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RYAN HAIGHT ONLINE PHARMACY CONSUMER PROTECTION ACT OF 2007

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Mr. LEAHY, from the Committee on the Judiciary, submitted the following

R E P O R T

[To accompany S. 980]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to which was referred the bill (S. 980) to amend the Controlled Substances Act to address online pharmacies, reports favorably thereon, with an amendment, and recommends that the bill, as amended, do pass.

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I. BACKGROUND AND PURPOSE OF THE RYAN HAIGHT ONLINE PHARMACY CONSUMER PROTECTION ACT OF 2007

Senators Feinstein and Sessions introduced the Online Pharmacy Consumer Protection Act of 2007 on March 23, 2007. Senators Biden, Coleman, Leahy, and Cornyn cosponsored the legislation (renamed the Ryan Haight Online Pharmacy Consumer Protection Act of 2007).

This legislation responds to the increasing use of prescription controlled substances by adolescents and others for non-medical purposes, which has been exacerbated by drug trafficking on the Internet. The Department of Justice (DOJ) has acknowledged that

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this "is a very significant problem and is a major concern of DOJ and the DEA."[1]

A. BACKGROUND

The Ryan Haight Online Pharmacy Consumer Protection Act of 2007 is the latest in a series of bills introduced to address the problem of rogue Internet pharmacies. The current legislation has origins in, but has also been modified substantially from, previous bills: S. 3834, the Online Pharmacy Consumer Protection Act of 2006, introduced by Senators Sessions and Feinstein in the 109th Congress; S. 399, the Internet Pharmacy Consumer Protection Act, introduced by Senators Coleman and Feinstein in the 109th Congress; and S. 2464, the Internet Pharmacy Consumer Protection Act, introduced by Senators Coleman and Feinstein in the 108th Congress.

B. NEED FOR LEGISLATION

1. The alarming rise in abuse of prescription controlled substances

Over the past decade, the United States has experienced a growing epidemic of prescription controlled substance abuse involving opiates like OxyContin and Vicodin, depressants like Valium and Xanax, and stimulants like Ritalin and Adderall. As Joseph A. Califano, Jr., former U.S. Secretary of Health, Education and Welfare and now President and Chief Executive Officer of the National Center on Addiction and Substance Abuse (CASA) at Columbia University, testified before this Committee, "Over the past 12 years, the fastest growing drug abuse among our Nation's children involves prescription drugs."[2]

In its 2005 report, Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S., the National Center on Addiction & Substance Abuse (CASA) reported that, from 1992 to 2002, prescriptions written for such controlled drugs increased more than 150 percent, 12 times the rate of increase in population and almost three times the rate of increase in prescriptions written for all other drugs.[3] The number of 12- to 17-year-olds who abused controlled prescription drugs jumped 212 percent and the number of adults 18 and older abusing such drugs climbed 81 percent. Abuse of prescription controlled substances has grown at a rate twice that of marijuana abuse; five times that of cocaine abuse; and 60 times that of heroin abuse.[4]

Mr. Califano told the Committee about the troubling implications that prescription drug abuse posed to children. From 1992 to 2002, new abuse of prescription opiates among 12- to 17-year-olds was up an astounding 542 percent, more than four times the rate of increase among adults. In 2003, 2.3 million 12- to 17-year-olds (near-

[1] Oversight of the U.S. Department of Justice: Hearing Before the S. Comm. on the Judiciary, 110th Cong. (Jan. 18, 2007) [hereinafter Jan. 2007 DOJ Hearing], Responses to Questions for the Record Posed to Alberto Gonzales, Att'y Gen. of the United States at 11.

[2] Rogue Online Pharmacies: the Growing Problem of Internet Drug Trafficking: Hearing Before the S. Comm. on the Judiciary, 110th Cong. (2007) [hereinafter Rogue Online Pharmacies Hearing] (testimony of Joseph A. Califano, President and Chief Executive Officer, Nat'l Ctr. on Addiction and Substance Abuse).

[3] Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S., Nat'l Ctr on Addiction & Substance Abuse (CASA) at Columbia Univ., July 2005, at 3, available at http://www.casacolumbia.org/absolutenm/articlefiles/380-Under%20the%20Counter%20-%20Diversion.pdf.

[4] Id. at 16.

ly one in 10) abused at least one prescription controlled substance; for 83 percent of them, the drug was an opiate. According to Califano, "Teens who abuse controlled prescription drugs are twice as likely to use alcohol, five times likelier to use marijuana, 12 times likelier to use heroin, 15 times likelier to use ecstasy and 21 times likelier to use cocaine, compared to teens who do not abuse such drugs."[5]

Joseph T. Rannazzisi, Deputy Assistant Administrator of the Office of Diversion Control at the U.S. Drug Enforcement Administration (DEA), confirmed in testimony before the Committee that there has been an "alarming" increase in non-medical use of addictive prescription drugs. Nationally, misuse of prescription drugs was second only to marijuana in 2005, in part due to a false sense of security associated with the abuse of prescription substances. Mr. Rannazzisi testified that "many feel as though if a doctor can prescribe it, the drug can't be as harmful to your health [as illegal drugs sold on the street]."[6] In reality, however, prescription controlled substances are not just highly dangerous, but also potentially lethal. The consequences for people who seek prescription controlled drugs illegally over the Internet can be severe. According to the DEA, abuse of prescription drugs can be just as dangerous and deadly as the consequences of abusing cocaine and heroin.

In testimony before the Committee at a Department of Justice Oversight hearing in January 2007, Attorney General Alberto Gonzales confirmed that the Department was concerned about the non-medical use of prescription controlled substances, and he verified that such drugs were "the fastest rising category of drug abuse in recent years."[7]

President George W. Bush has also acknowledged the growing problem of prescription drug abuse. On March 1, 2008, in his national radio address, President Bush noted that abuse of prescription drugs among the Nation's youth was a growing problem, and that the total number of Americans who have died from prescription drug overdoses was also increasing.[8]

2. Lack of effective controls over prescribed controlled substances distributed by rogue Internet pharmacies

Although many online pharmacies are legitimate businesses that offer safe and convenient services similar to those provided by traditional neighborhood pharmacies and large chain drugstores, other online pharmacies, often referred to as "rogue sites," engage in the illegal practices of distributing controlled substances without prescriptions or using a truncated prescription process so flawed that medical authorities reject it.[9]

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[5] Rogue Online Pharmacies Hearing, supra note 2.

[6] Rogue Online Pharmacies Hearing, supra note 2 (testimony of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.).

[7] Jan. 2007 DOJ Hearing, supra note 1, (statement of Alberto Gonzales, former Att'y Gen. of the United States); see also, Department of Justice Oversight: Hearing Before the S. Comm. on the Judiciary, 110th Cong. (April 19, 2007) [hereinafter Apr. 2007 DOJ Hearing] (statement of Alberto Gonzales, former Att'y Gen. of the United States).

[8] President George W. Bush, Radio Address: 2008 National Drug Control Policy (Mar. 1, 2008) [hereinafter Bush Radio Address], available at http://www.whitehouse.gov/news/releases/2008/03/20080301.html.

[9] "You've Got Drugs!" IV: Prescription Drug Pushers on the Internet, Nat'l Ctr on Addiction & Substance Abuse (CASA) at Columbia Univ., May 2007, at 7 [hereinafter You've Got Drugs IV] ("The Federation of State Medical Boards of the United States, Inc., the American Medical

Continued

Mr. Rannazzisi testified that the Internet has created a new marketplace and delivery system for drug traffickers. Mr. Rannazzisi called the Internet a "perfect medium" for the sale of illicit drugs, connecting people from anywhere around the world at any time and cloaking them in anonymity, and said that the Internet allows for a more rapid means of diverting large quantities of controlled substances.[10]

Indeed, many rogue Internet pharmacies appear to have been set up for the very purpose of promoting large sales of controlled substances. According to Mr. Rannazzisi, in 2006, 34 known or suspected rogue Internet pharmacies dispensed 98,566,711 dosages of hydrocodone combination products.[11] These 34 pharmacies alone dispensed enough hydrocodone combination products to supply 410,000 actual patients with a one-month supply at the maximum amount recommended per prescription. Mr. Rannazzisi said that a typical, traditional, independent brick and mortar pharmacy sells about 180 prescriptions per day. Of these sales, only 11 percent involved controlled substances. However, the typical online pharmacy sells around 450 prescriptions each day—425 of these sales, or 95 percent, involve controlled substances.[12]

Unfortunately, the number of rogue Internet sites only has grown. In CASA's fourth annual report on this topic, entitled You've Got Drugs! IV: Prescription Drug Pushers on the Internet, it found that from 2006 to 2007 there had been:

- A 70 percent increase in the number of websites advertising or selling controlled prescription drugs, from 342 to 581;[13]
- A 135 percent increase in the number of websites advertising prescription controlled substances, from 168 to 394;[14]
- A seven percent increase in the number of websites selling prescription controlled substances, from 174 to 187 (between 2004 and 2007, the number websites selling prescription controlled substances rose steadily from 154 in 2004 to 187 in 2007);[15]
- Eighty-four percent of the websites selling prescription controlled substances do not require a prescription from the patient's physician;[16] and
- No controls to stop the sale of these drugs to children.[17]

The current mechanism for certifying Internet pharmacy practice is purely voluntary.[18] Of the 187 selling sites identified by CASA in 2007, only two were certified by Verified Internet Pharmacy Practice Sites™ (VIPPS®).[19] Most often, according to Mr. Califano,

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Association, the National Association of Boards of Pharmacy, and the Drug Enforcement Administration (DEA) all agree that online consultations cannot take the place of a face-to-face physical examination with a legitimate physician."), available at http://www.casacolumbia.org/absolutenm/articlefiles/380-2007%20You've%20Got%20Drugs%20IV.pdf.

[10] Rogue Online Pharmacies Hearing, supra note 2 (testimony of Joseph T. Rannazzisi).

[11] Id.

[12] Id.

[13] You've Got Drugs IV, supra note 9, at 4.

[14] Id. at 5.

[15] Id.

[16] Id.

[17] Id. at 7.

[18] Verified Internet Pharmacy Practice Sites™ (VIPPS®), Nat'l Ass'n. of Bds. of Pharmacy, available at http://www.nabp.net/index.html?target=/vipps/intro.asp&.

[19] Verified Internet Pharmacy Practice Sites™ (VIPPS®), http://www.nabp.net/ (last visited Oct. 16, 2007) (the National Association of Boards of Pharmacy reported that 13 pharmacies had received VIPPS certification as of Oct. 16, 2007).

"Online purchase of controlled prescription drugs happens beneath the radar screens of Internet providers, financial institutions, shippers and parents."[20]

A recent study by the British Broadcasting Corporation (BBC) revealed the wide scope of rogue Internet pharmacies operating worldwide.[21] The BBC sought to identify all of the websites selling six popular prescription drugs online. In total, the BBC identified 3,160 online pharmacies. The number of the websites offering prescription controlled substances was not identified, but controls were clearly lacking—many websites advertised the fact that no prescription was required to buy medicines, and only four had VIPPS® accreditation. According to the BBC, many of the websites falsely claimed VIPPS® accreditation, and half of the websites did not safeguard customer details. The websites were also heavily trafficked—the websites averaged 32,000 visitors daily, which could equate to £2 billion in annual sales for the six drugs examined by the BBC study.[22]

In short, at a minimum, "[t]ens of thousands of 'prescriptions' are written each year for controlled and non-controlled prescription drugs through such Internet pharmacies, which do not require medical records, examinations, lab tests or follow-ups."[23]

Mr. Rannazzisi testified that the problem extends beyond Internet sales.[24] The sheer volume of prescription controlled substances being dispensed anonymously over the Internet also contributes significantly to other downstream methods of diversion, like children and young adults who obtain prescription controlled substances from the family medicine cabinet or other family and friends. Mr. Rannazzisi said that when these downstream individuals obtain these substances, they generally acquire only a few pills at a time. In contrast, individuals ordering over the Internet frequently receive 100–120 pills at a time, making the Internet purchaser a potentially much higher-volume source for friends and family than the family medicine cabinet.[25]

3. Disastrous consequences

Ease of access to the Internet, combined with lack of medical supervision, has led to tragic consequences in the online purchase of prescription controlled substances. News reports continue to document the growing list of examples:

• In 1999, an autopsy of 43-year-old Juris Abolins identified traces of OxyContin and diazepam (generic Valium). Relatives also found a bottle of Tussionex, a cough suppressant containing hydrocodone, which Abolins had purchased from a website based in Texas. Abolins had told friends he was suffering from kidney stones, but an autopsy found no evidence of this condition.[26]

• In September 2001, Douglas Townsend of South Carolina died after driving his car into a fence. His family said he took a generic

[20] Rogue Online Pharmacies Hearing, supra note 2 (testimony of Joseph A. Califano).
[21] Drug Website Safety Fears Raised, BBC News, Aug. 19, 2007, http://news.bbc.co.uk/2/hi/health/6951254.stm.
[22] Id.
[23] You've Got Drugs IV, supra note 9, at 7.
[24] Rogue Online Pharmacies Hearing, supra note 2 (testimony of Joseph T. Rannazzisi).
[25] Id.
[26] The Victims, Washington Post, Oct. 21, 2003, at A15, available at http://www.washingtonpost.com/wp-dyn/content/article/2007/06/28/AR2007062801388.html.

form of the tranquilizer Xanax, which he purchased from myprivatedoc.com, a now-defunct website based in Mesa, Arizona.[27]

• In April 2003, Elizabeth Carr found her 47-year-old husband and former triathlete, James Lewis, dead on their living room couch. An autopsy found excessive amounts of the painkiller Darvon, purchased through Internet pharmacies based in South Africa, Thailand, and Vietnam.[28]

• In July 2003, 33-year-old mother Sandra M. Waltz died of an overdose of Soma and generic Darvon. Her family discovered that she had ordered drugs from a computer at her workplace.[29]

• In December 2003, 19-year-old Jason Surks died of an accidental overdose of Xanax, which he had been buying along with OxyContin over the Internet.[30]

• In December 2003, Robin Bartlett of Florida died from complications of drug overuse after receiving 4,000 doses of prescription drugs, including Schedule II narcotics like hydrocodone, that were purchased over the Internet over a period of just 3½ months. After she died, her husband continued to get messages from Internet-based distributors, asking why his wife had not reordered more controlled substances.[31]

• In April 2004, 30-year-old plastics salesman Craig Schmidt suffered brain damage and nearly died after taking the anxiety drug Xanax and the painkiller Ultram, both of which he had purchased over the Internet. Schmidt reasoned that "spending $400 for brand-name drugs like Xanax and Ultram simply seemed easier and more discreet than visiting a doctor." But three weeks after taking tablets containing 2mg of Xanax (quadruple the typical initial dosage a physician would normally prescribe) he awoke in a Chicago hospital room with hypoxic encephalopathy—widespread brain damage.[32]

• In 2006, Justin Pearson of St. Cloud, Minnesota died on Christmas Day of an overdose after receiving at least 12 shipments of drugs purchased over the Internet. The man who sold Pearson and others controlled substances made $24 million before he was stopped, even though at least two other people had also died within 18 months of buying such drugs.[33]

4. Demonstrated need for a federal legislative solution

The DOJ recognizes the need for legislation to address the Internet-based pharmacy problem. During a July 2006 Department of Justice oversight hearing before this Committee, Attorney General Gonzales testified that the sale of pharmaceuticals over the Internet was a great concern and that rogue Internet pharmacies gave drug abusers the ability to obtain controlled substances and cir-

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[27] Id.

[28] Id.

[29] Id.

[30] Vincent Todaro, Center to memorialize local overdose victim Jason Surks, 19, died last year due to his abuse of prescription drugs, The Sentinel, Aug. 19, 2004; see also Linda Surks, A Lethal Prescription, Partnership for a Drug-Free America (May 18, 2006), http://www.drugfree.org/Portal/Memorials/A_Lethal_Prescription.

[31] Thomas Tryon, Wife's death leads husband to sue Internet prescription purveyors, Sarasota Herald-Tribune, Oct. 16, 2005, at F1.

[32] Keith Epstein, The Deadly Side Effects of Net Pharmacies, Business Week, Dec. 18, 2006, available at http://www.businessweek.com/magazine/content/06_51/b4014070.htm; see also Abdon M. Pallasch, Man Sues Over Online Prescription, Chicago Sun-Times, Jan. 10, 2006, at 8.

[33] David Unze, Internet Operation Puts Man in Prison, St. Cloud Times, Aug. 3, 2007, at 1B.

cumvent the law, as well as sound medical practice. The Attorney General testimony noted that because the websites associated with these online pharmacies either posted no identifying information or simply gave false information, it was difficult for law enforcement to track any of the individuals behind the websites. The Attorney General also noted that the DOJ was using all available tools to investigate and shut down rogue Internet pharmacies, but left no doubt of the difficulties law enforcement was facing in these investigations.[34]

In January 2007, Attorney General Gonzales testified that problems with the illegal sale of prescription drugs over the Internet remained and that increased enforcement efforts were simply not enough. Mr. Gonzales indicated that the DOJ looked forward to working with Congress to enact additional enforcement tools to address the problem.[35]

In responses to written follow-up questions, Mr. Gonzales explained that Internet technology had outpaced the enforcement scheme set forth in the 1970 Controlled Substances Act, which was enacted many years before the development and widespread use of the Internet.[36] Mr. Gonzales stated that the evolution of Internet technology had created a haven for individuals to operate rogue Internet pharmacies anonymously. Noting that currently no statutory definition of a valid doctor/patient relationship existed, Mr. Gonzales's testimony indicated that additional statutory clarification relating to the sale of controlled substances over the Internet would allow law enforcement to more readily distinguish between legitimate and rogue online pharmacies, and would also help in gathering information pointing to drug abuse patterns.[37]

Mr. Gonzales also testified that the statutory penalties associated with the sale of Schedule III–V controlled substances, the most common controlled substances sold over the Internet, were too lenient.[38] In later testimony before the Committee, Mr. Rannazzisi also singled out Schedule III and IV controlled substances, including hydrocodone combination products and anabolic steroids, as "increasingly accessible and often illegally purchased through the Internet."[39]

On March 1, 2008, in his national radio address, President George W. Bush called on Congress to enact legislation to address rogue Internet pharmacies.[40] While noting that legitimate Internet pharmacies provide substantial benefits, the President said that the Internet has created the opportunity for unscrupulous doctors and pharmacists to profit from addiction. The President specifically mentioned Ryan Haight, for whom the bill is named, who died of an overdose of pain killers that were illegally prescribed over the Internet, and called on Congress to pass legislation to end the illegal sale of prescription drugs over the Internet.[41]

Other groups have also called on Congress to enact legislation to address this problem. For example, CASA has noted that the lack

[34] Department of Justice Oversight: Hearing Before the S. Comm. on the Judiciary, 110th Cong. (July 18, 2006) (statement of Alberto Gonzales, former Att'y Gen. of the United States).
[35] Jan. 2007 DOJ Hearing, supra note 1; see also, Apr. 2007 DOJ Oversight, supra note 7.
[36] Jan. 2007 DOJ Hearing, supra note 1, at 12.
[37] Id.
[38] Id.
[39] Rogue Online Pharmacies Hearing, supra note 2 (testimony of Joseph T. Rannazzisi).
[40] Bush Radio Address, supra note 8.
[41] Id.

of clarity in Federal and State law over what constitutes a legitimate prescription and has stated that enforcement efforts on the part of law enforcement to address rogue Internet websites have been hampered by the lack of clear legislation on the issue.[42] CASA further concluded that because the Internet transcends State lines, Federal action is essential to address rogue Internet pharmacies.[43]

The bill has received endorsements from law enforcement organizations such as the Fraternal Order of Police and the National Narcotics Officers' Associations Coalition, from industry representatives such as the Healthcare Distribution Management Association, AmerisourceBergen Corporation, eBay Inc., and GoDaddy.com, and from the Federation of State Medical Boards.

II. History of the Bill and Committee Consideration

A. Introduction of the Bill

Senators Feinstein and Sessions introduced S. 980, the Online Pharmacy Consumer Protection Act of 2007, on March 23, 2007. The bill was referred to the Senate Committee on the Judiciary. Following the introduction of S. 980, Senators Biden, Coleman, Leahy and Cornyn joined as cosponsors of this legislation.

B. Committee Consideration

On May 16, 2007, the Judiciary Committee held a hearing entitled, "Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking."[44] Witnesses at the hearing included: (1) Francine Haight of Laguna Niguel, California, Founder of Ryan's Cause; (2) Joseph T. Rannazzisi, Deputy Assistant Administrator of the Office of Diversion Control at the U.S. Drug Enforcement Administration; (3) Joseph A. Califano, Jr., Chairman and President of the National Center on Addiction and Substance Abuse at Columbia University (and former U.S. Secretary of Health, Education and Welfare); (4) A. Thomas McLellan, Ph.D., Executive Director of the Treatment Research Institute at the University of Pennsylvania; and (5) Philip Heymann, the James Barr Ames Professor of Law at Harvard Law School (and former U.S. Deputy Attorney General).

During the hearing, Ms. Haight testified about her son Ryan, who died from an overdose of controlled substances that he ordered over the Internet at age 17.[45] Ryan, described as "the boy next door," was an honor student who maintained an academic average of at least 4.0 throughout high school, and a varsity athlete. Ryan also was computer savvy and was considering a possible career in computers after college. On February 12, 2001, Ryan's mother found him in bed, lifeless. Later analysis established an overdose of Vicodin, with traces of Valium and Morphine. His family did not know how Ryan had obtained such drugs until a friend of Ryan said he had bought them over the Internet. After examining Ryan's computer, the Haights learned that a doctor Ryan had never seen prescribed the medications, and an online pharmacy had delivered

[42] You've Got Drugs IV, supra note 9, at 3.
[43] Id. at 8.
[44] Rogue Online Pharmacies Hearing, supra note 2 (testimony of Joseph A. Califano).
[45] Rogue Online Pharmacies Hearing, supra note 2 (testimony of Francine Haight, Founder, Ryan's Cause).

them to him at home. Ms. Haight testified, "We did not know that drug dealers were in our own family room." Six years after the tragedy, Ms. Haight said that little has changed: "I am still shocked at the ease and availability of buying controlled substances on the Internet. I still receive emails to purchase drugs daily." She concluded: "Tighter controls on the sale of controlled substances on the Internet will not totally solve the drug problem, but I guarantee it will help and it's a good place to start."[46]

Mr. Rannazzisi testified about the methods historically used by many rogue Internet pharmacies, and named three primary facilitators of illegal pharmaceutical sales—the doctor, the pharmacy, and the Internet facilitator.[47] His testimony noted that these sales are promoted by Internet facilitators who lack medical training and are not DEA registrants and that these facilitators target doctors with significant debt and convince them to approve prescriptions because prospective Internet clients submit minimum "medical history" forms through the website.[48] Mr. Rannazzisi testified that such doctors approve prescriptions for Schedule III or IV controlled substances with the mistaken belief or justification that these substances are not as dangerous as those listed in Schedule II.[49] According to Mr. Rannazzisi, for every online prescription that doctors authorize, the Internet facilitator pays the doctor $10 to $25, and law enforcement has discovered website-affiliated physicians who authorized hundreds of online prescriptions a day.[50]

Mr. Rannazzisi testified that Internet facilitators also recruit brick and mortar pharmacies into their online schemes, often targeting small, independent pharmacies struggling to make ends meet.[51] According to the DEA, the Internet facilitator tells these pharmacies that all they have to do is fill and ship these prescriptions to customers. In addition to paying the pharmacy for the cost of the prescription, the Internet facilitator also pays the pharmacy a negotiated fee, sometimes amounting to millions of dollars.

Mr. Rannazzisi also testified that Internet facilitators host the websites that draw online customers into the rogue Internet pharmacy scheme. According to Mr. Rannazzisi, these websites often mislead customers by advertising the website as an actual pharmacy. In reality, the rogue Internet websites offer only a few pharmaceutical products for sale, typically limited to prescription controlled substances and lifestyle drugs. Mr. Rannazzisi testified that website advertising typically emphasizes the ability of online customers to acquire controlled substances without prescription or an appropriate medical examination, and none of the rogue Internet

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[46] Id.

[47] Rogue Online Pharmacies Hearing, supra note 2 (testimony of Joseph T. Rannazzisi).

[48] Id.

[49] Id.

[50] Id. See also You've Got Drugs IV, supra note 9, at 7 (The National Center on Addiction and Substance Abuse calls such physicians "script doctors," who "are willing to write prescriptions for a fee." It has identified some fees for certain prescriptions as high as $180); and Epstein, supra note 32 (noting that an "accomplished" doctor of this type, as the hired hand of an online pharmacy, "typically approves Internet prescriptions at a rate of more than 1,000 a day—without communicating with the purchaser, or in many cases, reading the questionnaire." It estimates that "[a]n ambitious doctor [of this type] can earn over $1 million a year."). See also http://sid.senate.gov/dana/home/launch.cgi?url=http%3A%2F%2Fwww.congress.gov%2F (Unfortunately, as the Congressional Research Service notes, "laws governing medical practice vary widely in strength and effectiveness from State to State. While some states have strong laws that explicitly prohibit activities such as prescribing drugs without conducting an in-person examination, other states have weak laws, lax enforcement, or both.")

[51] Rogue Online Pharmacies Hearing, supra note 2 (testimony of Joseph T. Rannazzisi).

pharmacies require an in-person medical examination from a licensed physician. He also testified that rogue Internet pharmacy websites rarely contain any identifying information on the website about where the pharmacy is physically located or who owns and operates it.[52]

In addition, Mr. Rannazzisi's testimony highlighted how customers of rogue Internet pharmacies obtain prescription controlled substances online. Typically, customers simply filled out a medical questionnaire, without any meaningful interaction between a doctor and the customer. In many cases, the questionnaire simply is a ruse created to identify exactly what type of prescription controlled substance the customer wants to purchase. In some cases, such website questionnaires will not permit the customer to continue until specific information justifying the purchase of a particular prescription controlled substance is entered.[53]

Mr. Rannazzisi also noted that prescription controlled substances in the United States are legitimately prescribed and dispensed within a closed system of distribution. With rogue Internet pharmacies, however, complicity exist among all of the participants, effectively eliminating all of the normal checks and balances. While acknowledging that rogue sites outside of the United States may prove more difficult to regulate, Mr. Rannazzisi testified that the "DEA believes a majority of the rogue sites operating today are based in the United States and work in concert with unscrupulous doctors and pharmacies." Other evidence indicated that offshore and foreign rogue sites are also a very significant problem.[54]

Mr. Califano testified that Federal enforcement efforts aimed at illegal Internet drug trafficking was complicated by outdated Federal law enacted before the advent of the Internet.[55] Given the widespread public health threat that rogue Internet pharmacies posed, Mr. Califano called on Congress to take action legislatively to clarify Federal law to prohibit the sale or purchase of prescription controlled substances on the Internet without a valid prescription, and to require certification of online pharmacies to assure that they meet rigorous standards of professional practice. Mr. Califano specifically described S. 980 as an important "step in the right direction."[56]

Dr. McLellan, whose Treatment Research Institute first completed a study of this issue in 2004, testified that "anyone—regardless of age or medical need can purchase pharmaceutical grade opiates, barbiturates, benzodiazepines and stimulants over the Internet without a prescription."[57] Despite intensive publicity in the past,[58] Dr. McLellan testified that nothing has changed and that it remains as easy to buy prescription controlled substances online as it is to buy a book or compact disc. He noted that while illicit drug use by teens had dropped 23% over the past five years, new users of prescription drugs have caught up with new users of marijuana. Dr. McLellan blamed the increase in prescription drug abus-

[52] Id.
[53] Id.
[54] Id.
[55] Rogue Online Pharmacies Hearing, supra note 2 (testimony of Joseph A. Califano).
[56] Id.
[57] Rogue Online Pharmacies Hearing, supra note 2 (statement of A. Thomas McLellan, Ph.D., Executive Dir., Treatment Research Inst., Univ. of Penn.).
[58] See, e.g., Gilbert M. Gaul and Mary Pat Flaherty, Doctors Medicate Strangers on Web, Washington Post, Oct. 23, 2003, at A1.

ers on the rise of rogue Internet pharmacies. He testified that "Internet savvy teenagers with their own credit cards or access to their parents' cards are increasingly disposed to prescription drugs to get high." In particular, Dr. McLellan singled out OxyContin and Vicodin—both in the same family of drugs as heroin—as two drugs teenagers are increasingly abusing. However, unlike heroin, OxyContin and Vicodin are appropriate for pain management when prescribed and taken under a physician's care, but are frequently available in large quantities through unscrupulous doctors and rogue Internet pharmacies.[59]

Dr. McClellan also discussed some of the more troubling marketing principles of Internet pharmacies' websites—including free or discounted first orders, shipments with no identifying information, and even credit card billings for drug orders made to look like charged "ring tones" for a student's cellular phone. While deferring to others on the proper policy response, Dr. McLellan testified:

> [We] should do all in our power to put it out of the reach of children. . . . for the majority of people in this country suffering from addiction, the roots of the disease can be traced to adolescence. More than 95% of people who are dependent on alcohol or other drugs started before they were 20 years old.[60]

Mr. Heymann testified that despite the public outcry against rogue Internet pharmacies, nothing was being done legislatively to stop the problem.[61] In Mr. Heymann's view, however, many rogue websites selling such narcotic painkillers as OxyContin and Vicodin are located abroad and will not be deterred by U.S. threats of increased penalties. Accordingly, Mr. Heymann suggested broader legislative approaches, such as Government funding of a private monitoring group, with immunity granted to companies taking actions recommended by that group. Other suggestions included legislation forcing Internet search engines to place warning banners on all online pharmacy websites, and efforts by Congress to enlist credit card companies and banks in enforcement efforts.[62] Mr. Heymann noted that his suggestions arose after six plenary meetings at Harvard Law School, which were attended by a collaboration of affected parties, including leaders of companies that play key roles in Internet commerce, banks, credit card companies and private carriers.[63] However, Mr. Heymann acknowledged that "not all agreed with each of our recommendations" that were being suggested by the plenary group's 5–6 leaders. While leading credit card companies and Internet service providers did express general

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[59] Rogue Online Pharmacies Hearing, supra note 2 (statement of A. Thomas McLellan).

[60] Id.

[61] Rogue Online Pharmacies Hearing, supra note 2 (statement of Philip Heymann, James Barr Ames Professor of Law, Harvard Law School, former U.S. Deputy Att'y Gen. of the United States).

[62] Id. ("[O]n receipt of information about illicit transactions from independent monitoring groups or from their own internal monitors, the financial institutions would and should be expected to identify the accounts that are being abused, presumably by putting through a 'test' order of their own. The drug merchant's bank would be contractually obligated to know its customer and to take steps to penetrate any pseudonyms used by the drug dealer. The dealer's merchant bank would also cut off credit to the offending account and to those behind the account if it is really a front—furnishing the information it learns about the illegal transaction to other credit card companies and to law enforcement.").

[63] "Keep Internet Neighborhoods Safe": A Proposal for Preventing the 1AIllegal Internet Sales of Controlled Substances to Minors, Harvard Law School Internat'l Ctr. for Criminal Justice, July 13th, 2006, available at http://www.law.harvard.edu/programs/criminal-justice/kins-draft.pdf.

support for many of the plenary group's ideas, their preference was for encouraging voluntary compliance rather than legislative or regulatory mandates. Several plenary participants, as well as several panelists at a Judiciary Committee roundtable briefing held by the Internet Drug Caucus Advisory Committee on June 22, expressed opposition to adding these proposals to S. 980.

In addition to the hearing before the Senate Judiciary Committee in the 110th Congress, other congressional hearings have also examined problems of rogue Internet pharmacies, providing background for this legislation. For example, the Permanent Subcommittee on Investigations of the Senate's Committee on Homeland Security and Governmental Affairs held a hearing on June 17, 2004, following the issuance of a Government Accountability Office report that documented the ease with which prescription drugs, including addictive narcotic pain killers, could be purchased over the Internet without a prescription.[64] On March 27, 2003 and March 18, 2004, the House of Representatives' Committee on Government Reform also held hearings at which the FDA's Associate Commissioner for Policy and Planning discussed illegal Internet sales of controlled substances.[65]

Chairman Leahy placed S. 980 on the Committee's executive business meeting agenda for consideration on September 20, 2007, and the bill was considered by the Committee on that same day. Senator Feinstein introduced an amendment in the nature of a substitute to the original bill which was adopted by the Committee. In addition to making various substantive changes, the substitute named the bill in honor of Ryan Haight. The Committee, by voice vote, reported the Ryan Haight Online Pharmacy Consumer Protection Act of 2007, with an amendment in the nature of a substitute, favorably to the full Senate.

III. Section-by-Section Summary of the Bill

Section 1. Short title

This section provides that the legislation may be cited as the "Ryan Haight Online Pharmacy Consumer Protection Act of 2007," in honor of Ryan Haight, a California high school honors student and athlete who died in 2001 from an overdose of controlled substances that he had purchased from a rogue online pharmacy.

Section 2. Requirement of a valid prescription for controlled substances dispensed by means of the Internet

This section adds a new subsection to section 309 of the Controlled Substances Act that requires a "valid prescription" for dispensing a controlled substance over the Internet. A "valid prescription" is defined as one issued for a legitimate medical purpose in the usual course of professional practice, by a practitioner who has conducted at least one in-person medical evaluation of the patient,

[64] Buyer Beware: The Danger of Purchasing Pharmaceuticals over the Internet—Day 2 Federal and Private Sector Responses: Hearing Before the Permanent Subcommittee on Investigations, S. Comm. on Homeland Security and Governmental Affairs 108th Cong., (2004); U.S. Gen. Accounting Office, Internet Pharmacies: Some Pose Safety Risks for Consumers and Are Unreliable in Their Business Practices (2004), available at http://www.gao.gov/new.items/d04888t.pdf.

[65] Hearings Before the H. Comm. on Gov't Reform on Internet Drug Sales, 108th Cong. (2003, 2004) (testimony of William K. Hubbard, Assoc. Comm'r for Policy and Planning, Food and Drug Admin., Dep't of Health and Human Servs.).

or a covering practitioner (as requested by a practitioner who had conducted an in-person medical evaluation of the patient within the past 24 months). Certain telemedicine practices are exempted from the in-person medical evaluation requirement.

The Committee recognizes that telemedicine is a practice tool that can improve health outcomes and reduce costs. It is not the intent of the Committee to restrict the legitimate practice of telemedicine or the emerging practices of telemedicine which are consistent with medical practice guidelines of the State in which the practitioner is licensed, provided such practices do not contravene the goal of effectively controlling the diversion of controlled substances.

The Committee recognizes that telemedicine offers options for specialty and primary care not available in many remote areas, and that practitioners with prescriptive authority are often not available on-site at the time of tele-consultations. It is not the intent of the Committee to place unnecessary restrictions on the operations or growth of telemedicine organizations that both conduct telemedicine consultations and provide Internet prescription services to its patients.

Accordingly, the statute provides that the Attorney General and the Secretary of Health and Human Services may promulgate regulations that allow for the full practice of telemedicine consistent with medical practice guidelines, so long as those regulations continue to effectively control diversion. The Committee anticipates that the Attorney General and the Secretary may update these regulations on an ongoing basis to reflect changes in telemedicine.

The legislation is intended to regulate practices related to the delivery, distribution, or dispensing of schedule II, III, IV, and V controlled substances by means of the Internet. The bill does not address the delivery, distribution, or dispensing of any non-controlled substance by means of the Internet or any other means. The bill is not intended to infringe upon the powers of the Department of Health and Human Services and its Secretary with respect to non-controlled substances. Nor is it intended to infringe upon the traditional power of the States to regulate the practices of medicine and pharmacy with respect to the prescription of non-controlled substances. It is not the intent of the Committee to affect the delivery, distribution, or dispensing of non-controlled substances, approved by the Secretary of Health and Human Services or the regulatory bodies of the States, by means of the legislation.

Section 3. Amendments to the Controlled Substances Act

This section makes a number of changes to the Controlled Substances Act:

Section 3(a)—Definitions

This subsection defines "Internet", "deliver, distribute, or dispense by means of the Internet", "online pharmacy," and "practice of telemedicine." It also exempts from the definition of an "online pharmacy" non-pharmacy practitioners and mere advertisements that do not attempt to facilitate an actual transaction.

It is not the intent of the Committee, in paragraph (55)(B), to prohibit a licensed pharmacist, acting pursuant to a patient's request via the Internet, and in the usual course of professional prac-

tice, from contacting the patient's prescriber and receiving an order for a new prescription for a previously prescribed controlled substance that has expired or has no remaining valid refills. Similarly, as a general rule, it is not the intent of the Committee, in paragraphs (56)(A), (B), and (C) to prohibit a pharmacist from contacting a practitioner under all the circumstances described in either paragraph (55) or (56). The lone exception is that a practitioner, acting in the usual course of professional practice and for a legitimate medical purpose, can direct the pharmacist that the patient should be prescribed a different controlled substance and specify the new prescription, provided that the pharmacist subsequently contacts the patient by telephone or in person to notify the patient of the practitioner's change in prescription and provides appropriate information and instructions to the patient regarding the change in medication.

Therefore, it is the intent of the Committee that the modified registration, reporting, and website posting requirements applicable to online pharmacies would not apply to DEA-registered pharmacies whose Internet business consists solely of permitting consumers to use the pharmacy's Internet site to order refills in the scenarios described above.

Section 3(b)—Registration requirements

This subsection establishes that a pharmacy that seeks to dispense controlled substances via the Internet must register in accordance with regulations to be promulgated by the Attorney General.

Section 3(c)—Reporting requirements

This subsection requires that online pharmacies must report on substances dispensed in accordance with regulations to be promulgated by the Attorney General.

Section 3(d)—Online pharmacy licensing and disclosure requirement

This subsection requires that online pharmacies must clearly display notification that they comply with certain requirements set forth in the bill: Pharmacies must post information regarding: name of the owner, owner's contact information, list of states in which the pharmacy is licensed to distribute prescription drugs or controlled substances, name of the pharmacy, street address of the pharmacy, name and degree of pharmacist in charge, contact information for pharmacist in charge, and the name and contact information of affiliated practitioners. Their websites must also post a statement of compliance. Online pharmacies must also notify the Attorney General and State boards of pharmacy 30 days before they begin delivering, distributing, or dispensing a controlled substance.

Section 3(e)—Increased penalties for illegal distribution of schedules III–V controlled substances

This subsection increases the penalties for all illegal distributions of Schedule III, IV and V controlled substances (not just Internet sales). For Schedule III controlled substances, the maximum penalties are increased to 10 years for first offenders and 20

years for repeat offenders, and to 20 and 30 years, respectively, if death or serious bodily injury results. For Schedule IV substances, the new penalties are 5 years for first offenders and 10 years for repeat offenders. For Schedule V repeat offenders, the maximum penalty increases to 6 years. Supervised release terms after imprisonment for a Schedule V offense are also authorized for the first time.

Section 3(f)—Internet sales of controlled substances

This subsection clarifies that knowingly causing or facilitating the delivery or dispensing of controlled substances over the Internet in violation of this Act can be prosecuted and penalized in the same manner as illegal hand-to-hand drug sales. The subsection clarifies, however, that this provision does not apply to persons who register and follow the requirements of this Act, to those who merely advocate usage or list pricing information but do not promote or facilitate an actual transaction involving a controlled substance, or to anyone providing telecommunications, Internet services, or links to other websites unless they are acting in concert with persons violating this Act.

Section 3(g)—Advertising controlled substances

This subsection clarifies that Internet sales of controlled substances must follow the terms of this Act.

Section 3(h)—Injunctive relief

This subsection authorizes State attorneys general to file civil lawsuits in Federal court against online pharmacies and obtain nationwide relief if the residents of a State are threatened or adversely affected by noncompliance, and the U.S. Attorney General is notified in advance and also given a chance to intervene in the case within 120 days.

Section 3(i)—Forfeiture

This subsection expands the scope of property subject to civil forfeiture under Federal drug laws, to encompass "any property used, in any manner or part, to commit or to facilitate the commission of a violation" under titles II or III of the Comprehensive Drug Abuse Prevention and Control Act.

Concerns have been expressed about the potential impact of this provision upon responsible companies engaged in providing Internet marketplaces, electronic payment services, or similar e-commerce services whose property may be used without the companies' knowledge and consent to commit the new criminal offenses created by the bill to address illicit online pharmacies. Since such offenses will necessarily involve use of the Internet and likely will involve electronic payments, the Committee thinks it prudent to spell out its intent as to how this new authority should be used in this context.

The intent of section 3(i), as applied to online pharmacies, is to authorize Federal civil forfeiture of non-innocent owners' property that facilitates violations of the new statutes created by the bill. In this manner, this provision of the bill is intended to provide Federal law enforcement with an additional tool to combat the proliferation of Internet-based criminal operations that employ ever-

changing methods and technologies to deliberately distribute pharmaceutical controlled substances without a sound medical basis. This expanded civil forfeiture authority is necessary to provide law enforcement with a more effective and rapid means to bring to a halt the operation of such rogue Web sites, which the bill is designed to prohibit.

However, section 3(i) is not intended to authorize forfeiture of the property, including the computer equipment, facilities or networks of legitimate Internet marketplace companies or payment card systems that take reasonable precautions against the illegal use of their property, do not consent to such use, and, upon learning of any such use, do all that reasonably can be expected under the circumstances to terminate it. The Committee notes that responsible companies in this sector have adopted strong policies against use of their networks, websites, or services for illegal purposes, and have cooperated with law enforcement when they learned that their services were being abused for criminal purposes. The Committee commends those companies and encourages them to maintain and strengthen their anti-crime policies and their efforts to prevent criminal use of their property.

The Committee is aware that many existing civil forfeiture statutes authorize forfeiture of property that is involved in or facilitates other violations of Federal law that may be facilitated through the abuse of the Internet. This existing authority has not had disruptive impact on legitimate Internet marketplaces, payment card systems, or their legitimate customers because it has been exercised carefully and prudently to date, in accordance with internal controls intended to prevent misuse. The Committee urges that such careful enforcement continue in service of the dual goals of detecting and preventing criminal use of the Internet and fostering the healthy growth of legitimate e-commerce.

Section 3(j)—Import and Export Act

This subsection makes the same penalty changes to the Import and Export Act that are being made to the Controlled Substances Act, so that illegal imports and exports of controlled substances will continue to receive the same penalties as illegal domestic sales.

Section 3(k)—Effective date

This subsection clarifies that the Act will become effective 60 days after enactment.

Section 3(l)—Regulations and guidelines

This subsection specifies that the Attorney General shall promulgate regulations as necessary to effect the Act, and the U.S. Sentencing Commission shall add or modify the Sentencing Guidelines as warranted.

Section 3(m)—Report to Congress

This subsection establishes that the DEA, after consulting with the State Department, must provide a report to Congress within 180 days of the Act's enactment, and annually thereafter for 2 years, describing the foreign supply chains and sources of con-

trolled substances illegally offered over the Internet, and the efforts and strategies being used to confront these challenges globally.[66]

IV. Congressional Budget Office Cost Estimate

The Committee sets forth, with respect to the bill, S. 980, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act of 1974:

U.S. Congress,
Congressional Budget Office,
Washington, DC, October 25, 2007.

Hon. Patrick J. Leahy,
Chairman, Committee on the Judiciary,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the enclosed cost estimate for S. 980, the Ryan Haight Online Pharmacy Consumer Protection Act of 2007.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Mark Grabowicz.

Sincerely,

Peter R. Orszag.

Enclosure.

S. 980—The Ryan Haight Online Pharmacy Consumer Protection Act

Summary: S. 980 would require businesses that distribute controlled substances using the Internet to register with the Drug Enforcement Administration (DEA). CBO estimates that implementing S. 980 would have no significant net cost to the Federal Government. Enacting the bill could affect direct spending and revenues, but CBO estimates that any net effects would not be significant.

S. 980 contains an intergovernmental mandate as defined in the Unfunded Mandates Reform Act (UMRA) because it would preempt certain State regulations governing controlled substances that are manufactured, distributed, or dispensed via the Internet. CBO estimates, however, that states would incur few, if any, costs as a result of that preemption, and therefore the costs to comply with the mandate would be well below the threshold established in UMRA ($66 million in 2007, adjusted annually for inflation).

The registration and reporting requirements and the requirement of a valid prescription for Internet distribution of controlled substances constitute private-sector mandates as defined in UMRA. CBO estimates that the direct costs of those mandates would not exceed the threshold established in UMRA ($131 million in 2007, adjusted annually for inflation).

Estimated cost to the Federal Government:

Spending subject to appropriation

S. 980 would establish new crimes and increase penalties for activities relating to illegal use of controlled substances. Because the

[66] As CASA recommends, "[T]he State Department should encourage and assist foreign Governments to crack down on Internet sites illegally selling controlled prescription drugs to U.S. citizens."

bill would establish new offenses, the government would be able to pursue cases that it otherwise would not be able to prosecute. We expect that S. 980 would apply to a relatively small number of offenders, however, so any increase in costs for law enforcement, court proceedings, or prison operations would not be significant. Any such costs would be subject to the availability of appropriated funds.

Direct spending and revenues

S. 980 would require businesses that distribute controlled substances using the Internet to register with the DEA. The DEA would charge a registration fee of $551 for a three-year period. Based on information from the DEA about the likely number of new registrants, CBO estimates that the agency would collect no more than a few million dollars each year. The DEA would spend those fees without further appropriation, mostly in the same year, to conduct inspections and carry out administrative activities related to the new registrants. Thus, CBO estimates that S. 980 would have no significant net effect on DEA spending.

Because those prosecuted and convicted under S. 980 could be subject to criminal fines, the Federal government might collect additional fines if the legislation is enacted. Criminal fines are recorded as revenues, then deposited in the Crime Victims Fund, and later spent. CBO expects that any additional revenues and direct spending would not be significant because of the small number of cases likely to be affected.

Estimated impact on State, local, and Tribal Governments: S. 980 contains an intergovernmental mandate as defined in UMRA because it would preempt certain State regulations of controlled substances that are manufactured, distributed, or dispensed via the Internet. Under current law, states license pharmacies and doctors to dispense controlled substances within each state. This bill would prohibit the sale of controlled substances that are sold over the Internet without a prescription and would require doctors to have at least one in-person consultation with patients for whom they prescribe controlled medications. Currently, all states allow medications to be purchased via the Internet, but some states do not specifically require in-person consultations for prescriptions. Enacting this provision would preempt State authority. CBO estimates, however, that states would incur few, if any, costs as a result of that preemption, and therefore the costs to comply with the mandate would be well below the threshold established in UMRA ($66 million in 2007, adjusted annually for inflation).

Estimated impact on the private sector: The registration and reporting requirements and the requirement to have a valid prescription for distributing controlled substances via the Internet constitute private-sector mandates as defined in UMRA. CBO estimates that the direct costs of those mandates would not exceed the threshold established in UMRA ($131 million in 2007, adjusted annually for inflation).

Estimate prepared by: Federal costs: Mark Grabowicz; Impact on State, local, and Tribal Governments: Melissa Merrell; Impact on the private sector: Colin Baker.

Estimate approved by: Theresa Gullo, Deputy Assistant Director for Budget Analysis.

V. Regulatory Impact Evaluation

In compliance with paragraph 11(b)(1), rule XXVI of the Standing Rules of the Senate, the Committee finds that the passage of S. 980 will require the Department of Justice to promulgate regulations governing the registration of, and reporting requirements imposed on, online pharmacies that dispense controlled substances by means of the Internet, and may require the Department of Health and Human Services and the Department of Justice to promulgate regulations governing certain practices relating to the practice of telemedicine.

VI. Conclusion

The Congressional Research Service has stated:

> The current legal framework for regulating online pharmacies and doctors is a patchwork of Federal and State laws regarding controlled substances, prescription drugs, pharmacies, and the practice of medicine. Although many doctors and pharmacies who use the Internet prescribe and dispense drugs in a safe and legal fashion, others have exploited gaps in the current system to prescribe and dispense potentially dangerous quantities of highly addictive prescription drugs.[67]

Passage and enactment of the bipartisan Ryan Haight Online Pharmacy Consumer Protection Act of 2007, S. 980, will address the intolerable "wide-open channel of distribution" that currently exists for prescription controlled substances sold over the Internet, which represents an "easy availability [that] has enormous implications for public health, particularly the health of our children."[68] The Committee believes that the time has come for Congress to act, and that S. 980 is an appropriate response that should be adopted by Congress.

VII. Changes to Existing Law Made by the Bill, as Reported

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 980, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

TITLE 21, UNITED STATES CODE

* * * * * * *

CHAPTER 13—DRUG ABUSE PREVENTION AND CONTROL

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[67] See Legal Issues Related to Prescription Drug Sales on the Internet (RS21711, updated September 19, 2007) https://sid.senate.gov/dana/home/launch.cgi?url=http%3A%2Fst%2F www.congress.gov%2F.

[68] You've Got Drugs IV: Prescription Drug Pushers on the Internet, at 8 (White Paper issued by the National Center on Addiction and Substance Abuse at Columbia University, May 2007).

Subchapter I—Control and Enforcement

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Part A—Introductory Provisions

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§ 802. Definitions

As used in this subchapter:

(1) * * *

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(50) The term "Internet" means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information to all kinds by wire or radio.

(51) The term "deliver, distribute, or dispense by means of the Internet" refers, respectively, to any deliver, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

(52) The term "online pharmacy"—

(A) means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet: and

(B) does not include—

(i) manufacturers or distributors registered under subsection (a), (b), (c), or (d) of section 303 who do not dispense controlled substances to an unregistered individual or entity;

(ii) nonpharmacy practitioners who are registered under section 303(f) and whose activities are authorized by that registration;

(iii) mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance; or

(iv) a person, entity, or Internet site which is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States.

(53) The term "homepage" means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.

(54) The term "practice of telemedicine" means the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a

telecommunications system referred to in section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)).

* * * * * * *

Part C—Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§ 823. Registration requirements

(a) * * *

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(i) DISPENSER OF CONTROLLED SUBSTANCES BY MEANS OF THE INTERNET.—

(1) An online pharmacy shall obtain a registration specifically authorizing such activity, in accordance with regulations promulgated by the Attorney General. In determining whether to grant an application for such registration, the Attorney General shall apply the factors set forth in subsection (f).

(2) Registration under this subsection shall be in addition to, and not in lieu of, registration under subsection (f).

(3) This subsection does not apply to pharmacies that merely advertise by means of the Internet but do not attempt to facilitate an actual transaction involving a controlled substance by means of the Internet.

* * * * * * *

§ 827. Records and reports of registrants

(a) INVENTORY.—

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(d) PERIODIC REPORTS TO ATTORNEY GENERAL.—

(1) Every manufacturer registered under section 823 of this title shall, at such time or times and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances, identifying by the registration number assigned under this subchapter the person or establishment (unless exempt from registration under section 822(d) of this title) to whom such sale, delivery, or other disposal was made.

(2) A pharmacy registered under section 303(i) shall report to the Attorney General the controlled substances dispensed under such registration, in such manner and accompanied by such information as the Attorney General by regulation shall require.

* * * * * * *

§ 829. Prescriptions

(a) * * *

* * * * * * *

(e) CONTROLLED SUBSTANCES DISPENSED BY MEANS OF THE INTERNET.—

(1) No controlled substance may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

(2) As used in this subsection:

(A) The term "valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—

(i) a practitioner who has conducted at least one in-person medical evaluation of the patient; or

(ii) a covering practitioner.

(B)(i) The term "in-person medical evaluation" means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

(ii) Nothing in the clause (i) shall be construed to imply that one in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(C) The term "covering practitioner" means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who—

(i) has conducted at least one in-person medical evaluation of the patient during the 24-month period ending on the date of that medical evaluation; and

(ii) is temporarily unavailable to conduct the evaluation of the patient.

(3) Nothing in this subsection shall apply to—

(A) the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine if—

(i) the telemedicine is being conducted while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f), and the practitioner conducting the practice of telemedicine is registered under section 303(f) in the State in which the patient is located and is acting in the usual course of professional practice and in accordance with applicable State law;

(ii) the telemedicine is being conducted while the patient is being treated by, and in the physical presence of, a practitioner registered under section 303(f) who is acting in the usual course of professional practice, and the practitioner conducting the practice of telemedicine is registered under section 303(f) in the State in which the patient is located and is acting in the usual course of professional practice and in accordance with applicable State law; or

(iii) the telemedicine is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety; or

(B) The dispensing or selling of a controlled substance pursuant to the practices as determined by the Attorney

General by regulation, which shall be consistent with effective controls against diversion.

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§ 830. Regulation of listed chemicals and certain machine

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§ 831. Online pharmacy licensing and disclosure requirements

(a) IN GENERAL.—An online pharmacy shall display in a visible and clear manner on its homepage a statement that it complies with the requirements of this section with respect to the delivery or sale or offer for sale of controlled substances and shall at all times display on the homepage of its Internet site a declaration of compliance in accordance with this section.

(b) LICENSURE.—Each online pharmacy shall comply with the requirements of State law concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses or offers to deliver, distribute, or dispense controlled substances by means of the Internet.

(c) COMPLIANCE.—No online pharmacy or practitioner shall deliver, distribute, or dispense by means of the Internet a controlled substance without a valid prescription (as defined in section 309(e)) and each online pharmacy shall comply with all applicable requirements of Federal and State law.

(d) INTERNET PHARMACY SITE DISCLOSURE INFORMATION.—Each online pharmacy site shall post in a visible and clear manner on the homepage of its Internet site or on a page directly linked from its homepage the following:

(1) The name of the owner, street address of the online pharmacy's principal place of business, telephone number, and email address.

(2) A list of the States in which the online pharmacy, and any pharmacy which dispenses, delivers, or distributes a controlled substance on behalf of the online pharmacy, is licensed to dispense controlled substances or prescription drugs and any applicable license number.

(3) For each pharmacy identified on its license in each State in which it is licensed to engage in the practice of pharmacy and for each pharmacy which dispenses or ships controlled substances on behalf of the online pharmacy:

(A) The name of the pharmacy.

(B) The street address of the pharmacy.

(C) The name, professional degree, and licensure of the pharmacist-in-charge.

(D) The telephone number at which the pharmacist-in-charge can be contacted.

(E) A certification that each pharmacy which dispenses or ships controlled substances on behalf of the online pharmacy is registered under this part to deliver, distribute, or dispense by means of the Internet controlled substances.

(4) The name, address, professional degree, and licensure of practitioners who provide medical consultations through the website for the purpose of providing prescriptions.

(5) A telephone number or numbers at which the practitioners described in paragraph (4) may be contacted.

(6) The following statement, unless revised by the Attorney General by regulation: This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner, which includes at least one prior in-person medical evaluation. This online pharmacy complies with section 309(e) of the Controlled Substances Act (21 U.S.C. 829(e)).

(e) NOTIFICATION.—(1) Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing, the online pharmacy shall notify the Attorney General, in the form and manner as the Attorney General shall determine, and the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances.

(2) The notification required under paragraph (1) shall include—

(A) the information required to be posted on the online pharmacy's Internet site under subsection (d) and shall notify the Attorney General and the applicable State boards of pharmacy, under penalty of perjury, that the information disclosed on its Internet site under to subsection (d) is true and accurate;

(B) the online pharmacy's Internet site address and a certification that the online pharmacy shall notify the Attorney General of any change in the address at least 30 days in advance; and

(C) the Drug Enforcement Administration registration numbers of any pharmacies and practitioners referred to in subsection (d), as applicable.

(3) An online pharmacy that is already operational as of the effective date of this section, shall notify the Attorney General and applicable State boards of pharmacy in accordance with this subsection not later than 30 days after the effective date of this section.

(f) DECLARATION OF COMPLIANCE.—On and after the date on which it makes the notification under subsection (e), each online pharmacy shall display on the homepage of its Internet site, in such form as the Attorney General shall by regulation require, a declaration that it has made such notification to the Attorney General.

(g) REPORTS.—Any statement, declaration, notification, or disclosure required under this section shall be considered a report required to be kept under this part.

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Part D—Offenses and Penalties

§ 841. Prohibited acts A

(a) UNLAWFUL ACTS.—

* * * * * * *

(b) PENALTIES.—Except as otherwise provided in section 849, 859, 860, or 861 of this title, any person who violates subsection (a) of this section shall be sentenced as follows:

(1)(A) * * *

* * * * * * *

(C) In the case of a controlled substance in schedule I or II, gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 3(a)(1)(B) of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000), or [1 gram of] flunitrazepam, except as provided in subparagraphs (A), (B), and (D), such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 6 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this subparagraph which provide for a mandatory term of imprisonment if death or serious bodily injury results, nor shall a person so sentenced be eligible for parole during the term of such a sentence.

(D) In the case of less than 50 kilograms of marihuana, except in the case of 50 or more marihuana plants regardless of weight, 10 kilograms of hashish, or one kilogram of hashish oil [or in the case of any controlled substance in schedule III (other than gamma hydroxybutyric acid), or 30 milligrams of flunitrazepam], such person shall, except as provided in paragraphs (4) and (5) of this subsection, be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior con-

viction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to such term of imprisonment.

(E)(i) In the case of any controlled substance in schedule III, such person shall be sentenced to a term of imprisonment of not more than 10 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 20 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, or $500,000 if the defendant is an individual or $2,500,000 if the defendant is other than an individual, or both.

(ii) If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 30 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both.

(iii) Any sentence imposing a term of imprisonment under this subparagraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to such term of imprisonment

(2) In the case of a controlled substance in schedule IV, such person shall be sentenced to a term of imprisonment of not more than [3 years] *5 years*, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation [after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final] *after a prior conviction for a felony drug offense has become final*, such person shall be sentenced to a term of imprisonment of not more than [6 years] *10 years*, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least one year in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment.

(3) In the case of a controlled substance in schedule V, such person shall be sentenced to a term of imprisonment of not more than one year, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $100,000 if the defendant is an individual or $250,000 if the defendant is other than an individual, or both. If any person commits such a violation [after one or more convictions of him for an offense punishable under this paragraph, or for a crime under any other provision of this subchapter or subchapter II of this chapter or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final] *after a prior conviction for a felony drug offense has become final*, such person shall be sentenced to a term of imprisonment of not more than [2 years] *6 years*, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $200,000 if the defendant is an individual or $500,000 if the defendant is other than an individual, or both. *Any sentence imposing a term of imprisonment under this paragraph may, if there was a prior conviction, impose a term of supervised release of not more than 1 year, in addition to such term of imprisonment.*

* * * * * * *

(h) OFFENSES INVOLVING DISPENSING OF CONTROLLED SUBSTANCES BY MEANS OF THE INTERNET.—

(1) Except as authorized by this title, it shall be unlawful for any person to knowingly or intentionally cause or facilitate the delivery, distribution, or dispensing by means of the Internet of a controlled substance.

(2) Examples of activities that violate paragraph (1) include, but are not limited to, knowingly or intentionally—

(A) delivering, distributing, or dispensing a controlled substance by means of the Internet by a pharmacy not registered under section 303(i);

(B) writing a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of subsection 309(e);

(C) serving as an agent, intermediary, or other entity that causes the Internet to be used to bring together a buyer and seller to engage in the dispensing of a controlled substance in a manner not authorized by sections 303(i) or 309(e); and

(D) making a material false, fictitious, or fraudulent statement or representation in the submission to the Attorney General under section 311.

(3)(A) This subsection does not apply to—

(i) the delivery, distribution, or dispensation of controlled substances by nonpractitioners to the extent authorized by their registration under this title;

(ii) the placement on the Internet of material that merely advocates the use of a controlled substance or includes pricing information without attempting to propose or facilitate an actual transaction involving a controlled substance; or

(iii) except as provided in subparagraph (B), any activity that is limited to—

(I) the provision of a telecommunications service, or of an Internet access service or Internet information location tool (as those terms are defined in section 231 of the Communications Act of 1934 (47 U.S.C. 231)); or

(II) the transmission, storage, retrieval, hosting, formatting, or translation (or any combination thereof) of a communication, without selection or alteration of the content of the communication, except that deletion of a particular communication or material made by another person in a manner consistent with section 230(c) of the Communications Act of 1934 (47 U.S.C. 230(c)) shall not constitute such selection or alteration of the content of the communication.

(B) The exceptions under subclauses (I) and (II) of subparagraph (A)(iii) shall not apply to a person acting in concert with a person who violates subsection (g)(1).

(4) Any person who knowingly or intentionally violates this subsection shall be sentenced in accordance with subsection (b) of this section.

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§ 843. Prohibited acts C

(a) * * *

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(c) ADVERTISEMENT.—

(1) It shall be unlawful for any person to place in any newspaper, magazine, handbill, or other publications, any written advertisement knowing that it has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule [1] I controlled substance. As used in this section the term "advertisement" includes, in addition to its ordinary meaning, such advertisements as those for a catalog of Schedule [1] I controlled substances and any similar written advertisement that has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule [1] I controlled substance. The term "advertisement" does not include material which merely advocates the use of a similar material, which advocates a position or practice, and does not attempt to propose or facilitate an actual transaction in a Schedule [1] I controlled substance.

(2)(A) Except as authorized by this title, it shall be unlawful for any person by means of the Internet, to knowingly advertise the sale or distribution of, or to offer to sell, distribute, or dispense, a controlled substance.

(B) Examples of activities that violate subparagraph (A) include, but are not limited to, knowingly or intentionally causing the placement on the Internet of an advertisement that refers to or directs prospective buyers to Internet sellers of controlled substances who are not registered under section 303(i).

(C) Subparagraph (A) does not apply to material that either—

(i) merely advertises the distribution of controlled substances by nonpractitioners to the extent authorized by their registration under this title; or

(ii) merely advocates the use of a controlled substance or includes pricing information without attempting to facilitate an actual transaction involving a controlled substance.

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Part E—Administrative and Enforcement Provisions

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§ 881. Forfeitures

(a) SUBJECT PROPERTY.—The following shall be subject to forfeiture to the United States and no property right shall exist in them:

(1) * * *

* * * * * * *

(4) [All conveyances, including aircraft, vehicles, or vessels, which are used, or are intended for use, to transport, or in any manner to facilitate the transportation, sale, receipt, possession, or concealment of property described in paragraph (1), (2), or (9).] *Any property, real or personal, tangible or intangible, used or intended to be used to commit, or to facilitate the commission, of a violation of this title or title III, and any property traceable thereto.*

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§ 882. Injunctions

(a) JURISDICTION.—The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of this subchapter.

(b) JURY TRIAL.—In case of an alleged violation of an injunction or restraining order issued under this section, trial shall, upon demand of the accused, be by a jury in accordance with the Federal Rules of Civil Procedure.

(c) STATE CAUSE OF ACTION PERTAINING TO ONLINE PHARMACIES.—

(1) In any case in which the State has reason to believe that an interest of the residents of that State has been or is being threatened or adversely affected by the action of a person, entity, or Internet site that violates the provisions of section 303(i), 309(e), or 311, the State may bring a civil action on behalf of such residents in a district court of the United States with appropriate jurisdiction—

(A) to enjoin the conduct which violates this section;

(B) to enforce compliance with this section;

(C) to obtain damages, restitution, or other compensation, including civil penalties under section 402(b); and

(D) to obtain such other legal or equitable relief as the court may find appropriate.

(2)(A) Prior to filing a complaint under paragraph (1), the State shall serve a copy of the complaint upon the Attorney General and upon the United States Attorney for the judicial district in which the complaint is to be filed. In any case where

such prior service is not feasible, the State shall serve the complaint on the Attorney General and the appropriate United States Attorney on the same day that the State's complaint is filed in Federal district court of the United States. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or any other proceedings under this title or any other laws of the United States.

(B)(i) Not later than 120 days after the later of the date on which a State's complaint is served on the Attorney General and the appropriate United States Attorney, or the date on which the complaint is filed, the United States shall have the right to intervene as a party in any action filed by a State under paragraph (1).

(ii) After the 120-day period described in clause (i) has elapsed, the United States may, for good cause shown, intervene as a party in an action filed by a State under paragraph (1).

(iii) Notice and an opportunity to be heard with respect to intervention shall be afforded the State that filed the original complaint in any action in which the United States files a complaint in intervention under clause (i) or a motion to intervene under clause (ii).

(iv) The United States may file a petition for appeal of a judicial determination in any action filed by a State under this section.

(C) Service of a State's complaint on the United States as required in this paragraph shall be made in accord with the requirements of Federal Rule of Civil Procedure 4(i)(1).

(3) For purposes of bringing any civil action under paragraph (1), nothing in this Act shall prevent an attorney general of a State from exercising the powers conferred on the attorney general of a State by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses of or the production of documentary or other evidence.

(4) Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business or wherever venue is proper under section 1391 of title 28, United States Code. Process in such action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

(5) No private right of action is created under this subsection.

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Subchapter II—Import and Export

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§ 960. Prohibited acts A

(a) UNLAWFUL ACTS.—

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(b) PENALTIES.—

(1) * * *

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(3) In the case of a violation under subsection (a) of this section involving a controlled substance in schedule I or II, gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 3(a)(1)(B) of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000), or flunitrazepam, the person committing such violation shall, except as provided in paragraphs (1), (2), and (4), be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years and not more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 6 years in addition to such term of imprisonment. Notwithstanding the prior sentence, and notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this paragraph which provide for a mandatory term of imprisonment if death or serious bodily injury results**[**, nor shall a person so sentenced be eligible for parole during the term of such a sentence**]**.

(4) In the case of a violation under subsection (a) of this section with respect to less than 50 kilograms of marihuana, except in the case of 100 or more marihuana plants regardless of weight, less than 10 kilograms of hashish, *or* less than one kilogram of hashish oil, **[**or any quantity of a controlled substance in schedule III, IV, or V,[3] (except a violation involving flunitrazepam and except a violation involving gamma hydroxybutyric acid)**]** the person committing such violation shall be **[**imprisoned not more than five years, or be fined not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If a sentence under this paragraph provides for imprisonment, the sentence shall, notwithstanding section 3583 of title 18, in addition to such term of imprisonment, include (A) a term of supervised release of not less than two years if such controlled substance is in schedule I, II, III, or (B) a term of supervised release of not less than one year if such controlled

substance is in schedule IV] *sentenced in accordance with section 401(b)(1)(D) of this title (21 U.S.C. 841(b)(1)(E)).*

(5) In the case of a violation of subsection (a) of this section involving a controlled substance in schedule III, such person shall be sentenced in accordance with section 401(b)(1)(E).

(6) In the case of a violation of subsection (a) of this section involving a controlled substance in schedule IV (except a violation involving flunitrazepam), such person shall be sentenced in accordance with section 401(b)(2).

(7) In the case of a violation of subsection (a) of this section involving a controlled substance in schedule V, such person shall be sentenced in accordance with section 401(b)(3).

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