Biotechnology Innovation Organization
1201 New York Ave., NW
Suite 1300
Washington, DC, 20005
202-962-9200

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Matthew G. Olsen
Assistant Attorney General for National Security
National Security Division
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Washington, D.C.

BIOTECHNOLOGY INNOVATION ORGANIZATION

Notice of Proposed Rulemaking

Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons

The Biotechnology Innovation Organization (BIO) welcomes the opportunity to provide comments in response to the Department of Justice's Oct. 29, 2024 Notice of Proposed Rulemaking relating to the implementation of the Feb. 28, 2024 Executive Order "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern."

BIO believes that together and with appropriate consultation, the U.S. Government can develop effective national security measures that strengthen the legitimate protections of U.S. individuals' privacy rights and health-related data, while also safeguarding the responsible use of this data to accelerate and drive biomedical research in the United States. We believe that rules can and must be structured in a manner that preserves U.S. leadership in the life sciences and in the development of cutting-edge biopharmaceutical treatments for the benefit of patients around the world.

BIO stresses the importance of striking the right balance between addressing legitimate national security concerns and the promotion of a predictable, reliable and secure global legal ecosystem that allows for the responsible and secure sharing of data essential to promoting scientific collaborations, driving innovation, and enhancing overall public welfare through the development and delivery of innovative biotherapeutic treatments.

For reasons elaborated in more detail in the pages that follow, the NPRM, despite efforts to address BIO's previously stated concerns, falls short in striking this balance and presents several consequential challenges for the U.S.-based innovative biopharmaceutical sector. We are hopeful that our submission provides the DOJ with reasonable proposals to develop calibrated rules that balance legitimate national security concerns while also minimizing risks and disruptions to the global, innovative biopharmaceutical research ecosystem.

Biotechnology as a National Security Imperative

BIO believes that biotechnology is a national security imperative.[1] The United States and our allies need a robust and vibrant American biotechnology industry. Biotechnology is a vital strategic asset that is essential to strengthen and protect our public health generally, and as well in our response to future pandemics and the potential for bioterrorism. It is also an essential element of our ability to project abroad the principles and benefits of a free and democratic society.

The capabilities and capacity to create, manufacture, and distribute state-of-the-art newer and better medicines and vaccines is the foundation for America to continue its essential role as the "World's Medicine Chest." Securing and advancing our pre-eminence in biomedical innovation and biomanufacturing are key components of a multi-prong approach at BIO to secure and advance this strategic imperative in biotechnology.

In addition to our commitment to securing and advancing our pre-eminence in biomedical innovation and biomanufacturing, BIO supports carefully calibrated policy measures that aim to secure American individuals' bulk sensitive personal data from countries of concern that may use and exploit this data to the detriment of U.S. national security interests. We encourage the National Security Division of the DOJ to consider input from our sector as the Division continues its efforts to clarify the process for implementing this authority.

[1] https://www.bio.org/press-release/biotechnology-national-security-imperative-says-bio-ceo

The Convergence of Biotechnology and Digital Transformations to Drive Life Sciences Innovation

Healthcare is experiencing a major paradigm shift, from traditional one-size-fits-all medical care to personalized medicine tailored to the genomic, molecular, and lifestyle characteristics of individual patients. Unlocking the power of healthcare data to fuel innovation in medical research is at the heart of today's health care revolution, where medicine is increasingly a collaboration between data science and clinical science realms. Harnessing health data offers biopharmaceutical companies deeper understanding of disease pathways and ultimately helps develop targeted treatments with improved efficacy and safety. As a result, cellular therapies, gene therapies and genome editing with the potential to cure once incurable diseases are a reality today. The pipeline of biopharmaceutical innovation is rich with these transformative therapies that would not exist were it not for this remarkable convergence of modern biotechnology and the digital sciences.

The ability to timely and efficiently access and leverage health data to drive biomedical research – while appropriately protecting patient privacy - is critical for life science companies engaging in research and development both domestically and internationally. Policies restricting data collection, use, and sharing for healthcare and research purposes will hinder coordination and collaboration amongst research partners globally and, as a result, will impact the American biopharmaceutical industry's ability to rapidly develop and deliver breakthrough therapies to patients around the world. Accordingly, policies restricting data transfers - if not carefully calibrated - will disrupt ongoing research and development activities, frustrate global collaborations, and compromise U.S. leadership in the life sciences.

Comments re: Subpart E – Exempt Transactions

In our April 19, 2024 submission to the DOJ in response to the ANPRM, BIO proposed an exemption to the rules which would allow for companies to submit data as part of a regulatory submission to government regulatory bodies in order to obtain licensure to lawfully provide and distribute drugs to patients in countries of concern, as well as for clinical investigations and post-marketing surveillance data. We believe exemptions, in contrast to potential licensing tools modeled on the regime used by OFAC as envisioned in this NPRM, could contribute to a more efficient framework that enables continued U.S. leadership in the research, development, and delivery of breakthrough biomedical technologies for patients around the world.

Section 202.510 – Exemption for Drug, biological product, and medical device authorizations

The exemption provided in Section 202.510 establishes that the provisions regulating prohibited (Subpart C) and restricted (Subpart D) transactions would not apply to data transactions "necessary to obtain or maintain regulatory approval to market a drug… in a country of concern." In the Discussion of the Proposed Rule in Section IV of the NPRM, the DOJ states, "[t]his exemption balances the need to mitigate the risks to U.S. national security from the unrestricted transfer of bulk U.S. sensitive personal data to countries of concern *against the scientific, humanitarian, and economic interests in enabling the sale of medicines in those countries* [emphasis added]." This exemption and the DOJ's intent, therefore, appears to address one of BIO's core positions in response to the initial ANPRM, which is to ensure that the rules do not create barriers for U.S. based biopharmaceutical firms to obtain the necessary regulatory approval in order for innovative drugs and treatments to be delivered and administered to patients in countries of concerns.

This exemption as currently drafted, however, falls short of conferring any material benefit to biopharmaceutical firms seeking regulatory approval for drugs in countries of concern.

Example 3 provided in Section 202.510(d)(3) illustrates precisely why this exemption as currently drafted presents such significant concern. This example clarifies that the exemption would only apply to data transferred directly to the government regulatory authority and not to an entity in the country of concern, including subsidiaries of U.S. headquartered companies, responsible for preparing and ultimately filing regulatory submissions with their governments' regulatory body.

This particular example is of such concern because companies cannot legally submit data directly to a foreign government's regulatory body. In other words, only entities incorporated under the laws of a specific country of concern are permitted to submit data for regulatory approval before their respective government agency.

For example, according to Article 9 of the Order of State Administration for Market Regulation, No. 27, issued by the State Administration for Market Regulation in China on July 1, 2020, only entities incorporated under the laws of China may submit drug applications to the National Medical Products Administration (NMPA), the Chinese equivalent to the U.S. FDA, "Applicants shall be those enterprises or drug development institutions, etc. that can assume corresponding legal responsibilities. An overseas applicant shall designate a business corporation within the territory of China to handle matters related to drug registration."

Accordingly, in order to obtain regulatory approval necessary for the delivery and administration of drugs in China, a U.S.-based biotech firm must engage with a local entity, either its locally established subsidiary or, for those biotech firms without local subsidiaries, another company incorporated under the laws of China to file the paperwork with the NMPA. Given that all regulatory submissions in China would fall under the fact pattern of Example 3 and require the use of a covered person to file and prepare the submission, Example 3 provided in Section 202.510 undercuts, in its entirety, the intent of the exemption that the DOJ sought to confer to biopharmaceutical firms in the first place.

Outcomes, such as the one arising from Example 3 in Section 202.510, would significantly disrupt the ability for U.S. based firms to access markets and deliver breakthrough treatments to patients in countries of concern. This outcome is wholly inconsistent with the DOJ's stated assertion that "[the NPRM does not] seek to broadly prohibit U.S. persons from conducting commercial transactions with entities and individuals located in countries of concern or impose measures aimed at a broader decoupling of the substantial consumer, economic, scientific, and trade relationships that the United States has with other countries."

To resolve this issue and clarify the true intent of this proposed exemption, we strongly propose striking in its entirety Example 3 in Section 202.510(d)(3).

We also request the DOJ to expressly state and clarify the exemption in Section 202.510 to apply to all data transfers necessary to obtain or maintain regulatory approval to market a drug in a country of concern, including in situations where a transfer to a covered person is legally required by local law in order to submit applications to a regulatory authority.

Furthermore, in keeping with the spirit of the proposed exemption, BIO strongly encourages the DOJ to clarify that covered data transfers submitted to government authorities in countries of concern responsible for authorizing research engagements, such as approvals to conduct clinical studies, benefit from the exemption in Section 202.510. These transfers seem to be contemplated since "regulatory approval data" in Section 202.510 (b) includes data required for authorization or approval to research or market a drug. However, BIO would appreciate DOJ's express confirmation that research authorizations are within scope.

It is also necessary for the DOJ to clarify that the term "regulatory entities" comprise national and local regulatory agencies. For instance, in China, unlike in the U.S., both national and local regulatory bodies are involved in the authorization of clinical research. Regulatory entities should therefore refer to any regulatory body at either a national or local level involved in authorizing clinical research and/or reviewing or approving safety and efficacy data necessary to obtain or maintain regulatory approval for a product in a country of concern.

Regulatory authorities in countries of concern may also require human biospecimen sample transfers for assay cross validation purposes. These transfers, if requested by a regulatory authority, are essential for obtaining marketing authorizations and should, therefore, also benefit from this exemption, even though samples would be transferred to a covered person, such as a local laboratory, and not directly to the regulator.

We believe these clarifications are necessary and justified and can be tailored in such way to maintain the integrity of the proposed rules in the NPRM and safeguard access to Americans' bulk sensitive personal data. As provided for in the Discussion of the Proposed Rule in Section IV of the NPRM, the DOJ acknowledges the marginal risk to national security from granting additional covered persons access to the submission data may be low, given that the submission data is ultimately being transferred directly to the government.

The DOJ, in its discussion of this proposed exemption affirms that "the Department does not *currently believe* that it is reasonably necessary to use a covered person… to prepare and submit data for regulatory submission [emphasis added]." The Department based on this input should now fully appreciate that a range of transfers to covered persons are not only reasonably necessary but legally necessary to submit data for regulatory approval to commercialize a drug or to commence clinical research. The exemption provided for in Section 202.510 should therefore reflect this reality and confer on U.S. biopharmaceutical firms the full intended benefit of a regulatory exemption so that drugs may be researched, delivered, and administered to patients in countries of concern.

Section 202.511 – Exemption for other clinical investigations and post-marketing surveillance data

The exemption provided in Section 202.511 would apply to transactions that are "ordinarily incident to and part of clinical investigations regulated by the U.S. FDA" and transactions that are "ordinarily incident to and part of the collection or processing of clinical care data indicating real-world performance or safety of products… necessary to support or maintain authorization by the FDA."

These provisions appear to confer meaningful exemptions to the biopharmaceutical sector; however, the proposed rules lack specificity around the types of transactions that would be considered "ordinarily incident to and part of" and, due to this ambiguity, present concerns to BIO.

BIO maintains that the transfer of data, pursuant to an employment or vendor agreement, to conduct statistical and scientific analyses of data related to a clinical trial or the analysis of real-world data and post-marketing surveillance data should be considered "ordinarily incident to and part of" research activities required to support and maintain authorizations by the U.S. FDA. In addition, early research that is a necessary precursor to clinical investigations should be considered "ordinarily incident to" such studies. An acknowledgement in the rules or an example that clarifies that these transactions are considered by the DOJ "ordinarily incident to and part of" would provide important clarity for BIO members engaged in this research to understand the full scope of this exemption.

To further illustrate, the FDA may also require the transfer of covered data for purposes of cross-validation studies. The FDA specifically requires cross-validation of data obtained within a study from different laboratories with the same bioanalytical method, involving, for instance, the transfer of human biospecimens. Such transactions to satisfy FDA cross-validation requirements should also be considered "ordinarily incident to and part of" supporting or maintaining an FDA approval.

If the term "ordinarily incident to and part of" were to be narrowly interpreted, routine and scientifically necessary data transfers would potentially be categorized as restricted or prohibited transactions. Were this to be the case, the rules may compromise the ability for U.S. based biopharmaceutical companies to comply with FDA requirements and may, at worst, jeopardize industry's ability to efficiently assess the full safety and efficacy profile of drug candidates and to assess approved drugs' post-marketing safety data. Restricting the transfer of this data may lead to unnecessary delays in assessing safety profile of approved drugs, which may impact the safe administration of drugs to patients in the U.S. and throughout the world.

Deidentified Data

The exemptions provided in Sections 202.510 and 202.511 only apply to data that is "deidentified." BIO notes, however, that the NPRM does not provide a definition of deidentified data. In such case, we encourage the DOJ to apply these exemptions to data that is pseudonymized in accordance with the International Council of Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH) Good Clinical Practice guidelines.

Clinical trial data and post-marketing surveillance data, two types of data contemplated in the exemptions, are commonly key-coded, in accordance with the ICH-Good Clinical Practice guidelines, where names and addresses of individual patients are not used but rather a unique code is assigned to identify the patient. Certain data is included that is relevant to properly ascertain drug safety and this necessary safety information provided in coded form is essential for drug regulators. For example, this coded data, according to FDA Guidance 2008-D-0199, allows for clinical monitoring, subject follow-up, or the addition of new data from the subject in a trial. This key-coded data reflects the form of data that is expected and required by regulators in ICH countries, including the U.S. FDA and NMPA, in China.

If key-coded data were not included in the final rules, there would be no practical effect of the exemptions in Sections 202.510 and 202.511 because this key-coded data is precisely the type of data collected and ultimately required of regulatory authorities. Clarity around this question of whether key-coded data is within scope of the proposed rule is imperative if the DOJ intends to confer on

biotech firms the full intent of these exemptions to seek and maintain drug approvals in the U.S. and in countries of concern.

Section 202.504 – Exemption for Federally-funded Research / Official Business of the United States Government

Given the limitation in the exemptions for clinical trial research for U.S.-based biopharmaceutical companies in Section 202.510 and the ambiguity in the exemption provided in Section 202.511, BIO seeks clarification from the DOJ regarding the broad exemption provided in Example 1 of Section 202.504. Example 1 establishes in clear and unambiguous terms that federally funded research is fully exempt from the rules concerning prohibited and restricted transactions.

BIO and its members welcome feedback and rationale from the DOJ that would permit transfers of bulk sensitive personal data for federally funded research but not for privately funded research. If such a broad exemption for federally funded scientific research exists, it should follow that a similar exemption for scientific research, conducted in accordance with all relevant laws, regulations, and appropriate ethical oversight, should be conferred to all researchers, regardless of whether the source of the funding is from the private sector or the federal government.

This incongruity may also present challenges and legal uncertainty in situations where companies partner with federally funded research institutions or in situations when companies themselves receive federal funding. Robust scientific collaboration between public and private sectors is one of the hallmarks of the U.S. biopharmaceutical sector and what propels the quintessentially American entrepreneurial spirit and the generation of new biotech firms. BIO encourages the DOJ to contemplate how this exemption could potentially be broadened to apply to research scenarios that have a mix of federal and private funding, scenarios which represent a more comprehensive view of the early-stage biopharmaceutical research ecosystem that exists in the United States.

Section 202.506 – Corporate group transactions

The proposed rule exempts covered data transactions to the extent that they are (1) between a U.S. person and its subsidiary or affiliate located in (or otherwise subject to the ownership, direction, jurisdiction, or control of) a country of concern and (2) ordinarily incident to and part of administrative or ancillary business operations (e.g. HR systems). This proposed rule is too narrow and does not cover product development activity between U.S. entities and affiliates in countries of concern. BIO encourages the DOJ to consider in its final rules more corporate substantive operations-related activity to be in scope of the contemplated Corporate Group Transactions exemption.

For instance, in Subpart C, Section 202.303, the transfer of human genomic data or human biospecimens, from which genomic data could be derived, is prohibited. This presents significant challenges to global companies with affiliates in countries of concern where intra-affiliate transfers of such covered data are transferred for R&D purposes, and not necessary or immediately related to obtaining regulatory approval to research or commercialize a drug, in which these latter transactions directly related to regulatory submissions would, in the most generous interpretation of the proposed rules, be exempted.

In addition, AI is an emerging and key area for life science companies' drug development programs and part of global R&D activities related to the development of AI models could involve intra-

company sharing of covered data. The preamble discussion in Section 202.304 regarding AI models in the context of the prohibition on evasion/circumvention of the regulation is relevant to an expanded corporate group transactions exemption. An exemption permitting a larger range of corporate group transactions would support greater U.S. led innovation in these emerging fields. Failure to include these intra-company R&D transactions may delay development of AI models and place U.S. based firms at a competitive disadvantage globally.

Contemplated Time-Limitations of Exemptions

BIO is also concerned that the DOJ is contemplating in its Discussion of the Proposed Rule in Section IV of the NPRM whether the exemptions in Sections 202.510 or 202.511 could be time-limited and, thus, potentially expire.

Failure to maintain these exemptions throughout the entirety of the implementation of the final rules would result in significant operational and scientific disruptions to the global R&D ecosystem. Without these exemptions, BIO members and the U.S. biopharmaceutical community at large will face significant challenges with the rules for prohibited and restricted transactions, as currently drafted.

Lack of clarity on the time duration of these exemptions could impact companies' ability to market new drugs in countries of concern. This would effectively deny patients in countries of concern access to life-saving treatments, raising serious ethical concerns. Restrictions would also likely disrupt global clinical trials, threaten scientific progress, and reduce the diversity and scalability of clinical trials – as diverse populations have significant biological differences that translate into better data and more personalized, effective, and safer medicines.

BIO, therefore, strongly encourages the DOJ to consider maintaining these exemptions, with our suggestions incorporated, throughout the implementation of the proposed rules.

Comments re: Subpart D – Restricted Transactions

Compliance with CISA Data Security Requirements

As demonstrated in Example 2 of Section 202.401, failure by a U.S. person to comply with the security requirements incorporated by reference in Section 202.402 would result in an otherwise allowable "restricted transaction" being categorized as an unauthorized prohibited transaction.

The security requirements incorporated by reference in Section 202.402 are the Cybersecurity and Infrastructure Agency ("CISA") Security Requirements for Restricted Transactions, established pursuant to Executive Order 14117, and concomitantly under a separate, parallel, public comment review process (Docket No. CISA-2024-0029).

Recognizing the appropriate venue for substantive comments on the CISA proposed security requirements resides in the parallel Department of Homeland Security process, it is necessary, nevertheless, to provide the DOJ in this present submission comments on the CISA security requirements, given the regulatory overlay and connectivity between the NPRM and the CISA proposal.

The Security Requirements as currently proposed by CISA impose significant challenges and seem impractical to implement within a reasonable short- or mid-term horizon. CISA is requiring the deployment of highly sophisticated, state of the art encryption and privacy enhancing technologies to be in compliance with the Security Requirements. These state-of-the-art tools present tremendous promise and potential; however, these are not methodologies that are widely available or deployed across sectors of the U.S. economy. Years and great expenses would be required to repurpose existing IT infrastructure to approach a potential full implementation of the proposed CISA requirements.

Furthermore, the CISA Security Requirements concerning specific data-level requirements (Section II) lack clarity as to the precise combination of contemplated mitigations (e.g. data masking, encryption techniques, deployment of privacy enhancing technologies) that would be considered acceptable by CISA and the DOJ to "fully and effectively prevent access to covered data by covered persons and/or countries of concern." The proposed rules merely point to a combination of measures but do not provide adequate legal clarity that companies' mitigation techniques would be fully compliant with the security requirements.

The consequences are significant in that, if the security requirements are not met, all restricted transactions by definition default to unauthorized, prohibited transactions subject to general or specific licensing requirements.

Given the foreseen challenges for biopharmaceutical firms of all sizes to comply with the proposed CISA Security Requirements completely undermines the ability for biopharmaceutical companies to avail themselves of the provisions in Section 202.401. Companies would by necessity have to treat all transactions as prohibited transactions, requiring compliance with the licensing mechanisms provided for in Subpart H of the rules. Such an outcome seems inconsistent with the intent of the proposed rules and does not strike the right balance sought by the DOJ. Accordingly, BIO asks that time, guidance, resources, and a degree of leniency with respect to implementation of CISA's Security Requirements be granted to companies so that companies may avail themselves of the provisions allowing for restricted transactions. An alternative approach that maintains flexibility in technical, organizational, and security requirements, with an emphasis on security and privacy by design and default, would be better fit for purpose.

Clarifications Necessary to Distinguish between Vendor Agreements and Data Brokerages

According to Subpart C, Section 202.301, all covered data transactions involving a data brokerage with a country of concern constitute prohibited transactions. Final rules providing greater clarity on the types of transactions that constitute the involvement of data brokerages would be helpful so that BIO members can more confidently ascertain whether a covered data transaction would be considered by the DOJ a prohibited transaction.

A range of routine data transactions could potentially implicate the involvement of a data brokerage based on the definition provide in section 202.214. The terms "sale of, licensing of access to, or similar commercial transactions" could encompass a broad range of meaningful and routine transactions of data. Indeed, the term "transaction" as defined in the NPRM applies broadly to any use, transfer, or holding of data.

Considering the prohibition of data brokerage transactions and resulting implications, the definition's scope should be narrowed and clearly distinguish between the sale of data for monetary purposes (where the data is the object of the commercial transaction) versus the transfer of data pursuant to normal business operations, where it is incidental to the development, testing or sale of a product or service. These transfers pursuant to normal business operations, as illustrated below, should be classified as vendor or employment agreements and not interpreted as data brokerages.

Transfers to Third-Party Collaborators

A U.S. company may enter into a licensing agreement with a Chinese company, pursuant to which the U.S. company has licensed IP and clinical trial data from that Chinese company for development/commercialization in markets outside of China, including in the U.S. and rest of world (RoW). Often these Chinese companies do not have the workforce, or local knowledge, to be able to develop or commercialize products outside of China so these licensing arrangements ensure that U.S. patients can access potentially life-saving medicines that they otherwise may not have access to. The licensing agreement may require the U.S. company to share covered data with the Chinese licensor/collaborator for regulatory or pharmacovigilance purposes. It is unlikely that companies in China would agree to license their IP and technology to foreign entities for development of products in RoW without an obligation on the licensee to share data stemming from such RoW development back to the Chinese licensor/collaborator for purposes of satisfying their regulatory and pharmacovigilance obligations, as required by local laws and regulations.

If not otherwise exempted, as addressed in our comments on Section 202.511, such data transfer should be categorized as a vendor agreement, and, therefore, subject to the provisions concerning restricted transactions. The final rules should include such a scenario as an example. These transactions should not be considered data brokerages, because the data is not being transferred solely in exchange for monetary consideration and, hence, such transactions should not be subject to the provisions concerning prohibited transactions.

BIO welcomes the additional clarity in the final DOJ rules concerning these potential business development and commercial collaborations with companies originating in countries of concern, such as strategic collaboration agreements to develop and commercialize new drugs in the U.S. and RoW. These transactions are essential for maintaining regulatory approval both in the U.S. and abroad and, thus, should be exempted pursuant to 202.510 and 202.511. If they are not exempted, these transactions should be categorized as vendor agreements and restricted transactions, not as data brokerages. Without such clarifications, U.S. competitiveness internationally will be compromised as U.S. businesses will be siloed from the global marketplace of ideas and innovation.

Transfers to Subsidiaries and Covered Persons Submitting Data to NMPA on behalf of U.S. based Biotech Firms

BIO encourages the DOJ to also clarify that covered data transfers, not exempted according to the provisions in Sections 202.506, 202.510 and 202.511, to covered persons for R&D purposes should be categorized as vendor agreements, and, therefore, subject to the provisions concerning restricted transactions. These transactions should not be considered data brokerages, as the covered data transactions are not solely for monetary consideration, nor should they be subject to the provisions concerning prohibited transactions.

Comments re: Subpart H - Licensing

Given the uncertainty around the current proposed rules, inability to fall within the scope of an exemption or satisfy the requirements of the proposed CISA Security Requirements for Restricted Transactions, many routine transactions companies of all sizes engage in with covered persons in countries of concern may be considered prohibited transactions and, thus, subject to the licensing provisions in Subpart H.

Reliance on licensing mechanisms present major concerns to the innovative biopharmaceutical sector. Requirements to seek licenses raises the risk of research and costs of doing business, due to the potential for a license to be denied and the costs involved with requesting licenses for routine and essential transactions.

The proposed rules also do not provide clarity insofar as the mechanisms for requesting general or specific licenses. BIO members would benefit from clearer guidance outlining the specific steps for requesting general or specific licenses.

Notwithstanding, it is a major concern to BIO that in Section IV of the NPRM - Discussion of the Proposed Rules – the DOJ states, on p. 138, "[t]he Department anticipates that licenses *will be issued only in rare circumstances as the Attorney General deems appropriate* [emphasis added]." Given the potential high likelihood that companies would need to resort to a licensing mechanism to be compliant with the rules (given the aforementioned challenges with respect to the rules around the exemptions for scientific research and the rules regarding restricted transactions), it is imperative the DOJ create, at a minimum, a transparent, efficient, and functional licensing mechanism. Given the totality of the present rules, and potential reliance on the use of licensing mechanisms, the licensing regime contemplated by the DOJ should not be made available only in "rare circumstances" and operate under a presumption of denial. This could have significant scientific and business consequences for U.S. based biotech enterprises.

Section 202.801 regarding general licenses provides no language committing the DOJ to a response. Furthermore, in Section 202.802(g), the proposed rules provide that the DOJ "shall endeavor" to respond to any request for a specific license within 45 days after receipt of the request. BIO urges the DOJ to firmly commit to responding to license requests on a timely basis, where failure to respond would result in an automatic approval. Otherwise, indefinite delays could significantly derail scientific research and impact the ability for patients in the U.S. and around the world, including in countries of concern, to receive their treatments.

The proposed rules fail to state whether this response in 45 days is to indicate an application has successfully been submitted, whether additional information is necessary, or whether one should anticipate an outcome of the license application within this timeframe.

Licenses could potentially take months for approval and with DOJ's stated presumption of denial, there is significant risk licenses could be denied. If OFAC licenses are the model the DOJ will follow, the licensing mechanism should mimic OFAC's general licenses for medicines and list a broad range of activities that are permitted. A mechanism for emergency authorization or expedited licenses, for example, should be contemplated to cover multiple covered data transfers as opposed to seeking individual licenses for each transaction.

Comments re: Subpart B - Definitions

Section 202.205 and Section 202.206 – Bulk and Bulk U.S. sensitive personal data

The rules, just as in the ANPRM, continue to treat all data the same regardless of whether the data is aggregated, anonymized, pseudonymized, de-identified, or encrypted.

BIO does not believe that the calculus for determining volume thresholds for bulk U.S. sensitive personal data for anonymized, pseudonymized, de-identified, and encrypted data should be the same as the calculus for determining volume thresholds for bulk U.S. sensitive personal data of personally identifiable information.

Although reidentification of data is, in theory, a possibility, the volume thresholds should be more carefully calibrated to account for the scientific community and industry's ability to anonymize, pseudonymize, and de-identify data sets in a manner that preserves the scientific integrity of research data, promotes legitimate national security concerns, and that appropriately safeguards U.S. individuals' privacy rights.

For example, the genomic, biometric, and personal health data on U.S. individuals biopharmaceutical firms routinely use, collect, process, disclose, and maintain in the course of research and development efforts are pseudonymized/key-coded pursuant to ICH – Good Clinical Practices or de-identified in accordance with the requirements for de-identification set forth in section 164.514 of title 45 of the Code of Federal Regulations.

If the proposed bulk volume thresholds for aggregated, anonymized, pseudonymized, and de-identified data were the same as the thresholds for personally identifiable information, innovative biotech firms in the U.S. will, in the natural course of their research and commercial efforts, quickly exceed minimum bulk volume thresholds proposed in the rules.

BIO appreciates the DOJ's efforts in the NPRM to develop calibrated measures defining volume thresholds for each category of sensitive personal data, as opposed to an absolute prohibition on any transfer. However, as BIO articulated in detail in our response to the ANPRM, the proposed bulk thresholds would be exceeded in the normal course of BIO members' research and business operations.

Given the ease by which biopharmaceutical firms will surpass these bulk thresholds, it is imperative the DOJ's final rules provide greater clarity around the availability of certain research exemptions and clarity around the rules for restricted transactions as well as around licensing mechanisms necessary to permit prohibited transactions.

Section 202.223 – Human biospecimens

BIO strongly encourages the DOJ to exclude materials intended for direct medical use, such as cell or gene therapies, from the proposed definition of human biospecimens. Prohibiting transactions involving lifesaving products, such as cell or gene therapies, by having these products within the scope of the human biospecimen definition will have significant public health consequences for patients in countries of concern who rely on these treatments. To address this issue, we strongly encourage DOJ to expressly exclude finished medical products from the definition.

Section 202.224 – Human genomic data

BIO acknowledges questions posed by the DOJ considering the potential inclusion of bulk human 'omic data, other than human genomic data, as a new category of sensitive personal data in the final rules.

Given the emergence of the scientific field around multi-omics research and its implications to the pipeline of biopharmaceutical research, BIO strongly urges the DOJ to delay any final rulemaking involving the categorization of human 'omic data as being subject to either prohibited or restricted transactions. Inclusion of multi-omic data as a category of sensitive data in the final rules without robust public consultation has the potential to significantly impact scientific development and U.S. leadership in this space.

We ask the DOJ to please consider this request to postpone rulemaking and engage in a more robust consultative process with industry. Given the scope of the rules and the condensed timeframe to respond to the present NPRM, a response on this new category of sensitive data merits more robust engagement.

Conclusion

As aforementioned, biotechnology is a national security imperative for BIO. We support the Executive Order and the development of tailored rules surrounding international transfers of Americans' bulk sensitive personal data to strengthen our national security and protect the exploitation of sensitive personal data by countries of concern. We also, however, believe that U.S. leadership in the life sciences is a critical element of a robust and comprehensive national security plan and future rules, therefore, must carefully balance these considerations.

The proposals in this NPRM present challenges for the U.S.-based innovative biotechnology sector that if not remedied have the potential to significantly disrupt clinical research programs, affecting the speed and efficiency by which we are able to drive innovation and advance science. This has consequences for our companies that operate globally, for sustained U.S. leadership in the life sciences, and for those patients and their families around the world who depend on our industry's innovations that save and greatly improve quality of life.

BIO appreciates the DOJ's efforts to carefully consider rules and calibrate actions that minimize risks and disruptions to the U.S.-based innovative biopharmaceutical sector. Given the potential of the rules as currently drafted to introduce risk and significantly alter the landscape for global biomedical research, we strongly encourage the DOJ to consider greater collaboration on this topic with our sector, spanning early-stage startup biotech firms, pre-commercial SMEs, and larger multinational biotechnology companies, prior to finalizing rules.

If countervailing national security concerns necessitate the immediate release of finalized rules, we ask that the DOJ consider granting general licenses, effective immediately, for our sector as well as an adequate implementation period for companies to build compliance programs so that research programs are not suddenly upended and patients around the world maintain access to treatments and therapies. There are significantly long lead times in research and immediate implementation of rules could cause significant impact to the global pipeline of biopharmaceutical innovation, over 70% of which originates from U.S.-based biotech firms.

About BIO

BIO is a non-profit organization based in Washington, D.C. with a membership of more than 1,000 biotechnology companies throughout the United States. BIO's members research and develop innovative health care, agricultural, industrial, and environmental biotechnology products. Over 90% of BIO's members are small and medium sized enterprises, many of whom are still pre-commercial.

Sincerely,

/s/ Justin D. Pine

Justin D. Pine
Sr. Director, Health Policy
Biotechnology Innovation Organization (BIO)