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Testimony Before the
Committee on Health, Education, Labor, and Pensions
United States Senate

Hearing on Medical Privacy

Re: The Notice of Proposed Rulemaking Clarifying Certain Provisions of the Medical Privacy Regulation Promulgated Under HIPAA

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Mr. Chairman and Members of the Committee:

My name is Michael Werner. I am Vice President for Bioethics for the Biotechnology Industry Organization (BIO). BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

Thank you for holding this hearing on the recently issued notice of proposed rulemaking ("NPRM") proposing to modify and clarify certain provisions of the Health Insurance Portability and Accountability Act ("HIPAA") privacy regulation. Because this is such a critical issue, we appreciate the opportunity to submit comments for the record.

BIO has long argued that it is important to protect individuals' privacy. Equally important, however, is the need to perform biomedical research that will lead to cures and treatments to meet currently unmet medical needs. In fact, protecting privacy and facilitating research are mutually attainable goals. However, the existing regulation contains several provisions that will harm research.

The NPRM is a step in the right direction. It goes a long way toward remedying many of the provisions of the regulation that would inhibit BIO members' ability to conduct important research activities.

The specific improvements that are included in the NPRM are:

- added protection for post-marketing surveillance and registry activities;
- simplification of the research authorization requirements; and
- more realistic criteria for waiver of authorization by an institutional review board ("IRB") or privacy board, including elimination of the subjective review criteria.

Unfortunately, one key provision of the existing regulation not changed by the NPRM is the regulation's definition of "de-identified" data. BIO is hopeful that this can be remedied as the regulatory process advances.

Post-Marketing Surveillance Activities Protected

In keeping with the renewed interest in public health surveillance, HHS proposes to modify the existing regulation's public health provisions to make clear that covered entities may disclose protected health information (PHI) to manufacturers for inclusion in patient registries and for other important post-marketing surveillance purposes. The regulation currently permits the disclosure of PHI for post-marketing surveillance conducted by a FDA-regulated entity only "to comply with the requirements or at the direction of" that agency. However, many critical public health-related activities are conducted *voluntarily* by manufacturers in accord with FDA registry guidelines, not because they are mandated by the agency. Therefore, the regulation's provisions would not permit these important disclosures. The NPRM solves this problem. It permits

disclosures of PHI to "[a] person subject to [FDA jurisdiction] with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity." This will facilitate this important public health function.

Research Authorization Requirements Simplified

The NPRM simplifies many of the existing regulation's authorization provisions. These provisions are confusing, often inconsistent with existing requirements applicable to research, and do not enhance privacy protection for research participants.

It eliminates the existing privacy regulation's differing authorizations for research that involves treatment (e.g., clinical trials) and for research that does not (e.g., studies of product safety and retrospective chart reviews) and, where research involves treatment, to distinguish PHI used for research purposes from PHI to be used for treatment purposes. Specifically, the NPRM eliminates the requirements for new authorization for "research related to treatment." Instead, HHS now proposes a uniform set of requirements applicable to all authorizations, including those for research purposes.

Moreover, under the NPRM, HHS would permit research authorizations to be combined with any other written permission relating to the same study (e.g., the informed consent document). The NPRM also would standardize and broaden the regulation's transition provisions to allow the continued use and disclosure of PHI obtained *before or after* the compliance date for a specific study—whether or not the study involves treatment—if, prior to the compliance date, the covered entity has obtained legal permission to use or disclose the participant's information for the study *or* an IRB has waived informed consent in accordance with the Common Rule or the Food and Drug Administration's ("FDA's") human subject protection regulations.

Finally, HHS has recognized that requiring covered entities to track disclosures authorized by an individual and, upon request, provide the individual with a history of such disclosures over the previous six years, imposes an unnecessary and costly administrative burden on academic medical centers and other research partners. Thus, HHS proposes to eliminate the six-year accounting requirement for PHI disclosed pursuant to an individual authorization. This change responds directly to BIO's assertion that the regulation's administrative requirements would have the unintended consequence of making academic medical centers and others reluctant to host sponsored research or incur greater cost in doing so.

Criteria for Waiver of Authorization for Research Streamlined

BIO has argued that the existing regulation's criteria for waiver of research authorization are both confusing and inconsistent with the Common Rule's waiver criteria. The NPRM deletes or modifies several criteria that are duplicative or impractical to apply to patient privacy. For example, HHS proposes to eliminate the requirement that an IRB or privacy board determine that the privacy risks to the study participants are reasonable in relation to the anticipated benefits, if any, to the individual and the importance of the knowledge that may reasonably be expected

from the research. This provision in the existing regulation was a major – and particularly objectionable – expansion of the Common Rule.

In addition, the NPRM clarifies that IRBs and privacy boards may grant waivers of authorization for the specific purpose of disclosing PHI to researchers and sponsors as necessary to contact and recruit potential study participants.

Comments Sought on Safe Harbor For Research Use of Facially De-identified Information

BIO has consistently argued that the existing regulation's de-identification safe harbor is so stringent as to be useless for many research purposes. The result is that the regulation makes epidemiological and outcomes research comply with the rule's patient authorization requirements. This is inconsistent with the public interest in the results of that research and is entirely unnecessary to protect the privacy interests of individuals.

The NPRM acknowledges this problem. HHS has specifically requested public comment on a proposal (not incorporated in the regulatory text of the NPRM) to create an alternative de-identification standard that would permit uses and disclosures of a "limited data set" of facially de-identified information for research, public health, and health care operations.

Research entities that arrange for the secure research use of data that is stripped of direct identifiers (such as name, Social Security Number, and email address) should be allowed access without special authorization or review. These identifiers are those that may reasonably be used to identify a data subject directly in the course of routine, daily use of the data set. Their removal would render the data "facially de-identified." Although these data would not include direct identifiers, they would include dates (including birth dates) and zip codes. Researchers and sponsors who receive limited data sets would be required to enter into data use or similar agreements in which the recipient agrees to limit the use of the data to research purposes, to limit who may use or receive the data, and not to re-identify or contact the individuals to whom the information refers.

BIO supports this approach. It is critical that the regulation's definition of de-identified is changed to be consistent with good research practice. Specifically, inclusion of dates, including dates of birth, as well as geographic units other than addresses are critically important for many research activities. Thus, HHS should allow use and disclosure of this information for research and public health purposes.

Importantly, this approach also protects privacy. Confidentiality obligations that are assumed by the recipient/researcher guard against the unintended misuse of the data set, while removal of direct identifiers minimizes the chance the data subject's identity will be revealed.

In sum, the NPRM contains many provisions that will remove the regulation's impediments to medical research. Moreover, BIO recommends adoption of a new definition of de-identified data that will facilitate research while protecting privacy.

Thank you for your consideration on this important matter.