



Increased Consumer Risk

**from Erectile Dysfunction
Medication Advertised and
Sold on the Gray Market**

NOVEMBER 2018

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Foreword



When it comes to healthcare in the digital age, consumers face new opportunities and new challenges. Increasingly, people are seeking the convenience offered by online pharmacies to purchase prescription medicines, but if the right precautions are not taken convenience can come at the cost of safety and security. When consumers cut corners by shopping at illegitimate online sources, they inadvertently place themselves at risk of falling victim to internet scams or of purchasing ineffective or even unsafe medicines that fail to comply with drug safety regulations.

Medications for erectile dysfunction (ED) are among the most commonly sold medications by illegal online pharmacies—which are part of the gray market. Because ED can take a significant psychological and emotional toll, ensuring that men have access to safe and effective ED medicines is critical to improving quality of life for millions with the condition. As an organization founded in 1899 with the goal of promoting consumer safety and a fair marketplace, the National Consumers League (NCL) is working to ensure consumers are aware of the serious health and financial risks associated with the gray market.

This white paper explores and exposes the dangers consumers face when purchasing ED medicine from gray market websites and provides actionable policy recommendations to increase safe access to ED medicine and protect consumer health and safety. It is our hope that this paper increases awareness of the gray market, sparks further discussion about the policy changes needed to protect consumers, and promotes further research into the consequences of illegal online pharmacies.

At NCL, we are committed to ensuring that every American has access to safe and effective medicines, but we recognize that we cannot overcome the obstacles facing that goal without the combined efforts of government, pharmaceutical manufacturers, patient and consumer advocates, healthcare providers, and non-governmental organizations.

On behalf of my colleagues and the National Consumers League, I look forward to strengthening our collective efforts to address this issue and pursue new strategies, research, education, and policies that protect consumers.

NCL appreciates the opportunity to have consulted on this research, value its important findings, and welcome its release. We look forward to continuing to participate in the public-private partnerships needed to address these issues and to pursuing new strategies and policies to protect consumers.

A handwritten signature in black ink that reads "Sally Greenberg".

Sally Greenberg
Executive Director, National Consumers League





Executive Summary

Erectile dysfunction (ED) is a significant and widespread health issue that affects 24 percent of the adult male population in the United States, yet goes largely untreated. Not only can ED lead to significant psychological and emotional effects, it can also indicate an underlying medical condition such as heart disease or other cardiovascular comorbidities. This white paper explores the dangers consumers face by purchasing medication to treat ED through illegal online pharmacies, and provides policy recommendations to safely increase access to ED medicine while mitigating risks associated with unsafe and illegitimate online sources.

The most common first-line treatments for ED are prescription medications known as phosphodiesterase type 5 inhibitors (PDE5i) that work by increasing blood flow to the penis. The PDE5i medications approved by the U.S. Food and Drug Administration (FDA) currently on the market are sildenafil, vardenafil, tadalafil and avanafil.

Many men with ED choose not to visit a doctor for consultation or to obtain prescriptions for these medications due to embarrassment over discussing the issue, because they lack sufficient insurance coverage or simply out of a preference for convenience. Increasingly, men are turning to online pharmacies, the vast majority of which (95 percent) do not operate within U.S. state and federal law and do not meet relevant pharmacy practice standards.¹ The drugs sold by these illegal actors to unsuspecting consumers may contain too much, too little or no active pharmaceutical ingredients (APIs). Likewise, these products may contain substitutes and altogether different pharmaceutical compounds or ingredients found to be ineffective, harmful or even deadly. In a small percentage of cases, patients receive genuine pharmaceutical products.²





In addition to posing significant health risks, these “gray markets” also expose men to identity theft or other financial risks and increase their exposure to illegal drugs, such as controlled substances or illicit narcotics.

The dangers associated with purchasing ED medication on the gray market create a clear impetus to prioritize policy changes that can improve consumer safety and alleviate the burden the gray market currently places on the U.S. healthcare system, law enforcement and economy. Gray market deterrents should be an integral component of health policy in the digital age, and supplement a national agenda that enhances consumer awareness and health literacy; encourages healthcare provider training and education; supports collaborative law enforcement and regulatory

efforts; augments attention to the gray market in health policy decision making; and contributes to additional research on the subject.

One specific proposal that has the potential to negate a portion of gray market demand for these products and subsequently enhance consumer safety, is reclassifying ED medications as over-the-counter (OTC) drugs. OTC availability would increase safe access to ED medications from the legitimate supply chain and alleviate health risks faced by consumers who, by circumventing traditional methods to obtain these drugs, do not receive legitimate products, necessary product information or directions for safe use as indicated. Further, by using legitimately sourced medications, individuals face a lower risk for adverse drug events, which can ultimately reduce costs to the U.S. healthcare system.^{3 4}

Collaborative efforts between public- and private-sector stakeholders and informed policies can safely expand access to ED medicines, ultimately leading to improved quality of life for millions of men, reduced costs to treat the condition and improved sexual function.



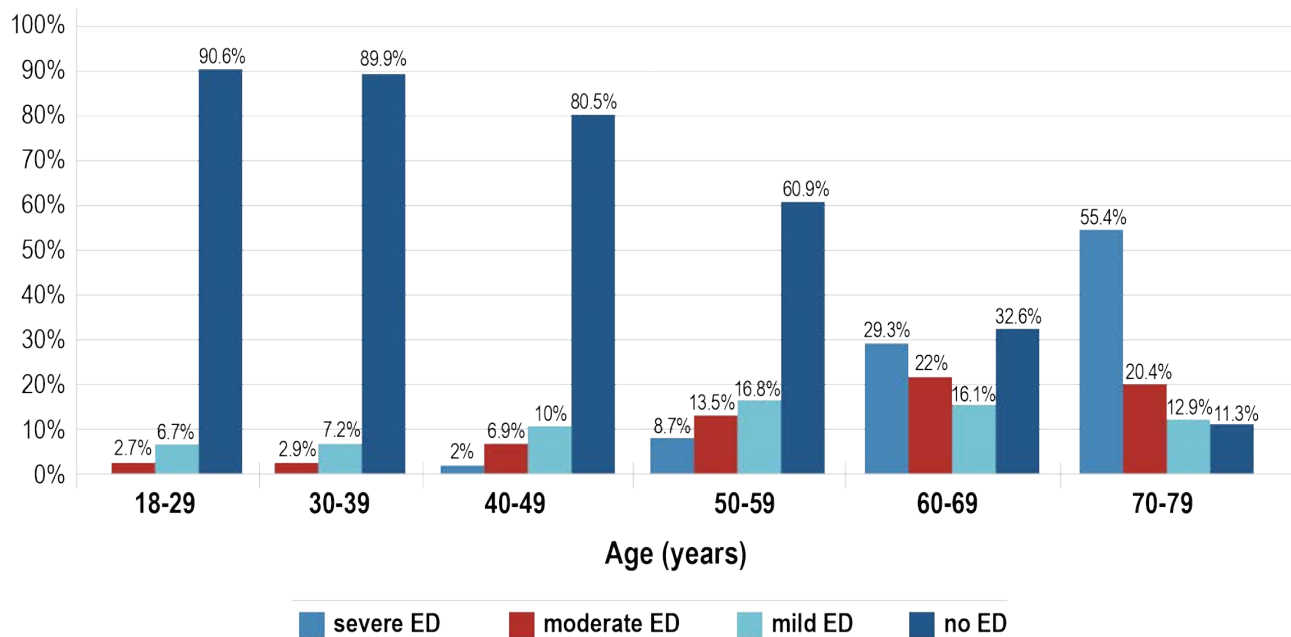
I. Introduction

Erectile Dysfunction in the United States

Erectile dysfunction, or ED, is defined as having difficulty achieving or maintaining an erection firm enough for satisfying intercourse. It is the most common sexual health problem that men report to their healthcare providers and affects 24 percent of the U.S. adult male population age 18 or older, which is as many as 30 million men, and 150 million men worldwide.^{5 6 7 8 9}

Twenty percent of men under age 40 have ED, and that number increases steadily after age 40, reaching more than 80 percent by the eighth decade of life.¹⁰

ED According to the EF Domain in Different Age Groups



Source: *Erectile dysfunction, discrepancy between high prevalence and low utilization of treatment options: results from the 'Cottbus Survey' with 10 000 men (2007)*



COMMON EFFECTS OF ED

depression

low self-esteem

decreased productivity at work

harm to interpersonal relationships

While these demographics support the common perception that ED is a condition that affects aging men, a recent exploratory analysis found that one in four patients seeking medical help for new-onset ED is under 40. Almost half of these younger men suffer from severe ED, a rate that compares to that of older men.¹¹ In these individuals, ED is more likely to be an indicator of underlying medical conditions such as diabetes or cardiovascular disease (CVD).

Whatever its cause, ED can also have substantial psychological and emotional effects for those who experience it. ED can negatively impact a man's mental and emotional health, and has been linked to depression and low self-esteem.^{12 13} Further, men who experience ED may suffer decreased productivity in the workplace and the condition can cause harm to interpersonal relationships.^{14 15}

Seeking Treatment

Treatment options for ED include lifestyle changes, oral medications, injections and surgery. However, despite its prevalence and the efficacy of available treatments, only 25 percent of men diagnosed with ED receive treatment and about three-quarters of those are treated using PDE5i medication.¹⁶

The low level of treatment and the reluctance many men feel to seek medical care for ED can be attributed to several factors, including¹⁷:

- **demographic characteristics** of the healthcare provider (i.e. a preference to consult a physician of a specific gender or age);
- **perceived attitudes** of healthcare providers toward sexuality or sexual health issues;
- **attribution** of sexual problems to “normal aging”;
- **shame, embarrassment or fear** about admitting to having ED;
- **perception** of sexual problems as “not serious”; or
- **lack of knowledge** about appropriate treatments.

In addition, economic factors such as a lack of insurance coverage, insufficient insurance coverage for prescription ED treatments or high co-pays may place a personal financial burden on men that further impedes their ability to pursue and/or obtain safe and effective ED medicines.

25%

OF MEN DIAGNOSED WITH ED receive treatment and about three-quarters of those are treated using PDE5i medication





II. *The Gray Market In The United States*

The Rise of Online Pharmacies, Internet Sellers and Virtual Marketplaces

Over the past two decades, the number of online pharmacies has grown rapidly, mirroring global purchasing trends that demonstrate an increased reliance on and preference for e-commerce.

For the healthcare industry, the shift toward e-commerce corresponds with increased consumer access to prescription medicines via online pharmacies, internet sellers and virtual marketplaces, and alarmingly, to counterfeit or adulterated products sold by illegal actors.

As the costs of prescription medicines and patient out-of-pocket costs continue to rise in the United States, more consumers are turning to online pharmacies and other untraditional sources in search of cost savings. From 1999 to 2003 alone, online sales of prescription drugs in the United States grew from \$160 million to \$3.2 billion.¹⁸ In addition to financial incentives, many consumers also value the convenience and privacy of purchasing their medicines online.

However, as legitimate online pharmacies have provided benefits to consumers, concerns about bad actors have been raised in equal measure. This white paper focuses on consumers who obtain medication through online pharmacies, which are defined as pharmacies that operate over the internet to provide consumers access to medications that are subsequently shipped through the mail or via private express shippers. To be legal, online pharmacies must comply with all relevant federal and state laws, and pharmacy practice standards that relate to the sale and distribution of pharmaceutical products, especially prescription-only or controlled substances, in their jurisdiction of operation as well in the jurisdiction where the individual purchaser is located.¹⁹

In contrast, illegitimate – also called “rogue” or “illegal” – online pharmacies give unfettered access to prescription medications, controlled substances and illicit narcotics, often without medical examination, consultation or valid physician prescription.²⁰

At any given time, it is estimated that there are between 30,000 and 35,000 active online pharmacies. Approximately 20 new illegal online pharmacy websites are created daily, totaling more than 600 new sites per month.²¹ Products purchased from these sites can be of unknown origin, content, potency, efficacy and safety, and may pose serious, if not deadly, risks to consumers.²²

*In a review of more than 11,000 websites selling medication to consumers, the National Association of Boards of Pharmacy (NABP) found that **89 percent did not require a valid prescription to purchase prescription-only products.**¹*

The Gray Market for ED Medication

ED medicines are among the most commonly offered medications by illegal online pharmacies.²³ Potentially facing access, emotional or financial barriers to treatment, men seeking medication for ED may circumvent the traditional supply chain and prescribing avenues by turning to these illegitimate and/or unsafe online pharmacies – a component of the illegitimate supply chain known as the gray market.

The gray market, for the purposes of this white paper, is defined in two ways:

1. an online source that does not require a valid prescription¹ to dispense prescription medicines; or
2. an online source that either requires a valid prescription issued by another prescriber or offers a telemedicine consult that results in the issuance of a valid prescription based on the telemedicine diagnosis and meets one of the following conditions:
 - ships medicine from outside the United States;
 - offers unregulated forms or names (e.g. super, extra, gummies, oral jelly) of medicine;
 - offers to auto-refill purchases without consultation with a healthcare provider or with no time limits; and
 - encourages purchase of larger quantities (e.g. buying bulk supply to save money).

Gray Market Survey

To better understand the prevalence of the gray market and what motivates men to make gray market purchases, in 2018, the global research firm Ipsos conducted a survey of men in the United States that sought to:

- quantify the number of U.S. men purchasing ED medications from the gray market;

¹ A “Valid Prescription” is issued in accordance with the standard of care and not issued solely on the basis of an online form



- understand the demographic profile of these gray market consumers compared to those who use legitimate channels to treat ED and obtain ED medications; and
- understand the motivation to purchase medicines on the gray market and the potential risk associated with forgoing the traditional healthcare system.

16%

OF MEN USE THE GRAY MARKET

to purchase their ED medication

Ipsos recruited more than 3,000 men age 18 or older who had experienced ED in the past 12 months to learn more about those who pursued gray market purchases of ED medications and their experience using the gray market. The survey assessed perceptions of gray market websites and purchase motivation and behaviors, and collected information on the purchase process and products received. The sample was balanced to census demographics of adult men age 18 and over in the United States.

Overall, the survey found that 16 percent of men who suffer from and treat ED with medication, had previously or currently purchase it through a gray market channel. Using current population data, this is equivalent to an estimated 2.4 million men age 18 and over who suffer from and treat ED with medication purchased on the gray market.⁹

Consumer Profile

The survey results indicate that gray market purchasers and non-gray market purchasers are largely similar in terms of age and marital status. Men who purchase ED medication on the gray market report being slightly more sexually active than men who treat ED with prescription medication purchased or obtained through legitimate channels.

The survey also found that 81 percent of gray market purchasers had previously received a prescription for ED medication from their healthcare provider. Of the 19 percent who had not been prescribed ED medication in the past, the top three reasons they gave for not being given a prescription were: they did not have insurance that would cover the medication; their doctor recommended other treatment methods like exercise, meditation or therapy; or their doctor felt they didn't need it.

	ED Sufferers (n=3018) A	P12M ED Treaters Non-Gray Market (n=1201) B	P12M Gray Market (n=221) C
18-29	7%	7%	10% A
30-39	14%	21% A	20% A
40-49	15%	18% A	20% A
50-59	20% C	20%	15%
60-69	28% B	23%	24%
70-79	14% BC	10%	10%
80-89	2%	—	—
Single, never married	18%	17%	21%
Living with partner	8%	7%	10% B
Married	60%	64% AC	57%
Widowed	3%	3%	1%
Divorced or separated	11% B	9%	10%

Source: Ipsos Gray Market Survey



Awareness and Perceptions of the Gray Market

Most gray market purchasers become aware of the gray market through web searches (70 percent). Other referral sources for the gray market include email advertisements (31 percent) and word-of-mouth recommendations from family or friends (29 percent).

While only 24 percent of respondents felt that products from gray market sites are FDA approved, most nevertheless feel they are effective (71 percent) and more than half feel they are the same quality as products available at their local pharmacy (55 percent). The majority believe the websites offer a more affordable solution for ED than products purchased at a brick-and-mortar pharmacy or other licensed sources (69 percent).

Surprisingly, 24 percent of survey respondents became aware of gray market websites from their doctor or another healthcare professional. Further, 28 percent of respondents perceive that gray market websites have been approved by doctors and healthcare professionals.

Choosing the Gray Market

The same factors that make many men reluctant to seek medical care for ED correlate with their motivation to purchase ED medications through the gray market. Respondents to the survey indicated that convenience, preservation of privacy or avoidance of embarrassment, the absence of or limited insurance coverage and the availability of preferred strength or dosage were the top reasons they sought out ED medication on the gray market.



Source: Ipsos Gray Market Survey

Insufficient Product Information Provided by Gray Market Websites

Of all gray market purchasers, 25 percent or fewer were asked to provide medical history, specifically about heart health, before purchasing ED medication. Furthermore, more than half (55 percent) of gray market purchasers were not provided with or do not recall receiving any information regarding the possibility that their ED may indicate an underlying cardiovascular condition.

In addition, two-thirds of gray market purchasers reported that the package they received did not include information about contraindications related to nitrates/nitroglycerin use. Other warnings and product information were also infrequently provided to purchasers.



Purchasing Behaviors

Gray market websites encourage larger purchases of ED medications, capitalizing on consumers' reported cost-consciousness and desire for convenience. Eight in 10 survey respondents were encouraged to purchase larger quantities of ED medication to save money, and half received follow-up calls to purchase larger quantities or received an offer to auto-refill their prescription.

Additionally, 35 percent of gray market purchasers have bought non-FDA-approved forms of ED products from gray market websites, such as pills that dissolve on or under the tongue (21 percent), oral jelly (14 percent), gummies (12 percent) and powder (12 percent). Four in 10 have ordered ED medication labeled "Extra, Super, Active," etc.



8 in 10

Were encouraged to purchase larger quantities to save money



5 in 10

Received follow-up calls to purchase larger quantities



5 in 10

Received an offer to auto-refill their prescription



III. Consumer Safety And The Gray Market

Regulating Online Pharmacies

Illegal online pharmacies – with operations in countries worldwide – that ship non-FDA-approved medicines into the United States present a serious enforcement challenge for state and federal regulators and law enforcement officials.²⁴ Illegal online pharmacies are often complex global operations that may involve hundreds or thousands of related websites,²⁵ and the operators of these sites take deliberate steps to disguise their identity.²⁶ The vast majority of online pharmacies are in fact illegitimate; a review by the National Association of Boards of Pharmacy (NABP) found that **only 2.4 percent of online pharmacies comply with U.S. pharmacy laws and practice standards**, which include requiring a valid prescription and only selling FDA-approved products.^{1 27}

Not Recommended Sites	
Physical Location:	<ul style="list-style-type: none"> • 2,609 (23%) outside US • 1,580 (14%) inside US • 7,085 (63%) no location posted on website
Prescription Requirements:	<ul style="list-style-type: none"> • 10,086 (89%) do not require valid prescription • 6,270 (55%) issue prescriptions per online consultations or questionnaires only
Medications:	<ul style="list-style-type: none"> • 5,890 (52%) offer foreign or non-FDA-approved medications • 1,527 (13%) dispense CS
Encryption:	<ul style="list-style-type: none"> • 1,964 (17%) do not have secure sites, exposing customers to financial fraud and identity theft
Server Location:	<ul style="list-style-type: none"> • 4,835 (43%) outside US • 6,008 (53%) inside US • 464 (4%) have unknown server locations
Affiliations:	<ul style="list-style-type: none"> • 9,689 (86%) appear to have affiliations with rogue networks of internet drug outlets

Source: Characteristics of drug sites listed as Not Recommended on the safe.pharmacy website as of June 30, 2018.



Health Risks

ED medicines purchased on the gray market may contain contaminated, subpotent or altogether incorrect active ingredients that could pose dangerous, or even deadly, consequences to users.²⁸ Beyond irregularities in the amount and purity of APIs – either too much, too little or no API – these medicines may be less effective or have unexpected side effects.²² Counterfeit medicines have been found to include adulterants such as concrete, floor wax, lead, mercury, paint thinner, sawdust and boric acid.²⁹

Further, as confirmed by the Ipsos Gray Market Survey, medicines procured on the gray market infrequently come with prescription information or directions for use, which may put men at higher risk of adverse events. As noted above, the survey found 25 percent or fewer purchasers were asked to provide medical history, specifically as it relates to heart health, before purchasing ED medication. Without sufficient knowledge about warnings associated with using the medication or comorbidities associated with concomitant medications, men may not have the information they need to safely use the products they purchase.

25%

OR FEWER PURCHASERS

were asked to provide medical history before purchasing ED medication

The lack of information provided to consumers can create significant danger. Seven in 10 men receiving a prescription ED medication have an underlying medical diagnosis. One analysis of nearly 25,000 people evaluated for prescription ED medication found that 11.5 percent had a new underlying disease discovered upon consultation, the most common of which was an undiagnosed vasculogenic disease (4.1 percent).³⁰

While there are no publicly available data sources that estimate the cost of treating adverse drug events directly linked to gray market purchases of ED medicines, it can be extrapolated from data collected about other substandard and falsified medications and the costs associated with adverse drug events as a whole, that the financial impact is substantial. For example, adverse drug events may increase costs due to hospitalization associated with illegitimate drug use, prolongation of hospital stay and additional clinical investigations in more serious cases. Aside from the direct financial costs, indirect costs for individuals and their caregivers resulting from adverse drug events could include missed days from work (absenteeism and lost productivity) and/or comorbidities such as anxiety from the episode.³¹

Further, adverse effects caused by substandard and falsified medical products may lead to additional spending on repeat treatment with quality-assured medicines or consultation with a healthcare provider, as well as extra healthcare costs associated with adverse reactions that would not have occurred had the original product been safe and effective.³¹



Exposure to Controlled Substances

The majority of illegal online pharmacy websites offer a wide array of prescription and over-the-counter medicines covering various therapeutic categories and delivery mechanisms. According to NABP's February 2018 Internet Drug Outlet Report, 54 percent of websites surveyed sold controlled substances, up from an average of 10 – 12 percent historically. The concurrent sale of ED medication and controlled substances on an illegal online pharmacy website may create the opportunity for consumers to purchase medicines with abuse potential, such as anti-anxiety medications or prescription opioids that are otherwise not clinically indicated or for which the consumer does not have a valid prescription.

Financial Risks

In addition to health risks and increased access to illicit drugs, gray market pharmacies may put consumers' personal and financial information at risk. Personal data may be sold to other illegal websites or consumers may be exposed to identity theft or other types of fraud.²⁷





IV. *Economic Burden Created By The Gray Market*

Counterfeit medications have a clearly demonstrable economic impact on individuals as well as healthcare providers, insurers and the government. According to the World Health Organization,³² the economic impact of counterfeit medications can include:



increased out-of-pocket expenses
for individuals



economic losses
for individuals, families, health systems and drug manufacturers



increased burden
for healthcare professionals, national medicine regulatory authorities, law enforcement and criminal justice



lost personal income
for people who have taken counterfeit medications and suffered prolonged illness and/or productivity losses caused by the need to pursue medical care

Systemic Burdens

Numerous federal and international law enforcement agencies monitor and regulate the gray market. In 2010, the Office of the U.S. Intellectual Property Enforcement Coordinator (IPEC) established an interagency working group on counterfeit pharmaceuticals to bring together the expertise of the federal agencies that work to address the issue. The working group includes the FDA; U.S. Department of Commerce; U.S. Department of Homeland Security's Customs and Border Protection (CBP) and U.S. Immigration and Customs Enforcement (ICE) agencies; U.S. Department of Justice; U.S. Department of State; and U.S. Agency for International Development.³²

Each organization plays a distinct role and, in many cases, multiple organizations work together to combat rogue online pharmacies.²⁸ However, no one agency or organization in the United States is designated to lead the response to the gray market, and it is difficult to quantify a total, comprehensive number that accounts for all budget and resources allocated to and spent on the effort to combat gray market prescription drug sales.²⁸

Statistics indicate, however, a substantial focus by the federal agency partners mentioned above to combat this issue. From fiscal years 2010 through 2012:

FDA opened 227 rogue internet pharmacy investigations, which led to the conviction of 219 individuals and more than \$76 million in fines and restitution²⁸

ICE initiated 138 investigations¹ and its investigations led to 56 convictions and the seizure of nearly \$7 million

DEA conducted 49 investigations into rogue internet pharmacies and seized more than \$1 million²⁸

International Coordination

On an international level, the United States participates in Operation Pangea, a week of action organized by INTERPOL to tackle the online sale of counterfeit and illicit medicines and highlight the dangers of buying medicines online.

In October 2018, Operation Pangea XI brought together police, customs and health regulatory authorities from 116 countries and resulted in 859 arrests worldwide and the seizure of USD 14 million worth of illicit and counterfeit medicines. The Operation also shut down 3,671 web properties, including websites, social media pages, and online marketplaces, and close to one million packages were inspected during the week of action (9 – 16 October). In total, 500 tons of illicit and counterfeit medicines were seized worldwide, including anti-inflammatory medication, painkillers, ED medication, hypnotic and sedative agents, anabolic steroids, slimming pills and medicines to treat HIV, Parkinson's and diabetes.³³





V. Policy And Regulatory Recommendations

Having established the dangers of purchasing ED medication on the gray market, there is a clear need to prioritize policy changes that can improve consumer safety and alleviate the burden the gray market currently places on the U.S. healthcare system, law enforcement and economy.

Protecting consumers from the dangers of the gray market should be an integral component of health policy in the digital age, and we propose the following blueprint to address this problem and serve as the foundation for a national agenda for gray market policy action:

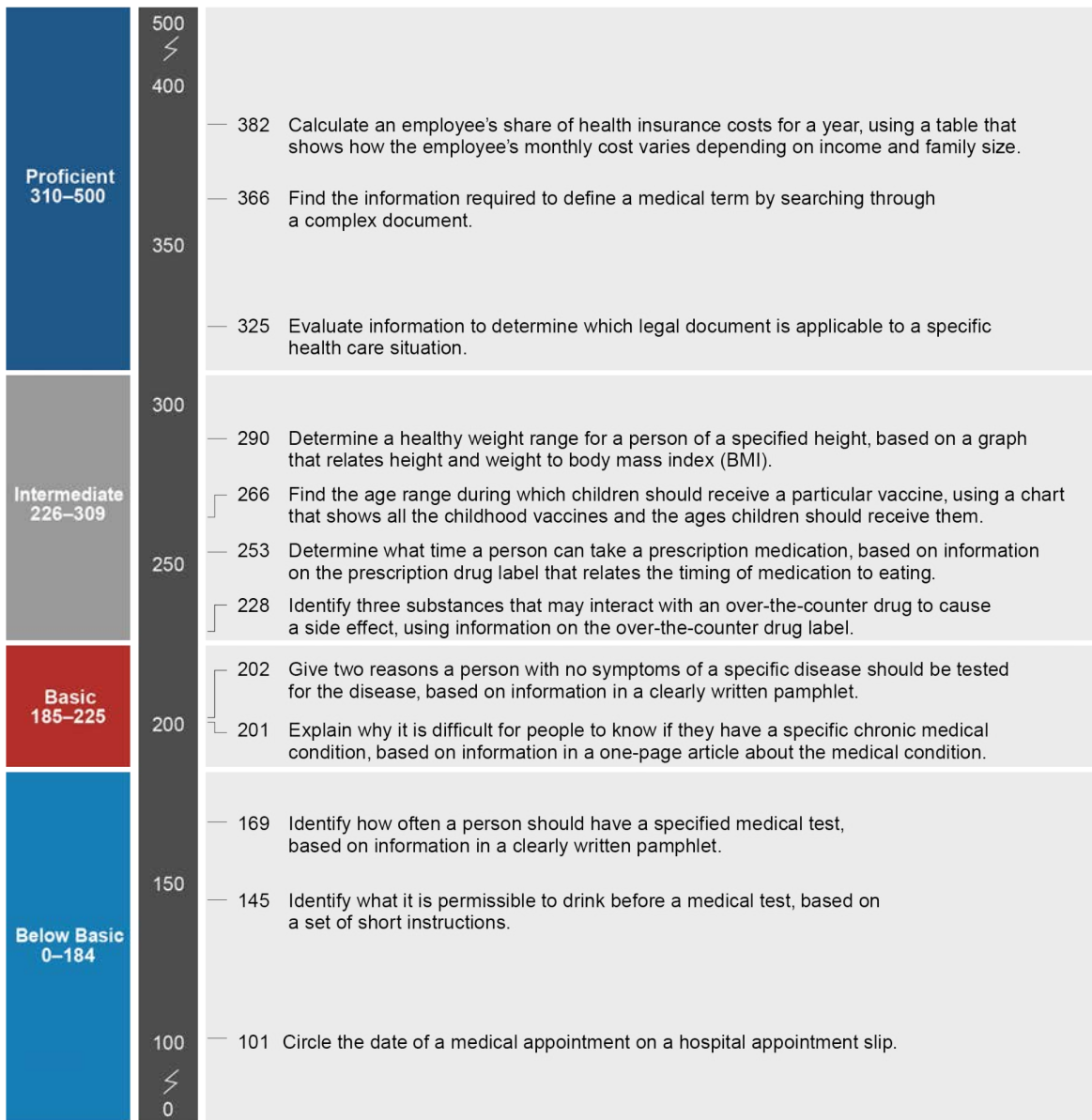
1. Enhance Consumer Awareness of the Gray Market and Support Health Literacy

The National Assessment of Adult Literacy (NAAL) published a study on adult health literacy and found that 36 percent of adults in the United States were considered to be at basic or below basic health literacy levels.³⁴

Health literacy is particularly important in the digital age as consumers have an enormous amount of information and sources at their fingertips. Consumers are increasingly choosing to use the internet to research issues related to their health, seek second opinions and talk with others about their medical conditions. New resources like GoodRx, Iodine, Healthline, WebMD and others are increasingly relied upon by people who seek information on health and prescription medicine topics.

This open access to information has altered the traditional relationship between healthcare provider and patient; often, healthcare professionals are no longer the primary source individuals seek for medical advice. Misinterpreted information obtained from unreliable online resources can lead to medical decisions that endanger lives.³⁵

Health Literacy Scale: Difficulty of selected health literacy tasks, 2003



NOTE: The position of a question on the scale represents the average scale score attained by adults who had a 67 percent probability of successfully answering the question. Only selected questions are presented.

Scale score ranges for performance levels are referenced on the figure.

SOURCE: U.S. Department of Education, Institute of Education Sciences, National Center for Education Statistics, 2003 National Assessment of Adult Literacy.

Addressing health literacy in a coordinated way has the potential to increase the safety, quality and sustainability of health systems by enabling and empowering consumers to make effective decisions and take appropriate action for their own health and the health of loved ones.³⁶ Without proficiency in understanding prescription medical labels, identifying substances that may interact with medicines, and knowledge of how often a person should have specified medical tests, individuals are at greater risk for adverse events and poor health outcomes.

Health literacy is important for men seeking treatment for ED on the gray market because, as noted previously, many men who receive a prescription ED medication have an underlying medical diagnosis. If the gray market is used to obtain these prescription medications, poor health literacy and high-risk comorbidities place patients and caregivers at increased risk for adverse events or harm.

Further, to be most effective, health literacy initiatives must be adapted and customized to meet the needs of different segments of the population, taking into account relevant social, financial and environmental barriers such as language, poverty, gender, employment or education issues.³⁷

2. Encourage Healthcare Provider Dialogue about the Gray Market and Ongoing Education on the Issue

As noted in the Ipsos consumer survey, 24 percent of respondents became aware of gray market websites sites from their doctor or another healthcare professional. Additionally, 28 percent *perceive* that gray market websites are approved by doctors and medical professionals.

Policies to limit the reach and accessibility of illicit, gray market pharmacies must encourage education for healthcare professionals to learn more about the risks and dangers associated with illegal online pharmacies, and

support training opportunities for providers to learn best practices for talking to their patients about the internet, both in terms of finding health information and purchasing medications.

Additionally, encouraging frequent and detailed communication between law enforcement agencies and healthcare providers about recent indictments and illegal online pharmacies will be an important component of any recommendations to mitigate the gray market's impact on consumers. Through collaboration and open lines of communication, law enforcement can work with healthcare professionals to prevent harm and educate patients about the importance of using legitimate pharmacies – either brick-and-mortar or verified online pharmacy websites – to fill all prescriptions and to purchase ED medication only when medically appropriate.

3. Support Collaborative Law Enforcement Efforts

Law enforcement agencies at the state, federal and international levels play a critical role in investigating illegal online pharmacies and protecting consumers from substandard or falsified products. With so many players involved, there is an opportunity to build institutional leadership and ownership over the issue, and establish a model of collaboration that ensures information, data and best practices are shared among all.



As outlined in the 2011 Counterfeit Pharmaceutical Inter-Agency Working Group Report to the Vice President of the United States and to Congress, a collaborative effort by the U.S. government is necessary to protect consumers against the growing threat of counterfeit medicines.³⁸

The Working Group highlighted the key elements necessary to combat this threat:

- Law enforcement actions domestically that strive for a more strategic approach, obtaining better data and sharing information;
- Law enforcement actions internationally that improve cooperative international law enforcement efforts;
- Tackling the proliferation of illegal internet pharmacies through voluntary cooperative efforts;
- Improving public awareness about counterfeit medicines within the United States;
- Working internationally to address the counterfeit pharmaceutical problem through public awareness, information-sharing and training; and
- Ensuring that U.S. taxpayer dollars are not spent on foreign aid that procures counterfeit pharmaceuticals.

The government, however, cannot achieve these goals alone. A multisector approach with active participation from biopharmaceutical manufacturers and distributors; patient advocates; healthcare providers; internet, technology and social media companies; and non-governmental organizations must also be a mainstay of long-term strategies to combat illegal drug advertisements and sales on the gray market.



"[Industry support] forms a bridge between the public and private sectors and will assist Interpol and each of its 190 member countries to more effectively tackle the problem of medical product counterfeiting."

— Former INTERPOL Secretary General Ronald K. Noble (2000 – 2014)

Initiatives like the Pharmaceutical Industry Initiative to Combat Crime, an agreement between INTERPOL and 29 of the world's largest pharmaceutical companies to provide €4.5 million over three years to boost law enforcement's response to pharmaceutical crime, provide a model for how the public and private sectors can unite on a global scale to address this issue.³⁹

4. Consider the Gray Market in Health Policy Decision Making

The scope of the gray market and proliferation of counterfeit medicines must be considered closely in healthcare policymaking. As PDE5i drugs and similar therapeutic products are some of the most sought after medicines on the gray market, several targeted actions could help reduce reliance on these illicit channels:

a. Encourage Discussion about Consumer Access to Legitimate ED Treatment

Continuing efforts to destigmatize ED and reduce embarrassment and hesitancy to acknowledge and discuss the issue will go a long way in encouraging men to seek legitimate treatment for the condition. Encouraging primary healthcare providers to inquire about sexual function during routine care and include sexual health in evaluations of general health and well-being could advance this effort.

b. Make ED Medications Available Over-the-Counter (OTC)

Reclassifying ED medications as OTC drugs has the potential to enhance consumer safety by reducing reliance on illegal online pharmacies and other gray market pathways while alleviating economic burdens on consumers, the U.S. healthcare system and law enforcement, as discussed above.

Consumer Safety

For consumers, the safety benefits of OTC availability are of paramount importance. Inherent in switching a medication from prescription to OTC status is the understanding that product labels and packaging become the primary method of communication with a consumer rather than consultation with a healthcare provider. As the Ipsos survey showed, many consumers who purchase ED medication on the gray market do not receive directional information or health warnings⁹.

WHAT'S ON THE LABEL

All nonprescription, over-the-counter (OTC) medicine labels have detailed usage and warning information so consumers can properly choose and use the products.

Below is an example of what the new OTC medicine label looks like.

ACTIVE INGREDIENT
Therapeutic substance in product; amount of active ingredient per unit

USES
Symptoms or diseases the product will treat or prevent

WARNINGS
When not to use the product; conditions that may require advice from a doctor before taking the product; possible interactions or side effects; when to stop taking the product and when to contact a doctor; if you are pregnant or breastfeeding, seek guidance from a health care professional; keep product out of children's reach

INACTIVE INGREDIENTS
Substances such as colors or flavors

PURPOSE
Product action or category (such as an antihistamine, antacid, or cough suppressant)

DIRECTIONS
Specific age categories, how much to take, how to take, and how often and how long to take

OTHER INFORMATION
How to store the product properly and required information about certain ingredients (such as the amount of calcium, potassium, or sodium the product contains)

The Drug Facts labeling requirements do not apply to dietary supplements, which are regulated as food products, and are labeled with a Supplement Facts panel.

For more information visit: www.fda.gov/cder or call 1-888-INFO-FDA
U.S. Department of Health and Human Services
Food and Drug Administration

OTC availability of ED medication can increase the amount of health and safety information a consumer receives that is written specifically at a level consumers understand. In fact, the FDA-controlled process to determine if a prescription medication can be switched to an OTC product requires rigorous label comprehension testing to ensure consumers can understand information on an OTC Drug Facts label and make an appropriate self-selection decisions.

The Ipsos Gray Market Survey found that a majority of gray market purchasers surveyed (70 percent) said they would buy ED medicines if available as an OTC product, further supporting the impact the switch in designation could have on deterring use of the gray market.

Economic Benefits

Programs to make ED medication available OTC and to generate health benefits and economic savings are also being considered abroad. The United Kingdom recently approved an ED medication OTC switch and economic studies have been conducted in Australia and Canada to demonstrate potential savings if products were to be approved OTC. The case studies on the next page outline the economic benefits achieved or projected in these markets.

5. Add to the Body of Evidence on the Gray Market and use this Evidence to Guide Policy

As noted throughout this white paper, more coordinated and comprehensive research and studies are needed about the dangers of the gray market to demonstrate:

- Adverse events that are the direct result of purchasing counterfeit medications, particularly ED medications, on the gray market;
- The economic impact of the gray market on both individuals and the U.S. healthcare system as a whole; and
- The financial burden shouldered by law enforcement officials from all departments and agencies involved at the state and federal level in the United States.



United Kingdom

The United Kingdom recently approved ED medication that can be purchased over-the-counter. Approved by the Medicines and Healthcare Products Regulatory Agency (MHRA) in November 2017, the medicine hit pharmacy shelves in the spring of 2018.

While too recent for an economic analysis to be released, analysts anticipate the impact on the reduction of healthcare costs to the U.K. to be significant. With OTC availability, physician visits by men seeking this drug are no longer necessary and will pay for this drug individually.

“Erectile dysfunction can be a debilitating condition, so it’s important men feel they have fast access to quality and legitimate care, and do not feel they need to turn to counterfeit online supplies which could have potentially serious side effects.”

—Mick Foy, MHRA’s Group Manager in Vigilance and Risk Management of Medicines

Australia

In Australia, current savings from over-the-counter medicines coupled with future savings from potentially switchable prescription medications could amount to savings of more than AUS \$12.54 billion. Of this, AUS \$5.0 billion could be attributed to direct value of saved doctor’s visits (estimated at 75 million) and nearly AUS \$7.54 billion could account for the indirect value of lost productivity.

Savings for ED medications specifically would be most significant for government-sponsored healthcare programs, followed by individual cash expenditures and private insurance coverage.⁴⁰

Canada

Overall, the annual economic value of making prescription ED medication available over the counter is estimated at CAN \$106.2 million. Fifty-three percent (CAN \$56.8 million) of this value would result from increased efficiency and productivity gains in the workplace due to fewer primary care visits, and 46.6 percent (CAN \$49.5 million) would result from a lower over-the-counter price for ED drugs.⁴¹



VI. Conclusion

ED is a serious health issue that can substantially impact psychological and emotional health. Often associated with chronic conditions such as diabetes and cardiovascular disease, ED should not go untreated. Prioritizing policy changes that expand access to treatment while improving consumer safety and discouraging use of the gray market can have substantial benefits for public health and patient safety while reducing financial strains to the U.S. healthcare system, law enforcement and economy.

Gray market deterrents should be an integral component of health policy in the digital age. Consumer and healthcare professional education, enhanced coordination of law enforcement efforts, additional research and making ED treatments available OTC would reduce reliance on illegitimate and potentially unsafe online pharmacies while also increasing access. With collaboration across government, biopharmaceutical manufacturers and distributors, patient advocates, healthcare providers and non-governmental organizations, quality of life can be improved for millions of men.

Glossary Of Terms

1. **Auto-Refill:** The ability for consumers to automatically have their prescription medication refilled at the pharmacy before they run out of medication. In the context of the gray market where patients may not have a valid prescription or any prescription at all, this service could allow for a consumer to receive continuous refills of the medication with no limitations on duration.
2. **Counterfeit Medications (WHO Definitions)⁴²**
 - a. **Substandard Medications:** Authorized medical products that fail to meet either quality standards or specifications, or both.
 - b. **Unregistered/Unlicensed Medications:** Medical products that have not undergone evaluation or approval by the federal regulatory agency in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation or legislation.
 - c. **Falsified Medications:** Medical products that deliberately or fraudulently misrepresent their identity, composition or source. Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product.
3. **Counterfeit Medications (U.S. Federal Food, Drug and Cosmetic Act)⁴³:** A drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.
4. **Erectile Dysfunction:** The Mayo Clinic defines erectile dysfunction (impotence) as the inability to get and keep an erection firm enough for sex, characterized by persistent symptoms such as trouble getting or keeping an erection or reduced sexual desire.
5. **Gray Market:** A source for products, in this case erectile dysfunction medications, that falls outside of the traditional manufacturer-distributor supply chain. For the purpose of this research, Gray Market Purchasers were defined as consumers who purchased erectile dysfunction medications in the past 12 months from an online website that either did not require a valid prescription or required a valid prescription and shipped from outside of the United States, offered unregulated products, offers auto-refill purchases, and/or encouraged purchase of bulk quantities.
6. **Internet Sellers:** The act or process of selling goods, products or services online via an internet or mobile app, auction site, online classified advertisement, online shop, social networking sites, social media or webshop.

7. **Online Pharmacy:** A pharmacy that operates over the internet to provide consumers access to medications that are subsequently shipped through the mail or via private express shippers given a valid prescription. To be legal, online pharmacies must comply with all relevant federal and state law and pharmacy practice standards that relate to the sale and distribution of pharmaceutical products, especially prescription-only or controlled substances, in their jurisdiction of operation as well in the jurisdiction where the individual purchaser is located.
8. **Telemedicine:** The remote delivery of health care services and clinical information – including evaluation, diagnosis and treatment – using telecommunications technology, such as the internet, wireless, satellite and telephone media. Examples of telemedicine practice includes: store-and-forward, remote patient monitoring and real-time engagement. Telemedicine is distinguished from an online pharmacy in that telemedicine may involve the *diagnosis* of a condition, whereas online pharmacy/online sales involve *dispensing* of medications ordered online.
9. **Virtual Marketplace:** Umbrella term for commercial web portals. The term is often used to refer to third parties selling wares under the umbrella of a major online site like Amazon. Also called an "e-commerce marketplace," such markets provide the website, shopping cart, return labels and related services for the vendor, which may or may not have its own e-commerce website. ⁴⁴

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