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Reprint

The FTC-Lilly Consent Decree: What it Means for PHARMA Vendors and Partners

By **John Mack**

"You may be one e-mail away from a [privacy] crisis."
Stan Crosley, Chief Privacy Officer, Eli Lilly

By now, every pharmaceutical marketer should know about the inadvertent e-mail message that led to Eli Lilly becoming the first major pharmaceutical company to settle an online consumer privacy complaint with the FTC. If not, you can read about it on the FTC's Web site (see Resource List, http://www.pharma-mkting.com/resources/index.html).

The consent decree, which remains effective until 2022, requires that Lilly and its "agents…acting within the scope of their authority on behalf of, or in active concert or participation with, Eli Lilly and Company" abide by a four-part information security program described below.

It is noteworthy that the decree extends beyond Lilly itself to its agents who collect personally identifiable information from consumers in "connection with the advertising, marketing, offering for sale, or sale of any pharmaceutical product…"

Such agents could include interactive agencies that build and maintain Web sites, direct marketing agencies, fulfillment centers, market researchers, etc. It behooves these service providers, therefore, to carefully upgrade their own privacy and security practices in order to work with Lilly as well as with other pharmaceutical companies that are now likely to invoke "privacy due diligence" when selecting providers.

Get With the Program

Under the conditions of the decree, Lilly is required to establish and maintain a four-stage information security program designed to establish and maintain reasonable and appropriate administrative, technical, and physical safeguards to protect consumers' personal information against any reasonably anticipated threats or hazards to its security, confidentiality, or integrity, and to protect such information against unauthorized access, use, or disclosure. Specifically, FTC requires that Lilly (and its agents!):

1. designate appropriate personnel to coordinate and oversee the program (i.e., a privacy officer or someone with privacy officer responsibilities)
2. perform a risk analysis to identify internal and external security risks, including "any such risks posed by lack of training"
3. conduct a yearly annual written review to monitor and document compliance with the program
4. adjust the program in light of any findings and recommendations resulting from reviews or ongoing monitoring, and in light of any material changes to Lilly's operations that affect the program

This program serves as a useful model for any company desiring to implement an internal privacy and data protection program, which soon may be required for preferred vendor status at many pharmaceutical companies.

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