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VIEWPOINT

Health, Wealth, and the 21st Century Cures Act

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Americans are increasingly apprehensive about our future, so it is inspiring when Congress produces legislation intended to both enhance our health and expand our economy. The 21st Century Cures Act,¹ recently passed by the House with an impressive bipartisan majority vote of 344 to 77, intends to accelerate the many-step process of drug discovery and development, from basic scientific research to clinical development to delivery, distribution, and ongoing monitoring. Among other things, the legislation boosts National Institute of Health funding, dramatically speeds up the US Food and Drug Administration (FDA) approval process, and aims to make use of new information technology to better monitor the performance of medical products after they reach the market. This landmark bill now awaits a comparable piece of legislation being developed by the Senate Health Education, Labor, and Pensions Committee. Together, they will transform the biomedical ecosystem and provide the foundation for the next several decades of innovative life-saving and health-enhancing solutions for our nation and the world.

The genesis of this legislative effort was a growing awareness by policy makers on both sides of the aisle in Congress and in the White House that science and technology are expanding opportunities in medicine at an exponential pace, but our ecosystem for transforming a discovery in the laboratory to a solution for patients suffering and dying of disease is woefully inadequate. Following an overwhelming outpouring of testimony and support by a broad cross section of stakeholders from academia, industry, clinicians, and, most important, patients, the 21st Century Cures Act represents public policy at its best—accelerating our understanding of the genetic, molecular, and cellular mechanisms of diseases while more quickly developing precise interventions that are tailored and efficiently delivered to each individual is the realization of the emerging era of personalized medicine.

Americans have invested heavily and enthusiastically in biomedical research over the years, motivated by the hope for better health. But what has not been apparent is the fact that such investments will also dramatically improve our nation's economy. Some have raised concerns that such innovative medical products will raise the costs of health care and wreck our economy. The exact opposite is true. Providing effective targeted new therapies that prevent or eliminate the morbidity and mortality of disease has multiple positive effects on growing the economy by improving human productivity and actually reducing the net costs of health care by producing better outcomes and eliminating the costly waste of an ineffective or excessive therapy.

The fact that the biomedical innovation stimulated by 21st Century Cures will likely have enormous economic benefits is supported by a large body of evidence.

Economists have estimated that the overall gains in longevity from about 40 to 73 years over the 20th century—even when ignoring equally impressive reductions in morbidity—are equal in value to all growth in GDP per capita, from about \$5000 to \$40 000 per capita during that century. In this sense, the growth in lifespan itself was perhaps the most important economic achievement of the past 100 years. Biomedical innovation and our increased understanding of diseases was an important part of that achievement. For example, the incremental gains achieved in the so-called war on cancer declared in 1971 yielded benefits to Americans estimated to be about 6 times the costs spent on the research, a huge economic success despite the negative rhetoric and popular debate surrounding this war. More importantly, research across many diseases, such as human immunodeficiency virus (HIV), heart disease, as well as cancer, has shown that when new therapies are introduced into the market, patients—not manufacturers—capture most of their economic value (on average, 80%-95%). As an example, a future stem cell therapy that could even partially restore or delay the need for hemodialysis or kidney transplants produces cost savings to society, and the value to patients—improved longevity, vitality, and earnings—would dwarf the profits of the innovators.

For those concerned about 21st Century Cures initiatives increasing health care costs, it is important to distinguish the bill's impact on the *price of health* as opposed to the *price of health care*. Before a new therapy is introduced, the price of better health is effectively infinitely expensive for patients who do not respond to existing standards of care; they can't go anywhere to buy more health at any price. If the legislation creates genuinely new and effective therapies, this always *lowers* the price of health. To illustrate, before the breakthrough highly active antiretroviral therapy (HAART) for HIV in 1996, HIV-positive individuals could not buy longer lives anywhere at any price. The introduction of the effective HIV cocktails therefore dramatically reduced the price of longer lives for patients with HIV. These are the types of price cuts 21st Century Cures will offer. Moreover, new innovations have the important economic effect of providing more competition between manufacturers, further lowering the price of health.

An even more important objective of 21st Century Cures is to not only lay the foundation on which future biomedical innovation and economic growth will be built but also attract increased investments by the private sector. The current bounty of new cancer therapeutics—22 FDA-approved cancer drugs in 2013 and 2014—is a direct result of the 1971 National Cancer Act and more than 4 decades of sustained government-sponsored research and development (R & D). The fact that the private sector now invests

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even more in oncology-related R & D than the government underscores the virtuous cycle created by public funding of basic scientific research. By supporting advances in our understanding of cancer biology, the National Cancer Institute has provided the biopharmaceutical industry with clear targets, mechanisms, and pathways for developing breakthrough therapeutics. In areas where such support is lacking, we see corresponding gaps in knowledge and, consequently, private-sector investment. For example, we have yet to direct the same type of government funding toward neurodegenerative diseases, such as Alzheimer disease and dementia; hence, it should come as no surprise that not a single new Alzheimer drug has been approved by the FDA in over a decade, and several big pharmaceutical companies have scaled back or shut down their Alzheimer therapeutics programs.

If passed, the 21st Century Cures Act will be a milestone in US legislation of medical innovation, giving us the opportunity to save countless lives in the coming years around the world. The overwhelming support for 21st Century Cures in the House must be tempered by the fact that nothing will happen until the Senate takes up this issue and both crafts and passes its own version of the legislation. An unnecessary delay that results in the demise of the House effort would be tragic, not just because it would be a major setback to patients and their families, but also because of the missed opportunity to accelerate economic growth for all Americans in this unprecedented era of breakthroughs in biomedicine. In an industry catalyzed by recent scientific breakthroughs but challenged by complexity, this legislation will reenergize scientists, clinicians, investors, and other stakeholders, and is just what the doctor ordered.

ARTICLE INFORMATION

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Conflict of Interest Disclosures: Dr Lo has personal investments in BridgeBio Capital (also an adviser), ImmuneXcite, KEW, MPM Capital,

Novalere, Royalty Pharma, and Visionscope and is a director of the MIT Whitehead Institute. Dr Philipson consults to the medical product industry and is the cofounder of Precision Health Economics. No other disclosures are reported.

Additional Information: Dr von Eschenbach is the former director of the National Cancer Institute and

commissioner of the US Food and Drug Administration.

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1. US House of Representatives. 2015, 21st Century Cures Act. <https://www.congress.gov/bill/114th-congress/house-bill/6>. Accessed August 26, 2015.