

Infectious Disease in Hematopoetic Stem Cell Transplantation-Research @ Point of Care



# Evaluation of pharmacists' awareness of illegal online pharmacies and perceived impact on safe access to medicines

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#### **Abstract**

**Background:** An estimated 95% of all online pharmacies operate unlawfully. Illegal online pharmacies distribute substandard and falsified medical products that may result in patient harm and suboptimal treatment, leading to an overall mistrust of medications, healthcare providers, and health systems. As medication experts, pharmacists are trusted to guide patients in selection of safe and effective medication therapy.

**Objective:** The objective of this study was to determine gaps in knowledge and recognition of the negative clinical and safety impacts associated with illegal Internet pharmacies by licensed pharmacists.

**Methods:** A 37-question electronic survey was developed and distributed to pharmacists across the United States by email via a database from the American Pharmacists Association. Descriptive statistics was utilized to analyze data.

**Results:** A total of 347 pharmacists from across the United States responded to at least one question in the survey. In all, 58% of pharmacists reported a lack of confidence in their ability to counsel patients on the identification of illegal pharmacy websites. Fewer than 60% of pharmacists were able to accurately identify the legitimacy of a webpage based on visual characteristics. In addition, 75% of pharmacists reported being unfamiliar with resources available to help consumers identify safe and legitimate online pharmacies.

**Conclusion:** Integration of the topic into pharmacy education curricula, training on available resources, and additional research into the prevalence and impact of illegal pharmacy websites are necessary to ensure that pharmacists and other healthcare professionals are adequately prepared to protect their communities from the threat of illegal online pharmacies.

## **Keywords**

Illegal online pharmacy, substandard, falsified, illegal Internet drug sellers

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# **Background**

The 2019 Annual Internet Crime Report released by the US Federal Bureau of Investigation (FBI) identified over 450,000 reports of Internet crime activity. Over the past 5 years, the cost of Internet crime—related losses have more than tripled, reaching an estimated cost of US\$ 3.5 billion in 2019. Over 1 million of this total cost stems from healthcare-related crimes that range from insurance fraud to diversion and fabrication of prescription medications that may be sold on illegal online pharmacies.<sup>1</sup>

Illegal online pharmacies are those that act in violation of the US Federal Food, Drug, and Cosmetic Act (FDCA) by

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selling prescription drugs without a valid prescription, adequate directions for safe use, or required warnings and with unclear safety and efficacy information.<sup>2</sup> Online pharmacies are in violation of federal law when they lack a physical address and telephone number in the United States, do not hold a valid pharmacy license in all states in which they operate, and do not employ state-licensed pharmacists.<sup>2</sup> Research conducted by the National Association of Boards of Pharmacy (NABP) found 95% of pharmacy websites in violation of regulations, validating similar research.<sup>3,4</sup>

Illegal online pharmacies often take part in the distribution of substandard and falsified (SF) medical products. The World Health Organization (WHO) defines SF products as authorized medical products that fail to meet quality standards and specifications or deliberately misrepresent their identity, composition, or source.5 SF medications may contain widely varying levels of active ingredient (from too much to none at all) and/or harmful substances such as paint, antifreeze, and heavy metals.<sup>6</sup> SF medications can be nearly indistinguishable from their legitimate counterparts. Risks associated with the use of SF medications may include patients receiving the incorrect product or products manufactured or stored in unsafe conditions. Use of illegal Internet pharmacies may additionally result in the misuse of personal health and financial information, as criminal organizations collect personal financial and location data to process payments for the ordered products. The WHO emphasizes that SF products may result in patient harm and suboptimal treatment, leading to an overall mistrust of medications, healthcare providers, and health systems.<sup>7</sup>

The increased use of the Internet and social media technology has also been associated with new and evolving options for sellers of medical products that are of questionable quality, origin, and authenticity. Online content is often misleading, fraudulent, and illegal as it includes the marketing and sale of prescription medicines as "no prescription necessary" and use of unsubstantiated medical questionnaires in lieu of a prescription.8 Previous research has detected illegal opioid sales on several social media platforms, including Twitter, Facebook, and Instagram. The COVID-19 pandemic and other public health emergencies expose patient safety issues that arise when fear and misunderstanding drive patients to purchase untested treatments and cures over the Internet. The Food and Drug Administration (FDA) has intervened issuing warning letters to those selling "unapproved and misbranded drugs related to coronavirus disease."10

According to a recent Gallup poll, pharmacists are rated as one of the most highly trusted professions. <sup>11</sup> Pharmacists are widely considered medication experts and directly interact with patients regarding their drug therapy more often than physicians. To become licensed professionals, pharmacists study pharmacotherapy, pharmacokinetics, pathophysiology, and other related topics in a comprehensive professional curriculum lasting at least four academic years in addition to at least 2 years of prerequisite didactic instruction. In the United

States, Doctor of Pharmacy programs are accredited by the Accreditation Council for Pharmacy Education (ACPE). The most recent 2016 ACPE accreditation standards do not require incorporation of SF medical product and illegal online pharmacy education into curricula. As pharmacists serve as medication experts for their communities, their ability to identify and counsel potential illegal websites and SF medical products is essential for mitigating patient harm.

There are resources available to pharmacists to assist in identification of illegal online pharmacies, including the website verification tool offered by the Portland, Oregonbased LegitScript (https://www.legitscript.com/). NABP has established the (dot) .Pharmacy Verified Websites Program which provides pharmacists and consumers with an updated list of reputable online pharmacies. Without ACPEmandated education requirements, it is unclear how familiar pharmacists are with this topic and available resources. If pharmacists are able to identify illegal online pharmacies and recognize risks associated with their use, they may be better able to educate patients and caregivers and collaborate with other healthcare professionals to improve patient outcomes.

# **Objective**

The objective of this study was to determine gaps in knowledge and recognition of the negative clinical and safety impacts associated with illegal Internet pharmacies by pharmacists.

# **Methods**

# Design

To accomplish this study objective, a descriptive survey design was developed. Data were collected through an electronic questionnaire distributed to pharmacists in the American Pharmacists Association (APhA) database throughout the United States. Descriptive statistical analysis was performed to assess pharmacist knowledge gaps and the ability of pharmacists to identify illegal online pharmacies. This study was reviewed by Butler University's Institutional Review Board and determined to be exempt from full review. Participation was voluntary and the results were anonymous.

# Setting and study participants

Inclusion criteria for this study were inclusion in the APhA contact database and identified as a pharmacist (n=6345). At a 90% confidence level (error margin  $\pm$  5), the ideal sample size was calculated to be 260 participants. This threshold was purposefully conservative to account for variability in responses to each question item. Pharmacists not in the APhA database or that did not consent to survey participation were excluded from this study. Requests for survey participation were sent to both APhA members and non-members, equally,

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as part of the database sample. The survey was sent electronically through the APhA database throughout the United States and territories. Study participants did not receive financial compensation for survey completion.

#### Instruments

The Qualtrics® tool was used to create a web-based survey. The survey consisted of 37 questions. including a combination of multiple-choice, Likert-type scale, and yes/no questions. Survey questions were developed through an expert panel consensus approach, incorporating validated questions from APhA. The survey was estimated to take around 10 min to complete, and questions had been validated by previous national surveys. The questions focused on the participants' overall knowledge and confidence of the prevalence and negative clinical and safety impacts associated with illegal Internet pharmacies. Additional questions were designed to gauge participants' confidence level regarding the topic when counseling patients. The survey and specific questions are provided in the supplemental material.

To assess pharmacist ability to identify illegal online pharmacies based on webpage appearance, two known illegal (or rogue) websites and one known legal website were identified and screen-captures were provided to pharmacists to assess the apparent legitimacy.

# **Procedure**

The electronic survey was created utilizing the Qualtrics® tool. A small pilot was initiated to validate the survey instrument. Various pharmacists and pharmacy learners provided feedback regarding length and readability of the survey. Edits were made following the pilot to ensure clarity throughout, and the survey was finalized for distribution

APhA sent an email with the survey link in May 2019 explaining the research project and requesting voluntary participation. Three reminder emails were subsequently sent to the same study population in 1-week increments during June 2019.

Participants consented to the study before reading an informational summary about legal and illegal Internet pharmacies. The summary was followed immediately by the first survey question. Survey participants answered questions independently with no time or Internet usage restrictions, and there were no required questions. The survey was closed on 22 June 2019, and the descriptive statistics were used to analyze the results.

#### Results

A total of 349 (6%) study subjects responded to the survey, with 347 individuals consenting to participate in the survey and answering at least one question. However, as response to each question was not mandatory, the denominator used to evaluate the results of each question item

Table I. Demographics.

	n	%
Gender (n = 257)		
Male	82	32
Female	170	66
Prefer not to answer	5	2
Pharmacy degree (n = 262)		
BS	93	35
MS	2	1
PharmD	176	67
Graduation year $(n=260)$		
1988 or before	73	28
1989–1998	26	10
1999–2008	56	22
2009–2013	53	20
2014–2019	52	20
Post-graduate training $(n = 222)$		
PGYI	36	16
PGY2	7	3
Fellowship	3	1
MS	12	5
PhD	1	0
MBA	19	9
Not applicable	144	65
Other	9	4
Practice site $(n=260)$		
Community chain/grocery	114	44
Community independent	52	20
Ambulatory/outpatient clinic	36	14
Managed care	10	4
Long-term care	9	3
Specialty	10	4
Hospital	9	3
Currently not working	6	2
Other	14	5

PGY: post-graduate year.

varied. The reported locations of the respondents represented 36 states within the United States. Approximately 66% of the survey participants were female and 32% were male. The majority of study participants possessed a Doctor of Pharmacy degree (67%) and reported working in a community-based practice site (64%). Additional detailed demographic information is provided in Table 1.

Approximately 87% (282/324) of pharmacists reported some knowledge of the existence of illegal online pharmacies prior to completing the survey. The most commonly reported information sources were news media, independent study, and workplace experience. It is estimated that between 95% and 96% of Internet pharmacies operate illegally; however, 93% (279/299) of pharmacists estimated the true percentage of illegal sites to be less than 81%.<sup>3</sup> Seven percent of pharmacists (23/312) reported receiving practice site training on the provision of education to patients on illegal Internet pharmacies. Up to 96% of

**Table 2.** Summary of pharmacists' confidence in their own knowledge and ability to counsel patients.

	Summary of pharmacists' confidence in their own knowledge of the shown statements				Summary of pharmacists' confidence in ability to counsel patients and caregivers on the shown statements				
	Confident		Not confident		Confident		Not confident		
	n	%	n	%	n	%	n	%	
Prevalence of illegal Internet pharmacies	131	46	155	54	150	52	136	48	
Availability of illegal Internet pharmacies to patients	159	56	127	44	158	55	128	45	
Ability to determine the legitimacy of an Internet pharmacy	125	44	161	56	120	42	165	58	
Types of medications sold by illegal Internet pharmacies	113	40	173	60	121	42	165	58	
Risks associated with medications sold by illegal Internet pharmacies	208	73	77	27	203	71	82	29	

Table 3. Pharmacists' knowledge and perception of internet medicine sales and access.

For each of the following statements, pharmacists were asked to indicate the extent to which they agreed or disagreed

	Strongly agree		Somewhat agree		Somewhat disagree		Strongly disagree	
	n	%	n	%	n	%	n	%
Illegal Internet pharmacies are easily identifiable	8	3	72	26	136	50	56	21
Legitimate Internet pharmacies must have a brick-and-mortar facility to operate consistent with applicable law and regulations	95	35	104	38	50	18	24	9
Illegal Internet pharmacies may sell prescription medications without a valid prescription	88	32	66	24	10	4	109	40
All medications sold on the Internet to US patients are FDA-approved	21	8	13	5	42	15	197	72
All medications sold on the Internet to US patients comply with US drug and pharmacy laws	22	8	12	4	44	16	195	71
A majority of medications sold on the Internet are not deemed to be substandard or falsified	29	П	77	28	108	40	58	21

FDA: Food and Drug Administration.

pharmacists reported discussing the risks of counterfeit medications with fewer than half of their patients. Reports suggest that approximately one-third of patients have ordered medications from an online pharmacy with upward of 55% having previously purchased or considering purchasing prescription drugs via the Internet; however, a majority of pharmacists (71%) estimated that 40% or fewer of their patients have done so.<sup>10</sup>

Awareness of patients or caregivers that have purchased prescription drugs from an online pharmacy was reported by 55% (162/296) of pharmacists, but 62% (101/162) of those pharmacists were unaware of the type or quantity of medication purchased. Twenty-three pharmacists reported knowledge of an adverse impact experienced by a patient related to medications obtained online; examples include a patient receiving "counterfeit Eliquis® confirmed by the manufacturer," a patient experiencing "liver toxicity," and a patient receiving a benzodiazepine derivative powder that

was estimated to have "ten times the recommended prescription dose." A majority of pharmacists reported confidence in their own knowledge and in their ability to counsel on the risks associated with medications sold by illegal online pharmacies, but they were not confident in their own knowledge or their ability to counsel on the prevalence and availability of illegal online pharmacies. Pharmacists' confidence in their own knowledge and in their ability to counsel patients and caregivers on various aspects of illegal online pharmacies is summarized in Table 2.

When asked specific questions about the operation of online pharmacies, most pharmacists disagreed that all medications sold online to patients in the United States are FDA-approved and comply with US drug and pharmacy laws. Some pharmacists were unsure whether online pharmacies are able to legally sell medications without a valid prescription. A summary of pharmacist agreement with statements regarding online pharmacies is available in Table 3. In

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addition, the majority of pharmacists believed that purchasing medications online, including "Canadian" online pharmacies, is less expensive than what is available in the United States when this may not necessarily be the case. <sup>11</sup>

Approximately 86% (244/283) of pharmacists reported that the web address was important for the identification of illegal online pharmacies, yet 33% (87/263) were able to perform accurate identification when presented with an image of an illegal online pharmacy webpage (Figure 1). Seventy-five percent of pharmacists reported being unfamiliar with resources available to help consumers identify safe and legitimate online pharmacies, and a majority of those pharmacists were not familiar with the NABP .Pharmacy initiative.

# Discussion

Results from this study demonstrate that while pharmacists are aware of the existence of-and risks associated with—illegal online pharmacies, they were not aware of the scope of the issue. Many pharmacists underestimated the number of illegal online pharmacies currently in operation as well as the number of patients utilizing online pharmacies. It is estimated that 55% patients have ordered medications or would consider purchasing from an online pharmacy and that 95% online pharmacies operate illegally.<sup>3,14</sup> Pharmacists' lack of awareness and scope of this issue may contribute to the reportedly few discussions pharmacists in this study describe having with their patients about illegal online pharmacies and associated general lack of awareness by patients. This need for more awareness and education is not only limited to the United States, it is also global. For example, one study from 2018 found 82.65% participants were aware medications could be obtained online. Furthermore, the authors emphasized the number of individuals open to purchasing online was expected to grow, with 23.3% of study participants stating they were either very likely or likely to purchase medications online in the future. 15

When pharmacists did discuss purchasing of online medications with their patients, health and financial consequences were identified. Several pharmacists were able to provide specific examples of patient harm attributable to the use of medications purchased from an online pharmacy. In terms of cost, many pharmacists were under the same assumptions as their patients that medications were less expensive when purchased from a "Canadian" online pharmacy; however, a comparative survey completed by the Fraser Institute estimated that Americans would actually pay more for their generic medications if they purchased them all in Canada. 16 Potential for harm and cost considerations with illegal online pharmacies are two key points for patient education; however, pharmacists reported a lack of self-knowledge and confidence in their ability to counsel patients. As the most accessible healthcare professional, it is essential pharmacists are well-trained and equipped to assists those patients struggling to stay safe online.

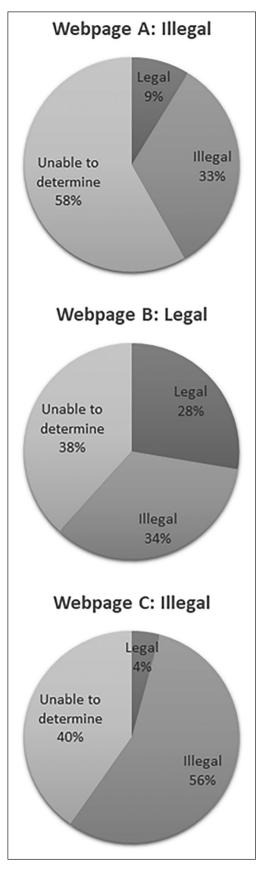


Figure 1. Pharmacists were shown screen-captures of real websites and asked, "Based on the look of this webpage, do you think this Internet pharmacy website is legal or illegal?"

Current circumstances surrounding the COVID-19 pandemic also highlight the immense patient health and safety concerns associated with the advertisement and sale of fraudulent or counterfeit treatments, cures, related interventions, and associated misinformation. With more than 100,000 new websites launching in the month following the announcement of a public health emergency including terms such as "covid" and "corona," patients and caregivers remain at risk of leveraging online sources that could prove harmful and thwart the global pandemic response.<sup>17</sup> NABP confirmed over 90% of the COVID-19-related domain names identified were registered anonymously, bringing into question the legitimacy of these sites and making investigation challenging.<sup>18</sup> In those first 8 weeks of the pandemic, the FDA and Federal Trade Commission (FTC) issued 120 distinct warning letters to individuals and companies for "unapproved and misbranded products related to [COVID-19]."10

Specifically, to prevent patient harm, it is important for pharmacists to be able to direct their patients to legitimate online pharmacies, a skill with which many pharmacists noted a lack of confidence. This was emphasized when fewer than 5% pharmacists were able to accurately identify the legitimacy of all three pharmacy webpages. Less than one-third of participants were able to determine the legitimacy of a single online pharmacy webpage. Online pharmacies are a lucrative business—for legitimate and especially illegitimate actors—and improve convenience and access for many patients; therefore, the availability of purchasing medication online is unlikely to decrease. This underscores the need for appropriate education for all within the healthcare delivery system, patients included. As pharmacists are highly trained, trusted, and readily accessible healthcare professionals in the community, it is vital they serve as a valuable resource for education on online pharmacies and SF medical products. As stated in one paper by Ferrario and colleagues, "there is no access to medicines without quality and more emphasis on training of pharmacists in SF medicines is urgently needed." To support pharmacists in this role, it may be necessary for ACPE to update their accreditation standards to include these topics in pharmacist education. This will ensure all pharmacists are aware of resources available, such as NABP's . Pharmacy Program, and are confident in their ability to educate their patients and members of the community. Ultimately, pharmacists around the world must prioritize asking patients, "where do you get your medication?" Using this simple prompt will enable pharmacists to follow-up, intervene, and ensure safe access to medication therapy. Regardless of the distributional channel, pharmacists must be a highly accessible and reliable source of medication information. Providing accurate and timely information will help prevent public misinformation campaigns and limit illegal online pharmacy sales.

Given the survey-based nature of this study, there are several limitations to address. First, only members of APhA's distribution list were eligible for inclusion, which may limit generalizability to all pharmacists. In addition, distribution of survey participants across the United States was unequal by State that may limit broad generalizability. That said, regionally the database is representative of how pharmacists are distributed nationally (compared to the US Bureau of Labor Statistics). Not all questions were required to be answered by survey participants, sometimes yielding partial data. This likely increased survey participation overall, but led to results with differing percentage estimates by question. Finally, the length of the survey may have decreased participation; this was made clear by the steady decrease in recorded responses to later questions in the survey. Both overall response rate and individual item responses were consistent with similar surveys; however, relatively low rates can limit broader generalizability.

# **Conclusion**

SF medical products obtained from illegal online pharmacies present eminent risk to unsuspecting patients and pharmacists are in a unique position to intervene. This study demonstrated that pharmacists are aware that illegal online pharmacies exist, and generally understand the risks associated with their use, but currently lack the necessary skills to adequately educate and protect the public. Pharmacists were not able to determine the validity of online pharmacies based on webpage characteristics and reported a lack of personal knowledge and confidence in their ability to counsel patients on illegal online pharmacies. Increased compulsory education requirements, training, and continuing education modules on available resources are needed. Pharmacists must always ask their patients, "where do you get your medication?" Additional research into the prevalence and impact of illegal pharmacy websites is vital to ensuring pharmacists and other healthcare professionals are adequately prepared to protect the public from the threat of illegal online pharmacies.

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## **Author contribution**

J.B.H. was involved in study design, study initiation, data collection, and authorship. S.M.J. and C.J.H. were involved in authorship. M.J.R. was involved in study design, data collection, and manuscript review.

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## Supplemental material

Supplemental material for this article is available online.

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