

A narrative review of illegal online pharmacies and contemporary issues with restricting FDA-approved medication access

The Journal of Medicine Access
2023, Volume 7: 1–9
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DOI: 10.1177/27550834231220512
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Zarnab Jillani, Lauren Reinhard and John Hertig 

Abstract

The rapid growth of technology has transformed the way the public purchases many products, including medications. Online medication purchasing has become a convenient and confidential route for patients to access healthcare without leaving their homes. Online pharmacies have many benefits but also present an increased risk for patient harm caused by unintentionally purchasing from illegal online pharmacies. Illegal online pharmacies are those that operate online without the requisite valid licenses or supply drugs not approved by the Food and Drug Administration (FDA). As obtaining certain medications has become restricted, either due to policy or drug shortages, more patients are relying on services provided by Internet pharmacies. The overturning of *Roe versus Wade* has caused an emerging drug restriction that may coerce the public to turn to Internet pharmacies for purchasing medications. A narrative review was conducted to analyze both the past and present effects of medications sold by illegal online pharmacies to help recognize the implications of restricting access to FDA-approved medications. Several large science and health literature databases were searched to find relevant references. Resulting resources, which referenced the connection between restricting access to FDA-approved medications and the increase in illegal online sales, were included in this review. The information evaluated in this article will help inform healthcare providers and policymakers of the inadvertent effects of restricting access to FDA-approved medications.

Plain language summary

A Narrative Review of Illegal Online Pharmacies and Contemporary Issues with Restricting FDA-Approved Medication Access

Background:

- Illegal online pharmacies target vulnerable patient populations such as patients affected by drug shortages or patients who require restricted access medications.
- Increased production of substandard or falsified medications is rampant during drug shortages or restricted access use and can lead to patient harm.
- The overturning of *Roe versus Wade* in the United States may illicit a response from the public to acquire their medications through illegal online pharmacies which may be providing substandard or falsified medications.

Methods:

- A narrative review was conducted to understand the implications of restricting access to FDA-approved medications. Previous instances of drug shortages and restricted access use medications were analyzed to understand the effects the overturning of *Roe versus Wade* may have on patient harm.

Butler University, Indianapolis, IN, USA

Corresponding author:

John Hertig, Butler University, 4600 Sunset Avenue, Indianapolis, IN 46208, USA.
Email: jhertig@butler.edu



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Results:

- Illegal online pharmacies continue to threaten patient harm by supplying substandard or falsified medications to patients.
- Patient harm from substandard and falsified medications has been observed through previous abortion bans.

Conclusion:

- Purchasing abortive medications from illegal online pharmacies is correlated with an increase in the number of serious or fatal events.
- This phenomenon can continue to impact the healthcare system as legal implications surrounding abortion develop.
- Education and advocacy to safe and effective abortive medications are key in ensuring patient safety in reproductive care.

Keywords

Abortifacient restriction, illegal online pharmacies, substandard and falsified medications, counterfeit drugs, online purchasing, Roe versus Wade, access to medications for abortion

Date received: 16 February 2023; accepted: 24 November 2023

Introduction

The Internet has revolutionized healthcare practices and has led to an increasing trend for consumers to replace a trip to their local pharmacy with Internet purchasing.¹ For many, buying prescription medications online offers advantages not available at a “brick-and-mortar” pharmacy. An online pharmacy, also referred to as an Internet pharmacy, is defined a retailer of non-prescription and prescription medications that dispenses or sells medicines directly to patients through the mail and provides information on their products via the Internet.² The general shift toward telehealth has made online pharmacies especially more appealing because of convenience, cost, and access.³ In addition, one of the many benefits of online pharmacies includes a greater availability of medications for those that have geographical limitations. The convenience and ease of comparing different websites to find the best price for medications also makes online pharmacies a more palatable option than a traditional visit to the pharmacy.⁴ The Internet provides access to various medications without restrictions or limitations, creating an appeal for consumers. Online pharmacies have many benefits associated with them, but they also present an increased risk for patient harm caused by unintentionally purchasing from illegal online pharmacies.⁵

Given the recent rulings of Roe versus Wade, which overturned women’s access to safe reproductive care, women may need to rely on unsafe sources such as illegal online pharmacies for reproductive medications to obtain an abortion. Women’s healthcare, specifically maternal health has often been overlooked, and despite healthcare advances in the past few decades, women still face gaps in treatment.⁶ With this added restriction, we can anticipate further major health issues and disparities. Evaluations of trends in illegal online pharmacies exhibit that patient harm can be generally underreported,³ and due to the

sensitive nature of abortion, there are not many direct patient case reports that show the harm that has been caused by restricting access to reproductive healthcare. The aim of this narrative review is to strive toward closing the women’s healthcare gap by highlighting the specific under-represented and under-reported topic of restricting access to abortion.

Methods

This review is intended to discuss past and present issues relevant to the impact of restricting access to FDA-approved medications or drug shortages. A narrative review was conducted using keyword combinations to identify appropriate sources. Our search was conducted between November 2010 and May 2023 in the following databases: PubMed, EMBASE, Cochrane, and Google Scholar. Articles were found from a wide range of key terms including: “medication restriction,” “restricting access,” “drug shortage,” “abortion restriction,” “abortifacients,” “misoprostol/mifepristone restriction,” “illegal online pharmacies,” “substandard and falsified medications,” “counterfeit drugs,” “online purchasing,” “Roe vs Wade,” “access to medications for abortion,” and “harm with restricted abortifacients.” The search yielded research articles, reviews, commentaries, conference papers, and news reports related to consumer restricted access to medication or harm associated with illegal online pharmacies. The pertinent data identified from these sources were included in this narrative review.

What are illegal online pharmacies?

The increased use of online healthcare has incited a marketplace where an estimated 35,000 online pharmacies are operating at any given time.⁴ Online pharmacies offer and dispense non-prescription and prescription medications

directly to patients through an Internet website.⁷ However, due to the intangible nature of the Internet and low-controlled environment, not all online pharmacies are legitimate.⁸ To classify an illegally operating online pharmacy, it is important to understand the difference between legal and illegal online pharmacies. Legal online pharmacies in the United States comply with the laws and regulations of the state where operations occur. In addition, they must also operate in accordance with the state to which the pharmaceutical products are shipped. On the contrary, illegal online pharmacies are defined as those that fail to meet any sort of regulatory requirements and are not appropriately licensed to dispense prescription medications. Illegal pharmacies are commonly identified as advertising the sale of prescription drugs without a valid prescription.⁴ With one click, consumers access thousands of pharmacies which can pose danger to many who might not be able to identify the indicators of a fraudulent pharmacy. Identifying an illegal online pharmacy has become more difficult as these online pharmacies use fraudulent seals and licenses to lure consumers.⁴ As of 30 June 2018, The National Association of Boards of Pharmacy (NABP)⁹ reviewed 11,943 illegal online pharmacies selling prescription medications to US patients and found that 96% of these pharmacies were operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice.

Rogue or illegal online pharmacies offer potentially adulterated, misbranded, or dangerous prescription medications outside of the regulated drug supply system to American consumers. According to the US Food and Drug Administration (FDA),¹⁰ adulterated medications are those that do not follow strength, purity, or quality standards and the differences are not noted on the drug label whereas misbranding is the labeling of medications in a false or misleading manner. These online pharmacies can provide substandard and falsified medications that are both misbranded or adulterated without adequate FDA-required directions for use, warning, and contraindications.¹¹ The inherent risks associated with these drugs may be linked to contamination, varying amounts of active ingredients, or containing different ingredients altogether.¹² Marketing strategies lure customers in through advertising the benefits of online pharmacies including convenience, discounts, privacy, bulk orders, and lack of a healthcare provider visits.¹³ Most commonly, social media platforms or other smartphone applications have become a popular route for unscrupulous sellers to market to vulnerable populations.¹⁴ Consumers who purchase medications online are at risk of experiencing adverse outcomes due to disproportionate amounts of active ingredients.¹⁵ Previous evaluations of trends in illegal online pharmacies revealed that SF product harm is severely under-reported, which in turn, makes it difficult to protect patients and advocate for reform.¹⁶ Aside from non-health-related risks, there are risks associated with consumer fraud, breach of privacy, and stealing of personal data.⁴

Previous issues with restricted access medications

Root causes of online pharmacy purchasing could be attributed to restricted access medications or medications affected by drug shortages.¹⁷ Restricted access medications that are commonly sought out on illegal online pharmacies include products for weight loss, erectile dysfunction, or hormone replacement.^{18–20} Highly regulated weight loss products such as phentermine and Qsymia are commonly purchased through online sources due to stringent legal restrictions.²¹ Qsymia is specifically regulated by the FDA through a Risk Evaluation and Mitigation Strategies (REMS)²² program. REMS are drug safety programs required by the FDA²³ for medications that have serious safety concerns where risk can outweigh benefit if it is not properly utilized and monitored. Obtaining highly regulated medications can be a burdensome process for consumers but illegal online pharmacies make acquiring medications more convenient.⁴ However, the safety measures implemented by the FDA programs exist to mitigate risk and prevent patient harm and therefore should not be disregarded.

Previous issues with medication supply chain

In cases of drug shortages reported across the world, an increased amount of adverse events have occurred as a result.²⁴ A supply and demand imbalance can also present an opportunity for unscrupulous producers, distributors, and sellers. As observed with previous pandemics, the COVID-19 pandemic rendered the global supply chain increasingly more vulnerable and allowed for an increase of SF medications.²⁵ As claims of medications such as ivermectin, an antiparasitic, and hydroxychloroquine, an immunomodulator and antimalarial, became publicized as treatments for COVID-19, online counterfeiters quickly began marketing these products through exaggerated and persuasive claims.²⁶ Since the declaration of the pandemic in February 2020, a special task force was designed by the US government to combat fraudulent medical products. In fact, the FDA issued 120 warning letters, 270 virtual marketplace reports, and 225 domain registrar complaints surrounding the public against the use of unapproved COVID-19-related drug products.¹⁷ A more recent example of limited access due to drug shortage can be observed with the amphetamine salts shortage that began in July 2022.²⁷ By September of 2022, over 80% of patients diagnosed with attention-deficit/hyperactivity disorder (ADHD) stated that they have had difficulty accessing their medications and therefore worry about withdrawal symptoms.²⁸ As a result, patients have resorted to online sources to obtain these medications.²⁹ This shortage remains a prevalent issue and many cases of patient harm and even death have been reported as a result of buying

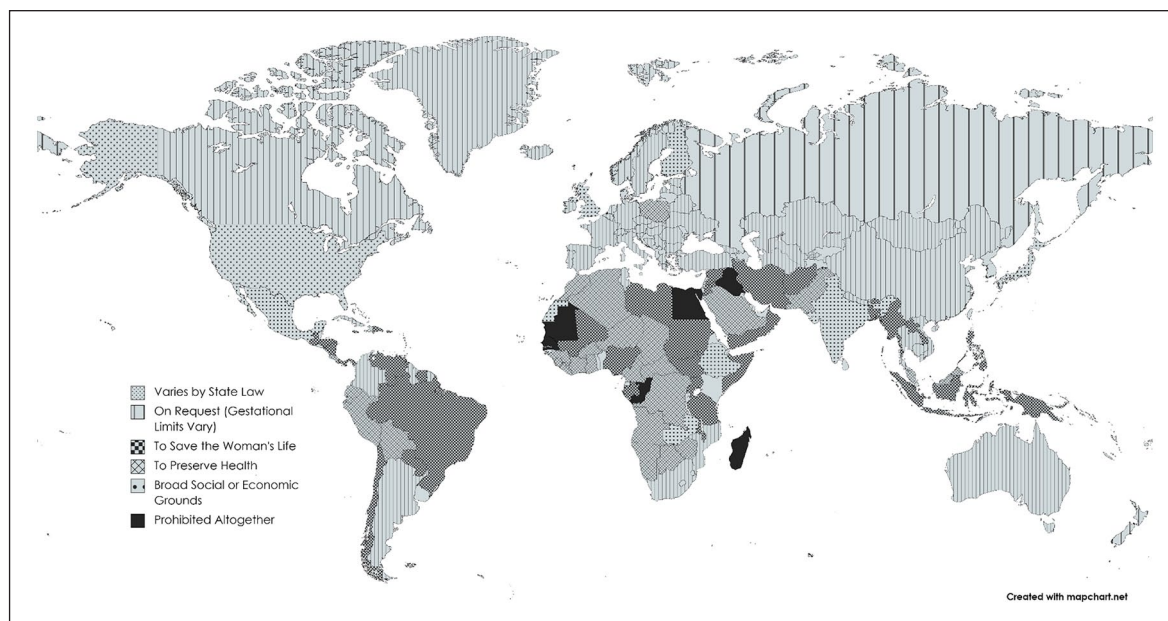


Figure 1. Worldwide abortion laws.
Source: Center for Reproductive Rights.³⁵

amphetamine salts from illegal online pharmacies that were found to contain impure ingredients.³⁰ In May 2023, two college students in the United States died from fake Adderall pills that contained fentanyl. Due to the emergence of this issue, an urgent warning was issued from the Drug Enforcement Administration (DEA) to the operators of illegal websites that Schedule II stimulants, including amphetamine drug products marketed as Adderall, without a prescription.³¹ These warnings also serve as an alert to consumers of the dangers of online pharmacies that provide adulterated and misbranded medications. The restrictions that are placed on the public due to drug shortages further facilitate danger from substandard or falsified medications that can be obtained from illegal online pharmacies.

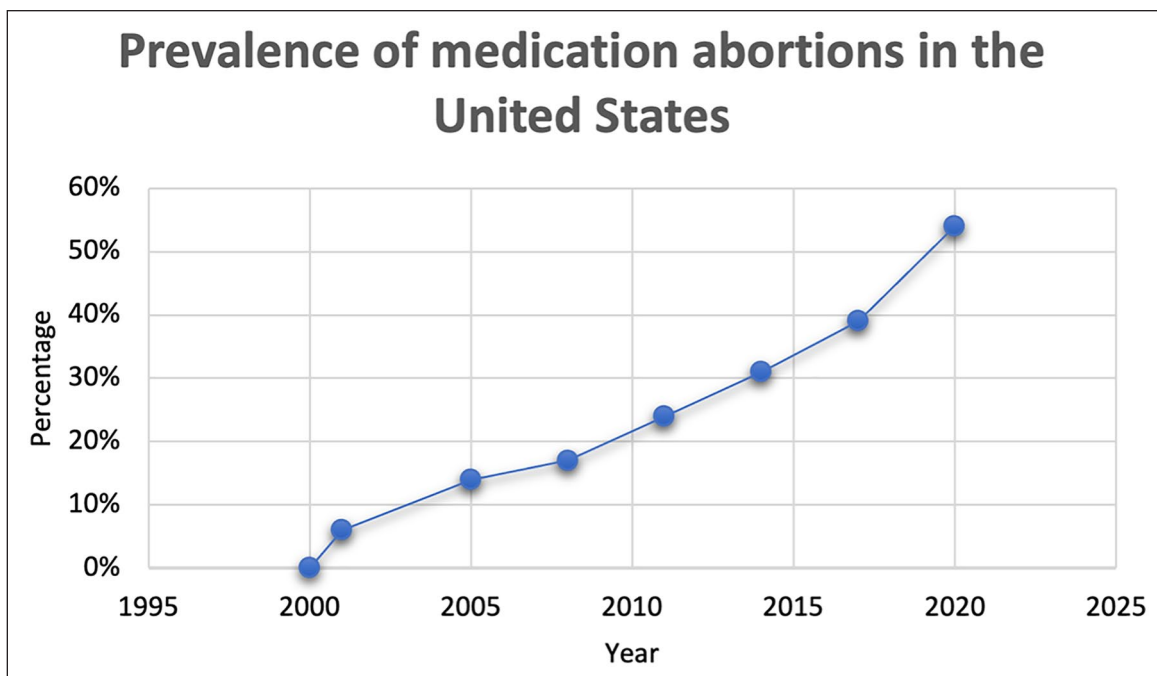
Recent changes in US policy

A contemporary example of how policy may impact the method by which patients access healthcare include the recent changes in US policy surrounding abortion. Given various state restrictions and previous issues with the medication supply chain, the public can anticipate an increase in the vulnerability of the supply chain with SF medications. Since 1973, the US Supreme Court recognized that the decision to continue or end a pregnancy belongs to the individual, not the federal government. Within the past year, the Supreme Court overturned the Roe versus Wade ruling which will remove federal protection of abortion in each state.³² New state restrictions pertaining to abortion access have already begun to develop which may coerce

the public to turn to online purchasing of FDA-approved abortifacients such as mifepristone. Cost and convenience are normally the main proponents that lead patients to resort to online pharmacies, but with these new state restrictions, access will become the main proponent. With a plethora of unsafe and unverified sources, this can quickly emerge into a global health crisis. The period following the overturn of Roe versus Wade, 1–8 May 2022, corresponded with the greatest number of Google searches for abortion medication in the United States, with about 350,000 Internet searches.³³ While mifepristone remains on the market at this time, litigation in the Supreme Court is ongoing which will affect the option American women have to access safe and effective abortion by medication.

Issues surrounding abortion ban in other countries

As noted with previous bans on abortion and abortifacients in other countries, restricting access is correlated to an increased number of patient harm from consumers purchasing abortive medications from online counterfeit pharmacies.³⁴ In the United States, it is illegal to obtain a prescription medication, such as an abortifacient, without a valid prescription or under the supervision of a physician. Therefore, due to legal implications, there are limited direct case reports that demonstrate harm in patients who have obtained abortifacients illegally, but cumulative data collected indicate patient harm can occur. As seen in Figure 1,³⁵ the Philippines is one of the few countries in the world that have taken steps to criminalize abortion in all circumstances with no exceptions. Due to this, women



Graph 1. Prevalence of medication abortions.
Source: Jones et al.⁴¹

in the Philippines seeking abortions continue to die or suffer complications due to unsafe abortive procedures or counterfeit abortion medications. Although it was criminally banned in 2008, there were an estimated 560,000 medication or surgical induced abortions performed from 2008 to 2010 alone. Out of the women that sought these abortive measures, 90,000 required treatments for complications and of those women, 1000 fatalities occurred.³⁶ These tragic and preventable deaths are a direct consequence of the Philippines' restrictive abortion laws. The implications of violating this law could result in 6 years of imprisonment, even for physicians or midwives if they perform an abortion.³⁷ Similar to the Philippines, Brazil enforces punitive restrictions against abortion or abortifacients. Therefore, women in this region are forced to purchase abortifacients through illegal sources.³⁸ Although purchasing medications through this route provides access, many of these online pharmacies do not include any counseling, directions for proper use, or common side effects. The restrictions that are placed on the public warrant for harm not only from SF medications but also leave the public to make autonomous clinical decisions.

Patient harm associated with restricted use of abortifacients

As we have observed with other countries placing these bans and restrictions on abortion, there can be a multifold of effects on maternal health. In comparison to other developed countries, the United States has the highest maternal mortality rate. The rate for maternal deaths in the United

States was 32.9 per 100,000 live births compared to other high-income countries such as Australia, Austria, Israel, Japan, and Spain, which all reported rates between 2 and 3 deaths per 100,000 in 2020.³⁹ Researchers have estimated that the total abortion ban could increase the number of maternal deaths by 24%, with the greatest impact on African American women, at 39%.⁴⁰ The US maternal mortality rate already disproportionately impacts women of color. African American women are specifically more at risk as they are three times more likely to die from pregnancy-related causes compared to Caucasian women.⁴⁰ Abortion by medication, such as misoprostol and mifepristone, has been an increasingly common option for women who live below the poverty line, women of color, women with disabilities, and those that live in healthcare deserts.^{41,42} As seen in Graph 1, the prevalence of use of abortifacients for pregnancy termination was over 51%.⁴¹ This new restriction will disproportionately impact those that are already experiencing healthcare disparities in reproductive healthcare access.^{40,41}

Many states have already restricted access to abortifacients through telemedicine and Planned Parenthood which puts those that are already vulnerable in an even more complex position.⁴³ Research suggests that women who are denied abortions are at an especially high risk for pregnancy-related issues and will often try to acquire medications online without the help of a healthcare provider.⁴³ With the predicted increase in the number of patients who will resort to online pharmacies for abortifacients, the market for abortive medications is likely to increase as well.

With reviewing previous drug restrictions and drug shortages, it is beyond reasonable doubt that counterfeiters will capitalize on this market. It is estimated that before 1973 when abortion was illegal in the United States, approximately 200,000–1,200,000 million illegal abortions were performed each year.⁴⁴ Even when abortion did become legalized, women continued to self-induce abortions through various methods with the knowledge that it could potentially be ineffective, unsafe, and cause complications.⁴² With the recent overturning of *Roe versus Wade*, and possible prescription restrictions of abortifacients the public can anticipate a rise in the number of self-induced abortions in the United States.

Counterfeiters have previously moved quickly to increase production of highly sought-after medications during public health emergencies, and this will likely occur for abortion causing medications. Numerous resourceful websites exist with the goal of helping women access safe reproductive care. Plan C⁴⁵ is an example of an informative and resourceful website that provides information on “self-managed, at-home abortion with pills.” Although these websites have no malicious intent, they redirect customers to online pharmacies that are not verified. Therefore, they are leading patients to purchasing SF medications. To ensure patients access safe and verified sources of abortifacients, resources like Plan C could update their point-of-sale interface by identifying common methods to verify online legitimate pharmacies. These methods of verification can include the following warning signs of an unsafe online pharmacy: offering discounts on medication, the strength of medication sold differing from what is approved on the market, no licensed pharmacist or staff available to answer patient questions, and advertisements for unrelated products on the website.⁴⁶

Experts worry that obtaining medications through back channels can raise the risk of quality or safety issues.⁴⁷ With the limited chemical assays performed, a previous study has indicated that abortive medications retrieved from online pharmacies do not contain the appropriate amounts of active ingredients when compared with FDA-approved products.⁴⁸ In this study, researchers mimicked common search methods such as “buy abortion pills online” and “abortion pills online” and ordered 22 products from four different states that claimed to contain either misoprostol and mifepristone or misoprostol alone. Findings prove that many of the sites were run by the same vendor and contained varying amounts of the active ingredient of both misoprostol and mifepristone. This study validates concerns surrounding the safety and efficacy of medications purchased online.

Education and advocacy

Without access to FDA-approved medications, public health is at risk. As healthcare providers, patient wellbeing is paramount, and restricting access to abortifacients will

disrupt continuity of care.⁴⁹ To combat this, resources and procedures need to be developed for healthcare professionals, policymakers, and advocates. Abortion and utilization of abortifacients are an under-reported topic due to the privacy and legal implications that can arise. For this reason, educating others on this rising global issue and advising them on how to properly locate safe and effective medications online is obligatory. To negate these online illegal sources, there are many online verification sources that have been implemented. Common sites that operate to verify online pharmacy sources include LegitScript, FDA.gov, BuySafeRx.pharmacy, and safe.pharmacy. Whenever purchasing any medication online, one should ensure that the website they are intending to acquire from is following all federal and state regulations.

An increasing number of people may choose to self-manage abortion in coming years because of restrictive abortion policies. Currently, there are three states that explicitly criminalize self-managed abortion and many other states that bring murder and homicide charges against people who have self-managed abortions. Lawmakers must strengthen legal protections for those who choose to self-manage an abortion.⁵⁰ Moreover, the American College of Obstetricians and Gynecologists (ACOG)⁵¹ warns against legislation that criminalizes abortion care by banning safe, medically indicated treatment options or procedures. In fact, the ACOG provides an up-to-date evidence-based approach on medication abortion to provide the public with accurate information on performing medication abortions at home.

Limitation of the review

In this narrative review, we included both peer-reviewed literature and other sources of information discussing effects of medications sold by illegal online pharmacies to understand the implications of restricting access to FDA-approved medications. However, the available literature focused on the increase in use of illegal online pharmacies with past examples of drug shortages and restricted access but was limited in analyzing the effects of restricting access to abortifacients. Due to the sensitivity and legal implications in the United States from accessing abortifacients from illegal online pharmacies, there were no case reports found of women who reported harm from obtaining abortifacients from unverified sources. Therefore, previous examples of restricted access and drug shortages were leveraged to demonstrate the potential impact recent policy changes on abortion could have on the public.

Conclusion

The rapid growth of technology has transformed the way the public purchases many products, including medications. Online medication purchasing has become a convenient and confidential route for patients to obtain their

medications but has also introduced a rising patient safety issue. The saturated illegal online pharmacy market targets those in need of restricted access medications; making those who are vulnerable susceptible to harm caused by SF medications. A contemporary example of this in the United States could be observed from the recent overturning of Roe versus Wade and possible prescriptive restriction of FDA-approved abortifacients. The ruling of the Supreme Court will allow states the right to ban abortifacients which could invoke a response from the public to access their medications through online markets that supply SF medications. As observed from other countries, purchasing abortive medications from online illegal pharmacies is correlated with an increase in the number of serious or fatal events. This phenomenon can continue to impact our healthcare systems in many facets. In cases of restricted access to medications, education, and advocacy are key in ensuring patient safety. Advocacy for access to safe and effective abortive medications will ensure patient safety in reproductive care.

Declarations

Ethics approval and consent to participate

This article reports a review of publicly available shortages as well as a literature review. No animal or human studies were carried out. No secondary analysis of data collected from humans was carried out. Therefore, ethics approval and informed consent to participate were not sought.

Consent for publication

Not applicable.

Author contributions

Zarnab Jillani: Data curation; Formal analysis; Investigation; Resources; Writing—original draft; Writing—review and editing.

Lauren Reinhard: Data curation; Formal analysis; Resources; Writing—original draft; Writing—review and editing.

John Hertig: Conceptualization; Methodology; Project administration; Supervision; Writing—review and editing.

Acknowledgements

The authors thank the Alliance of Safe Online Pharmacies (ASOP) Global Foundation for being dedicated to addressing the growing public health threat of illegal online drug sellers through strategic efforts around the globe.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Competing interests

John Hertig is an Associate Editor of The Journal of Medicine Access and an author of this paper; therefore, the peer-reviewed

process was managed by alternative members of the board and the submitting editor was not involved in the decision-making process.

Availability of data and materials

Not applicable.

ORCID iD

John Hertig  <https://orcid.org/0000-0001-9869-2903>

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