PREVENTING ACCESS TO US SENSITIVE PERSONAL DATA AND GOV'T RELATED DATA BY COUNTRIES OF CONCERN OR COVERED PERSONS

PERSONAL HEALTH DATA & GENOMIC DATA

Agenda for Discussion

- Definition of Key Terms
- Prohibitions Related to Genomic Data
- Restrictions Related to Personal Health Data
- Three Major Exemptions

Key Terms - Definitions

• 202.205 – Bulk

The term *bulk* means any amount of sensitive personal data that meets or exceeds the following thresholds at any point in the preceding 12 months, whether through a single covered data transaction or aggregated across covered data transactions involving the same U.S. person and the same foreign person or covered person:

- (a) Human genomic data … on more than 100 U.S. persons;
- (b) Biometric identifiers … on more than 1,000 U.S. persons;
- (d) Personal health data … on more than 10,000 U.S. persons;
- (g) Combined data, meaning any collection or set of data that contains more than one of the categories in paragraphs (a) through (g) of this section, or that contains any listed identifier linked to categories in paragraphs (a) through (e) of this section, where any individual data type meets the threshold number of persons or devices collected or maintained in the aggregate for the lowest number of U.S. persons or U.S. devices in that category of data.

- **202.224: Human genomic data**

The term *human genomic data* means data representing the nucleic acid sequences that constitute the entire set or a subset of the genetic instructions found in a human cell, including the result or results of an individual's "genetic test" (as defined in 42 U.S.C. 300gg-91(d)(17)) and any related human genetic sequencing data.

202.241: Personal Health Data

The term *personal health data* means health information that relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual. This term includes basic physical measurements and health attributes (such as bodily functions, height and weight, vital signs, symptoms, and allergies); social, psychological, behavioral, and medical diagnostic, intervention, and treatment history; test results; logs of exercise habits; immunization data; data on reproductive and sexual health; and data on the use or purchase of prescribed medications.

202.223 – Human Biospecimens

The term *human biospecimens* means a quantity of tissue, blood, urine, or other human-derived material, including such material classified under any of the following 10-digit Harmonized System-based Schedule B numbers:

- (a) 0501.00.0000 Human hair, unworked, whether or not washed or scoured; waste of human hair
- (b) 3001.20.0000 Extracts of glands or other organs or of their secretions
- (c) 3001.90.0115 Glands and other organs, dried, whether or not powdered
- (d) 3002.12.0010 Human blood plasma
- (e) 3002.12.0020 Normal human blood sera, whether or not freeze-dried
- (f) 3002.12.0030 Human immune blood sera
- (g) 3002.12.0090 Antisera and other blood fractions, Other
- (h) 3002.51.0000 Cell therapy products
- (i) 3002.59.0000 Cell cultures, whether or not modified, Other
- (j) 3002.90.5210 Whole human blood
- (k) 3002.90.5250 Blood, human/animal, other
- (l) 9705.21.0000 Human specimens and parts thereof

202.204: Biometric Identifiers

The term *biometric identifiers* means measurable physical characteristics or behaviors used to recognize or verify the identity of an individual, including facial images, voice prints and patterns, retina and iris scans, palm prints and fingerprints, gait, and keyboard usage patterns that are enrolled in a biometric system and the templates created by the system.

Other 'Omic Data

Department of Justice is considering regulating, as prohibited or restricted transactions in the final rule, certain transactions in which a U.S. person provides a country of concern (or covered person) with access to bulk human 'omic data, other than human genomic data. The 'omics sciences examine biological processes that contribute to the form and function of cells and tissues.

The Department is considering whether to include the following definitions:

- 1. Epigenomic data: data derived from the analysis of human epigenetic modifications, which are changes in gene expression or cellular phenotype that do not involve alterations to the DNA sequence itself. These epigenetic modifications include modifications such as DNA methylation, histone modifications, and non-coding RNA regulation.
- 2. Glycomic data: data derived from the analysis of the structure, function, and interactions of glycans (complex carbohydrates) within human biological systems. The field of glycomics generally aims to understand the roles of glycans in cell-cell communication, immune responses, and various diseases.
- 3. Lipidomic data: data derived from a systems-level characterization of lipids from a human or human cell, including their identification, quantification, and characterization in biological systems. Routine clinical measurements of lipids for individualized patient care purposes would not be considered lipidomic data because such measurements would not entail a systems-level analysis of the complete set of lipids found in such a sample.
- 4. Metabolomic data: data derived from the analysis of metabolites, the small molecules produced during metabolism, that aim to understand disease mechanisms, identify biomarkers for diagnosis, and develop targeted treatments by revealing the dynamic biochemical activities in a living system. This data provides a general snapshot of an organism, tissue, or cell, offering insights into physiological and pathological processes.
- 5. Meta-multiomic data: The Department is considering the following options for defining meta-multiomic data: (i) Datasets that include two or more categories of human 'omic data identified in this regulation, which can include data derived from the human genome, proteome, transcriptome, epigenome, or metabolome; or (ii) Datasets that include two or more categories of human 'omic data identified in this regulation and that include 'omic data from another species.
- 6. Microbiomic data: data derived from analysis of all the microorganisms of a given community within the human body (including a particular site on the human body). Microbiomic data is implicated in the field of metagenomics, which generally aims to investigate and understand genetic material of entire communities of organisms, including the composition of a microbial community.
- 7. Phenomic data: data derived from analysis of human phenotypes, including physical traits, physiological parameters, and behavioral characteristics.
- 8. Proteomic data: data derived from analysis of human proteomes, which refers to the entire set of proteins expressed by a human genome, cell, tissue, or organism. The field of proteomics generally aims to identify and characterize proteins and study their structures, functions, interactions, and post-translational modifications.
- 9. Transcriptomic data: data derived from analysis of a human transcriptome, which is the complete set of RNA transcripts produced by the human genome under specific conditions or in a specific cell type. The field of transcriptomics generally aims to understand gene expression patterns, alternative splicing, and regulation of RNA molecules. The Department is considering excluding from the definition of other human 'omic data pathogen-specific data embedded in 'omic data sets.

The Department does not intend the definition of meta-multiomic data to include nonhuman data separated from human data or for the definition of microbiomics data to include data related to individual pathogens, even when derived from human sources.

Predicate Acts – Prohibited Genomic Transactions; Restricted Transactions involving Personal Health Data

• 202.303 – Prohibited Genomic Transactions

[N]o U.S. person… may knowingly engage in any covered data transaction with a country of concern or covered person that involves access by that country of concern or covered person to bulk U.S. sensitive personal data that involves bulk human genomic data, or to human biospecimens from which bulk human genomic data could be derived.

- **202.401 – Restricted Transactions (e.g,. Personal Health Data)**

- [N]o U.S. person … may knowingly engage in a covered data transaction involving a vendor agreement, employment agreement, or investment agreement with a country of concern or covered person unless the U.S. person complies with the security requirements required by subpart D of this part and all other applicable requirements under this part.

- This subpart does not apply to covered data transactions involving access to bulk human genomic data or human biospecimens from which such data can be derived that is subject to the prohibition in § 202.303 of this part.

Health-Related Exemptions

• 202.510: Drug, Biologic, and Medical Device Authorizations

Exemption for data transactions that:

- (1) Involves "regulatory approval data" as defined in this section and
- (2) Is necessary to obtain / maintain regulatory approval to market a drug, biological product, device, or a combination product in a country of concern, provided that the U.S. person complies with the recordkeeping and reporting requirements set forth in §§ 202.1101(a) and 202.1102 with respect to such transaction.

Regulatory approval data. For purposes of this section, the term *regulatory approval data* means de-identified sensitive personal data that is required to be submitted to a country of concern regulatory entity to obtain or maintain authorization or approval to research or market a drug, biological product, device, or combination product, including in relation to post-marketing studies and post-marketing product surveillance activities, and supplemental product applications for additional uses. The term excludes sensitive personal data not reasonably necessary for a regulatory entity to assess the safety and effectiveness of the drug, biological product, device, or combination product.

(c) *Other terms*. "Drug," "biological product," "device," and "combination product" have the meanings given to them in 21 U.S.C. 321(g)(1), 42 U.S.C. 262(i)(1), 21 U.S.C. 321(h)(1), and 21 CFR 3.2(e).

- *Example 1*. A U.S. pharmaceutical company seeks to market a new drug in a country of concern. The company submits a marketing application to the regulatory entity in the country of concern with authority to approve the drug in the country of concern. The marketing application includes the safety and effectiveness data reasonably necessary to obtain regulatory approval in that country. The transfer of data to the country of concern's regulatory entity is exempt from the prohibitions in this part.
- *Example 2*. Same as Example 1, except the regulatory entity in the country of concern requires that the data be de-anonymized. The transfer of data is not exempt under this section, because the data includes sensitive personal data that is identified to an individual.
- *Example 3*. Same as Example 1, except the U.S. company enters a vendor agreement with a covered person located in the country of concern to store, organize, and prepare the bulk U.S. sensitive personal data for submission to the regulatory agency. The transaction is not exempt under this section, because the use of a covered person to prepare the regulatory submission is not necessary to obtain regulatory approval.

• 202.510: Drug, Biologic, and Medical Device Authorizations

Additional details:

- (1) Involves "regulatory approval data" as defined in this section and
- (2) Is necessary to obtain / maintain regulatory approval to market a drug, biological product, device, or a combination product in a country of concern, provided that the U.S. person complies with the recordkeeping and reporting requirements set forth in §§ 202.1101(a) and 202.1102 with respect to such transaction.

Regulatory approval data. For purposes of this section, the term *regulatory approval data* means de-identified sensitive personal data that is required to be submitted to a country of concern regulatory entity to obtain or maintain authorization or approval to research or market a drug, biological product, device, or combination product, including in relation to post-marketing studies and post-marketing product surveillance activities, and supplemental product applications for additional uses. The term excludes sensitive personal data not reasonably necessary for a regulatory entity to assess the safety and effectiveness of the drug, biological product, device, or combination product.

(c) *Other terms*. "Drug," "biological product," "device," and "combination product" have the meanings given to them in 21 U.S.C. 321(g)(1), 42 U.S.C. 262(i)(1), 21 U.S.C. 321(h)(1), and 21 CFR 3.2(e).

- *Example 1*. A U.S. pharmaceutical company seeks to market a new drug in a country of concern. The company submits a marketing application to the regulatory entity in the country of concern with authority to approve the drug in the country of concern. The marketing application includes the safety and effectiveness data reasonably necessary to obtain regulatory approval in that country. The transfer of data to the country of concern's regulatory entity is exempt from the prohibitions in this part.
- *Example 2*. Same as Example 1, except the regulatory entity in the country of concern requires that the data be de-anonymized. The transfer of data is not exempt under this section, because the data includes sensitive personal data that is identified to an individual.
- *Example 3*. Same as Example 1, except the U.S. company enters a vendor agreement with a covered person located in the country of concern to store, organize, and prepare the bulk U.S. sensitive personal data for submission to the regulatory agency. The transaction is not exempt under this section, because the use of a covered person to prepare the regulatory submission is not necessary to obtain regulatory approval.

• 202.510: Drug, Biologic, and Medical Device Authorizations (cont'd)

Additional Details

- This exemption is limited to data that is
  - De-identified;
  - Required by a regulatory entity to obtain or maintain authorization or approval to research or market a drug, biological product, device, or combination product (*i.e.*, covered product); and
  - Reasonably necessary to evaluate the safety and effectiveness of the covered product.
  - For example, de-identified data that is gathered in the course of a clinical investigation and would typically be required for Food and Drug Administration ("FDA") approval of a covered product would generally fall within the exemption. Conversely, clinical participants' precise geolocation data, even if required by a country of concern's regulations, would fall outside the scope of the exemption because such data is not reasonably necessary to evaluate safety or effectiveness.
- The Department recognizes that data collection and submission continue beyond the initial regulatory approval process, and it intends the term "regulatory approval data" to include data from post-market clinical investigations (conducted under applicable FDA regulations, clinical care data, and post-marketing surveillance, including data on adverse events.
  - For example, where continued approval to market a drug in a country of concern is contingent on submission of data from ongoing product vigilance or other post-market requirements, the exemption applies.
- The exemption applies even where FDA authorization for a product has not been sought or obtained. The Department does not, in these regulations, intend to require U.S. companies to first seek authorization to market a product in the United States before seeking regulatory approval from a country of concern.
- The exemption is limited to transactions that are necessary to obtain or maintain regulatory approval in the country of concern. The Department specifically invites comments on the types of transactions that are necessary to that end.
  - Example 3 of § 202.510, as proposed, would not exempt a vendor or employment agreement with a covered person to prepare data for submission to a country of concern's regulatory entity because the Department does not currently believe that such transactions are necessary to obtain regulatory approval. The Department seeks comments on whether, and why, such a vendor or employment agreement with a covered person to prepare data for submission is necessary and should be exempt.

- **202.511: Other clinical investigations & post-marketing surveillance data**

Exemption for data transactions that are:

- (1) Ordinarily incident to and part of clinical investigations regulated by the U.S. Food and Drug Administration ("FDA") under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") or clinical investigations that support applications to the FDA for research or marketing permits for drugs, biological products, devices, combination products, or infant formula; or

- (2) Ordinarily incident to and part of the collection or processing of clinical care data indicating real-world performance or safety of products, or the collection or processing of post-marketing surveillance data (including pharmacovigilance and post-marketing safety monitoring), and necessary to support or maintain authorization by the FDA, provided the data is deidentified.

- **202.511: Other clinical investigations & post-marketing surveillance data**

Additional Details (1)

- DoJ agrees that some exemption or accommodation for clinical research may be appropriate.
- The United States has a national security interest in the development, authorization, and availability of medical products, including medical countermeasures to diagnose, treat, or prevent serious or life-threatening diseases or conditions that may be attributable to biological, chemical, radiological, or nuclear agents.
- DoJ seeks to mitigate this national security risk described in the Order without unduly burdening the biomedical innovation that benefits U.S. persons. The Department is considering how to effectively strike that balance and how to scope an exemption for transactions related to or supporting FDA-regulated research to meet that goal.
- DOJ is considering the scope of a possible exemption along three axes. First, in terms of the types of data that would be within the exemption; second, in terms of the types of transactions involving that data that would be exempted; and third, in terms of the duration of any exemption.
- **Types of Transactions**
  1. Any exemption would concern data obtained in the course of clinical investigations related to drugs, biological products, devices, and combination products…
  2. The exemption would also apply to clinical care data indicating real-world performance or safety of products, or post-marketing surveillance data (including pharmacovigilance and post-marketing safety monitoring), where necessary to support or maintain authorization by the FDA. These submissions to FDA involve deidentified data and the exemption arising under proposed § 202.511(a)(2) would apply only to deidentified data.
  3. The Department seeks comment on whether the exemption should exempt clinical investigations data related to other products, such as foods (including dietary supplements) that bear a nutrient content claim or a health claim, food and color additives, and electronic products.
  4. FDA regulations in 21 CFR parts 50, 56, 312, and 812 (e.g. on informed consent of human subjects and Institutional Review Boards ("IRBs")) are principally focused on patient privacy, and do not directly address the national security concerns that animate the Order…. National security measures focus on collective risks and externalities that may result from how individuals and businesses choose to sell and use their data, including in lawful and legitimate ways.

- **202.511: Other clinical investigations & post-marketing surveillance data**

Additional Details (2)

- **Types of Transactions / Data that Should be Exempted**

1. DoJ is considering what kinds of transactions to exempt when they involve data that implicates the exemption—such as, hypothetically, bulk U.S. sensitive personal data collected in the course of an FDA-regulated clinical investigation to develop a drug.
2. One possibility would be to exempt all transactions that are part of the conduct of the investigation.
3. Another possibility would be to limit an exemption to only certain types of transactions that are especially important to the conduct of a clinical investigation and that cannot feasibly be avoided without jeopardizing the clinical investigation.
4. The Department seeks additional comments on:

- Whether, why, and to what extent it would be necessary for U.S. persons to transmit bulk U.S. sensitive personal data to a covered person in order to support a clinical investigation taking place in a country of concern.
- Whether a vendor agreement for clinical investigations should be considered to be "ordinarily incident to and part of" a clinical investigation; how prevalent and important the practice of sending bulk U.S. sensitive personal data to a covered person in a country of concern is; and the potential impacts to clinical research, medical product development and authorization, and industry if such transactions were restricted or prohibited.
- How pervasive and important the practice of outsourcing the processing of adverse event reports to a covered person is, as well as on how pervasive and important it is to share adverse event information concerning U.S. persons with drug distributors in a country of concern. The Department seeks comments on the potential impacts to patient safety, industry, and the feasibility of obtaining or maintaining regulatory authorizations if such transactions were to be prohibited.

- **202.511: Other clinical investigations & post-marketing surveillance data**

Additional Details (3)

- **Types of Transactions / Data that Should be Exempted (Examples)**

A. Example 1: A U.S. sponsor conducts a clinical investigation to determine the safety and effectiveness of an investigational drug product. The clinical investigation involves a multinational trial with both U.S. citizens and non-U.S. citizens enrolled in the trial at different sites across the world, including in a country of concern, to support authorization of the product in the intended use populations. As part of the investigation, and pursuant to an employment or vendor agreement, the sponsor transmits bulk U.S. sensitive personal data to covered persons in the country of concern to conduct a data analysis of the product's safety and effectiveness across different population groups. This clinical investigation supports an application for a marketing permit for a product regulated by the FDA (*i.e.*, a drug for human use). The trial in this example is subject to the FDA's regulatory framework for clinical investigations.

B. Example 2: A U.S. pharmaceutical company is required to submit reports to the FDA of adverse events related to its FDA-approved drug for human use, consistent with the requirements under21 CFR 314.80. The firm markets many other drug products; has a wide global distribution, including in a country of concern; and receives thousands of reports per year for its various marketed products. Under a vendor agreement, the firm may outsource processing of these reports to entities outside of the United States, including in a country of concern. The firm may also need to exchange adverse event information about its FDA-approved drug product with its distributors in a country of concern to pool the data and identify any adverse events trends across different population groups or conditions of use and submit those data to the FDA.

- *The Department believes that, absent an exemption, the vendor and/or employment agreements in these examples would be restricted transactions (or prohibited transactions, if it involves the transfer of bulk human genomic data or biospecimens from which such data could be derived). The Department also seeks comments on a possible regulatory exemption vs. a general license.*

- **202.511: Other clinical investigations & post-marketing surveillance data**

Additional Details (4)

- **Duration**

A. DoJ is considering whether any exemption, or parts of it, could feasibly be time-limited to allow industry to shift existing processes and operations out of countries of concern over a transition period. DoJ is cognizant of the long planning times and high costs associated with clinical research.

B. If the DoJ does not broadly exempt clinical research from the scope of the prohibitions, it may consider delaying the effective date of the proposed rule with respect to such research to enable affected entities to complete ongoing or imminent trials without disruption or delay, while transitioning planning and policies for future trials.

C. DoJ could potentially implement such a delay by general or specific licenses, and could use a set period of time or could limit the exemption to studies already past a certain stage, such as submission of an Investigational New Drug application to the FDA by a set date.

D. DoJ seeks comment—taking into account other exemptions, such as for federally funded research—on the number of clinical investigations that would be disrupted, and the extent of such disruption, if the prohibitions were immediately applicable; how long and how to structure any delay to minimize disruption without inviting misplaced reliance; and the best mechanism for implementing such a delay.

202.___: Possible exemption for biospecimens

- DoJ is considering whether it is necessary or appropriate to adopt a tailored exemption that would permit covered data transactions involving the export to countries of concern or transfer or sale to covered persons of certain human biospecimens, like blood plasma, intended for direct medical use that the proposed rule would otherwise prohibit.
- DoJ welcomes views about the specific types of biospecimens exported to countries of concern, or transferred or sold to covered persons for direct medical use that DoJ should consider exempting from the prohibition on bulk transfers of human genomic data or biospecimens from which bulk human genomic data could be derived.
- Important considerations could include the importance of the biospecimens for direct medical use; the relative ease with which a country of concern or covered person could derive bulk human genomic data from the biospecimens; the economic and humanitarian value of permitting such transactions; and any other national security concerns that DoJ should consider.

GLOBAL DATA ALLIANCE

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Please direct any questions to gdainfo@bsa.org