NOTICE OF PROPOSED RULEMAKING DOCKET NO. NSD-104
AG ORDER NO. 6067-2024; RIN 1124-AA01
89 FR 86116 (Oct. 29, 2024)

DEPARTMENT OF JUSTICE: PROPOSED RULE ON PROVISIONS PERTAINING TO PREVENTING ACCESS TO U.S. SENSITIVE PERSONAL DATA AND GOVERNMENT-RELATED DATA BY COUNTRIES OF CONCERN OR COVERED PERSONS

MEETING SUMMARY

RE: MEETING WITH THE PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA ("PhRMA") REGARDING THE DEPARTMENT OF JUSTICE'S PROPOSED RULE ON PROVISIONS PERTAINING TO PREVENTING ACCESS TO U.S. SENSITIVE PERSONAL DATA AND GOVERNMENT-RELATED DATA BY COUNTRIES OF CONCERN OR COVERED PERSONS

DATE/TIME OF MEETING: NOVEMBER 25, 2024 2:30 PM – 3:00 PM EST

PLACE OF MEETING: VIRTUAL

ATTENDEES:

FROM THE NATIONAL SECURITY DIVISION OF THE DEPARTMENT OF JUSTICE

Jailene Acevedo, Paralegal
Jennifer Roan, Program Analyst
Allison Harrington, Attorney
Lee Licata, Deputy Chief for National Security Data Risk
Joe Bartels, Attorney
Joe Lullo, Attorney

FROM THE DEPARTMENT OF COMMERCE

Marvin Wiley, Policy Advisor

FROM THE PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA

Jennifer Osika, Vice President, International Advocacy
Neil Pratt, Senior Assistant General Counsel and Head of International Legal Affairs
Philip Chen, Deputy Vice President, International

SUMMARY OF MEETING:

On November 25, 2024, representatives from the Department of Justice ("DOJ") and the Commerce Department ("Commerce") engaged with representatives from The Pharmaceutical

Research and Manufacturers of America ("PhRMA") regarding PhRMA's comments on DOJ's October 29, 2024 Notice of Proposed Rulemaking ("NPRM") entitled "Proposed Rule on Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons." *See* 89 FR 86116. These notes are a summary of the engagement; they are not a transcript. The Department of Justice has not shared these notes with meeting participants to confirm their accuracy.

During the engagement, a representative from DOJ briefly discussed the NPRM's proposed requirements, including exceptions to the proposed rule, changes from DOJ's March 5, 2024 Advanced Notice of Proposed Rulemaking ("ANPRM"), and comments received on the ANPRM. *See* 89 FR 15780. DOJ also noted that the NPRM comment period is open until November 30, 2024, and encouraged participants to submit comments on the proposed rule. Representatives from DOJ also invited meeting participants to ask questions about the NPRM from participants.

Commerce asked that PhRMA describe their role in industry and raise their concerns, if any, pertaining to DOJ's NPRM.

PhRMA started by expressing their concern with the record-keeping guidelines on the NPRM. Regarding thresholds, PhRMA stated that they would not feel comfortable giving input because they are unclear on which exemptions would be applicable to their business.

Additionally, PhRMA stated that also are seeking clarity on the scope of the clinical trial exemptions. Specifically, PhRMA raised concerns that (1) they want to ensure the exemptions cover all of the activities related to a clinical trial, not just marketing approval, (2) that the exemptions would allow for submissions for approval to multiple regulators in a country of concern (not just national government regulators, but also provincial or local governments), and (3) that the exemptions would allow for the use of employees and contractors in a country of concern to submit the clinical trial data to the regulator. PhRMA expressed their need to be able to conduct trials and have the data shared with various regulators as appropriate.

PhRMA noted their view that other 'omic' data should not be regulated at this time but should be subject to a policy process. Additionally, they noted that it was hard for them to evaluate the bulk threshold of 100 US persons' genomic data without fully understanding the scope of the clinical trials exemptions.

PhRMA also raised the question the requirements and which entities qualify for exemptions on effectually funded research. They noted that majority of research is done by private industry, which requires an adequate exemption.

PhRMA expects to post a comment on the NPRM on Friday, November 29th.

PhRMA had no further questions.