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At the broadest level, Dr. Carlson is interested in the future role of biology as a human technology. He has worked to develop new biological technologies in both academic and commercial environments, focusing on molecular measurement and microfluidic systems. Dr. Carlson has also developed a number of new technical and economic metrics for measuring the progress of biological technologies. Carlson is the author of the book *Biology is Technology: The Promise, Peril, and New Business of Engineering Life*, published in 2010 by Harvard University Press; it received the PROSE award for the Best Engineering and Technology Book of 2010 and was named to “Best Books of 2010” lists by writers at both *The Economist* and *Foreign Policy*. He is a frequent international speaker and has served as an advisor to such diverse organizations as The Hastings Center, the PICNIC Design Festival, the UN, the OECD, the US Government, and companies ranging in size from startups to members of the Fortune 100. Carlson earned a doctorate in Physics from Princeton University in 1997.

In 2012 Dr. Carlson was a Senior Lecturer in the Department of Computer Science and Engineering at the University of Washington, where he taught a class on developing strategy and policy in the context of rapid technological change. From 2002 to 2007, Carlson was a Senior Scientist in the Electrical Engineering department at the University of Washington. From 2003 to 2008, he provided technology analysis and strategic consulting as a Senior Associate at Bio-Economic Research Associates (Bio-era), writing extensively on pandemic preparedness, synthetic vaccines, biofuels, and biological technologies, and presenting briefings on these subjects to executives and government officials around the world. From 1997 to 2002 he was a Research Fellow at The Molecular Sciences Institute in Berkeley, CA. Links to additional articles and a weblog can be found at www.synthesis.cc.

March 2019

Robert Carlson, PhD
“Engineering Our Way to a Sustainable Bioeconomy”
Written Testimony for a hearing of the Subcommittee on Research and Development of the House Committee on Space, Science, and Technology, U.S. House of Representatives
12 March, 2019

Ladies and Gentlemen, Members of this Committee, first let me thank you for the opportunity to testify today and to share what I have learned about the size and scope of the bioeconomy in the U.S., and also about the role of engineering biology for our physical and economic well-being and security. Before I continue, I would also like to thank the Committee staff for their assistance in arranging my participation today.

I was asked to address specific questions in my testimony, which I reproduce below for the record:

1. What is the size of the U.S industry in engineering biology across various sectors? What is the potential for this technology across the economy?
2. How does the US compare internationally in terms of the level of investment in engineering biology R&D? Please provide a snapshot of other leading countries, including the extent to which those countries have developed national plans for engineering biology.
3. How can scientists and engineers collaborate with experts in the humanities, law, and social sciences to integrate social, legal, environmental, and other ethical considerations into the design and conduct of engineering biology R&D?
4. How can scientists and engineers collaborate with security experts to incorporate security concerns into the design and conduct of engineering biology R&D?
5. What recommendations, if any, do you have for improvements to the *Engineering Biology Act?* What additional recommendations, if any, do you have for Congress or for federal science agencies that fund engineering biology research?

Summary: Engineered biological systems already generate approximately 2% of US GDP on an annual basis. As biological engineering becomes more sophisticated and capable, it will have an increasingly broad impact on the economy. This potential has not been lost on other governments around the world, and the engineering of biology is seen by many nations as a low cost route to technological maturity and geopolitical influence. Engineering a sustainable bioeconomy in the U.S., and maintaining our technological lead, will require appropriate attention, investment, and nurturing; this includes broad public involvement in discussions of how taxpayer funds are spent on research and development. The result will be not just a more sustainable future, but a better future, as biology replaces existing products with more capable ones across the healthcare, food, and, in particular, materials industries. The core technical capability to enginee biology will have far reaching impacts well beyond the scope of products and manufacturing historically considered to be the business of biology.

Introduction

I have participated in the bioeconomy as an academic scientist, as an entrepreneur in technology companies, as a strategist, as a technical and economic analyst, as a consultant on economics and security to the U.S., other governments, and international organizations, and now as Managing Director of Bioeconomy Capital, an early stage venture capital firm with offices in Seattle and San Francisco. Over the years, I have written articles, a book, and patents on the topic of biological technologies, some of

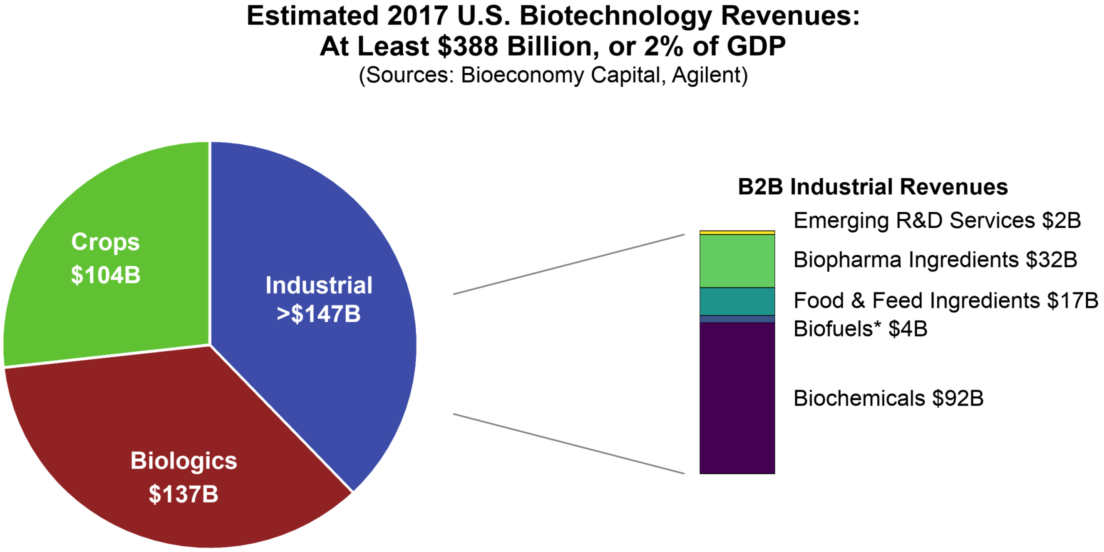

Figure 1: Estimated 2017 U.S. Biotechnology Revenues. Data and methods described at the Bioeconomy Dashboard: https://bioeconomy.capital/bioeconomy-dashboard/.

which are referenced as support for this testimony. In order to expand the conversation about how biological technologies may impact humans and the planet we live on, I have participated in many discussions across public and private forums, including The Hastings Center for Bioethics, the National Academies of Science, Engineering, and Medicine, The Presidential Commission for the Study of Bioethical Issues, the World Health Organization, and the Biological Weapons and Toxins Convention.

The Size of the Biotechnology Industry

U.S. revenues from engineered biological systems reached at least $388 billion in 2017, or 2% of GDP[1]. The figures in this testimony are based on an analysis published in *Nature Biotechnology*, with updates published at the Bioeconomy Capital website on the Bioeconomy Dashboard. For comparison, if considered as an industrial sector unto itself, biotechnology contributes more to the economy than mining, utilities, or a number of other construction and industrial sectors[2],[3].

Those biotechnology revenues comprise three sub-sectors, biologics (i.e., biologically manufactured drugs) at $137B, genetically modified (GM) crops and seeds at $104B, and industrial biotechnology, which includes materials, enzymes, and engineering tools, which is at least $147B (see Figure 1).

I note here briefly that a broader definition of the bioeconomy, one that includes agriculture, forestry, fisheries, the impact of invasive species, and the value of water and air purification, could easily bring the

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[1] Carlson, R., “Estimating the biotech sector's contribution to the US economy”, Nature Biotechnology, 34, 247–255 (March, 2016). For updates, see the Bioeconomy Dashboard: https://www.bioeconomy.capital/bioeconomy-dashboard/

[2] ibid.

[3] BEA, GDP By Industry, https://apps.bea.gov/iTable/index_industry_gdpIndy.cfm

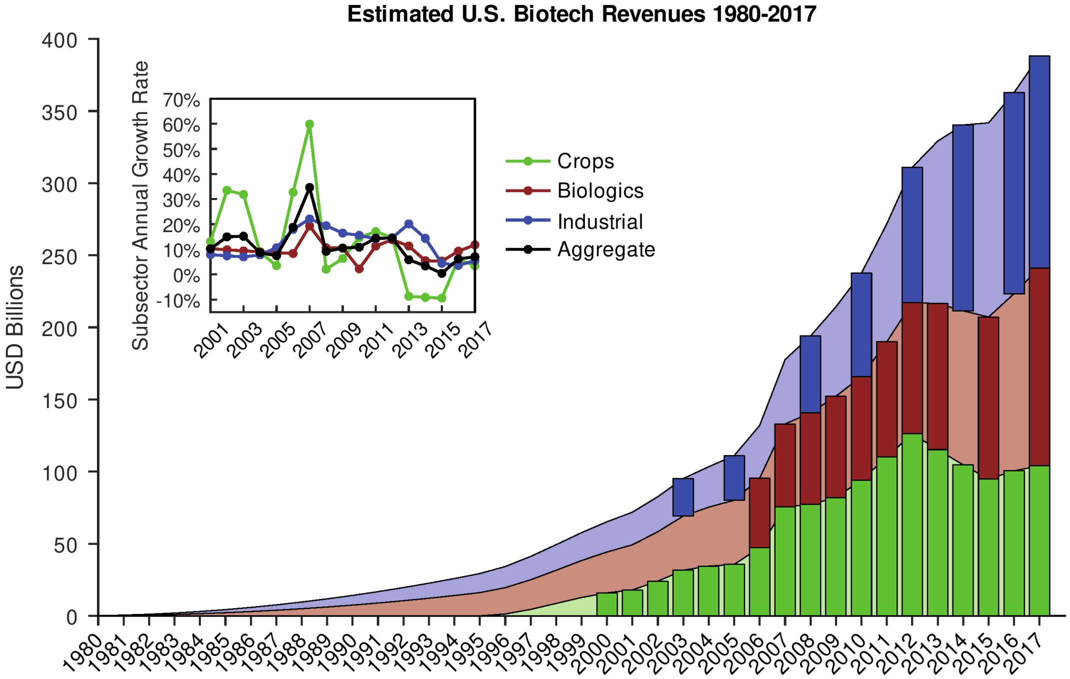

Figure 2: Estimated U.S. Biotech Revenues 1980-2017. Bars are data, shaded areas are generated using a numerical model, from which growth rates (inset) are calculated. Data and methods described at the Bioeconomy Dashboard: https://bioeconomy.capital/bioeconomy-dashboard/.

economic impact of biology to 20% of GDP[4]. Given that we are already considering deploying biological engineering to combat invasive pests, ranging from mosquitos to citrus tree pathogens, it would behoove us to better understand this broader economic contribution of biological systems to the nation's welfare.

Biologics

The U.S. accounts for about 73% of global biologics revenues, a fraction that has held nearly constant for most of the last decade. The $137B figure does not include many billions in revenues from maintaining and selling model organisms such as genetically modified mice, nor does it include the value biotechnology provides to that portion of the pharmaceutical industry that develops and manufactures small molecule drugs, all of which depends heavily on biotechnological tools. That is, the revenues described here as “biologics” are certainly an underestimate of this portion of the bioeconomy, and proper accounting would in all likelihood significantly increase the total.

GM Crops

The GM crop revenues comprise GM seed revenues and farm scale revenues that farmers receive. The U.S. accounts for approximately 40% of total planted area of GM crops, and thus about 40% of global GM crop revenues. Not included in these figures are small, but growing, revenues from GM papaya, alfalfa, squash, apples, and potatoes. These revenues do not include additional significant economic benefits that GM crops provide to farmers and the environment, including reduced water and fuel use, and

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[4] Carlson, 2016.

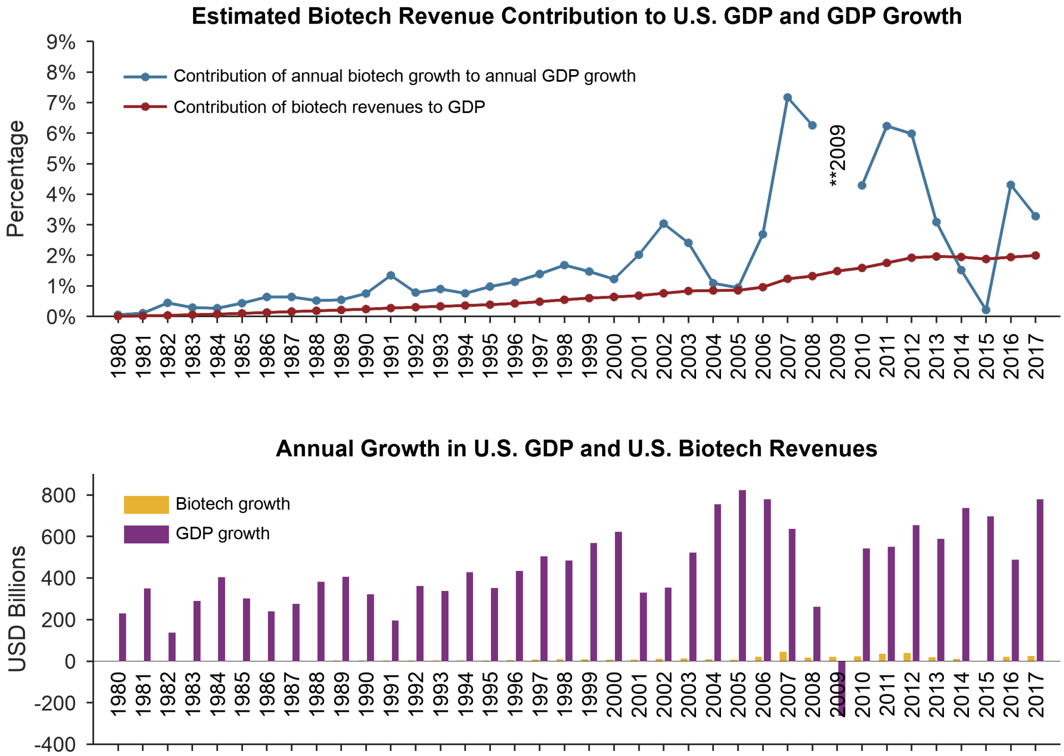

Figure 3: Top: Estimated biotech revenue contribution to U.S. GDP and GDP growth. The 2009 percentage contribution is omitted because GDP growth was negative that year. Bottom: Absolute annual growth in U.S. GDP And biotech revenues. Based on numerical model fit to data in Figure 2. Data and methods described at the Bioeconomy Dashboard: https://bioeconomy.capital/bioeconomy-dashboard/.

reduced time spent plowing and spraying. Beyond benefits to farmers who grow GM crops, several studies have estimated that as much as 70% of the total benefits from such crops accrue to farmers who plant standard crops on adjacent fields, where those farms benefit from the so-called halo effect of pest suppression by the GM crops[5]. Again, a full and proper accounting of these added benefits would substantially swell the economic impact of GM crops to farmers in the United States.

Industrial Biotechnology

The breakdown of 2017 industrial biotechnology revenues in Figure 1 was graciously provided by Agilent's Gary Carter, and then corrected slightly by me to remove the cost of corn from biofuels revenues to avoid double counting. Note that the value added contribution of biofuels, which comes to mind for many as the primary example of an industrial biotech product, only amounted to $4.3B. This should be compared to approximately $91B of value added from biochemicals, which include higher value compounds such as plastics precursors, solvents, and other materials. This $91B comprises business-to-business (B2B) revenues, and the final consumer level impact of these products could be 10–30% higher

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[5] Carlson, 2016.

due to the increased margins in moving from wholesale to retail, and thus could be in the range of $100B–$120B.

Public and private investment in new biological engineering and manufacturing technologies is accelerating. Private capital is being invested in early stage companies at remarkable rates: $1.7B in 2017 and more than $3.7B in 2018[6],[7]. The U.S. government is investing in technology development via DARPA, the NSF, the NIH, and the DOE. While this is an excellent foundation, the potential of engineering biology to grow the economy requires that we invest even more.

Implications and Potential for the Future

Biotechnology has been a growing contributor to the economy for nearly four decades (see Figure 2). When compared to the economy as a whole, it is clear that biotechnology is increasingly important not merely for its absolute size, but also because it is apparently more stable and resistant to recessions than other sectors, with the caveat that swings in commodities prices can have large impacts on sector revenues through crop revenues (see Figure 3). Generally, when the rest of the economy slows or contracts, biotechnology has picked up the slack, contributing as much as 7% of annual GDP growth during the recent recession.

If the size of these revenue estimates comes as a surprise, that is because the U.S. government does not measure the contribution of biotechnology to the economy. The particular structural reason for this lack of data gathering is the absence of any codes for biotechnology within the North American Industrial Classification System (NAICS)[8]. The NAICS is used to categorize economic data from across the economy, including such details as value added by particular sectors, as well as employment, with the added benefit of geographical specificity. In lieu of having access to NAICS data, I published the first full estimates of biotech revenues in the U.S. in 2016 using data drawn from public company reporting, private consulting reports, marketing reports, and national and international surveys. This data is of varying quality, and sourcing and analysis frequently are poorly described. That article also examined the shortcomings of the current NAICS codes and suggested how to fix them[9].

As one implication of poor measurement, consider the following surprising calculation. As best I can tell, the revenues described above demonstrate that biochemicals are directly outcompeting petrochemicals in the U.S. market on cost and performance, to the tune of somewhere between $100B and $120B in revenues annually. Depending on the source, and on how one adds up the subsectors, annual revenues from chemicals manufacturing in the U.S. are between $350B and $750B[10],[11]. It is currently not possible, given the structure of data based on NAICS codes, to know whether biochemicals revenues are included in the total reported for "chemicals" or if those revenues are going completely unreported in economic statistics. Consequently, if the biochemicals revenue estimates are accurate, biochemicals have quietly grown to constitute at least 17% of chemicals revenues in the U.S., and perhaps significantly more.

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[6] Calvin Schmidt, "These 33 synthetic biology companies just raised $925 million", Synbiobeta, July 5, 2018, https://synbiobeta.com/these-33-synthetic-biology-companies-just-raised-925-million/

[7] John Cumbers, at Safeguarding the Bioeconomy, National Academy of Sciences, 28 January 2019, Washington, DC.

[8] Carlson, 2016.

[9] ibid.

[10] BEA, GDP By Industry, https://apps.bea.gov/iTable/index_industry_gdpIndy.cfm

[11] Statista: U.S. Chemical industry - Statistics & Facts. https://www.statista.com/topics/1526/chemical-industry-in-the-us/

Despite this uncertainty, it is clear that, far from simply being a technology with a bright future, the age of biomanufacturing is already upon us.

And the future is very bright indeed. The economic impact of biochemical manufacturing is likely to grow significantly over the next decade. Government and private sector investments have resulted in the capacity today to biomanufacture not just every molecule that we now derive from a barrel of petroleum, but, using the extraordinary power of protein and metabolic engineering, to also biomanufacture a wide range of molecules that cannot plausibly be made using existing chemical engineering techniques. This story is not simply about sustainability. Instead, the power of biology can be used to imbue products with improved properties. There is enormous economic and technical potential here. The resulting new materials, manufactured using biology, will impact a wide range of industries and products, far beyond what has been traditionally considered the purview of biotechnology.

New Materials

For example, our portfolio company Arzeda is now scaling up the biomanufacturing of a methacrylate compound that can be used to dramatically improve the properties of plexiglass. This compound has long been known of by materials scientists, and long been desired by chemical engineers for its utility in improving such properties as temperature resistance and hardness, but no one could figure out how to make it economically in large quantities. Arzeda's biological engineers combined enzymes from different organisms with enzymes that they themselves designed, and that have never existed before, to produce the compound at scale. This new material will shortly find its way into such products as windshields, impact resistant glass, and aircraft canopies.

Similarly, our portfolio company Zymergen is pursuing remarkable new materials that will transform consumer electronics. Zymergen is developing a set of films and coatings that have a set of properties unachievable through synthetic chemistry and that will be used to produce flexible electronics and displays. These materials simply cannot be made using the existing toolbox of synthetic chemistry; engineering biology gives access to a combination of material properties that cannot be formulated any other way. Engineering biology will bring about a renaissance in materials innovation.

New Data Storage and Processing Technologies

Beyond manufacturing novel materials, biological technologies are being eyed as important functional components of systems now produced from silicon and metal. In addition to my role as an investor, I am fortunate to work as a consultant to Microsoft on a project to store digital information in DNA, and I have watched first-hand as this technology developed over just the last three years. I have become convinced that not only is this technology technically and economically feasible, it is inevitable and necessary.

The problem at hand is that the internet is expanding so rapidly that our need to archive data will soon outstrip existing technologies. If we continue down our current path, in coming decades we will need not only exponentially more magnetic tape, disk drives or flash memory, but exponentially more factories to produce these storage media, and exponentially more warehouses to store them. Even if this is technically feasible, it is economically implausible. Biology can provide a solution. DNA is by far the most sophisticated and densest information-storage medium we have ever encountered, exceeding by many times even the theoretical capacity of magnetic tape or solid-state storage.

A massive warehouse full of magnetic tapes might be replaced by an amount of DNA the size of a sugar cube. Moreover, whereas magnetic tape might last decades and paper might last millennia, we have found intact DNA in animal carcasses that have spent 750,000 years frozen in the Canadian tundra. Consequently, there is a push to combine our ability to read and write DNA with our accelerating need for more long-term information storage. Encoding and retrieval of text, photos and video in DNA has already been demonstrated[12].

Governments and corporations alike have recognized this opportunity. Both are funding research to support scaling up the infrastructure to sequence and synthesize DNA, that is, to read and write DNA, at sufficient rates to support its use as a storage medium. In order to compete with a typical tape drive that is used for storage today, a single “DNA drive” must be able to write and read the equivalent of approximately ten human genomes a minute, which is more than ten times the current global annual demand for synthetic DNA. Consequently, when DNA data storage becomes a commercial reality, it is very likely that reading and writing arbitrary DNA sequences will cost orders of magnitude less than they to today, and will be even more widely distributed. That is, the scale of the demand for DNA storage, and the price at which it must operate, will completely alter the economics of reading and writing genetic information, marginalizing the scale of use by existing multibillion-dollar biotech markets while at the same time massively expanding capabilities to reprogram life. This sort of pull on biotechnology from non-traditional applications will only increase with time as our ability to engineer biology improves. In order to understand the consequent impact on the economy, and on the people who work in it, we must lay the groundwork for better measurement of that economy, in part to better invest in it, and in part to better protect it.

On the Need for Better Quantification of the Bioeconomy

The size of the economic contribution of biotechnology, the uncertainty about that size, and the inability to use NAICS codes to track products, means that biotech products could already be an important part of the supply chain for U.S. government acquisitions, including the Department of Defense, and there would be no way to easily track these products.

Consequently, not only does the U.S. government have no means to track the size and shape of the bioeconomy, it has no way to measure 1) the impact of federal R&D and procurement dollars, 2) nor the number of businesses involved in biotechnology, 3) nor the number of people employed in any of those businesses, other than what companies choose to disclose to investors. We do not know how big an enterprise the bioeconomy represents, nor how much other critical parts of our economy depend on biologically manufactured materials. Therefore, we do not understand the scope of our exposure to various risks. Moreover, our ignorance means that we are able to measure our progress and capabilities against other nations only through headlines and trumpeted achievements. Ultimately, we cannot tell if we are winning or losing.

The U.S. government has solved similar problems in the past. The contribution of semiconductors to the American economy was tracked by the Department of Commerce at least as early as 1958, when it was less than 0.05% of GDP[13]. Even in 1958, it was obvious that quantifying the production of

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[12] Organick, L., *et al*, “Random access in large-scale DNA data storage”, *Nature Biotechnology*, 3 (36), 2018.

[13] U.S Bureau of the Census, Annual Survey of Manufacturers 1971, U.S. Department of Commerce, 1973. https://books.google.com/books?id=mvxhxSOQ0joC.

semiconductors, which was then a brand new technology, was already of critical importance to the Department of Defense, and thus to the nation. Biotechnology is nearly 40 years old as a commercial enterprise, and, as I have described, it is already quite clearly critical to the nation. It is well past time that we measure and understand the impact of biological technologies across the economy.

My reading is that the *Engineering Biology Research and Development Act of 2019* does not currently address quantifying the role of biotechnology in the economy[14]. Moreover, this legislation may not be the appropriate means to fix this knowledge gap. However, I would exhort this Committee to 1) at a minimum work with the appropriate Congressional and Executive Branch personnel to amend the NAICS codes to track biotechnology, and 2) if appropriate, take the stronger step of amending the language of the Act to direct the Economic Classification Policy Committee to issue supplementary codes as soon as possible to eliminate this knowledge gap.

In my view, the estimated size of this market, and the voluntary ignorance of the details of this market, represent a security threat to the United States that comes in two forms. Firstly, we are basing an increasingly large fraction of our economy on a technology that is having impacts that are not well understood and therefore cannot be managed with respect to investment and educational planning. Secondly, we therefore do not understand what our exposure is to risks from competition, theft, or direct physical threat. We continue in ignorance at our peril.

International Competition

At least 32 countries around the world have identified biological engineering as a strategic technology and are investing accordingly (see Table 1)[15]. However, just as the U.S. government is failing to adequately measure the domestic bioeconomy, we are failing to assess the capabilities and intent of other nations.

Africa (1)
South Africa

Asia (8 plus Hong Kong)
Australia
China
Hong Kong
India
Japan
Korea
Malaysia
New Zealand
Singapore

Mideast (2)
Israel
Turkey

Americas (5)
Brazil
Canada
Chile
Mexico
United States

Europe (22) – EU has its own policy
Austria
Belgium
Czech Republic
Denmark
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Netherlands
Norway
Poland
Portugal
Russian Federation
Slovenia
Sweden
Switzerland
UK

Table 1: Countries that have stated strategies, or clear national or institutional interest, to develop advanced biological engineering capabilities. (Source: OECD)

The only semi-official U.S. government estimate of global biotechnology revenues was performed by me for the 2012 Biodefence Net Assessment (BNA), published by the Homeland Security Studies and Analysis Institute. This effort only scratched the surface of the problem by looking at five countries,

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[14] https://www.congress.gov/bill/115th-congress/house-bill/7171
[15] Organisation for Economic Cooperation and Development. Emerging Policy Issues in Synthetic Biology, 2014.

including the U.S.[16]. In that Assessment, national biotechnology industry revenues were used as a proxy for domestic technical capability, which is otherwise very difficult to assess. In the few years since that document was published, the list of countries expressing the intent to develop domestic biotechnology industries has grown significantly.

Many of the countries shown in Table 1 view domestic development of biotechnology and biomanufacturing as a less capital-intensive path to economic development than that pursued by the United States, Europe, and Japan in the 20th century. This is consistent with the stated strategic aims I uncovered in the course of my work for the BNA.

China, in particular, has clearly identified its intention to become a dominant global power via domestic development and mastery of biotechnology. Repeated statements by the country's leaders demonstrate that they believe biotechnology is a critical tool in their efforts to sustain both China's economic development and the health of its population. In 2002, President Jiang Zemin stated publicly that the government would use all means available to improve the health of the population, including genetic modification of its citizens[17]. In September of 2008, Premier Wen Jiabao stated, “To solve the food problem, we have to rely on big science and technology measures, rely on biotechnology, rely on [genetic modification].”[18] The “food problem” to which the Premier referred is a combination of a still-increasing population and a recent, precipitous decrease in arable land.[19] On January 9, 2006, Premier Wen Jiabao announced a plan to “catch up with the most advanced nations in biotechnology” while strengthening “independent” or “indigenous” innovation.[20] These plans and statements have continued apace for the last decade, resulting in significant domestic investment and innovation.

As of 2010, China reportedly generated an estimated 2.5% of GDP from biotechnology, with a 2020 target of 5–8% of GDP[21]. Last spring, at the World Bioeconomy Summit in Berlin, Yin Li, Deputy Director-General of Bureau of International Cooperation for the Chinese Academy of Sciences, reported that the bioeconomy in China is growing at 15% annually and in 2015 generated $700B, or ~4% of GDP, with a government target to more than double this to $1.6T by 2020. These figures are roughly in line with my projections from a decade ago.

Part of the strategy to improve China's domestic biotechnology capabilities has been to import knowledge and technology from abroad. In addition to ongoing efforts to lure home more “sea turtles” — students who had left China to study overseas, but have now “swum home”, bringing knowledge with them — there are an increasing number of “seagulls” – Chinese professionals who transit multiple times between China, the United States, and Europe, maintaining collaborations around the world and serving as conduits for knowledge. To facilitate the transfer of knowledge and expertise to China, in 2008 the government launched the “Thousand Talents Program”, which paid approximately 6,000 foreign and Chinese born scientists to relocate to China[22]. This program has come under scrutiny of late, in part due to action by the U.S. Congress. And yet the money is spent, and the people have moved, and the substantial support for

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[16] Carlson, R., “Causes and Consequences of Bioeconomic Proliferation: Implications for U.S. Physical and Economic Security", Biodefense Net Assessment 2012, Homeland Security Studies and Analysis Institute, 2011.

[17] Carlson, 2011.

[18] ibid.

[19] ibid.

[20] ibid.

[21] ibid.

[22] “China hushes up scheme to recruit overseas scientists”, Yuan Yang and Nian Liu, *The Financial Times*, 9 Jan, 2019.

these researchers is buttressed by additional investment in commercialization, which has resulted in a profusion of biotech start-ups over the last decade[23]. The U.S. government should expect that China will continue to vie for international leadership in the development of biotechnology.

Security

My charge for the 2012 BNA was to assess the implications for U.S. physical and economic security of rapidly spreading biological technologies. I concluded that the overall paucity of information about international industrial capability was of particular concern because,

> *When combined with the torrid pace of economically-driven proliferation, this lack of information and awareness will eventually lead to surprises. In the context of this report "surprise" means an innovation by a particular actor that could not be easily foreseen by tracking the prior development of that actor and that may pose a risk to U.S. interests; i.e., "a threat."*[24]

Two components of security that were outside the primary purview of my 2012 BNA report were IP security and foreign investment in biotechnology. These components turned out to comprise a different sort of surprise than anticipated by either myself or the Executive Review Panel for the 2012 BNA. Aggressive foreign acquisition of biological technologies via both upfront investment and outright theft have turned out to be a substantial threat to U.S. interests. I commend the Congress for its recent efforts to steward U.S. intellectual property, and the substantive biotechnology innovations funded by U.S. taxpayers, by bringing biotechnology explicitly into the remit of the Committee on Foreign Investment in the United States[25].

It appears that the added scrutiny brought to bear on investment in, and acquisition of, technologies developed domestically has slowed foreign investment, which, to be sure, has directly impacted the ease with which companies in our portfolio have been able to raise capital. Yet I would like to personally state for the record that it *should* be harder for foreign entities, particularly those backed implicitly or explicitly by foreign governments, to acquire critical early stage technologies developed in the United States, particularly those funded by U.S. taxpayers.

Domestically, the relationship between scientists and the security and law enforcement communities has not always been smooth. However, I would like to credit by name FBI Supervisory Special Agent Ed You for his yeoman efforts to develop outreach programs that have built trust and lines of communication between academic scientists, garage biology enthusiasts, entrepreneurs, and the U.S. government. The FBI now considers anyone interested in biology to be part of its early warning system for identifying potential misdeeds[26],[27]. It is my personal experience that FBI agents in local offices are encouraged by their leadership to reach out and develop constructive relationships with those maintaining labs in their homes. These efforts will become increasingly important as the bioeconomy grows and incentivizes more commercial activity in the form of start-ups that will crop up in any working space that they can afford. The U.S. government should encourage this activity, rather than fear it or suppress it, but should also devote

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[23] "China's great leap forward in biotech", Henry Sender, *Nikkei Asian Review*, 3 Oct, 2018.
[24] Carlson, 2011.
[25] "In New Slap at China, U.S. Expands Power to Block Foreign Investments", Alan Rappeport, *The New York Times*, 10 Oct 2018.
[26] "Biohackers of the world, unite", *The Economist*, 10 Sept, 2014.
[27] "On Patrol with America's Top Bioterror Cop", Antonio Regalado, *Technology Review*, 20 Oct, 2016.

resources to continuing engagement activities that are, in my experience, the best single step that the U.S. government has taken to improve security.

We all have a great deal of work ahead of us in shepherding the growing bioeconomy as it begins to impact an ever broader swath of the economy. The ongoing National Academies study "Securing the Bioeconomy", sponsored by the Office of the Director of National Intelligence, is in my view a significant step forward in identifying and highlighting the challenges faced by the United States in navigating the rapidly evolving world of biotechnology. I hope that similar efforts will continue to serve the dual purposes of informing the U.S. government about the critical role of biotechnology in the economy while also informing the scientific community about the reality of biotechnology being a powerful geopolitical tool on the global stage that must be respected and protected accordingly. We must do better in both the public and private sectors to develop and secure the bioeconomy.

Public Conversations

The public has a passion for learning about biology. It's understandable. We are biology. We eat biology. We are surrounded by biology. Human society and population levels today are viable only because over the last century our well-being and lifespans have been significantly impacted by biological technologies. Moreover, biotechnologies are rapidly improving in price and performance. It is natural that the public wants to know more about how new means to measure and manipulate nature might affect not just humans, but all life around us. It is incumbent upon the government to engage scientists, entrepreneurs, and the public on issues of safety, security, and ethics. This engagement is foundational to both science and democracy, particularly in the context of taxpayers' interests in how the government spends their money. But beyond the role of two-way communication in the future of engineering biology, is the growing, and critically important, participation of the public in the practice of biotechnology itself. As biotechnology becomes less expensive, and more capable, it is finding its way into community laboratories, garages, and other so-called "unconventional spaces", where members of the pubic are enthusiastically taking part. As rapidly as biological engineering is being developed in high-end academic, corporate, and government labs, it is migrating to the street.

The U.S. Economy Begins in Garages

The democratization of technical capability, and the distributed innovation it enables, is the foundation of modern innovation. According to a study for the U.S. Small Business Administration, nearly every technology that we now consider important in the modern economy passed through an unconventional space at some point in its development cycle[28]. To summarize an argument from my book, *Biology is Technology*, there is every reason to expect the biotechnology industry to develop along these same lines and to depend heavily on entrepreneurs and small organizations in garages to produce innovation[29]. Governments at local, regional, and national levels around the globe appear to agree, and continue to provide incentives for biotech start-ups and clusters with the goal of fostering economic development and technological competitiveness. This trend is only going to accelerate, and it should be embraced. The U.S. government would do well to develop a network of community laboratories that would provide access

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[28] Baumol, W., *Small Firms: Why Market-Driven Innovation Can't Get Along Without Them*, 2005, U.S. Small Business Administration.

[29] Carlson, R., *Biology is Technology: The Promise, Peril, and New Business of Engineering Life*, Harvard University Press, Cambridge, MA, 2010.

to infrastructure, increase communication between innovators, and facilitate engagement with the U.S. government in regards to national security and national technology development goals[30]. In addition to providing venues for education and public conversations, this strategy would facilitate economic development via start up formation, thereby accelerate job creation, and would dovetail nicely with the aforementioned existing FBI outreach activities.

The U.S. National Security Council determined nearly a decade ago that openness should be the foundation of biotech and health security strategy. Moreover, these security professionals concluded that restricting access is counterproductive and that only through openness and the development of collective norms can we reduce the emergence, and impact, of threats.

In particular, the 2009 National Strategy for Countering Biological Threats, which carried the signature of the President of the United States, explicitly set out policy to embrace and encourage garage biology[31]:

> *The beneficial nature of life science research is reflected in the widespread manner in which it occurs. From cutting-edge academic institutes, to industrial research centers,* ***to private laboratories in basements and garages, progress is increasingly driven by innovation and open access to the insights and materials needed to advance individual initiatives.*** [emphasis added]
>
> *Our Strategy is targeted to reduce biological threats by: (1) improving global access to the life sciences to combat infectious disease regardless of its cause; (2) establishing and reinforcing norms against the misuse of the life sciences; and (3) instituting a suite of coordinated activities that collectively will help influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences.*

In other words, the National Security Council, after due study and deliberation, decreed that garage biology is good and necessary for the physical and economic security of the United States. The 2018 U.S. National Biodefense Strategy affirmed that “promoting American prosperity increasingly will depend on a vibrant life sciences and biotechnology enterprise”[32]. I have argued elsewhere that all nations who hope to sustain their physical and economic security must similarly embrace and encourage diversity in innovation and commercialization; those who do not will almost certainly place themselves at a disadvantage[33],[34].

The broader implications of this proliferation should, of course, be at the forefront of thinking about the future of biotechnology. We must confront any opportunity or threat with the attention due each. What will the world look like as more powerful biological technologies can be employed by a greater number, and diversity, of individuals around the world? We are about to find out.

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[30] Carlson, R. “Building a 21st Century Bioeconomy: Fostering Economic and Physical Security Through Public-Private Partnerships and a National Network of Community Labs”, Biodesic, 2011.

[31] “National Strategy for Countering Biological Threats”, National Security Council, 2009. https://obamawhitehouse.archives.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf

[32] “National Biodefense Strategy”, The Executive Office of the President of the United States, 2018.

[33] Carlson, 2010.

[34] Carlson, R., “Causes and Consequences of Bioeconomic Proliferation: Implications for U.S. Physical and Economic Security", Biodefense Net Assessment 2012, Homeland Security Studies and Analysis Institute.

Recommendations

My first recommendation is to centralize the strategy formation and policy response functions of the United States government in regards to the bioeconomy. The responsibility to understand, prepare for, and respond to threats to the bioeconomy is balkanized, and therefore dysfunctional, spread across at least nine Departments and Agencies within the Executive Branch: Health and Human Services, Agriculture, Commerce, Energy, Defense, Homeland Security, Justice, as well as the special responsibilities of the CDC and the Intelligence Community. That the bioeconomy touches so many of the functions of the U.S. government should clarify the scope of the problem. Whether your immediate concern is infectious disease response, antibiotic resistant pathogens, food security, farming, bioterrorism, invasive species, or the DOD supply chain, all these problems involve biology. We do not benefit from maintaining a fragmented perspective. These interagency problems require a full time position to integrate and coordinate across the U.S. government in order to streamline decision making.

Let me clarify here that the very last thing I want to do to this nascent and important enterprise is to smother it with bureaucracy or overly precautionary regulation. Nevertheless, I strongly recommend that Congress find ways to encourage coordination across government agencies and industry to develop and execute a strategy for keeping the United States at the forefront of technology development and of economic realization of the fruits of engineering biology. It is my personal experience that biosecurity, inclusive of both natural and artificial threats, and of both economic and physical well being, is disjointed and inadequately funded. I have come to the conclusion that this failing is due to the lack of a strategic function, and of an individual who is responsible for advocating to Congress. This headless fragmentation puts the United States at a distinct disadvantage with respect to countries that have proceeded with a clearly stated industrial policy and clearly understood lines of communication, if not clear lines of authority. Our laissez-faire approach does have its advantages, but also its costs, where the latter now negatively impact our security.

Next, I would strongly recommend that, in addition to legislation aimed at bolstering the strategic understanding and prominence of biological engineering and manufacturing in the economy, this Committee also broaden its focus to examine the net contribution of all of biology to U.S. physical and economic security. While this task may sound daunting and complex, the rationale is very simple: just as we do not quantitatively understand the role of engineered biological systems in our economy, and just as this lack of understanding constitutes a security risk, we also do not understand the role of natural biological systems in supporting our economy, which ignorance may represent an even more significant security risk. Without the air, water, and food supplied by natural biological systems, without the fire suppression, flood control, and coastal protection respectively provided by forests, wetlands, and coral reefs, the rest of our economy has no value at all. In that regard, our entire economy is synonymous with the bioeconomy, which should be afforded the same level of attention as we pay to the rest of the enterprise.

Entities ranging from small farmers, to the all of the States of the Union, to the Department of Defense are already facing the reality that their dependence on finite biological resources constitute physical and economic risks, which in each case could cost tens to hundreds of billions of dollars to remediate with technology or other interventions, if that is even possible.

To be sure, these risks may be addressable through greater biological engineering capabilities, and I strongly suggest that this Committee include such remediation within the scope of the biological engineering strategy and projects considered in any legislation. But relying on that technical capability, which could take decades to develop, clearly must be secondary to first measuring, and then preserving, the utility of natural systems to provide those same services.

Finally, I close with a quote from my recent *Nature Biotechnology* article, which encapsulates my perspective on the challenges we face going forward:

> *Biosecurity has typically been interpreted as the physical security of individuals, institutions and the food supply in the context of threats such as toxins and pathogens. These will, of course, continue to be important concerns. Yet governments can no longer limit their concern to the proverbial white powder produced in a state-sponsored lab, a 'cave' in Afghanistan or a garage in Seattle. Safeguarding the large and rapidly growing bioeconomy requires embracing a more substantial challenge; it is essential to have a refined and ongoing understanding of what must be secured and from where threats might arise. Economic demand is driving technological proliferation, [which] must necessarily inform the evolving definition of biosecurity. Alongside the preexisting bioeconomy, we are building a system composed of inherently 'dual-use' engineering technologies that will constitute critical infrastructure for the future economy. …Biosecurity is now clearly synonymous with economic security. The focus of biosecurity policy must shift from protecting specific targets from specific threats to securing the bioeconomy as a system that increasingly drives economic growth and employment and, ultimately, enables humans to thrive on a global scale.*[35]

Thank you for your attention, and thank you for the opportunity to address this Committee.

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[35] Carlson, 2016.