UNITED STATES OF AMERICA

BEFORE THE

NATIONAL TELECOMMUNICATIONS AND INFORMATION ADMINISTRATION

Developing the Administration's Approach	**)**	
To Consumer Privacy	**)**	**Docket No. 180821780-8780-01**

Comments of the International Pharmaceutical & Medical Device Privacy Consortium

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The International Pharmaceutical & Medical Device Privacy Consortium ("IPMPC") welcomes the opportunity to respond to the National Telecommunications and Information Administration (NTIA)'s September 26, 2018 Request for Comment ("RFC") on user privacy outcomes.

The IPMPC is comprised of chief privacy officers and other data privacy and security professionals from a number of research-based, global pharmaceutical companies and medical device manufacturers.[1] IPMPC is the leading voice in the global pharmaceutical and medical device industries to advance innovative privacy solutions to protect patients, enhance healthcare, and support business enablement.[2]

Support for pre-emptive federal privacy action

The IPMPC supports federal privacy efforts to create a harmonized set of requirements throughout the United States. However, any federal effort must preempt state laws that impose higher or lower standards. A patchwork of state and local laws restricts the conduct of interstate business and limits innovation by imposing undue restrictions on nation-wide activities. Federal action that does not preempt state laws simply creates another standard that must be accommodated, possibly in conflict with existing standards, and would be of limited value (if at all).

Support for an "accountability" or "risk-based" framework.

The IPMPC supports the development of an "accountability" or "risk-based" framework that allow companies to adopt controls appropriate to the activities in which they are engaged. Risk-based frameworks allow for individualized decision-making that promotes innovation by incentivizing the development of new or customized approaches to privacy and security issues. By contrast, a "one-size-fits-all" approach forces the use of methods that may not be appropriate to each use case and discourages the development of innovative consumer-facing methodologies that are not explicitly contemplated by existing requirements.

Support for a framework that recognizes the importance of biomedical research

The IPMPC supports the development of a framework that demonstrates a focus on promoting and supporting the biomedical research needed to develop new treatments, therapies, devices, technology solutions, drugs, and procedures. The IPMPC believes this goal should be clearly articulated in any federal framework and not left to the discretion of a rule-making agency responsible for implementing an appropriate approach. Commercially-oriented developmental research in the health care and life science sector improves the well-being and quality of life of Americans. The importance of this research (and the existence of robust ethical

[1] IPMPC members may also operate related businesses, including CLIA laboratories.
[2] More information about IPMPC is available at https://www.ipmpc.org/. This filing reflects the position of the IPMPC as an organization and should not be construed to reflect the positions of any individual member.

and legal controls that currently govern its conduct) requires clear support for continued research activity in any federal privacy framework.

Biomedical research is a category of scientific research that involves the study of biological processes and diseases with the goal of developing effective treatments and cures.[3] Biomedical research fundamentally requires access to personal information about patients and research subjects. The life-saving treatments available today were made possible by an environment that fostered health research and recognized that medical innovation benefits society. Medical discoveries rely on the ability to safely and effectively collect and analyze personal information concerning patient treatment and outcomes. Without personal information, scientists would lack insight into the causes and symptoms or identifiers of certain conditions and diseases, and development of curative, diagnostic, and preventative measures would be impossible. In each of the steps in the scientific process – i.e., an observation leading to a hypothesis, followed by testing and then confirmation – the ability to effectively collect, analyze, and re-analyze patient information is crucial. The ability to sustain and expand on such scientific innovations depends upon the continued availability of patient information to meet researchers' needs.

Currently, biomedical research is regulated by guidance and regulations (including the Common Rule) promulgated by the Department of Health and Human Services and its component agencies, like the Food and Drug Administration. Research involving patients currently receiving treatment is further regulated by the Health Insurance Portability and Accountability Act and its implementing regulations. Even when these requirements do not directly apply, long-standing medical ethics requirements impose similar obligations on the conduct of biomedical research. Together, these regulations and ethical frameworks focus on obtaining consent prior to human experimentation. The practice of obtaining informed consent to participate in medical research involving human experimentation can be traced back to the Nuremberg Code of 1947.[4] Since then, this practice has become a bedrock principle of modern

[3] There are multiple ways to classify biomedical research, irrespective of whether the research is public or private. For example, basic research aims to advance fundamental knowledge about medical science whereas applied research focuses on the practical application of science to medicine. Another classification focuses on whether the research is clinical or epidemiological. Clinical research involves the investigation of medicines, medical devices, and diagnostic products to evaluate their safety and effectiveness. Epidemiological research examines the distribution and changes of the frequency of diseases in defined populations with the goal of identifying causes. A third possible classification focuses on the role of the investigator and whether the research is interventional versus observational. Interventional research (sometimes also referred to as "experimental research") involves the administration of a test article or change to clinical practice or to research participants' usual behaviors. In contrast, in observational research, patients are allocated treatments based on clinical decisions and researchers simply observe how differences in clinical decisions result in different health outcomes. Yet another classification focuses on the temporal nature of the study design and looks at whether the research is prospective versus retrospective. Prospective studies are forward-looking whereas retrospective studies involve the analysis of historical data.

[4] "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences

medical ethics, incorporated into the World Medical Association's Declaration of Helsinki, and adopted by governments throughout the world.[5] Obtaining consent for participation in clinical trials ensures that patients are informed of potential risks and safeguards each patient's rights to autonomy, self-determination, and inviolability. These laws and ethical guidelines provide a framework that protects patients but permits innovation.

Unfortunately, overly broad consumer protection laws can interfere with the conduct of already regulated research by applying concepts appropriate to the provision of goods and services to the conduct of experimental research. For example, to be scientifically valid and reliable, research depends on accurate and complete data sets composed of patient information. Giving research participants a broad right to have data about them erased risks creating an unreliable data set and introducing error into the conclusions drawn from the research project. Such a scenario also has impact on necessary filings with regulatory bodies for approval and/or clearance of any deriving product and on-going adverse event reporting. Any new privacy requirements that impact biomedical research should be developed by those federal departments and agencies that are most familiar with the existing regulatory and ethical frameworks for such research – namely, the Department of Health and Human Services and the Food and Drug Administration.

Conclusion

The IPMPC appreciates the opportunity to comment on the NTIA's proposed privacy framework, and we support the creation of a federal privacy framework that preempts state law, recognizes "accountability" or "risk-based" approaches, and clearly supports biomedical research – either by exempting it from the scope of such framework or by providing strong support for research activities.

and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment."

[5] See, e.g., International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (E6), which has been adopted by medicines authorities in the European Union, United States, and Japan. See also Article 7 of the United Nations International Covenant on Civil and Political Rights (ICCPR).