INTERNATIONAL PHARMACEUTICAL PRIVACY CONSORTIUM

November 7, 2014

**International Pharmaceutical Privacy Consortium**

*Comment to the House Energy and Commerce Committee*

"21st Century Cures"

These comments are submitted on behalf of the International Pharmaceutical Privacy Consortium, a group of leading companies addressing health privacy issues affecting the pharmaceutical industry (the "IPPC"). Members of the IPPC are involved in research and development of new drugs and biologics for the U.S. and global markets. The IPPC appreciates this opportunity to provide input on how Congress can promote healthcare innovation leading to the development and delivery of new life-saving cures.

The pharmaceutical industry spends billions of dollars every year on research and development of new medicines. The science of drug discovery and development is increasingly complex and advances are typically the product of incremental gains in knowledge over time as opposed to sudden, dramatic discoveries. Our understandings of particular disease states and drug discovery efforts relies on the analysis of information and data -- much of it personal in nature -- on how patients respond to existing and potential new treatments. Traditionally, this has occurred through study of new test articles (i.e., new chemically manufactured active-substance small molecules or biotech-engineered large protein molecules) in volunteers with well controlled clinical settings. Clinical trials continue to be a cornerstone of determining the safety and effectiveness of potential new medicines, but researchers are also exploring new ways of gathering information on how patients react to available treatments. Exploratory or secondary use of existing clinical data and real world health data presents such opportunities.

Personal health data is essential to cutting edge science in genetics and biomarker[1] discovery, and is increasingly being used for determining genetic patterns in drug development research and identifying appropriate patients populations for clinical studies. Limitations on biopharmaceutical researchers' ability to access and use personal health data create a barrier for U.S. innovation and the advancement of cures and treatments for patients that need them.

## I. Enabling Effective Research.

Clinical trials are integral in the development of hundreds of life saving drugs and provide the opportunity for in-depth and precise understanding of human biology and reactions to medicine. The typical clinical trial is a detailed and expensive process. Each trial involves establishing a number of study sites globally through partnerships with health care providers who will oversee the administration of the study; implementing a thorough and legally approved study protocol; and recruiting a large number of patient volunteers who meet the study criteria.

[1] A biomarker is a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.

Each trial not only provides valuable insight on the treatments investigated at hand, it also provides the study sponsor with access to substantial amounts of patient and treatment data that is valuable for further research. The re-use of such data for ongoing research into the condition or treatment at issue reduces the need to obtain new data through another costly and time-consuming clinical trial. Accordingly, Congress should act to promote the productive use of existing trial data for further research into life-saving therapies.

In accordance with this objective, Congress should consider what legal barriers might discourage companies from reanalyzing existing clinical trials data. Until recently, Health Insurance Portability and Accountability Act (HIPAA) regulations contained such a barrier. Prior to amendments to the HIPAA regulations issued in January 2013, the U.S. Department of Health and Human Services (HHS) interpreted the Privacy Rule to require that each purpose of a requested use or disclosure of protected health information (PHI) described in an authorization form be "study specific." HHS stated that authorizations for "future unspecified research" were not permitted. In the January 2013 amendments, HHS indicated that it was modifying its prior interpretation concerning the acceptability of authorizations for future research. Under the new interpretation, authorizations for uses and disclosures of PHI for future research purposes are valid as long as they "adequately describe such purposes such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research."[2] Nevertheless, HHS has not taken steps to preempt state laws that can be interpreted as being stricter than HIPAA regulations. In order to prevent inconsistencies between state and federal law and the frustration of Congress's objective of promoting healthcare innovation, ***Congress should preempt individual state authorization standards and provide for one universally applicable standard for permitting uses of patient data for research.***

In addition, real world health data, meaning the collection or generation of data under everyday conditions rather than from randomized, controlled trials, is increasingly being stored in digital format accessible through electronic health records, claims data, and observational studies. Analytics can be used to derive real world evidence from this real world health data to inform on a drug's effectiveness in everyday conditions and safety for broader populations. There is a growing need for real world evidence in order to obtain a comprehensive understanding of treatment. This real world evidence can be important for answering questions such as:

- Are we achieving the outcomes we expect based on clinical trial data?
- Is the drug being used properly (right patient, dose, duration, etc.)?
- Are there quality of life or productivity benefits?
- Is use of the drug associated with any unexpected events (whether adverse or beneficial)?

[2] "Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule" at 78 Fed. Reg. 5566, 5612.

This biomedical informatics holds enormous potential for advancing our understanding of diseases and conditions, and what preventative and therapeutic interventions are likely to be most effective. By analyzing aggregated medical records of large numbers of patients, scientists can discover patterns that help to improve individual health, health care, public health, and biomedical research. In this regard, the IPPC supports a framework for researcher access to government health databases as described by the Biotechnology Industry Organization in its concept paper, "Harnessing 'Big Data' and Real-World Evidence to Advance the Development of 21st Century Cures."

Here again, however, steps are needed to remove legal barriers to medical researchers' ability to access and use real world health data. Under the HIPAA Privacy Rule "Safe Harbor" de-identification standard, researchers needing to access information such as the timing of drug administration and the date some later health event occurred (e.g., to examine the relationship of the drug to the event) must follow HIPAA regulatory requirements for PHI. That is because any dates related to a patient's health or treatment are presumptively treated as "identifiable." Accordingly, the process of de-identification may senselessly require the removal of critical information, such as treatment dates, that would not be otherwise used to identify the patient. Furthermore, even where fake or dummy dates can be substituted to de-identify a data set in a manner that adequately reflects key events, this manual manipulation of dates substantially delays the use of the data and creates significant potential for errors.

In addition, though a covered entity could permit a researcher to have access to a "limited data set" of patient information, this information remains PHI and therefore limited by HIPAA restrictions. Specifically, Section 13405(d) of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) prohibits the "sale" of PHI, and therefore researchers are prohibited from purchasing access to health care databases held by covered entities. In effect, valuable data remains locked and inaccessible to health care researchers precisely because it is *of value*.

***Accordingly, Congress should (1) amend the Privacy Rule's "Safe Harbor" de-identification standard to permit the sharing of certain dates relating to an individual when used for research purposes and (2) eliminate the prohibition on covered entities receiving remuneration in exchange for PHI in the context of the disclosure of a limited data set***.

## II. Enabling Effective Health Care Delivery.

Pharmaceutical companies also look to advance the success of the cures and treatments they develop by ensuring patients can access the drugs they need and stay on them for as long as necessary to achieve their therapeutic benefits. For example, through the creation of digital reimbursement assistance platforms, pharmaceutical companies are attempting to ensure a quick and easy process for communication between health care providers, patients, payors, and pharmacies. Such streamlined processes will lead to increased prescription fulfillment and provide patients with access to necessary drugs at an accelerated pace.

Likewise, drug companies have been developing patient support programs and platforms to encourage patient adherence to their doctor-prescribed treatment regimen. The development of a drug and its placement on the market are just the first steps in treating diseases and patient conditions. The actual success of a treatment is dependent on patient adherence. Greater adherence will improve patient health outcomes and reduce the costs to the U.S. health care system. Indeed, the problem of patient non-adherence has been estimated to cost the U.S. health care system hundreds of billions of dollars.

Unfortunately, the current U.S. regime for obtaining patient authorization for sharing of health data inhibits the important goal of increased access and adherence to medication for improved patient outcomes. Under HIPAA regulations, health care providers are generally prohibited from sharing patient protected health information without authorization. Likewise, because HIPAA permits states to enact their own restrictions on uses and disclosures of health information, many states have enacted laws that, whether intentionally or not, make it difficult for patients to make use of pharmaceutical company reimbursement assistance and patient support programs due to onerous authorization requirements. For example, some states require that authorizations for use and disclosure of PHI be made in written form, meaning that patients are unable to request assistance over the phone.

***Congress should explicitly authorize covered entities to share PHI with entities providing treatment support services on behalf of the patient, subject to strict confidentiality requirements. Furthermore, Congress should preempt state laws that create barriers to such programs.***

## III. Conclusion.

Congress can help to advance 21st century cures by creating a consistent and research-friendly legal framework for personal health data use and sharing. Through assimilating federal and state standards to permit collaboration and data sharing between health care providers interacting directly with patients and those entities engaged in the development of treatments, Congress can accelerate health care innovation.