

# USA criminal and civil prosecutions associated with illicit online pharmacies: legal analysis and global implications

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## ABSTRACT

The rise of digital technologies has created a complex online environment that now includes illicit Internet pharmacies, online facilitators, advertising sites, and foreign entities. Collectively, these networks create significant patient safety risks, including acting as unregulated access points encouraging prescription drug abuse. Although law enforcement is active in combating this form of cybercrime, there are several difficulties in prosecuting individuals involved in online prescription drug distribution. We characterize these challenges by conducting a comprehensive legal review and analysis of USA civil and criminal cases associated with online pharmacies. This is accomplished by reviewing legal documents/filings available via the Public Access to Court Electronic Records (PACER) database, the Drug Enforcement Agency's website, and structured search queries using the Google search engine. We found more than 100 cases, including criminal indictments, sentencing documents, judgments, forfeiture orders, motions, civil complaints, and restitution documents. Our review indicates that current legal tools and regulatory policies do not effectively deter this highly profitable criminal activity. Hence, we issue a "Call to Action," advocating the need for more robust legal remedies and criminal penalties, and greater legal and policy coherence at the domestic, regional, and global level aimed at improving patient safety and ensuring the integrity of the drug supply chain.

**Keywords:** Controlled substances, Internet pharmacy, Online pharmacy, Patient safety, Pharmaceutical policy, Prescription drug abuse

## Introduction

In 2008, the United States Congress passed the Ryan Haight Online Pharmacy Consumer Protection Act (RHA) (1, 2). The Act, which in part amends the Federal Controlled Substances Act (CSA) states, "no controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription"

(3). Ryan Haight, who the legislation was named after, was an 18-year-old honors student who ordered prescription painkillers online and died from an overdose in 2001 (1, 2). In an effort to prevent future deaths and combat the emerging threat of illegal Internet purchases of controlled substances, new provisions of the CSA, as amended by the RHA, now require at least 1 in-person medical evaluation by a physician prior to issuing a prescription for a controlled substance, and Internet pharmacy site disclosure information (see Table I for a full list of RHA disclosure requirements) (3).

Notably, after the passage of the Act, a senior Drug Enforcement Agency (DEA) official said, in 2011, "[The Act] has pretty much eliminated the online business in the United States and the DEA hasn't found a large number of foreign sites selling controlled substances to the U.S." (4). However, close to a decade after the RHA's passage, proclamations by the DEA that the Act would halt the operation of online pharmacies appear to be premature, even within the narrower context of controlled substances (1). In 2016, a report prepared by the Internet monitoring service company LegitScript,

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**TABLE I** - Ryan Haight Online Pharmacy Consumer Protection Act online pharmacy disclosure requirements

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- (1) The name and address of the pharmacy as it appears on the pharmacy's Drug Enforcement Administration Certificate of Registration.
  - (2) The pharmacy's telephone number and email address.
  - (3) The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.
  - (4) A list of the States in which the pharmacy is licensed to dispense controlled substances.
  - (5) A certification that the pharmacy is registered under this part to deliver, distribute, or dispense by means of the Internet controlled substances.
  - (6) The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.
  - (7) 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. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309."<sup>1</sup>
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LLC, reported that there were an estimated 30,000-35,000 illicit online pharmacies selling prescriptions drugs (4). Disturbingly, this same report found that 92% have serious criminal aspects related to patient harm. Additional studies have documented the online sale of controlled substances, including those leveraging new and ubiquitous Internet technologies, such as popular social media channels (5-13). Although illicit online pharmacies are inherently global in their reach (as the Internet is not generally jurisdictionally limited), the USA is likely the largest target consumer market (9, 12). Supporting a focus on the USA consumer, LegitScript's report found that approximately 82% of online pharmacies advertise in English, while 85% of all online pharmacies offer to ship to the USA (4).

Critically, the ability to monitor and police tens of thousands of illicit online pharmacies at any given time is extremely difficult from a legal perspective (14-17). Moreover, the multi-jurisdictional nature of illicit online pharmacy networks can create legal barriers to the investigation and prosecution of individuals living outside the USA (9, 18-20). Another hurdle to curbing the illicit sale of pharmaceuticals online is the vast amounts of money involved juxtaposed against weak penalties that fail to deter this criminal activity. To better characterize these legal and policy-based challenges, we conducted a comprehensive review and analysis of USA court documents both pre- and post-RHA, aimed at demonstrating the inherent limitations in containing and reducing this illegal online trade, with a particular focus on online pharmacies distributing and selling controlled substances.

## Methods

Our review of legal documents associated with illicit online pharmacies was conducted in 2 distinct phases. In the first phase, we used a systematic keyword search on the popular web search engine Google, to query information about online pharmacy legal actions. Google searches were conducted periodically from May 2015 to April 2017 and limited to the first 10 pages of search results in order to identify cases occurring prior to and during this search period. Google searches included the following key terms: online pharmacy prosecutions, online pharmacy civil prosecutions, illegal online pharmacies, online pharmacy indictments,

online pharmacy criminal organizations, and international online pharmacy crimes. Many of the Google search results led to hyperlinks to websites for the DEA, Department of Justice (DOJ), and the Federal Bureau of Investigation (FBI), which contained press releases with the names of criminal organizations and/or defendants involved in prosecuted online pharmacy criminal cases. On occasion, some of the press releases or articles also included a case name and number. Based on this initial search, we compiled a list of defendants and criminal organizations as well as any case identifying information.

In the second phase, we cross-referenced each defendant and criminal organization identified in the first phase of the search through the Public Access to Court Electronic Records (PACER). PACER is a fee-based publicly available database that includes information for federal court cases nationwide (including access to case and docket information from U.S. District Courts, U.S. Courts of Appeal, and U.S. Bankruptcy Courts). We then compiled a database of PACER court documents (for document types see Appendix A, available online as Supplementary material at <http://medicine-access.pointofcarejournals.com>) and conducted a content and legal analysis for the following characteristics: (i) jurisdiction(s) of case; (ii) types of legal charges and amounts of penalties/restitutions; (iii) number of defendants and related parties; (iv) amount of medicines and money reportedly involved; and (v) therapeutic class of medicines traded (with a focus on controlled substances). We then examined and described specific cases to characterize prosecutions related to large and small networks of illicit online pharmacies to illustrate their complexity and varying scope of criminal activities. Due to the interstate nature of Internet-related crimes, it is highly likely that all, if not the vast majority of, cases with a USA-based defendant involving illicit online pharmacies are available in PACER. Based on these combined search phases, the earliest case we detected was from 2000 and the most recent case was from 2016.

## Results

There were more than 150 individual defendants identified in this legal review exclusive of the institutional defendants that had to pay restitution (such as pharmacies or

business entities). The exact number of cases is difficult to ascertain due to the complexities of defendants' involvement in multiple online pharmacy networks. For instance, in some cases, defendant physicians were prescribing pharmaceuticals for multiple named entities (as illustrated in the case studies below). When one entity was found to be involved in criminal activity and the physician was part of the scheme, law enforcement was able to find out who else the physicians worked for, resulting in further prosecutions, but with different case numbers. Hence, the subsequent overlap, consolidation, and transfer of cases made it difficult to ascertain the exact number of cases (estimated between 25 and 30) reviewed in this study. The totality of cases reviewed indicate that pharmaceuticals were prescribed online by physicians from all over the USA and Puerto Rico, and shipped to all 50 states.

### ***Multijurisdictional and complex: the case study of Affpower***

The complex structure of organizations involved in online pharmacy prosecutions makes it difficult to accurately quantify the number of cases that were domestic versus multijurisdictional. Despite this challenge, at a minimum, 11 cases in excess of 100 defendants not only had a nationwide distribution chain, but also had certain international components. Multiple cases involving an organization named "Affpower" underscored one of our primary findings that many USA-based cases involving illicit online pharmacies were multijurisdictional and complex in nature.

In July 2007, federal law enforcement charged 18 members of the Affpower organization for operating an online pharmaceutical distribution network involving domestic and foreign entities (21). According to the indictment, Affpower used the Internet to distribute and dispense controlled and noncontrolled prescription drugs nationwide and unlawfully from August 2004 to June 2006. The organization included: (i) managers and administrators; (ii) merchant websites for the purchase of drugs; (iii) affiliated websites that marketed and promoted sales; (iv) a network of physicians who issued prescriptions for the pharmaceuticals; (v) a network of pharmacies that dispensed the drugs; and (vi) credit card processors to process the drug purchases.

Affpower's administrative headquarters and customer service department were located in San Jose, Costa Rica and servers that hosted merchant websites were located in Nicosia, Cyprus. David Glass, the owner and operator of Affpower, Inc., resided in California but had bank accounts in Panama, Cyprus, and Costa Rica, which were used to further the illegal activity. Affpower used a credit card processor in Israel and bank accounts and an accounting firm in Cyprus. Additionally, Affpower recruited licensed physicians throughout the USA and Puerto Rico to review and approve orders for prescriptions illegally. Leveraging this global operation, Affpower generated over 1 million prescription orders in 2 years (22).

In addition to managing its own websites and recruiting physicians to prescribe products, Affpower also actively recruited and partnered with various brick-and-mortar and online pharmacies to participate in their network. For example, Claude Covino, an Affpower defendant, operated Saveon RX Pharmacy in Florida, which existed solely to service online pharmacy networks and was used to recruit other pharmacies

to participate in the Affpower network. In total, Affpower recruited over 30 pharmacies, which typically received between \$5 and \$13 in fees for each order they shipped. Multiple defendant physicians licensed in Puerto Rico, Kentucky, Ohio, Georgia, and Massachusetts issued prescriptions on behalf of Affpower.

The Affpower enterprise further consisted of marketing affiliates who operated multiple affiliate websites. These websites provided affiliate marketing services for the Affpower network in exchange for payments. The marketing affiliates allowed the Affpower network of providers to broaden their consumer reach through various forms of search engine marketing and digital advertising. Affpower also leveraged a network of payment processors to effectuate sales generated through their pharmacies and marketing affiliate partners. To further extend their business model, the Affpower syndicate allowed the creation of other online pharmacy enterprises that were spun off the original network based on a similar model of illicitly marketing and dispensing prescription drugs online.

Associated Affpower cases demonstrate the complexity of this network. Michael Bezonsky acted as the California-based owner and operator of www.Affpower.com and www.GRBGlobal.com. These two websites were the controlling websites for the network's Internet pharmacy portals. The websites marketed prescription pharmaceutical drugs for sale direct-to-the-consumer, without requiring a valid or lawful prescription. Affiliate websites were then established using a template provided by Affpower or GRBGlobal, and were electronically linked to Affpower or GRBGlobal websites. When a customer attempted to purchase pharmaceuticals from an affiliate website, they were redirected to a site controlled by Affpower or GRBGlobal for payment processing. After the order was designated as approved by a physician, Affpower or GRBGlobal would forward the order to a participating pharmacy for fulfillment (23). From June 2004 to June 2006, associated defendants involved in this scheme generated approximately \$160 million in sales.

### ***Amount of money involved: Affpower, Bansal, and Gallinal case studies***

This section presents 3 case studies that illustrate the exorbitant financial gains generated by online pharmacy networks that were later prosecuted. The case studies are on the Affpower, Bansal, and Gallinal criminal networks.

#### *Affpower*

As discussed in the previous section, the amounts of money generated from the Affpower criminal network equated to hundreds of millions of dollars, which was dispersed across a number of different actors including the central Affpower entity, affiliated pharmacies, marketing affiliates, wholesalers and distributors, and the prescribing physicians. In only a 2-year period, the Affpower enterprise engaged in illegal online prescription drug sales generated in excess of \$126 million in revenue (22).

To put this into context, Affpower associated defendant, United Pharmacy Solutions, Inc., shipped over 180,000



prescriptions in just a 10-month period. The shipments included 135,272 controlled substances and 48,798 noncontrolled substances, which generated \$8,229,119 in gross payments to United Pharmacy Solutions and another pharmacy owned by a related defendant, RX Medical One. RX Medical One, then dispensed the controlled substances directly to the patient, generating \$33,676,926.63 in gross revenue in a 9-month period. RX Medical One also paid Dr. Ranvir Ahlawat (who also owned and operated his own separate Internet site [www.rx-stop.com](http://www.rx-stop.com)) \$1,344,505 for reviewing online orders and prescribing 114,684 controlled substances and 69,766 noncontrolled substances in a 16-month period.

### *Bansal Organization*

Large financial gains were not limited to the Affpower affiliated cases. The “Bansal organization,” as it’s referred to in an 81-page criminal indictment, involved 17 individual defendants, and some additional individuals (including 2 from Costa Rica) who were criminally charged in an associated case. The Bansal Organization sold more than 11 million prescription pills, many of them controlled substances, to more than 60,000 purchasers in the USA and grossed at least \$8 million dollars in just over 1 year.

Akhil Bansal, a licensed physician in India completing his MBA and a Masters in Healthcare Finance at Temple University, was the head of the organization. His father, Brij Bansal was also a licensed physician in India where he received drug orders from the USA and elsewhere. The organization sold to customers throughout the USA without requiring a medical exam by a physician, and shipped products to other countries. Akhil’s sister and brother-in-law, (also residing in India) acted as sales and marketing managers. Atul Patil, Akhil’s roommate, resided in Pennsylvania and solicited individuals on behalf of the Bansal Organization to ship controlled substances, and established offshore accounts. With the large quantities of pharmaceuticals being shipped from India to fulfill consumer orders, the Bansal Organization required a depot center where the drugs could be stored until their final shipment to USA customers. Bansal depot centers were operated from New York and serviced other Internet pharmacy websites based in Costa Rica, employing over 50 people.

In furtherance of this illegal activity, the Bansal Organization used financial institutions outside the USA to transact payments, including numerous wire transfers to and from Cyprus, India (multiple locations), Singapore, the Channel Islands, Isle of Man, the West Indies, Antigua, and Canada (24). Multiple USA financial institutions were involved including Bank of America, Fleet Bank, Wachovia, United National Federal Credit Union, PNC Bank, Commerce Bank, Citizens Bank, and Fifth Third Bank, all of which were identified as either receiving or sending wire transfers to facilitate payment for controlled substances (24). There were 41 bank accounts used in this illegal operation – 26 in the USA and the remainder located in foreign countries.

### *Juan Gallinal Network*

In the case against Juan Gallinal and 6 co-defendants, a smaller criminal network and its characteristics are described.

Vineet Chhabra (head of the Chhabra Organization that also engaged in illegal sales of controlled substances) introduced former Virginia police officer, Juan Gallinal, to the business of Internet pharmacies. In an effort to hide their illegal actions, the defendants set up sham corporations and used a server in Switzerland. The defendants made approximately \$9.8 million during a 3-year period.

Gallinal’s organization shipped hydrocodone, Xanax, codeine, and phentermine nationwide from a “pill mill” in Florida. Gallinal and his co-defendants (which also included another ex-police officer) fraudulently used physicians’ DEA numbers to legitimize prescriptions without the physicians’ knowledge or consent (25). When the Gallinal organization received an Internet order they would sometimes contact the physician’s office listed on the online patient questionnaire. The physician’s office would either respond saying they did not authorize the prescription or they would not respond at all. The defendants would then find a physician in the vicinity of the patient’s address and locate that physician’s DEA number. They would then fraudulently use the DEA number and ship the prescriptions to the patient, many times charging 10 times the price of the drugs.

### *Classes of drugs: the case of Pharmacom*

Our legal review included cases involving both controlled and noncontrolled substances dispensed online, but the most common class of drugs implicated in prosecuted cases were controlled substances. (For a complete list of the drugs identified in court documents see Appendix B, available online as Supplementary material at <http://medicine-access.pointof-carejournals.com>).

Illustrating the scope of illegal online sale and distribution of controlled substances is a case that occurred in 2003, 5 years prior to the passage of the RHA. At the time, this was the largest federal prosecution of an Internet pharmacy case. In 2003, the Union Family Pharmacy in Dubuque, Iowa, dispensed diet pills to a customer in California. The doctor who issued the prescription was a resident of, and licensed to practice medicine in, Mississippi and dispensed the drug based on an online questionnaire. This was just the beginning of unraveling a much larger case, which eventually resulted in the conviction of over 25 defendants and over \$7 million in forfeitures. It also resulted in the investigation and successful prosecution of 2 Internet-based pharmacy entities: Pharmacom and Medical Web Services.

In the Pharmacom case, federal law enforcement agents, executing a search warrant at the Union Family Pharmacy, uncovered that the pharmacy had unlawfully dispensed more than 1.1 million pharmaceuticals over a 6-month period. The pharmaceuticals included prescription pain, diet, and psychiatric pills. Many of the prescriptions resulted from client questionnaires that originated with Pharmacom International Corporation. Agents also discovered that during a 3-week period in 2003, the Union Family Pharmacy had filled approximately 5,172 online-prescriptions for Pharmacom alone; none were issued in the usual course of professional treatment. Alarming, over 94% of these orders were for controlled substances, with the overwhelming majority dispensed for hydrocodone (26).

In September 2003, federal law enforcement was alerted by Federal Express that it had a number of parcels that were returned to the Union Family Pharmacy from its customers. In 1 of the packages, a letter from an attorney in Wisconsin stated, "UFP sent valium and vicodin to our son, Kyle, a minor, with a prescription issued by Dr. Carlos Barrera prescribed from information provided over the Internet and phone" (26). According to an In Rem forfeiture document, employees at the Union Family Pharmacy stated they had received several complaint calls from parents of minors that had ordered and received prescription drugs through Internet transactions. Another complaint came from an individual who claimed her neighbor was receiving packages of drugs from the Union Family Pharmacy and selling them on the street.

Case documents also revealed that physicians involved with the Union Family Pharmacy were involved with other Internet pharmacy schemes. For example, some of the physicians charged in this case also issued prescriptions for the Bezonsky and Affpower cases previously discussed.

### **Patient safety issues: multiple cases**

Patient safety concerns regarding illegal online pharmacies focus on the inherent risks associated with physicians prescribing pharmaceuticals to patients with whom they have never had any physical contact or relationship. Further illustrating this risk, there were a number of physicians in Puerto Rico who prescribed pharmaceuticals to patients throughout the USA. In *United States of America v. Alfred Valdivieso-Rodriguez et al*, 7 Puerto Rican physicians were indicted and sentenced. In the superseding indictment, it was noted that an individual "was hospitalized for a drug overdose and was in the possession of two prescription bottles of phentermine authorized Dr. Valdivieso-Rodriguez" (27). Dr. Valdivieso-Rodriguez had prescribed 2 prescriptions for a total of 180 units of 37.5 mg of phentermine on the same day to the individual who overdosed. Aside from the criminal aspect of violating USA laws regulating controlled substances, the action could also constitute medical negligence given the risk to the patient of overdose, and that the physician had never had a face-to-face consult.

In the same indictment, Dr. Maileen Lugo-Torres prescribed 90 units of hydrocodone, a Schedule III controlled substance to "G.K." A mere 2 days later, Dr. Lugo-Torres issued a prescription to the same person for another 90 units of hydrocodone. Eight days later, court documents state that "as a result of the two prescriptions issued by [Dr.] Lugo-Torres, G.K. died of a drug overdose of hydrocodone" (27). In the subsequent prosecution, Dr. Lugo-Torres was given 3 years' probation, 800 community service hours, and paid a \$100 Special Assessment after pleading guilty to Conspiracy to Distribute a Controlled Substance.

Another associated patient safety event occurred in Chicago when Doctors Ranvir Ahlawat and Steven Klinman were sued civilly for injuries to a patient to whom they prescribed pharmaceuticals. The patient, Craig Schmidt, sued both doctors for injuries he suffered after being prescribed alprazolam by Dr. Klinman, and Ultram by Dr. Ahlawat. Leading up to the injury, Schmidt filled out an online questionnaire for Xanax on May 7, 2004. Unbeknown to Schmidt, both doctors were able

to obtain the questionnaire and authorize the prescriptions. Dr. Klinman prescribed alprazolam (2 mg) and Dr. Ahlawat prescribed Ultram (50 mg). Schmidt received packages containing the drugs from 2 separate online pharmacies, took the pills, and was later pulled over by police and charged with driving under the influence after a hit and run. Later that day, he suffered a heart attack and anoxic encephalopathy before falling into a coma, and he spent several weeks in the hospital. Allegedly, the alprazolam he received contained more than the usual dosage a doctor would prescribe.

Dr. Klinman settled outside of court for \$650,000 after unsuccessfully trying to file a third-party complaint against the Police Department. Dr. Ahlawat took the case to trial and the jury found in his favor. Dr. Ahlawat's lawyer was able to prove that the higher dosage Xanax was the cause of Schmidt's injuries as opposed to the Ultram he prescribed. Both physicians were later successfully criminally charged and sentenced in other cases (Dr. Ahlawat was involved in 8 federal criminal cases and Dr. Klinman 3 criminal cases, all involving illegal issuance of online prescriptions).

Other patient safety issues were also detailed in the Pharmacom case previously discussed. The Iowa Board of Pharmacy interviewed customers who purchased from Pharmacom-related websites and discovered the following patient safety issues (among others):

- One customer stated that he purchased 60 hydrocodone pills, but he was given the wrong strength.
- Another patient stated that after placing her order she received an email stating that the physician needed to speak with her. She was never contacted, but still received her order of hydrocodone.
- A recovering narcotics addict and former nurse stated that she had degeneration of the cervical spine and needed Norco. However, it was discovered during the investigation that she did not have cervical spine degeneration and that she was so well-known in Iowa as a drug addict that she could not obtain drugs anywhere but online.
- A lawyer and recovering substance abuser was purchasing Xanax online. He said purchasing drugs online was an easy way to take care of his habit (26).

### **Types of charges and penalties**

Many of the cases reviewed involved similar charges but had disparate outcomes in relation to sentencing. Since these criminal enterprises involved a multitude of individuals who were used to achieve their criminal objectives, the charge of conspiracy (18 USC 371) was used in many indictments. For example, many defendants were charged with conspiracy to distribute controlled substances (21 USC 846) or conspiracy to launder money (21 USC 1956). Table II includes a list of the common charges included in criminal indictments, and Table III provides details on criminal defendant networks from cases reviewed and discussed.

Alarmingly, none of the cases reviewed involved charges associated with serious bodily injury or manslaughter for the negligent distribution or dispensing of pharmaceuticals by physicians to patients with whom the physicians never had contact. The absence of criminal charges likely relates to the

inability to prove intent to harm. However, it could be argued that at the very least, doctors who prescribed drugs that resulted in injuries or death were reckless or negligent. In many cases prosecutors likely chose to pursue charges that could be more easily proved in order to avoid drawn-out trials.

However, given the clear patient safety risk associated with the operation of illicit online pharmacies (including the sale of controlled substances), penalties imposed by federal prosecutions do not appear to have parity. Penalties varied widely in respect to restitution as well as imprisonment. The maximum sentence observed was 30 years imprisonment while the shortest sentence involved neither imprisonment nor probation. Restitution varied from zero to more than \$24 million for individual defendants. Legitimate business entities, such as Google and United Parcel Service, paid the highest fines for their involvement in these schemes (discussed below).

In considering whether sentencing is a strong deterrent, one example is Puerto Rican physician, Dr. Lugo-Torres, who prescribed drugs to a patient who then overdosed on those same drugs. Though there was a patient death directly attributable to this activity, Dr. Lugo-Torres received only 3 years' probation and 800 hours of community service, and did not pay any fines or restitution. Dr. Ogle, implicated in the death of Ryan Haight, received a sentence of 24 months and criminal restitution in excess of \$8,000 to the parents of Haight. He was also jointly and severally liable for \$2 million in civil damages.

At the other end of the spectrum, individual defendants who were owners of online criminal enterprises faced more severe sentences and much higher fines and restitution. Christopher Smith, a spammer, and owner of Xpress Pharmacy, received 30 years imprisonment and a fine in excess of \$24 million. Akhil Bansal (Bansal Organization) received 30 years imprisonment and a fine in excess of \$8 million for his role in importing and selling drugs to USA consumers. Michael Bezonsky (Affpower) received a sentence of 5 years and was fined in excess of \$12 million. None of these individuals were directly implicated in causing the death of a patient consumer, but received high fines and sentencing because of their extensive involvement and management of large-scale Internet pharmacy criminal networks that illegally generated large sums of money.

In a rare case of high-profile corporate enforcement, the technology company Google agreed to forfeit \$500 million resulting from its online sponsored ads for prescription drug sales originating from Canadian online pharmacies. Similarly, United Parcel Service, Inc. agreed to forfeit \$40 million for shipping drugs purchased from illegal Internet pharmacies. FedEx Corp., on the other hand, was able to avoid fines as high as \$1.6 billion for shipping illegal online prescriptions when federal prosecutors dismissed the case during trial (28). FedEx nevertheless said it would cease shipping packages from the illegal pharmacies.

## Discussion

Based on our review, one primary conclusion stands out: punishment has not acted as a sufficient deterrent given the vast sums of money that can be generated through criminal

**TABLE II** - Common criminal charges in cases reviewed

United States Code	Charge
18 U.S.C., Sec. 371	Conspiracy
18 U.S.C., Sec. 1341	Mail Fraud
18 U.S.C., Sec. 1956(h)	Conspiracy to Commit Money Laundering
18 U.S.C., Sec. 1956 (a)(1)(B)(i)	Money Laundering
18 U.S.C., Sec. 1956(a)(1)	Promotional Money Laundering
18 U.S.C., Sec. 1956(a)(2)	International Money Laundering
18 U.S.C., Sec. 1957	Transactional Money Laundering
18 U.S.C., Sec. 2	Aiding & Abetting
18 U.S.C., Sec. 982(a)(1)	Criminal Forfeiture
18 U.S.C., 1957(a)	Monetary Transactions in Proceeds of Specified Unlawful Activity
18 U.S.C., Sec. 1962(d)	Racketeering Conspiracy
18 U.S.C., Sec. 1962(c)	Racketeering
18 U.S.C., Sec. 1349	Conspiracy to Commit Wire and Mail Fraud
18 U.S.C., Sec. 1343	Wire Fraud
18 U.S.C., Sec. 982	Criminal Forfeiture
18 U.S.C., Sec. 1001	False Statement During a Federal Investigation
21 U.S.C., Sec. 846	Conspiracy to Distribute Controlled Substances
21 U.S.C., Sec. 841(a)(1)	Distribution of Controlled Substances
21 U.S.C., Sec. 331(k)	Distribution of Misbranded Drugs
21 U.S.C., Sec. 963	Conspiracy to Import Controlled Substances
21 U.S.C., Sec. 848	Continuing Criminal Enterprise
21 U.S.C., Sec. 331(a)	Introduction of Misbranded Drugs Into Interstate Commerce

participation in illicit online pharmacies. Examples of this imbalance occur throughout this "alternate" supply chain, including physicians like Dr. Ahlawat who had his own private practice, and who was issuing prescriptions for multiple online pharmacies, including Affpower. In a 10-month period he made \$1.3 million dollars for issuing prescriptions to patients with whom he never had contact (23). His prosecution resulted in a loss of his medical license, but he only received probation and experienced no time in custody. Pharmacists and pharmacies were also in the position to reap financial rewards, such as the \$8.2 million dollars paid to Atchildev (pharmacist in Affpower case) in a 10-month period for filling and shipping pharmaceuticals (23). Atchildev received a sentence of 2 years' probation and his pharmacy, Universal Pharmacy Solutions, Inc. had to forfeit more than \$18 million (29, 30).

TABLE III - Defendants and associated penalties

Puerto Rico Physicians	
Name/Role	Conviction/Sentence
Dr. Lugo/Physician (patient death due to overdose)	Distribution of Controlled Substances, Conspiracy to Distribute Controlled Substances, Distribution of Misbranded Drugs, Aiding & Abetting, Wire Fraud, Money Laundering and Criminal Forfeiture
Dr. Valdivieso-Rodriguez/Physician (patient overdose)	Distribution of Controlled Substances, Conspiracy to Distribute Controlled Substances, Distribution of Misbranded Drugs, Aiding & Abetting, Wire Fraud, Money Laundering and Criminal Forfeiture
Dr. Plaza-Rodriguez/Physician	Distribution of Controlled Substances, Conspiracy to Distribute Controlled Substances, Distribution of Misbranded Drugs, Aiding & Abetting, Wire Fraud, Money Laundering and Criminal Forfeiture
Dr. Seda-Olmo/Physician	Distribution of Controlled Substances, Conspiracy to Distribute Controlled Substances, Distribution of Misbranded Drugs, Aiding & Abetting, Wire Fraud, Money Laundering and Criminal Forfeiture
Dr. Ramos-Gonzalez/Physician	Distribution of Controlled Substances, Conspiracy to Distribute Controlled Substances, Distribution of Misbranded Drugs, Aiding & Abetting, Wire fraud, Money Laundering and Criminal Forfeiture
Dr. Tosado-Polanco/Physician	Distribution of Controlled Substances, Conspiracy to Distribute Controlled Substances, Distribution of Misbranded Drugs, Aiding & Abetting, Wire Fraud, Money Laundering and Criminal Forfeiture
Dr. Lecompte-Torres/Physician	Distribution of Controlled Substances, Conspiracy to Distribute Controlled Substances, Distribution of Misbranded Drugs, Aiding & Abetting, Wire Fraud, Money Laundering and Criminal Forfeiture
<b>Pharmacom</b>	
Orlando Birbragher/Principal owner and operator of Pharmacom	Drug Conspiracy and Money Laundering

To be continued

TABLE III - Continued

Puerto Rico Physicians		Conviction/Sentence
Name/Role	Charges	
Marshall Kanner/Principal owner and operator of Pharmacom.	Drug Conspiracy and Money Laundering	Plead guilty to conspiracy to dispense controlled substances and conspiracy to launder money.  32-month sentence, 500-hour residential drug abuse treatment program, 2 years' supervised release, \$200 special assessment, & forfeit \$1,575,964.45 (1999 Baja 38-foot boat and other seized to satisfy forfeiture judgment)
Alexis M. Avello/Secretary & Director of Pharmacom	Willfully Making and Subscribing a False Tax Return	Willfully making and subscribing a false tax return.  36-month sentence, 1 year supervised release, \$100 special assessment, \$558,566 restitution to IRS, \$61,4147[AUTHOR: please check and amend this dollar amount.] reimburse cost of prosecution, & forfeited \$19,313.47 held in bank account. (Should have forfeited a total of \$3,001,835 in ill-gotten gains from Pharmacom)
Miguel Harris-Birbragher/Physician Recruiter	False Statement During a Federal Investigation	Plead guilty to false statement during a federal investigation.  3-month sentence, 3-month home confinement, 2 years' supervised release, \$100 special assessment and \$3,000 fine
Dr. Peter Lopez/Physician (not licensed at time of issuing prescriptions for Pharmacom)	Conspiracy to Distribute Controlled Substances, Conspiracy to Launder Money, Distribution of Controlled Substances, and Criminal Forfeiture	Plead guilty to conspiracy to dispense & cause to dispense controlled substances, and conspiracy to launder money.  22-month sentence, 2 years' supervised release, \$200 special assessment, and \$242,171 forfeiture
Dr. Armando Angulo/Physician (FL)	Conspiracy to Distribute Controlled Substances, Conspiracy to Launder Money, Distribution of Controlled Substances, and Criminal Forfeiture	Charges dismissed with prejudice because he fled to Panama after indictment. Panama does not extradite their citizens. The evidence in his case exceeded more than 400,000 documents and two terabytes of ESI that federal law enforcement says it's too expensive to maintain
Dr. Roselyn Rice/Physician (VA)	Conspiracy to Distribute Controlled Substances, Money Laundering, and Forfeiture	Conspiracy to distribute controlled substances and money laundering.  22-month sentence, 2 years' supervised release, \$200 special assessment, and forfeited \$137,180
Dr. Thomas Hamny/Physician (CT)	Conspiracy to Distribute Controlled Substances, Money Laundering, and Forfeiture	Conspiracy to distribute controlled substances and money laundering.  33-month sentence later amended to 23 months, 2 years' supervised release, \$300 special assessment and \$57,329.39 forfeiture

*To be continued*





TABLE III - Continued

## Puerto Rico Physicians

Name/Role	Charges	Conviction/Sentence
Dr. Mario Diaz/Physician (FL)	Conspiracy to Distribute Controlled Substances, Money Laundering, and Forfeiture	Conspiracy to distribute controlled substances and money laundering.
Dr. Carlos Barrera/Physician (FL)	Conspiracy to Distribute Controlled Substances, Money Laundering, and Forfeiture	30-month sentence, 2 years' supervised release, \$200 special assessment, and \$272,061 forfeiture. Lost license Conspiracy to distribute controlled substances and conspiracy to launder money.
Dr. Magaly Bethencourt/Physician	Conspiracy to Distribute Controlled Substances and Forfeiture	6-month home confinement, 3-years' probation, \$200 special assessment and \$10,000 criminal fine. Forfeited license Plead guilty to conspiracy to distribute controlled substances.
Dr. Apryl Miamzette McNeil/Physician (NY)	Conspiracy to Distribute Controlled Substances, Conspiracy to Launder Money and Forfeiture	6-month home detention, 2 years' probation, \$100 special assessment, \$7,710 forfeiture and lost license Plead guilty to conspiracy to distribute controlled substances and conspiracy to launder money.
Dr. Absyloym Nyamekye/Physician (NY)	Conspiracy to Distribute Controlled Substances, Conspiracy to Launder Money and Forfeiture	20-month sentence, 2 years' supervised release, \$200 special assessment and \$26,960 forfeiture. Lost license Plead guilty to conspiracy to distribute controlled substances and conspiracy to launder money. 20-month sentence, 2 years' supervised release, \$200 special assessment and \$36,286 forfeiture. Lost license

## Medical Web Services

Medical Web Services (Orlando) Birbragher was one of the owners)	Conspiracy to Distribute Controlled Substances and Distribution of Controlled Substances	Plead guilty to conspiracy to distribute controlled substances. 2-year probation involving resuming business operations, \$400 special assessment, \$1,000,000 fine, \$459,114.81 forfeiture and \$526,343.98 forfeited by owners
Dr. Stephen Ancier/Physician (PA and WA)	Conspiracy to Distribute Controlled Substances and Distribution of Controlled Substances	Pled guilty to conspiracy to distribute controlled substances. 60-month sentence, 3 years' supervised release, \$100 special assessment, \$7,500 fine, \$465,955 forfeiture (Hawaii property seized as partial satisfaction)
Dr. David Baron/Physician (CO)	Conspiracy to Distribute Controlled Substances and Distribution of Controlled Substances	Pled guilty to conspiracy to distribute controlled substances. 27-month sentence, 2 years' supervised release, \$100 special assessment, and \$65,099 forfeiture
Dr. Felix Rodriguez-Schmidt/Physician (PR)	Conspiracy to Distribute Controlled Substances and Distribution of Controlled Substances	Entered into Pre-trial Diversion Agreement and the case was dismissed without prejudice. No other facts are known
Dr. Alexis Roman-Torres/Physician (PR)	Conspiracy to Distribute Controlled Substances and Distribution of Controlled Substances	Pled guilty to conspiracy to distribute a controlled substance. 18-month sentence, 3 years' supervised release, \$100 special assessment, and \$134,130 forfeiture
Dr. Kimberly Trever/Physician (MI)	Conspiracy to Distribute Controlled Substances and Distribution of Controlled Substances	Entered into Pre-trial Diversion Agreement and the case was dismissed without prejudice. No other facts are known

*To be continued*

TABLE III - Continued

Name/Role	Charges	Conviction/Sentence
<b>Puerto Rico Physicians</b>		
Eric Spears/Recruited Physicians	Conspiracy to Distribute Controlled Substances and Distribution of Controlled Substances	Plead guilty to conspiracy to distribute controlled substances. 36-month sentence, 12 months' supervised release, \$100 special assessment and \$37,698.47 forfeiture
Dr. Rene Guerra/Physician (FL)	Conspiracy to Distribute Controlled Substances and Forfeiture	Pled guilty to conspiracy to distribute controlled substances. 18-month sentence, 2 years' supervised release, \$100 special assessment, and \$6,000 fine
Dr. Jose Crespin/Physician (FL)	Conspiracy to Distribute Controlled Substances, Money Laundering and Forfeiture	Pled guilty to conspiracy to distribute controlled substances and money laundering.
Dr. Michael Millette/Physician (IL)	Conspiracy to Distribute Controlled Substances, Money Laundering and Forfeiture	7-month sentence, 2 years' supervised release, \$200 special assessment, and \$75,398 forfeiture
Dr. Juan Oscar Gonzalez/Physician (PR)	Conspiracy to Distribute Controlled Substances, Money Laundering and Forfeiture	Pled guilty to conspiracy to distribute controlled substances and conspiracy to launder money.
Dr. Edward Schwab/Physician (LA)	Conspiracy to Distribute Controlled Substances, Money Laundering and Forfeiture	41-month sentence, 2 years' supervised release, \$300 special assessment and \$1,600,000 forfeiture
Douglas Bouchey/Pharmacist (IA & MI)	Drug Conspiracy and Money Laundering	Pled guilty to conspiracy to distribute controlled substances and money laundering. 8-month home detention, 2 years' probation, \$200 special assessment and \$7,500 forfeiture
Jack Huzi/Pharmacist and owner of Union Family Pharmacy	Conspiracy to Distribute Controlled Substances, Money Laundering and Forfeiture	Pled guilty to conspiracy to distribute controlled substances and money laundering. 22-month sentence, 2 years' supervised release, \$200 special assessment and \$500,209 forfeiture
<b>Bansal Organization</b>	Conspiracy to Distribute Controlled Substances, Continuing Criminal Enterprise, Conspiracy to Introduce Misbranded Drugs into Interstate Commerce, Conspiracy to Commit Money Laundering, International Money Laundering, Transactional Money Laundering, and Promotional Money Laundering, Aiding & Abetting, and Criminal Forfeiture	Pled guilty to conspiracy to introduce misbranded drugs into interstate commerce. 6-month probation, \$25 special assessment and \$29,209 forfeiture The case against him was dismissed due to his death
Akhil Bansal/Indian licensed physician living in U.S. & head of Bansal Organization	Conspiracy to Distribute Controlled Substances, Continuing Criminal Enterprise, Conspiracy to Introduce Misbranded Drugs into Interstate Commerce, Conspiracy to Commit Money Laundering, International Money Laundering, Transactional Money Laundering, and Promotional Money Laundering, Aiding & Abetting, and Criminal Forfeiture	Found guilty of: Conspiracy to Distribute Controlled Substances, Continuing Criminal Enterprise, Conspiracy to Introduce Misbranded Drugs into Interstate Commerce, Conspiracy to Commit Money Laundering, International Money Laundering, Transactional Money Laundering, and Promotional Money Laundering 30 years' incarceration, 5 years' supervised release, \$1,600 special assessment, \$250,000 criminal fine, and \$8,094,439.75 in forfeitures

To be continued



TABLE III - Continued

Puerto Rico Physicians		
Name/Role	Charges	Conviction/Sentence
Brij Bansal/Indian licensed physician living in India. Head of Bansal Organization in India		4 years in Indian custody
<b>U.S. vs. Christopher Smith et al 05-cr-00282</b>		
Christopher William Smith (owner of Online Payment Solutions, Inc.)	Conspiracy to Distribute Controlled Substances, Unlawful Distribution & Dispensing of Controlled Substances, Introduction of Misbranded Drugs into Interstate Commerce, Conspiracy to Commit Money Laundering, Continuing Criminal Enterprise, and Forfeiture Allegations	Found guilty of all but Conspiracy to Distribute Controlled Substances. 30 years' imprisonment, 5 years' supervised release, \$800 special assessment to the Crime Victims Fund, and \$24,240,747 forfeiture (included the seizure of real and personal property as well as bank accounts)
<b>Chhabra Organization</b>		
Vineet Chhabra, head of organization	Conspiracy to Distribute Controlled Substances, Continuing Criminal Enterprise, Unlawful Distribution and Dispensing of Controlled Substances, Conspiracy to Launder Money, Promotional Money Laundering, Transactional Money Laundering, Introduction of Misbranded Drugs into Interstate Commerce, and Forfeiture	Conspiracy to Violate the Controlled Substances Act, Unlawful Distribution & Dispensing of Controlled Substances, and Forfeiture 33 months imprisonment, 3 years supervised release, \$100 special assessment and \$16,000,000 judgment (includes seizure of 2014 Tesla)
<b>Bezonsky/Affpower</b>		
Michael L. Bezonsky	Conspiracy, Mail Fraud, Conspiracy to Commit Money Laundering, Monetary Transactions in Proceeds of Specified Unlawful Activity, Money Laundering, Aiding & Abetting and Criminal Forfeiture	Pleaded guilty to Conspiracy to Distribute Controlled Substances, Mail Fraud and Conspiracy 70 months imprisonment, 3 years' supervised release, \$300 special assessment and \$12,257,161.53 forfeiture *This sentencing info encompasses 2 criminal cases filed against him
Dr. Ahlawat		Pleaded guilty to Conspiracy to Distribute Controlled Substances and Money Laundering. 5 years' probation, lost medical license, \$700 in special assessments, \$6,000 in fines, and \$2,120,257 in forfeitures. *This sentencing info encompasses 8 cases filed against him
Dr. Klinman		Pleaded guilty to Conspiracy to Distribute Controlled Substances and Money Laundering. 4 years' probation, \$300 special assessment, \$30,000 fine, and \$654,365 in forfeitures. *This sentencing info encompasses 3 cases filed against him
Atchildiev, pharmacist		Pleaded guilty to Distribution of Misbranded Drugs and Aiding and Abetting. 2 years' probation, \$25 special assessment and \$1,000 fine
Universal Pharmacy Solutions (owned by Atchildiev)		Pleaded guilty to Conspiracy to Distribute Controlled Substances, Distribution of Misbranded Drugs, Aiding & Abetting, and Money Laundering. \$1,725 special assessment and \$18,773,000 in forfeitures



Additionally, the Google, United Parcel Services, and FedEx cases demonstrate how large corporate entities can help in identifying complex online pharmacy criminal networks. Leading up to Google's prosecution, the technology company provided direct customer support to online pharmacy advertisers "to assist them in placing and optimizing their AdWords advertisements, and in improving the effectiveness of their websites" (31). As a result of the investigation and subsequent prosecution, Google changed some of their practices as they pertained to online pharmacy e-commerce policies. This included requiring online pharmacy advertisers to be certified by the National Association of Boards of Pharmacy's (NABP) Verified Internet Pharmacy Practices Sites (VIPPS) program (31). Google has also instituted similar policies in Europe, where a valid license is required in the country of residence prior to opening a Google Ad word account. Overall, Google's advertising policies of "healthcare and medicines" are jurisdictional specific and state that promotion of online pharmacies are only allowed in 20 countries (which includes the USA) and that they must be "certified" by Google by filling out an application form. Currently, for the USA, online pharmacy Google certification requires either NABP VIPPS accreditation or participation in the .pharmacy Verified Websites Program (essentially requiring a website to secure a .pharmacy generic top-level domain name from NABP). However, even with this change in policy (that only impacts sponsored search results and ad words), "no-prescription online pharmacy" results continue to populate Google search engine results.

Other social media platforms have also attempted to update their terms and conditions for online pharmacy content. For example, Facebook's pages terms states that while pages must not promote the sale of prescription pharmaceuticals, online pharmacies may be permitted with prior approval from Facebook, though the exact process is not well defined. Further, Facebook's advertising policies previously stated that online pharmacies could fill out a "Pharmaceutical Advertiser Application Form," but it appears that Facebook is no longer accepting these applications. Twitter's "Health and Pharmaceutical Products and Services" terms are also jurisdiction specific. For the USA, advertisements from online pharmacies are only allowed if they are accredited by NABP. However, the effectiveness of such terms are difficult to measure, particularly given that studies have found that these platforms continue to host content associated with illicit online pharmacies, including the illegal sale of controlled substances (1, 12, 13, 32).

Moving to logistic providers, during the DOJ's investigation into United Parcel Services, it was uncovered that executives were on notice about shipments from illicit online pharmacies as early as 2003. Employees raised their concerns with senior management but nothing was done to curb the shipments that generated profit for the company. According to the DOJ, despite law enforcement warnings and notifications, UPS failed to implement procedures to remove shipping accounts of illegal online pharmacies, hence, facilitating the shipment of controlled substances and prescription drugs from 2003 to 2010 (33, 34). In response, UPS created an online pharmacy compliance program in accordance with a DOJ's nonprosecution agreement.

In summary, our legal review and analysis of illegal online pharmacy prosecutions and their associated defendants

demonstrates the difficulties inherent with detecting and prosecuting these types of health- and cyber-related criminal cases. Patient safety takes a back seat to the large financial gains common to this criminal activity, which is taking advantage of advances in online technology, unsuspecting consumers, and websites that aggressively market the "no-prescription" sale of drugs conveniently over the Internet. Moreover, criminal penalties have not been an effective deterrent nor do they fit the severity of the crime perpetrated in many instances. The multijurisdictional aspect to many of these cases also makes it difficult to fully prosecute all individuals; therefore, it is nearly impossible to stop the proliferation of illegal online sale of pharmaceuticals that can originate from all around the world. Though Mr. Haight's death led to legislation designed to address many of these challenges, our legal review illustrates that there is much more work to be done.

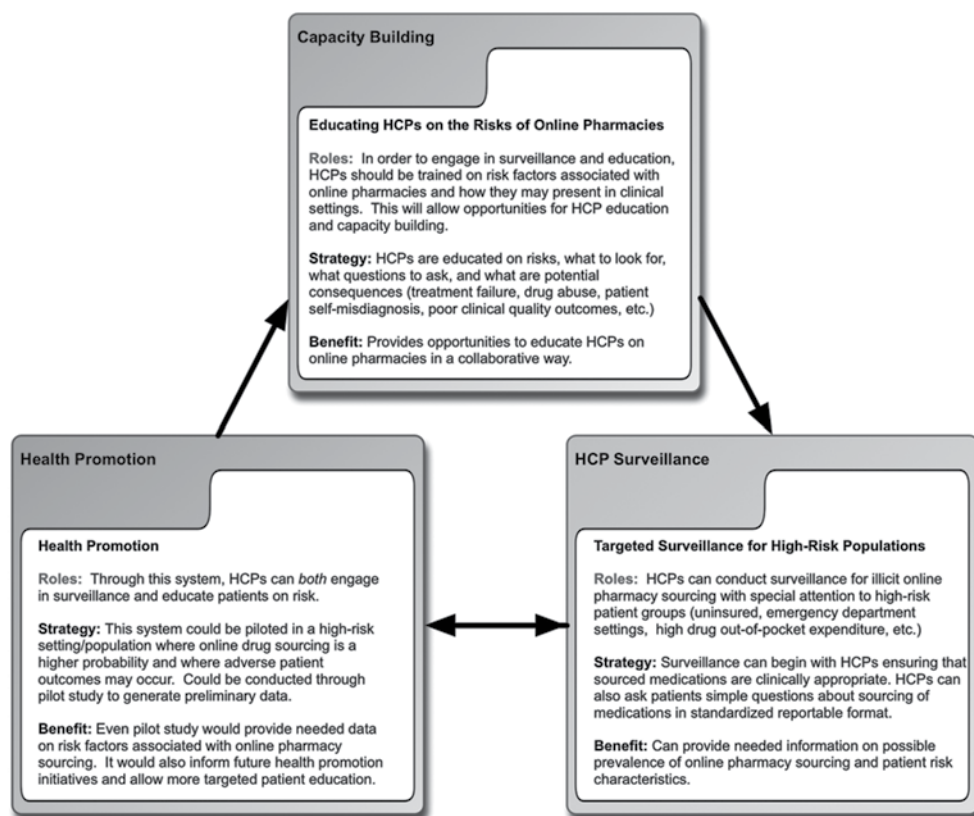
### Call to action

The challenges associated with appropriately deterring criminal activities of illicit online pharmacies, penalizing their actions, and successfully prosecuting those who are caught engaged in this digital form of pharmaceutical crime must be addressed from the collective perspectives of law enforcement, regulatory agencies, and patient safety stakeholders. This includes enabling better coordination and harmonization of these efforts in the USA and beyond given the global reach and international complexity of online pharmacy networks as illustrated in the cases reviewed. We therefore issue a "call to action," focusing on enhancing criminal laws associated with illegal online distribution of medicines, improving prosecutorial and judicial capacity by advocating for a redistribution of restitution and criminal fines back into prevention and training efforts, and establishing better policy coherence globally through existing legal and regulatory medicine safety frameworks.

### Enhancing criminal penalties in the USA

A critical area that needs legal and policy attention is strengthening criminal laws to enhance sentencing and restitution to aid efforts by law enforcement, regulators, and aggrieved patients. Our study findings indicate that USA sentencing and restitution were applied differently depending on the characteristics of the case, with some cases sharing similarities but different sentencing outcomes. Additionally, our informal conversations with prosecutors and judges indicated that there is general consensus that participation in illegal online pharmacies is viewed as a white-collar crime, which may be a reason for seemingly lenient punishment.

It is also clear that U.S. Federal Sentencing Guidelines are not sufficiently punitive to deter criminal activity associated with illegal online pharmacies. Policy changes that aim to strengthen punishment against this form of cybercrime have previously died in committee. For example, the Counterfeit Drug Penalty Enhancement Act of 2012, sponsored by Rep. Patrick Meehan (R – H.R. Pennsylvania), passed the U.S. House of Representatives in 2012. It was received by the Senate in 2012 and then sent to the Committee on the Judiciary, but there has been no further progress. The Act would have established stronger criminal penalties for trafficking, or attempting to traffic in counterfeit



**Fig. 1** - Framework for healthcare professionals' engagement on illicit online pharmacies.

drugs. Although not all online pharmacies are trafficking counterfeit drugs, this law could be used as an example of establishing appropriate penalties for illegal online pharmacies illegally selling and importing drugs. The Act also attempted to ensure that sentencing guidelines met the purposes of sentencing as set forth in section 3553(a)(2) of title 18, USC.

Section 3553(a)(2) of title 18, USC enumerates factors to be considered in imposing a sentence. Two of the factors that are important to our analysis are "the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct" and "the need to provide restitution to any victims of the offense" (35). Our review of sentencing documents of doctors, for example, demonstrates the need for more uniform sentencing for their criminal conduct that directly harms the patient.

### **Redistribution of criminal restitutions to enhance judicial capacity and prevention**

Relatedly, USA prosecutions resulting in restitution and forfeitures from illicit online pharmacies have provided a substantial amount of money that can be shared with law enforcement organizations and public health officials. Given that current prosecutions lack sufficient deterrence, we argue that a portion of this money should be used to bolster training in more proactively identifying these criminal activities, strengthen existing laws, and fund prescription-drug-abuse programs to help curb the contribution of online pharmacies to substance abuse behavior and prescription misuse.

Importantly, restitution and criminal fines could be used to train and educate law enforcement, public health officials, technology companies, and consumers to identify and combat illegal Internet pharmacies (2, 36). For example, healthcare professionals (HCPs; including physicians, pharmacists, nurses, and other allied health workers) from the USA, Europe, and other countries where consumers regularly use Internet technology to query health information and shop online, could be provided more education and public information regarding risk factors associated with purchasing medicines online. This includes ensuring that HCPs are (i) aware that their patients may engage in sourcing drugs online in their course of care- and health-seeking behavior; (ii) aware of the risk factors that may be associated with this behavior (e.g., adverse prescription drug events, high out-of-pocket prescription drug expenses, etc.); and (iii) asking patients where they source their drugs if these risk factors are present. Ideally, this would enable HCPs to actively participate in surveillance, capacity building, and health education regarding online pharmacy risks (see a proposed HCP Engagement Framework in Fig. 1).

Additional resources also can be devoted to national public service announcements and patient safety awareness campaigns to educate consumers about online pharmacy dangers (including bolstering existing consumer education efforts by FDA's "BeSafeRx" initiative, Interpol, the Alliance for Safe Online Pharmacies, and other organizations) (36). Resources could also be used to fund independent compliance programs and online watchdogs to ensure large businesses, pharmacies, physicians, and other actors are in compliance with existing federal and state law. The compliance programs put in place by

Google, UPS, and FedEx are examples of what could be implemented, but have largely been in response to federal prosecutions, not proactive measures to protect online consumers.

Also, it could be argued that judicial expediency plays a role in disparate results in criminal sentencing/punishment. Most defendants in the cases we reviewed were charged with several counts of various crimes. However, they pleaded to less than a handful of counts that, in turn, carried a lesser sentence and criminal fine. The few defendants whose cases were adjudicated by trial received much steeper sentences and criminal fines. Due to budget cuts in the judiciary and the rising expense of trials, it is common for defendants to take a plea agreement prior to trial – 97% of federal cases are settled [this] way (37). We suggest that a portion of criminal restitution be provided to the courts and prosecutorial agencies to hire more judges and prosecutors specifically trained in this form of cybercrime and healthcare fraud. Hiring more prosecutors with this training could help alleviate the need to settle cases pretrial due to general high volume. Likewise, hiring more judges to clear the backlog of cases would allow for more trials to go forward. This could limit the ability of defendants to plead to lesser counts, and if found guilty, higher penalties could be applied.

In summary, a better and more equitable distribution of restitution could help address challenges discussed by providing a more even distribution of resources to law enforcement, the judiciary, regulators, and consumer protection groups to prevent, detect, prosecute, and educate about online pharmacy risks. Additionally, restitution could be used to fund research needed to build evidence quantifying the public safety and economic consequences of illicit online pharmacies, which could further support evidence-based policy making.

### ***International policy coherence***

Finally, though strengthening USA domestic criminal penalties and enhancing judicial capacity can help balance the scales of justice, the globalized nature and inherent multijurisdictional challenges of criminal online pharmacy networks demands solutions that go beyond national efforts. Illustrating that these shared challenges extend beyond USA borders, a recent European research project conducted by the ALPhA group found that across 28 EU Member States the legal landscape related to online pharmacies had high variance, was characterized by consumer lack of knowledge of risks, and similarly incentivized criminal operation due to high profits and a low risk of prosecution (38). Hence, there is a need to harmonize international legal frameworks at the USA, European, and regional levels to ensure that illicit online pharmacies are regulated consistently (e.g., establishing common terminology for fake, falsified, fraudulent, substandard, and counterfeit medical product variations), establishing appropriate coverage of national laws, regulations, and licensure standards to control illicit online pharmacy sales that occur transnationally, and enabling better cooperation and coordination between law enforcement and regulators (e.g., ensuring more robust track and trace systems, the application of extradition treaties, asset recovery and forfeiture, mutual legal assistance, and multijurisdictional prosecutions) for criminalization and applying sanctions (38-41).

Though achieving these goals may seem daunting, medicines safety legal frameworks already exist in places like the USA and Europe, and can be harmonized and extended to other countries. This includes the Council of Europe's MEDICRIME Convention (entered into force on 1 January 2016), which is the first legally binding instrument making counterfeiting of medical products a criminal offense, including the sale of fake and counterfeit medicines via the Internet (42, 43). Recently, the MEDICRIME Convention was ratified by Turkey, bringing the total number of ratifying countries to 11 (which does not include the USA or the UK), though it is notable that the treaty is open to state parties outside of the Council of Europe's membership upon invitation, meaning that more widespread adoption could lead to a treaty instrument with more multilateral coverage (43). Other policy instruments, such as the Council of the European Union's Falsified Medicines Directive and USA domestic laws including the 2013 Drug Supply Chain Security Act and the RHA, could also form the basis of a framework of domestic and regional laws that could be harmonized with MEDICRIME for more global coverage (44). Similarly, proposals for an International Model Law on Medicine Crime advocated by Professor Amir Attaran and applying existing treaty instruments (e.g., the United Nations Convention against Transnational Organized Crime) to the fake medicines and online pharmacy problem could further expand this policy framework (39, 45, 46). Finally, coordinated law enforcement efforts, such as Interpol's Operation Pangea, illustrate that international cooperation is indeed possible, though established policy networks are needed for sustainable and proactive measures.

In conclusion, the USA cases involving prosecutions of illicit online pharmacies reviewed in this study are simply a microcosm of a much larger and complex global public health problem, and one that demands solutions shared and implemented across a wide spectrum of stakeholders. Strengthening local, domestic, regional, and international law and regulation to better criminalize this form of cyber pharmaceutical crime is critical, and will help to ensure that the Internet is a place for promoting health not subverting it.

### **Disclosures**

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