



October 17, 2019

Mr. Thomas Feddo  
Assistant Secretary for Investment Security  
U.S. Department of the Treasury  
1500 Pennsylvania Avenue, NW  
Washington, DC 20220

Submitted electronically *via* <https://www.regulations.gov>.

Re: Biotechnology Innovation Organization Comments on the Department of Treasury Proposed Rule Regarding Certain Investments in the United States by Foreign Persons (RIN 1505-AC64)

Dear Mr. Feddo,

The Biotechnology Innovation Organization ("BIO") thanks the Department of the Treasury ("Treasury") for the opportunity to submit comments regarding the proposed rule, "Provisions Pertaining to Certain Investments in the United States by Foreign Persons," 31 CFR Part 800. BIO fully supports the mission of the Committee on Foreign Investment in the United States ("CFIUS" or "the Committee") to protect our national security. While acknowledging the clear effort undertaken by the Committee to craft regulations that balance national security interests with the continuing need for direct foreign investment, BIO believes that the proposed rules, along with CFIUS's Critical Technology Pilot Program announced in October 2018, inadvertently miss the mark by unnecessarily expanding the scope of transactions subject to review by CFIUS in a manner which has the potential to inhibit investment in, and damage the vitality of, the U.S. biotechnology industry.

BIO is the world's largest trade organization in the biotechnology sector, representing over 1,000 biotechnology companies, academic institutions, investment firms, state biotechnology centers, and related organizations across the United States. BIO member companies vary in size, technologies, manufacturing capacity, and product range, but they, along with our member institutions, are all

highly innovative, heavily invested in research and development, and require significant amounts of domestic and, importantly, foreign investment. More than 90% of drug candidates fail to advance to FDA approval,<sup>1</sup> which makes early-stage biotechs uniquely dependent on investment capital (as opposed to traditional sources of capital such as banks and the public capital markets).

A strong U.S. biotechnology industry is an important factor in the national and economic security, health, and welfare of this nation. In fulfilling its vital role in protecting national security, the U.S. biotechnology industry is now actively developing products with significant national security benefits, including vaccines, therapeutics, diagnostics, rapid response systems and decontamination enzymes, all of which are aimed at neutralizing the agents of chemical, biological, radiological and nuclear ("CBRN") warfare or addressing other serious public health emergencies. As evidenced by BIO's long-standing policy of opposing the use of biotechnology to develop weapons of any sort that contain pathogens or toxins aimed at killing or injuring humans, crops or livestock, BIO members are committed to ensuring appropriate uses of biotechnology, which include products and services to inoculate citizens against infectious agents that may be used in an attack, to detect CBRN attacks, and to diagnose and treat those who may have been exposed in such an attack. Keeping biotechnology companies in the United States, while providing a pathway for approved foreign investment through appropriately tailored regulations, is a crucial piece to maintain the long-term strength of both the U.S. biotechnology sector and our national security.

The biotechnology industry is critical for the nation's economic health as well. More than 1.7 million Americans are employed in the biosciences across the United States, and the industry is growing jobs at a rate that is double the national average. More than 13.3 million farmers around the world use agricultural biotechnology to increase yields and prevent crop damage from pests. More than 50 biorefineries are being built across North America to test and refine technologies to produce biofuels and other biobased products.<sup>2</sup>

The promise of the biotechnology industry to improve lives is unparalleled. The industry is still in many ways in its infancy, but in just four decades, the scientists, researchers, and entrepreneurs working in the industry have revolutionized modern medicine. Hepatitis C, a once incurable disease, now has cure rates above 90%. HIV/AIDS is no longer fatal and is now considered a chronic manageable condition. The cancer death rate has fallen by 20% since its peak in 1991 and 83% of children with cancer survive, compared to 58% in 1970. And

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<sup>1</sup> Biotechnology Innovation Organization, "Clinical Development Success Rates 2006-2015," available at <https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf>.

<sup>2</sup> Biotechnology Innovation Organization Issue Brief: "What is Biotechnology?" available at [https://www.bio.org/sites/default/files/DGP\\_1.pdf](https://www.bio.org/sites/default/files/DGP_1.pdf)

more than 730,000 children's lives in the United States over the last 20 years have been saved because of advances in vaccines.<sup>3</sup> Notably, the United States is responsible for the creation of nearly 60% of the world's new medicines, more than the rest of the world combined.

Placing *unnecessary* burdens on the industry puts all that success and hope at risk without any additional increase in national security. To ensure that continued innovation in the biotechnology sector leads to the next generation of biotechnology breakthroughs that will contribute to national security and help heal, feed, and fuel the world, it is imperative that the finalized CFIUS regulations are specifically tailored in a manner that continues to fuel private investment, and encourage the entrepreneurial spirit that has made America the leader in this cutting-edge field.

In particular, BIO is concerned about the breadth of the definition of "sensitive personal data" as it applies to both "genetic information" and "identifiable data." BIO believes that the definition of genetic information is unnecessarily broad to address specific national security concerns. In addition, although the proposed rules apply a number of limiting criteria to the definition of "identifiable data," many of these criteria are subjective and ambiguous. As a result, BIO believes the proposed rules have the potential to adversely affect the U.S. biotechnology industry far beyond what is necessary to address legitimate national security concerns. This is especially true as investments in U.S. biotechnology companies in many cases are already structured, and legally obligated, to prevent an investor from gaining any special access to sensitive personal data.

## **I. Use of Genetic Data in the Biotechnology Industry**

Genetic data is essential to the development of more targeted and effective treatments that address the underlying cause of a disease. Genetic data may be collected along with other health information for multiple purposes, including helping identify new pathways/targets involved in disease, determining the risk of adverse drug effects, and identifying patient populations for whom the treatment may be most effective. Genetic data is also essential in disease diagnosis for many diseases. For example, a clinical trial evaluating a drug to treat a rare disease caused by a specific genetic mutation may collect genetic information from patients to ensure that the patients have the specific genetic mutation prior to enrolling them in the clinical trial. Drug developers may collect genetic information from patients with a particular disease with an unknown cause in order to determine if a gene mutation causes the disease and can, in turn, be targeted with a potential treatment.

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<sup>3</sup> Biotechnology Innovation Organization Issue Brief: "Innovation Saves", available at <https://www.bio.org/sites/default/files/docs/toolkit/IGP14.pdf>

Accordingly, a significant number of early drug discovery projects as well as clinical trials collect limited genetic data. This data is typically coded (with no direct identifiers), and subsequently de-identified (stripped of personal identifiers so the genomic information cannot be associated with a specific individual) prior to research uses. Further, the limited genetic data collected (e.g. fragments of DNA) for a given project will vary by biological pathway or focus of the technical study or target. Additionally, many research projects and clinical trials collect genetic information from large heterogeneous populations that cannot later be associated with smaller specific subgroups within the United States. As a result, this information is neither identifiable to a specific person, nor does it provide sufficiently specific genetic data to identify a narrow population.

In addition, our increasing understanding of human genetics is expected to become a critical component in improving population health with positive implications for healthcare systems. As such, CFIUS should carefully consider how to ensure that its rules will not impede the ability of the industry within the United States to maintain its competitiveness. Without properly tailoring CFIUS review to the national security risks, the Committee is putting all of these advances in jeopardy.

## **II. CFIUS Reviews Should Remain Focused Exclusively on National Security to Avoid Undue Harm to the Biotechnology Industry**

The expansive CFIUS rules regarding genetic information– as described in specific detail in Section III – will impose significant burdens on the U.S. biotechnology industry and threaten to reduce a critical source of capital, the lifeblood of young biotechnology companies. In addition, they also run the risk of forcing changes to the industry that could have lasting implications for the development of breakthrough medicines and cures for the U.S. market, while benefiting the development of foreign biotechnology industries.

While protecting the United States and its citizens from malevolent foreign interests is certainly of paramount concern, doing so in a manner that doesn't stifle the robust U.S. biotechnology industry and its role in protecting national security and its promise of combating debilitating and rare diseases, reducing our environmental footprint, feeding the hungry, using less and cleaner energy, and providing safer, cleaner, and more efficient industrial manufacturing processes should be balanced in any governmental actions.

### **a. Decline in Investment in U.S. Biotechnology Industry**

The biotechnology industry is unique compared to other industries in that a biotechnology company operates, on average, for 10 to 15 years before generating product revenue. Throughout this time, the company remains entirely unprofitable

as resources are largely directed toward R&D. The U.S. relies on small biotechnology companies for innovation – nearly 70% of innovative clinical programs are being led by small companies. Small to mid-cap U.S. biotechnology companies in turn rely heavily on domestic and foreign capital to fund their extensive research and development operations. Without adequate capital, the U.S. biotechnology industry will thus be in danger of stagnating. In recent years, foreign investors have become an increasingly critical source of funds for the industry. When finalizing the regulations, it is crucial to avoid an approach that may dampen foreign investment in the U.S. biotechnology industry with no commensurate increase in national security protections.

Venture investment into U.S. biotechnology companies in 2018 totaled more than \$12 billion.<sup>4</sup> Between Q1-Q3 2018 and Q1-Q3 2019, however, our analysis of the BioCentury BCIQ data shows venture investment into U.S. biotechnology companies declined 20% in dollar terms and the number of deals declined by 27%. While the decrease in venture funding in the U.S. biotechnology industry may not entirely be a result of the recent expansion of CFIUS’s jurisdiction under FIRRMA, VC funding of the European biotech industry has increased by 23% in dollar terms over the same period. Whatever the precise magnitude of the decrease attributable to expanded CFIUS jurisdiction, we believe the Pilot Program and the proposed part 800 regulations are injecting greater uncertainty and risk for foreign investors in an already extraordinarily risky industry.

Given the potential delays and cost that CFIUS review adds to investments by foreign investors, these proposed regulations may further discourage investment in the U.S. biotechnology industry. Further, by reducing the pool of foreign investors, U.S. biotech entrepreneurs will have fewer options to command favorable terms from other early-stage investors.

#### **b. Benefit to Other Countries’ Biotechnology Industries at the Expense of the U.S. Industry**

An overly-broad CFIUS review regime can also hurt the U.S. biotechnology industry by causing investors and biotechnology companies alike to focus on other markets, potentially including countries of special concern.

First, an overly-broad regime may cause investors to look for biotech investments in other countries. Investors in the biotechnology industry tend to be very specialized and focus on biotechnology specifically. Thus, when faced with

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<sup>4</sup> BIO 2019 Emerging Therapeutic Company Trend Report, *available at* <http://go.bio.org/rs/490-EHZ-999/images/BIO%202019%20Emerging%20Company%20Trend%20Report.pdf>

potential CFIUS impediments, rather than look for other U.S.-based investments, they are more likely to look for biotech investments in other countries. Accordingly, the U.S. biotechnology industry may suffer the double blow of reduced investment in the U.S. industry and greater growth in foreign biotechnology industries.

In addition, biotechnology companies themselves may face an incentive to shift their research and clinical trial operations overseas to avoid collecting genetic information from U.S. citizens that puts the company under CFIUS's ambit. There are several factors, such as costs, that already encourage companies to conduct clinical trials outside the United States. This rule would further discourage U.S. trials and thus could result in U.S. patients unable to take part in as many clinical trials for lifesaving therapies.

Alternatively, biotechnology companies could seek to re-domicile overseas (to avoid being deemed a U.S. business) and run U.S. clinical trials from abroad. Countries welcoming U.S. biotechnology R&D and clinical trials could potentially include the very countries of special concern to CFIUS.

Creating incentives to move important biotechnology operations overseas could also contribute to a weakening of the U.S. biotechnology infrastructure, which, over time, would translate into a weakening of the industry overall.

BIO understands that CFIUS's expanded authority under FIRRMA and its implementing rules are a response to real and serious national security concerns, and BIO supports CFIUS's efforts to address them. This decline in investment and the weakening of the biotechnology infrastructure, however, would have real and lasting consequences for the health, economy, and national security of the United States. A declining U.S. biotechnology industry not only leaves the nation more vulnerable to foreign economic competition and national security threats, it directly contributes to the growth of foreign biotechnology industries, including potentially in countries of particular concern. These public harms must be balanced against the specific and concrete threats identified by CFIUS.

Accordingly, BIO offers the following comments on the proposed regulations to mitigate any unnecessary chilling effects on and disruption to a critical U.S. industry.

### **III. The Definition of "Sensitive Personal Data" Should Be Narrowly Tailored to Actual National Security Risks**

#### **a. Sensitive Personal Data in Proposed Regulations**

The proposed rules describe two types of sensitive personal data. The first type is "identifiable data" maintained or collected by a U.S. business that targets or tailors its products or services to sensitive U.S. government personnel or contractors, or has collected or maintained data on greater than one million

individuals in the past 12 months (or intends to collect or maintain such data). Identifiable data includes ten categories of data, including data relating to the physical, mental, or psychological health condition of an individual. While BIO appreciates the effort to impose limitations on this definition, we have concerns about the vagueness of such limitations, as discussed further below.

The second type of sensitive personal data is “genetic information” as defined under the HIPAA regulations at 45 CFR 160.103.<sup>5</sup> Unlike identifiable data, the definition of genetic information does not include any gating limiters. Pursuant to the HIPAA regulations, the definition of genetic information covers data relating to “an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes.” This HIPAA definition of genetic information is intentionally broad because it is only applied in a narrow and clearly defined context: to prevent individual discrimination in the health insurance marketplace to ensure the integrity, confidentiality, and availability of protected health information.

Unlike the intentionally broad HIPAA definition, any definition of sensitive personal data used by CFIUS, including the definition of genetic information, must be narrowly tailored to address only data that could be exploited in a manner that threatens national security. The Committee specifically acknowledges in its discussion of the proposed rules that Section 1703 of FIRRMA authorizes CFIUS to review non-controlling investments in U.S. businesses that collect or maintain sensitive personal data of U.S. citizens only if such data could be “exploited in a manner that threatens national security.” As described in greater detail above, genetic data is widely collected in the biotechnology industry, much of which poses no national security concerns. As drafted, however, the proposed rules would capture virtually all genetic data by employing an overly-broad definition of “genetic information.” By using a definition of genetic information designed for an unrelated purpose, the proposed regulations would exceed Congress’s mandate that CFIUS “remain[] focused exclusively on national security”<sup>6</sup> and would do so in a manner that disproportionately harms the U.S. biotechnology industry. Such harm to the biotechnology industry can only be justified if it is tethered to a clear and significant corresponding national security benefit.

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<sup>5</sup> Under 45 CFR 160.103, genetic information includes information about (i) an individual’s genetic tests; (ii) the genetic tests of family members of an individual; (iii) the manifestation of a disease or disorder in family members of an individual; or (iv) any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by an individual or any family member of the individual. “Genetic tests” include any “analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes.” “Genetic services” include genetic tests, genetic counseling, and genetic education.

<sup>6</sup> U.S. Department of the Treasury, “FIRRMA FAQs,” *available at* <https://www.treasury.gov/resource-center/international/Documents/FIRRMA-FAQs.pdf>.

## **b. Balance Burden on Industry with Specific National Security Risks**

As described above, the biotechnology industry is a vital part of U.S. national security protections, the U.S. economy in terms of growth and other economic measures, and its contribution to the health and well-being of its citizens. Accordingly, perceived national security risks should be balanced against the actual risks of undermining an essential U.S. strategic industry. BIO presents below examples of conditions under which the use of genetic information in the biotechnology industry poses limited risks. In order for the biotechnology industry to understand the rationale for the final regulations, BIO submits that where CFIUS chooses not to adopt our suggested limitations on the definition of genetic information, it should clearly outline the national security risks posed by each of these conditions. In addition, if risks are posed only when multiple conditions are present, CFIUS should so explain and limit its definition only to those situations.

BIO submits that de-identified or coded (pseudonymized) genetic data or aggregated genetic data (grouped information, without patient level detail) in particular presents limited national security risks. As described above, the proposed adoption of the HIPAA definition of "genetic information" captures a significant amount of research and clinical trial data that is too limited to be used to identify a specific individual. Accordingly, BIO believes that de-identified/coded genetic data (i.e., data that is stripped of personal identifiers and does not possess enough unique characteristics to be traced back to an individual or subgroup), such as fragments of DNA (partial DNA), should be excluded from the definition of "genetic information." Even as applied in the HIPAA context, genetic information that has been de-identified is not considered "individually identifiable health information" nor "protected health information" under HIPAA.<sup>7</sup> Similarly here, CFIUS should not treat de-identified/coded or aggregated genetic information that cannot be traced back to an individual by the company holding the data as "sensitive personal data." To the extent that CFIUS identifies specific types of genetic information that present a risk even if not traceable to specific individuals, it should clearly identify the types of data and the specific risks.

This limited risk from aggregated data is true even of large data sets. As described above, the proposed definition of genetic information covers a vast range of genetic data that cannot be used to develop insights or target a specific subpopulation in any meaningful fashion. BIO submits that the definition of genetic information should be narrowed to include only genetic data that presents

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<sup>7</sup> See 45 CFR 164.514. Under HIPAA, a covered entity may determine that health information is not "individually identifiable information" if either (1) a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable determines that the risk is very small that the information could be used to identify an individual who is a subject of the information, or (2) certain specifically enumerated individual identifiers are removed from the data.



legitimate national security risks based on scientific understanding. This means evidence-based risks developed in consultation with stakeholders and scientific agencies such as the National Institutes of Health (NIH) and others. BIO stands ready and willing to assist further in this effort. Moreover, as CFIUS recognizes in its discussion of the proposed rules, CFIUS can revisit and revise these definitions if needed to account for technological developments and the evolving use of data in the future.

In addition, given the diverse U.S. population, there are few, if any, unique genetic characteristics of U.S. citizens that cannot be represented in data sets of non-U.S. citizen data. Except in very limited cases, bad actors would be able to gather similar data on patient populations using foreign clinical trials. Accordingly, the definition of genetic information should be limited to situations where there is a unique risk from the collection of specifically U.S. citizen data that cannot be obtained from foreign sources.

Finally, CFIUS should consider that many investments in U.S. biotechnology companies – both foreign and domestic – are already structured so as not to afford the investor any special access rights to genetic information or other sensitive personal data that the company may collect or maintain on behalf of U.S. citizens. Indeed, U.S. biotechnology companies are legally obligated to comply with HIPAA and other applicable privacy laws and also have practical economic incentives to protect and limit the disclosure of genetic information and other sensitive personal data. Such safeguards include, for example, storing sensitive personal data on access-controlled servers and otherwise limiting access on a need-to-know basis, employing third parties to de-identify data prior to using the data for R&D purposes, and conducting risk-based assessments prior to sharing any such data to ensure that it cannot be used to re-identify any specific individuals.

Accordingly, BIO also urges CFIUS to follow the letter of FIRRMA and exclude from the definition of “covered investment” any investments in companies that collect or maintain sensitive personal data if the data could not be “exploited in a manner that threatens national security.” For example, transactions in which a foreign person is not afforded access to a U.S. business’s sensitive personal data and the U.S. business has a demonstrated program of compliance with HIPAA and other applicable privacy laws are far less likely to present any national security risks.

For these reasons, BIO respectfully requests that CFIUS provide the following exceptions for genetic information in 31 C.F.R. § 800.241:

1. Genetic information that is collected or obtained as part of drug discovery or clinical trials shall not be deemed to be sensitive personal data where that genetic information is (i) anonymized, aggregated, or de-identified; and (ii) the U.S. business has implemented physical and/or virtual safeguards to handle the data in compliance with HIPAA requirements.

2. Genetic information from large heterogeneous sections of the population that cannot be associated with a particular individual or a specific subgroup of U.S. citizens shall not be deemed to be sensitive personal data.

As explained in greater detail above, clinical trial data is critical to the biotechnology industry and ultimately benefits patients through the introduction of new and better medicines, effective diagnosis of diseases, and development of targeted treatment programs. Implementing these tailored exceptions for genetic information will help the United States ensure a robust and vibrant U.S. biotechnology industry capable of developing the vaccines, drugs, and therapeutics needed for the health and welfare of our people, while simultaneously protecting sensitive genetic information of individuals.

### **c. The Scope of Sensitive Personal Data Should Be Narrowed and Clarified as Applied to Identifiable Data**

As noted above, sensitive personal data under the proposed regulations also includes "identifiable data" (such as health information), as long as certain criteria are met. While BIO appreciates the Committee's explanation that aggregated and anonymized data are generally not intended to be treated as identifiable data under the proposed rules, the limiting criteria are subjective and ambiguous in a number of ways that could render the definition overly broad. For example, the proposed regulations provide that identifiable data could be treated as sensitive personal data to the extent that the U.S. business "[h]as a demonstrated business objective to maintain or collect such data on greater than one million individuals." However, the proposed rule provides no guidance or clarification regarding the particular facts and circumstances that would evidence a "demonstrated business objective." The resulting lack of clarity will make it extremely difficult for companies to understand whether they are covered by the new rules and in some cases could even lead to the odd result of CFIUS jurisdiction hinging on the subjective intent or ambition of a particular company's founders.

Many of the criteria pertaining to aggregated and anonymized data are similarly ambiguous and unclear. The proposed rules provide that "aggregated data or anonymized data is identifiable data if any party to the transaction has, or as a result of the transaction will have, the ability to disaggregate or de-anonymize the data, or if the data is otherwise capable of being used to distinguish or trace an individual's identity." In practice, as long as a U.S. business has effectively implemented measures to aggregate and anonymize its data (such as through compliance with the objective HIPAA standards discussed above), the U.S. business is likely to have little more than speculative insight into whether a foreign investor has or will have the ability to disaggregate or de-anonymize the data as a result of the transaction or whether the data is "otherwise capable of being used to

distinguish or trace an individual's identity." Accordingly, the definition of identifiable data should exclude data that the U.S. business itself does not have the capability to disaggregate or de-anonymize, without requiring speculation into the capabilities of the foreign investor.

#### **IV. Provisions Governing Excepted Foreign Investors and Excepted Foreign States Must Be Implemented Immediately to Reduce the Chilling Effect on Foreign Investment in U.S. Biotechnology Companies**

As the Committee recognizes in its discussion of the proposed rules, FIRRMA directed CFIUS to limit the application of its expanded jurisdiction to certain categories of foreign persons. Accordingly, the proposed rules exclude from the definition of "covered investment" investments made by "excepted investors" with close ties to "excepted foreign states." BIO appreciates Treasury's clarification during its September 27, 2019 teleconference briefing that an initial list of excepted foreign states will be published together with the final rules. Non-controlling investments involving foreign investors with close ties to U.S.-allied countries that have a demonstrated history of partnering with the United States on matters relating to investment security are far less likely to pose a national security threat. The immediate implementation of these provisions upon publication of the final rule will help to mitigate the negative impact that the new regulations are expected to have on the U.S. biotechnology industry, which, as noted above, is uniquely dependent on investment capital due to the high-risk nature of its business.

#### **V. CFIUS Should Eliminate the Mandatory Filing Requirement Under CFIUS's Critical Technology Pilot Program**

The Committee notes in its discussion of the proposed rules that it is still considering whether to maintain the mandatory filing requirement for covered transactions involving critical technology in the context of CFIUS's Critical Technology Pilot Program. While BIO recognizes that FIRRMA expanded CFIUS's jurisdiction to cover certain non-controlling investments in U.S. critical technology companies, the statute does not require CFIUS to impose a mandatory filing requirement with respect to such transactions. As BIO explained in its November 9, 2018 comments on the Pilot Program interim final rule, this mandatory filing requirement presents unique challenges to the U.S. biotechnology industry. For example, many biotech investments are made through syndicates composed of both U.S. and foreign investors that involve multiple closings, as well as a variety of other investment structures that do not fit neatly within the definitions of the Pilot Program. Transactions involving multiple closings over the course of several years may also be affected by the open-ended nature of the Commerce Department's identification of "emerging and foundational technologies," which will be treated as "critical technologies" for CFIUS purposes. The resulting uncertainty and lack of clarity render the mandatory filing requirement and corresponding penalty provision

of the Pilot Program particularly ill-suited to investments in the U.S. biotechnology industry.

Moreover, as with traditional covered control transactions as well as the new covered investments in critical infrastructure and sensitive personal data businesses under FIRRMA, parties to such transactions will continue to have a strong incentive to voluntarily file with CFIUS to take advantage of the safe harbor provision and avoid a potential future divestiture. Accordingly, BIO respectfully requests that CFIUS eliminate the mandatory filing requirement under CFIUS's Critical Technology Pilot Program and allow parties to such transactions to file with CFIUS on a voluntary basis. BIO understands that the parties to a covered transaction will remain obligated to file with CFIUS to the extent that the transaction would result in the acquisition of a substantial interest in a critical technology company or other Technology, Infrastructure, and Data ("TID") U.S. Business by a foreign person in which a foreign government has a substantial interest.

BIO appreciates this opportunity to submit comments regarding the proposed rules and would be pleased to provide further input or clarification of these comments, as needed. Thank you for your consideration of BIO's views and recommendations.

Sincerely,



Tom DiLenge

President, Advocacy, Law & Public Policy