International Pharmaceutical
PRIVACY CONSORTIUM

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June 27, 2005

By Hand

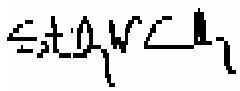
Federal Trade Commission
Office of the Secretary, Room H-159
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: CAN-SPAM Act Rulemaking, Project No. R411008

To Whom It May Concern:

We enclose herewith the comments of the International Pharmaceutical Privacy Consortium on the Notice of Proposed Rulemaking concerning "Definitions, Implementation, and Reporting Requirements Under the CAN-SPAM Act" (70 Federal Register 25426). We appreciate the opportunity to participate in this rulemaking.

Sincerely,



Stanley W. Crosley
Chair

I. Introduction

The International Pharmaceutical Privacy Consortium is an association of research-based pharmaceutical companies formed for the purpose of addressing privacy issues as they affect the core activities of member companies. Its members include Abbott Laboratories, AstraZeneca Pharmaceuticals, Bristol-Myers Squibb, Eli Lilly and Company, Endo Pharmaceuticals Holdings, Elan Pharmaceuticals, Hoffmann-La Roche, Johnson & Johnson, Merck & Co., Novartis Pharmaceuticals, Pfizer, sanofi-aventis[1], Takeda Pharmaceuticals, and Wyeth. On behalf of the above-mentioned members, the Consortium is pleased to submit these comments on the notice of proposed rulemaking concerning "Definitions, Implementation, and Reporting Requirements Under the CAN-SPAM Act" (70 Federal Register 25,426; 12 May 2005) (NPRM).

II. Comments

A. Prohibition Against Failure to Effectuate an Opt-Out Request Within Three Business Days of Receipt

The CAN-SPAM Act prohibits senders from initiating the transmission of a commercial e-mail message to a recipient more than ten business days after senders have received a recipient's opt-out request. In the NPRM, the FTC proposes to shorten the ten business day time period to three business days. FTC states that this modification "is supported by the record that current technology allows for processing such opt-out requests more expeditiously than the current ten-business-day time frame."[2] The IPPC believes that three business-days is too short a period for organizations to process opt-out requests. We provide below two examples of problems with a three business-day opt-out.

- ***Need for Manual Processing of Opt-Outs Sent Via Reply Electronic Mail:*** The CAN-SPAM Act provides that a commercial email message must include "a functioning return electronic mail address or other Internet-based mechanism" that a recipient may use to opt-out of receiving future messages. It is not uncommon for businesses to provide a link to a web site for recipients to opt out and yet still to receive opt-out requests via reply email messages. These reply messages must be individually reviewed in order to determine that the individual wishes to opt-out, as well as to determine whether there is other correspondence in the reply email requiring action (***e.g.***, drug adverse event reports).

[1] Sanofi-aventis operates through its affiliates Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals Inc. in the U.S.

[2] 70 Fed. Reg. at 25,442.

» ***Manual Syncing of Suppression Lists:*** In a typical email marketing campaign, a pharmaceutical company will provide a list of email addresses to a third party vendor who initiates the transmission of the message. Opt-out requests sent in response to the message may be received either by the vendor, on behalf of the pharmaceutical company, or by the pharmaceutical company directly. If they are first received by the vendor, they must also be transmitted to the pharmaceutical company for purposes of suppressing those email addresses in the pharmaceutical company's database of recipients. The pharmaceutical company must also transmit the opt-outs to other vendors undertaking separate marketing campaigns. Presently, most companies do not have in place technologies to facilitate automatic syncing of suppression lists.

B. Definition of "Sender"

The CAN-SPAM Act defines "sender" as "a person who initiates [a commercial email] message and whose product, service or Internet Web site is advertised or promoted by the message." In the NPRM, the FTC proposes criteria for identifying the "sender" when more than one person's products or services are advertised or promoted in a single message. Under this proposal, if only one person both is within the Act's definition of "sender" and meets one or more of the following criteria, only that person will be deemed the "sender":

(1) The person controls the content of such message;
(2) The person determines the electronic mail addresses to which such message is sent; or
(3) The person is identified in the "from" line as the sender of the message.

The FTC states that this proposal will enable sellers to structure the sending of an email message so that there is but one "sender," thereby ameliorating obstacles to multiple-advertiser messages.

The IPPC requests that the FTC clarify in the Final Rule that a company will not be deemed to control the content of one of these types of messages simply because it controls the content of the portion of the message that advertises its product, even if this content represents a substantial portion of the message. In order to ensure compliance with FDA regulations concerning prescription drug advertising and promotional labeling, pharmaceutical companies must control the content of advertisements for their own products. Ultimate control over compiling the content of a message that advertises multiple companies' products may reside in the hands of a third party. Message recipients would be able to opt-out of receiving future commercial email messages from this third party.

If control over only a portion of message content were deemed to trigger criterion (1), above, pharmaceutical companies would be unable to participate in email messages advertising or promoting more than one person's products or services where there would be only one "sender." This, in turn, would result in all of the problems of single message / multiple advertiser scenarios highlighted by commenters: the difficulty of providing multiple opt-out mechanisms and valid physical postal addresses in a single message; the burden of maintaining multiple suppression lists; the possible violation of privacy policies and statutes; and frustration of consumer expectations.[3]

The IPPC also requests that the FTC further consider the proposed "sender" definition in the context of co-branded messages. In the pharmaceutical industry, it is not uncommon for products to be co-marketed. When a co-branded commercial email message is sent, it is possible under the proposed definition that both co-marketing partners would be considered "senders" of the message. This is because both partners may approve, and as necessary, require changes to, the content of the message to ensure compliance with FDA regulations. We note that if both partners were considered "senders," opt-out requests would need to be transmitted to and processed by both co-marketing partners. This would be very difficult to achieve within the proposed three business-day time period. The IPPC suggests that the FTC consider adoption of a "safe harbor" under which companies whose products are co-marketed could designate one company as the "sender."

C. Other Comments

The IPPC wishes to register its position on several additional questions the FTC raised for comment in the NPRM.

- The NPRM asks whether the Commission should adopt a safe harbor with respect to opt-out and other obligations for companies whose products or services are advertised by affiliates or other third parties.[4] The IPPC supports the adoption of such a safe harbor.

- The NPRM asks whether email messages whose primary purpose is to deliver newsletters or similar content (***e.g.,*** coupons) should be deemed transactional or relationship messages in situations in which a recipient has entered into a transaction with a sender that entitles the recipient to receive such electronically delivered content, such as by registering to receive such content.[5] The IPPC supports classifying such messages as transactional or relationship messages.

[3] 70 Fed. Reg. at 25,429.
[4] 70 Fed. Reg. at 25,450.
[5] Id.

III. Conclusion

The International Pharmaceutical Privacy Consortium appreciates this opportunity to participate in the FTC's rulemaking on the implementation of the CAN-SPAM Act. We look forward to the Commission's response to these comments.