

# Health Care Fraud

COMMENTARY

REPRINTED FROM VOLUME 12, ISSUE 7 / JANUARY 2007

## Internet Prescribing: It's Fast and Easy, But Is It Legal?

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The Internet pharmacy industry is booming and apparently will only get bigger, unless, that is, the federal government decides that prescriptions written without a face-to-face meeting between the physician and patient are invalid. Given its recent enforcement efforts, the government may well be headed in that direction.

According to a report by Jupiter Research, Americans spent nearly \$5.1 billion for online prescription drugs in 2006 alone, up from \$3.2 billion the previous year and just \$158 million in 1999. Not surprisingly, the number of Web sites offering prescription drugs has grown rapidly as well, from 400 in 1999 to more than 1,000 today.

This exponential growth is not without controversy. On the one hand, online drug sales offer consumers enhanced privacy, convenience, access (especially for the disabled or homebound) and information. On the other hand, they present a host of concerns, including inadvertent sales to minors, prescriptions issued without adequate or verifiable medical histories, and consumers actively lying (about height, weight, etc.) to get drugs. Policymakers and law enforcement officials wrestle with safety issues, jurisdictional challenges (relating to where the consumer, the physician and the server used to operate the pharmacy are located), sales of counterfeit drugs and how to permit legitimate companies to stay in business while curbing illegal activities.

One sure sign of the controversial nature of the business: In each of the past several years, Congress has considered legislation that would make Internet prescribing illegal, and each year the bill has died in committee. Another sign is the degree to which Internet prescribing practices are becoming federalized. Until recently, the Department of Justice and other federal enforcement authorities have

generally deferred to state law to determine whether a prescription issued solely on the basis of an online questionnaire was valid in that state.

Prosecutions focused on Internet pharmacies that only pretended to operate legally, particularly those that sold controlled substances and/or did little, if anything, to ensure that physicians actually prescribed the drugs that were sold. Many of these initially targeted businesses also engaged in other obviously criminal conduct, such as money laundering and counterfeiting, and illegal importing or smuggling of drugs. It appears, however, that the federal government now intends to cast a wider net.

This commentary surveys how the federal and state governments have regulated and challenged the Internet pharmacy industry to date and what future enforcement may look like.

### Online Pharmacy Business Models

Internet pharmacies operate under many different business models. At one end of the spectrum, a number of so-called "pharmacies" distribute prescription drugs, including controlled substances, simply upon receipt of a customer's order and without pharmacist or physician involvement; they also engage in money laundering, counterfeiting and illicit imports of drugs. Few would question the government's attempts to crack down on such operations, which constitute little more than drug trafficking.

More difficult legal questions arise at the other end of the online pharmacy spectrum — more mainstream ventures that seek to capitalize on the enormous consumer demand for convenience and privacy, while still complying as much

as possible with applicable state pharmacy laws. Because many of these laws were enacted before the advent of e-commerce, determining the legality and continued viability of these ventures can be a daunting task.

In most cases, mainstream Internet pharmacies are essentially a web of contractual relationships. The primary business entity usually serves as a broker, coordinating these relationships, contracting with physicians and pharmacies, and providing technology support. The typical business model is as follows:

- After accessing an Internet pharmacy Web site, a customer initiates the prescribing process by completing an online questionnaire, in which he or she supplies the type of health information typically solicited by a physician during an office visit;
- A physician then reviews the completed questionnaire and, if the doctor deems it medically appropriate based on the responses, issues the requested prescription, signing it digitally and sending it electronically to the pharmacy, which is on the same server. The physician receives a fee for each questionnaire reviewed — regardless of whether a prescription request is approved — and is only allowed to review a certain number of questionnaires each day; and
- A pharmacist then accesses the prescription from the server, printing it with a both a shipping label and drug label. After checking the prescription against a “blacklist” of customers who have demonstrated abuse or fraud and verifying that there are no contraindications, the pharmacist fills the prescription and ships it.

A “mainstream” Internet pharmacy establishes its formulary by evaluating what medications it believes may be safely prescribed without a physical examination and in the absence of contraindications or other possible adverse reactions. Popular Internet formulary medications include “lifestyle” drugs such as Viagra or symptom relief medications such as Prilosec. Controlled substances, such as diet drugs and pain medications, however, represent the most lucrative source of online drug sales.

## Legal Framework

Online pharmacies are regulated federally by the Food and Drug Administration, the Drug Enforcement Administration and the Federal Trade Commission. At the state level, they are regulated (if at all) by state pharmacy boards. Prescribing physicians are subject to regulation by

their respective state medical boards. Professional associations have also adopted policies as to the propriety of online prescribing.

## Federal Regulation

The federal Food, Drug and Cosmetic Act regulates all drugs imported, marketed and sold in the United States, including prescription and non-prescription drugs. Among other things, the FDCA prohibits the introduction into commerce of any drug that is “misbranded,” which is defined to include drugs dispensed without a valid prescription.<sup>1</sup>

The Department of Justice, which prosecutes FDCA violations, has stated that the fundamental issue under the statute is whether the online interaction between the physician and patient results in a valid prescription pursuant to 21 U.S.C. § 353(b).<sup>2</sup> The agency’s position has been that an online pharmacy may be found guilty of distributing “misbranded” drugs under the FDCA if applicable state law prohibits prescribing solely upon an online questionnaire.

The FDA has publicly recognized both the benefits of online drug sales and the challenges of allowing legitimate electronic commerce to flourish while ensuring consumer safety. The agency has expressed specific concern that online pharmacies may use the Internet to bypass state regulatory systems and recognized standards of practice.<sup>3</sup> Further, online pharmacies’ improper use of questionnaires may jeopardize the privacy of a patient’s medical records.

The Controlled Substances Act establishes accountability for controlled substances (again, the largest source of revenue for online prescribing) from production through distribution to patients to reduce diversion of these drugs from legitimate medical or scientific use. The law requires all people engaged in the manufacture, importation and distribution of controlled substances, including those who prescribe and dispense them, to register with the DEA and meet other requirements, including dispensing only upon a written prescription.<sup>4</sup> Any other knowing or intentional distribution violates the statute.<sup>5</sup>

Although the Controlled Substances Act exempts registered practitioners (including physicians and pharmacists) from its prohibitions, case law holds that practitioners are subject to prosecution under the statute when they prescribe or distribute a controlled substance other than for a legitimate medical purpose and “their activities fall outside the usual course of professional practice.”<sup>6</sup>

The Federal Trade Commission Act is designed to prevent deceptive or unfair acts or practices in commerce and

specifically prohibits the false advertisement of drugs.<sup>7</sup> Thus, an online pharmacy that makes false representations regarding the drugs it sells (or arranges to be sold) may be subject to prosecution under the statute.

### **State Regulation**

As part of a state's police power, a state pharmacy board has authority to regulate pharmacy practice within the state, including (generally) the distribution of prescription drugs to state residents. About 14 states have laws or regulations that expressly prohibit pharmacies and/or pharmacists subject to their regulatory jurisdiction from dispensing prescriptions that are based, or that the pharmacist reasonably believes are based, solely on online questionnaires. Another 10 or so states prohibit pharmacies and/or pharmacists from dispensing absent a "valid patient-practitioner relationship," which is often defined to require a physical examination.

Other states regulate Internet pharmacies more indirectly, such as by requiring that any out-of-state pharmacy employ a resident-licensed pharmacist. Yet other states require certification by the Verified Internet Pharmacy Practice Sites program. Created by the National Association of Boards of Pharmacy in 1999, VIPPS requires a pharmacy to comply with the licensing and inspection requirements of the state of its physical location and of each state into which it dispenses prescription drugs, thereby posing a very high practical bar for compliance.<sup>8</sup>

Most states also require out-of-state pharmacies to register with or obtain a license or permit from the state's pharmacy board before delivering prescription drugs into the state. Through this registration, the out-of-state pharmacy becomes subject to some degree of regulation in the state where it delivers drugs.

States, of course, are also authorized to regulate the physicians who write the online prescriptions. All states require a physician to be licensed in the state in which he or she practices medicine. To address the increasing frequency of practicing medicine across state lines, many states also have developed alternative licensure mechanisms, including consultation exceptions, licensure by endorsement, reciprocity and special licenses, that allow telemedicine practitioners to avoid having to obtain a full license.

In at least 35 states, a statute, regulation or policy prohibits, or deems unprofessional conduct, prescribing drugs via the Internet for an individual the physician has never examined. Although a violation of a professional regulation does not *necessarily* establish a violation of a criminal law,<sup>9</sup> online prescribing in derogation of such professional

regulation is not without consequence. Many states that deem online prescribing unprofessional conduct provide that prescriptions resulting from online prescribing are invalid and thus cannot be legally filled. A pharmacist who fills an invalid prescription is thereby implicated, as well.

### **Association Policies**

The American Medical Association has staked out a clear position against online prescribing absent a physical examination. In a policy titled "Guidance for Physicians on Internet Prescribing," the AMA says physicians who prescribe via the Internet must establish a valid patient-physician relationship that includes a physical examination, be licensed in the jurisdiction where patients reside and disclose physician-identifying information on the Web site.

The Federation of State Medical Boards similarly opposes online prescribing without a face-to-face encounter between physician and patient. Its Special Committee on Professional Conduct and Ethics has stated that prescribing solely on the basis of an electronic questionnaire fails to meet an acceptable standard of patient care and is outside the bounds of professional conduct.

Although the FSMB maintains that a physician-patient relationship is established whenever a doctor agrees to undertake diagnosis and treatment of a patient, regardless of whether there has been a personal encounter between the two, it has also expressly said that "treatment, including issuing a prescription, based solely on an online questionnaire does not constitute an acceptable standard of care."<sup>10</sup>

### **Congressional Action**

Beginning in 2000 the House of Representatives has held a series of hearings on Internet pharmacies. In December 2005 the House Subcommittee on Oversight and Investigations heard testimony from representatives of companies such as Google, Visa, MasterCard, UPS and FedEx that provide support services to Internet pharmacies. That testimony indicated that these companies are cooperating with various government agencies to identify Internet pharmacies that the agencies consider illegal operations. In some instances, these companies are refusing to do business with such pharmacies.

### **Enforcement**

Using the laws and regulations discussed above, federal and state authorities have brought enforcement actions against Internet pharmacies under a variety of legal theories.

### State Efforts

States have actively enforced their consumer-protection laws against Internet pharmacies, physicians, pharmacists, and other individuals and entities involved in the online pharmacy business to prevent them from operating in the state without a non-resident registration.<sup>11</sup> These actions can be especially effective, as state authorities wield the power of injunction and can thus fine or shut down an Internet pharmacy that they conclude jeopardizes the health and safety of state residents.

State attorneys general in Illinois, Kansas, Michigan, Missouri, New Jersey, Pennsylvania, Texas and West Virginia have also instituted legal actions — and often obtained injunctions — against Internet pharmacies and affiliated physicians. In October 1999, for example, the Missouri attorney general obtained a permanent injunction against a Texas-based Internet pharmacy and its owner for illegally selling Propecia and Viagra. The attorney general alleged that the pharmacy violated Missouri medical and merchandising laws by dispensing prescription drugs to Missouri consumers based solely on online questionnaires, without a Missouri pharmacy license.<sup>12</sup>

State pharmacy boards have also brought enforcement actions against pharmacies and pharmacists. In a highly publicized 2002 case the California State Board of Pharmacy levied an \$88 million fine against Los Angeles pharmacy Total Remedy & Prescription Center and two in-state pharmacists, alleging violations of a California statute that prohibits Internet pharmacies from filling residents' prescriptions without a "good-faith prior examination."<sup>13</sup> Similarly, the Texas Board of Pharmacy issued a \$3.8 million fine against The Pill Box, a large Internet pharmacy based in the state, for dispensing prescriptions without physical examinations.<sup>14</sup>

State medical boards have in turn sanctioned physicians, including those out of state, involved in Internet prescribing.<sup>15</sup> The California Medical Board has fined at least six out-of-state doctors \$6 million for prescribing online to state residents,<sup>16</sup> and Illinois fined and suspended a state-licensed physician who worked as a consultant for the Texas-based Pill Box.

### Federal Efforts

The Justice Department has been at the forefront of federal prosecutions of Internet pharmacies, while the FTC has typically deferred to state medical boards and enforcement agencies.<sup>17</sup> However, *FTC v. Rennert* is a notable and instructive exception to that general rule.<sup>18</sup> In *Rennert* the FTC's final order permitted an Internet pharmacy to continue operations if it met specific and extensive requirements, including providing:

- Full information about the dispensing pharmacy and the reviewing physician, including the states of registration and licensure;
- Contact information for the entity offering the prescription drugs;
- The state(s) from which the Internet pharmacy accepts orders; and
- A statement on its Web site that dispensing a prescription drug without a valid prescription violates federal law.

As noted in the chronology of cases discussed below, although the Justice Department initially focused its enforcement efforts on Internet pharmacies that sold controlled substances<sup>19</sup> or failed to engage physicians in the operation (no doctors reviewed patient-completed questionnaires), its focus appears to be expanding.

**Norfolk Men's Clinic.** This early case illustrates a relatively uncontroversial prosecution shutting down an operation that created phony prescriptions and failed to provide for physician reviews of patient-completed questionnaires. In 2000 four individuals, none of whom were licensed, and a pharmaceutical supply firm that operated a Web site called Norfolk Men's Clinic were indicted in the U.S. District Court for the Middle District of Alabama for illegally offering prescription drugs over the Internet to consumers.<sup>20</sup>

According to the indictment, the Web site represented that a physician would review patient-completed online questionnaires before the drugs could be shipped. In fact, the defendants created phony prescriptions in the name of a foreign doctor and no such medical review or consultation ever occurred. An Alabama physician then rewrote the prescription on Alabama prescription forms without any contact with the consumers who ordered the drugs. An Alabama pharmacy dispensed the prescription.

In 2002 a jury convicted the operators on all 23 counts brought against them and imposed jail terms and fines. The president of the pharmaceutical supply firm pleaded guilty to dispensing misbranded prescription drugs and was ordered to perform community service, placed on probation and fined.<sup>21</sup>

**KwikMed Inc.** This case offers an interesting dichotomy: truly egregious conduct and then a remarkable effort to achieve legitimacy. In 2002 an Arizona federal grand jury returned a 198-count indictment against KwikMed Inc., Cymedic Health Group, four owners of these corporations and two physicians.<sup>22</sup> The indictment alleged that defendants operated Web sites through which they sold prescription

drugs, including Viagra, Celebrex and Propecia, without valid prescriptions.

The Web sites required consumers to complete online questionnaires, which supposedly would be reviewed by a physician. According to the indictment, however, doctors never reviewed the questionnaires. It also alleged that the defendants, who were neither registered manufacturers nor licensed pharmacies, illegally repackaged medications obtained from a drug wholesaler.

In 2003 after several defendants pleaded guilty, KwikMed changed ownership. After 14 months spent overhauling the company, the new owner won a consent order from Utah for the right to prescribe drugs online. KwikMed.com is now the only online prescribing Web site in the country to win explicit approval from a state to dispense medication based on a remote medical consultation.

To obtain that consent, the revamped KwikMed voluntarily submitted itself to the jurisdiction of the Utah medical and pharmacy boards and gave them veto power over virtually everything from the drugs KwikMed sold, to the doctors and pharmacists it hired, to the terms of its contracts. The company agreed to allow Utah regulators to access a database containing its patients' medical histories and the results of online consultations.

The company also said it would use advanced medical diagnostic software when evaluating patients remotely, a critical reason for it being exempt from Utah's laws that otherwise require prescriptions to be based on face-to-face doctor-patient relationships. KwikMed also agreed to maintain a current pharmacy license, provide contact information on its site, publish a privacy policy that protects personal information and transmit financial transactions securely. Finally, KwikMed sells only four medications: three for erectile dysfunction and one for hair loss.

**Rx Clinic.** This case involved the classic prosecution of Internet pharmacies that sell controlled substances without physician review of patient-completed questionnaires. In December 2003, a Virginia federal grand jury issued a 108-count indictment against three companies and 10 individuals, including the operators of the business, five physicians and a pharmacist.<sup>23</sup>

They were charged with, among other things, conspiring to unlawfully distribute Schedule III and IV controlled substances (mostly prescription diet pills) without a legitimate medical purpose and outside the usual course of professional practice (without being physically examined by a doctor). In 2004 several defendants, including the operators and a pharmacist, pleaded guilty to various charges; they were sentenced to prison and fined.

**WorldExpressRx.** In 2004 the Justice Department targeted another egregious Internet pharmacy, WorldExpressRx, a worldwide operation engaged in diverting and counterfeiting prescription drugs. WorldExpressRx.com directed customers to complete an online health questionnaire and pay a \$35 physician consultation fee. According to the government, however, no doctor ever reviewed the patient-completed questionnaires.

The operators of WorldExpressRx also caused counterfeit drugs labeled as generic versions of Viagra, Cialis, Levitra, Celebrex and Xenical to be manufactured in Mexico, smuggled into the United States, and repackaged for distribution throughout the world. In January 2005 a California federal judge sentenced the Internet pharmacy's operator, Mark Kolowich, to prison and ordered a substantial forfeiture.<sup>24</sup>

**Operation Cyber Chase.** The DEA has devoted enormous resources to prosecuting international Internet drug trafficking. In April 2005 "Operation Cyber Chase," a year-long DEA investigation targeting international Internet pharmacy traffickers, resulted in federal grand jury indictments in Pennsylvania and New York. The Pennsylvania indictment charged more than 20 individuals with participating in an international conspiracy to import and distribute millions of dollars worth of prescription drugs to consumers in the United States through Internet pharmacy Web sites.<sup>25</sup>

The indictments alleged that from 2003 until 2005, Brij Bhushan Bansal of India and his son Akhil Bansal of Pennsylvania led a drug ring that supplied nearly 2.5 million doses of controlled and non-controlled prescription drugs to consumers. The Bansal organization served as a fulfillment center for numerous Internet pharmacy Web sites that sold prescription drugs directly to consumers without valid prescriptions or a medical examination.

Specifically, the India-based members of the Bansal conspiracy solicited business from Internet pharmacy Web site operators, offering to fill prescriptions ordered by consumers over their sites. The Internet pharmacy operators sent orders to the Bansal organization in the form of spreadsheets containing names of consumers, their mailing addresses and requested prescriptions.

The organization then filled the orders for both controlled and non-controlled prescription drugs and shipped them directly to the consumers. None of the Web sites involved required a consumer to provide a prescription or receive a medical examination, and the drugs were not sold through a pharmacy.

Last April a Philadelphia federal jury convicted two of the defendants, including Akhil Bansal, of conspiracy to distribute and import controlled substances.

**Operation CYBERx.** In addition to pursuing international drug rings, U.S. authorities have also set their sights on Internet drug trafficking in this country. In September 2005 federal authorities in Texas and Florida broke up a \$200 million Internet pharmacy ring in what prosecutors described as the largest crackdown on online drug trafficking in the United States. The 15-month DEA-led investigative effort, which targeted more than 22 rogue Internet pharmacies, resulted in the arrest of 18 individuals and the issuance of a 201-count indictment filed in the U.S. District Court for the Northern District of Texas.<sup>26</sup>

The indictment charged that the individuals who operated these pharmacies sold controlled substances over the Internet without a valid prescription. Specifically, each of these e-traffickers allegedly owned and operated an Internet facilitation center, which funneled information from Web sites, took customer orders and distributed prescriptions to pharmacies (both Internet and storefront) where they were filled and shipped to customers throughout the United States. Selling the drugs at four times the retail value, the pharmacies averaged more than \$50,000 in daily profits. To date, one pharmacy operator has pleaded guilty; the other defendants are awaiting trial.

**Rx Medical One Inc.** This 2006 case signals a potential expansion of the Justice Department's enforcement efforts beyond the Internet pharmacy operations described above that amount to little more than drug trafficking rings or that sell prescription drugs without the involvement of any licensed individuals.

Last August a grand jury in the Eastern District of Pennsylvania issued an indictment against the operators of a seemingly mainstream Internet pharmacy and its affiliated physicians, pharmacists and pharmacy.<sup>27</sup> Despite the more conventional business model, which called for doctor review of each customer questionnaire, at least one physician "reviewed" an unlikely 1,000 to 1,500 prescriptions per day at Rx Medical One Inc. Further, although the pharmacy sold both controlled and non-controlled prescription drugs, the majority of its business involved controlled substances.

The indictment alleged that defendants conspired knowingly and intentionally to distribute controlled substances by issuing prescriptions, or causing them to be issued, without a legitimate medical purpose and outside the course of usual professional practice and that they distributed controlled substances without valid prescriptions. Although the counts on misbranding involve only controlled substances, the indictment's language pertaining to misbranding is not limited to prescriptions of controlled substances. Thus, the indictment seemingly articulates

for the first time the Justice Department's position that prescriptions for non-controlled prescription drugs issued solely on the basis of an online questionnaire are invalid.

The indictment charged violations of the Food, Drug and Cosmetic Act. It said: "Under the federal FDCA, a prescription drug may only be dispensed upon a valid prescription from a medical doctor or another practitioner licensed by law to administer that drug. The dispensing of a prescription drug based only on a doctor's review of a medical questionnaire is not a dispensing of that drug upon a valid prescription."

To support the allegation that a review of a questionnaire is an inadequate basis for prescribing, the indictment said the Rx Medical physicians:

- "Did not physically examine, meet, or talk to any of the customers for whom they authorized prescriptions";
- "Did not contact or attempt to contact the customers' personal physicians"; and
- Never "attempted to verify the accuracy of the personal, health and medical information provided by the customers in their online questionnaires."

Because none of these rationales is unique to the provision of controlled substances, the fact that charges in this indictment were limited to controlled substances may be only a matter of prosecutorial discretion.

**Friendly Pharmacy/Main Street Pharmacy.** An October decision by the U.S. Court of Appeals for the 5th Circuit illustrates the evolution, and current state, of the Justice Department's prosecution theories as upheld by a federal appellate court.<sup>28</sup> Trial testimony established that customers of Friendly Pharmacy and Main Street Pharmacy completed online questionnaires and selected their controlled substance of choice. Physicians, paid by the Internet pharmacies per signed prescription, issued more than 38,000 prescriptions, with sales of \$8 million, without seeing the patients. The pharmacies primarily dispensed the highly addictive prescription painkiller hydrocodone.

The 5th Circuit held that it was sufficient for the government to charge and prove that the controlled substances sold through the defendants' Internet pharmacies were dispensed "outside the usual course of professional practice"; the government was not required also to prove that the defendant pharmacists dispensed drugs without a legitimate medical purpose, as prior case law had held.

The court also affirmed the convictions of the defendant operators of the Internet pharmacies, who argued that they did not know that the manner in which the controlled substances were dispensed was outside the usual course of professional practice. The evidence was sufficient, the court found, to support an inference that the operators were subjectively aware of a high probability that such procedure was outside the usual course of professional practice and that they purposely contrived to avoid learning of the illegal conduct.

One Internet pharmacy has recently taken the offensive and filed a declaratory judgment action in the Eastern District of Pennsylvania, challenging the government's authority to mandate that a face-to-face examination is necessary for a valid prescription.<sup>29</sup>

The plaintiff seeks a judicial declaration that the Justice Department and DEA lack the authority under the Controlled Substances Act to declare that a patient-physician relationship requires a face-to-face meeting and cannot interfere with the operation of legitimate e-commerce in pharmaceuticals.

The court dismissed the complaint Nov. 13, and the plaintiffs have appealed to the 3rd Circuit.

## Conclusions

The pivotal issue in assessing the legality of the mainstream Internet pharmacy business model is whether an online consultation creates the requisite physician-patient relationship for lawful prescribing. Federal enforcement authorities have sought to make a valid physician-patient relationship contingent on a face-to-face consultation, a position supported by both the AMA and the Federation of State Medical Boards.

Historically, enforcement actions have largely focused on "drug trafficking" Web sites merely disguised as pharmacies. The Department of Justice, juries and at least one federal court have easily found these operations, which often make no pretense of involving a physician or pharmacist in issuing and dispensing prescriptions, blatantly illegal. Other enforcement actions have targeted sales of controlled substances by businesses that appeared to attempt to comply with relevant law, but ultimately proved to operate with nominal or no physician and/or pharmacist involvement.

Until recently, the Justice Department relied on DEA regulations to prosecute Internet pharmacies that sold controlled substances and publicly deferred to state law as to what constituted a valid prescription for a non-controlled substance. In the Rx Medical One indictment in August, however, the Justice Department articulated the more

sweeping position that *any* prescription written without a face-to-face consultation is invalid, thereby potentially federalizing the standards for all online prescribing.

If this is indicative of the direction enforcement efforts will take, those "mainstream" Internet pharmacies selling non-controlled prescription drugs, including symptom relief and lifestyle medications such as Prilosec and Viagra, solely on the basis of patient-completed online questionnaires can expect much closer scrutiny by the federal government in the future.

## Notes

<sup>1</sup> 21 U.S.C. § 352; 21 U.S.C. § 353(b)(1).

<sup>2</sup> Statement of Ethan M. Posner, Deputy Associate Attorney General, U.S. Department of Justice, Before the Subcommittee on Oversight and Investigations Committee on Commerce, U.S. House of Representatives, May 25, 2000.

<sup>3</sup> Statement of William K. Hubbard, Associate Commissioner for Policy and Planning, Food and Drug Administration, Before the Committee on Government Reform, U.S. House of Representatives, March 18, 2004, available at [www.fda.gov/ola/2004/Internetdrugs0318.html](http://www.fda.gov/ola/2004/Internetdrugs0318.html).

<sup>4</sup> 21 U.S.C. § 822(a); 21 U.S.C. § 829; 21 C.F.R. § 1301.11.

<sup>5</sup> 21 U.S.C. § 801 *et seq.*; 21 C.F.R. Parts 1300-1316.

<sup>6</sup> *United States v. Moore*, 423 U.S. 122, 124 (1975); see also *United States v. Feingold*, 454 F.3d 1001 (9th Cir. 2006); *United States v. Leigh*, 487 F.2d 206 (5th Cir. 1973).

<sup>7</sup> 15 U.S.C. § 52.

<sup>8</sup> See [www.napd.net](http://www.napd.net).

<sup>9</sup> *United States v. Hitzig*, 63 Fed. Appx. 83 (4th Cir. 2003).

<sup>10</sup> Federation of State Medical Boards, Model Guidelines for the Appropriate Use of the Internet in Medical Practice (2002).

<sup>11</sup> See Internet Pharmacies, Adding Disclosure Requirements Would Aid State and Federal Oversight, No. 01-69 (G.A.O. October 2000).

<sup>12</sup> See State AG Files Suit Seeking to Halt Internet Prescription Drug Sales, 8 BNA HEALTH L. REP. 1139 (July 15, 1999).

<sup>13</sup> See Bus. & Prof'l Code § 4067; *California Regulators Fine Pharmacists for Filling Viagra Prescriptions Over Internet*, 10 BNA HEALTH CARE POL'Y REP. 778 (June 3, 2002); *The Script*, BOARD OF PHARMACY NEWSLETTER, 7 (October 2003).

<sup>14</sup> See State Charges Texas Online Pharmacy with Illegal Sales of Drugs Over Internet, 10 BNA HEALTH L. REP. 1786 (Nov. 29, 2001).

<sup>15</sup> See GAO Report at 34-39.

<sup>16</sup> See Medical Board Fines Six Doctors \$48 Million for Internet Prescriptions, 8 BNA HEALTH CARE DAILY (Feb. 13, 2003).

<sup>17</sup> Drugstores on the Net: The Benefits and Risks of On-Line Pharmacies: Hearing Before the Subcomm. on Oversight and Investigations,

House Comm. on Commerce, 106th Cong. 48 (1999) (statement of Jodie Bernstein, Dir. of Bureau of Consumer Prot., F.T.C.).

<sup>18</sup> See *FTC v. Rennert*, No. Civ-S-00-0861-JBR (D. Nev. July 6, 2000).

<sup>19</sup> See Hubbard statement, *supra* n. 4.

<sup>20</sup> *United States v. Yates*, No. 00-00109-CR-N-2, indictment filed (M.D. Ala. 2000).

<sup>21</sup> *United States v. Yates*, 438 F.3d 1307 (11th Cir. 2006). On appeal, the 11th Circuit overturned the convictions of the operators on constitutional grounds and remanded the case for a new trial, which is currently scheduled for February.

<sup>22</sup> *United States v. KwikMed Inc.*, No. 02-CR-993, indictment filed (D. Ariz. Oct. 1, 2002).

<sup>23</sup> *United States v. Chhabra*, No. 03-530-A, indictment filed (E.D. Va. 2003).

<sup>24</sup> *United States v. Kolowich*, No. 04m00724 (S.D. Cal. 2005).

<sup>25</sup> *United States v. Bansal*, No. 2:05-CR-00193-PD-ALL, indictment filed (E.D. Pa. Apr. 6, 2005).

<sup>26</sup> *United States v. Saran*, No. 305-CR-0240P, indictment filed (N.D. Tex. Sept. 20, 2005).

<sup>27</sup> *United States v. Bezonsky*, indictment filed (E.D. Pa. Aug. 2, 2006).

<sup>28</sup> *United States v. Fuchs*, No. 05-10426, 2006 WL 2949288 (5th Cir. Oct. 17, 2006).

<sup>29</sup> *PSA LLC v. Gonzales et al.*, No. 06-3212, complaint filed (E.D. Pa. July 2006).

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