CSIS BRIEFS

When Biosecurity Is the Mission, the Bioeconomy Must Become Government's Strategic Partner

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THE ISSUE

Biosecurity—protecting humans, animals, and plants from biological threats—is an essential government mission, the importance of which has been dramatically highlighted by the Covid-19 pandemic. The government's pandemic response has been enabled by the emerging bioeconomy, which provides core biosecurity capabilities that are essential to the success of the mission. The government's engagement with the bioeconomy has grown in recent years, encompassing a range of agencies with a focus on laboratory and product safety and an emphasis on supporting research and development (R&D). However, the government lacks mechanisms for providing a broader strategic focus that integrates priorities, including biosecurity, in partnering with the bioeconomy. As a result, the government's engagement with the bioeconomy remains insufficient to support the translation and integration of R&D into the delivery of biosecurity capabilities. The government is often not able to fully capitalize on the innovations happening throughout the bioeconomy, especially those developing outside the sphere of government-sponsored research. Today's imperative toward better preparing for future pandemics must be leveraged to produce a true strategic engagement with the bioeconomy across multiple levels of government and critical agencies in the biosecurity community of interest.

ENABLING THE BIOSECURITY MISSION

The Covid-19 pandemic has highlighted the critical importance of biosecurity to Americans' lives and way of life. The pandemic provided an unmistakable reminder that biological pathogens can cause widespread death, illness, and disruption—and can do so for sustained periods of time. Covid-19 is far from an isolated case. It is simply the latest in a long line of pathogens (e.g., SARS, MERS, Ebola, H1N1, and avian flu) that have circulated among people and animals creating substantial negative effects, though Covid-19's consequences have been the most severe and widespread of any pathogen that has emerged in recent decades. In addition to the huge number of naturally occurring pathogens, there is also a risk of engineered pathogens being used by one nation to attack another.

To combat these pathogens, government entities at the federal, state, and local level must understand and embrace biosecurity as an essential mission. Combatting the outbreaks of these pathogens requires massive resources and sophisticated coordination, tasks which demand government action to accomplish. The interconnectedness of the international community also requires governments to coordinate action with other countries, as well as with intergovernmental organizations and localities. The United States cannot succeed in its biosecurity efforts alone, and other countries share many of the same interests in protecting against biological pathogens.

The tasks performed by governments to provide biosecurity are diverse and can easily become disjointed, as the Covid-19 pandemic has illustrated. Governments purchased personal protective equipment (PPE) and

ventilators; imposed quarantines, social distancing, travel restrictions, and mask mandates; set up and helped supply tests and testing centers; set up systems for tracking Covid-19 infections and variants; and helped develop, authorize, purchase, and distribute vaccines and therapeutics. While Covid-19 illustrated the importance of government in managing a biosecurity crisis, there are also a range of important longer-term government biosecurity initiatives that lay critical groundwork for future success in the biosecurity mission, including innovative basic research on viruses and other pathogens, drug and vaccine research, investment in public health infrastructure, and investments in planning and preparedness, such as biosurveillance.

The success of governments in performing the many tasks in the biosecurity mission depends critically upon capabilities in the private sector. Private sector entities are responsible for the production of biosecurity equipment, test supplies, drugs, and vaccines. As advances in the field of biotechnology have accelerated in recent years, there has been increasing recognition that the portion of the economy that produces products from and for the biological world, the bioeconomy, is a coherent sector that merits greater investigation, protection, and support. Governments around the world, including adversaries of the United States, have begun to recognize the importance of biotechnology as among the key emerging technologies shaping the modern world, and the bioeconomy as critical to economic and national security.

The capacity, vitality, and innovativeness of the bioeconomy enables success in the biosecurity mission. Numerous recent advances in the bioeconomy have all contributed to the crisis response for Covid-19 and provide the potential for significant biosecurity advances against future threats. These include: the development of messenger RNA (mRNA) technology, upon which several of the Covid-19 vaccines are based; new vaccine production techniques, which have dramatically accelerated vaccine production; multiple new forms of tests for Covid-19, including rapid diagnostics; and cutting edge-production capabilities for a wide range of biologics.

The government's relationship with the bioeconomy has been extensive, but even with the explosion of government purchases from the bioeconomy during Covid-19, it has mostly been focused on early-stage R&D of bioeconomy technologies. The government has engaged much less with the bioeconomy as a partner in the production and purchasing of products and new capabilities over time as it does with other key industries that support critical government missions. Given the importance of the government's biosecurity mission, and the centrality of the bioeconomy to that mission, a more strategic government relationship with the bioeconomy must be developed.

DEFINING TERMS: BIOSECURITY AND BIOECONOMY

How key terms are defined is more than a matter of semantics. Definitions shape and are shaped by the conceptual framework that underlies policy discussion. Understanding what is meant by the terms biosecurity and bioeconomy is key to developing a productive partnership between the government and the private sector in this area. Currently, there is not a clear consensus on the meaning of these terms within and among key stakeholder communities. Instead, the terms are variously defined by different stakeholders, who often adopt definitions particular to their area of focus. However, there are several good definitions that have been developed that can inform the issue and clarify future discussions.

BIOSECURITY

U.S. government definitions of biosecurity are too limited to support the scope and scale of the mission. Federal government agencies currently define biosecurity as a subset of safety practices in the handling of pathogens. Because these definitions focus on the safe handling of pathogens, often in a laboratory setting, they address only a portion of the governmental responsibilities demonstrated as part of Covid-19 response. The definition of biosecurity used by the Department of Health and Human Services (HHS) is part of regulations enforcing its statutory responsibility for the safe handling of biological agents and toxins that pose a threat to public health.[1] HHS defines biosecurity as protecting biological agents from theft, loss, or misuse.[2] There are related requirements at the Department of Agriculture (USDA), which maintains a list of biological threats to animals and plants. In the same vein, the Department of Defense (DoD) primarily defines biosecurity as an issue for the safe handling of pathogens within DoD laboratories performing work as part of its biodefense programs.[3] DoD's programs are designed to protect against risks from engineered pathogens, such as weaponized anthrax. DoD defines biosecurity as "the discipline addressing the security of microbiological agents and toxins and the threats posed to human and animal health, the environment and the economy by deliberate misuse or release."[4]

International organizations such as the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations have a much broader definition of biosecurity: "a strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life and health and associated risks for the environment."[5] When considering biosecurity as an essential mission for governments at every level, this broader definition is much more inclusive of the full range of key governmental tasks identified earlier. As used in this issue brief, therefore, biosecurity should be understood in the context of a broad definition: *Biosecurity is an integrated approach to assessing and managing risks posed by biological agents and biotechnology to human, animal, and plant life and health*. It would be beneficial for the federal government to adopt this definition of biosecurity, collaborating with state and local governments as well as the private sector, as part of guidance for performing the biosecurity mission that incorporates the more focused definitions currently used by federal agencies in fulfillment of their statutory responsibilities.

BIOECONOMY

The bioeconomy also has a range of definitions associated with it, but this brief focuses on specifying a definition for policy purposes. In 2010, support for a "21st century bioeconomy" was established among the federal government's science and technology priorities for the federal budget.[6] The White House subsequently issued a 2012 *National Bioeconomy Blueprint* establishing five strategic objectives for the development of the bioeconomy, including supporting R&D investments, facilitating the transition of biotech inventions to market, developing and reforming regulations, training the workforce, and building public-private partnerships.[7]

Subsequent policy development included an increasing focus on protecting the bioeconomy, which led to a seminal 2020 report from the National Academies of Sciences, Engineering, and Medicine (NASEM), *Safeguarding the Bioeconomy*. The NASEM report undertakes a comprehensive effort to develop a clear definition of the bioeconomy, tying it to innovation in the life sciences and biotechnology along with advances in engineering and computing.[8] The NASEM report also identifies six broad economic categories, included within identified categories in the North American Industrial Classification System (NAICS), that contain elements of the bioeconomy: (1) genetically modified crops and products, (2) biobased industrial materials, (3) biopharmaceuticals and biologics and other pharmaceuticals, (4) biotechnology consumer products, (5) biotechnology R&D business services, and (6) design of biological data-driven patient healthcare solutions.[9] The European Union's definition of the bioeconomy, updated in 2018, includes agricultural sectors that the U.S. definition excludes, but it also excludes medicines that the U.S. definition includes.[10] This brief recommends the use of the NASEM definition of the bioeconomy: "*economic activity that is driven by research and innovation in the life sciences and biotechnology, and that is enabled by technological advances in engineering and in computing and information sciences*." This definition is already the de facto U.S. government definition, and it provides a useful starting point for understanding the bioeconomy's contribution to the biosecurity mission, especially because of its inclusion of medicines. Because the bioeconomy is an inherently dynamic sector of the economy that is growing and innovating rapidly, it is essential for the U.S. government to periodically update its definition of the bioeconomy to keep up with these developments.

CORE BIOSECURITY CAPABILITIES OF THE BIOECONOMY

The capacity, vitality, and innovativeness of the bioeconomy is central to the government's biosecurity mission. The bioeconomy is responsible for producing the products needed for the biosecurity mission, for ramping up production during a crisis, and for rapidly developing new solutions in the face of emerging bio threats. Particularly when unexpected challenges arise, the ability of the bioeconomy to help government respond is critical. But not all elements of the bioeconomy are equally important to the biosecurity mission. Rather, there is a definable set of core capabilities that underpin biosecurity. As the United States mulls recalibrating its long-term approach to biosecurity—and the bioeconomy—an accounting of the core biosecurity capabilities provided by the bioeconomy is critical to shaping a potential policy approach. This section of the brief examines four core biosecurity capabilities: (1) detecting, characterizing, and attributing biological threats; (2) manufacturing PPE and vaccines; (3) developing treatments, countermeasures, and biosecurity infrastructure; and (4) building data technologies and situational awareness for tracking the progression of bio threats and enabling biotechnologies.

DETECTING, CHARACTERIZING, AND ATTRIBUTING BIOLOGICAL THREATS

Developing the capacity for early, rapid detection, characterization, and attribution of biological agents is critical to the biosecurity mission. By swiftly identifying and assessing such agents, governments can craft and deploy measures designed for disease containment. To achieve this feat, a deep understanding of potential biological threats is key, as is a surveillance infrastructure. The bioeconomy enables this, in part, through advances in genetic sequencing. Sequencing a wide variety of pathogens provides a foundation for detecting and tracking emerging threats in both human and animal populations by developing a library of genetic signatures for detecting threats. The bioeconomy also generates capabilities for biosurveillance. Effective biosurveillance requires investing in capabilities to detect pathogens as they emerge and spread new diseases, characterize diseases, and monitor pathogens' evolution. Biosurveillance capabilities are needed in a wide range of countries as well, as biological pathogens are highly likely to propagate across international boundaries. A real-time biosurveillance system could also mitigate the tendency for individual governments to suppress information about outbreaks, as such a system would potentially be able to record and share significant information about an outbreak before a local government could organize efforts to suppress such information. The bioeconomy can enable the United States to cooperate with international counterparts to integrate national and global epidemic surveillance systems, which would detect, share, and publicize early signs of outbreak in near real time.

MANUFACTURING PERSONAL PROTECTIVE EQUIPMENT AND VACCINES

Maintaining and expanding the manufacturing capacity to produce PPE and vaccines is another core biosecurity capability of the bioeconomy. The rapid deployment of PPE is necessary to protect populations against emerging biological threats. These tools likewise can serve to curb the circulation of long-standing infectious diseases if used properly in more normal circumstances. The federal government, and some state and local governments, maintain stockpiles of PPE for emergencies.[11] The Covid-19 pandemic exposed shortcomings in systems for the maintenance, allocation, and rapid supplementation and refilling of these stockpiles as supplies ran low.[12] A number of stopgap measures to provide PPE were adopted by the Trump administration, including bans on PPE exports, substantial new PPE contracts, and efforts to onshore PPE production using the Defense Production Act.[13] The Food and Drug Administration (FDA) also continues to list multiple categories of PPE on its medical device shortage list.[14] Longer term, however, governments need the bioeconomy to make PPE supply chains more agile, robust, and resilient.

Vaccine development and production is another critical biosecurity capability of the bioeconomy. The bioeconomy has pioneered new methods for vaccine development, including mRNA vaccines and other new approaches to boosting immunity against biological pathogens. These new approaches, combined with extensive government support, allowed for the development of multiple new vaccines in record time in 2020 and 2021.[15] In addition to these new processes for developing vaccines, the bioeconomy has made significant advances in techniques for vaccine production so that millions of vaccine doses can be rapidly produced and distributed in the time it would have taken to produce thousands of doses using older techniques. The recent progress with vaccines is remarkable, and the bioeconomy can provide even more improvements in vaccine development and production in coming years.

DEVELOPING TREATMENTS, COUNTERMEASURES, AND BIOSECURITY INFRASTRUCTURE

While PPE and vaccines are designed to slow or stop the spread of disease, the bioeconomy also provides a core capability for treating humans and animals that contract disease. Treatments and medical countermeasures such as antiviral medications and ventilators are critical tools in mitigating the risk and impact of biological pathogens. Since the outbreak of the Covid-19 pandemic, the FDA has approved several antiviral therapeutics as treatments for Covid-19: remdesivir, baricitinib, and bamlanivimab. (The FDA revoked the emergency use authorization for bamlanivimab in April 2021.[16]) These therapeutics have been associated with diminished viral load in patients, decreased recovery time, and reduced disease progression. These novel therapeutics were helpful, but there is a compelling need for additional therapeutics in the tool kit. The ability to develop these therapeutics is another core biosecurity capability of the bioeconomy.

The Covid-19 pandemic also accelerated the adoption of telemedicine technologies across the United States. These emerging capabilities extended the reach of medical institutions and share information, enabling healthcare professionals to remotely evaluate, diagnose, and treat patients. The use of digital health technologies

also expanded the severely strained capacity of medical institutions while limiting the circulation of pandemic pathogens. Such medical infrastructure is also part of this core capability.

BUILDING DATA TECHNOLOGIES AND SITUATIONAL AWARENESS

Information and data technologies are key to biosecurity. During the Covid-19 pandemic, effective response efforts were driven by data gathering and data analysis of where infections were happening and where medical infrastructure was being overwhelmed. The bioeconomy developed new data solutions to leverage this data and help target government efforts. New, innovative approaches, including mobile-phone tracking and data mining of search engines and social media, were particularly instrumental in providing policymakers with insights on the rapidly evolving trajectory of the pandemic. Data technology is essential to developing the situational awareness required for effective biosecurity.

As data is increasingly integrated into public health interventions, developing transparent, effective biosecurity-related data governance frameworks is essential for stakeholders to maximize data utility, derive critical insights, and craft durable policy interventions. Over the longer term, data technologies are critical to all aspects of the bioeconomy. Bioeconomy capabilities such as genetic sequencing and vaccine and drug development depend on an underpinning of health-related information technologies which gather, store, and process large volumes of information. The bioeconomy's ability to develop, sustain, and innovate in the management of biosecurity data is a key core capability.

GOVERNMENT ENGAGEMENT WITH THE BIOECONOMY

Given the importance of the bioeconomy's core biosecurity capabilities to the performance of the government's mission, the nature and extent of the government's engagement with the bioeconomy is of utmost importance. A close examination of this relationship shows that the government's involvement with the bioeconomy is extensive and has grown, particularly due to the Covid-19 pandemic. However, it is also clear that the government's support is heavily weighted in the direction of early-stage research, and that later-stage purchases are modest, with the notable exception of Covid-19 vaccine purchases. Further, while there is clear evidence of strategic prioritization in the early-stage work with the bioeconomy, as demonstrated by the R&D priorities established by the White House in 2010 and reiterated and updated multiple times since, there is no clear strategic prioritization for the government's later-stage involvement with the bioeconomy.

The government's involvement with the bioeconomy spans a range of agencies. Central pillars in the effort are HHS and its National Institutes of Health (NIH) component. The Departments of Defense, Agriculture, and Homeland Security are also substantial players. In the event of a biosecurity crisis, other government agencies, including the Federal Emergency Management Agency and the Centers for Disease Control and Prevention, also get deeply involved in response and control efforts.

Due to the government's extensive focus on early-stage R&D in the biotechnology arena, the NIH is currently the linchpin of its bioeconomy engagement and a substantial provider of funding for R&D in the bioeconomy, which will be examined in more detail later in this section. The NIH'S Office of Science Policy houses the Biosafety, Biosecurity, and Emerging Biotechnology Policy Division, which oversees the development and implementation of policies designed to promote ethical approaches to life sciences research. The division's Biosecurity Policy Program (BPP) also administers the National Science Advisory Board for Biosecurity, a federal advisory committee that addresses issues pertaining to biosecurity and dual-use biological research. In addition, the NIH's Emerging Biotechnology Policy Program monitors and assesses the scientific, ethical, and social implications of emerging biotechnologies.

The NIH is also a player in the biotechnology innovation ecosystem. In 2011, it founded the National Center for Advancing Translational Sciences. The institute provides funding to the private sector to accelerate the development of novel diagnostics and therapeutics. In February 2020, HHS launched the Foundry for American Biotechnology. The initiative established a public-private partnership to help commercialize biotechnology innovations to respond to natural disasters and public health emergencies.[17] To date, the foundry has focused on building mobile devices capable of producing on-site medicines across disaster zones.

HHS houses the FDA, which regulates and ensures the safety of drugs, vaccines, and medical devices, among other bioeconomy products. HHS also includes the Biomedical Advanced Research and Development Authority (BARDA), an office which forms partnerships with private sector actors in the bioeconomy to develop vaccines, drugs, therapies, and diagnostic tools for public health

emergencies. BARDA lists 61 products supported by the authority which have been approved for use by the FDA.[18] In addition, the FDA's Center for Devices and Radiological Health is implementing the Medical Device Innovation Initiative, which has created an innovation pathway for prioritizing and streamlining approval for pioneering technologies and streamlined the pathway for *de novo* devices, which are lower-risk devices for which there is no predicate.[19] The initiative has increased the rate at which innovative new products can receive approval.

The USDA engages with the bioeconomy through its Animal and Plant Health Inspection Service (APHIS). The USDA's involvement is important because animal and plant health are key elements of biosecurity and because products developed for this purpose are important within the bioeconomy. Currently, however, it is not clear that the USDA's engagement with the bioeconomy is integrated across the various services within APHIS. APHIS's Biotechnology Regulatory Services regulates genetically engineered biotechnology products that affect animal and plant health. APHIS also regulates veterinary biologics, including vaccines and diagnostics, through its Center for Veterinary Biologics. In addition, APHIS's Veterinary Services engages in biosurveillance of animal diseases as part of efforts to contain outbreaks such as avian and swine flus, facilitated by the National Veterinary Services Laboratories.

Biosecurity is an important part of the Department of Homeland Security's (DHS) wide-ranging portfolio. The DHS Science and Technology Directorate's National Biodefense Analysis and Countermeasures Center (NBACC) is likewise a key node of the U.S. biosecurity arsenal. Founded in 2004, the NBACC provides capacity to address biological threats and includes the National Bioforensic Analysis Center and the National Biological Threat Characterization Center. These centers enable the United States to rapidly probe biological threats and share intelligence with government stakeholders, thus informing potential response interventions.

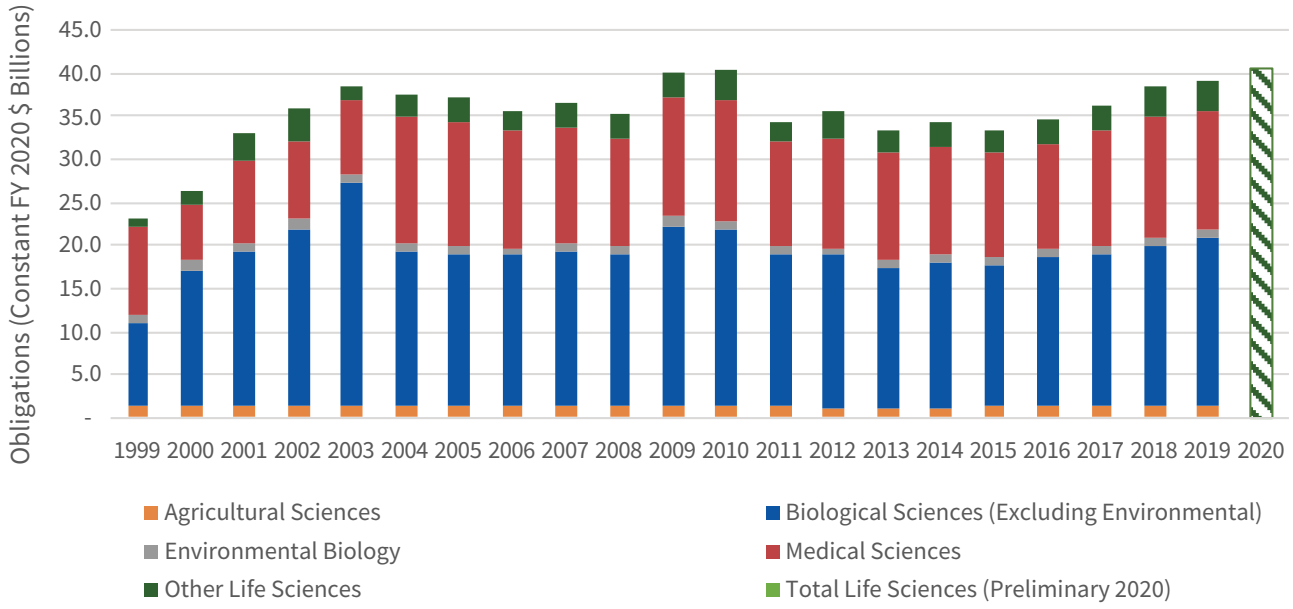
Historically, the DoD has played a critical role in fostering innovation in emerging technologies. While not previously a priority, a growing awareness of the benefits and threats posed by emerging biotechnologies in recent years is pushing the Pentagon to embrace the life sciences, including the work of the National Security Commission on AI.[20] In 2019, the Pentagon designated biotechnology as one of its modernization priorities.[21] The Defense Science Board (DSB) established a Biology Task Force to examine the applications of emerging life sciences. In September 2020, the task force released its final report, which featured a list of recommendations to leverage biotechnologies for the military.[22] Among other matters, the report recommended the under secretary of defense for research and engineering establish an assistant director of defense research and engineering for biotechnology post and foster a public-private biotechnology innovation ecosystem. Prior to the release of the final report—at the behest of the task force—the DoD implemented this recommendation and established an assistant director for biotechnology in 2019. Congress also included a provision in the National Defense Authorization Act for Fiscal Year 2020 that requires the Defense Science Board to perform a study that examines the national security implications of emerging biotechnologies. The study was initiated in January 2021 and is poised to explore the potential advantages afforded by advances in biotechnologies while also assessing the challenges posed by the militarization of these capabilities among adversaries.[23]

The Covid-19 pandemic has also animated a raft of biotechnology initiatives at the Pentagon. Many of these efforts aim to buoy biomanufacturing capabilities, such as the Bioindustrial Manufacturing Innovation Institute. This initiative, launched in October 2020, is focused on advancing sustainable and reliable bioindustrial manufacturing technologies.[24] DoD was also deeply engaged in Covid-19 response efforts, including through use of the Defense Production Act, Operation Warp Speed, and the DoD-led Joint Acquisition Task Force, which together carried out most of the federal government's purchases of PPE, vaccines, and vaccines supplies.[25]

FEDERAL SUPPORT TO THE BIOECONOMY FOR R&D AND PURCHASES

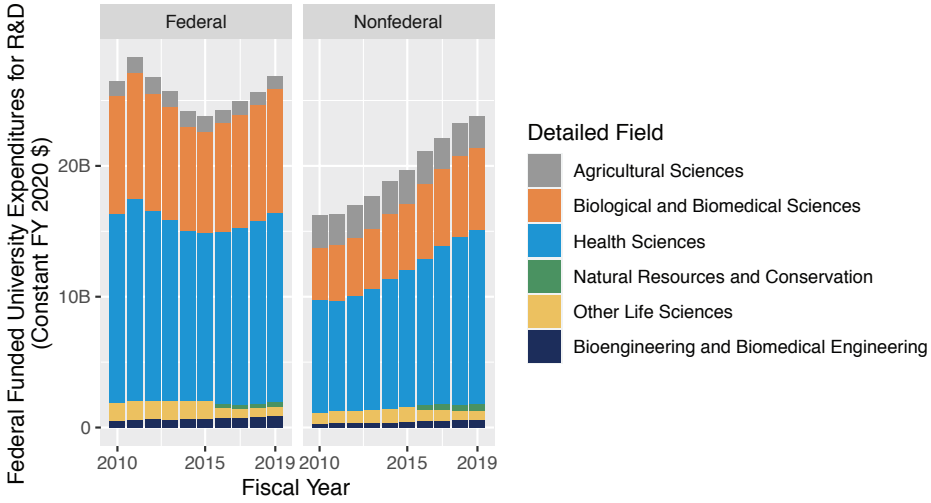
One of the most critical ways the federal government engages with the bioeconomy is through its support to R&D and its purchases of bioeconomy products. As the data presented below will demonstrate, in dollar terms the focus of federal support is overwhelmingly on the R&D side, particularly support to university-based research. While the purchases of Covid-19 vaccines and PPE may make 2021 something of an exception, federal support to R&D has historically been roughly an order of magnitude larger than federal purchases of products from the bioeconomy. As a result, the government's engagement with the bioeconomy is likely insufficient to support the translation and integration of R&D into the delivery of biosecurity capabilities. The government is often not

Figure 1: Federal Obligations for Life Sciences Research



Source: CSIS analysis; "Survey of Federal Funds for Research and Development," National Center for Science and Engineering Statistics, https://ncsesdata.nsf.gov/builder/ffs.

Figure 2: University Expenditures for Bioeconomy-Related R&D



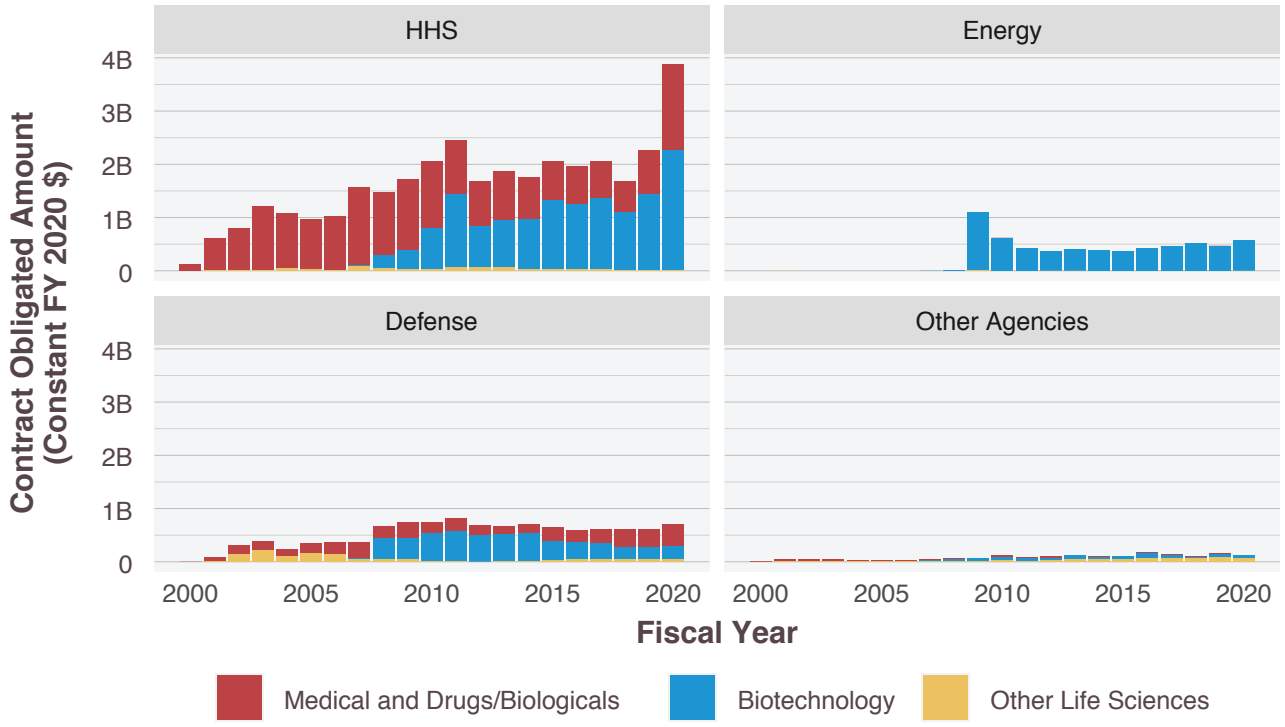
Source: CSIS analysis; "Higher Education Research and Development Survey," National Center for Science and Engineering Statistics, https://ncsesdata.nsf.gov/builder/herd.

able to fully capitalize on the innovations happening throughout the bioeconomy, especially those developing outside the sphere of government-sponsored research.

Federal obligations for life sciences research rose dramatically at the start of the century due to funding increases enacted at that time for the NIH but have been comparatively flat in real terms since that initial increase. Having reached just over $35 billion in 2002, as measured in 2020 dollars, spending even during the pandemic year of 2020 is estimated at $40.7 billion, only a 0.67 percent annual growth rate. In percent of GDP terms, despite the increase in expenditure in 2020 and the economic crisis, life sciences research expenditures stood at 0.194 percent, well below the 2009–2010 peak around 0.230 percent. Life sciences are the largest category of federal research, accounting for 47.7 percent of obligations in 2020. However, these figures cover only basic and applied research and not development, such as bioengineering. These later stages are where advances in the life sciences flow out into the larger economy and to biosecurity applications.

Federal funding for university expenditures for R&D peaked in 2011, later than for overall federal research, and has slowly climbed back from a trough in 2015, growing by less than 0.2 percent annually since 2010. Meanwhile, non-federally funded university research has grown steadily, at an average annual rate of 4.4 percent, although the federal government is still the larger funder overall. In percent of GDP terms, federal funding has declined from 0.149 percent in 2010 to 0.124 percent in 2019, a slight uptick over 2018. Bioengineering and biomedical engineering

Figure 3: Federal Contract Obligations for Bioeconomy R&D Services



Note: Builds on National Academies of Sciences, Engineering, and Medicine category of Bioeconomy R&D Services. Classification assisted via Product or Service Codes.

Source: CSIS analysis; Federal Procurement Data Service via USAspending.gov Award Data Archive.

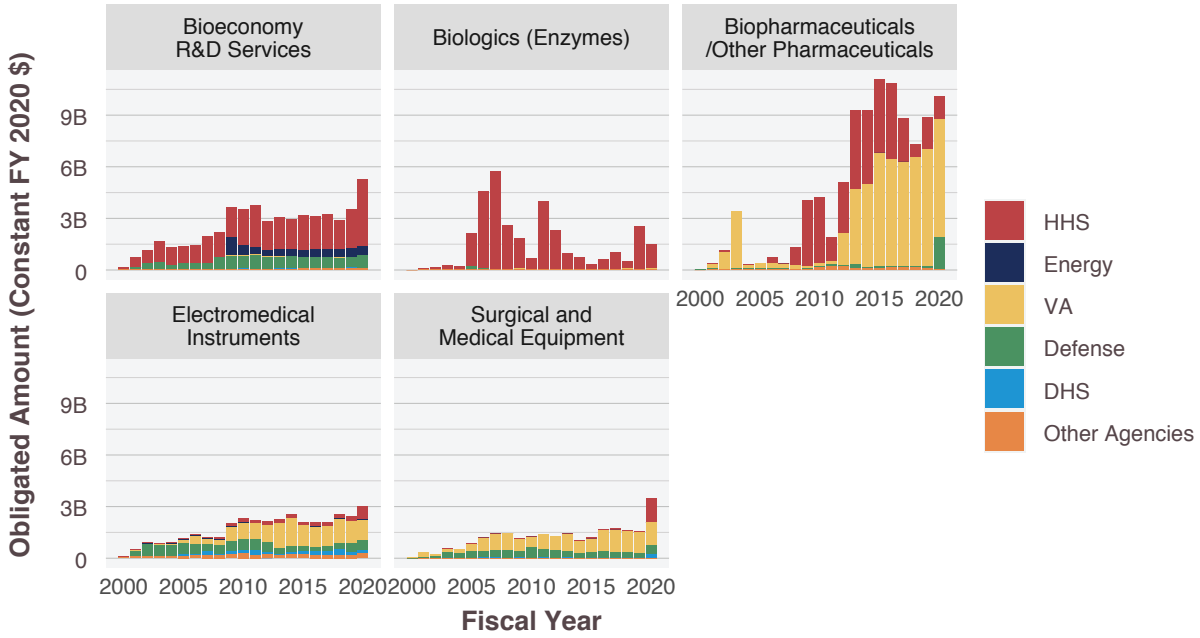
have grown steadily over this period, though the average federal growth rate for this engineering category is 5.35 percent, lower than for non-federal funding (6.58 percent). That said, it remains a tiny proportion of R&D, accounting for $897 million of $26.9 billion in 2019 federal funding.

To better understand the transition of R&D to application, it is helpful to look at the federal acquisition system, which contracts for a variety of bioeconomy goods and services. While the federal grant system focuses on basic and applied research and other public purposes, the contracting system is the typical means through which the federal government acquires innovations for its own use. The sheer size of federal government contracting—over half a trillion dollars a year, "roughly the size Sweden's economy"—means that in some sectors, such as aerospace, the federal government has both historically shaped the sector and remains a major customer.[26] However, unlike the Cold War era, the federal role in emerging technologies, including aspects of the bioeconomy, is often eclipsed by global private sector investment.

The NASEM *Securing the Bioeconomy* report identifies more than a dozen illustrative sectors to estimate the size of the private and public sector economy. The chart below shows five: bioeconomy R&D services; biologics (enzymes); biopharmaceuticals and other pharmaceuticals; electromedical instruments; and surgical and medical equipment. In four of the five sectors, there is a sharp increase in 2020 that is directly attributable to responses to the Covid-19 pandemic. For the manufacturing of pharmaceutical preparation, electromedical instruments, and surgical medical equipment, the Department of Veterans Affairs (VA) is the lead department, as there is a role for direct provision of care within the VA, while Medicare and Medicaid work through third-party providers. However, increases during Covid-19 went to HHS and DoD.

Bioeconomy R&D services are a subset of the federally supported research data already covered above, as the majority of obligations are for basic and applied research. However, across the period, nearly 7.9 billion was spent on advanced technology development, and $1.383 billion was spent on subsequent R&D phases. The marked increase in 2007 and 2008 is due to the creation of a new category for biotechnology R&D, and the remainder of the funding is for life sciences or medically relevant products and services identified from within a larger sector that includes physical sciences and engineering. HHS is the largest spender,

Figure 4: Federal Contracting for Selected Illustrative Bioeconomy Segments



Note: Builds on National Academies of Sciences, Engineering, and Medicine categories, including Bioeconomy R&D Services. Classification assisted via Product or Service Codes.

Source: CSIS analysis; Federal Procurement Data Service via USAspending.gov Award Data Archive.

but both DoD and the Department of Energy's Renewable Energy Laboratory have consistent funding. Finally, the biologics (enzymes) category, which covers biological product manufacturing, with the exceptions of diagnostics, is the domain of HHS and has been trending downward, receiving $192 million in Covid-19 related funding.

The size of the increases demonstrates the extent to which the bioeconomy acts as a reservoir of capability for federal biosecurity responses. Comparing 2016 spending with the National Academies' estimates for the size of the bioeconomy, federal contract spending in these sectors ranges from 4 to 9 percent of the private sector spending value added. While vaccine manufacture continues to ramp up, policymakers face choices in other sectors, including what level of capacity to maintain as emergency needs decrease and where the bioeconomy can be more effectively leveraged for prevention.

POLICY CHOICES FOR THE BIOECONOMY

The government's current engagement with the bioeconomy is heavily weighted in both institutional and financial terms toward support of early-stage R&D. Support for R&D is a traditional role for the government, and one in which it performs well. However, orienting government engagement so thoroughly to this role is unlikely to fully support the government's biosecurity mission in the longer term. More active and far-reaching engagement with the bioeconomy has been essential to the government's response during the Covid-19 pandemic, and it is likely to be essential also to fostering and fully leveraging the core biosecurity capabilities of the bioeconomy.

The Biden administration and Congress are considering several efforts that seek to expand the government's engagement with the bioeconomy. The American Rescue Plan, the administration's Covid-19 relief package, which was enacted on March 11, 2021, included several areas of funding for the bioeconomy, including billions for the manufacturing and purchasing of vaccines and therapeutics, $1.75 billion for genomic sequencing and surveillance, and millions for data modernization and forecasting.[27]

The Biden administration's proposed infrastructure plan, the American Jobs Plan, includes proposals for a $50 billion technology directorate at the National Science Foundation (NSF) intended to help migrate emerging technologies, including biotech, from the traditional NSF grant research stage to later stages of development.[28] In addition, the American Jobs Plan proposes $30 billion for taking prototype vaccines and therapeutics through phase I and phase II trials. It also earmarks $40 billion for upgrades to research infrastructure at laboratories as well as computing capabilities

and networks. The American Jobs Plan is currently the subject of negotiations in Congress. However, parts of the proposal were incorporated into the United State Innovation and Competition Act of 2021, an updated version of S.1260, introduced as the Endless Frontier Act, which passed the Senate on a bipartisan vote on June 8, 2021. The Senate bill would create a technology directorate at NSF and a science workforce education and development program, doubling annual funding for the NSF by 2026.[29] A critical question is whether the proposed technology directorate at the NSF would seek to support the development of key biosecurity technologies in the commercial sector or whether it will support the same or similar organizations as the current NSF grant process. An increase in support to existing NSF grant recipients, while likely worthwhile, would not address the existing gap in federal support for translating R&D into biosecurity capabilities.

Congress is considering several other bills affecting the bioeconomy, including H.R.2731, the House version of the Endless Frontier Act; S.1624, the National Laboratory Biotechnology Research Act; H.R.2153, the Securing American Leadership in Science and Technology Act; and S.3734, the Bioeconomy Research and Development Act.

These proposals will generate additional engagement with the bioeconomy. They build off the existing infrastructure of federal support for R&D, which means they are mostly more related to the later stages of R&D than they are to the purchase of finished products. One initiative that operates in the purchase of end products is the federal preference for purchasing biobased products identified by the USDA. This category of federal purchases is mostly leveraged currently for agricultural products. A similar or expanded model could be applied to the core biosecurity capabilities of the bioeconomy.

DEVELOPING A STRATEGIC ENGAGEMENT WITH THE BIOECONOMY TO SUPPORT BIOSECURITY

Biosecurity policymakers need to consider how to engage strategically with the bioeconomy beyond the stage of R&D. Today, there is not an agency or coalition of agencies that maintains a strategic engagement with the bioeconomy in the way that the federal government engages with the aerospace industry. Multiple parts of the government engage strategically with the aerospace industry, including DoD, the Federal Aviation Administration, the National Aeronautics and Space Administration, and the Department of Commerce. The basis for a federal community of interest in biosecurity is becoming increasingly clear and includes the Office of Science and Technology Policy, National Security Council (NSC), Federal Bureau of Investigations, State Department (for international engagement), NSF, HHS, DoD, DHS, and USDA. In addition, state and local government has a critical role to play in biosecurity and should be involved in this strategic engagement. The NSC probably provides the best focal point for developing a strategic engagement mechanism, working with a lead federal agency such as HHS, which can help organize the various parties in the discussion. The issue of pandemic preparedness provides a clear near-term imperative for organizing this strategic engagement. The continuing crisis of the Covid-19 pandemic and the need to prepare now for a similar event is a major spur to action. It makes sense to approach the issue with a long-term vision for success in the biosecurity mission at the same time.

A key task for those directing the government's approach to the bioeconomy will be to address the existing gap in federal support for key biosecurity capabilities through new and existing federal funding mechanisms. Future CSIS briefs on biosecurity will explore promising policy options in this arena derived from studying relevant case studies and engaging with experts. ■

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