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Reprint

MANAGING PRIVACY RISKS IN YOUR COMMERCIAL PRACTICES

By **John Mack**

Since the privacy and security regulations under HIPAA (the Health Insurance Portability and Accountability Act of 1996) do not directly apply to pharmaceutical companies, there's not much need to be concerned, right?

Wrong!, says Allison J. Gassaro, Senior Attorney, NA Legal at Aventis Pharmaceuticals. She was speaking at the **Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum** held November 12 to 14, 2003, in Washington, DC. Her co-presenter was Paul A. Sundberg, Staff Counsel, Commercial Legal Operations at Takeda Pharmaceuticals North America, Inc.

The Effects of HIPAA

Gassaro and Sunberg pointed out that many pharma activities and activities of pharma business partners are affected by HIPAA. On the R&D side, the industry has had to work diligently (and deftly) with health care providers and IRBs to implement HIPAA privacy and security regulations and adjust consent forms for clinical research.

On the commercial side of the business, pharmaceutical sales reps have found that their access to physicians, especially in hospital settings, has been negatively impacted. HIPAA privacy rules, rightly or wrongly, have been cited as one reason.

Gassaro and Sundberg warned against the common misconception that "privacy is the latest flash-in-the-pan. The trend," they say, "is in the opposite direction. HIPAA may have only heightened privacy sensitivities." HIPAA has raised the bar on privacy concerns of patients and physicians and states are passing laws and regulations that directly cover the pharmaceutical industry (see Box).

Pharma Partners Are Also Affected

Privacy issues should also be of concern to agencies that act on behalf of pharma companies to collect personal consumer data (PCD; aka, "personally identifiable information;" see Box, next page). Pharmaceutical companies typically out source many commercial activities that are impacted by privacy regulations. These include sales and marketing activities such as Web site development and maintenance, direct marketing,

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State Privacy Laws of Interest to Pharma & Their Partners

HIPAA is a federal law that specifically acts as a "floor" for medical privacy regulation across the U.S. Individual states, however, are permitted to enact more restrictive legislation, and some are in the process of doing just that, or trying to at least. Here are a few states to watch.

Texas – SB 11/SB 1136 (Texas Medical Privacy Law): This law extends certain HIPAA privacy provisions to pharmaceutical companies and their agencies if they use Protected Health Information (PHI, as defined by HIPAA) for marketing. Specifically, companies must obtain "clear and unambiguous permission" from individuals to use their PHI. Sending "switch" letters to patients, if paid for by a third party (not the pharmacist of physician) is considered marketing.

California – AB 715: This bill adds many types of "marketing" to the list of prohibited uses and disclosures of individually identifiable medical information by health care providers and health plans. It would exclude communications for which the communicator does not receive remuneration from a 3rd party, communications to plan enrollees to inform them of their benefits and plan procedures, unremunerated treatment-related communications, and remunerated "disease management" communications for life-threatening or seriously debilitating conditions with opportunity for patient to opt-out.

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market research, and the collection of physician prescriber data. Other pharma activities impacted are preceptorships (where sales reps or market researchers sit in on patient-physician consultations), and adherence, disease management, and patient assistance programs.

There are signs that as pharmaceutical companies upgrade their privacy and security programs in response to public demand, they also will require vendors to certify that their practices with regard to PCD are compliant with good privacy practices. "Part of the problem facing pharma," notes Gassaro, "is getting your arms around what vendors are doing."

Privacy Best Practices and Compliance

Gassaro points out that there is a need to balance a company's interest in promoting products with the public's demand for privacy. "We not only need to consider our legal obligations," she said, "but also what is the right thing to do. A best practice approach to privacy may in fact be in the company's best interest. This requires developing a coherent privacy program."

Personal Consumer Data (PCD, aka, Personally Identifiable Information)

The Federal Trade Commission (FTC), in its 2002 consent decree with Lilly, defined "Personally identifiable information" or "personal information" as "individually identifiable information from or about an individual consumer including, but not limited to: (a) a first and last name; (b) a home or other physical address, including street name and name of city or town; (c) an email address or other online contact information, such as an instant messaging user identifier or a screen name that reveals an individual's email address; (d) a telephone number; (e) a social security number; (f) an Internet Protocol ("IP") address or host name that identifies an individual consumer; (g) a persistent identifier, such as a customer number held in a "cookie" or processor serial number, that is combined with other available data that identifies an individual consumer; or (h) or any information that is combined with (a) through (g) above."

Gassaro stated that "privacy is another element of compliance." She and Sundberg outlined a verifiable privacy program for pharmaceutical companies, the elements of which include:

- appointing a Chief Privacy Officer or an individual responsible for privacy
- developing policies and procedures for data collection and retention that are consistent with FTC "Fair Information Practice Principles"
- having a policy for choosing vendors that addresses the maintenance and security of PCD and assures that vendors adhere to your privacy policy
- training and education of personnel
- auditing and monitoring of the program
- having an appropriate disciplinary model
- implementing an incident mitigation and response program

These are all elements of a good compliance program and the HIPAA privacy and security regulations, while not directly applicable to pharma, can serve as models for what needs to be done.

Some Practical Advice

When developing a privacy program, Gassaro and Sundberg offered other practical advice. For example, ask yourself what level do you want to achieve: Gold, Silver, or Bronze? "Be sure that your written polices and procedures accurately reflect actual practices and system capabilities," Sundberg warned. "Finally," Gassaro noted, "communicate! Maintain privacy awareness and account-ability among management, employees, affiliates, and business partners."

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State Privacy Laws (continued)

California – AB 68 (Online Privacy Protection Act of 2003): This bill requires operators of commercial web sites or online services that collect personal information on California residents through a web site to conspicuously post a privacy policy on the site and to comply with its policy.

SB 1386 (Security Breach Information Act): This bill requires "Any person or business that conducts business in California, and that owns or licenses computerized data that includes personal information, [to] disclose any breach of the security of the system … to any resident of California whose unencrypted personal information was, or is reasonably believed to have been, acquired by an unauthorized person."

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