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.**

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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