Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products

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Thank you, Senator Talent, Commissioner Wessel, and the Commission for inviting me to provide this testimony on China's biotechnology industry. Most of the information presented in this testimony I collected while researching the report "China's Biotechnology Development: The Role of U.S. and Other Foreign Engagement," submitted to the Commission in February of this year, and in following the trends and developments in this arena since. The scope of that report encompassed biotechnology applications in healthcare and other industries, including biopharmaceuticals (i.e., biotech drugs), but did not include the traditional pharmaceutical industry (i.e., "small molecule" drugs). As such, I will describe how advances in China in the biopharmaceutical industry, as well as related biotechnology fields such as genomics, are impacting the U.S. with respect to its own biotechnology industry as well as its economic and national security.

Biotech products and services provided to the U.S. by Chinese firms

Over the past five years, China has advanced is biotechnology capabilities and offerings primarily through three industries: therapeutics (i.e., biopharmaceuticals), contract research and manufacturing, and DNA sequencing and related technologies. Although in many cases China is still catching up to the major players in the global biotechnology market, they are beginning to make inroads and, in some cases (notably genomics), are along the leading edge of technology.

Development of therapeutic biologics has contributed a large part of China's biotechnology growth in the past five years. According to a 2017 analysis of China's biologics market by Goldman Sachs, investigational new drug (IND) filings (i.e., applications for drug candidates to be used in clinical trials) for biologics in China have increased from fewer than ten per year before 2013 to 30-40 annually during 2014-2017.[1] The types of biologics being developed are primarily protein-based therapeutics targeting chronic diseases such as cancer, diabetes, and autoimmune diseases, especially antibodies and antibody-based drugs. Many of the biologic drugs being developed in China are biosimilars, meaning a highly similar—although not identical—molecule to an existing approved biologic drug. Such products have a lower risk associated with development because the compound has already been shown to be effective, although the economic return is diminished as a result (similar to producing generic drugs). Existing biologic therapies drawing a lot of attention from Chinese biosimilar developers include Humira (adalimumab—an immunosuppressive drug for treating conditions such as arthritis, psoriasis, and ulcerative colitis), Avastin (bevacizumab—an immunotherapy for several types of cancer), Rituxan (rituximab—for treating non-Hodgkin's lymphoma and chronic lymphocytic leukemia), and Herceptin (trastuzumab—an immunotherapy for breast, stomach, and esophageal cancer).

The biologic R&D activity of Chinese biotech companies, however, is largely focused on developing products for the Chinese domestic market. Many of the biologic drugs sold in China are imported, and

[1] Yeh et al. (2018) China: Healthcare: Biotechnology: Biologics: Balancing quality and affordability; Fosun Pharma up to Buy.

Chinese companies are looking to take a larger share of that market. Biologics developed in China are also not yet making it into the U.S. market. Few, if any, biologic drugs currently approved by the Food and Drug Administration (FDA) were developed by Chinese companies (although I have not performed a thorough assessment of FDA approvals, I am not aware of any such products). In at least one case, a Chinese company has acquired an FDA-approved biologic through direct investment: in 2017, Sanpower Group, a private Chinese technology conglomerate, bought Dendreon, producer of the prostate cancer immunotherapy Provenge. Provenge is not a blockbuster drug, however, and Dendreon was struggling to find a successful market at the time of the sale.

Supporting the boom in biologics R&D in China and globally is a large contract research and manufacturing industry. Contract research organizations (CROs) support pharmaceutical, biologics, and medical device companies by providing outsourced services for preclinical or clinical development. CROs can perform preclinical studies for a drug candidate, such as safety and efficacy trials and pharmacodynamics studies, as well as conduct Phase I-IV clinical trials. CROs play a prominent role in drug development worldwide, with more than half of all pharmaceutical companies employing them. In 2017, there were more than 1,100 CROs worldwide, with around 400 of them in China.[2] China's WuXi AppTec is a leading global CRO—according to the company, its biologics-focused component WuXi Biologics managed 205 projects at the end of 2018, including 97 in the pre-clinical development stage, 94 in phase I and II clinical development, 13 in phase III development, and one in commercial manufacturing. Unfortunately, determining the customer base of WuXi Biologics or any other CRO is a difficult endeavor, and data are not available on how many U.S. companies, or what portion of the U.S. market, are using CROs in China. Because a large part of CRO services is navigating regulatory requirements, use of foreign CROs for advanced-stage clinical development would likely be for products intended to be marketed in that country, although services such as pre-clinical development and manufacturing will still be valuable regardless of the location of the company.

China also hosts several companies providing DNA sequencing services, including some of the world's largest sequencing companies. BGI is the third largest company behind U.S.-based companies Illumina and Thermo Fisher and offers sequencing for basic research and pharmaceutical purposes as well as reproductive-health services. As part of its business strategy, BGI has formed numerous clinical research partnerships with U.S. institutions, including leading U.S. academic research centers, providing DNA sequencing and analysis services. (BGI also sells DNA sequencing machines, which are competitors to those sold by Illumina and Thermo Fisher.) Other top genomics companies in China include WuXi NextCODE, Novogene, and CloudHealth Genomics, which provide services such as DNA sequencing and bioinformatics (i.e., computational analysis of genetic data). WuXi NextCODE was formed in 2015 when WuXi PharmaTech acquired U.S.-based NextCODE Health. In addition to sequencing and genomics, Chinese companies can provide molecular diagnostics services (i.e., detection of specific proteins or genetic sequences to indicate disease), such as "liquid biopsy" for cancer diagnostics and noninvasive prenatal testing—including HaploX Biotechnology, Singlera Genomics, Berry Genomics, and Annoroad Genomics.[3]

In the U.S., clinical testing providers need certification to show that they comply with the requirements set in the Clinical Laboratory Improvement Amendments (CLIA) program, which assures appropriate standards are in place to ensure the validity of test results. Certification can occur through third-party accreditation, the most prominent being the College of American Pathologists (CAP). In our research for our report to this commission, my colleagues and I identified 23 companies with a Chinese nexus that have CLIA/CAP accreditation and perform genome sequencing, molecular diagnostics, or other genetic

[2] Chiu N. (2017) Contract Research Organization Market. GF Securities (Hong Kong) Brokerage LTD.; PR Newswire. (2018) Contract Research Organizations Global Market Opportunities and Strategies To 2021.

[3] GenomeWeb. (2018) Chinese Firm HaploX Biotechnology Raises $32M in Financing. GenomeWeb.; Singlera Genomics. (2018) Singlera Genomics Raises $60 Million in Series A+ Financing. https://www.prnewswire.com/news-releases/singlera-genomics-raises-60-million-in-series-a-financing-300619990.html.; Sun Y. (2017) China Doubles Down on the Double Helix. Neo.life. https://medium.com/neodotlife/cloudhealth-the-booming-genomics-industry-in-china-2e5476f469b0.; Illumina. (2015) Berry Genomics NextSeq CN500 Instrument and Non-Invasive Prenatal Testing Reagent Kit Receives Chinese FDA Premarket Clearance. https://www.illumina.com/company/news-center/press-releases/press-release-details.html?newsid=2030982.; GenomeWeb. (2017) Chinese Genomics Firm Annoroad Raises $105M. https://www.genomeweb.com/business-policy-funding/chinese-genomics-firm-annoroad-raises-105m#.XSuTbOhKiUk

testing, including WuXi NextCODE and Novogene. Unfortunately, we don't know how many U.S. customers or what share of the U.S. market they have.

In January 2017, Chinese artificial intelligence company iCarbonX announced the Digital Life Alliance, a new collaborative effort designed to give people a deeper understanding of the medical, behavioral, and environmental factors that contribute to proper health. iCarbonX was founded in China in 2015 by the former CEO of BGI and aims to build an internet-based ecosystem of digital life based on artificial intelligence and an individual's biological, behavioral, and psychological data.[4] The consortium ultimately aims to merge comprehensive biological and patient-generated data with artificial intelligence (AI) technology and predictive algorithms to provide data-based insights into an individual's health, disease progression, and aging and deliver a personalized guide for living well. The system could also be leveraged by the healthcare industry to improve precision medicine. Companies within the Digital Life Alliance bring expertise in fields such as protein measurement, microbial detection and isolation, human health modeling, enzymatics, the study of immune system regulation, data analysis, and artificial intelligence, and include the U.S.-based companies SomaLogic, HealthTell, AOBiome, and GALT. PatientsLikeMe, a U.S.-based company that collects health records and other data from U.S. patients (through self-submission) was also part of the consortium until they were made to divest from the alliance earlier this year following review by the Committee on Foreign Investment in the United States (CFIUS).

Activities of Chinese biotechnology firms in the United States

Several Chinese biotechnology companies have started new R&D facilities in the U.S., generally focused in major biotech hubs such as Boston, San Francisco, and the Research Triangle area in North Carolina. By locating in major U.S. biotech regions, Chinese companies are seeking access to advanced technologies and expertise, a well-educated workforce, and top-tier research universities and biotech companies to foster collaboration. Two high-profile examples are QLB Biotherapeutics, a branch of Qilu Pharmaceutical, and VcanBio USA, started by VcanBio Cell & Engineering Corporation, one of the largest biotech companies in China. Both startups are located in the Boston area and develop cancer immunotherapy products and related technologies. Companies operating in genomics and molecular diagnostics are also opening research centers in the U.S. Novogene established a genome sequencing center on the campus of the University of California, Davis, and Genetron Health opened their molecular diagnostics and precision medicine center, Genetron Health Technologies, in Research Triangle Park, NC.

In addition to R&D startups, and sometimes in combination with them, some Chinese biotech companies have opened biotech incubators in the U.S. Startup incubators refer to a range of commercial facilities and organizations that provide infrastructure and support to help new companies grow and develop. The simplest biotechnology incubators provide laboratory space and equipment, allowing fledgling companies to share and distribute those startup costs, which in biotechnology are high. Incubators also frequently provide business support, including leveraging their expertise and networks to facilitate expansion and marketing, as well as providing basic legal and accounting support. Incubators are often linked to or sponsored by investors in the companies within the incubator, thereby increasing the probability that those investments result in a successful company and a positive return to those investors. In the case of Chinese biotechnology incubators in the U.S., parent companies are often looking to help companies develop products for the Chinese market while benefiting from access to U.S. expertise and technologies. Some of the large companies have opened incubators that are collocated with their U.S. R&D facilities, including Qilu Pharmaceutical's Qilu Boston Innovation Center. Although most endeavors are from private companies, the China-U.S. Biotechnology Innovation Center currently being built in Houston, which specializes in IT, biomedicine, and nanotechnology, is a product of the Jiangsu Industrial Technology Research Institute, a major nonprofit research institute founded and supported by the Jiangsu provincial government.

[4] iCarbonX. (2017) iCarbonX Expands Digital Life Alliance to Accelerate Development of Global Health Ecosystem. https://www.businesswire.com/news/home/20170105005285/en/iCarbonX-Expands-Digital-Life-Alliance-Accelerate-Development.

Chinese biopharmaceutical companies looking to develop drugs for the global market also conduct clinical trials in the U.S. For example, Chinese biopharmaceutical leader Innovent has three drug candidates for which they have received IND approval from the FDA (the initial step in starting clinical trials for a drug), all for monoclonal antibody therapeutics. As of yet, though, no such products have successfully advanced to commercialization.

These activities of Chinese biotechnology companies in the U.S. are for the most part spearheaded by private industry (only three percent of investment involved state-owned enterprises) and are seemingly driven by market forces. The Chinese government, whether at the national or provincial level, does not appear to be providing significant incentives specifically for biotech companies to be doing business internationally. Of course, several prominent national plans and industrial policies promote the development of biotechnology as a key industry to the country's growth and economic advancement, including the 13th Five-Year Plan, Made in China 2025, and numerous industry development plans and roadmaps. These policies direct development of China's biotechnology industry—one of nine strategic emerging industries, along with others like clean energy, next generation IT, and high-end equipment manufacturing—to create a strong domestic market but also to be competitive globally. Some of the major national policies identify utilization of foreign capital and markets as a means for doing so but do not provide specific pathways or mechanisms for doing so.

Trends and implications of Chinese investment in the U.S. health, biotech, and pharmaceutical industries

In our report to the Commission, my colleagues and I described a rapidly growing landscape of Chinese investments in the U.S. biotechnology industry. $3.57 billion was spent by Chinese firms (in 144 transactions) on direct investments and venture capital from 2013-2017, with very little investment activity in the 13 years prior ($256 million in 49 transactions). Over this period of rapid growth, the number of transactions increased year over year, as did total investment value for all years but one. In 2018, the health and biotechnology sector (encompassing all of the healthcare sector, including traditional pharmaceuticals) became the top recipient of Chinese capital (foreign direct investment) in the U.S., surpassing more traditional sectors such as real estate and transportation. While overall Chinese investment in the U.S. has faced a tremendous decline recently—from $46 billion across all industries in 2016 to $5 billion in 2018—health and biotechnology has shown to be more resilient than other industries.

The detailed data on Chinese investments in U.S. biotech through 2017 showed a few key points:

1) Almost all Chinese investment in U.S. biotechnology occurred in medically related segments. Seventy percent of total Chinese investment has been in biologics and contract research and manufacturing, reflecting China's stated policy interest in biopharmaceuticals and demand on the healthcare market and mirroring the high level of biologics development activity occurring domestically in China. Another 22 percent was in genomics, molecular diagnostics, and precision medicine.
2) Chinese investment in the U.S. biotech sector is overwhelmingly private—only three percent of the total Chinese investment in biotech since 2000 came from formally state-owned actors. The role of state-owned investors is much smaller in biotech than in overall Chinese investment in the U.S., where an average of 24 percent of investment dollars come from state-owned enterprises.
3) Both acquisitions and venture capital (VC) financing have contributed significantly to the rise in Chinese investment in U.S. biotech, comprising 96 percent of all investment value (67 percent in acquisitions of U.S. companies and 29 percent in VC and other portfolio investment).

Experts in the U.S. biotechnology industry paint a similar picture of recent abundance of Chinese financing, especially VC. Biotech-specific funds were created starting in early 2017 to get in on the biotech investment boom. This is not unique to China, as biotech investments are a new trend globally. Chinese biotech investors have many of the same qualities as U.S.-based venture capitalists. They are interested in the same companies and the same technologies as they follow trends looking for value and

high returns. Like investment firms globally, Chinese biotech investors span a range of sophistication from highly professional to questionable, but there is nothing to indicate that they are on average more or less legitimate than investors in other countries. U.S. investment firms may tend to provide greater biotechnology or drug development expertise than Chinese firms, though; as a result, Chinese investors may provide higher valuations for startups or otherwise offer better deals in an attempt to close the gap.

Chinese venture capital in U.S. biotech has increased overall since 2014, and in the second half of 2018 surpassed the other major industry for Chinese VC, information and communications technology. In the past year, however, Chinese investment in the U.S. has dropped significantly, and biotech has not been spared. According to a report by Bay Bridge Bio, the number of venture rounds led by Chinese investors in the first half of 2019 dropped 83 percent compared to the same period in 2018.[5] These investors provided 40 percent of the venture funding in in the first three quarters of 2018, but that has virtually disappeared in 2019. Fortunately, U.S. investors seem to be picking up the slack in biotech; Series B investment, where the biggest shift has occurred, has been stronger in the first two quarters of 2019 than in any quarter of 2018.

The drop in Chinese investment in the U.S., and in biotech specifically, has largely been credited to the reforms passed last year to the CFIUS review process. Because of CFIUS's expanded review authority for transactions involving critical technologies, many Chinese biotech investors are restructuring their deals or pulling out completely. The president of Fosun Healthcare Holdings, a major Chinese biopharmaceutical investor, said the firm would be limiting its investments in U.S. biotech to avoid such scrutiny. Caution is being exercised on both sides, as U.S. startups are also turning down Chinese money to avoid attracting attention from regulators. Whether or not this was the intended effect, the changes to regulatory review of foreign transactions are causing a major shift in the investment landscape, resulting in uncertainty in the near term. The effects of these changes will need to be monitored closely so that adjustments can be made, if necessary, to ensure U.S. biotech companies don't suffer due to lack of capital.

Risks of Chinese biotechnology activities to U.S. economic and national security

Chinese biotechnology investments and research ventures help to bring technologies and products into the Chinese market, advancing China's stated goals of becoming a global leader in biotechnology. A large focus of Chinese investments is geared toward advancing their capabilities in developing biologics for healthcare. It is still too early to determine how effective these investments have been, as drug development can take a decade or more, but so far, the number of innovative biopharmaceuticals coming from China remains low.

The risks presented by China's increased activities in U.S. biotechnology are largely economic and are associated with increased competition in the marketplace, such as potential loss of market share and transfer of wealth overseas. (Because the R&D in China is largely in therapeutics, and the products being developed are very specific to their purpose, there is little opportunity to subvert these technologies for offensive uses.) Chinese startups in the U.S. take advantage of the research knowledge and innovation pipeline here to try to produce drugs for both the Chinese and U.S. markets. Utilizing U.S. research infrastructure and personnel to develop products that will be marketed and sold abroad or domestically by a foreign company does represent a drain on U.S. R&D capital and a loss of potential return on investment. However, we have no indication that China is doing this more so than other countries, or that they are particularly successful yet. More importantly, the sizeable lead we have—China's biotech market is less than a tenth the size of the U.S.'s—and the superior innovation infrastructure and technological expertise suggest that China will not threaten the U.S. global standing in the near future. In the long-term, a sustained increase in technology investment by the federal government will help to ensure our continued dominance in this field.

[5] Bay Bridge Bio. (2019) Chinese investment in US biopharma startups down over 80% in 2019. https://www.baybridgebio.com/blog/chinese_investment_down_1h2019.html.

Theft of intellectual property by foreign nationals has been a concern in technology fields for many years and will continue to be. Several instances of theft of trade secrets by Chinese researchers and technology employees in the U.S. have been documented, going back decades, although the rate of known such occurrences is very small compared to the number of opportunities. Recently, the National Institutes of Health (NIH) has addressed this issue and has taken steps to ensure disclosure of foreign sources of funding by its researchers. Last year, it began an investigation and has since sent letters to over 60 institutions regarding 180 individuals suspected of violating disclosure rules; 18 of these have been escalated to the Department of Health and Human Services for further investigation. The course of action taken by the NIH is necessary, but also a measured one—no new restrictions have been enacted, the agency is simply improving enforcement of existing rules. Additionally, NIH has increased outreach to its funding recipients to increase their awareness of potential security risks and how to properly mitigate them. This approach serves as a good model for how to monitor and mitigate potential risks from China and other countries without imposing restrictions that may hinder research.

Perhaps the most significant potential risk stemming from China's biotechnology development is their advancement in medical and genetic sequence data collection and analysis. China is prioritizing genetic and healthcare data as a valuable resource, perhaps to a much greater extent than is the U.S.—as evidenced by their $9 billion precision medicine initiative (compared to the $215 million dedicated to the U.S. initiative). China has established national and regional centers focused on big data in health and medicine, including a goal to build a genetic database containing the genomes of one million ethnic Chinese, and use that information to study the relationship between genetics, disease, and the environment. As companies like BGI and others continue to form research partnerships in the U.S., the size and diversity of available data grows. Such data, when combined with advanced analytical technologies including AI, can be used to identify new determinants of disease to be targeted for development of drugs or molecular diagnostics or to guide or precision medicine.

China's activity in genomics has raised some serious human rights issues with regard to surveillance of people, especially ethnically driven surveillance. Last February, it was reported that the Chinese region of Xinjiang, with a large population of the Uighur ethnic group, collected DNA samples and biometric data from 36 million people through a program billed as providing physicals to residents. The Chinese police used DNA sequencing machines purchased from U.S.-based Thermo Fisher Scientific for this program (the company has since said they will no longer sell sequencers in Xinjiang). Additionally, studies investigating genetic markers for ethnic populations and genetic determinants of ethnicity-specific facial features (to aid in AI-based facial recognition) have been published by Chinese research groups. Given the history of surveillance and mistreatment of the Uighur population by the Chinese government, these uses of genetic data cause grave concern, not necessarily specific to the U.S., but certainly for human rights around the world.

U.S. competition from China is also a major risk in the field of genomics. The investments China is pouring into genomics and AI could provide opportunities for Chinese companies to make significant advances in medical biotechnology including biologics and diagnostics. We are still at the dawn of the machine learning and artificial intelligence age, with the most transformative discoveries likely yet to come. Large healthcare data sets are likely to drive new discoveries and cures. Today, the U.S. appears to undervalue healthcare data when compared to the major efforts underway in China and by Chinese firms—not only in analyzing these data sets but also building and gathering them. Still, the U.S. maintains a lead in science and technology activity and holds a strong, if not leading position in machine learning and AI. Given these advantages, the U.S. appears well-positioned to compete for the lead in future innovation in healthcare data analytics should it choose to prioritize it.

Sourcing vulnerabilities for the U.S. vis-à-vis Chinese medical and biotech companies

Many reports have documented the large extent to which China supplies generic drugs and active pharmaceutical ingredients for the U.S. I will not speak to this issue here, as the research my colleagues and I have performed did not cover traditional (small molecule) pharmaceuticals, and others testifying before you will have more insight into the topic. I would, however, like to draw a contrast to the issue of supply chain vulnerabilities as it relates to biopharmaceuticals. In the traditional pharmaceutical market,

the chemical entities that are the active ingredients in drugs can be synthesized through relatively simple processes, and generic versions of drugs can be inexpensively produced and quickly marketed. Biopharmaceuticals, on the other hand, are highly complex large molecules produced by engineered cells or organisms. Because of this, generic versions of biologics do not exist—companies wishing to duplicate successful biopharmaceutical products will need to re-engineer cell systems to produce a highly similar, though not identical, biosimilar drug. Such an endeavor requires more advanced technology and comes at a higher cost than production of generic drugs. Furthermore, although biosimilars do enjoy an abbreviated regulatory approval pathway in the U.S., it is more extensive than the approval of generics, as companies need to demonstrate that their imitator molecule is biologically equivalent to the existing drug.

The difficulties in developing biosimilars provide a significant barrier that limit China's ability to produce low-cost drug alternatives as they have done for traditional pharmaceuticals. Although China's biologics industry focuses heavily on biosimilars, it is too nascent to yet have produced significant results. Currently, no biosimilars from China are approved in the U.S., and only a handful are marketed in China. As I mentioned earlier in my testimony, China also has yet to become a significant source of novel biologics in the U.S. It is possible that China is (or could become) a significant source of critical biotechnology ingredients (e.g., media, nucleotides, enzymes, etc.), but I have not examined this aspect of the biotechnology market.

Another major segment of China's biotech sector is its large CRO industry. CROs are an integral part of the global biopharmaceutical industry, but it is unclear how much of the U.S. biotech industry is dependent on Chinese CROs. Regardless, the U.S. CRO industry is still the world's largest, and U.S. firms would likely be able to fill the gap if the Chinese market were to decline or otherwise be obstructed.

U.S. ability to address risks posed by China's biotech development

The reforms to CFIUS review authority brought about by the passage of the Foreign Investment Risk Review Modernization Act last year are a significant step in broadening the U.S.'s power to monitor and regulate biotechnology investments from China and other foreign countries. By expanding the types of covered transactions involving critical technologies (as yet to be defined but potentially including biotechnology) and personal information, The U.S. has a greater ability to address potential threats from China through such investments. The expanded authority still does not allow scrutiny of venture financing with foreign limited partners, however, so these types of investments can still go unmonitored. The risk from such investors is low, though, given the low level of control they typically have.

Protection of dual-use biotechnology in the U.S. through export control has been traditionally focused on materials such as equipment (e.g., fermenters) and specific biological agents, and is ill-equipped to deal with the changing nature of biotechnology threats. Acquisition of intellectual property, not physical property, has become the greater threat when it comes to dual-use biotechnology, and the export control laws of the U.S. are only now beginning to catch up. The Export Control Reform Act, passed as part of the National Defense Authorization Act for fiscal year 2019, adds foundational and emerging technologies to the commerce control list, which may include biotechnology, including synthetic biology, genomics, and genetic engineering. Although this change potentially allows the U.S. to control a much broader set of technologies, the broad and undefined nature of foundational and emerging technologies opens a risk of casting too broad of a net and overburdening and hindering legitimate research with limited utility in deliberately harming U.S. national security (e.g., genome editing, which was listed as a weapon of mass destruction in 2016 by the Director of National Intelligence). The Department of Commerce's Bureau of Industrial Security is undergoing a process to define the terms, and the outcomes of this effort could have a significant effect on biotechnology research in the U.S. As this process unfolds, any technology of concern should undergo a detailed risk assessment to understand current and near future capabilities, comparative advantages to existing technologies, indications of convergence with other fields, and level of maturity. Furthermore, technologies with little or no credible risk to national security or which embargoed countries could easily acquire or develop through other means should not be subject to export control.

One industry segment in which the U.S. is seeing strong competition from China is genomics and related fields (including molecular diagnostics and precision medicine). The large data sets of medical and genomic information that Chinese companies are developing, in part through investments and research collaborations in the U.S., are fueling advances in this area. Currently, protections the U.S. places on such data are minimal, and an imbalance in data sharing between the U.S. and China exists. Chinese law prohibits any personal information generated within its borders from being transmitted or stored overseas, and specifically includes genetic and population health data in this restriction. The U.S. has no similar regulations controlling foreign access to personal data—the primary law protecting health data in the U.S., the Health Insurance Portability and Accountability Act, is designed to ensure patient privacy but not protect the data itself. Given the growing importance and value of personal data in not only biotechnology but many other industries, careful control of who has access to data generated in the U.S. is crucial to ensure the economic and societal benefits stemming from the use of such data are secured. Therefore, **Congress needs to enact comprehensive data protection laws that delineate acceptable use of and access to personal data while protecting individuals' rights and privacy.** A strict prohibition on data export may not be necessary; the General Data Protection Regulation, which went into effect last year in the European Union, strikes an appropriate balance and could serve as a model framework for such a law.

Additional recommendations for Congress

As China's biotechnology industry grows, so does its standing as a competitor to the U.S. Currently, Chinese biopharmaceuticals lag behind the U.S. significantly, although their genetic technology companies are becoming world leaders. In addition to their market lead, the U.S. has a superior innovation infrastructure through its top research universities and institutes and federal support for technology transfer. However, to ensure the U.S. maintains its standing and does not forfeit economic opportunities to China, **Congress must increase and sustain federal funding for basic and applied research across the sciences.** In constant-dollar terms, total life science R&D obligations peaked in 2010 and declined 18 percent by 2015.[6] The trend in all life science subcategories, as well as across all science and engineering fields (e.g., physical sciences, engineering, social sciences, life sciences, etc.), is similar. Fortunately, R&D spending is trending upward again, and the budget for the NIH has increased by approximately $2 billion in each of the last four years. Still, given the continuing expansion of the U.S. biotech industry, U.S. researchers may turn to China to fund their work if domestic funding is in short supply. In addition, a shortage of federal R&D funding could open a window for other nations, including China, to compete with the U.S. Given China's continued trend in increased R&D spending and the growth of their biotech industry, China appears to be attempting to capitalize.

At a speech before the American Association for the Advancement of Science in February, White House Office of Science and Technology Policy director Kelvin Droegemeier made an argument for greater private funding of science and technology research. Although private investment is welcome and indeed necessary, the federal government plays a critical role in supporting such endeavors, especially in basic research where a return on investment is too far removed and too uncertain for industry to gamble on. In biotechnology and medicine, some of the most groundbreaking discoveries have come from such studies; the rapid gene-editing technology known as CRISPR came from a basic study of bacterial defense mechanisms. Ensuring sustained federal funding for science and technology research will help drive the U.S. innovation engine and lead to continued economic prosperity.

To support federal investment in science and technology, and specifically biotechnology, a clear understanding of the contributions of the industry to the greater economy is needed. The U.S. developed a National Bioeconomy Blueprint in 2012 which outlined strategic goals for growing the U.S. biotechnology industry, but it is far out of date compared to current technology trends and failed to foresee risks to U.S. competitiveness that are now arising. **Congress should call for an update to the National Bioeconomy Blueprint to provide a strategic framework by which the U.S. could ensure**

[6] National Science Board. (2018) Science and Engineering Indicators. https://www.nsf.gov/statistics/2018/nsb20181/. [Figure 4-9; Appendix Table 4-24].

the vitality and competitiveness of its biotechnology industry in the face of a dramatically changing global industry landscape.

The National Academies of Sciences, Engineering, and Medicine, through the ongoing Safeguarding the Bioeconomy project, is laying much of the groundwork that could be utilized in an effort to revive this strategy. Building off of this effort (which will be completed later this year), a refresh of the Blueprint would underscore the importance of the biotechnology industry to the greater U.S. economy and illustrate how the federal government can support its future growth. In order to provide clear guidance, the Blueprint should include an assessment of U.S. dependence on foreign industries, including recognition of rising players on the world stage, such as China, and an analysis of the health and stability of the U.S. biotechnology sector, including identifying which segments are strong, which are vulnerable to foreign competition, and which may be key to future growth of the sector. A National Bioeconomy Blueprint containing these pieces can serve as a guiding document to support implementation of specific mitigations against foreign interference in the biotechnology industry. Given the effects on Chinese investment already seen as a result of new review authorities through CFIUS, a carefully measured approach guided by rigorous assessments such as these is needed as the U.S. moves toward greater oversight of foreign interactions.