Comments of the International Pharmaceutical Privacy Consortium on Health Research and the Privacy of Health Information Under the HIPAA Privacy Rule

The International Pharmaceutical Privacy Consortium (IPPC) appreciates the efforts of the Committee on Health Research and the Privacy of Health Information to examine the impacts of the HIPAA Privacy Rule on research. The IPPC is an organization formed in 2002 and comprised of chief privacy officers and other privacy professionals from 15 research-based global pharmaceutical companies. Membership and mission of the IPPC is described in Attachment A. As sponsors of clinical studies, pharmaceutical companies are keenly aware of the impact of the Rule on research.

I. Recommendations Concerning Specific Privacy Rule Modifications

a. Implementation of NCVHS and SACHRP Recommendations

The challenges in implementing the Privacy Rule in the context of health research have previously been documented, both by the Subcommittee on Privacy and Confidentiality of the National Committee on Vital and Health Statistics in March 2004[1] and by the Secretary's Advisory Committee on Human Research Protections (SACHRP) in September 2004.[2] In particular, SACHRP's detailed recommendations concerning, ***inter alia***, research recruitment, research authorizations, de-identification standards, and accounting requirements would simplify the operation of the Rule and remove unnecessary research impediments. Regrettably, the recommendations of these bodies largely remain yet to be implemented.

b. Alterations and Waivers of Authorization

The IPPC also wishes to express support for certain other recommendations that were suggested by speakers at the Committee meeting on October 1-2, 2007. The IPPC supports:

- Requesting HHS to issue guidance, including a series of case examples, on how "practicability" should be interpreted by IRBs (or privacy boards) in the context of granting alterations, waivers, or partial waivers of authorization. One of the criteria for granting alterations/waivers is that the IRB must determine that "the research could not practicably be conducted without the waiver or alteration."[3] There is much uncertainty in the IRB community as to how this criterion should be interpreted. For example, IRBs have questioned the degree to which cost can be considered in this analysis. HHS commentary in the December 2000 Final Rule suggests that cost is a factor that can be considered, but the commentary is brief and has not been

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[1] Letter from John R. Lumpkin, Chairman of the National Committee on Vital and Health Statistics, to Tommy G. Thompson, Secretary of HHS (March 5, 2004), ***at*** http://www.ncvhs.hhs.gov/040305l2.htm.
[2] Letter from Ernice D. Prentice, Chair of SACHRP, to Tommy G. Thompson, Secretary of HHS (Sept. 1, 2004), ***at*** http://www.hhs.gov/ohrp/sachrp/hipaalettertosecy090104.html.
[3] 45 CFR 164.512(i)(2)(ii)(B).

subsequently highlighted by the Department. HHS states that an example of impracticability (as opposed to impossibility) may be the following: "[I]n a research study that involves thousands of records, it may be possible to track down all potential subjects, but doing so may entail costs that would make the research impracticable."[4]

- Requesting that HHS or, as necessary, Congress expressly insulate IRB members and institutions from liability for good faith, reasonable determinations to grant alterations or waivers of authorization. The growth over the last decade of lawsuits naming individual IRB members as defendants has created a chill that threatens the willingness of volunteers to serve on IRBs. Moreover, it results in an over-abundance of caution that upsets the careful balance between research and privacy that HHS attempted to reach in drafting the waiver criteria. A clear message should be sent that frivolous lawsuits will not succeed.

c. Pharmacoepidemiologic Research

Finally, the IPPC wishes to comment on the considerable challenges the Rule presents to retrospective pharmacoepidemiologic research. It would be of great scientific value for researchers to be able to supplement a limited data set received from one covered entity with limited data sets from others and to combine data that relates to the same patient. This would enable a more robust analysis of risk factors, outcomes, and extended follow-up time. However, to do this, a researcher must be able to identify records being received from different sources as relating to the same individual, which is not possible given the partially de-identified nature of a limited data set.

The IPPC therefore recommends a modification to the term "data aggregation" at 45 CFR 164.501 and corresponding change to the data aggregation services a business associate is permitted to provide a covered entity at 42 CFR § 164.504(e)(2)(i)(B). The goal of these modifications would be to allow an entity acting as a business associate of multiple, unaffiliated covered entities to match records pertaining to the same individuals in order to create an aggregated limited data set that could be disclosed to researchers.[5] These suggested modifications are underlined:

§ 164.501
Data aggregation means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a

[4] Standards for the Privacy of Identifiable Health Information, 65 Fed. Reg. 82461, 82697 (proposed Dec. 28, 2000).

[5] The Privacy Rule already safeguards personal information held by business associates. It requires a covered entity to stipulate by contract that a business associate will prohibit further use or disclosure other than as permitted by the contract or by law; use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the contract; report to the covered entity any unauthorized use or disclosure; and ensure that agents and subcontracts agree to the same restrictions and conditions with respect to the information. 45 C.F.R. 164.504(e)(2).

covered entity, the combining of such protected health information by the business associate with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities or to create an aggregated limited data set.

§ 164.504(e)(2)(i)
(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity or for the purpose of the creation of an aggregated limited data set.

The business associate would then be permitted to disclose the aggregated limited data set to a researcher, provided the appropriate data use agreements between the recipient and covered entities were in place.[6]

II. Future Considerations

The suggestions above are offered in the spirit of addressing problems that researchers have experienced to date with implementing the Privacy Rule. However, an assessment of the impact of HIPAA on research would be incomplete without consideration of whether and how the Privacy Rule must be adapted to accommodate anticipated and ongoing technological and social changes. For example, advances in adoption of electronic health records (EHRs) and growth in the size and number of biological repositories raise additional questions that policy makers will need to consider looking forward.

EHR systems have the potential to improve public health by enabling better post-marketing drug surveillance and facilitating the locating of potential subjects for clinical trials and other health care research. The public's support for the development and implementation of EHR systems will likely depend on the public's confidence that EHRs have been adequately secured. Robust data security is essential to protect EHRs from unauthorised access, which could lead to embarrassment, stigmatization, or discrimination. At the same time, authorities should recognize the substantial public interest in permitting the use of EHRs for medical research, provided appropriate safeguards are put in place.

Genomics promises to replace our empirical classification of illnesses with a new molecular taxonomy. It may allow early detection of illness and prediction of disease susceptibility and drug response. It may allow us to greatly expand the pool of gene-based targets for therapeutic intervention. Organizations in both the public and private sector are creating ever larger biological repositories to facilitate genomics research and the achievement of these objectives. However, since as few as 30-80 statistically independent single nucleotide polymorphisms could uniquely identify an individual, it is critical that these biobanks are fully secured. Moreover, employment and insurance discrimination on the basis of asymptomatic genetic factors should be prohibited. In contrast, policy makers should recognize the legitimate

[6] Moreover, the Privacy Rule allows the intended recipient of a limited data set to also act as a business associate of the covered entity to create the limited data set, provided the required business associate agreement is in place. 67 Fed. Reg. at 53237.

need of medical researchers to access and use biological samples and the benefits such research offers society.

In his comments before the Committee at its meeting on February 14, Professor Fred Cate discussed the informational needs of medical researchers and emphasized the importance of security and accountability. He noted that other legal systems, such as Ontario, Canada, have developed alternative models for granting researchers access to personal health information for biomedical research while limiting reuse and ensuring data protection. The IPPC encourages the Committee to examine such alternative models and consider whether they could operate successfully in the United States.

III. Conclusion

Thank you for your consideration of these comments. Please do not hesitate to contact us if further clarification is required.

We look forward to the publication of the Committee's report later this year.

Attachment A

MEMBERS

The IPPC is an association of companies that face worldwide responsibility for the protection of personal health information and other types of personal data. Members of the IPPC include:

- Abbott Laboratories
- AstraZeneca Pharmaceuticals
- Bristol-Myers Squibb
- Elan Pharmaceuticals, Inc.
- Eli Lilly and Company
- GlaxoSmithKline
- Johnson & Johnson
- Merck & Co., Inc. *(operating as Merck Sharp & Dohme in most countries outside USA)*
- Novartis
- Pfizer Inc.
- Roche
- sanofi-aventis
- Schering-Plough Corporation
- Takeda Pharmaceuticals
- Wyeth

MISSION

The IPPC works to promote responsible privacy and data protection practices by the research-based, global pharmaceutical industry. Maintaining data confidentiality and subject privacy are essential to clinical research, pharmacovigilance, and other activities of the pharmaceutical industry. The IPPC seeks to increase awareness of privacy and data protection issues and to engage government in a dialogue about the need for data to support cutting edge biomedical research and other public health activities. The IPPC pursues opportunities to collaborate with government and other stakeholders to develop data protection practices that enhance data subject privacy.

GOALS

The IPPC goals are to:

- Engage government and stakeholders in the biomedical research and healthcare communities in a constructive dialogue on significant issues of privacy and data protection.
- Serve as a resource for sound analyses of privacy and data protection requirements and compliance tools tailored to the pharmaceutical industry.
- Serve as a forum for industry dialogue and promote responsible privacy and data protection practices.
- Promote consistent privacy and data protection standards that can be achieved on a worldwide basis.
- Remain on the leading edge of privacy and data protection.

SCOPE OF ACTIVITIES

The IPPC advances understanding of existing and emerging data protection and security rules in Europe, the US, and other key countries. The Consortium engages regulators and policymakers in the following areas:

- Biomedical research
- Pharmacovigilance
- Sales and marketing
- Market research
- Human resources programs
- Other corporate programs