Ryan Haight didn’t have to lurk in a deserted parking lot or hang around the high school boys’ bathroom to buy drugs. The college-bound 17-year-old placed his order on a computer in the family den. He ordered 100 tablets of hydrocodone—a generic for the powerful painkiller Vicodin—from an online pharmacy on Dec. 6, 2000. Two months later, his mother found him dead in his bedroom. In his blood was a mixture of hydrocodone and morphine ordered from www.nationpharmacy.com. The pills were “prescribed” by a doctor in Texas, fulfilled by an Oklahoma pharmacy, and delivered to the Haights’ home in La Mesa, Calif.

Ryan Haight’s death typifies the most extreme risks that emerge when pharmacy meets the Internet. Anyone with an Internet connection can buy potentially dangerous medicines online. There are hundreds of websites, doctors who never meet their patients, and pharmacies all over the world.

At the other extreme, the Internet allows law enforcement and boards of pharmacy to shine a brighter light on illegal prescribing practices. The power of aggregated data, compiled through web databases, helps officials identify and stop patterns of drug abuse and trafficking.

Finally, using the Internet to transmit prescriptions might even save thousands of lives. Doctors make fewer errors, and pharmacists can catch adverse drug interactions with e-prescribing.

One day, online pharmacy transactions will be safe, convenient, inexpensive and private. Until then, legislators are experimenting with ways to limit Internet pharmacies’ harm while promoting their greatest good.

By Rachel Brand


It’s So Easy

First, the bad news. The Internet has put addictive drugs just mouse-clicks away from anyone.

Instead of seeing a doctor, a buyer goes online and fills out a questionnaire that pops up after he chooses a medication. The questionnaire might be sent to a physician for approval. But it’s unlikely to be scrutinized: doctors associated with rogue sites are known to write 200 to 700 prescriptions a day—in itself not illegal. The prescription is fulfilled in another locale, and sent to the buyer as soon as the credit card is approved. “It’s a real market for drug traffickers and hard core abusers,” said Carmen Catizone, executive director of the largest association of pharmacists in Canada and the United States. “It’s easier and cheaper and more profitable to sell these prescription drugs on the Internet than to sell heroin and cocaine on the street.”

Running an online pharmacy is not illegal. But a prescription based solely on an online
questionnaire is not valid, according to the federal Drug Enforcement Administration. And the distribution of controlled substances or dangerous pharmaceuticals without a valid prescription is illegal.

Yet the borderless nature of online pharmacies makes it easy for rogue operators to stay a step ahead of the law. Poorly funded state pharmacy and medical boards have trouble keeping up.

In an effort to crack down locally, about a third of states have amended their medical practice acts to require a physical examination as part of a legitimate online doctor-patient relationship.

Other states put the responsibility on pharmacists to verify that an Internet prescription was written pursuant to a valid patient-prescriber relationship. Kentucky is among the states that require online pharmacies to be registered with the Verified Internet Pharmacy Practice Sites program, a product of the National Association of Boards of Pharmacies. Only 12 pharmacies nationwide have won the accreditation, which includes an on-site inspection, verification of licensure, and a review of the Web site.

THE GOOD SIDE

Some think these special rules for Internet commerce may discourage the development of more efficient medical care.

Consider this case: A patient wants a prescription for Viagra. His doctor is out of town. Can he explain his need to a covering physician and get a prescription? Or must he now get a physical? Perhaps the covering physician isn’t required to perform an examination and simply reviews the patient’s records to rule out dangerous side effects. Why can’t a doctor at an online pharmacy perform that same record review, and prescribe the same drug?

“Face to face is an abused requirement,” said John Bick, a professor of Internet law at Rutgers Law School. “It sounds good; it’s easy to explain, but it’s political medicine.”

An Arizona-based pharmacy exemplifies what it calls a legitimate Internet pharmacy. KwikMed sells “lifestyle” drugs such as Viagra, Cialis and Propecia. Its representatives say their sophisticated online questionnaire is virtually impossible to fake, and that a doctor reviews the answers before filling a prescription.

Knowledge is power, the saying goes. Now, state lawmakers are wondering if the drug industry has too much knowledge about physicians’ prescribing habits—and too much power as a result.

At least 13 states are considering laws to limit the use of information about physicians’ prescribing patterns. So called “data-mining” firms, which include Connecticut-based IMS Health, buy data on physician prescribing patterns from pharmacies. Matching the data to records provided for a fee by the American Medical Association, these intermediaries create detailed records about how 700,000 U.S. doctors prescribe any of 10,000 drugs. Finally, the records are sold to Wall Street analysts, researchers and drug companies. It allows them to paint a crystal-clear picture of an individual physician’s prescription patterns.

Some legislators oppose data-mining, especially when it is used by drug companies to increase sales. They say it violates physician privacy, and they argue that it pushes up drug spending.

New Hampshire Representative Cindy Rosenwald sponsored the nation’s first law on the issue last year, but it was struck down April 30 by a federal judge. The state will appeal, she says.

Rosenwald’s law forbid selling physician-identifiable prescription data except for a small range of research and care-related uses. U.S. District Court judge Paul Barbadoro said the law violated the First Amendment by restricting commercial speech.

“Drug companies are peering into physicians’ brains without any permission from them,” Rosenwald says. “We would never accept that on an individual level.” She expressed disappointment in the ruling saying that “corporate interests took precedent over the needs of the people in New Hampshire.”

Rosenwald doesn’t believe the ruling will stop lawmakers in other states. “I don’t think this issue is going to go away.”

Opponents of data-mining argue that sales representatives use the data—all along with gifts, free lunches, and luxury vacations—to pressure doctors into prescribing pricey brand-name drugs. The final result: higher drug costs.

According to the New Hampshire Medical Society, the combination of identity data-mining and targeted detailing is “extremely effective at prompting physicians to alter their prescribing behavior.”

But not everyone agrees. The American Medical Association, which opposes the New Hampshire law, counters that physicians can opt out of their database.

“Physicians—if they do not want their data released—can call, write or go online to restrict the data from being released to sales representatives,” says Robert Musacchio, senior vice president of business and publishing at the AMA.

But data-mining opponents think the association’s remedy isn’t strong enough. Even if doctors opt out, data are still collected and sold. The program prevents only drug company sales representatives from having the data. It simply doesn’t provide enough protection to physicians, they say.

Proponents of data-mining, including the drug industry lobby PhRMA and the AMA, say prescriber data are used for law enforcement, clinical trial research and to reach physicians when needed. For example, the federal government requires manufacturers of certain drugs with known dangerous side effects to develop risk management plans. So the manufacturer of Accutane, an acne medicine that causes birth defects, must know which doctors are prescribing the drug.

“They typically buy that information from the data aggregation companies,” says Marjorie Powell, PhRMA’s assistant general counsel.

In addition, clinical trial researchers sift through the data to find patients with rare diseases. And continuing medical education providers use the data to design physician training programs. For instance, the AMA is designing an education program that allows doctors to compare their prescribing patterns with anonymous peer data.

Hundreds of millions of dollars are at stake. According to public filings, IMS Health posted revenues of nearly $2 billion in 2006, and about half was earned from optimizing drug companies’ sales forces. The AMA earned $44.5 million from all its database services in 2005, but the association declined to say how much came from its contracts with data-mining companies. That money represents just 15 percent of the AMA’s overall revenues.
KwikMed’s advertising copy says people are more honest in online questionnaires than in person, especially when discussing sensitive topics. “There are numerous ailments that can be effectively diagnosed through an online consultation—including erectile dysfunction and hair loss,” the website says.

Utah’s board of pharmacy has entered into a consent agreement with KwikMed that allows state regulators to track complaints against the pharmacy. There have been no complaints so far.

Still, the site has its detractors.

“I can’t believe it’s legal,” says Utah Senator Pete Knudson who saw fellow legislators reject a bill that would have required certification for KwikMed. Knudson argues that erectile dysfunction drugs can be deadly for people with heart disease. “Frankly, these drugs for some people are not safe,” he said.

It boils down to weighing risks against costs, says legal scholar Bick.

Of course, an in-person examination is the highest standard of medical care. “The question is, is it relevant?” Bick asks. Sometimes yes, sometimes no.

“Then, there’s a cost-benefit issue,” he continues. Erectile dysfunction drugs are generally safe, he said, so as a society we must decide how much money we’re willing to spend to protect against what degree of risk. “Yes, we can regulate it,” Bick says. “But then there are some societal and individual costs to regulation.”

MONITORING FOR SAFETY

Is the Internet a shadowy haven for drug pushers to hide, or a brightly lit trading post that keeps a record of every sale?

In some ways, the latter. Web-based prescription monitoring programs—which help curb drug abuse—are spreading across states like wildfire. They aim to stop doctor-shopping, prescription forgery and reckless prescribing of controlled substances. At least 33 states have enacted Prescription Drug Monitoring Programs and at least 15 other states are considering them.

Pharmacists record, in a web database, when they fill a controlled substance prescription, and for whom. Doctors then check the database before writing a prescription. Based on what they find, a doctor can refuse to write the prescription or counsel the patient to seek help.

Monitoring programs are not subject to open records laws. They’re off-limits to law enforcement without a court order. State boards of medicine can look at the data only after they get a complaint. In all states, unauthorized use brings penalties.

Still, states say these programs have been extremely effective in curbing prescription drug abuse. President Bush wants every state to have a monitoring program by 2008, and he’s authorized $100 million since 2002 to launch them. The federal government also wants to develop a way to exchange data between states. That system could track mail-order and Internet pharmacy abuse.

But privacy advocates raise a red flag, saying such databases are ripe for abuse.

PRIVACY CONCERNS

“There’s an enormous amount of data out there,” says Professor John Soma, executive director of the Denver-based Privacy Foundation. “I wonder how tight the access is [to the database] given the enormous sensitivity of this information. Are they monitoring access to make sure it is being used appropriately?”

Likewise, the American Civil Liberties Union has generally opposed such legislation on privacy grounds.

This year Oregon Senator Bill Morrisette proposed legislation to create a monitoring program because “there’s been a lot of concern about doctor-shopping,” he says.

His bill would authorize the state board of pharmacy to create and oversee the database. Pharmacies would report the name, address and birth date of patients; the name, dose and quantity of the controlled substance; the dispensing pharmacy; and the prescribing physician. Social Security numbers are not included.

Morrisette says that doctors testifying in support of the bill said, “We need something like this because we don’t know if that sweet little lady out there is indeed out there calling lots of other pharmacies.”

But, the Oregon chapter of the ACLU opposed the bill saying the database treats all drug users like abusers. The list of registered substances includes common drugs such as Ambien, Xanax, cough medicine with codeine and Ritalin—prescribed to thousands of the state’s residents, the ACLU notes.

“It will interfere with your doctor/patient relationship,” according to the ACLU’s statement read on the Senate floor, “put your personal data at risk, provide you with no remedy if you are wrongly identified, and give you no recourse if the state or anyone else releases your data.”

THE READABILITY FACTOR

Finally, the Internet’s simple requirement that orders be typed rather than hand written could save thousands of lives.

Americans get 3 billion, often illegibly marked, paper prescriptions a year. The Institute of Medicine estimates that problems with paper prescriptions (wrong dosages, inappropriate medication) cost the health care system $77 billion annually. Software is already available to collect those prescriptions electronically, compare them to a patient’s formulary, and transmit them to a local pharmacy. Such e-prescribing could prevent many of the 7,000 deaths and 1.5 million injuries sustained each year from prescription errors, according to the National ePrescribing Patient Safety Initiative.

Advocates see the potential in reducing drug costs as well. E-prescribing software can remind doctors that therapeutically equivalent generics are available for a fraction of the cost.

New Hampshire Governor John Lynch has set an ambitious goal of getting all state providers to send prescriptions from office computers or hand-held devices to pharmacies by October 2008.

And in what seems to be at least one commonly agreed upon public benefit, at least 39 states have amended their medical practice acts to allow for e-prescribing, with legislation pending in others.