

Online Physician Prescribers Targeted by Feds

BY JENNIFER SILVERMAN
Associate Editor, Practice Trends

Federal investigators are targeting physicians who help Internet sites sell drugs to buyers without legitimate prescriptions.

"The Internet has brought drug dealers from the back alleys directly into every American home wired for e-mail and the World Wide Web," Karen Tandy, administrator of the Drug Enforcement Administration, recently testified before the Senate Governmental Affairs Permanent Subcommittee on Investigations.

Such Web sites are heavily advertised through spam e-mail and on the Web, selling as much as \$50 million annually per site in some cases, the DEA estimates.

Web sites, such as Medexplorer.com and LegalMedsOnline.com, that sell common prescription brands, did not respond to requests for an interview.

Physicians associated with such Web sites typically have a business relationship with a pharmacy and almost never have a valid doctor-patient relationship under accepted medical practices, Ms. Tandy said. "Acting together, the physician and pharmacist dispense controlled substances [to those] without a legitimate medical need, resulting in widespread self-medication over the Internet.

Often the physician will ask the patient only three or four questions before prescribing the drug, Michael Schaff, a lawyer

specializing in health care and corporate law in Woodbridge, N.J., said in an interview. To Mr. Schaff, it's illogical how a physician could make a diagnosis without seeing the patient.

To date, Justice Department investigations have discovered 14 deaths or overdoses and 15 people who have entered addiction rehabilitation or sustained injuries from drugs obtained illegally over the Internet, Ms. Tandy said.

The Government Accountability Of-

fice, in its analysis of drugs from 68 Web sites around the world, found that some Internet pharmacies pose safety risks for consumers and have unreliable business practices. While some in the United States and Canada required the patient to provide a doctor's prescription, other sites provided prescriptions based on their own medical questionnaire or had no prescription requirement.

Doctors not involved in Internet pharmacies face another threat: They have no

way to know how many Web sites a patient might be using to obtain drugs, said James Saxton, chair of the healthcare liability and litigation practice group of the American Health Lawyers Association. From a medical liability perspective, "this is a disaster waiting to happen," he said.

More than 90 active investigations involving the diversion of pharmaceutical controlled substances over the Internet are underway, covering 537 Web sites, Ms. Tandy said. In the current fiscal year, the

Liability Risk Is Only a Click Away

Physicians caught in Internet prescribing activities that result in patient injury face a number of liability scenarios.

Those who prescribe over the Internet could be sued for malpractice "if you're prescribing medication for someone who [doesn't] need it," Ms. Hager told this newspaper.

Malpractice actions may also come up if a physician licensed in one state prescribes the wrong drug to a patient in another state, she said. The trick with these cases, however, is, "Where do you sue that physician? Normally you would sue in the state where the patient got hurt," but the seamless world of Internet prescribing makes it much harder to prosecute someone.

To settle the jurisdiction issue, lawyers in some states might begin suing physicians under a tort action, which relates to any action that harms someone else, she said. The argument would be, "You prescribed medication; you harmed my client," she said.

But if drugs are prescribed in another jurisdiction, the physician could conceivably be accused of practicing without a license, which in some states is the basis for a claim of punitive damages, she said.

For your psoriasis patients...

Continuous control is possible.



Genentech

©2004 Genentech, Inc., So. San Francisco, CA 7518100

RAPTIVA® [efalizumab] is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

DEA has shut down 25 Internet pharmacy organizations and seized \$3.3 million and 3.2 million dosage units. "Eleven million dollars is pending forfeiture," she said.

The Food and Drug Administration also has been investigating Internet pharmacies and referring cases for criminal prosecution and initiating civil enforcement actions against online sellers of drugs and other FDA-related products, John M. Taylor, FDA's associate commissioner for regulatory affairs, testified at the Senate hearing.

A number of state laws regulate the practice of pharmacy and medicine to protect patients from harm resulting from the use of unsafe drugs and the improper

practice of medicine and pharmacy, Mr. Taylor said, adding that the statutes may not have enough teeth to efficiently regulate online pharmacies. In addition, many states have not yet fully determined how to address the issues that arise from online prescribing. As a result, the attempt to stop some physicians and online pharmacies from issuing prescriptions without an exam aren't always successful.

Other testimony before the Senate investigations panel addressed what Internet portals are doing to crack down on illegal Internet pharmacies.

Representatives from Yahoo! Inc. and Google Inc. described their efforts to en-

sure that their advertisers engage in best practices approved by the National Community Pharmacists Association. Both online providers use SquareTrade, an online trust infrastructure company that verifies that the online pharmacy and its pharmacist are appropriately licensed.

Yahoo! specifically prohibits online pharmacies from advertising FDA schedule II drugs, testified John Scheibel, Yahoo's vice president for public policy.

The DEA is also working with search engines and Internet service providers to warn consumers about dangerous drugs. "We have also established a link to the DEA's homepage to allow citizens to re-

port suspicious Internet pharmacies," Ms. Tandy said.

For the law to fully catch up with the Internet, Congress should enact legislation that would set parameters for all of the states on how to legally administer these drugs online, suggested Rose Hager, a health care lawyer with Kathleen L. DeBruhl & Associates LLC in New Orleans.

Internet pharmacies will be around for some time, she said. "You won't be able to stop it."

Mr. Saxton agreed, but noted that a multimillion-dollar verdict against a Web site and its participants could have a chilling effect on this type of activity ■

RAPTIVA is designed to deliver it.

RAPTIVA provides ongoing control of psoriasis with:

SAFETY

The safety profile of RAPTIVA was established in the largest clinical trial database of psoriasis patients studied for any biologic therapy.

In clinical trials

- Infection and malignancy rates were low and similar to placebo.¹
- No demyelinating disorders were observed.
- Adverse events did not increase over time or depending on dose.
- No new or reactivated cases of tuberculosis were reported.
- No new-onset congestive heart failure was reported.

EFFICACY

Effective with rapid onset.

- Significant improvement for some patients at 4 weeks.²
- Increased improvement over time.*¹

CONVENIENCE

Convenient for you and your patients.

- One SC injection, once a week, at home after training by a healthcare professional.
- Consistent, weight-based dosing of 1 mg/kg/wk.

For more on how RAPTIVA can change the way you treat psoriasis, ask your Genentech Clinical Specialist, visit www.raptiva.com, or call 1-877-RAPTIVA.

* In clinical trials, improvement was demonstrated at 3 months and sustained over 6 months

References

1. Prescribing Information for RAPTIVA, October 2003.
2. Data on file, Genentech, Inc.

The most serious adverse reactions were serious infections requiring hospitalization (0.3% of RAPTIVA-treated patients), malignancy (1.8 per 100 patient-years for RAPTIVA-treated patients vs 1.6 per 100 placebo-years for placebo-treated patients), thrombocytopenia (0.3%), and psoriasis worsening and variants (0.7%). Physicians should follow patients for signs and symptoms of thrombocytopenia; platelet monitoring is recommended. Patients taking RAPTIVA should not receive vaccines.

Please see accompanying Brief Summary of Prescribing Information.

Once-Weekly
RAPTIVA[®]
e f a l i z u m a b