

Opinion: Will Privacy Fears Stifle New Medical Frontiers?

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Imagine you brought home a new baby girl today. And along with the standard package of well-baby materials came her electronic medical record. To your fascination, the electronic file was stored on an encrypted card backed up with the federal government in Washington. This file would follow her throughout life, enabling her doctors to detect diseases in their earliest stages.

For the sake of your child's health, you'd have a hard time saying no to that, right?

Then imagine having the peace of mind that your daughter would probably never have an adverse reaction to prescription drugs, because the drugs would be designed specifically for her and the DNA she keeps on file with your preferred pharmaceutical companies.

If this sounds as implausible as a sci-fi novel, think again. These kinds of strides toward personalized medicine are already being made in the pharmaceutical industry and considered in the halls of Congress.

In a speech in March, Eli Lilly CEO Sidney Taurel outlined these advances, promising a biomedical revolution springing forth from the Human Genome Project. These new discoveries, he said, would move medicine from a treatment industry to a prevention industry, eliminating waste and cutting cost.

"The ultimate vision would be to predictably deliver to the patient the right dose of the right drug at the right time," he said.

The stakes are high. According to a [study](#) by the [U.S. Department of Health and Human Services](#) (HHS), between 2% and 7% of hospital

admissions result in adverse drug reactions, with 770,000 injuries and deaths occurring each year.

But will people trust the health care industry, and possibly the government, to collect and share their sensitive health information and comprehensive medical histories in order to improve this situation?

I recently sat down to explore this question with the privacy leaders of pharma giants [Eli Lilly](#) and [Schering-Plough](#). We spoke about where we are with these types of medical advances and the kinds of privacy protections they're requiring.

So, what's the status of e-medical records?

According to Stan Crosley, chief privacy officer at Lilly, HHS is leading the push for the integration of Americans' medical files. HHS's charge is to meet [President Bush](#)'s objective that most Americans will have access to secure e-health records by 2014. To establish the interoperability standards needed to make this happen, HHS formed the [American Health Information Community](#) (AHIC).

According to its Web site, the AHIC foresaw that this amount of data sharing would raise privacy risks, and so last year, it dedicated one of its four working groups to privacy. The co-chairman of this working group is Kirk Nahra, a respected attorney in the privacy industry who is associated with [Wiley Rein LLP](#) in Washington.

"Our main challenges," Nahra told me, "are to balance patient privacy with the goals of this integrated system — better, safer health care and administrative savings; determine if HIPAA needs to be amended to address these new developments; and see if there are other players in the health care arena that need to be covered for the sake of patient privacy."

So, greater file sharing will be coming, along with new privacy standards. And where are we on personalized drugs?

"We're currently producing medicine for people with certain symptoms," Crosley said. "The next step would be developing medicine for people *like* me, and only after that would we get to making medicine for *just* me."

Crosley likened the situation to the next natural outgrowth of a process that started 75 years ago. Using the evolving treatment of diabetes as a reference point, Crosley said people who developed the disease before 1920 were treated primarily with starvation therapy to prolong their lives.

An "overnight change" occurred in the 1920s after the University of Toronto and Lilly collaborated to bring insulin to the market. Many diabetics subsequently started to live extended lives with regular insulin shots.

Through subsequent research over the next decades, Crosley explained, additional treatments were developed that differentiated between Type I and Type II diabetics. With a little more information about diabetes patients, they could be appropriately diagnosed and more effectively treated. More personal information, better treatment.

Further research and additional familiarity with the personal health of diabetics led to a deeper understanding of peripheral neuropathy among diabetics and the dangers associated with it, such as damage to limbs and extremities that led to limb amputation, as well as the heightened risks of smoking to some diabetics, Crosley elaborated.

"More closely personalizing medicines so that we can achieve the goal of providing the right dose, of the right drug, at the right time, is just the next logical progression," Crosley said.

So what is the pharmaceutical industry doing to address the privacy issues associated with these medical advances?

According to Dean Forbes, senior director of global privacy at [Schering-Plough](#), the [International Pharmaceutical Privacy Consortium](#) has become the locus of industry collaboration on privacy. Formed in 2002 by Lilly, [Pfizer](#) and Abbott Laboratories, the IPPC now comprises these three, Schering-Plough and 10 other research-based, global pharmaceutical companies: AstraZeneca, Bristol-Myers Squibb, Elan Pharmaceuticals,

GlaxoSmithKline, Johnson & Johnson, Merck & Co., Roche, Sanofi-Aventis, Takeda and Wyeth.

A team from the Washington office of law firm [Drinker Biddle & Reath LLP](#) coordinates the consortium and serves as its legal counsel.

According to Mary Devlin Capizzi, an attorney at the firm, "The IPPC mission is threefold: to provide a forum for pharmaceutical industry consideration of best practices for protecting personal information; to develop proposed solutions and tools for managing personal information and keeping it secure; and to engage government and stakeholders in a constructive dialogue on significant issues of data privacy."

Neither Crosley nor Forbes sees the new medical advances getting ahead of the necessary privacy protections. They noted that protecting patient privacy is already ingrained in the culture of medical research and reflected in U.S. federal regulations protecting research subjects.

"The industry appreciates that the rights, safety and well being of the research subject are paramount," Crosley said. "Patient privacy and confidentiality have, and will continue to be, one of our foremost considerations."

So, will Americans be sharing more of their personal health information with their health care networks in the future? Undoubtedly. The benefits will be too great to pass up. And will that sharing increase the need for greater privacy protections? Clearly. But will industry deliver on those protections? The early work of the AHIC and the IPPC are good signs that this is already happening.

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