

October 15, 2019

Mr. Sean Bonyun
Chief of Staff
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington DC 20504

Re: Request for Information on the Bioeconomy (84 Federal Register 47561)

Dear Mr. Bonyun:

On behalf of the Information Technology and Innovation Foundation (ITIF), I am pleased to submit the following information in response to the Office of Science and Technology Policy's (OSTP's) Notice of Request for Information for Bioeconomy (84 Federal Register 47561, September 10, 2019).

ITIF is a nonprofit, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy. Recognized as the world's leading science and technology think tank, ITIF's mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress. More information is on our website, www.itif.org.

Thank you for the opportunity to submit this response.

Sincerely yours,



Dr. Robert D. Atkinson
President, Information Technology and Innovation Foundation

COMMENTS BY THE INFORMATION TECHNOLOGY AND INNOVATION FOUNDATION IN RESPONSE TO AN OSTP REQUEST FOR INFORMATION ON THE BIOECONOMY

As the request for information states, the bioeconomy includes a number of industries including “healthcare, medicine, pharmaceuticals, biotechnology, manufacturing, energy production, and agriculture.” Each of these industries has in common the potential to be radically transformed by the application of biotechnology, which is the manipulation of carbon-based lifeforms to accomplish specific tasks. ITIF believes that collectively, biotechnology represents a major general-purpose technology that could significantly improve human lives and U.S. competitiveness. There is also a growing strategic dimension to the bioeconomy. America’s security will be threatened unless important aspects of these technologies are first developed by the United States or its allies.

However, many of these opportunities will not happen on their own. A variety of market failures and bureaucratic obstacles deter companies from making the large investments needed to develop the technology, and companies in the United States face significant unfair competition from other nations, especially China. Government policies can play a large role in shaping these barriers, either ensuring steady progress in overcoming the many scientific and market hurdles remaining or presenting counterproductive obstacles and barriers to entry. Positive interventions include increased funding for research and support for technology transfer, strong intellectual property rights, smart regulation that strikes the right balance between innovation and public safety, enforcement of trade rules against nations that would seek to gain advantage in this technology and industry area by unfair means, and the expansion of a highly skilled bioeconomy workforce.

U.S. biotechnology policy can be improved in a number of specific areas, including drug pricing, regulation, and data sharing. In addition, broader policies such as increased research funding, tax incentives, and workforce support would bring benefits to many parts of the bioeconomy. ITIF has written extensively in this area, recommending proposals that would significantly strengthen the bioeconomy,¹ including initiatives covering the workforce, taxes, and research funding.²

Drug Pricing

Biotechnology forms an important share of the world’s pharmaceutical industry, which is one of the most high-value, research-intensive businesses in the world. In 2014 American pharmaceutical companies plowed back 43.8 percent of their value added into research.³ This was by far the highest proportion for any industry in any country. This continued investment is necessary to discover the next round of breakthrough drugs.

As a result, the biopharmaceutical industry is one of America’s leading sectors in terms of funding research and employing scientists. Business expenditure for health-related R&D as a percentage of

GDP in America is over twice what it is in Europe.⁴ The growth of drug research from 2014 to 2018 was 8.6 percent, compared to only 3.8 percent in Europe.⁵ In 2016 (the latest year for which NSF data is available), the biotechnology industry and the pharmaceutical industry and medicine companies funded a combined \$66.5 billion in research and development.⁶ Over 85 percent of this total was performed domestically. Biopharmaceutical companies employed 687,000 domestic employees, over 9 percent of all R&D workers funded by industry.⁷

A recent ITIF report documents the strong consensus among academic studies that there is a close positive relationship between current drug prices and revenues on the one hand and investment in research on new drugs and therapies on the other.⁸ Information constraints in the financial markets make retained earnings a much cheaper form of raising capital than the sale of either equity or bonds.⁹ Policies that artificially restrict the price drug manufacturers can charge for their products will result in fewer new drugs, including biologic drugs, in the future.

While Americans deserve affordable drugs, they also deserve the most competitive and innovative biopharmaceutical industry in the world. Artificial price controls will threaten both by reducing the industry's ability to fund future research and testing. A recent study shows that the drug industry captured only 5 percent of the total value added from the discovery of HIV/AIDS drugs since the 1980s.¹⁰ Looking more broadly, the same study found that manufacturers were able to capture more than 25 percent of the total value roughly a quarter of the time. Thus, even with current prices, new drugs are delivering tremendous social value that companies are unable to fully capture.

The delivery of new biopharmaceutical drugs therefore creates significant social value. A recent report by the Alzheimer's Association estimated that by 2050 16 percent of Americans 65 and older will suffer from some form of the disease, with 6.5 million individuals in the severe stage needing round-the-clock care. By then the annual cost of treatment will rise to \$1.4 trillion in 2019 dollars. Discovering a drug by 2015 that would delay the onset of Alzheimer's by just five years would reduce the cost of treatment by one-third, saving \$935 billion in the first ten years.¹¹ A retroactive study of past medical services found benefit-to-cost ratios of between 3.1:1 and 10.1:1.¹²

Of the portion of social value that drug companies are able to capture, a large share goes to compensating them for the risk associated with the development process. A recent report by the Congressional Budget Office estimated that drug firms need to earn a 62.2 percent rate of return on their successful products in order to realize a 4.8 percent rate of return on their overall investment. The report assumed that only 10 percent of all projects are successful. It also estimated that the time

lag between initial research and the first significant revenues was 12 years.¹³ Policies to reduce either of these constraints would significantly reduce the necessary margins.

Drug affordability is a serious issue, but there are policies Congress can pursue that will not threaten future discoveries. One is to extend affordable health insurance, including prescription coverage, to all Americans. Congress could also streamline regulations that govern the testing and manufacture of drugs. Finally, the United States should press countries to pay their fair share of the cost of developing new drugs. Because of price controls abroad, Americans pay roughly 70 percent of global drug profits even though they account for only half of the international market in terms of the drugs consumed.¹⁴ Higher prices abroad would increase research spending even further.

Funding for Research

Federal funding for research is the backbone of a strong bioeconomy. Ample evidence shows that government investments in research are a complement to private research, not a substitute.¹⁵ By increasing the amount of research being done, federal funding lowers the risk of private sector research and improves its effectiveness. Studies show that both the public research and the private sector research it encourages produce large social benefits.¹⁶ Although nominal funding for the National Institutes of Health increased by 64 percent between 1990 and 2019, as a share of GDP it peaked in 2003 and declined through 2015. Despite recent increases, as a share of GDP it remains 12 percent below its 2003 level.¹⁷ Although Congress has committed to rapid increases during some periods, these have been episodic, fitful, and not strategic, discouraging some scientists from conducting research and disincentivizing strategic investments from the private sector. Meanwhile, China has made a major commitment to lead the world in biotech by 2025. Although it spends less on overall spending in biomedical research than the United States, its funding levels are increasing, especially in targeted areas. For example, China funded its precision medicine initiative with \$9.2 billion over 15 years. The NIH effort is only \$1.5 billion over ten years.¹⁸ Congress should boost NIH's budget by \$8 billion and then pass continued increases of 2-3 percentage points over the rate of GDP growth.¹⁹

Regulation

The Food and Drug Administration has many ways in which it can improve the regulatory process to reduce the costs of testing and make approval decisions more rapidly.²⁰ Its Sentinel System for post-approval monitoring of drug risks should be fully funded and staffed and it should increase its monitoring of real-world data outside of medical records and insurance claims. It should also improve the reliability of data used in foreign clinical trials, encouraging their use where appropriate.

Finally, there is strong evidence that strict regulatory constraints prevent significant increases in the productivity of manufacturing medicines at a cost of \$50 billion per year.²¹

Biotechnology is also making huge advances in agriculture. Advances in plant and animal breeding in recent years have been considerable, driven largely by recombinant DNA and related technologies. But with the advent of gene editing, in the last five years it has become possible to imagine far more powerful changes much more easily reached.²² Despite the explosion in technological capability and considerable technical challenges, perhaps the biggest deterrent and disincentive to the application of these new techniques to real-world problem solving is government regulation.

The purpose of agricultural regulation is straightforward, and one with which most would agree: to protect the health of humans and the environment while enabling needed innovations. But in defiance of both logic and decades of experience, the regulations imposed on crops and livestock improved through biotechnology do little or nothing to advance safety, and much to deter and disincentivize R&D investment and innovation, particularly in the developing world.²³

The biggest problem is that the products of modern breeding technologies are singled out for the highest level of regulatory scrutiny simply due to the use of specific technologies, some of which are now decades old and which have an excellent safety record. These technologies are vastly more precise, and therefore much more predictable in outcomes than the conventional breeding programs built on radiation or chemically induced random mutagenesis. Regulators both in Europe and the United States have specifically demonstrated that the use of these technologies is not predictive of hazard, and that, if anything, their products are safer than those produced with older methods.²⁴ And yet governments around the world, including those in industrial nations, apply scientifically indefensible and unjustified regulations that have negative impacts on human and environmental health and economic growth.²⁵ Such regulatory regimes, dubious at best when they were first adopted in the last century, have long been shown to be counterproductive, and the time to retire them is past. Perhaps no other measure would lead as rapidly to greater economic impacts and public/environmental health benefits as re-casting regulations applied to crops and livestock improved through biotechnology to restore the original intent that regulations be proportional to the hazards they aim to mitigate and targeted at preventing unreasonable risks while encouraging and enabling innovation.

A recent ITIF report makes several specific recommendations for improving the cost/benefit ratio for biotechnology innovations in agriculture. These include:²⁶

- The Animal and Plant Health Inspection Service should revise dramatically or set aside its current proposal for process-based regulations;
- The Food and Drug Administration (FDA) should enforce the federal law prohibiting misleading food labels;
- FDA should revise its current proposal for regulating gene-edited animals, withdraw its proposal for gene-edited plants, and develop new proposals to exercise discretion in preventing unreasonable risks;
- The Environmental Protection Agency should not prematurely obstruct gene-silencing technologies;
- The Administration should pursue cases at the World Trade Organization to hold China and the European Union accountable for discriminating against crops improved through biotechnology without any scientific evidence that they are unsafe.

Protect Intellectual Property

The high upfront costs of biotech compound development combined with the low marginal costs of production require strong property rights, often in the form of patents. Otherwise a company that spent billions of dollars and years of testing getting a drug or plant approved could see its competitors copy the drug or plant and sell it for much less.

One of the most important applications of patent law has been the Bayh-Dole Act, which gave contractors, including universities and research institutions, patent rights to the intellectual property stemming from federal research. These institutions can then license the technology to private-sector entities able to invest the time and money needed to take new products to market.²⁷ This Act spurred universities to work more closely with industry and dramatically increased the effective transfer of knowledge from research to commercialization.

Some advocates have recently called on the federal government to assert its “march-in rights” to force patent holders to grant a license to third parties even when a drug is being successfully commercialized. This would be a big mistake. The previous experience regarding the use of march-in rights prior to the Act’s creation suggests the dramatic negative impact it will have on the commercialization of new research.²⁸

Promote a Skilled Workforce

The U.S. bioeconomy cannot be competitive without a broad, deep, and highly skilled workforce capable of handling the many demanding jobs involved in research, development, production and the use of new technologies. There are a host of steps the federal government could take, including offering planning grants for regions that want to create focused STEM high schools or universities. It should also establish cash prizes for colleges and universities that succeed in graduating more of the best prepared STEM students. Congress should enable more foreign talent easily to live and work in the United States. These workers will either work to help our companies become the most competitive in the world or they will work for our competitors, some of whom are geopolitical rivals. Congress should do this by making it easier for international students with science, technology, engineering, and mathematics degrees who have job offers obtain a Green Card.

Improve Tax Laws

Most bioeconomy firms are extremely R&D intensive. As such, Congress should increase the Alternative Simplified Credit for R&D from 14 to at least 20 percent in order to boost private R&D. It should also broaden and expand the R&D credit for collaborative research. Presently, companies receive a 20 percent flat credit for collaborative research, but only for energy research. This kind of research, conducted at universities, federal labs, or research consortia tends to focus on the type of basic and exploratory research that is most needed in the life sciences. Because of its general nature, this work has large spillover effects. That is why a number of developed countries have expanded their support for this type of research.²⁹

In addition, Congress should allow U.S. companies to pay a lower corporate tax rate on income generated from innovation-based products, similar to “patent boxes” in other countries.³⁰ This benefit should require the research to be conducted domestically, thus spurring innovation-based job creation and discouraging attempts to move intellectual property to low-tax countries.

Third, Congress should allow small research companies to carry their net operating losses forward even after a change in ownership. A great deal of biotechnology research is currently done by small companies focused on one or two areas of research. Once these companies achieve a certain degree of success, they are often bought out by larger companies that have the resources to test, manufacture, and market a commercial product. Under Section 382 of the tax code, the new investors cannot carry the losses of the pre-revenue company forward due to the change in ownership. This substantially lowers the price companies will pay and therefore the potential rewards from pursuing basic research.

Finally, Congress should restore/extend the ability to expense research spending, which is scheduled to end in 2022. Expensing rather than writing the spending off over five years, which will be required after 2022, decreases the after-tax cost of research and results in a closer match between tax liability and actual cash flow, especially for smaller research-focused companies.

Expand Medical Data Availability and Use

ITIF recently published another report showing why, with respect to biopharmaceuticals, policymakers' top priority should be to dramatically increase the availability of data for drug development.³¹ Whether screening biologic compounds, optimizing clinical trials, improving post-market surveillance of drugs, or matching the right therapies to the right patients, the increased use of data and better analytical tools such as artificial intelligence have the potential to transform drug development. But first the federal government must address a number of obstacles. Doing this will accelerate access to more effective and affordable treatments.

Although public attention is often focused on invasions of privacy and data security (for understandable reasons), widespread data sharing also brings several benefits. And it is possible to enjoy those benefits while adequately ensuring both privacy and security. First, participant-level data can help researchers understand the results of trials and tests, so that they can better link treatments to outcomes. In addition, shared data helps researchers verify medical studies and identify cases of data fraud and research misconduct. Lastly, shared data can be combined and supplemented to support new discoveries. Yet, while patients are often willing to share their data in order to improve medical research, few are given the option of doing so.

ITIF's report calls for several specific reforms. First, in order to increase data availability, Congress should create a National Health Research Data Exchange to improve the collection and sharing of patient medical data for research purposes. The Exchange would allow patients to quickly share their data for the purpose of advancing medical research. Any researcher or institution that qualifies would have access to longitudinal, up-to-date data for research purposes, including drug development, regardless of where it is stored. A few data registries already exist but many of these are confined to a specific disease. Patients should have their data included in the Exchange unless they specifically opt out. The data would be protected by existing rules under the Health Insurance Portability and Accountability Act and contractual provisions. The Department of Health and Human Services should also facilitate the creation of data trusts to simplify data sharing between private parties.

Congress should also direct HHS to implement a system of unique patient identifiers. Healthcare providers currently do not have access to an accurate and efficient method of matching patients' records across platforms. This makes it difficult to get a view of a patient's entire history. Existing methods are unreliable and prone to error. HHS cited an "urgent and critical" need for such a system two decades ago.³²

Researchers are often reluctant to share their proprietary data in order to limit competition from rival researchers and companies. HHS should do a better job of enforcing existing rules requiring the release of data from federally funded research and clinical trials. The release of trial data would increase transparency around the efficacy and potential risks from new drugs. Yet a 2012 study found that 25 to 50 percent of all clinical trials are never published or are only published years after the fact.³³ Although reporting rates have increased since then, they still remain too low.

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