

Internet Pharmacy Harms

Proprietors of rogue Internet pharmacies—those pharmacies offering prescriptions for drugs solely on the basis of an online consultation or questionnaire—offer the defense that people are not harmed by their actions. They claim that Internet pharmacies provide access to needed care; are cheaper and more convenient than face-to-face interaction between a physician and a patient; and that patients are often embarrassed to discuss their health problems with a physician in the traditional setting. However, a number of instances of real patient harm has been documented over the past few years in court cases and news stories. In this issue of *Rx Beat*, I have provided the opportunity for three people to relay their stories to you, the regulatory and law enforcement personnel charged with protecting the public from the dangers associated with Internet pharmacies.

Leisa Kelly and Ryan Kelly

Candy Kelly's daughter, 46-year old Leisa Kelly, and grandson, 17-year old Ryan Kelly, committed suicide in January 2004 after obtaining the antidepressant amitriptyline from an online pharmacy. The physician involved in this case, Dr. Everett Echols, reportedly treated 244,000 patients online in an eight-month period. The North Carolina Medical Board revoked Dr. Echols' license in 2004. Candy Kelly acknowledges that her daughter Leisa had problems, and that Ryan would do anything asked of him, including committing suicide with his mom. Leisa was seeing a psychiatrist for her problems even as Ryan obtained the amitriptyline from the Internet pharmacy. When Candy confronted the psychiatrist to find out why he had prescribed this medication to Leisa, she found out that the prescription had not come from him. Instead,

she learned of the availability of dangerous drugs via the Internet. She believes that the ease of access and anonymity of the online pharmacy environment contributed to the deaths of her daughter and grandson (summarized from Creative Loafing article dated 7/12/2006 and from communication with Candy Kelly).

John McKay

John McKay was a nationally known debate champion from the San Francisco Bay Area, and had just finished his freshman year at Stanford University when he purchased fluoxetine, the generic version of Prozac, from an Internet pharmacy. The 19-year old obtained the prescription from Colorado physician Christian Hageseth III, whom he never met or spoke with. Dr. Hageseth's license had restrictions in place at that time prohibiting him from prescribing medication to patients. According to family members, John did not appear to be depressed or suicidal. Antidepressants such as fluoxetine are being investigated for possible links to suicides of children and adults, but no conclusive study has demonstrated this link. The FDA did issue a Public Health Advisory Oct. 15, 2004, directing manufacturers of all antidepressant drugs to revise the labeling for their products to include a boxed warning and expanded warning statements that alert health care providers to an increased risk of suicidality (suicidal thinking and behavior) in children and adolescents being treated with these agents. David McKay, John's father, believes that "John would still be alive today if he hadn't been able to get these pills. He didn't realize the risks. They didn't inform him of the risks. I'd like to see these people held responsible." John's parents are suing the Internet site operator, the doctor and the pharmacy for wrongful death and negligence. In addition to the civil complaint, a criminal complaint against

Dr. Hageseth is pending in California for practicing medicine without a license in that state (summarized from Mercury News article dated 3/14/2006 and from communication with David McKay).

Ryan Haight

Ryan Haight overdosed and died in February 2001, after taking Hydrocodone and Morphine he purchased on the Internet. He was 17 when he purchased the drugs, and 18 when he died. He utilized a credit card he had been given to use to buy baseball cards on Ebay. He learned about purchasing drugs on the Internet from online chat rooms. Dr. Robert Ogle of Texas prescribed the drugs to him, and has since had his medical license revoked. Francine Haight, Ryan's mother, established www.RyansCause.org in 2004. The organization focuses on cutting off the flow of dangerous prescription drugs over the Internet and on educating youths about the dangers and risk associated with these drugs. Over the past few years, legislation has been introduced in Congress titled the "Ryan Haight Act" that would regulate these types of enterprises and grant state attorneys general the right to issue a nationwide injunction against illegal operations. The FSMB supports this legislation (summarized from www.RyansCause.org and from communication with Francine Haight).

National Association of Boards of Pharmacy

VIPPS Program Designed to Protect Consumers—Introduced in February 1999 after the proliferation of both legitimate and illegitimate online pharmacies, the National Association of Boards of Pharmacy's® (NABP®) Verified Internet Pharmacy Practice Sites™ (VIPPS®) accreditation program enables consumers to access with confidence important information regarding the licensure, confidentiality, and practices of America's foremost Internet pharmacies. The VIPPS accreditation program verifies the licensure of Internet pharmacies with local state boards of pharmacy, which assure consumers that if there is a dispute with an online pharmacy, the consumers' interests are represented by the appropriate state board.

It is designed to accredit an Internet pharmacy that complies with the laws and regulations for appropriately dispensing pharmaceuticals to the public. It is only after successfully completing the extensive application, verification, and on-site inspection process that the Internet pharmacy is awarded VIPPS accreditation.

VIPPS applicants are evaluated against a 19-point rigorous criteria, which was developed through expertise provided by a coalition of state boards of pharmacy, FDA, American Medical Association, DEA, Association of Food and Drug Officials, Federal Trade Commission, and prominent Internet pharmacies. The criteria includes questions in Internet and practice-based areas such as how the patient's or caregiver's identity is verified, patient medication consultation, the steps taken to ensure the patient's confidentiality, how medications are dispensed, and how controlled substance medications are secured and tracked when shipped to the patient.

An on-site inspection is conducted in order to ensure the pharmacy's operations, policies, and staff are compliant with the VIPPS criteria in practice. The on-site inspection is conducted by one or more inspectors who historically have been investigators for state boards contracted and trained through NABP; however, in the future inspectors will also include those with backgrounds from federal and state agencies.

VIPPS-accredited online pharmacies display the VIPPS Seal on their website's home page. By clicking on the VIPPS Seal hyperlink, visitors are able to access NABP's VIPPS website and instantly obtain information regarding the Internet pharmacy.

Once an Internet pharmacy becomes accredited, an annual review and a re-accreditation process is conducted. Random site visits are projected for one-third of the VIPPS-accredited pharmacies each year, with all pharmacies being visited once every three years to ensure they continue to meet the VIPPS criteria. For more information about the VIPPS program, visit NABP's website at www.nabp.net.

News of Interest

- The Medical Council of New Zealand recently approved a Statement on use of the Internet and

electronic communication. A physician residing in New Zealand that provides services to patients in another country is expected to be registered in the country where the patient is located. Further, physicians may only prescribe medication when they have had a face-to-face consultation with a patient or have discussed the patient's treatment with another doctor who can verify physical data and identity. The complete Statement can be viewed at www.mcnz.org.nz

- A criminal indictment was issued August 8 in the U.S. District Court for the Northern District of Georgia against Christopher Stoufflet, Troy Sobert, Vladimir Andries, M.D., Thu Anh Hoang, M.D., Steven Daniel Hollis, M.D., Ahsan Rashid, M.D., and Andre Smith, M.D., alleging conspiracy to distribute and dispense Schedule III and IV controlled substances via the Internet. The defendants used some of the following businesses: escripts-md.com, myemd.com, Lifespan, and Virtual Wellness Networks.
- A criminal indictment was issued August 2 in the U.S. District Court for the Eastern District of Pennsylvania against Michael Bezonsky, Thomas Beaulieu, Ranvir Ahlawat, M.D., Steven Kilnman, M.D., Alexander Atchildiev, and Universal Pharmacy Solutions, Inc., alleging conspiracy to distribute and dispense Schedule III and IV controlled substances via the Internet.
- A civil action was filed July 21 in the U.S. District Court for the Eastern District of Pennsylvania by PSA, L.L.C., Christopher Napoli, Joseph J. Carozza, M.D., and Alan White, R.Ph., against the Attorney General, Alberto Gonzales, the Drug Enforcement Administration Administrator, Karen Tandy, and the U.S. Attorney for the Eastern District of Pennsylvania, Patrick Meehan, seeking a declaratory judgment that the defendants (a) lack the authority to declare that no legitimate doctor-patient relationship can be established without a face-to-face meeting between a physician and a patient, and (b) cannot interfere with the operation of legitimate electronic commerce in pharmaceuticals.

Disciplinary Actions

The following is a partial list of recent disciplinary actions taken against physicians who prescribed medicine via the Internet.

- CLARIFICATION—Florida Board of Medicine—Mario Alberto Diaz, M.D., license suspended May 17, 2006. (Identified only as Mario Diaz, M.D., in the last issue).
- Medical Board of California—Joel A. Hendler, M.D., license revoked Sep. 14, 2006, but revocation was stayed and respondent placed on five years probation.
- Delaware Board of Medical Practice—Miles Jones, M.D., license revoked Oct. 3, 2006.
- Massachusetts Board of Registration in Medicine—Gerald Morris, M.D., surrendered license Sep. 20, 2006.

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