IMPLEMENTING A PRECAUTIONARY APPROACH IN DECISIONS AFFECTING HEALTH, SAFETY, AND THE ENVIRONMENT: RISK, TECHNOLOGY ALTERNATIVES, AND TRADEOFF ANALYSIS*

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Abstract

The precautionary principle is in sharp political focus today because (1) the nature of scientific uncertainty is changing and (2) there is increasing pressure to base governmental action on more "rational" schemes, such as cost-benefit analysis and quantitative risk assessment, an embodiment of 'rational choice theory' promoted by the Chicago school of law and economics. The precautionary principle has been criticized as being both too vague and too arbitrary to form a basis for rational decision making. The assumption underlying this criticism is that any scheme not based on cost-benefit analysis and risk assessment is both irrational and without secure foundation in either science or economics. This paper contest that view and makes explicit the rational tenets of the precautionary principle within an analytical framework as rigorous as uncertainties permit, and one that mirrors democratic values embodied in regulatory, compensatory, and common law. Unlike other formulations that reject risk assessment, this paper argues that risk assessment can be used within the formalism of tradeoff analysis--a more appropriate alternative to traditional cost-benefit analysis and one that satisfies the need for well-grounded public policy decision making. This paper will argue that the precautionary approach is the most appropriate basis for policy, even when large uncertainties do not exist, especially where the fairness of the distributions of costs and benefits of hazardous activities and products are a concern. Furthermore, it will offer an approach to making decisions within an analytic framework, based on equity and justice, to replace the economic paradigm of utilitarian cost-benefit analysis.

In the United States, a precautionary approach has been applied in various ways in decisions about health, safety, and the environment for about 30 years, much longer than recent commentaries would have us believe, and earlier than the appearance of the 'Precautionary Principle' in European law[1]. In interpreting congressional legislation, the US courts have argued that federal regulatory agencies are required to err on the side of caution in protecting workers, and to protect public health from emissions to air with an ample or adequate margin of safety. One scholar seeks to make a distinction between a precautionary approach and the precautionary principle, asserting that "[w]ith rare exceptions, US law balances precaution against other considerations, most importantly costs" and hence is better described as a preference, rather than a principle[2]. I find this distinction superficial, or at least unhelpful, if not often inaccurate, and when understood within the context of Roman/Napoleonic-law based European legal systems preferring "codes' to court-based evolution of common law, a semantic rather than a real distinction. In the United States, in a series of industry challenges to regulations, courts acknowledged that even in the case where the scientific basis for a threat to health or the environment is not compelling, regulators have the discretion to 'err on the side of caution', without laying down a requirement to do so, although the directive to do so is often found in the enabling legislation of various regulatory regimes.

In this decade, the precautionary inclinations of the American and Anglo-Saxon jurisprudential systems, as well as codified expressions of the precautionary principle in German law, for example, have found their way into multilateral environmental agreements and international law. Principle 15 of the Declaration of the 1992 UN Conference on Environment and Development [the Rio Declaration] states: "In order to protect the environment, the precautionary approach shall be widely used by States according to their capabilities. Where there are threats of serious and irreversible damage, lack of full scientific

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certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." This is perhaps the best known statement of the precautionary principle, but the word 'approach' rather than 'principle' is used, and considerations of cost are certainly present in the phrases 'according to their capabilities' and 'cost-effective measures'. Nonetheless, it is a principle – but one to be balanced in one way or another against other principles – no different than the situation in US law. Curiously, this statement of the principle is expressed in the negative: uncertainty should not be used to delay protection, rather than a statement that protection should be embraced deliberatively even in the face of uncertainty – a subtle but important distinction. The debate in Europe today is not whether the precautionary principle is a principle, but whether it trumps other international law, particularly the manner in which risk assessment is addressed and is relevant to trade law involving the World Trade Organization[3].

What brings the precautionary principle into sharp political focus today are (1) the fact that the nature of scientific uncertainty is changing and (2) the increasing pressure to base governmental action on more "rational" schemes, such as cost-benefit analysis and quantitative risk assessment, an embodiment of 'rational choice theory' promoted by the Chicago school of law and economics. The precautionary principle has been criticized as being both too vague and too arbitrary to form a basis for rational decision making. The assumption underlying this criticism is that any scheme not based on cost-benefit analysis and risk assessment is both irrational and without secure foundation in either science or economics. This paper contest that view and makes explicit the rational tenets of the precautionary principle within an analytical framework as rigorous as uncertainties permit, and one that mirrors democratic values embodied in regulatory, compensatory, and common law. Unlike other formulations that reject risk assessment, this paper argues that risk assessment can be used within the formalism of tradeoff analysis--a more appropriate alternative to traditional cost-benefit analysis and one that satisfies the need for well-grounded public policy decision making.

The recent crescendo of commentary on the legal application of the precautionary principle, following its increased incorporation into national and multilateral environmental agreements, has focused on situations in which there are significant uncertainties about the safety, health, and environmental effects of products, technologies, and other human activities. Where those uncertainties do not exist, it is often conceded – by default if not explicitly -- that cost-benefit analysis is an appropriate approach to designing policies. This paper will argue that the precautionary approach is a more fitting basis for policy even when large uncertainties do not exist, especially where the fairness of the distributions of costs and benefits of hazardous activities and products are a concern. Furthermore, it will offer an approach to making decisions within an analytic framework, based on equity and justice, to replace the economic paradigm of utilitarian cost-benefit analysis.

I. Elements of the Precautionary Principle

The application and discussion of the precautionary principle have focused on action to prevent, or refrain from contributing to, possible serious irreversible harm to health and the environment--whether on an individual basis or in terms of widespread environmental or health consequences. In particular, the precautionary principle has become embodied in regulations directed toward persistent and/or bioaccumulative toxic substances. Here it is worth reviewing the fact that the nature of uncertainty in the problems that now concern health, safety, and environmental regulators and advocates is changing. Formerly, concentrating on the magnitude of risks and their uncertainties -- in a probabilistic sense -- consumed the attention of the decision maker. Since better science would be expected to yield a better basis for decisions, it could be argued that risk management decisions should await its arrival. Today, problems of indeterminacy and ignorance increasingly characterize the risks we face[4]. It is no longer a question of waiting for the science to be developed. The limitations of 'knowing with greater accuracy'

and ‘not knowing what we don’t know’ attend – and will continue to attend in the foreseeable future -- modern day risks and confound so-called rational approaches to dealing with these hazards. The social concern with genetically modified organisms (GMOs) or with bioterrorism are examples. The proponents of GMO’s deride social attempts to exercise caution over risks we cannot estimate or imagine, but who is arguing that taking precaution against terrorism is ‘irrational’? Ought we expect ‘consistency’ in the management of highly uncertain (i.e., indeterminable or unknowable), possibly catastrophic risks? Perhaps a different theoretical framework is needed – one outside of deterministic choice theory.

I go one step further. The precautionary principle need not be restricted to cases of irreversibility or large uncertainty of effect. It might also be applied to mitigate a harm that is ultimately reversible--if reversing the damage could be more costly than preventing it. And what of the cases in which there are no uncertainties--for example, when we know that future generations will be harmed? Cost-benefit analysis is biased against investing heavily in the present to prevent such future harm, because of the use of discounting of cost and benefit streams over time. And there are many situations in which we are aware of our ignorance: for example, we know that only a very small percentage of all chemicals in commerce have been tested for toxic effects. In these cases, too, precaution is appropriate.

However, it is not the precautionary principle per se that is amenable to replacing cost-benefit analysis as a "decision rule" for action. Nor does the precautionary principle replace risk assessment. Attempts to establish a threshold of harm above which the precautionary principle is triggered, for example, have been less than satisfactory. Rather, a precautionary approach or principle is most useful in guiding the selection of policies, and aiding in the establishment of priorities, in an attempt to deliver justice and fairness within a more appropriate framework that cost-benefit analysis. Precaution rightly focuses on uncertainty and irreversibility as two important factors, but others must be considered as well. A complete list of the important elements must include:

--the seriousness and irreversibility of the harm addressed;

--the societal distribution of possible costs and benefits of policies and technologies;

--the technological options for preventing, arresting, reversing, or mitigating possible harm; and the opportunity costs of selecting a given policy option.

--society's inclinations regarding erring on the side of caution and erring on the side of laxity;

Uncertainties in all these elements are relevant to the precautionary principle. Since most attention has been focused on the first, this paper will give special attention to the other three.

II. The Limits of Cost-Benefit Analysis in Addressing Distributional Concerns

During the past two decades, cost-benefit analysis has become the dominant method used by policy makers to evaluate government intervention in the areas of health, safety, and the environment. In theory, cost-benefit analysis of a policy option enumerates all possible consequences, both positive and negative; estimates the probability of each; estimates the benefit or loss to society should each occur, expressed in monetary terms; computes the expected social benefit or loss from each consequence by multiplying the amount of the associated benefit or loss by its probability of occurrence; and computes the net expected social benefit or loss associated with the government policy by summing over the various possible consequences[5]. The reference point for these calculations is the state of the economy in the absence of the government policy, termed the "baseline".

The mechanics of constructing a cost-benefit analysis can be seen with reference to Table 1, which presents a relatively disaggregated matrix of the various positive and negative consequences of a government policy for a variety of actors. The consequences are first separated into economic, health and safety, and environmental effects, and those affected are organized into policy-relevant groups of actors, such as firms, workers, consumers, and "others". Initially, the consequences are represented in their natural units: economic effects are expressed in monetary units; health and safety effects are expressed in mortality and morbidity terms; and environmental effects are expressed in damage to eco-systems, etc. Economic analysis is used to evaluate monetary costs and benefits related to economic effects. Health and environmental risk assessments inform the entries in the last two columns of the matrix.

TABLE 1
Matrix of Policy Consequences for Different Actors

Group	Economic Effects	Health/Safety Effects	Environmental Effects
Producers	$C_{\$}$		
Workers	$C_{\$}$	$B_{H/S}$	
Consumers	$C_{\$}$	$B_{H/S}$	
Others	$C_{\$}$	$B_{H/S}$	$B_{Environment}$

All of the consequences of a candidate policy (or regulation) are described fully in terms of the times during which they occur. What traditional cost-benefit analysis does is translate all of these consequences into "equivalent" monetary units (since a dollar/euro in an earlier time period could be invested to earn interest over time) by discounting each to present value and aggregating them into a single dollar/euro value intended to express the net social effect of the government policy.
This poses two problems. One is the difficulty, even arbitrariness, of placing a monetary value on human life, health, and safety and a healthy environment. Another is that by translating all these consequences into equivalent monetary units, discounting each to present value (since a dollar/euro invested now is expected to earn interest over time), and aggregating them into a single dollar/euro value, the effects on the economy from investing now in future health, safety, and environmental benefits are weighted far more heavily than those benefits that occur in the future, including those to future generations.

As a decision-making tool, cost-benefit analysis offers several compelling advantages. It clarifies choices among alternatives by evaluating consequences systematically. It professes to foster an open and fair policy-making process by making explicit the estimates of costs and benefits and the assumptions upon which those estimates are based. And by expressing all gains and losses in monetary terms, cost-benefit analysis permits the total impact of a policy to be summarized in a single dollar/euro figure. (Cost-effectiveness analysis relies on a benefit-to-cost ratio, rather than a net benefit calculus but otherwise shares the other weaknesses of a cost-benefit approach.)

This final step, however, may be stretching analytic techniques one step too far. An alternative approach, called tradeoff analysis, begins in the same way as does cost-benefit analysis, but does not aggregate like effects into a single benefit or cost stream, and it stops short of assigning monetary values to non-monetary consequences. Instead, all effects are described in their natural units. The time period in which each effect is experienced is fully revealed, but future effects are not discounted to present value. Uncertainties are fully described – all kinds of uncertainties – risk, probability distributions, and indeterminacy. It is pretty hard to know what we don't know, but confidence that we have fully described the world is a proxy. Tradeoffs between worker health or environmental improvements and costs to

producers and consumers are made apparent, because the different cost and benefit elements are not aggregated.

Using tradeoff analysis, politically accountable decision makers could make policy choices in a transparent manner. Who bears the costs and who reaps the benefits from a policy option would not be hidden in a single, aggregate dollar/euro figure. Decisions would be based on accountability rather than accounting. Note that while cost-benefit is formulaic – i.e., a single figure of merit is sought for a policy/regulation such as the 'net benefit' or a 'benefit to cost ratio' – tradeoff analysis seeks to 'bound the set of not clearly incorrect, i.e., unfair decisions'. This has important implications for policy choices. Under a cost-benefit framework, one can easily demand prioritization of risk-reduction options based on the ranking of net benefits or cost-benefit ratios – with choices representing violations of the ranking being allegedly inconsistent or irrational. However, where large uncertainties exist, and the distributions of risks and benefits are of concern, there is no uniquely correct prioritization scheme or metric demanding 'consistency'. Advances in risk assessment techniques and economic analysis that takes technological innovation into account (see below) can narrow the uncertainties, but can never provide a unique best answer. That process ultimately has to reflect political, social, and value judgments – preferably informed by public participation/stakeholder processes and transparent for all to see. Taking care to include concerns for effects, their uncertainties, and their distributional consequences – i.e., exercising precaution – to make responsible, accountable decisions is possible using tradeoff analysis, but not cost-benefit analysis.

III. Promoting Rational Technology Choices

One important element often left out of the traditional cost-benefit matrix has been the consideration of technological alternatives[6]. Regulatory agencies have a mixed history in making information about cleaner and safer technologies available and promoting their adoption. Agencies could help prevent pollution and accidents by helping firms to think about their technological options in a more formal and systematic fashion.

Options for technological change must be considered according to a variety of criteria, including economic, environmental, and health and safety factors. Identifying these options and comparing them against the technology in use is called Technology Options Analysis[7]. Unlike traditional technology assessment, Technology Options Analysis does not require absolute quantification of all the variables: one has only to demonstrate, in a comparative manner, that one technology is better or worse than another in performance, health, safety, ecological effects, and so forth. It is likely to be less sensitive to initial assumptions than, for example, cost-benefit analysis, and would enable industry and government to identify more creative cost-effective solutions. Government might require industries to undertake Technology Options Analysis, instead of traditional technology assessment focusing on technologies already existing within, or easily accessible to, the firm or industry. The latter would likely address only the technologies industry puts forward; it may thus miss the opportunity to identify and subsequently influence the adoption or development of superior technological options.

Once superior existing technologies--or technologies within easy reach--are identified, industries may be motivated to change their technology out of economic self-interest, or in order to avoid future liability. On the other hand, government might either force the adoption or development of new technology, or provide technical or financial assistance. Requiring firms to change technology can itself be a risky venture. Developing a new technology or adopting a technology new to a firm or industry introduces new uncertainties and financial risks. If this is done, policy should allow for error and accommodate industry for failures in bona fide attempts to develop new technologies, for example by allowing more time or sharing the financial risk.

Whichever route is taken by government, the precautionary principle requires the investigation of technology options for the development and adoption of cleaner and inherently safer (i.e., sustainable) technologies.

IV. Which Errors Are Worse?

Policy makers must address both uncertainty about (1) the nature and extent of health, safety, or environmental risks, and about (2) the performance of an alternative technology. First, they must choose whether to err on the side of caution or risk. With regard to the first type of uncertainty, two mistakes can be made. A "Type I" error is committed if society regulates an activity that turns out later to be harmless and resources are needlessly expended. Another error, a "Type II" error is committed if society fails to regulate an activity that finally turns out to be harmful[8]. A "Type III" error is said to occur when one provides an accurate [or precise] answer to the wrong problem[9].

Similarly, where uncertainty exists on the technology side, Type I errors can be said to be committed when society mandates the development or adoption of a technology which turns out to be much more expensive or less reducing of risks than anticipated, and resources are needlessly or foolishly expended. Type II errors might be said to be committed when, because of insufficient commitment of resources or political will, a significant missed opportunity is created by which society fails to force or stimulate significant risk-reducing technology. An important distinction between a cost-benefit approach and one based on precaution is that the former is 'risk-neutral' in the balancing of costs and benefits with their attendant uncertainties, and the latter reflects 'risk averseness' for some kinds of errors.

Value judgments clearly attend decisions whether to lean toward tolerating Type I or Type II errors with regard to both risk and technology choices. This is because the cost of being wrong in one instance may be vastly different from the cost of being wrong in another. For example, banning a chemical essential to a beneficial activity such as the use of radionuclides in medicine has potentially more drastic consequences than banning a nonessential chemical for which there is a close, cost-comparable substitute. It may be perfectly appropriate to rely on 'most likely estimates' of risk in the first case and on 'worst-case analysis' in the second. A Type II error on the technology choice side was committed in the case of the Montreal Protocol banning CFCs by creating a scheme by which DuPont and ICI, the producers of CFCs, were allowed to promote the use of their own substitute, HCFCs, rather than adopt a more stringent protocol which would have stimulated still better substitutes.

Evaluating errors and deciding which way to lean is not a precise science. However, making those evaluations and valuations explicit within a tradeoff analysis will reveal the preferences upon which policies are based and may suggest priorities.

V. Further Grounds For Invoking The Precautionary Principle

Democratic decision making. The extent to which affected parties participate in identifying, evaluating, and selecting a protective policy may influence the acceptability of the policy. In the case of a possible, but highly uncertain harm, an equitable outcome may depend more on an equitable decision-making process than on a defensible argument about the technical correctness of an outcome based on existing information. The precautionary principle may be invoked to ensure a fair decision-making process, as much as to prevent harm.

Burdens of persuasion and proof. Part of the perceived fairness of the process involves the burden of persuasion--that is, the designation of which party has the burden of demonstrating or refuting a presumed

fact. This is distinct from the burden of proof--a term referring to the strength of the evidence (data and information) needed to justify taking action. Both terms are relevant in formulation of the precautionary principle.

Much discussion has focused on cause-and-effect relationships between exposure/other events and harmful effects for which a high statistical confidence level or strength of association is traditionally required. To escape the rigors of these requirements, some proponents of the precautionary principle argue that the burden of persuasion should be shifted to the proponents of a potentially harmful technology. Opponents argue against so radical a shift, pointing out that negatives are harder to prove.

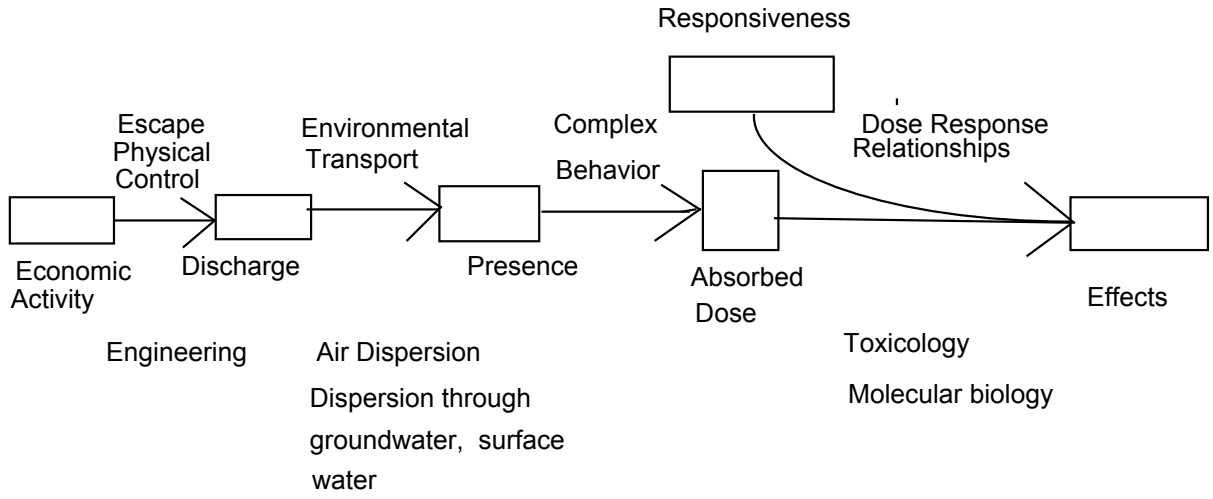
Of course, uncertainties of cause-and-effect relationships are by no means the only determinations to which the precautionary principle should be, or is applied. Others are (1) the complex sets of rights and duties embodied in so-called right-to-know including (a) the duty of potential wrong-doers to generate information, (b) the duty to retain information, (c) the duty to provide access to information to the potential victims of possible harm, and (d) the duty to warn the potential victims of possible harm; (2) providing funds to mitigate actual future harm to health or the environment; (3) compensating victims of unmitigated harm, and (4) the duty to prevent harm. The strength of the evidence required for these other, equally important factually-informed determinations may be much less than the traditional standard of proof in usual cause-and-effect determinations. [Much of the discussion of the precautionary principle focuses on cause and effect relationships for which a high statistical confidence level (p. 0.05) or strength of association is traditionally required in scientific publications. It should be remembered that the convention of requiring a p value no higher than 0.05 was an arbitrary historical choice. Critics of those wishing to invoke the precautionary principle by reducing the strength of causal proof would do well to remember this.] In addition, other ways of knowing besides statistical correlations might be pursued[10].

Other standards (burdens) of proof commonly invoked in public policy determinations include, in decreasing order of stringency: "strict liability for harm" (in the area of compensation, the "polluter pays principle" is sometimes invoked in statutory language or by the courts in fashioning equitable relief to victims), "clear and convincing evidence," "more probable than not" or "preponderance of the evidence," "substantial cause or factor," and "contributing factor." This "sliding scale" of evidentiary strength can be thought of as invoking the precautionary principle by expanding the "allowable possible error" in factual determinations. An alternative to shifting the burden of persuasion to another party is to lessen the burden of proof required to trigger an intervention to prevent or mitigate harm to health, safety, or the environment.

Also ignored by many commentators is the fact that burdens of persuasion often shift in the course of fact finding. Thus, depending on the nature of the intervention (notification, control, prevention, compensation, etc.), even if it is necessary for the regulator or potential victim initially to prove a [potential] harm, that proof is often not a high burden. A presumed fact (though a rebuttable presumption) might even be established by statute on the showing of certain other factual elements, such as the very existence of harm. Then, the burden of persuasion shifts to the intended regulated industry or alleged [potential] wrong-doer to refute the presumed or initially-established fact, often with a higher burden of proof. Legal injunctions against potentially harmful action are granted by the courts as equitable remedies. The commentators on the precautionary principle have often ignored a rich and important set of policy interventions or actions which are informed, but not dictated, by factual determinations. Regulatory agencies themselves--depending on their statutory mandates--are not bound by traditional burdens of proof. Further, reviewing courts usually give deference to factual findings by the agencies, as long as they stay within the "zone of reasonableness" defined by those mandates.

Where to Intervene. A precautionary approach should also address where control or regulation should be focused in the causal pathway the production or release of hazardous products or substances. The following figure provides a schematic of the possibilities. Waiting until ultimate health/ecological impacts are manifest is a much less precautionary approach than preventing the manufacture or use of potentially hazardous substances in the first place. The latter is described as cleaner and inherently safer production or pollution prevention and is in contrast to after-release or end-of-the-pipe control. Thus pollution prevention strategies are inherently precautionary in nature.

Figure 1
The Biological Impact Pathway



Source: N.A. Ashford, D. Hattis, E.M. Zolt, J.I. Katz, G.R. Heaton, and W.C. Priest, Evaluating Chemical Regulations: Trade-Off Analysis and Impact Assessment for Environmental Decision-Making Final Report to the Council on Environmental Quality under Contract No. EQ4ACA35. CPA-80-13, 1981. NTIS # PB81-195067.

VI. Precaution In Hindsight

It would be instructive to see how well we have fared with the implementation of the precautionary principle over the past 25 years. Scientific knowledge related to emerging health, safety, environmental, or public health problems began with a suggestion--sometimes a mere whisper--that trouble was brewing. Those suggestions and whispers ultimately ripened into full-fledged confirmations that our worst fears were not only true; reality often exceeded those fears. Examples that come to mind include asbestos-related cancer and the toxic effects of benzene, lead, and Agent Orange--to name just a few.

The frightening, but enlightening, reality is that with few memorable exceptions, the early warnings warranted heeding and the early predictions were certainly in the right direction--even understated[11]. In retrospect, not only were all precautionary actions justified; we also waited far too long to take those actions.

Barry Commoner, in The Closing Circle, warned us to avoid exposures "not consonant with our evolutionary soup." Theo Colborn has assembled in Our Stolen Future striking examples of why this is so. Endocrine disrupting chemicals present an opportunity to act earlier, although some damage has already been done. Similarly, intervening now to prevent the next generation of developmentally or immunologically compromised, chemically intolerant persons, or otherwise chemically damaged individuals, many of them children, is both possible and necessary[12].

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