Biotechnology Innovation Organization

November 9, 2018

Mr. Thomas Feddo
Deputy 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 Interim Department of Treasury Rule Regarding Temporary Provisions Pertaining to a Pilot Program to Review Certain Transactions Involving Foreign Persons and Critical Technologies

Dear Mr. Feddo,

The Biotechnology Innovation Organization ("BIO") thanks the Department of the Treasury ("Department") for the opportunity to submit comments regarding the Department's interim rule, "Determination and Temporary Provisions Pertaining to a Pilot Program to Review Certain Transactions Involving Foreign Persons and Critical Technologies," 31 C.F.R. Part 801 (the "Pilot Program"). The Pilot Program, together with the Foreign Investment Risk Review Modernization Act of 2018 ("FIRRMA"), expands the scope of transactions subject to review by the Committee on Foreign Investment in the United States ("CFIUS") and requires mandatory declarations to CFIUS for certain transactions.

BIO is the world's largest trade organization in the biotechnology sector, representing over 1,000 biotechnology companies, academic institutions, 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 in the biotech industry fail at some point during the pre-clinical phase or during clinical trials[1], which, given these risks, makes early-stage biotechs uniquely dependent on investment capital (as opposed to traditional sources of capital such as banks and the public capital markets). So far in 2018 alone, private and institutional

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

foreign investors contributed nearly $10 billion into the U.S. biotech ecosystem[2], which underscores the significance of this interim rule to the sector and the importance of such foreign investment to maintaining the United States' global leadership and comparative economic advantage in biotech innovation.

BIO fully supports CFIUS's important role in ensuring appropriate national security screening of certain foreign investments. BIO likewise supports the modernization of CFIUS through FIRRMA and seeks to work with the Department to ensure that CFIUS continues to fulfill its mission in assessing certain transactions involving foreign entities for national security considerations, while maintaining a robust investment climate. To that end, the Pilot Program will have a significant impact on BIO members due to the high-risk, investment-intensive, and lengthy nature of the research and development periods that underpin scientific advancement. BIO believes that the Department should issue additional guidance during the Pilot Program implementation period to provide parties to transactions in the biotechnology sector and beyond with regulatory certainty and predictability, which are essential to promote continued investment in innovation.

As it stands now, however, the Pilot Program has created considerable concern and uncertainty that risk significantly disrupting such investment. We urge the Department to work with BIO and other stakeholders to provide clarity on the many questions that have arisen and will likely continue to arise during the course of the Pilot Program.

With these concerns in mind, BIO respectfully submits the following comments for consideration by the Department in the implementation of the Pilot Program.

1. BIO requests that the Department clarify the meaning of "promptly" as it is used in Section 801.404(a). The predictability of the CFIUS process is crucially important to U.S. businesses and their investors. Delays in the CFIUS review process can frustrate the execution of transactions and even hinder the influx of investment that U.S. biotechnology companies need to continue advancing their research and development. Most investments into such companies, for example, are made not by individual investors in binary transactions alone, but rather through syndicates composed of both U.S. and foreign investors working together through multiple closings. Such transaction structures require certainty about the timing of their execution so that the U.S. and foreign investors, as well as the U.S. businesses into which they invest, may transact and develop the budgets, operating plans and financing alternatives of such companies simultaneously. Accordingly, *BIO requests that the Department provide guidance clarifying the timing provisions of the Pilot Program to ensure that parties may complete a proposed investment no later than 45 days after the submission of a mandatory declaration.* Prompt and predictable review timelines are critical to avoid unduly disrupting routine, benign investments into U.S. biotechnology (and other) companies. In particular, we request guidance on how CFIUS will prioritize its caseload to avoid unnecessary disruption to benign non-controlling investments, such as in initial public offerings (IPOs) of U.S. companies, which require prompt capital commitments to avoid delaying or derailing such IPOs.

[2] Reuters, "U.S. biotech sees surge of Asian investment," Data as of September 4, 2018, https://fingfx.thomsonreuters.com/gfx/rngs/BIOTECH-CHINA-INVESTMENT/0100806Y0EC/index.html.

2. BIO believes that the time, expense, and deal uncertainty introduced by the Pilot Program could have a chilling effect on investments in critical technologies. There is further uncertainty regarding the "emerging" and "foundational" technologies that will be immediately captured by the Pilot Program once they are identified by the Commerce Department. The uncertainty with regard to the scope of such "emerging" and "foundational" technologies, coupled with the immediate effective date of the Pilot Program's mandatory declarations for transactions involving such technologies, is already interrupting investment flows into projects that could potentially be subject to controls. Such disruption could last for an extended period of time while the Department of Commerce develops its process for determining what qualifies as emerging and foundational technologies, and thus it could unnecessarily divert investment away from the development of vital biotechnologies during that time. For example, many investments into U.S. businesses occur through agreed transactions that are signed presently but have multiple closings over the course of several years based on milestones achieved by the particular U.S. business. Yet those future investments may be at risk because of this future uncertainty and, secondly, may result in the U.S. business not receiving such contractually pre-agreed capital from their foreign investors in a timely manner in the future. Accordingly, *BIO recommends that the Department provide an appropriate phase-in period between the date that the Department of Commerce publishes its list of "emerging" or "foundational" technologies and the date when they are subject to mandatory declarations under the Pilot Program, to minimize uncertainty and avoid disruption to investment deals already in progress at the time that the "emerging" or "foundational" technologies are defined.*

   Moreover, as described above, many transactions have multiple closings that can occur over the course of several years and, as such, *BIO requests that the Department confirm that the term "pilot covered investment" under Section 801.209 would not apply to such "subsequent closings" if: (i) the foreign investor held the "initial closing" for an investment before November 10, 2018; (ii) the foreign investor previously complied with the mandatory declarations at the "initial closing," if such closing occurred after November 10, 2018; or (iii) the foreign investor's stake in the U.S. business at such subsequent closing is only passively increased because of the failure of one or more co-investors to participate in any such subsequent closing.*

3. Section 801.409 of the Pilot Program regulations provides that any person who fails to satisfy the mandatory filing requirement under Section 801.401 may be liable for a civil penalty in an amount up to (but not to exceed) the value of the transaction. Given the current state of uncertainty and lack of awareness among industries that are likely to be impacted by the Pilot Program, *BIO requests that the Department provide guidance and clarity regarding the specific circumstances under which it will seek a penalty, how it will calculate any given penalty, and whether it will consider any mitigating factors when assessing whether to impose a penalty.* Such mitigating factors may include a party's good faith efforts to assess whether a certain transaction falls within the scope of the Pilot Program, whether the transaction raises any national security concerns, the lack of intent (scienter) on the part of a party unintentionally failing to comply with the mandatory disclosure requirement, the size of the U.S. business receiving the investment (indicated, for example, by a minimum amount of revenue), or the submission of a voluntary self-disclosure in cases where

the parties learn that they unintentionally failed to comply with Section 801.401. In addition, BIO requests that the Department consider as a mitigating factor a circumstance where an item is added to the Export Control Reform Act's list of emerging and foundational technologies in Section 801.204(b)(e).

4. BIO requests clarification from the Department regarding the interim rule's definition of "pilot program U.S. business." Section 801.213 defines a "pilot program U.S. business" as any U.S. business that "produces, designs, tests, manufactures, fabricates or develops a critical technology that is: (a) utilized in connection with the U.S. business's activity in one or more pilot program industries; or (b) designed by the U.S. business specifically for use in one or more pilot program industries." Regarding this section, BIO requests guidance in two specific areas. First, BIO requests clarity as to the use of NAICS codes to identify Pilot Program industries. As NAICS codes are self-reported by companies themselves, *BIO asks the Department to provide guidance as to whether NAICS codes are dispositive in identifying Pilot Program businesses, and how individual companies can verify the accuracy of their NAICS code classifications. Second, BIO requests guidance clarifying the responsibilities of U.S. businesses in the following circumstance:* Company A is a U.S. business that designs a critical technology specifically for use by another U.S. business, Company B, which does not have a NAICS code listed in Attachment A of the interim rule, but which, unbeknownst to Company A, intends to use the critical technology in activities related to its activity in a pilot program industry. Does Company A have a responsibility to determine the specific purpose for which Company B intends to use critical technology?

5. In accordance with its mandate under Section 1723 of FIRRMA, BIO appreciates that the Department will consider the effect of filing fees on small companies, including in the biotechnology sector. Biotechnology companies are unique in that they may be highly valued in the market due to the potential of the science and technology underpinning their businesses, while having few if any product revenues. *BIO believes that revenue (rather than valuation/market cap) is the true indicator of company size and recommends that, to avoid undue hardship on emerging biotech companies, CFIUS base its filing fees on this important metric when it promulgates filing fee regulations pursuant to Section 1723 of FIRRMA.*

6. Biotechnology companies use a variety of investment structures that do not fit neatly within the definitions of the Pilot Program, but for which these innovative start-up companies could be strictly liable for failing to submit a mandatory filing. *BIO requests that the Department publish guidance on a continuing basis regarding the nature of transactions determined to not be covered by the Pilot Program to clarify the covered transaction analysis conducted by CFIUS for such transactions.* BIO anticipates that CFIUS will receive numerous filings while companies learn which specific investment structures now fall under CFIUS's jurisdiction. Accordingly, BIO expects that CFIUS will have a significant dataset from which to choose in developing a process by which the Department publishes guidance (similar to tax guidance provided by the Internal Revenue Service or Foreign Agents Registration Act guidance provided by the Department of Justice) to inform foreign investors and U.S. businesses regarding which transactions are subject to CFIUS jurisdiction.

BIO appreciates this opportunity to submit comments to the Department regarding the Pilot Program 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