International Pharmaceutical
PRIVACY CONSORTIUM

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June 4, 2010

Representative Rick Boucher
U.S. House of Representatives
2187 Rayburn HOB
Washington, DC 20515

Re: Representative Boucher Proposed Privacy Bill

Dear Representative Boucher:

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 research-based, global pharmaceutical companies. The IPPC is committed to the promotion of sound policies for the protection of patient privacy and advancement of drug development and treatment. Information concerning IPPC membership and its mission is provided in Appendix A.[1]

We appreciate this opportunity to present our views on the privacy legislation discussion draft issued by you and Representative Stearns early last month. More specifically, we intend to address the following aspects of the proposed legislation:

1) The requirement to give notice "in writing" for collection conducted via means other than the Internet;

2) The extent and impact of the "Required Information" for giving adequate notice to consumers;

3) The proposed legislation's enforcement strategy and preemption of state and local laws;

4) The proposed legislation's potential impact on critical research activities; and

5) The proposed legislation's impact on marketing practices.

In the next four sections, we will illustrate how the proposed legislation may impact IPPC principles and activities that are intended to help provide both important personal health information and privacy and security protections to consumers.

I. Section 3 Notice and Consent Requirements

A. Manual Collection of Information by Means Other than Through the Internet (Sec. 3(a)(2)(A)(ii)) and "Express Affirmative Consent"

The proposed legislation contemplates two methods by which a covered entity collects covered information – those that take place in the context of the Internet and those that do not. While the pharmaceutical industry does use the Internet for many of its activities, a significant portion of its

[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.

interaction with health care providers and health care consumers occurs "off-line." Section 3(a)(2)(A)(ii) of the proposed legislation requires that "if the covered entity collects covered information by any means that does not utilize the Internet, the privacy notice required by this section shall be made available to an individual *in writing* before the covered entity collects any covered information from that individual." (emphasis added).

The IPPC discourages this requirement insofar as it may limit a consumer's ability to obtain necessary health information. Many pharmaceutical company interactions with consumers occur by phone through responses to inquiries and requests for information. Providing written notice to consumers prior to the collection of covered information in this context is not feasible. Under the proposed bill, companies could not obtain basic personal information in order to fulfill a request for information at the time of the request, or to fulfill a specific request of a consumer to enroll in a specific program such as a savings card program, or receive additional information in the future. The unfortunate result of this regulation would be that many consumers would be precluded from receiving information about our products that they explicitly request.

The requirement to provide the required notice also would significantly restrict, if not preclude, the use of a business response card ("BRC") to request information. For example, it is a common practice in many industries to include a BRC in a magazine or journal. As written, the bill would require that a company would be required to print on the BRC the full required notice (which as noted below, could be so long as to preclude its being printed on one side of a BRC) or to include the notice in its advertisement, which again could take up significant space or cause significant increased costs to reprint.

To respond to these situations, the IPPC suggests that you consider other methods for providing notice to consumers, either in an abbreviated manner, or by the provision of a website address posting the required information.

It is noted that there is an exception in the bill for the collection of basic information (name, address, email address) for a "transactional purpose" but the definition of the term "transactional purpose" is unclear. For example, if a person calls for information that might be considered marketing information, is that a transaction or a marketing purpose? It is our view that the fulfillment of any request for information should be deemed a transaction for purposes of the bill.

Further, it is unclear on the face of the legislation what exactly is required to attain "express affirmative consent" from consumers. The IPPC requests clarification in the law on this point, but suggests that overly prescriptive requirements on this front could hinder meaningful communication with patients. The IPPC suggests that express oral or touch-tone consent should be explicitly recognized as adequate to obtain "express affirmative consent" prior to collection and use of health information for which notice and choice have not already been provided to the patient/consumer. Similarly, express oral or touch-tone consent should be explicitly recognized as adequate to obtain "express affirmative consent" for the disclosure of personal health information to an unrelated third party as required under Sec. 3(b)(1) or 3 (c)(2).

B. Required Information (Sec. 3(a)(2)(B))

The notice provided to individuals pursuant to the proposed legislation requires a significant amount of information of varying degrees of difficulty to gather, as some information may be difficult to collect, and to provide. The bill as written will require most companies to create a notice statement that is extremely long, difficult to understand and cumbersome to deliver. For example, subsection (vi) requires notification of "how the covered entity may merge, link, or combine covered information collected...with other information…acquire[d] from unaffiliated parties." This notification paragraph alone covers a sufficiently broad amount of information such that compliance could result in a notice policy, as long as, if not longer than any privacy policies now in place. The ability and proclivity of consumers to both read and understand this notice decreases both meaningful notice and consent. In the context of a telephonic

transaction, for example, this type of notice is impractical. If a company is required to read a full notice statement via telephone, a consumer is likely to end the communication – or disengage – before notice has been properly given.

The IPPC supports the ability of consumers to play an active role in their healthcare by researching health conditions and treatments both online and by contacting its members through off-line methods. The benefits of patient empowerment are described in the attached 2004 IPPC white paper *Dissemination of Prescription Drug Information Enhances Patient Healthcare* (see Appendix B). In order to allow the free flow of information between consumers and health product manufacturers, the transmission of covered information is necessary. The IPPC thus discourages the imposition of overly prescriptive requirements for what must be included in a consumer notice or the form of such notice. We are concerned that laws or regulations requiring lengthy notice will have the unintended effect of preventing consumers' ability to receive important and desired information.

The IPPC believes that consumers should be provided with the choice to decide whether or not their personal health information will be used or disclosed and for what purposes. The IPPC suggests that one method for ensuring adequate notice without hindering important health communication is to allow layered privacy notices or other methods for highlighting uses of health information in lieu of mandatory written or lengthy oral notices.

C. Opt-Out Consent Requirements (Sec. 3(a)(3))

The IPPC also asks that the bill be clarified to make it clear that the requirement under Section 3(a)(3) which provides that if an individual opts out, that the collecting entity can no longer use covered information that was previously collected, will not override other federal laws, such as HIPAA that specifically permit the right to use information even if authorization is subsequently withdrawn.

We recognize that the legislation states that it has no effect on activities covered by HIPAA. It is unclear, however, whether and how this exemption would apply outside the context of HIPAA covered entities. For example, HIPAA covered entities may disclose health information to a pharmaceutical company pursuant to an authorization. The subsequent use and/or disclosure of the information by the pharmaceutical company, which is not a HIPAA covered entity, is technically not covered by HIPAA. This issue is exacerbated by the fact that the proposed legislation's definition of "covered data" could possibly include pseudonymized data, as the definition includes any data associated with "[a]ny unique persistent identifier, such as a customer number, unique pseudonym or user alias, Internet Protocol address, or other unique identifier, where such identifier is used to collect, store, or identify information about a specific individual." Pharmaceutical companies receive key-coded data pursuant to patient authorization in clinical trials, and any restrictions or requirements that the proposed legislation places around the use and/or disclosure of such data would be problematic. The IPPC, therefore, urges you to clarify this point in the law and explicitly exempt the patient authorization scenario from the proposed legislation's application.

D. Express Consent for the Disclosure of Sensitive Information (Sec. 3(c)(2))

In Section 3(c)(2) of the bill, in the case of sensitive information, a covered entity cannot collect sensitive information about a person without the affirmative consent of the person to whom the information relates. In the health care area, this requirement could put significant barriers on caregivers for patients whose health conditions render them unable to give consent to the collection, or for whom obtaining consent would be impractical, if not impossible. For example, under this provision, a caregiver of an Alzheimer's patient or mental health patient may not be able to request a savings card or participation in a health care program on behalf of the patient since obtaining the patient's consent might not be possible. Similarly, a doctor could not request enrollment on behalf of a patient without the patient's specific consent to the company at the time of enrollment.

II. Enforcement Strategy and Preemption

The IPPC supports the proposed legislation's enforcement strategy as outlined in Sections 8 and 9. More specifically, we agree that the Federal Trade Commission should be granted authority to intervene in actions brought by the states' Attorneys General, and to preempt those actions where the Commission has already instituted an action. Likewise, the IPPC believes that any resulting legislation should not provide a private right of civil action relating to regulated activities but that enforcement should be handled solely by the government.

The IPPC also supports the proposed legislation's preemption of state and local laws that include requirements for the collection, use or disclosure of covered information, as outlined in Section 10. For businesses that operate throughout the US, keeping track of varied, and sometimes conflicting, state and local requirements is a significant compliance burden that this legislation would address.

III. Impact on Research Activities

In implementing new protections to ensure consumers are provided with notice and choice around the use and disclosure of their personal information, care must be taken to avoid creating impediments to the use and disclosure of health information for biomedical research purposes and public health activities. A clear delineation must be made around the standards that apply to the collection and use of personal health information for marketing purposes versus the collection and use of personal health information for scientific research. The IPPC believes that in light of the complexity of ethical issues related to biomedical research, some of which we describe further below, and in order to avoid inconsistencies with other laws and regulations applicable to biomedical research, the regulation of uses and disclosures of personal health information for biomedical research purposes should be addressed through a uniform approach to health research, such as the approach recommended by the Institute of Medicine in its report *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*.[2]

Personal health data is essential for, *inter alia*, conducting research involving genetics and biomarkers,[3] seeking genetic patterns in the safety and effectiveness of drug therapies, determining the safety and effectiveness of new treatments, and locating appropriate participants for clinical research studies. Despite the clear importance of the ethical principles of respect for persons and autonomy, which serve as the basis for informed consent requirements, these principles are not absolutes and must be balanced with other ethical principles, such as beneficence. Beneficence requires that members of society recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel treatments.

Informed consent was originally conceived as a protection against physical harm to patients, permitting informed, competent patients to refuse unwanted medical interventions and to ensure patients were informed of the physical risks involved in medical research. However, informed consent has come to be used as protection against a broad range of nonphysical harms, such as breaches of privacy and confidentiality. The reliance on notice and choice as the basis for permitting analysis of patient information for pharmacoepidemiological research[4] or using biospecimen samples for biomarker and genomics research is becoming increasingly unworkable. Several alternative ethical frameworks to notice and choice have been proposed for balancing patient privacy interests and researchers' data needs. These include:

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[2] IOM (Institute of Medicine). 2009. *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research.* Washington, DC: The National Academies Press.

[3] 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.

[4] Pharmacoepidemiology is the study of the use and effects of drugs in populations.

(i) Research subjects treated as donors (Subjects as Donors Model). In this Model, the law of property with respect to inter vivos gifts is applied to informational privacy. In essence, the idea is simply that where there is (1) present intent of a human subject to donate his biological materials or health information, (2) delivery of the sample or information in question by the subject to the researcher, and (3) acceptance of the gift by the researcher, the researcher becomes the 'owner' of the samples or information immediately and absolutely.[5]

(ii) Reciprocity as a guiding principle (Reciprocity Model). The reciprocity model seeks to address the situation where there is no consent for future research uses (whether specified or unspecified). Its proponents argue that by accepting the benefit of past medical research (which is inherent in the use of medical services), a patient agrees to allow the use of health information about him or her in future research for the common good.[6]

(iii) Informational restrictions narrowly tailored to address the specific risks associated with unauthorized use of that information (Harms-Based Model). Potential harms associated with the unauthorized use of personal health information include discrimination and stigmatization; and an erosion of the doctor-patient relationship, leading to compromises in health care. To address these risks, a harms-based model might call for the adoption of non-discrimination legislation and a requirement that entities with a legitimate need for health information secure the information against unauthorized access.

(iv) Alternative construction of the fair information practice principles of notice and choice to develop other models of transparency such as one-time general consent for biobanking or genomics research, global publication of research results, and reporting validated results to specific groups of donors who elect to be notified directly.

IV. Marketing

A. IPPC Practices and Recommendations

As addressed above, the free flow of information between consumers and health product manufacturers is critical to a patient's ability to become fully engaged in his or her health care. The IPPC developed in 2008 the attached *Privacy Guidelines for Marketing to U.S. Consumers* (see Appendix C) which we believe strike the appropriate balance between enabling the free-flow of information between consumers and health product manufacturers and preventing unwanted marketing uses and disclosures of personal information.

The IPPC supports a consumer's choice to decide whether or not their personal health information will be used or disclosed for marketing purposes. Section 3(d) of the proposed legislation requires the above discussed lengthy notice and express consent for the collection or disclosure of all or substantially all of an individual's online activity. We propose that meaningful notice and consent can be provided for marketing by adhering to the following guidelines, some of which have been noted earlier:

- Layered privacy notices or other methods for highlighting marketing uses of health information should be considered.

[5] *cf. Wash. U. v. Catalona* (8th Cir. 2007).
[6] *See* Edison T. Liu, *The Importance of Research Using Personal Information for Scientific Discovery and the Reduction of Disease,* in Personal Information for Biomedical Research (Singapore Bioethics Advisory Committee, May 2007) at Annex A. *See also* B.M. Knoppers and R. Chadwick, *Human Genetic Research: Emerging Trends in Ethics*, 6 Nature Rev. Genetics (Jan.) at 75-79.

- Express permission should be obtained before health information is used for marketing purposes for which notice and choice have not already been provided to the patient/consumer.
- If a third party provides remuneration in exchange for marketing communications to be made about that third party's products or services, each marketing communication should include an indication of this fact in addition to other notices of this fact that may have been previously provided.
- Patients/consumers should be provided with the ability to opt-out of receiving further marketing communications.

Consumers should have the right to decide for themselves the scope of marketing permission they wish to grant, including whether to provide consent solely for a specific product or a range of products for a particular disease state.

In addition to providing consumers with the ability to opt-out of receiving further marketing communications, the IPPC supports providing consumers with the ability to find out how their personal health information was obtained by a pharmaceutical company. It should be understood, however, that it may not be possible for a company to pinpoint the source of a particular element of information as information may be aggregated from multiple sources.

The members of the IPPC follow reasonable procedures to ensure that personal information that is obtained from third parties is being provided to companies with the consumer's consent. However, aside from contractual requirements that the third party data provider obtained consent for the data sharing, there may be little a pharmaceutical company can do to verify what has been represented. Where representations have been made about the source of a consumer list and permissions associated with that list, accountability for unauthorized uses and/or disclosures of the information should rest with the party making such representations, should they later prove false or misleading.

B. Commitment to Privacy in U.S. Consumer Marketing: Myths and Facts

The IPPC is aware that there may be certain misperceptions about how pharmaceutical companies collect and use personal health information, and we have therefore developed the attached document entitled *Commitment to Privacy in U.S. Consumer Marketing: Here Are the Facts* (see Appendix D, adopted in 2008) to help correct these misunderstandings. This document is intended to make clear the following points:

- Pharmaceutical companies do not purchase identifiable patient health data (i.e., information relating to the medical conditions or treatments of named or otherwise identifiable patients) from pharmacies and health plans in order to market their products and services.

- Pharmaceutical companies do not have access to written and electronic health records in order to send consumers targeted marketing communications without their permission. As further described in the Appendix, pharmaceutical companies may sponsor compliance and other treatment-related programs offered through pharmacies and health plans.

- Records from clinical research studies sponsored by pharmaceutical companies are not reused for marketing purposes.

- Spam email is not sent to consumers by pharmaceutical companies for the purpose of advertising prescription drugs.

V. Conclusion

Finally, the IPPC appreciates the opportunity to engage in dialogue with you on the development and impact of the proposed legislation. The IPPC has similarly engaged with the FTC, providing comments to the FTC in relation to its Privacy Roundtable event, and we are eager to continue this conversation. We believe that further consideration about how this legislation would affect biomedical research and public health activities is warranted. Therefore, we encourage you to have further dialogue with the IPPC and other relevant groups to delve more deeply into these issues before taking any further action with respect to the proposed legislation.

We thank you for your consideration of our comments and would welcome the opportunity to discuss these issues with you. Please do not hesitate to contact us with any questions.

Sincerely,

International Pharmaceutical Privacy Consortium

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:

- Abbott Laboratories
- AstraZeneca
- Baxter International
- Bristol-Myers Squibb
- Elan Pharmaceuticals, Inc.
- Eli Lilly and Company
- GlaxoSmithKline
- Merck & Co., Inc.
- Novartis
- Pfizer Inc.
- Genentech (Roche)
- Sanofi-aventis
- Takeda Pharmaceuticals

MISSION

The IPPC was formed in 2002 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

APPENDIX B: DISSEMINATION OF PRESCRIPTION DRUG INFORMATION ENHANCES PATIENT HEALTHCARE

I. Consumer-Directed Information

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

A. Background

The most important healthcare relationship is between patient and physician. While this relationship is vital to each patient's medical care, patients also obtain valuable health-related information from other sources. The wide availability of health information on the Internet and through other sources has empowered individuals to learn more about health conditions and treatments.[i]

While the majority of prescription drug promotional and educational activities is directed toward physicians[ii], pharmaceutical companies also provide a range of information to consumers. Consumer-directed information about medical conditions and new and existing prescription drugs and devices is provided in many different forms and media. On company web sites, consumers can access information, sign-up to receive newsletters, or request brochures and other product-related materials. Many companies operate call-centers, enabling patients to request materials over the phone. Pharmaceutical companies provide materials to physician offices, hospitals, clinics, and other medical centers for distribution to patients. Companies sponsor pharmacy programs designed to promote patient adherence to physician-prescribed treatments. Companies also work with health care providers and health plans to promote disease management.

Information provided by pharmaceutical companies on prescription drugs, unlike much other healthcare information (*e.g.*, medical information on the Internet, information on alternative medicines), is subject to intense regulatory scrutiny by the Food and Drug Administration (FDA). FDA protects public health by helping to ensure that pharmaceutical manufacturers provide truthful, balanced, and accurate health-related information to consumers and patients.[iii] In recent draft guidance on drug product advertisements, FDA noted that available data and information, including results of FDA's own research, have led the Agency to believe that consumer-directed promotion of prescription drugs can convey useful health information to patients.[iv]

B. Benefits of Consumer-Directed Information

- ***Empowers Patients with Information***. Consumers who recognize disease symptoms and understand treatment options can more effectively seek appropriate care and make better-informed health decisions.[v] 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.

- ***Encourages 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. FDA consumer surveys in 1999 and 2002 demonstrate that consumer-directed prescription drug information encouraged substantial numbers of patients to ask a doctor about a previously untreated medical condition or illness.[vi] Moreover, 93% of patients prompted by pharmaceutical advertising to discuss a drug with their doctor report that their doctor welcomed the question.[vii]

- ***Decreases Patient Inhibitions in Addressing Sensitive Conditions***. Consumer-directed information about available prescription therapies encourages patients to speak with physicians 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 their physicians their symptoms and possible treatments.[viii]

- ***Promotes 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. Data from FDA show that about one-third of patients fail to take their medications as prescribed. Parental non-compliance with drug therapies prescribed for their children exceeds 50%, and non-compliance among elderly patients ranges from 26% to 59%.[ix] Industry-sponsored communications, such as refill reminders and other consumer-directed information, facilitate medication compliance.[x] Direct-to-consumer prescription drug advertisements prompt patients to take their medicine regularly and refill prescriptions as necessary.[xi]

II. Physician-Directed Information

By providing scientific and educational information about prescription products, pharmaceutical sales representatives enhance the ability of healthcare providers to care for patients. Sales representatives meet with physicians to provide product information, answer questions regarding the use of their products, and deliver product samples. Ongoing research and development into safer and more effective medicines means that treatment standards are constantly evolving. It is important that healthcare professionals have the latest, most accurate information available regarding prescription medicines.

Prescription medicines play an ever-increasing role in patient healthcare, and it is critical that healthcare providers receive the latest information on the benefits and risks of those medicines. Traditionally, on-site visits by sales representatives have enabled physicians to get needed information and product samples with minimal disruption to patient care. In turn, direct interactions with physicians have enabled manufacturers to receive important product feedback.

As the external pressures of managed care place increasing demands on providers' time and focus, pharmaceutical companies have responded by delivering targeted information based on the needs and preferences of individual practitioners. Historical data on filled prescriptions (deidentified as to individual patients) helps pharmaceutical companies to understand the range of health conditions served by individual providers. This knowledge in turn enables companies to determine which product information is likely to be of most use to those providers. The ability to tailor information to individual provider needs is important not only to informing physicians of product advances and advantages, but also to alerting prescribers to newly discovered drug interactions and adverse events.

The delivery of high-quality healthcare depends upon the successful collaboration of multiple players. Pharmaceutical companies serve an important role by providing patients and physicians with necessary information.

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[i] The Internet and advertising provide patients with increased access to health care information. For example, 24% of online information relates to healthcare and more than 50% of adults who access the Internet use it for health-related information. (Lyn Siegel, "DTC Advertising: Bane or Blessing?" *Pharmaceutical Executive*, October 2000).

[ii] Rosenthal M, Berndt E, Donohue J, Frank R, Epstein, A., "Promotion of Prescription Drugs to Consumers," *New England Journal of Medicine*, Vol. 346, No. 7, February 14, 2002.

[iii] Statement of Dr. Janet Woodcock, Director, CDER, FDA, before the Senate Special Committee on Aging, July 22, 2003, Hearing on Direct-to-Consumer Advertising of Prescription Drugs: What Are the Consequences?

[iv] Draft Guidance for Industry, "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements," p. 7, January, 2004, http://www.fda.gov/cber/gdlns/consumad.pdf.

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[v] For instance, in industry guidance FDA has commented: "FDA believes that disease awareness communications can provide important health information to consumers and health care practitioners, and can encourage consumers to seek, and health care practitioners to provide appropriate treatment. This is particularly important for under-diagnosed, under treated health conditions, such as depression, hyperlipidemia, hypertension, osteoporosis, and diabetes." Draft Guidance for Industry, "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms, p.1, January, 2004, http://www.fda.gov/cber/gdlns/helpcomm.pdf.

[vi] Statement of Dr. Janet Woodcock, Director, CDER, FDA, before the Senate Special Committee on Aging, July 22, 2003, Hearing on Direct-to-Consumer Advertising of Prescription Drugs: What Are the Consequences?; See also Direct to Consumer Advertising of Prescription Drugs: Preliminary Patient Survey Results at http://www.fda.gov/cder/ddmac/DTCnational2002a/; See also 2000 Scott Levin survey reporting that 56% of physicians agree that direct-to-consumer advertising brings in patients to seek treatment that would otherwise go untreated.

[vii] Direct to Consumer Advertising of Prescription Drugs: Preliminary Patient Survey Results at www.fda.gov/cder/ddmac/DTCnational2002a/sld001.htm.

[viii] David M. Cutler and Mark McClellan, "Is Technological Change in Medicine Worth It?" Health Affairs, Vol.20, No. 5, September/October 2001, noting the significant treatment expansion for persons with clinical depression.

[ix] 60 *Fed. Reg.* 44,182, 44,286 (Aug. 24, 1995). See also Sullivan, S.D., *et al*., "Noncompliance with Medication Regimes and Subsequent Hospitalization: A Literature Analysis and Cost of Hospitalization Estimate," Journal of Research in Pharmaceutical Economics, 1991, stating that 5.5% of all hospital admissions are due to non-compliance, resulting in $8.5 billion annually in unnecessary hospital-related expenditures, plus another $17-$25 billion in estimated indirect costs; See also Berg, *et al*., *The Annals of Pharmacotherapy*, 27 (9): S3-S22 (1993), finding that patients who do not adhere to drug therapy cost the U.S. health care system an additional $100 billion each year.

[x] *See, e.g.,* JS Benner (Brigham and Women's Hospital / Harvard Medical School), DA Ganz (Brigham and Women's Hospital / Harvard Medical School), et al. "Is It Cost-Effective to Improve Compliance with Lipid-Lowering Therapy?" (concluding that compliance-enhancing interventions appear to be an attractive way to recover some of the clinical benefits that are lost due to noncompliance with statins and that the most cost-effective intervention was to provide patient education and refill reminders via the mail and telephone); Ross T. Tsuyuki, Jeffrey A. Johnson, et al., "A Randomized Trial of the Effect of Community Pharmacist Intervention on Cholesterol Risk Management," *Arch. Intern. Med.* 162: 1149-75, 2002 (concluding that pharmacist intervention improved cholesterol management in high-risk patients).

[xi] 5th annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines, Emmaus, PA, Rodale, 2001-2002, reporting that 17% of consumers stated that direct to consumer advertising made it more likely (versus 2% less likely) that they would take their medicine regularly and 12% stated that these ads made them more likely to refill prescriptions.

APPENDIX C: 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.

Policies or practices for addressing these guidelines vary by company. For information on an individual company's privacy practices, please refer to the company links at the end of this document.

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.

Endorsing Companies *(as of March 7, 2008)*

Abbott Laboratories	Website Privacy Policy: http://www.abbott.com/global/url/content/en_US/0:0/general_content/General_Content_00029.htm
AstraZeneca Pharmaceuticals	Privacy Statement: http://www.azprivacystatement.com
Bristol-Myers Squibb	Internet Privacy Statement: http://www.bms.com/legal/data/privacy.html
Eli Lilly and Co.	Website Privacy Statement: http://www.lilly.com/privacy.html
Johnson & Johnson	Website Privacy Policy: http://www.jnj.com/privacy_policy/index.htm
Merck and Co., Inc.	Internet Privacy Policy and Privacy Notice for U.S. Patients, Consumers and Caregivers: http://www.merck.com/policy/commitment/home.html
Pfizer	Privacy Policy: http://www.pfizer.com/general/privacy_policy.jsp
Roche	Online Privacy Statement: http://www.rocheusa.com/privacylegal/privacy.asp
sanofi-aventis	Online Privacy Policy: http://legalnotice.sanofi-aventis.us/
Schering-Plough Corp.	Online Privacy Notice: http://www.spfiles.com/policy/IWW0341.jsp?site=www.schering-plough.com&wm=privacyoffice@spcorp.com
Takeda Pharmaceuticals	Website Privacy Policy: http://www.tpna.com/privacy.asp

International Pharmaceutical PRIVACY CONSORTIUM

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APPENDIX D: COMMITMENT TO PRIVACY IN U.S. CONSUMER MARKETING: *HERE ARE THE FACTS*

The International Pharmaceutical Privacy Consortium is comprised of research-based pharmaceutical companies that are actively addressing privacy issues. Our ability to access and use personal information is critical to the work we do in researching and developing medicines and communicating with our customers. We have developed this document to better inform the U.S. public of our practices for respecting and protecting personal information in consumer marketing.

Myth 1:	*Pharmaceutical companies purchase identifiable patient health data (i.e., information relating to the medical conditions or treatments of named or otherwise identifiable patients) from pharmacies and health plans in order to market their products and services.*

Fact:

Pharmaceutical companies DO NOT purchase identifiable patient health data from pharmacies or health plans. In fact, most pharmacies and health plans are prohibited by law from disclosing identifiable patient health information to any third parties for marketing without the explicit permission of the patient.

Anonymized, Aggregated Data

Pharmaceutical companies do purchase anonymized, aggregated health data for research purposes. Anonymized, aggregated data do not contain patient identifiers such as name, address, or other contact information; such data may include age, dates and geographic information. Anonymized, aggregated data are used, for example, to study the incidence, distribution and control of disease and to enable the development of programs that are designed to improve patient health outcomes.

Compliance and Adherence Programs

In addition, pharmaceutical companies may sponsor compliance and other treatment-related programs offered through pharmacies and health plans. For example, some pharmacies send refill reminders to customers when their prescription is due for refilling, and the program may be sponsored by a pharmaceutical company. The sponsoring company IS NOT provided with access to the customer records or any other identifying information about the customers to whom the refill reminders are sent unless the customer provides explicit permission. The sponsoring company often requires the program provider (i.e., the pharmacy or health plan) to provide its customers with the ability to decline these refill reminders (in some states, this is required by law).

Patient Assistance Programs

Pharmaceutical companies may receive identifiable patient health information from health plans to verify a person's eligibility for patient assistance programs or prescription discount programs. The information is usually transferred with the patient's explicit consent, and identifiable patient health information received under these circumstances is used solely for such programs.

Myth 2:	*Pharmaceutical companies have access to written and electronic health records in order to send consumers targeted marketing communications without their permission.*

Fact:

No, pharmaceutical companies do not have access to written and electronic health records in order to send consumers targeted marketing communications without their permission. Pharmaceutical companies send direct-to-consumer (DTC) marketing communications and offerings to individuals who have signed up and given their permission to receive such materials. DTC marketing and related programs are always *permission-based* (in certain states, this is required by law) and consumers usually have the ability to withdraw permission at any time. Consumers may provide permission via company web sites and call centers, business reply cards, or other avenues. In some cases, permission is obtained by a third party who then, in turn, provides the consumer's contact information to the pharmaceutical company.

Pharmaceutical companies do have an interest in obtaining anonymized, aggregated health data for scientific research purposes in order to design programs to improve patient health outcomes. For example, anonymized, aggregated data are a valuable source of information for studying the incidence and spread of disease or analyzing and comparing the cost-effectiveness of different drug therapies and the cost of hospitalization.

Myth 3:	*Records from clinical research studies sponsored by pharmaceutical companies are reused for marketing purposes.*

Fact:

No, such records are not reused for marketing purposes. In the course of a clinical study, medical records are generated or received by the physician or other medical professional under whose direction an investigational drug is given. This person is called an "investigator." Investigators maintain the medical records of study participants and report the study-related data back to the sponsor of the study. As sponsors of clinical studies, pharmaceutical companies receive data which has had the identities of participants replaced with unique codes, the keys to which are held by the investigators. Pharmaceutical companies do not receive those keys and do not receive the names or other contact information of study participants, except in very limited circumstances as described below.

First, a sponsor may be given the contact information of a study participant who has experienced an adverse event if further information is necessary for analysis of possible safety issues. Such contacts are a standard component of pharmacovigilance, the science of activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. Employees of the sponsor who are responsible for conducting pharmacovigilance activities are bound by obligations of confidentiality covered by the company's employment contracts, policies or standard operating procedures.

Second, sponsors are given access to the medical records held by investigators to verify that the scientific data reported to the sponsor matches what is recorded in the investigator's copy of the records. Sponsor personnel involved in conducting such on-site quality inspections are required to maintain the confidentiality of patient identities and may not share this information for unrelated purposes.

Prior to enrolling a patient in a clinical study, investigators are required to explain what data will be collected, how it will be used, and to whom and for what purposes it will be disclosed. The patient's consent is documented in a written authorization.

Myth 4:	*Spam email is sent to consumers by pharmaceutical companies for the purpose of advertising prescription drugs.*

Fact: **No, pharmaceutical companies do not send spam email. Pharmaceutical companies have no interest in sending customers unwanted email messages. In contrast, drug counterfeiters and illegal distributors often send spam email, in violation of federal law (*i.e.,* the CAN-SPAM Act). Some pharmaceutical companies might send unsolicited emails to consumers who have agreed to receive other emails from the company, but only in limited and unusual circumstances, such as to provide recall or safety information, and the communications would be expected to be in compliance with applicable laws.**