INTERNATIONAL
PHARMACEUTICAL
PRIVACY CONSORTIUM

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June 9, 2014

Mr. Donald S. Clark
Secretary
Federal Trade Commission
Room H-113 (Annex J)
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Spring Privacy Series: Consumer Generated and Controlled Health Data, Project No. P145401

Dear Mr. Clark:

The International Pharmaceutical Privacy Consortium (IPPC) is an organization formed in 2002 and comprised of chief privacy officers and other data privacy and security professionals from a number of global pharmaceutical companies. The IPPC is committed to the promotion of sound policies for the protection of privacy and advancement of drug development and treatment. Information concerning IPPC membership and mission is described in Appendix A.[1]

We appreciate this opportunity to provide information and comment on the movement of health data outside the traditional medical provider context. In this submission, we will address the following questions:

1) How can consumers benefit from websites, products and services used to generate and control consumer health data?

2) What are pharmaceutical companies doing to protect consumers' privacy and security when acting as sponsors of these products and services?

I. Benefits to Consumers

In the pharmaceutical context, data collection and use are essential to provide consumers and caregivers seeking information on medical diseases, conditions and treatments with the information they seek. This may occur, for example, in a digital context through online interactions, through Mobile Health tools such as mobile apps, and through social media or more traditional settings such as over the phone, or at health fairs and clinics. Here, we briefly outline some of the benefits that data collection and use can bring to patients through digital platforms.

Websites and Online Tools for Patient Engagement

A 2009 survey by the Pew Research Center found that 61% of American adults (83% of Internet users) look for health information online.[2] 42% of all adults say that they or someone they know has been

[1] For further information concerning the IPPC, please visit our website at www.pharmaprivacy.org. All Appendices referenced in this comment, and additional documents adopted by the IPPC, are publicly available on this website.
[2] Susannah Fox & Sydney Jones, Pew Internet and American Life Project, The Social Life of Health Information – Americans' Pursuit of Health Takes Place Within a Widening Network of Both Online and Offline Sources 4 (June 2009).

helped by following medical advice or health information found on the Internet.[3] Nevertheless, the Internet supplements but does not replace the advice of health professionals. 86% of Americans still ask a health professional when they need health information.[4] For prescription drugs, information found online serves to encourage open patient-physician communications, but it is the healthcare provider who ultimately determines what to prescribe based on his or her professional judgment.

Pharmaceutical companies play an important role in the healthcare system not only by manufacturing prescription and over-the-counter (OTC) drugs and devices but also by serving as an informational resource for interested patients and physicians. Healthcare outcomes and costs are improved when patients are informed and engaged in their treatment program. Informed and engaged consumers are more likely to recognize disease symptoms, seek appropriate care, and adhere to physician-prescribed treatment regimens. Appropriate, proactive, and consistent use of prescription and OTC medications helps individuals to lead healthier lives and can prevent or delay the need for more costly medical services and procedures. Online media serve these goals in the following ways:

- ***Empower Patients with Information***. Consumers who recognize disease symptoms and understand treatment options can more effectively seek appropriate care and make better-informed health decisions in consultation with their health care providers. Heightened awareness of available therapies and the benefits, risks and side effects of these therapies, empowers patients to work with their physicians to make important decisions about their healthcare.

- ***Encourage Patients to Communicate with Physicians***. Pharmaceutical company communications about prescription drugs encourage patients to consult with their physicians about health conditions to determine what treatment options are available.

- ***Decrease Patient Inhibitions in Addressing Sensitive Conditions***. Consumer-directed information about available prescription therapies encourages patients to speak with health care providers about their medical symptoms and treatment options. Patients who suffer from medical problems that may carry a social stigma or historically have been viewed as too personal to discuss with a physician are now, as a result of greater information, education, and understanding, more likely to discuss with a healthcare professional their symptoms and possible treatments.

- ***Promote Improved Medication Compliance***. Medication non-compliance is a significant public health concern – it has a negative impact on patients' health and significantly raises healthcare costs. Direct-to-consumer informational material on prescription drugs prompts patients to take their medicine regularly and refill prescriptions as necessary.

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[3] Id. at 7.
[4] Id. at 15.

Pharmaceutical manufacturers communicate information to patients and physicians both directly through manufacturer-controlled online media, and indirectly through advertising on independent or manufacturer-supported online media. Data collection and use are necessary to communicate effectively with consumers and caregivers who go online seeking information. Simply put, the Internet is not a static medium. Instead, it allows for an interactive experience between the user and site operator, and among many users of the same site. This may occur, for example, through online tools that enable users to enter symptoms and in turn receive information on possible causes. Or it may occur through online tools that enable users to keep track of their symptoms and other health markers on a daily basis. Or it may occur via a user's registration to receive further information about a product or condition, or to sign up to receive a periodic newsletter. Along the same lines, social media have allowed for the creation of support groups and patient communities so that those suffering from or caring for someone with an illness can obtain information, advice and encouragement.

Mobile Tools for Health Management

Mobile Health (mHealth) is the use of mobile and wireless devices to improve health outcomes, health care services, and health research. Among a number of potential benefits, mHealth promises to bring greater efficiency to the healthcare industry, allowing real-time communication between health care providers and patients and enabling remote medical interventions. mHealth solutions can also be used to help detect the development of chronic conditions earlier, in turn accelerating the promotion of healthy behavior. Further, mobile health applications provide an opportunity for consumers to learn about health conditions and treatments and track their health status, thereby enabling consumers to play a more active role in their own health care and helping to reinforce individual health goals. These are just a few of the ways that pharmaceutical companies are leveraging mobile platforms. Overall, mHealth provides the opportunity for great advancement in drug research and patient care.

The Food and Drug Administration has published guidance describing different types of mobile health applications and explaining how medical device regulations will be applied to these various categories.[5] Among the categories of apps that the FDA has determined pose low risks to consumers and will not be regulated by the FDA at this time are the following:

- *Mobile apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment.* This category includes medication reminder apps intended to improve adherence, as well as apps that coach patients with specific conditions and promote strategies for maintaining health.
- *Mobile apps that provide patients with simple tools to organize and track their health information.* These apps may allow patients to input measurements and symptoms, but they do not provide any specific recommendations nor are intended to alter a previously prescribed treatment or therapy.
- *Mobile apps that provide easy access to information related to patients' health conditions or treatments (beyond providing an electronic "copy" of a medical reference).* These apps match patient-specific inputs regarding diagnosis, treatment, allergies, and/or symptoms to clinical reference information.
- *Mobile apps that are specifically marketed to help patients document, show, or communicate to providers potential medical conditions.* This would include, for example, apps that enable an individual to use a smartphone camera to take a photo of his/her condition and transmit the information to a healthcare provider.

[5] Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff (2013), available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf ("Guidance").

The FDA's overall regulatory approach to mobile health apps was reiterated and reinforced in the more recent publication by the Agency, in consultation with the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communications Commission (FCC), of a report providing a strategy and recommendations for a US regulatory framework for health IT.[6] Both the guidance and report reflect the government's objective of promoting the rapid development and adoption of health IT and the recognition that undue regulation can stifle innovation.

Pharmaceutical companies have been exploring how mobile applications can be used to improve patient education and promote prescription adherence. Many patients do not fill medication prescriptions they receive from their doctor and those who do often fail to take their medication on a regular basis. Lack of medication adherence has been estimated to cost the U.S. health care system between $100 billion and $289 billion annually in direct costs.[7] Pharmaceutical companies are increasingly sponsoring the development of mobile apps that can provide automated medication reminders and mobile dashboards to assist patients in tracking dosages and organizing medication schedules. These adherence solutions are consumer controlled. Mobile apps are also being developed to help educate patients on the importance of prescription adherence. Effective management of chronic conditions often depends on regular adherence to a prescription regimen; however, in contrast to medications for acute conditions, patients may not experience immediate relief of symptoms when taking a medication for a chronic condition or immediate relapse of symptoms when stopping such a medication or skipping a dose. Education is, therefore, critical. Apps are being developed to make education fun (e.g., gamification) and to encourage healthy behaviors. These are just a few of the ways that pharmaceutical companies are leveraging mobile platforms. Overall, mHealth provides the opportunity for great advancement in drug research and patient care.

II. Protection of Consumer Privacy and Security

As online and mobile opportunities continue to expand to provide consumers with greater ability to generate and manage their own health data, it is important to protect the consumer's choice to decide how his or her personal health information is used. A number of groups have issued guidelines to assist website and mobile app developers in building privacy and security controls into their products and services. These include:

- Digital Advertising Alliance, Self-Regulatory Principles for Online Behavioral Advertising (July 2009).
- Digital Advertising Alliance, Self-Regulatory Principles for Multi-Site Data (November 2011).
- Digital Advertising Alliance, Application of Self-Regulatory Principles to the Mobile Environment (July 2013).
- Mobile Marketing Association, Mobile Application Privacy Policy Framework (December 2011).
- CTIA-The Wireless Association, Best Practices and Guidelines for Location Based Services (March 2010).

These guidelines incorporate widely recognized data protection principles, including Transparency, Individual Choice, Purpose Limitation, Data Security, Privacy by Design, and Accountability. As these guidelines demonstrate, industry is actively pursuing responsible privacy and security practices in the development of mobile technology.

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[6] This Report fulfills Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112-144.
[7] Medication Adherence Interventions: Comparative Effectiveness, *available at* http://effectivehealthcare.ahrq.gov/ehc/products/296/1249/EvidenceReport208_CQGMedAdherence_ExecutiveSummary_20120904.pdf.

Within the IPPC, member companies regularly share best practices on how to build privacy and security into digital initiatives. The IPPC has developed a number of tools, such as checklists and templates, to assist members in doing so. In addition, in 2008, the IPPC set forth a set of voluntary privacy guidelines for marketing by pharmaceutical companies to U.S. consumers. These guidelines are regularly reviewed for consistency with new and emerging media and remain relevant today.

III. Requests of the IPPC

In light of industry's active, adaptable, and knowledgeable self-regulation in this area, the IPPC discourages the FTC from considering overly prescriptive requirements for consumer health websites, online tools, and mobile apps. Instead, we encourage the Commission to provide *examples* of privacy information notices, including language and formats that it finds meet its goals of clarity and comprehension for a variety of media. We also encourage the Commission to provide an example checklist of privacy and security questions that should be asked of developers hired to create a website or mobile app on behalf of a company. Similarly, an example checklist for privacy officers to use when reviewing new websites, online tools, and mobile apps could be of great utility.

We thank you for your consideration of our comments. Please do not hesitate to contact us with any questions.

Sincerely,

Mary Devlin Capizzi
Secretariat and Legal Counsel

APPENDIX A: INTERNATIONAL PHARMACEUTICAL PRIVACY CONSORTIUM

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:

- AbbVie
- Amgen
- Astellas Pharma, Inc.
- AstraZeneca Pharmaceuticals
- Baxter International, Inc.
- Bristol-Myers Squibb
- Celgene
- Eli Lilly and Company
- Genentech/Roche
- GlaxoSmithKline
- Johnson & Johnson
- Merck & Co., Inc.
- Novartis
- Novo Nordisk
- Otsuka Pharmaceutical Inc.
- Pfizer Inc.
- Sanofi
- Shire
- Takeda Pharmaceuticals

MISSION

The IPPC works to promote responsible privacy and data protection practices by the 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

APPENDIX B: PRIVACY GUIDELINES FOR MARKETING TO U.S. CONSUMERS

This document sets forth voluntary privacy guidelines for marketing by pharmaceutical companies to U.S. consumers. These guidelines are aspirational in nature. Companies endorsing this document aim to follow these guidelines in their day-to-day business operations in connection with the collection, use, disclosure, and maintenance of written and electronic personal information that identifies an individual consumer and is retained by a company for marketing purposes. These companies also take steps to ensure that vendors who may communicate with consumers on their behalf comply with these guidelines or applicable privacy and data protection laws.

I. NOTICE

1. When personal information is collected directly from consumers, inform those consumers about:

   (a) the identity of the entity collecting the information;

   (b) the purposes for which the information is being collected;

   (c) the types of third parties to whom the information may be disclosed; and

   (d) where provided, the means by which consumers can access and amend personal information about themselves.

2. Where the means by which personal information is being collected is not obvious (e.g., passive or automatic collection of information through website tracking), include a notice of this fact in a privacy statement.

3. When personal information about a consumer that will be used to market to that consumer is received from a third party, obtain assurances from that third party that notice was provided to the consumer and that appropriate permissions were obtained to share the personal information with the pharmaceutical company.

II. PERMITTED USES AND DISCLOSURES

1. Limit uses of personal information collected or received to:

   (a) those that are compatible with the purposes indicated in the notice given. Maintain processes to enable consumers to withdraw permission (opt-out) at any time and process such requests within a reasonable timeframe;

   (b) those that have been subsequently authorized by the consumer;

   (c) those that are necessary to comply with a legal or ethical obligation;

   (d) those that are necessary to ensure compliance with applicable laws and to detect and prevent inappropriate acts or practices, or to investigate, make or defend a legal claim; and

   (e) those that have been requested by governmental authorities.

2. Limit disclosures of personal information collected or received to:

   (a) others working for or on behalf of the company;

(b) others with whom the company jointly markets products or services;

(c) those that are compatible with the notice given at the time the information was collected;

(d) those that are incidental to permissible uses of the information;

(e) third parties to whom the consumer has authorized disclosure;

(f) in the event of a sale or transfer of the business, successors and assignees;

(g) those that are necessary to investigate, make or defend a legal claim; and

(h) those that have been requested by governmental authorities or compelled by legal process.

III. Access and Amendment

When contacted by a consumer who has provided appropriate verification of his or her identity with a specific request related to personal information, work reasonably with that individual to address his or her specific concern.

Circumstances that may prevent a company from fully complying with an individual's request include those that would:

- affect the company's ability to comply with a legal or ethical obligation;
- affect the company's ability to detect and prevent inappropriate acts or practices, or to investigate, make or defend a legal claim;
- result in the disclosure of proprietary information; or
- result in the disclosure of personal information of other individuals.

IV. Security

1. Take reasonable precautions to protect personal information from loss and misuse, as well as unauthorized access, disclosure, alteration and destruction, commensurate with the sensitivity of the information processed.

2. Obtain assurances from vendors that they will protect personal information from loss and misuse, as well as unauthorized access, disclosure, alteration and destruction, commensurate with the sensitivity of the information processed, and that they will promptly notify the company of security incidents involving personal information.

3. Promptly investigate security incidents involving personal information and provide appropriate notice in accordance with applicable law.

V. Enforcement

1. Employ appropriate measures to receive and, as appropriate, respond to privacy complaints and requests.

2. Adopt appropriate measures and take corrective actions against employees who are found to have violated company privacy policies. Take appropriate corrective actions against agents who have violated privacy policies or law.