tiered pricing – make different countries more or less

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manufacturing technologies, and chemical synthesis designs. The potential to rapidly apply such platform methods to developing new countermeasures will considerably shorten and streamline the process."

attractive for investments in production capacity. These and other economic factors have contributed to the steep decline in production capacity in the United States.[407]

The best recent analysis has been done on influenza vaccine production capacity, a capability that has some unique characteristics but illustrates the broader problem. HHS has set as a goal having enough influenza vaccine to vaccinate 300 million people within six months of a decision to do so. Current estimates of domestic production capacity are about 50 million vaccine doses in six months. Capacity when measured by global demand and capacity is worse: In 2007, 565 million doses of influenza vaccine were produced for the world's 6.6 billion people.[408]

*Transformative Strategies*

For the long-term, transformative strategies should be pursued. Transformative strategies – as the name implies – are the defensive medical countermeasures that could emerge over the long-term from rapidly advancing biotechnologies. Reports from the National Academy of Sciences warn that it is impossible to predict what progress could be made. The break-through technology most fervently sought is "broad spectrum" countermeasures. How "broad" is "broad" seems to vary person to person, but the idea is that a single countermeasure could defend against a broad set of attack pathogens, regardless of modifications to that pathogen. Only transformative strategies like broad-spectrum countermeasures afford much prospect of shifting biological attacks from offense dominant to defense dominant.

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[407] Gregory A. Poland and Edgar K. Marcuse, "Vaccine availability in the US: problems and solutions," *Nature Immunology,* Volume 5, Number 12, December 2004, page 1195-1198.
[408] Congressional Budget Office, Congress of the United States, "US Policy Regarding Pandemic-Influenza Vaccines," September 2008. Page 5.

There appears to be significant disagreement within the life sciences research community about the plausibility and timeline for developing broad spectrum countermeasures. A simple (and simplistic) description of a broad spectrum countermeasure is that a particular vaccine or therapeutic would confer protection against a broad category of pathogens, perhaps, for example, instead of a smallpox vaccine there would be a vaccine against pox viruses regardless of the particular type (chicken, mouse, et al) or genetic modification. An alternative strategy would be to significantly strengthen the innate immune system, making it more effective against all or large categories of attacks.[409]

The National Institutes of Health issued an update in 2007 for their "Strategic Plan for Biodefense Research." The original plan had been published in 2002. The principal substantive difference between the 2002 plan and the 2007 plan is a greater emphasis on seeking broad spectrum solutions, although how broad and how quickly is not entirely clear:

> Although the focus of this updated Strategic Plan continues to be on basic research and its application to product development, there is a shift from the current "one bug-one drug" approach toward a more flexible, broad spectrum approach. This approach involves developing medical countermeasures that are effective against a variety of pathogens and toxins, developing technologies that can be widely applied to improve classes of products, and establishing platforms that can reduce the time and cost of creating new products. The broad spectrum strategy recognizes both the expanding range of biological threats and the limited resources available to address each individual threat.[410]

The Defense Department also has launched a small research program to seek this sort of broad-spectrum countermeasure.[411]

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[409] Charles J. Hackett, PhD, "Innate immune activation as a broad-spectrum biodefense strategy: Prospects and research challenges," *Journal of Allergy and Clinical Immunology,* Volume 112, Issue 4, October 2003, pages 686-694.

[410] NIAID Strategic Plan for Biodefense Research, 2007 Update. Page 1-2.

[411] DoD Joint Service Chemical and Biological Defense Program, "Fiscal Year (FY) 2009 Budget Estimates," February 2008, Procurement, Defense-Wide. DoD Budget Submission. CBDP Budget Item Justification Sheet (R-2a Exhibit) page 17: The Transformational Medical Technologies Initiatives or "TMTI is a novel experiment to

*Conclusion*

The substance of a medical countermeasure strategy is quite complex. It should be a continuum of activities that exploits emerging technologies for defensive purposes and recognizes that adversaries could be exploiting the same technologies to strengthen their ability to launch an attack. It must seek to develop the long-term transformative capabilities that could make this area of warfare defense dominant. Shifting bioattack from defense dominant to offense dominant would both enable the protection of innocent civilians and would reduce and eliminate dynamics that can cause destabilizing events like wars of preemption and defensive arms races.

(2) *Structuring a Medical Countermeasure Strategy*

The previous section discussed in very broad terms the needed substantive content of a defensive medical countermeasure strategy. The next question is how to structure the implementation of such a strategy. This chapter recommends that a defensive countermeasure program be pursued as part of an international scientific exchange.[412] There are significant benefits to such an international approach – including reduced spiral model effects and strengthened deterrence model effects. The earlier chapter in the prevention section on norms

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develop drugs that are broad spectrum in nature by using non-traditional and high risk approaches to accelerate the development and licensure of new medicines."

[412] The issue of how to structure international cooperation is discussed very little in the literature. At least one author argues that the full program of activities – prevention, deterrence and defense – should be fundamentally international in nature. His argument is based on the logic of that approach – limited resources go further, disease is fundamentally international in such an interconnected world. He is silent on more hard-nosed calculations about how to manage political incentives to secure cooperate on other aspects of a biological agenda or how to overcome intractable constraints in production capacity. See Marc L. Ostfeld, "Strengthening Biodefense Internationally: Illusion and Reality," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science,* Volume 6, Number 3, 2008, pages 261-267. Ostfeld makes four recommendations: (1) Strengthen mechanisms to detect outbreaks and share information internationally....(2) Develop effective mechanisms to share medical countermeasures across borders....(3) Creat mechanisms to stimulate enhanced international cooperation on R&D of new, improved medical countermeasures....(4) Develop and implement more international exercises and training."

focused on another one of these benefits: catalyzing the broadest possible international adoption of norms on biosafety, biosecurity and worrisome dual use research. [413]

This dissertation's recommendation that the medical countermeasure strategy be pursued in the context of an open international scientific exchange appears to be in direct contradiction to emerging US policy. The United States appears to be constructing a national, unilateral system to enforce norms in this area. [414] A national, unilateral system would provide a security benefit but would impose security, economic and technological costs. This benefit and the associated costs are discussed in the earlier chapter on norms.

A decision about whether to pursue an international program would be very complex. It would turn on many assumptions, including assumptions about the evolution of the relevant technology that are not known or cannot be known. There are eight areas of concern. As a presentational device, they are stated as propositions in favor of the proposal but each rests on complicated judgment calls and could be legitimately questioned and rejected. All of these propositions would need to be plausible or likely for it to be wise to pursue an international program. There are eight propositions:

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[413] The value of these controls is discussed in Reynolds M. Salerno and Lauren T. Hickok, "Strengthening Bioterrorism Prevention: Global Biological Materials Management," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science,* June 2007, Vol 5, No. 2: 107-116. Another author who expresses concern about the vulnerability posed by the growing number of these programs in the United States is Laura H. Kahn, "Biodefense Research: Can Secrecy and Safety Coexist?," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science,* Volume 2, Number 2, 2004, pages 81-84.

[414] National Academy of Sciences, Biotechnology Research in an Age of Terrorism," see page 2: "In the United States, the USA PATRIOT Act of 2001 and the Bioterrorism and Response Act of 2002 already establish the statutory and regulatory basis for protecting biological materials from inadvertent misuse. Once fully implemented, the mandated registration for possession of certain pathogens (the "select agents"), designation of restricted individuals who may not possess select agents, and a regulatory system for the physical security of the most dangerous pathogens within the United States will provide a useful accounting of domestic laboratories engaged in legitimate research and some reduction in the risk of pathogens acquired from designated facilities falling into the hands of terrorists."

(1) Requiring the adoption of norms on biosafety, biosecurity and worrisome dual-use research as the price of admission to an international scientific exchange on defensive medical countermeasures would catalyze the broadest possible international adoption of these norms;

(2) The process of developing and implementing international norms and pursuing a shared defensive medical countermeasure program would cause a broader effect in the relevant technical communities of status quo states, reducing spiral model effects because of the vastly greater – although not necessarily complete – transparency;

(3) Given the global distribution of research excellence in the biotechnologies, creating an international research program would be the only strategy that could assure the US defensive medical countermeasure program remains at the cutting edge of technology;

(4) Given the inevitable limitations on national resources and the enormity of the technical challenge, an international scientific exchange would be the only strategy that has any prospect of applying sufficient resources to the challenge of developing a full suite of defensive countermeasures quickly enough that the scientific effort could achieve a core strategic objective -- moving biodefense from offense dominant to defense dominant in the foreseeable future;

(5) The benefits of secrecy would be limited (but not zero) in a defensive medical countermeasure program and these benefits would be expected to go down

over time as the program transitions from a strategy of stockpiling (or "one bug, one drug") to a strategy of rapid adaptation;

(6) Strengthening the defensive medical countermeasures available to the United States and to its partners through an international scientific exchange would greatly strengthen deterrence because it would increase the probability that a bioattack would fail because the defender had effective defenses;

(7) Because of various characteristics of the technology and the security environment, these norms and the countermeasure program would be best implemented through an informal scientific exchange instead of the institutionalized structure used more traditionally for arms control, like the IAEA and the OPCW; and

(8) An historical vulnerability of international agreements – an inappropriate surrender of domestic autonomy – would be avoided in this case and the United States would properly retain and exercise autonomy in pursuing any needed classified medical countermeasure programs and diplomatic, intelligence and law enforcement initiatives.

Each of these issues is discussed in turn.

*(1) Catalyzing Broad Adoption of Norms*

The first point is the one discussed previously: that the prospect of an internationalized medical countermeasure program could provide valuable leverage for the development and implementation of strong international norms governing biosafety, biosecurity and worrisome dual-use research. This argument was more fully developed in the chapter on norms. It noted

that the US appeared to be pursuing a national program of unilateral sanctions. The section discussed the security benefit of such a unilateral system but the significant associated security, economic and technological costs. US national security and international security more broadly would be greatly advanced through the broadest possible adoption of meaningful international norms on biosafety, biosecurity and worrisome dual-use research. These norms would be observed by straightforward programs and would help identify programs that were plausibly sources of concern. By reducing the number of programs of concern, diplomatic, law enforcement or investigative assets could be applied to further investigate worrisome programs.

It seems plausible that the prospect of participation in an internationalized research program could provide leverage for the formulation and adoption of these norms by legitimate researchers in participating countries. These "legitimate researchers" would be expected to constitute the vast proportion of researchers. The culling function associated with the formal adoption of these norms should facilitate the identification of worrisome programs and diplomatic, law enforcement and intelligence assets could be directed against these worrisome programs.

*(2) Reduced Spiral Model Effects*

The process of developing and implementing international norms and pursuing a shared defensive medical countermeasure program would cause a broader effect in the relevant technical communities of status quo states, reducing spiral model effects because of the vastly greater – although not necessarily complete – transparency it would create. Spiral model concerns arise when countries fear another state is pursuing capabilities that could threaten it. An open scientific exchange could reassure a country that only defensive capabilities are being

pursued and are available to it at the price of participation (which is national adoption of the international norms).

Transparency is one of the best and most useful tools for quelling spiral model fears of otherwise status quo states. Transparency need not be complete to be useful. This dissertation argues both that it is useful to pursue transparency and that it is necessary to preserve the option to conduct classified national research on defensive countermeasures, consistent with the Biological Weapons Convention. The approval and management structure for such classified research should be transparent and appropriate congressional oversight should be assured.

*(3) Staying at the Cutting Edge of Technology*

The third argument for such a program is that only an open, international research program could stay at the cutting-edge of the biotechnologies given their global diffusion.[415] Top-notch research is occurring abroad and the next cutting edge break-through in the biotechnologies could plausibly occur abroad. A recent report by the National Academies of Sciences warned that it was impossible to predict where geographically the next major breakthrough in the biotechnologies would be made.[416] In addition, complex academic studies on the general issue of innovation show that innovation is becoming increasingly international but that the benefits of that international activity flow differentially to countries depending on the

[415]National Academy of Sciences, *Biological Research in an Age of Terrorism*, see page 2: "[T]his country is only one of many pursuing biotechnology research at the highest level. The techniques, reagents, and information that could be used for offensive purposes are readily available and accessible. Moreover, the expertise and know-how to use or misuse them is distributed across the globe."

[416]National Academy of Sciences, *Globalization, Biosecurity, and the Future of the Life Sciences*, see page 4: "To a considerable extent, new advances in the life sciences and related technologies are being generated not just domestically but also internationally. The preeminent position that the United States has enjoyed in the life sciences has been dependent upon the flow of foreign scientific talent to its shores and is now threatened by the increasing globalization of science and the international dispersion of a wide variety of related technologies. The increasing pace of scientific discovery abroad and the fact that the United States may no longer hold a monopoly on these leading technologies means that this country is, as never before, dependent on international collaboration…"

relative favorability of national structures and policies.[417] Integration increasingly is required to be at the cutting edge of rapidly-evolving technologies.[418] There is growing international collaboration, particularly in the production of basic scientific knowledge.[419]

*(4) Vastly Increasing Net Resources*

An international scientific exchange would greatly increase the total resources devoted to developing defensive medical countermeasures. More scientists in more countries working on the problem should speed progress. This observation simply develops the point that more resources – both fiscal and technical – would be available to grapple with the problem if more countries contributed to the overall effort. Because of the significant offensive advantage of the biotechnologies, no one country – including the United States – could unilaterally fund a comprehensive defensive program. It is only a comprehensive program that holds out at least the prospect of turning biodefense from strongly offense-dominant (and hence vulnerable to wars of preemption and other destabilizing behaviors) to defense-dominant.[420]

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[417] Noisi and Bellon, "The Global Interdependence of National Innovation Systems." A broad point about the importance of the "public supply of infrastructures to make a country attractive for the deployment of S&T activities" is made in Archibugi and Michie, "Technological Globalisation or National Systems of Innovation?" see page 133: The evidence "seems to point uniformly to increasing interdependence of innovation systems in various countries....each of the authors also emphasizes the importance of national policies and institutions." Carlsson, "Internationalization of innovation systems: A survey of the literature," see page 60. See discussion of Bartholomew in Carlsson, see page 69: A study that focused exclusively on the biotechnology sector found, similarly, that "'forming cross-border alliances may thus be one of the most important means for firms to enhance their innovative capability in biotechnology'" but that the efficacy of these cross-border alliances rested on unique national systems.

[418] For example, Drake et al., "Proteomics for biodefense applications: progress and opportunities," see page 203: "...translating these proteomic discoveries to useful counter-bioterrorism products will require large collaborative research efforts across multiple basic science and clinical disciplines."

[419] See Niosi and Bellon, "The Global Interdependence of National Innovation Systems," see page 182: This can be seen in an "increase in the number of published articles coauthored by scientists in different countries, the number of countries that participate in international copublication, and the number of multiauthored articles." Wagner, "The Elusive Partnership: Science and Foreign Policy," pages 409-417.

[420] There has been a significant increase in the resources devoted to biodefense in the United States over the past ten years. The total amount of USG civilian biodefense funding has increased from $576 million in FY2001 to a request of $5, 421 million in FY2008, an order of magnitude increase. The size of the program from FY2001 through FY2008 request is estimated at $40 billion. The level hit about $8 billion in FY 2005 and saw relatively

(5) *Value of Secrecy to the Defender*

There is a legitimate argument about the value of secrecy for a defensive medical countermeasure program. How much benefit would a potential attacker derive from information about the defender's defensive programs? This remains necessarily somewhat speculative because it turns on details about the future evolution of the technology that are not known. The argument in favor of secrecy or controls on information about the defender's medical countermeasure program generally goes as follows: The greater the ambiguity about the nature of the defensive medical countermeasure, the harder it would be for the adversary to select a pathogen that confidently defeats the countermeasure. Examples of useful information about defensive medical countermeasures could be information about the precise composition of the antibiotic stockpile. If all or most of the antibiotics in the defender's stockpile were of one type, then the technical challenge to the attacker of developing an altered pathogen able to defeat that countermeasure is much more straightforward. There are, for example, several broad classes of antibiotics. There is a reasonable argument that a single alteration to anthrax, for example, could only defeat one class of antibiotics. If there was significant ambiguity about which class of antibiotics was in the stockpile, the technical challenge for an adversary of altering the anthrax to defeat the stockpiled antibiotics becomes greater.

The counterargument is threefold: First, the information about the contents of the stockpile would be very hard to keep secret from a determined adversary. There is a direct and

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small decreases in subsequent years. The Obama administration appears likely to only further reduce amounts. They identified the procurement fund for defensive medical countermeasures (Bioshield) as a source of reprogramming should additional funds be needed for H1N1 purchases. For the overall biodefense numbers, see Table 1in Franco and Deitch, "Billions for Biodefense: Federal Agency Biodefense Funding, FY 2007-FY2008." For the Obama administration request on reprogramming the Bioshield monies, see Hsu, "Bipartisan WMD Panel Criticizes Obama Plan to Fund Flu Vaccine."

an indirect cost of secrecy. One estimate is that the direct costs of implementing a secrecy program could be about $75 billion.[421] National security agencies have enough trouble keeping secrets even though keeping secrets is deeply engrained in the culture, values and practices of that professional community. Public health agencies have less tradition of keeping secrets. It is antithetical to the professional norms of the community and certainly there is little infrastructure, tradition or inclination to keep the information secret. The contents of the Strategic National Stockpile in the United States are not posted on the CDC website (an observation that would not have been true a few years ago) but are not classified and could be found in public documents.

In addition, the value of secrecy about the precise characteristics of medical countermeasures should decrease over time as the strategy shifts from stockpiling to rapid adaptation, thus reducing over time the principal vulnerability of an internationalized program.

*(6) Strengthening Deterrence Effects*

An open international scientific exchange should strengthen deterrence. This is because the proposed program should improve defensive countermeasures and get these improved countermeasures to more countries. These direct effects should reduce the benefit to an attacker, increasing tactical deterrence. Tactical deterrence is when the attack is successfully launched but the defenses are effective and so the attack has little effect.

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[421] Schwartz, S.I. "Four trillion dollars and counting," *Bulletin of the Atomic Scientists* 51 (Nov/Dec 1995): 32-52, see pages 50-51: "The financial costs [of classifying the information about the public health aspects of the biodefense program] could be considerable. An estimate of the costs of the U.S. nuclear weapons program between 1940 and 1945 suggests a rough figure of $75 billion secrecy. Representative items on the list that would apply to the control of biological select agents include costs for screening personnel; for secure filing cabinets; for guards; and for routine inventories of controlled material." National Academy of Science, *Biotechnology Research in an Age of Terrorism*, see footnote 18 and page 103: The cultural challenge of introducing classification into the public health world would also be very difficult. The public health and the life sciences community are built on an ethos of information sharing. The security community, in contrast, has a well-established cultural of controlling information consistent with security classification.

Other forms of deterrence also should be strengthened because of the indirect effects of this greater cooperation among status quo states. This cooperation should facilitate, for example, unified efforts to detect attempts by an adversary to test delivery modes. It also should facilitate broader political cooperation that would strengthen general non-proliferation norms and the willingness of the international community to mete out severe punishment to an adversary after an attack on a civilian population.

*(7) Informal Structure Would Work Best*

The type of research program recommended here would be centrally executed by an organization with a permanent bureaucracy. It would rather be a collaborative research effort with international conferences and some informal division of labor to advance the various elements of a shared and coherent substantive agenda.

The "Atoms for Peace" idea was eventually institutionalized in the IAEA program of technology sharing for peaceful purposes, with inspections to assure enriched uranium was only used for peaceful purposes. Given the technical characteristics of the biotechnologies, a much more loose collaboration is recommended, without the institutional structure seen in the IAEA. The structure should be more like an international scientific program, separately administered and funded in each nation, but intellectually complementary through scientific exchanges and conferences.

A more formal structure like the IAEA could not plausibly catch rule-breakers because of the significant differences between the nuclear and biological technologies: biotechnology sites could be concealed and even on-site inspections could not distinguish between a civilian and a military program in the general pre-attack stage. The entry costs – both fiscal and technical – for

a bioterrorism program are low and probably getting lower still. At some point, such a program could be developed by a serious non-state adversary with limited chance of detection.

A formal institution could be useful in the development, codification and updating of the norms on biosafety, biosecurity and worrisome dual-use research. It probably could not usefully extend into the type of enforcement and inspection role played by the IAEA or the OPCW, because of the unavoidable limits on inspections. There are some proposals for international groups that would pre-review worrisome biotechnology dual-use research.[422]

*(8) Domestic Autonomy Would Be Preserved*

Another risk is that an international research program would be falsely interpreted by the defender to provide complete protection against a catastrophic biological attack. Complementary diplomatic, law enforcement and intelligence efforts to further mitigate the risk of biological attack might be allowed to atrophy. The defender would perceive the international program as somehow controlling, like a treaty obligation, rather than as an open exchange of scientific information. The opposition of foreign governments could be perceived to constrain national action to take measures in the national interest. Some limited classified, national programs, for example, may still be necessary, although their approval and management structures should be rigorous and well-explained.

*Conclusion*

This dissertation makes recommendations on the substance and the structure for a defensive medical countermeasure program. On substance, it urges a strategy that pursues a continuum of solutions for the near, mid and long-term. This continuum seeks to develop

[422]Harris, E.D., "Dual-Use Biotechnology Research," in Rappert and McLeish, eds., *A Web of Prevention*. See also Steinbruner, J.D., et al., Controlling Dangerous Pathogens.

defenses that take advantage of the technology that emerges over time so as to defend against the evolving threat. It urges that the continuum of activities proceed from, first, stockpiling countermeasures against known threats, through, second, rapid adaptation, which seeks to improve the defender's ability to produce a tailored countermeasure after an adversary has launched an attack with a modified pathogen, to, third, transformative strategies that could shift biodefense from offense dominant to defense dominant.

On structure, the dissertation urges that efforts to strengthen medical countermeasures be placed in the context of an open international scientific exchange. This strategy would best align incentives and resources, both technical and fiscal, with the broader strategic objectives. An open international scientific exchange would have as its price of admission national adoption of norms on biosafety, biosecurity and worrisome dual use research. Other benefits could include dampened spiral model effects and strengthened deterrence effects – two outcomes greatly beneficial to international peace and security. There also should be significant benefits to the United States from the participation of other countries in the scientific enterprise – these benefits would be the direct benefits of technical and fiscal contributions by other nations and the indirect benefits of synergy of international research efforts in the biotechnologies.

## Defense: Chapter 12

### A Strengthened Public Health Response

The previous chapter outlined the two enabling conditions for an effective public health response in this post-drug age. First, the bug must be relatively slow in evolving to defeat the countermeasure; and second, the broader public health infrastructure must be sufficiently committed and coherent that it can provide supportive, ongoing care in an appropriate environment. The previous chapter discussed the expectation that the first condition would not be met. It outlined the challenges of shaping and executing a medical countermeasure strategy so as to keep pace with the likely evolution of the threat.

This chapter discusses the second enabling condition – that the broader public health infrastructure must be sufficiently committed and coherent that it can provide supportive, ongoing care in an appropriate environment. This second enabling condition also would not be expected to be met in a catastrophic biological attack. A catastrophic biological attack would stress the medical infrastructure anywhere and, while cross national comparisons are difficult, the United States is probably as well prepared as any other country. There is a broadly held view, though, that the current public health infrastructure in the United States would be overwhelmed by a bioattack of any significant size.[423]

The dissertation specifically makes two recommendations for strengthening the public health response. Both recommendations try to overcome some of the weaknesses inherent in the structure of the public health community in the United States for a problem of this type. The

[423] See, Inglesby, "Observations from the Top Off Exercise," see page 67: "Not unexpectedly, the logistics of antibiotic distribution proved quite complex....the ensuing local distribution process did not go smoothly." Falkenrath, et al., *America's Achilles Heel,* see page 311, "...local medical services could easily be overwhelmed after a large attack...."

structure of the public health community in the United States has many more strengths, including particularly those of federalism – local responsiveness and control. The weaknesses include a sometimes limited ability to reach agreement on and implement strategic change, particularly in the absence of a crisis. Most organizations, even if they have a unified structure, find it very difficult to make changes in strategic direction in the absence of a crisis of some sort. The public health community in the United States has a highly diffuse structure, with local, state and federal officials often working collegially and effectively on agreed problems. In the absence of a crisis, however, it takes some time for consensus to emerge within the broader community on a newly emerged problem, particularly one like biodefense that emerges from the concerns and responsibilities of an entirely different professional community.[424]

The two recommendations seek to accept and manage that diffuseness: (1) detailed, integrated planning on how to execute a response to a catastrophic biological attack should be undertaken, with an initial focus on how stockpiled countermeasures could be distributed on the needed timeline; and (2) detailed, technical analysis of public health response to a catastrophic biological attack, including particularly distribution of stockpiled countermeasures. This analysis should be embedded in a forum with legitimacy in the public health community, possibly the international scientific exchange recommended above, to strive to build greater agreement from the bottom up in the public health community on the potential challenge posed by bioattack. This call for integrated planning and technical analyses accepts the structure of the

[424]It should be noted that some could argue that the lack of focus in the public health community arises solely from a substantive disagreement between the security community and the broad public health community about the real risk of a catastrophic biological attack. Members of the public health community could argue that the problem is not their broader professional community's inability to respond to strategic change but rather the security community's inability to admit it is wrong about the risk of a catastrophic biological attack.

public health community but attempts to make it work effectively to solve this problem, in the near and mid-term.

For the near-term, should a crisis occur, the public health community at all levels would want to work together effectively. Developing detailed, integrated plans now increases the probability that the public health community would be able to respond effectively in a near-term crisis. The second recommendation – embedding technical analysis in a forum with credibility in the public health community -- tries to catalyze the cultural change needed to strengthen public health response to a catastrophic biological attack in the mid-term.

This chapter has three objectives: to (1) demonstrate the severe challenge of innovation given the diffuse structure of the public health community in the United States; (2) demonstrate that there are strategies that make it plausible to achieve timely distribution of medical countermeasures; and (3) demonstrate that there are approaches to non-pharmacological approaches that have not been well-researched.

*(1) Challenges of Change*

The dissertation outlines why the public health system is so diffuse. As in traditional defense of the homeland, there would be significant ambiguity about who was responsible for the public health response to a catastrophic biological attack. An earlier chapter -- on strategic, tactical and logistical responsibilities in the US system -- discussed two sources of ambiguity. First, like the broader homeland defense challenge, there is extreme ambiguity among local, state and federal officials about which level of government would be responsible in the US federal system for responding to a catastrophic attack. Second, there is ambiguity among federal

departments, including particularly the Departments of Health and Human Services and Homeland Security, about which department would lead the federal response.

In addition to these two sources of ambiguity, there is a third source of ambiguity which uniquely complicates planning for the public health response to a catastrophic biological attack. In the current situation, one professional community is worried about and responsible for mitigating the problem of bioattack (the security community) while a different community (the public health community) would need to sacrifice its time, energy and scarce assets to solve the problem. Public health response is a capability largely implemented by state and local public health officials who confront more illness than they can treat within current and foreseeable assets. It is perfectly reasonable that state and local public health officials tend to focus their energies on ameliorating extant public health problems. While officials of the federal public health agencies can and have devoted significant efforts to strengthening biodefense response capabilities, there remains a disconnect between their rhetorical calls for greater exertions and the reality that most public health assets are state and local.

The theoretical literature on innovation indicates that this structure of interests, benefits and costs is unlikely to yield significant progress, at least prior to some broader crisis. The literature on organizations generally argues that they are resistant to change and make changes only in response to a crisis or threats to their missions or autonomy. The most obvious crisis would be an effective bioattack. It would be vastly better if the public health response to a catastrophic biological attack would be strengthened through some other means, hence the recommendations made here.

Innovation literature generally focuses on change within an organization. The literature on innovation is extensive, complex and agrees on little, including whether the literature really offers useful insights on innovation.[425] As the literature outlines the elements necessary for successful change or innovation, it provides significant cautions about the prospect that the public health world can design or implement change to strengthen its ability to respond effectively to a catastrophic biological attack short of a crisis. In addition to all of the normal constraints to change or innovation that organizations face, the challenge is complicated by the reality that the public health community does not constitute an "organization." It is made up of a community of public health professionals who are employed by a variety of local, state or federal organizations with weak ability by any one actor to set objectives. Absent an external crisis, like a successful biological attack, there seems little prospect for change. The diffuse organizational structure of the public health community probably requires more of a cultural change, with values of the relevant professional community shifting over time to place a greater value on developing capabilities for bioattack.

Experience with public health response in other countries and in the United States, both today and historically, indicates that an effective response is possible but would need to be thoroughly planned in advance. With some isolated exceptions,[426] this type of detailed planning is not underway. There is probably no way to catalyze the needed planning other than securing

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[425] George W. Downs, Jr., and Lawrence B. Mohr, "Conceptual Issues in the Study of Innovation," *Administrative Science Quarterly,* Vol. 21, No. 4 (Dec. 1976), pp. 700-714.

[426] Henry H. Willis, Christopher Nelson, Shoshana R. Shelton, Andrew M. Parker, John A. Zambrano, Edward W. Chan, Jeffrey Wasserman, and Brian A. Jackson, "Initial Evaluation of the Cities Readiness Initiative," RAND Technical Report, Prepared for the U.S. Centers for Disease Control and Prevention, 2009. See the Preface: "Since 2004, CRI [Cities Readiness Initiative] has expended some $300 million to improve the ability of the nation's largest metropolitan regions to provide life-saving medications in the event of a large-scale bioterrorist attack or naturally occurring disease outbreak. The study found that the program, with its clear focus on a single scenario, along with performance assessments and technical assistance, has taken important steps toward improving participating regions' readiness to dispense medications on a large scale."

broader support from all segments of the highly diffuse public health community. Authority is sufficiently diffuse that there really is no one actor who could force the public health community to participate in this type of planning.

The needed planning would be very different from the strategic decision aids discussed previously. Those decision aids sought to inform the early, strategic decisions about whether medical countermeasures should be administered and, if so, to which segment of the population. The plans called for in this chapter would be focused on the tactical and logistical implementation of those decisions. The planning called for here would deal with detailed questions of, for example, how to set up and staff sites to swiftly provide countermeasures to all members of a community.

Additional resources would almost certainly be needed to implement the plans, but sound plans have not yet been developed much less implemented to swiftly distribute medical countermeasures. Similarly, detailed, robust technical analyses of how to maximize the technical benefits of non-pharmacological means to slow the spread of an infectious disease – like wearing masks or closing schools – have not been developed and vetted in a process that gives them meaningful standing in the public health community.

It certainly appears that the distribution of stockpiled medical countermeasure problem could be solved. It wouldn't be easy, but the success of National Immunization Days in countries like China, Brazil and Cuba to eradicate polio demonstrates the scale and speed of a possible public health response if there has been enough planning in advance. [427] While opinion

[427] Ciro A. de Quadros, Jon K. Andrus, Jean-Marc Olive, Caryle Guerra de Macedo and Donald A. Henderson, "Polio Eradication From The Western Hemisphere," *Annual Reviews of Public Health*, 1992, 13: 239-252. Kimberly M. Thompson, Radboud J. Duintjer Tebbens, and Mark A. Pallansch, "Evaluation of Response Scenarios to Potential Polio Outbreaks Using Mathematical Models," *Risk Analysis*, Vol 26, No 6, 2006, pages 1541 – 1556.

leaders in the public health community have warned starkly that a bioattack is inevitable, the broad consensus of the public health community is that a bioattack, particularly on the scale feared by the security community, is not likely.[428]

One professional community (the security community) is worried about the problem of bioattack, while another professional community (the public health community) would have to use its already stretched assets and capabilities to solve a problem that is not really within its professional sphere of responsibility. To further complicate the problem, the professional community that would need to respond to the new challenge has a highly diffuse leadership structure which further complicates the challenge of persuading it to take on a new mission. A review of the academic literature on innovation and cooperation finds a generally pessimistic assessment of solving a problem with this structure of interests, costs and benefits.

The literature on organizations generally argues that they are resistant to change and make changes only in response to a crisis or threats to their missions or autonomy. The literature on innovation is extensive, complex and agrees on little, including whether the literature really

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H. Harmanci, Y. Gurbuz, S.D. Torun, N. Tumerdem, and T. Ertuk, "Reasons for non-vaccination during national immuniuzation days: a case study in Istanbul, Turkey," *Public Health*, Volume 117, Issue 1, 1 January 2003, pages 54-61. M. Bonnet and A. Dutta, "World Wide experience with inactivated poliovirus vaccine," *Vaccine*, Volume 26, Issue 39, 15 September 2008, pages 4978 – 4983. See also "National Immunization Days and Status of Poliomyelitis eradication – Philippines, 1993," *Morbidity and Mortality Weekly Report,* Centers for Disease Control and Prevention, January 14, 1994; 43(1); 6-7, 13; CDC website (http://www.cdc.gov/mmwr/preview/mmwrhtm/00023565.htm accessed 12/19/2008). "National Immunization Days," Global Polio Eradication Initiative website (http://www.polioeradication.org/content/fixed/national.shtml accessed 12/19/2008).

[428] For warnings that a bioattack is inevitable, see, for example, Fauci, "Infectious Diseases," see page 678: "A bioterrorism attack against the civilian population in the United States is inevitable in the 21st century. The only question is which agent(s) will be used and under what circumstances will the attack(s) occur." Cohen, et al., "The Pitfalls of Bioterrorism Preparedness: the Anthrax and Smallpox Experiences," see from the abstract: "Bioterrorism preparedness programs have contributed to death, illness, and waste of public health resources without evidence of benefit....The present expansion of bioterrorism preparedness programs will continue to squander health resources, increase the dangers of accidental or purposeful release of dangerous pathogens, and further undermine efforts to enforce international treaties to ban biological and chemical weapons."

offers useful insights on innovation.[429] As the literature outlines the elements necessary for successful change or innovation, it provides significant caution about the prospect that the public health world could design or implement change to strengthen its ability to respond effectively to a catastrophic biological attack.

In addition to all of the normal constraints to change or innovation that organizations face, the challenge would be complicated by the reality that the public health community does not constitute an "organization." It is made up of a community of public health professionals who are employed generally by local, state or federal organizations with weak ability by any one actor to set shared objectives. The diffuse organizational structure of the public health community probably requires more of a broad cultural change in favor of greater emphasis on developing capabilities to respond to catastrophic bioattack.

Innovation "is defined as the development and implementation of new ideas by people who over time engage in transactions with others within an institutional context."[430] The study of innovation generally divides the problem into three parts: generation, development, and implementation.[431] The first stage is the generation or creation of the new idea. The second stage is the more detailed development of the idea, while the third is the incorporation of the idea into the standard operating practices of the implementing agency. Public sector innovation can

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[429] Downs et al., "Conceptual Issues in the Study of Innovation."

[430] Andrew H. Van de Ven, "Central Problems in the Management of Innovation, *Management Science,* Vol. 32, No. 5, Organization Design (May, 1986), pp. 590-607.

[431] This structure is from Fariborz Damanpour, "Organizational Innovation: A Meta-Analysis of Effects and Determinants and Moderators," *The Academy of Management Journal*, Vol 34, No. 3 (Sep., 1991), pages 555-590, see page 556: This structure is similar to the structure for cognitive evolution: "(1) *innovation,* the creation of new values and expectations that are accepted by a group; (2) *selection,* the extent to which values and expectations become embedded in the minds of the group; and (3) *diffusion*, the degree to which new values and expectations spread from one group or state to another." Italics in the original. The quote is from Dougherty and Pfaltzgraff, Jr., *Contending Theories of International Relations*, page 168. Dougherty and Pfaltzgraff cite Emanuel Adler, "Cognitive Evolution: A Dynamic Approach for the Study of International Relations and Their Progress" in Emanuel Adler and Beverly Crawford, eds., *Progress in Postwar International Relations* (New York: Columbia University Press, 1991), pp. 43-88.

be particularly complex. For example, public organizations tend to have "higher levels of bureaucratic control" than comparable private sector organizations: "High bureaucratic control (i.e., high formalization and centralization) in turn inhibits innovativeness."[432] Public sector innovation is often attempted using "ad hoc groups and processes." While these ad-hoc strategies work for at least a time, they can slow the implementation of the innovation because the core organization is not changed and the ad hoc structure may have little persistence or real influence.[433] The complexity of the task or the extent of the division of labor can affect the likelihood of a successful innovation. For example, a high degree of professionalism has a positive effect on innovation because it "increases boundary-spanning activity, self-confidence, and a commitment to move beyond the status quo;" specialization is considered to have a positive impact on innovation because it increases "the cross-fertilization of ideas."[434]

The innovation literature shows why the public health community is unlikely to generate and implement new ideas to successfully respond to the emerging problem of catastrophic biological attack. The definition of innovation used at the outset of this section refers to "the development and implementation of new ideas by people who over time engage in transactions with others within an institutional context."[435] For the public health elements of the biodefense problem, there are scant institutional contexts for sustained interaction. The security community is principally concerned with the problem of bioattack, as are certain officials in the federal public health infrastructure. This concern, though, is not shared throughout these organizations and, even if it was, the concern of federal public health officials would hardly create the type of

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[432] Damanpour, "A Meta-Analysis of Effects of Determinants and Moderators," page 560.
[433] Thomas N. Gilmore and James Krantz, "Innovation in the Public Sector: Dilemmas in the Use of Ad Hoc Processes," *Journal of Policy Analysis and Management,* Vol. 10, No 3 (summer, 1991), pages 455 - 468.
[434] Damanpour, "Organizational Innovation: A Meta-Analysis of Effects of Determinants and Moderators," page 558.
[435] Van de Ven, "Central Problems in the Management of Innovation,"

institutional context to facilitate the "development and implementation of new ideas" with individuals in the state and local public health context. The institutional context within which most public health experts operate in the United States is the context of local public health agencies. These agencies do a tremendous amount of good but they understandably do not consider preparing for a catastrophic biological attack to be one of their top priorities. They are focused on the current and deadly public health problems sickening or killing people today in their communities. Hence, there is no "institutional context" that contains both a commitment to developing capabilities to solve the problem of timely distribution of medical countermeasures and the assets needed to solve the problem.

Similarly, the positive benefits of professionalism and technical specialization can be gleaned only if some organizational device forces the representatives from the different professions together. There really is no such organizational device to force sustained interaction on the issue of biodefense. One study on the success of peacetime military innovation found that successful innovation was most strongly correlated with the creation of career paths for the practitioners of the new technology. These career paths assured that the cross-fertilization was institutionalized and sustained.[436] Hence, the cross-fertilization between different professions or specialties that benefits innovation does not occur and thus change is unlikely in the absence of some broader systemic shift.

The diffuseness of the public health community and the lack of concern in the public health community in general for the biodefense problem may indicate that the problem of generating reforms for bioattack cannot be solved through "innovation" with its focus on institutions. It may be more of a cultural change, with a professional community adopts within

[436] Rosen, *Innovation and the Modern Military*.

in its core professional norms more of a focus on bioattack. Such cultural change would be slow, absent a dramatic norm-altering event like a significant biological attack.

The two recommendations seek to accept and manage that diffuseness: (1) detailed, integrated planning on how to execute a response to a catastrophic biological attack should be undertaken, with an initial focus on how stockpiled countermeasures could be distributed on the needed timeline; and (2) this analysis should be embedded in a forum with legitimacy in the public health community, possibly the international scientific exchange recommended above, to strive to build greater agreement from the bottom up in the public health community on the potential challenge posed by bioattack. This call for integrated planning and technical analyses accepts the structure of the public health community but attempts to make it work effectively to solve this problem, in the near and mid-term.

For the near-term, should a crisis occur, the public health community at all levels would want to work together effectively. Developing detailed, integrated plans now increases the probability that the public health community would be able to respond effectively in a near-term crisis. The second recommendation – embedding technical analysis in a forum with credibility in the public health community -- tries to catalyze the cultural change needed to strengthen public health response to a catastrophic biological attack in the mid-term.

*Literature on Public Health Response*

There are two broad perspectives on this question – that of the public health community and that of the security community. The question has, as a general matter, been poorly examined because of the profoundly different core assumptions of the two relevant professional communities. The public health community has three strands. First, there are those who judge

that the risk of large bioattack is negligible or even manufactured and hence efforts devoted to solving it are a waste of time or, worse, a decrement from already underfunded public health efforts.[437] Second is the "dual use" school which reports that the best solution is to fund already planned and ongoing public health improvements.[438] The "dual use" assertion is often made but has not been systematically demonstrated. An attack in the thousands plausibly could be managed using traditional public health methods; it has yet to be demonstrated that classic public health methods could work in an attack where tens of thousands or hundreds of thousands of individuals were exposed simultaneously or near-simultaneously. Third, there is a small group of public health officials who judge the risk of bioattack is real, and warn that new approaches would be necessary to deal with such an attack effectively.[439]

The second community is the defense community. There are two subsets within the defense community. There are the security generalists who underscore that increasing defense is critical as the risk of biodefense increases;[440] and there is a much smaller subset of defense-oriented authors who have looked closely at the factual question of whether the existing or projected public health infrastructure could respond to a large bioatack. These more detailed

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[437] Cohen, et al., "The Pitfalls of Bioterrorism Preparedness," see from the abstract: "Bioterrorism preparedness programs have contributed to death, illness, and waste of public health resources without evidence of benefit....The present expansion of bioterrorism preparedness programs will continue to squander health resources, increase the dangers of accidental or purposeful release of dangerous pathogens, and further undermine efforts to enforce international treaties to ban biological and chemical weapons."

[438] Hupert, et al., "Community-Based Mass Prophylaxis:" Many plans of state and local health departments envision setting up classic public health "points of dispensing" but in greater quantity.

[439]See Onaro Lien, Beth Maldin, Crystal Franco, and Gigi Kwik Gronvall, "Getting Medicine to Millions: New Strategies for Mass Distribution," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science,* Volume 4, Number 2, 2006: Alternative approaches that have been proposed include using big-box retailers like Walmart to rapidly distribute the materials.

[440] Chyba, "Toward Biological Security." Koblentz, "Pathogens as Weapons," *International Security.* Danzig and Berkowsky, "Why Should We Be Concerned About Biological Warfare?" in Lederberg, ed., *Biological Weapons."*

studies have warned that the public health infrastructure would be overwhelmed by the demands of an attack and that there are no plans in place to fix this problem.[441]

*(2) Distribution of Stockpiled Medical Countermeasures*

Efforts within the United States to develop the ability to distribute stockpiled medical countermeasures quickly enough have received much attention in recent years.[442] The current assessment by most analysts who have looked closely at the question is that the capability to distribute these countermeasures in a crisis has not yet been developed.[443] There have been some pilot projects that have yielded some progress through the sustained, focused attention of local, state and federal public health officials.[444]

The integrated planning should focus on the distribution of medical countermeasures. The scenario where the greatest problem is distributing medical countermeasures is a reasonably favorable scenario for a catastrophic biological attack. The section discusses a situation where there is broad agreement an attack has occurred, medical countermeasures are available, and the challenge is getting the countermeasures to individuals on a timeline where they can be effective. This would be a significant challenge, particularly in a very large attack where there are

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[441] Falkenrath, et al., *America's Achilles' Heel*, see page 311.
[442] Willis, et al., "Initial Evaluation of the Cities Readiness Initiative," see the preface: "Since 2004, CRI [Cities Readiness Initiative] has expended some $300 million to improve the ability of the nation's largest metropolitan regions to provide life-saving medications in the event of a large-scale bioterrorist attack or naturally occurring disease outbreak. The study found that the program, with its clear focus on a single scenario, along with performance assessments and technical assistance, has taken important steps toward improving participating regions' readiness to dispense medications on a large scale."
[443] See Inglesby, "Observations from the Top Off Exercise," see page 67: "Not unexpectedly, the logistics of antibiotic distribution proved quite complex....the ensuing local distribution process did not go smoothly." Falkenrath, et al., see page 311, "...local medical services could easily be overwhelmed after a large attack...."
[444] Willis, et al., "Initial Evaluation of the Cities Readiness Initiative," see the preface: "Since 2004, CRI [Cities Readiness Initiative] has expended some $300 million to improve the ability of the nation's largest metropolitan regions to provide life-saving medications in the event of a large-scale bioterrorist attack or naturally occurring disease outbreak. The study found that the program, with its clear focus on a single scenario, along with performance assessments and technical assistance, has taken important steps toward improving participating regions' readiness to dispense medications on a large scale."

significant numbers of people who need medical assistance. While the timelines vary pathogen to pathogen, they almost always are extremely difficult and there is a broadly held view that the current public health infrastructure would be overwhelmed by a bioattack of any significant size.[445]

There are three broad strategies for distributing medical countermeasures. The strengths and weaknesses of each will be discussed. The three basic forms are, first, the classic points of distribution or "pull" methods where individuals come to a central distribution point and receive their medicine. PODs might be set up in elementary schools or post offices and staffed so as to screen individuals and give them the proper dose of the medicine. PODs are the technique that have been used most widely historically; most planned for in the future; most flexible in terms of being able to administer the widest range of medical countermeasures (vaccines, antibiotics); and the most likely to afford the opportunity for traditional, personalized medical screening for sub-populations most at risk of adverse reactions from the countermeasure. With these advantages, though, comes the disadvantage that PODs are probably the most vulnerable to being overwhelmed in a catastrophic biological attack, are the slowest to react, and require the largest number of additional staff.[446]

Two other techniques have been postulated and tested in at least limited situations. These two techniques are delivering medical countermeasures to individual homes in an emergency (the "push" approach) and giving people medical countermeasures to keep in their homes and

[445]See Inglesby, "Observations from the Top Off Exercise," see page 67: "Not unexpectedly, the logistics of antibiotic distribution proved quite complex....the ensuing local distribution process did not go smoothly." Falkenrath, et al., America's Achilles Heel, page 311, "...local medical services could easily be overwhelmed after a large attack...."

[446] Hupert, et al., "Community-Based Mass Prophylaxis," see page 2, "The 'pull' approach may increase efficient use of scarce health care providers and resources, enable medical evaluation of potential victims, and provide opportunities for centralized data collection and law enforcement investigation (in the setting of a known or suspected bioterrorism event). However, these advantages must be weighed against the delays and logistical challenges of setting up sufficient dispensing centers to handle high patient volumes."

use only in a catastrophic biological attack ("med kits"). Both of these techniques have the advantage of responding much faster than PODs in a crisis. Both techniques, though, also have significant disadvantages.

*Points of Distribution*

Once a decision had been taken to administer medical countermeasures to a certain population, the standard public health measure is to create "points of dispensing" or "PODs" that would administer the countermeasure while retaining some semblance of the traditional model of every individual having at least some personal contact with a health-care provider.

This method has been used successfully in smallpox epidemics in the past.[447] It is also being used to great effect today in an effort to eliminate polio. Polio, like smallpox, can be prevented by a vaccine.[448] Several countries have sponsored "national immunization days" where basically all children in a certain age group are given the oral polio vaccine. These "national immunization days" require extensive planning and significant logistics, but they demonstrate that "PODs" can work effectively if they are planned in advance with sufficient thoroughness.[449] While the numbers vary between countries, the NID program in Brazil in the

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[447] And some recent studies argue it could be effective for an anthrax attack. See Gregory S. Zaric, Dena M. Bravata, Jon-Erik Cleophas Holty, Kathryn M. McDonald, Douglas K. Owens, and Margaret L. Brandeau, "Modeling the Logistics of response to Anthrax Bioterrorism," *Medical Decision Making*, May-June 2008, 332-350. See abstract: "Effective preparations for response to potential bioterror attacks can avert deaths in the event of an attack."

[448] Long-term ambitions to eliminate polio get very complicated because the cheaper polio vaccine, usually used in the third world, causes a small number of cases. The much more expensive vaccine, usually used in the developed world, does not cause a few number of cases because of its difference mechanism. This will complicate eradication. See, for example, Donald A. Henderson, "Eradication: Lessons from the Past," *Morbidity and Mortality Weekly Report*, Centers for Disease Control and Prevention, Supplements, December 31, 1999/ 48(SUO1); 16-22.

[449] R.W. Sutter and C. Maher, "Mass vaccination campaigns for polio eradication: An essential strategy for success," *Current Topics in Microbiology and Immunology,* Volume 304, 2006, pages 195-220, see page 220: "To reach the highest possible coverage, detailed planning, meticulous execution, careful supervisions and standardized monitoring are critical." Zhang Jian et al., "Costs of Polio Immunization Days in China: Implications for Mass Immunization Campaign Strategies," *International Journal of Health Planning and Management*, 13, pages 5-25 (1998), see page 21-22: Interestingly, an analysis of China's NID's focuses on incremental cost but assumes that

1980s, for example, required 0.016 volunteers per child to vaccinate every child up to 4 years old in Brazil, regardless of previous vaccination status, on one of two Saturdays twice every year.[450]

To compare, there are about 56 public health officers (local, state and federal) per 10,000 members of the population in the United States.[451] To achieve the same type of coverage for a POD in the United States as used for NIDS in Brazil, all the public health officers in a community could provide only a third of the staffing for the POD. The other two-thirds would have to come from some other source of personnel. As the dissertation previously discussed, there are various theoretical sources for additional personnel in a crisis, but it is not clear whether these sources would be available. Private health providers in the affected community could help, non-health providers in the community could help, or possibly health care providers from surrounding communities, if they were willing and able to leave their own community in the midst of an attack. The planning for identifying and deploying these additional personnel has not been done.

The PODs would need security, but security personnel would be scarce in an affected community. Security personal would be needed to provide general security in the community, to provide security to the PODs, and to the caches of antibiotics or other medical countermeasures

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sufficient personnel would be available. It observes the importance of planning: "To ensure an effective NID conducted in an efficient manner, great attention should be paid to careful planning at township and village level. This planning must include preparation of vaccine, transportation, training, supervision as well as monetary field allowances and incentives. County and upper level health authorities should play a more active role by coordinating the technical support that is required to plan appropriately and ensure realistic forecasting of resource requirements."

[450] JB Risi, Jr., "The control of poliomyelitis in Brazil, *Reviews of Infectious Diseases*, 1984 May-Jun; 6 suppl 2:S400-3: "A new twice yearly vaccination day strategy was put in place in 1980, where all children up to 4 years were to be given oral vaccine, on a Saturday in June and August. The dates were chosen to take advantage of school facilities, volunteers, and the cool months of the year. 90,000 sites, 320,000 volunteers, 36 million doses of vaccine, and close cooperation between local, state and federal governments were involved. Nearly 20 million children, without regard to previous vaccination status, were vaccinated in each of 6 campaigns from 1980-1982."

[451] US Census Bureau; Federal, State and Local Government; Public Employment and Payroll; State and Local Government; *Compendium of Public Employment,2002;* Table 3: Summary of Public Employment and Payrolls by Function: March 2002. "Public safety officers" is calculated by adding "police protection" and "fire protection." "Public health officials" is calculated by adding "Hospitals" and "Health."

as they are in transit between sites.[452] There is only small capacity to surge local and state law enforcement capabilities. Most of the local capability would be used to provide general security for the community. Additional security for other tasks, such as securing the PODs and the caches of medical countermeasures, would need to be provided by law enforcement from surrounding communities, if they are made available, or from the federal government, most likely the National Guard or the active duty military.

The National Immunization Days (NIDs) are obviously easier to implement than would be the response to a catastrophic biological attack. The NIDs are planned long in advance, while the need to respond to a catastrophic attack would emerge unexpectedly on short warning. The date of the National Immunization Days often is selected to maximize the availability of personnel, facilities and supplies. At the same time, the successful implementation of immunization days throughout the world, including in the United States during smallpox epidemics and polio epidemics in the 1950s, seem to demonstrate that the needed rate of immunization could be achieved if detailed plans were developed in advance. Such integrated plans would not be developed in the current situation.

*Postal Delivery or "Push" Systems*

A second theoretical technique would be to deliver the needed medical countermeasure to individuals at home. There are several theoretical ways to do this, but the one being developed envisions mail carriers, escorted by police, delivering the countermeasures to each home using

[452] Hupert, et al., "Community-Based Mass Prophylaxis," see page 7: "[L]aw enforcement would have three distinct tasks in a mass prophylaxis response: maintaining the safety and security of both patients and medical stockpiles during the prophylaxis response, maintaining public order generally, and carrying out a criminal investigation of the attack. These three tasks may need to occur simultaneously at each DVC…"

the established mail routes.[453] Separate groups of public health workers could take countermeasures to dormitories, detention centers, and other large-group centers.

This approach has several advantages: pilot programs indicate it could be faster than the traditional PODs; it would probably require fewer personnel overall; it could serve the elderly and sick who would be disinclined or uncomfortable about coming to a central distribution point; it would keep more individuals away from hospitals and other health care sites that are notoriously effective places to transmit disease during an infectious disease epidemic.

This approach would have disadvantages, including that unless reengineered it would not have the best screening of individuals with contraindications for the medical countermeasure being distributed. It also would be poorly suited for more complex countermeasures – like vaccines – that cannot be self-administered.[454] One way to reengineer it would be to have a medical professional accompany the mail carrier and the policeman.

HHS has conducted pilot programs in Seattle, Philadelphia and Boston to demonstrate "the ability of letter carriers to quickly deliver door-to-door quantities of antibiotics from the Strategic National Stockpile to residential addresses. This quick-strike capability is intended to buy time for local and State public health authorities to set up points of dispensing for further provision of antibiotics across the community."[455]

The personnel requirements would be lighter at the outset than traditional PODs but would, even from the outset, require at least two pools of personnel: (1) postal carriers to cover

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[453] Lawrence M. Wein, "Neither Snow, Nor Rain, Nor Anthrax….., New York Times, October 13, 2008.
[454] Hupert, et al., "Community-Based Mass Prophylaxis," see page 2: "The 'push' approach may enable faster and more widespread coverage of an affected community, but it has little flexibility to handle medical evaluation for contraindications or dosage adjustment and may be infeasible fir vaccination campaigns."
[455] Department of Health and Human Services, News Release: "HHS Announces New Steps in Anthrax Preparedness," Released Wednesday, October 1, 2008. HHS website (http://www.hhs.gov/news/press/2008pres accessed 11/12/2008).

all established mail routes (with their understandable concerns about their safety and the safety of their families having been assured); and (2) a police officer or other security officer to accompany each of the postal carriers (there is general agreement that the postal workers, carrying significant caches of antibiotics in an infectious disease epidemic, would need some law enforcement protection). There might be a third requirement: for a medical professional to travel with the postal worker to administer a vaccine or provide some screening. Adding screening by a medical professional would greatly complicate and slow the rate of delivery, but would likely increase its accuracy. Easing delivery techniques, like making vaccines oral as opposed to injectable, would generally ease the distribution problem.[456]

While estimates are tough to come by, one could assume that the baseline numbers of state and local law enforcement personnel would be busy maintaining community security. The security personnel needed to accompany the postal carriers would probably need to be in addition to the local law enforcement community. The state and local public health community would be busy dealing with special physical communities (hospitals, retirement homes, dormitories) and populations (immunocompromised individuals, children, pregnant women) as well as setting up PODs to provide follow-on supplies of antibiotics to reach recommended 60-day amounts and provide some place for screening. Under all plans for "push" systems or postal delivery, there is an expectation that PODS would be opened up after a few days to provide

[456] NIAID, "Strategic Plan for Biodefense Research," 2007 Update, see page 5: NIAID has set as one goal developing "Broad Spectrum Technology:" "Broad Spectrum Technology refers to capabilities – such as temperature stabilization or delivery method – that can be engineered into a wide array of existing and candidate products. Developing countermeasures that will be useful in responding to future threats represents a major challenge, given the capabilities that these products must possess. They should be safe and effective against multiple pathogens in people of any age and health status. To be appropriate for storing in the Strategic National Stockpile, the products should be suitable for long-term storage at room temperature, have simple compact packaging, be easily delivered in a mass casualty setting, confer protection with limited dosing, and have single dose delivery devices that can be self-administered. Added to these factors is the potential need to produce additional quantities with little notice, requiring manufacturers to take the costly step of keeping production facilities on standby."

follow-on medications and additional screening.[457] Thus, there remain significant requirements for additional personnel that have not been resolved.

*Med Kits*

The third theoretical technique would be giving the countermeasures to individuals well in advance of an attack and letting them keep the countermeasures at home. This technique was tested by the CDC in a pilot project and it did well overall by the criteria CDC established. HHS has implemented it in the case of postal carriers in Seattle, Philadelphia and Boston who have agreed to deliver antibiotics in the event of an anthrax attack.[458] These individuals have caches of anti-biotics at home for themselves and their families so they are comfortable delivering antibiotics to others in a crisis.

The pilot study sought to establish whether individuals would only use the items consistent with instructions from public health leaders, and whether the individuals would misplace the antibiotics. In the pilot study, the vast number of individuals could find the antibiotics after six months, had not taken the antibiotics, and reported that they liked having the antibiotics in their home given the risk of a bioattack.[459] These were the criteria identified as the critical variables in the study.

The "med kit" approach has many strengths and weaknesses. The weaknesses include that it provides little flexibility in terms of the nature of the countermeasure and so is not responsive to modifications that may be discovered in the threat pathogen. It also violates most

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[457] Hupert, et al., "Community-Based Mass Prophylaxis." see page 2.
[458] Department of Health and Human Services, News Release: "HHS Announces New Steps in Anthrax Preparedness," Released Wednesday, October 1, 2008. HHS website (http://www.hhs.gov/news/press/2008pres accessed 11/12/2008).
[459] Department of Health and Human Services, News Release: "HHS Announces New Steps in Anthrax Preparedness," Released Wednesday, October 1, 2008. HHS website (http://www.hhs.gov/news/press/2008pres accessed 11/12/2008).

profoundly the traditional public health model of having at least some interaction between the patient and a public health provider.

Conclusion

Three methods for distributing medical countermeasures have been identified. They each have strengths and weaknesses. While there are significant differences between historical cases of infectious disease outbreaks and national immunization days and the type of challenge in a catastrophic biological attack, the methods indicate that an effective response should be possible to construct if detailed, integrated planning was undertaken prior to the outbreak of an attack. The diffuseness of the public health community means that no one actor could catalyze such planning and so the relevant actors should work together to get the planning undertaken. If a catastrophic attack never happens, the planning won't have cost too much time and effort and if one occurs, it could make the difference in terms of whether the response is effective.

*(3) Non-Pharmacological Methods to Slow the Spread of Disease*

The previous sections have made plain the significant challenges to timely response to a catastrophic biological attack. Particularly if the pathogen is modified, there would be a significant challenge to having the needed medical countermeasure in quantity and then distributing it to the exposed population in time to be effective. Thus, some attention needs to be given to the best possible use of "non-pharmacological" methods to slow the spread of infectious disease. These methods are basically the historical public health tool-kit: wearing face-masks, washing hands, closing schools and other public gathering places, and encouraging or imposing isolation of infected individuals and their contacts. Concerns about the reemergence of pandemic influenza, in particular, has caused some additional study of these traditional

techniques. The data is very poor, though, about how to optimize their use. Government documents tend to be very general and descriptive. More detailed information on these methods and their optimal application should be developed given the probability that they will constitute an important component of any response, particularly to an unusual or modified pathogen.[460] This is probable because of the likely delay, at least in the near or mid-term, in the availability of appropriate medical countermeasures.

*Infection Control*

There would need to be infection control measures implemented to combat an infectious disease. These are the classic measures of "hand hygiene and cough etiquette," according to the government document that probably best develops these issues.[461] The government document, though, is very general about what measures should be taken. Washing hands and cough etiquette is certainly always a good idea, whether visiting an elementary school on a normal school day or trying to quell transmission of a pandemic influenza or other contagious epidemic.

More detailed questions naturally get to the question of face masks or respirators and their possible utility in quelling the spread of infection. The government information on masks and respirators is not really helpful. The information notes that masks should only be used once (although stockpiles would doubtless be limited in a crisis) and that the masks would not protect against very small particles. There is no specification, though, of which bioagents would be "small particles" and how small they would have to be to defeat the effectiveness of masks. The

[460] The request for much more detailed information about the efficacy of these methods is the reasonable request, among others, of a recent paper authored by Richard J. Danzig, Rachel Kleinfeld, and Philipp C. Bleek, "After an Attack: Preparing Citizens for Bioterrorism," Center for a New American Security, June 2007.
[461] This is a document meant to support community planning for pandemic influenza, Department of Health and Human Services, "Community Strategy for Pandemic Influenza Mitigation," February 2007. PandemicFlu government website (http://www.pandemicflu.gov/plan/community/commitigation.html accessed 11/19/2008).

government materials also discuss the use of a "respirator" – an N95 or "higher filtering facepiece respirator" which protect against breathing in even very small particles. The government materials underscore that the respirators have to be specially fitted for each individual and should only be used once.[462] It is a fair criticism that the scientific data for the use of these items is poorly developed and even more poorly disseminated.[463] Particularly over time, as the risk of attack by a modified or unusual pathogen increases, it is likely that these basic infection control measures would be a critical element to at least slow the rate of spread of an infection while medical countermeasures are developed, produced and distributed.

*Closing Schools and other Public Gatherings*

Closing schools and other places of public gathering have long been a technique to control the spread of infectious disease. Current government documents note the particular ease of transmission by children and urge considering closing schools. It recommends that state and local public health authorities only "consider" closing schools and other gathering places (including workplaces) when the case fatality rate of a pandemic influenza was 1 percent or less. The government document would recommend to state and local public health authorities that they close schools and other gathering places if the case fatality rate rises above the 1 percent level but the tone of the recommendation is deferential to the local public health authorities. The 1918 pandemic is judged to have had a lethality rate of about 2.5 percent. It's probably worth

[462] Department of Health and Human Services. "Masks/Respirators" Pandemicflu government website (http://www.pandemicflu.gov/vaccine/mask.html accessed 11/19/2008).
[463] Richard Danzig et al., "After an Attack," see page 14: "The United States has not established research and development programs that would provide clarity as to the utility of masks, and filters or personal and home decontamination, and has not planned for surge production of these items or prophylactic medical treatments if policymakers conclude that they are useful. Nor has the United States developed consensus about how to react to risks once an attack has occurred. Broadly applicable public health advice and procedures for limiting contagion may be announced and implemented (avoid crowded places, close schools, etc.).

noting that many bioagents are as infectious as influenza and would be expected to have lethality rates significantly higher than 1 percent.

*Shelter in Place*

Another strategy to control the epidemic would be for individuals or families to choose to stay at home and hence avoid infection from others. The strategies to enable people to choose to shelter in place are not fully in place. Strategies to secure a building through the use of high-density filters, plastic-sheeting and duct tape, or other measures have not been thoroughly researched and certainly not outlined in a comprehensive and easily understood fashion. There would also need to be plans to provide food and other necessary supplies to individuals at home, and information about how to safely decontaminate a family member who went out into the community to get supplies or to go to work and to enable them to return home safely. The technical understanding of many of these measures is poor and they have not been clearly explained to the general public.

*Conclusion*

This chapter discusses the second enabling condition – that the broader public health infrastructure must be sufficiently committed and coherent that it can provide supportive, ongoing care in an appropriate environment. This second enabling condition also would not be expected to be met in a catastrophic biological attack. A catastrophic biological attack would stress the medical infrastructure anywhere and, while cross national comparisons are difficult, the United States is probably as well prepared as any other country. There is a broadly held view, though, that the current public health infrastructure in the United States would be overwhelmed by a bioattack of any significant size.

The dissertation specifically makes two recommendations for strengthening the public health response. Both recommendations try to overcome some of the weaknesses inherent in the structure of the public health community in the United States. The structure of the public health community in the United States has many more strengths, including particularly those of federalism – local responsiveness and control. The weaknesses include a sometimes limited ability to reach agreement on and implement strategic change, particularly in the absence of a crisis. Most organizations, even if they have a unified structure, find it very difficult to make changes in strategic direction in the absence of a crisis of some sort. The public health community in the United States has a highly diffuse structure, with local, state and federal officials often working collegially and effectively on agreed problems. In the absence of a crisis, however, it takes some time for consensus to emerge within the broader community on a newly emerged problem, particularly one like biodefense that emerges from the concerns and responsibilities of an entirely different professional community.[464]

The two recommendations seek to accept and manage that diffuseness: (1) detailed, integrated planning on how to execute a response to a catastrophic biological attack should be undertaken, with an initial focus on how stockpiled countermeasures could be distributed on the needed timeline; and (2) detailed, technical analysis of public health response to a catastrophic biological attack, including particularly distribution of stockpiled countermeasures. This analysis should be embedded in a forum with legitimacy in the public health community, possibly the international scientific exchange recommended above, to strive to build greater

[464]It should be noted that some could argue that the lack of focus in the public health community arises solely from a substantive disagreement between the security community and the broad public health community about the real risk of a catastrophic biological attack. Some members of the public health community would argue that the problem is not their broader professional community's inability to respond to strategic change but rather the security community's inability to admit it is wrong about the risk of a catastrophic biological attack.

agreement from the bottom up in the public health community on the potential challenge posed by bioattack. This call for integrated planning and technical analyses accepts the structure of the public health community but attempts to make it work effectively to solve this problem, in the near and mid-term.

## Section III

## Defense of the US Homeland

### Conclusion of the Defense Section

In traditional defense of the US homeland, state and local governments have taken principal responsibility for responding to the threats that have confronted the homeland -- disasters, accidents and epidemics. This generally has made sense and worked well because two enabling conditions were present. First, the nature of the threats was limited to relatively small disasters, accidents and epidemics whose response could be (and generally was) well-managed by state and local public safety officials, with their inherent ability to get to the scene first, generally high professional skills, and significant local expertise. Second, for the larger disasters or epidemics that inevitably did occur occasionally, the federal government had little unique assistance to offer, particularly in the time-sensitive early phases of the crisis.

*Likely Presence of Enabling Conditions*

Neither of these enabling conditions would be present in a catastrophic biological attack on the homeland. Most disasters and accidents in the homeland have killed fewer than 100 people. Only three episodes in the US homeland have caused more than 10,000 deaths, the number assumed in a catastrophic biological attack. Traditional defense approaches would be overwhelmed by the greater scale, speed and technical complexity of a catastrophic biological attack. With the advent of targeted medical countermeasures, there would at least be the prospect that federal expertise and materials could significantly improve the response in the very early hours and days of a possible biological event, long before the federal government generally gets involved in the detailed response to a homeland security event.

The reality that traditional approaches would be overwhelmed creates two problems: (1) additional capabilities are needed to respond effectively to these larger, catastrophic attacks, and (2) there is significant ambiguity in the US federal system about who would be responsible for handling the response to these larger events. This ambiguity complicates the development of the needed additional capabilities and their efficient use in an actual crisis.

*Recommendations for Refinements*

This dissertation makes two specific recommendations: (1) the president should explicitly have responsibility for making the needed strategic decisions to shape the response to a biological event and decision aids should be constructed to assist him; and (2) additional "modular" federal capabilities should be created to supplement state and local capabilities in a catastrophic crisis and a clear and agreed leadership structure should be created to assure its effective use in a crisis, consistent with US federal values.

An effective response to a catastrophic biological attack would require that complex and highly-contested strategic decisions be made and made quickly. There does not appear to be explicit recognition that these decisions would need to be made, appropriate analytical means to support them, or explicit authority or agreement on who should make them. This situation creates significant risk that in a catastrophic biological attack needed strategic decisions would not be made swiftly enough to be implemented. Traditional defense of the homeland usually does not require any official to make strategic decisions. The public safety objective is generally unstated but straightforward – maximize lives saved and minimize property damage. This dissertation urges that the president explicitly have responsibility for strategic decisions in a biological event and that an appropriate set of analytical tools and authorities be developed to

support him. The dissertation describes the type of analysis that should be used to support these decisions given the very limited information that would be available in an actual crisis. Given the tight timelines, the absence of a serious debate in the literature and in the policy world about how these decisions would be made and who would make them makes an effective response to a catastrophic biological attack unlikely.

State and local emergency response is usually effective at the tactical and logistical elements of a response. This dissertation urges the development of "modular" federal capabilities that can appropriately supplement state and local capabilities in a catastrophic event in the homeland. A variety of leadership models, consistent with US federal values, could work and should be evaluated. The capabilities are described as "modular" because they would not constitute a stand-alone, unique response structure for catastrophic events, but rather would be additional types or increments of capability to supplement existing capabilities. These "modular" federal capabilities make the integrated effort effective given the greater scale, speed and complexity of a catastrophic attack. The needed capabilities for these new "modular" pieces and how they would work with existing state and local assets have not been articulated, much less agreed or implemented between local, state and federal officials. There do not appear to be authorities, agreements or expectations that allow either the president or the governor to lead an integrated set of federal, state and local assets such as would be needed to respond effectively to a catastrophic event.

*Medical Aspects of Defense*

A catastrophic biological attack would pose some unique medical challenges. Public health was significantly transformed in the mid-1900s as targeted medical countermeasures

became widely available for the first time. The enabling conditions for an effective public health response in this post-drug age are two-fold: one scientific and one societal. First, the bug must be relatively slow in evolving to defeat the countermeasure; and second, the broader public health infrastructure must be sufficiently committed and coherent that it can provide supportive, ongoing care in an appropriate environment.

*Likely Presence of Enabling Conditions*

Neither enabling condition would be expected to be present in the case of a catastrophic biological attack. The first enabling condition -- the bug must be relatively slow in evolving to defeat the countermeasure – would be defeated by adversaries exploiting natural mutation or mutation facilitated by 21st century biotechnologies. A characteristic of the biotechnologies is that for the foreseeable future it is expected to be vastly easier to modify a pathogen than to modify the medical countermeasure needed to defeat the new pathogen. This characteristic of the biotechnologies favors the attacker over the defender. A situation where the attacker is favored over the defender is called offense dominant. Offense dominant situations are considered to be highly vulnerable to a host of destabilizing behaviors, including wars of preemption and defensive arms races.

The second enabling condition – that the broader public health infrastructure must be sufficiently committed and coherent that it can provide supportive, ongoing care in an appropriate environment -- also would not be expected to be met in a catastrophic biological attack. A catastrophic biological attack would stress the medical infrastructure in any country and, while cross national comparisons are difficult, the United States is probably as well prepared as any other country. There is a broadly held view, though, that the current public

health infrastructure in the United States would be overwhelmed by a bioattack of any significant size.

*Recommendations for Refinements*

This dissertation has four broad recommendations, two each for medical countermeasure strategy and for public health response. The two recommendations for defensive medical countermeasures urge that: (1) the substance of the strategy should be a continuum of activities focused on providing capabilities over time, as both the likely nature of the threat and of the possible defensive capabilities evolve, focusing on a strategy of stockpiling, and then of rapid adaptation, and then of transformative strategies; and (2) the institutional structure for pursuing a medical countermeasure strategy should be an international scientific exchange. This strategy would best align incentives and resources, both technical and fiscal, with broader strategic objectives. These strategic objectives include the long-term goal of shifting bioattack from offense-dominant to defense-dominant, as well as minimizing spiral model effects and strengthening deterrence model effects.

The two recommendations seek to accept and manage that diffuseness: (1) detailed, integrated planning on how to execute a response to a catastrophic biological attack should be undertaken, with an initial focus on how stockpiled countermeasures could be distributed on the needed timeline; and (2) detailed, technical analysis of public health response to a catastrophic biological attack, including particularly distribution of stockpiled countermeasures. This analysis should be embedded in a forum with legitimacy in the public health community, possibly the international scientific exchange recommended above, to strive to build greater agreement from the bottom up in the public health community on the potential challenge posed

by bioattack. This call for integrated planning and technical analyses accepts the structure of the public health community but attempts to make it work effectively to solve this problem, in the near and mid-term.

The challenges of updating traditional defense of the US homeland are significant, but surmountable. Unhappily, the same can be said about the challenge confronted by a talented and determined adversary seeking to develop a catastrophic weapons capability. History may record which party stays most tightly focused on their objectives and makes best use of available time and resources.

## Chapter 13

## Conclusion of the Dissertation

This dissertation finds that the full implementation of the traditional security approaches of prevention, deterrence and defense would not be effective at protecting the United States from a catastrophic biological attack. The traditional approaches would not merely fail but would prove to be counterproductive. Most of the relevant literature – in both the policy and academic worlds – urges the application of traditional strategies to the catastrophic biological attack problem.

The traditional approaches ultimately would be defeated by a changed world. It is a world still organized by nation-states but one affected by 21st century biotechnologies, with their more diffuse international distribution and unique technical characteristics, and one where important non-state actors with both economic and security ambitions constrain some state choices. The dissertation recommends refinements to the traditional strategies to strengthen their effectiveness against catastrophic biological attack. This concluding chapter restates these proposed refinements and then considers their possible broader application.

It particularly considers two broader applications. First, the biotechnologies are one of the first technologies with profound destructive potential whose advances are fueled by technologists in the civilian sector -- private companies, universities and research labs with no meaningful ties to the security community.[465] Unlike previous destructive technologies, which generally emerged from research funded by and nourished within the security community, there is no obvious group of experts who combine a deep understanding of the biotechnologies and of

[465] The other possible contender for "first" is the computer technologies; these technologies were born in the security world but have advanced well beyond it.

security issues. Technologies fueled by advances and practitioners in the civilian world pose a great challenge to traditional defense approaches and structures. The defense response is vulnerable to being perpetually out of date, particularly in a technology advancing rapidly.

The second broader issue is the general applicability of these refinements for catastrophic terrorism in general, as opposed to solely catastrophic biological terrorism. Some of these refinements almost certainly are relevant to other forms of catastrophic terrorism. The strongest example is that traditional methods for homeland defense would be overwhelmed by the greater scale, speed and technical complexity of most forms of catastrophic terrorism, not merely biological terrorism. Traditional defense must recognize the new requirement in these catastrophic events for strategic decision-making, as well as federal "modular" capabilities to supplement state and local capabilities for tactical and logistical response.

*Four Broad Recommendations*

The dissertation is organized by the three traditional strategies – prevention, deterrence, and defense. Prevention seeks to stop an adversary or a potential adversary from acquiring a capability that could be used to decisive effect in an attack. Deterrence seeks to dissuade an adversary from launching an attack by making it plain in advance that the costs would significantly outweigh the benefits. Defense is protecting against an adversary's attack so as to minimize its effects.

The dissertation specifies the traditional strategies and identifies the enabling conditions that were necessary to make these strategies effective in the past. It then considers whether these enabling conditions are likely to be present in the case of 21st century biotechnologies. In most cases, the dissertation finds that the enabling conditions cannot reasonably be expected to be

present in the case of the biotechnologies. Where the enabling conditions are not expected to be present, the dissertation proposes refinements to the traditional strategies. This concluding chapter restates these proposed refinements and then considers their broader applicability, particularly to other areas of technology being driven by civilian-sector advances and to other forms of catastrophic terrorism. The dissertation has four broad findings.

*(1) A Refined Prevention Strategy*

Prevention seeks to stop an adversary or a potential adversary from acquiring a capability that could be used to decisive effect in an attack. The traditional prevention strategy combined four tools: (1) export controls; (2) peaceful use limitations; (3) norms, sanctions and benefits; and (4) prohibitions. Export controls can prevent or at least slow the diffusion of worrisome technology. Inspections can assure peaceful use of worrisome technology. Norms define good behavior so worrisome behaviors are more noticeable and can be shamed or punished. Prohibitions are particularly useful if coupled with effective inspections that can assure others are not creating threatening capabilities and hence reduce spiral model incentives.

This dissertation finds that a prevention strategy would need to be significantly modified to be effective in the case of catastrophic biological attack. It argues that the first two traditional tools, export controls and peaceful use limitations, are unlikely to yield much security benefit in the biological case. This assessment is at odds with most of the literature, which assumes that the classic prevention tools should be applied to the biological case and would yield meaningful security benefits.

Export controls would be undercut by the diffusion of technology, lack of political consensus on controls, and emergence of significant non-state actors, both economic and

security, with interest and expertise in the biotechnologies. Knowledge and materials needed for catastrophic biological weapons attack are widely diffused abroad. Entry costs for biological weapons are low (defined in terms of both costs and technical knowledge).

Inspections to enforce peaceful use limitations would not work because there are no meaningful technical distinctions between a civilian and military program in the general pre-attack stage. They are further undercut because there would be no reliable external indicators of a biological program site, to check the declarations of a state actor or to discover the facilities of a non-state actor.

Instead, the dissertation urges a focus on norms. It recommends efforts to catalyze within the relevant international technical elite – the life sciences research community -- the development and adoption of broad, international norms on biosafety, biosecurity and worrisome dual-use research. Political science literature shows that international technical elites are the most promising place to root new norms, particularly when the norms are consistent with the core values of the technical elite. The dissertation urges that the proposed norms be developed and implemented in the context of the international life sciences research community.

Observance of norms can be strengthened through the use of sanctions or benefits. Sanctions work best in the national context or in the international context for issues perceived to be non-zero sum. Sanctions are more difficult to make work in issues perceived to be zero-sum, like security in the anarchic international security environment. Benefits often work best as an inducement for states to observe norms in the security realm. This dissertation urges that the adoption of norms should be catalyzed by the benefit of participating in a scientific exchange on defensive medical countermeasure research.

This dissertation's proposal to pursue international norms catalyzed by benefits is in contradiction to current US policy. Current US policy appears to be seeking to build a system of national, unilateral norms enforced by sanctions. Such national, unilateral norms would provide a security benefit but would impose security, economic and technological costs.

Norms can be imperfect but still be useful if they perform a culling function, helping to distinguish standard cases from worrisome cases. Worrisome cases would need to be further investigated through diplomatic, intelligence and law enforcement assets.

International norms, coupled with further investigation of worrisome cases, should strengthen the existing prohibitions against biological weapons acquisition and use. Prohibitions, particularly if coupled with effective confidence-building measures, can reduce spiral model tendencies. They can yield more stable security outcomes at lower costs and force levels than could have been otherwise achieved. Prohibitions are not, though, invariably a boon to peace and security. Poorly crafted prohibitions – particularly if the benefits of cheating are significant, if they principally accrue to the offense, and if verification or transparency is poor – could worsen spiral model effects and cause deterrence failures.

Spiral model effects seem most dangerous on other status quo states. Preserving and strengthening the international norm against biological weapons acquisition and use provides valuable benefits, as long as no significant policy-maker forgets that the norm is not verifiable in any meaningful sense. Deterrence effects seem most significant with non-state actors, who, because of the characteristics of the biotechnologies, could launch a catastrophic biological attack. This dissertation urges that policy should seek to minimize spiral model effects on other status quo states, but strengthen deterrence and defense against non-state actors.

This concluding chapter muses on the broader applicability of these findings for two broader phenomenon – first, the increasing importance of civilian-sector technologies (those technologies rapidly progressing because of advances and practitioners in the civilian sector and with few natural ties with the security community), and, second, the broader implications for all forms of catastrophic terrorism.

The biotechnologies provide the first powerful case of a technology driven by advances in the civilian sector, with few if any meaningful ties to the security world but profound destructive potential. These differences between the relevant professional communities have proven to be exceptionally difficult to manage. Both the public health/life sciences community and the security community have proud and distinguished intellectual and policy traditions. These traditions often mesh poorly, however, because of the different norms, values, backgrounds and technical expertise of the two groups. Progress is likely to be stymied on many policy fronts unless the challenge of shaping security policy for an area of technology with few natural ties to the security community can be overcome.

The broader implication of the insight that that unilateral control measures are unlikely to be effective is likely to be true over time for an increasing number of technologies. The effectiveness of control strategies is likely to vary somewhat across technologies. Some technologies are more easily controlled than others and some are more widely diffused. The general insight that a promising strategy is to use technical elites to build international norms probably would be useful in other technology areas. As in the biological case, international norms are not likely to be a complete solution in any technology area. As technology diffuses more widely, the importance of international norms likely also will grow more important. Even as the value of these international norms is recognized, however, their limitations also must be

clearly recognized and, where possible, minimized. In the case of international norms on biosafety, biosecurity and dual-sue research, the limitations must be acknowledged and the importance of supplementing the norms with diplomatic, law enforcement and intelligence efforts must be recognized.

*(2) A Refined Deterrence Strategy*

Deterrence seeks to dissuade an adversary from launching an attack by making it plain in advance that the costs would significantly outweigh the benefits. The dissertation finds that classic deterrence would not work in the case of a non-state actor contemplating catastrophic biological attack. It demonstrates the extreme limits of classic Cold War-style (post-attack retaliation) deterrence against non-state adversaries. Terrorists will be difficult to locate to target for retaliation and may not, on balance, care if they survive. New methods of deterrence can and should be shaped and implemented but they need to be more tailored -- focusing on particular political or territorial goals or risks associated with specific attack modes.

This dissertation has argued that a terrorist group could be shifted out of the biological attack mode into another attack mode through making clear the significant risks an attacker would confront in launching an effective attack and the very real risk that an attacker would, even in an unsuccessful attack, compromise their trained operatives, probably their most valuable operational asset.

The threat of post-attack retaliation is not a solid basis for deterrence against a non-state adversary contemplating a catastrophic biological attack. The limits on post-attack retaliation grow out of broad concerns that the threat of retaliation is weak against groups that could not be identified and located and may not, on balance, prefer to avoid their own devastation. A

determined and talented non-state actor probably could develop a biological weapons capability while generating few if any external indicators that could be used to locate the weapons facility. Destruction of the leadership team of the attacking organization may not matter – either to them or to the long-term health of the terrorist organization. Post-attack retaliation would not merely fail to deter a non-state adversary but would likely prove counterproductive. The terrorism literature warns that it is precisely such undifferentiated retaliation that proves a boon to the recruiting efforts of most terrorist groups.

Post-attack retaliation is a more potent threat to a nation-state. Post-attack retaliation probably would be sufficient to deter an overt attack by a nation-state. There are two remaining concerns: deterring covert assistance from a nation-state to a non-state actor or deterring a covert attack by a nation-state itself. These risks could be reduced through declaratory policy and strengthened attribution capabilities but probably never eliminated entirely.

Neither the United States government nor the academic literature has articulated a coherent declaratory policy against catastrophic biological attack by a non-state actor. US declaratory policy remains limited to a set of related but not directly germane observations that are largely unhelpful to the problem of deterring a non-state adversary.

This proposed shift from the Cold War's model of post-attack retaliation is significant. In the biological case, the declaratory policy should warn that the attack could fail and in that failure would almost inevitably expose the attackers' most valuable operational assets to destruction. The attacker's operational cells deploying the biological pathogen would very likely be caught by the defender's law enforcement forces, regardless of the ultimate effectiveness of the attack. These operational cells – like the 19 hijackers in the US who launched the 9/11

attacks – may be the non-state actor's most valuable assets: skilled, loyal operatives successfully concealed in the United States. However the leaders of the terrorist group may feel about their own destiny, they are likely to accept only so much risk that these operational assets would be destroyed in an attack mode with a meaningful risk of complete failure. The terrorist group may prefer to shift to a different attack mode, with a higher rate of operational success but a lower rate of death in the defender's population.

The biological attack could fail for one of three reasons: (1) the delivery mode fails because the attackers decide to avoid detection by foregoing testing (detection and disruption); (2) the attack would work but the defender effectively defends against its effects (tactical denial); (3) the attack works but fails to secure the attacker's strategic and tactical goals (strategic denial). These three outcomes are plausible, as is the argument that launching the attack would almost certainly expose the operational cells. Unhappily, as has been the focus of most of the rest of the dissertation, a plausible outcome also is that the attack is successful from the attacker's point of view. The declaratory policy cannot pretend that failure for the attacker is inevitable, but it should paint the starkest possible picture of the risk the attacker would be running with its very precious and limited operational assets.

The underlying capacity of the defender to cause the three deterrence outcomes – deterrence through detection and disruption, through tactical denial, and through strategic denial -- should be strengthened. Deterrence through detection and disruption largely relies on intelligence and law enforcement assets, like the technical capacity to observe the testing of aerosol delivery capabilities even in relatively remote parts of the world. Aerosol delivery systems are relatively easy to build but notoriously tricky to optimize and hence, for example, both the early US and Soviet systems found testing to be essential. Deterrence through tactical

denial relies on continued improvement to the nation's ability to respond to a biological attack in a timely and effective manner with needed medical countermeasures and supportive care. Deterrence through strategic denial – seeking to assure that the adversary does not achieve the sought political or territorial ambitions -- would be achieved through a variety of tools, including strengthened and updated non-proliferation norms robustly supported by the international community.

Deterrence would be greatly strengthened by shifting declaratory policy from post-attack retaliation to the real risk of failure and the almost inevitable exposure and destruction of key operational assets. But while worthy, deterrence will remain somewhat weak and uncertain. An attacker may decide they are prepared to risk failure. Risking it, they may well instead succeed, causing unprecedented deaths and strategic reversal for the United States. Deterrence strategy should be updated and strengthened as suggested here, but its inherent weakness in the case of catastrophic biological attacks must be recognized.

This concluding chapter considers some of the broader implications of this finding. The disconnects between the civilian-sector technology and the security community can be seen in some of the discussion of deterrence. The security analysts tend to apply traditional security thinking about deterrence, which primarily grew during the Cold war conflict with the Soviet Union. The relevant characteristics of a likely biotechnology program – like the ease of locating it to retaliate – seem to infrequently be reflected in this literature. These odd disconnects between the literature probably arise because of the poor connections between the two fields.

This concluding chapter also considers the applicability of these findings to other forms of catastrophic terrorism. This dissertation observes that post-attack retaliation is unlikely to be

effective against non-state adversaries in any warfare area. Deterrence policies effective against terrorist groups may be crafted, but they will need to be much more tailored, sensitive to the particular interests of the terrorist group and to the particular risks posed by different attack modes.

*(3) Defense of the Homeland Against Catastrophic Terrorism*

The third and fourth recommendations have to do with defense. Defense is protecting against an adversary's attack so as to minimize its effects. For catastrophic biological attack, there are two separate sections of defense, the traditional defense of the homeland challenges and the medical response. On traditional defense of the homeland, the defense section describes the traditional method for defense of the homeland with the leadership role played by state and local governments. It then demonstrates how these methods would be overwhelmed by the vastly greater scale, speed and technical complexity of a catastrophic biological attack. A well-conceived, well-executed biological attack is one of the few attack modes that could be implemented by a non-state actor and have catastrophic effects on a large and capable nation-state. The dissertation makes specific recommendations to supplement traditional defense methods to deal with catastrophic biological terrorism.

These traditional defense methods must be supplemented in two ways: (1) the president should explicitly have responsibility for making the needed strategic decisions to shape the response to a biological event and decision aids should be constructed to assist him; and (2) additional "modular" federal capabilities should be created to supplement state and local capabilities in a catastrophic crisis and a clear and agreed leadership structure, consistent with US federal values, should be created to assure its effective use in a crisis.

An effective response to a catastrophic biological attack would require that complex and highly-contested strategic decisions be made and made quickly. There does not appear to be explicit recognition that these decisions would need to be made, appropriate analytical means to support them, or explicit authority or agreement on who should make them. This situation creates significant risk that in a catastrophic biological attack needed strategic decisions would not be made swiftly enough to be implemented. Traditional defense of the homeland usually does not require any official to make strategic decisions. The public safety objective is generally unstated but straightforward – maximize lives saved and minimize property damage. This dissertation urges that the president explicitly have responsibility for strategic decisions in a biological event and that an appropriate set of analytical tools be developed to support him.

The dissertation has a lengthy discussion of the type of analytical tools that should be developed. The challenge of decision-making in a catastrophic biological attack has too often been ignored. The focus instead has been on getting accurate data about each diagnosis to enable accurate case management and comprehensive post-event review and assessment. In those cases where the challenge of decision-making has been seriously considered, the posited solution has generally been to get the data about each case more quickly to a central point and then swiftly aggregate it. This dissertation argues that in a possible catastrophic biological attack an alternative approach is needed: robust extrapolations using the limited data available early in the crisis. The extrapolations should be robust in their recognition of what is known (for example, speed of symptoms emerging after exposure for a particular pathogen) and what is not known (for example, maybe it's a catastrophic biological attack or maybe it's just a single, benign case from innocent exposure to an infected animal skin). Given the tight timelines, this absence of a serious debate in the literature and in the policy world about how these decisions would be made

analytically and who would make them vastly reduces the probability of an effective response to a catastrophic biological attack.

State and local emergency response is usually effective at the tactical and logistical elements of a response. This dissertation urges the development of "modular" federal capabilities that can appropriately supplement state and local capabilities in a catastrophic event in the homeland. A variety of leadership models, consistent with US federal values, could work and should be evaluated. The capabilities are described as "modular" because they would not constitute a stand-alone, unique response structure for catastrophic events, but rather would be additional types or increments of capability to supplement existing capabilities. These "modular" federal capabilities make the integrated effort effective given the greater scale, speed and complexity of a catastrophic attack. The needed capabilities for these new "modular" pieces and how they would work with existing state and local assets have not been articulated, much less agreed or implemented between local, state and federal officials. There do not appear to be authorities, agreements or expectations that allow either the president or the governor to lead an integrated set of federal, state and local assets such as would be needed to respond effectively to a catastrophic event.

The dissertation argues that traditional defense of the homeland methods would be overwhelmed in the case of catastrophic biological terrorism. This concluding chapter speculates that catastrophic terrorism in general could overwhelm traditional defense methods. There is a theoretical continuum of terrorist attacks on the homeland, starting at one end-point with an attack that is deadly but technically straightforward and limited in geographic area (for example, a small car bombing) and ranging to an endpoint with an attack that is deadly and very technically complex and causing broad destruction in a large geographic area (for example, a

large nuclear detonation). Subsequent analyses should extend the observation that at some point the scale, speed and technical complexity of any catastrophic terrorist event overwhelms traditional defense of the homeland methods. It seems plausible that this is true not only for catastrophic biological attacks but also for other types of catastrophic terrorist attacks.

*(4) A Refined Medical Response Strategy*

Defenses should be further strengthened through improvements in available medical countermeasures and response capability. This dissertation has four broad recommendations in the medical response area, two each for medical countermeasure strategy and for public health response. In each category, one recommendation focuses on the substance and one focuses on the structure needed to enable achievement of the substance. These recommendations are shaped most fundamentally by one of the broader implications considered in this concluding chapter – the difficulties of shaping and implementing security policy for civilian-sector technologies, technologies that are rapidly advancing, pushed fundamentally by advances and practitioners in the civilian sector, with few ties to the defense community.

The two recommendations for defensive medical countermeasures urge that: (1) the substance of the strategy should be a continuum of activities focused on providing capabilities over time, as both the likely nature of the threat and of the possible defensive capabilities evolve, focusing on a strategy of stockpiling, and then of rapid adaptation, and then of transformative strategies; and (2) the institutional structure for pursuing a medical countermeasure strategy should be an international scientific exchange. This strategy would best align incentives and resources, both technical and fiscal, with broader strategic objectives. These strategic objectives

include the long-term goal of shifting bioattack from offense-dominant to defense-dominant, as well as minimizing spiral model effects and strengthening deterrence model effects.

The dissertation outlines the recommended substance and structure for a comprehensive strategy to develop needed defensive medical countermeasures. The dissertation explains that the current medical countermeasure strategy needs to be refined to contain a continuum of activities that both extract the defensive benefits from newly emerging technologies and are sensitive to the implications of those advances for the nature of the threat that might emerge. The strategy should move through a strategy of stockpiling, to rapid adaptation, to transformative strategies. A characteristic of the biotechnologies is that for the foreseeable future it is expected to be vastly easier to modify a pathogen than to modify the medical countermeasure needed to defeat the new pathogen.

In terms of structure, the dissertation urges that the defensive medical countermeasure strategy be pursued in the context of an international scientific exchange. Such a collaborative approach would have significant benefits, but also some risks. The price of admission to the scientific collaboration should be national adoption of the scientific norms on biosafety, biosecurity and worrisome dual-use research. There should be other security and scientific benefits. The security benefit would be the benefit that pathogens in the United States and abroad would be subjected to stricter norms. Under the system of national, unilateral norms being pursued by the United States, only domestic pathogens would be better secured, a worthy objective but limited given the very real risk that the threat could come from abroad.

The scientific exchange should have further security benefits because it should reduce spiral model effects because of the greater transparency it would promote between the programs

of status quo states. The products that emerge from the scientific effort – improved vaccines and other therapeutics – should strengthen deterrence through reducing the benefits of an attack not only in the United States but in all partner countries. In a meaningful but less concrete fashion, it should strengthen the non-proliferation norm because of the greater sense of common purpose. Its scientific benefits should include the advantages of contributions – both technical and fiscal – from more countries throughout the globe.

This concluding chapter speculates on the broader applicability of this insight in an era of catastrophic terrorism that spiral model effects on other states should be minimized, even as deterrence effects on non-state adversaries are strengthened. To state these benefits in more theoretical terms, an additional benefit of the international scientific collaboration is that it should simultaneously reduce spiral model effects and strengthen deterrence model effects, increasing international security. Catastrophic biological attack may be unique, because strengthening deterrence against the non-state actors, most likely to launch such an attack, could have the effect of causing destabilizing spiral model effects on other status quo states. Other attack modes may be less neatly divided between the audience needing deterring and the audience needing reassurance.

The dissertation also makes two recommendations for strengthening the public health response: (1) detailed, integrated planning on how to execute a response to a catastrophic biological attack should be undertaken, with an initial focus on how stockpiled countermeasures could be distributed on the needed timeline; and (2) this planning should be embedded in a forum considered legitimate by the broader public health community, possibly the international scientific exchange recommended above. This proposal strives to overcome the great difficulty

in the highly diffuse US public health system of catalyzing appropriately detailed, integrated planning.

The challenges inherent in shaping a strengthened medical countermeasure strategy are fundamentally those of reaching across professional communities – of building a greater sense of common purpose between the technologists driving advances in the biotechnologies and the security community.

*Conclusion*

Henry Adams, a noteworthy observer of American life at the end of the 19th and the emergence of the 20th century, marveled at the "law of acceleration" that seemed to characterize the pace of scientific progress, studying closely the new technologies that powered ocean liners and railroads. He marveled that the amount of power a pound of coal could generate doubled every decade. He worried that while the technologists seemed to understand how the pulleys pulled and the steam engines pushed, the historians no longer seemed able to derive useful insights about the playing out of historical processes.[466]

Our generation confronts similar challenges with the biotechnologies. Some individuals are alive today and others are dead because of the remarkable power of 21st century biotechnologies. Both this power and its effect are likely to grow significantly. 21st century biotechnologies have not yet fully realized their potential for healing or for killing. Today's technologists are developing new approaches to advance these new forces yet further. New security approaches also are needed, to shape the use of these new forces for good or ill.

[466] Adams, *The Education of Henry Adams,* see pages 340-343. Also, 496.

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