PATIENT SAFETY BLOG

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Protecting Prescription Histories in the Era of Data Mining

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Pharmaceutical companies love dish about doctors and patients almost as much as they love drug profits. One source of information they like to plunder to expand their markets is doctors' prescribing histories. These "who," "what," "why" reports are one component of so-called "data mining" that has gotten much attention lately as a sometimes sneaky way to unearth potentially sensitive information.

The companies buy the reports from prescription drug intermediary (PDI) agencies that, as explained in an article in the New England Journal of Medicine, collect the prescription records from pharmacies and link them to physician information purchased from the American Medical Association.

Pharma sales representatives crunch the numbers in order to refine their sales pitches when they visit doctors' offices. Critics of this process, known as "detailing," claim that it:

- raises costs by increasing the use of brand-name drugs;
- jeopardizes patient safety through wider uses of drugs that haven't been studied appropriately; and
- compromises the privacy of doctors and their patients.

Patrick A. Malone Patrick Malone & Associates, P.C. 1331 H Street N.W. Suite 902 Washington, DC 20005 pmalone@patrickmalonelaw.com www.patrickmalonelaw.com 202-742-1500 202-742-1515 (fax) As the NEJM writers note, several states have passed laws to curtail detailing and restrict PDIs from providing prescribing information that identifies physicians. One PDI/pharma effort challenged a law in Vermont that prohibited pharmacies and PDIs from selling/licensing/exchanging prescriber-identifiable prescription information and from permitting its use for drug promotion. The case ended up in the U.S. Supreme Court on the claim that it unconstitutionally restricted free speech.

How information that is supposed to be private between a doctor and a patient can qualify as free speech seems preposterous on its face, but the court ruled in favor of the commercial interests in a long and carefully parsed finding that Vermont was biased against detailers and their free speech.

The authors of the NEJM article looked at both sides of the issue. "If laws like Vermont's were to become widespread," they wrote, "they would undercut pharmaceutical companies' ability to detail physicians effectively, with the probable consequence that detailing would be greatly reduced. Although this outcome might well reduce the cost of prescription drugs, it would also reduce the amount of information that doctors receive. ... detailing can have educational value. For all its problems, detailing — like its troublesome cousin, direct-to-consumer advertising — is probably of some benefit to patients."

They explain that PDI databases are used to benefit public health as research material, and if PDIs were deprived of data-mining income, they might not invest in keeping such complete records. They also explain that landmark legislation to protect patient privacy remains strong. "[T]he Court defended the patient privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, noting that HIPAA imposed a general ban on disclosure except in 'a few narrow and well-justified circumstances.' Although the Court did little to define the boundary between unconstitutional laws such as Vermont's and sacrosanct ones such as HIPAA, it is clear that some restrictions on data sales will, if tailored finely and fueled by strong governmental interests, survive."

The writers suggest that data-mining prohibitions could survive judicial scrutiny if they:

- broaden the ban so as not to finger only drug marketers; and
- sharpen the focus on privacy issues.

In other words, the authors found reason for hope that this one decision does not establish an impenetrable precedent for commerce to boost drug costs, pose a threat to public safety and invade private files.

Patrick A. Malone Patrick Malone & Associates, P.C. 1331 H Street N.W. Suite 902 Washington, DC 20005 pmalone@patrickmalonelaw.com www.patrickmalonelaw.com 202-742-1500 202-742-1515 (fax) Of course, doctors can always close their doors to sales reps, but that's more pipe dream than likelihood. Because even if doctors are as loath to open their files to Big Pharma as the industry is hungry for the information, and even if doctors know that a sales pitch is less than objective, they still can learn something new, and they value the free samples.

If you're concerned about this issue, and your doctor prescribes a drug:

- Ask if there is a generic option, and if it's suitable for you.
- Ask if he or she embraces the AMA's Physician Data Restriction Program (PDRP), which allows doctors to withhold prescribing data from sales reps but still share it for research purposes. According the NEJM, only 4% of physicians have signed on, probably because "the AMA's financial interests cut against strongly promoting the program."
- Tell him or her that you're uncomfortable with your drug history being shared, and request that he or she not entertain pharmaceutical sales calls.

These measures alone probably won't change anybody's practice, but they will let your caregiver know that you're informed and concerned. And that you can always find another doctor.

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