

The Hidden Risks of Using Counterfeit Drugs

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A known but underappreciated health crisis is the glut of counterfeit drugs sold on the world market. According to the World Health Organization (WHO), counterfeit drugs are those that are “*deliberately and fraudulently mislabeled with respect to identity, composition or source.*” The Drug Enforcement Agency (DEA) characterizes that counterfeit drugs are fake medications that are made to appear like legitimate drugs but differ in that they may not have the actual active ingredient, a substitution with another drug, or if they do have the active ingredient, the dosage is incorrect.¹

The WHO proposed the definition of “*substandard*” drugs for all those products that are authorized on a local basis but fail to meet quality standards for or specification.² Drug counterfeiting has been around since at least the 17th century when fake anti-malarial drugs were sold.³ The Pharmaceutical Security Institute (PSI), a not-for-profit, membership organization has made it its mandate to identify and help combat fake, fraudulently packaged, or stolen or illegally diverted pharmaceuticals.⁴ The PSI states that counterfeit products include drugs with no active ingredients to those with dangerous impurities. They can be copies of branded drugs, generic drugs, or over-the-counter drugs. They can be stolen (diverted) from legitimate sources or tampered with. The exact magnitude of counterfeit drug sale is unknown because of imprecise or, in some countries, non-existent tracking procedures. The DEA rather explicitly states “*Criminal drug networks are mass-producing fake pills and falsely marketing them as legitimate prescription pills to deceive the American public.*”¹

The risks to the health and safety of a large part of the world population are great, especially in countries with weak to non-existent regulatory agencies or the absence of legal sanctions. However, even here in the United States, with a Food and Drug Administration (FDA) that is the envy of the world in limiting ineffective or unsafe drugs from being licensed, and the DEA that polices illegal manufacture and sale of licit and illicit substances, there is a surfeit of counterfeit drugs. As recently as 2023 the DEA seized hundreds of millions of lethal doses of the opioid fentanyl, alone.⁵

The laboratory sources of fake drugs are not known and thus potentially endanger the health and even life of patients. Even if these drugs are compounded in foreign licensed pharmacies the regulations may not be as stringent as those required by American state boards of pharmacy. Risks to taking these medications include those due to drug substitutions, adulterations, impurities, unanticipated drug allergies or other adverse reactions, and infections from microbial contamination. The Committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products detailed the international crisis resulting from the contamination of counterfeit drugs, including fatalities.⁶ The sources of these drugs are usually (but not always) from outside the United States, yet users are blissfully unaware of these risks, putting their trust in laboratories sometimes run by criminal enterprises.

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Previously unknown medical problems that would normally be contraindications for these drugs may be manifested only when the fake drugs are taken for the first time. In addition to intentional drug overdoses, there are risks of insidious unintentional overdoses. Oftentimes this is due to unknown concentrations of the supposed active drug in the preparations or due to patient ignorance. The latter two problems could have been minimized or circumvented altogether had the drugs been prescribed and monitored by physicians or other licensed prescribers. Lastly, by failing to take prescribed drugs, medical conditions that would be effectively treated are not, placing the patient vulnerable.

Although drug overdoses to synthetic opioid and psychostimulants captures the attention of the public (in 2020 there were 91,799 drug overdose deaths in the United States), far less reported are the potential risks of non-psychoactive drugs.⁷ Here, we present this more hidden crisis of two such drug classes: weight-loss drugs and drugs for male sexual performance. Both types of drugs have been used or abused for decades. However, with the advent of online pharmacies, sales of these drugs have skyrocketed. These unregulated sites bypass stringent state and federal prescription laws. Another incentive is offering lower priced alternatives to those charged by legally regulated pharmacies, even when patient's costs would be partially offset by health insurance.

Before we discuss these specific drug classes it is important to discuss background material.

Why take illegally or unethically manufactured drugs when these drugs can easily be obtained legally with prescriptions?

The short answers are cost, privacy, avoidance of medical treatment, and scientific ignorance/mythology. Also, possibly contributory is a political bias against supporting the pharmaceutical industry.

Cost

Even with health insurance, the weight loss drug, semaglutide is quite expensive. According to a recent article by Leana S. Wen in the Washington Post the average yearly cost of the drug, which is available only on patent and sold under the brand names **Ozempic**, **Rybelsus**, and **Wegovy**, is \$13,000.⁸ Because many insurance companies do not discount the cost for these drugs, some of their subscribers may turn to the so-called grey market purchase of these drugs. These may be actual products diverted outside authorized distribution channels, or knock-off or fake drugs. As recently as June 24, 2024 it was reported that both WHO and the drug manufactures Eli Lilly warned customers to avoid counterfeit versions of the drug semaglutide.⁹ As we discuss below, we offer the following admonition: “*buyer beware!*” Or to put it another way, **what you get may not be what you see.**

Privacy

Patients may also be embarrassed about taking some drugs, even if they are prescriptive. This may be true for weight loss drugs. There is a real stigma in our society about the morbidly obese. The medical term is obesophobia but the common term is far more hurtful, “*fat*

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shaming.” This is also apparently true for drugs used to treat erectile dysfunction (ED). According to the National Institute of Health’s National Center for Complementary and Integrative Health as many as 30 million American men have ED.¹⁰ Unfortunately some of these sufferers may turn to knock off versions of sildenafil (**Viagra**) and tadalafil (**Cialis**) two of the major drugs used for ED.

Avoidance

Using a national data base, researchers¹¹ concluded that patients avoid consulting with physicians for the following reasons:

1. Low perceived need: a belief that medical care may not be necessary or that the condition will improve on its own.
2. Traditional barriers to medical care: financial (out of pocket costs, lack of health insurance), time constraints, difficulty with transportation, emotional (depression, anxiety), or (counterintuitively), feeling too sick.
3. Unfavorable evaluations of seeking medical care: physician factors (personality, communication skills, lack of trust in the physician’s skills), difficulty making appointments, long waiting times, fear (bad news, specific medical procedures) and embarrassment (weight, discussing sexual or other intimate body functions).
4. Self-ascribed personality traits: laziness, procrastination.

Scientific ignorance

Lastly, some patients opt for alternative health care rather than conventional medical care because they have a general lack of trust in and satisfaction with medical care.¹² On the one hand, concerns about manipulation of data or bias by the pharmaceutical industry have been raised.¹³ In addition, with the advent of advertising directly to patient and physicians, the pharmaceutical industry has introduced bias to influence consumer behavior.¹⁴ On the other hand, there is also health-related misinformation that ranges from deliberately deceitful to benign endorsement of specific products with claims that lack scientific credibility.^{15,16} Some of this is shown through traditional means (e.g., television), sometimes within the span of several minutes after an ad for a conventional medication. Social media has amplified the epidemic of fake or controversial health news. However, herbal or other natural products often lack proven efficacy and are not devoid of potential, sometimes life-threatening, toxicity.¹⁷

Concerns about taking grey market or counterfeit drugs

1. Efficacy. Does the product produce the necessary therapeutic effect? Considerations include insufficient dosage, drug substitution, or in the case of “*natural*” substances, absent or poorly conducted scientific research to substantiate online or printed claims.
2. Safety. Since these products do not fall under the aegis of the FDA consumers have no way of knowing what they are taking. There is uncertainty of the composition of these products. Is the advertised active ingredient present in the dosage stated or has there been a substitution? Have adulterants been added? Untoward or unanticipated adverse reactions may occur. In the extreme these preparations may lead to frank toxicity, with

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the possibility of organ failure and even death. Risk of bacterial infections due to unregulated manufacturing procedures is increased.

3. Drug-drug and drug-food interactions. Such interactions may occur on a molecular level (pharmacodynamic), metabolic, or organ level (e.g., decreased gastric emptying). Thus, the efficacy and safety of other prescriptive pharmaceuticals that the patient may be taking may be affected. In rare cases absorption of necessary vitamins or other nutrients may be lessened.

Treatment for weight loss

Obesity, considered a health care crisis, is characterized by a body mass index of 30 kg/m² or higher, is worldwide epidemic with prevalence rates of 27.5% for adults and 47.1% for children.¹⁸ This amounts to over 1 billion people worldwide.¹⁹ It has been conceptualized as an interrelationship of genetics, socioeconomic factors and cultural influences. The health implications of obesity include cardiac disease, diabetes mellitus, hypertension, and cancer.²⁰ There are economic and environmental factors that contribute to obesity.²¹

Treatment options incorporate lifestyle changes, pharmacotherapy, and surgical options.²² However not all those who seek treatment for weight loss meet criteria of obesity. This should be seen within the context of weight stigmatization. More than 40% of U.S. adults, across a range of body sizes report experiencing weight stigma at some point in their lives.²³ Social media and televised commercials for a host of purportedly effective pharmaceutical, herbal, and cosmetic surgical treatments (including liposuction) use actors and influencers to promote their products and lure in new customers, including those *who are not morbidly obese*.²⁴

Throughout the decades America's fixation on weight loss was addressed with exercise regimens, various diets of sometimes unproven validity, and pharmacologically. Although the most effective of the surgical treatments is bariatric surgery it is underutilized because of overestimations of risks and complications.¹⁸ However, an impediment to avail oneself of this option is cost. As a consequence, those who seek to lose weight turn to non-surgical alternatives, most especially pharmaceutical.

A host of psychostimulants like amphetamine and other anorectic agents (diethylpropion or **Fastin**) had huge markets that grew exponentially with the fen-phen (fenfluramine and phentermine) phenomenon of weight loss mills (6 million American).²⁵ However, the occurrence of pulmonary hypertension and heart valve problems that were attributed to fenfluramine and its sister drug, dexfenfluramine, resulted in legal damages that totaled US \$13 billion and the eventual withdrawal of these and several other weight loss drugs from the market.²⁶ What drugs did remain also had complications that limited their usefulness.

Semaglutide, the newest weight-loss drug, is pharmacologically different. It is a drug that mimics the gastrointestinal hormone, glucagon-like peptide-1 (GLP-1).²⁷ This drug helps the pancreas to release insulin in response to the blood sugar, glucose, and enables glucose to be taken up into body tissues for energy. Although its main indication is for type-2 diabetes, a consequence of this action is to lower body weight. The weight reduction effect became a

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second and even more profitable indication for this drug. According to recent estimates this market is almost US \$28 billion and predicted to grow to reach US \$50 billion by 2029.²⁸

As mentioned above, the cost of this drug is enormously expensive and thus created a market for a much cheaper alternative – knockoff or counterfeit versions of semaglutide. Yet the WHO reported just recently issued an alert of falsified batches of Ozempic, one of three licensed patented brands of semaglutide that had been detected in Brazil, the United Kingdom, and the United States in December 2023.²⁹ The FDA reports that seized “Ozempic” products also included counterfeit syringes of uncertain sterility.³⁰ Consequently, the risk of microbial infection, has been doubled because the sterility of the seized semaglutide itself may also be non-sterile.

Treatment for ED

The market for drugs to treat ED is also large. Approximately 322 million men worldwide are predicted to be affected by the year 2025.³¹ The market was valued at US \$2.46 billion in 2022 and is anticipated to grow at a compound annual growth rate (CAGR) of 8.8% from 2023 to 2030.³²

Like obesity, the etiology of ED may be multifactorial. Known contributors include psychological (depression, performance anxiety), endocrinological, vasculogenic, or neurogenic factors (perhaps secondary to diabetes mellitus, cardiovascular disease; neurological disease, iatrogenic injury), or from taking certain other medications (e.g., selective serotonin reuptake inhibitors).³³ There are many treatment options including lifestyle changes (e.g., decreased alcohol intake, cigarette smoking cessation), pharmacotherapy (oral or intraurethral suppositories; intracavernosal injections of vasoactive drugs), vacuum erection devices, and surgical (penile implants, penile revascularization).

The most used oral drugs are sildenafil (**Viagra**) and tadalafil (**Cialis**), phosphodiesterase type 5 inhibitors (PDE5is). Through this action these drugs relax blood vessels in the corpus cavernosa of the penis during sex.³⁴ As with weight loss drugs social media and television commercials abound. Millions of counterfeit PDE5is are seized yearly and account for the bulk of all counterfeit pharmaceutical product seizures.³⁵ There may be as many illegal as legal users of sildenafil (up to 2.5 million men in Europe).

Although the legitimate PDE5is are generally safe, morbidities, that include priapism and cardiovascular incidents, and death have been linked to increased dosages.³⁶ This risk increases with knockoff drugs with uncertain concentrations of the PDE5is or due to drug substitutions. Impurities in these online products have been reported.³⁷ Contaminants include talcum powder, commercial paint and printer ink, as well as the antidiabetic drug, glyburide.³⁸

Alternatives to PDE5 are also sold over the internet. One popular drug is the herbal preparation, yohimbe, which may or may not contain a different vasodilator, yohimbine, a centrally and peripherally active adrenergic drug with both agonist and antagonist activity.³⁹ This drug, like, PDE5, has an effect on the vasodilator nitric oxide, but therapeutically it has modest efficacy (So, any benefit derived is likely placebo – or as the late psychologist Arthur Weider put it,

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“mind over mattress.” (personal communication). Although generally safe, rare fatal overdoses have been reported in recreational drug users.⁴⁰

Female sexual dysfunction

Although less researched, there is also a market for female sexual dysfunction. Like male sexual dysfunction the etiology may be multifactorial including psychological (e.g., depression, anxiety, trauma or posttraumatic), interpersonal, hormonal (especially menopause), pathophysiological (e.g., diabetes mellitus, cancer, multiple sclerosis), or pharmacological (e.g., selective serotonin reuptake inhibitors or similar antidepressants).^{41,42,43} According to recent studies more than 40% of respondents reported sexual problems with desire, arousal, or orgasm.^{44,45}

Pharmacological treatments have included hormonal (estrogen, testosterone), herbal and pharmacological.⁴¹ Sildenafil was explored early on for female sexual dysfunction but it has not been found to be particularly effective. However, it is still sometimes prescribed off label by physicians.

The only drug to date that has been approved by the FDA for female sexual dysfunction is flibanserin (Addyi), a postsynaptic 5-hydroxytryptamine 1A agonist and 2A antagonist that decreases serotonin levels and increases dopamine and norepinephrine levels.⁴⁶ Of note, the drug was twice rejected by the FDA before being approved.⁴⁷ It only treats hypoactive desire (low libido) in premenopausal women, has minimal efficacy compared to a placebo and it does have side effects (e.g., somnolence and hypotension, both exacerbated if alcohol is also consumed; synergistic interactions with drugs that cause sedation. Although users reportedly “satisfying sexual events” the term “orgasm” is not explicitly stated.⁴⁸ (Joffe et al, 2016).

Online products target women with products of no proven efficacy. Like men, women are subject to possible untoward, toxic, or allergic reactions.

Recommendations

The literature for obesity and erectile dysfunction, as well as a host of other medical conditions, discusses multifactorial causes. To that end, we recommend the following:

1. Consult with your physician to have a thorough medical examination, with necessary bloodwork and other diagnostic procedures performed, to accurately diagnose the etiology of your problem.
2. If warranted consult with a psychologist or other licensed mental health professional for diagnosis, and possible psychotherapeutic treatment. This may be augmented with hypnotherapy by a qualified, licensed health professional.
3. Consider all options, including pharmacologic, surgical and lifestyle changes (e.g., modification of diet and alcohol consumption, exercise, relaxation procedures). This may include consulting with a nutritionist or dietitian as well as possibly joining support groups.
4. Try to avoid getting information about your specific problem from advertising, regardless of source (traditional, alternative, social media). If you do succumb,

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- a. Check independent reviews from multiple sources
 - b. Try to avoid confirmation bias (i.e., people who think exactly the way you do)
 - c. Try to educate yourself about what are reliable sources (e.g., FDA, CDC, NIH, PubMed).
5. Try to resist diagnosing yourself. There is an old axiom, “*A man who is his own lawyer has a fool for a client.*” We say, “*Those who act as their own physicians have fools for patients.*”
 6. Be aware of your emotions and your need for the drug. Recognize that you are vulnerable and may feel desperate. This can adversely affect your judgment. The same is true if your cognition is impaired.
 7. Determine if there is true economic benefit to buying drugs outside traditional channels. As noted earlier, the costs with or without hidden fees may be higher for some of the online pharmacies.
 8. Look for litigation against med spas, and wellness centers
 9. Remember that prescription drugs can only be authorized by a physician and certain other licensed health care providers. Check your state regulatory boards to determine if your provider has been granted prescription privileges in your state.
 10. Be aware that all drugs (regardless of where purchased), vitamins, minerals, herbs, and other natural products may be potentially toxic.
 11. The purity and dosage of drugs is regulated by the FDA and state pharmacy laws. Anything acquired elsewhere may be fake, have the wrong dosage, or be adulterated or contaminated with toxic metals, bacteria or other substances.
 12. Do not take radical steps on your own to being thin or a stud. Social media, in particular, may increase your vulnerability to being shamed or feeling inadequate.

Lastly, it behooves the use to follow the dictum of the DEA

(<https://www.dea.gov/documents/2021/2021-09/2021-09-27/counterfeit-pills-factsheet>)

“The only safe medications are ones that come from licensed and accredited medical professionals...pills purchased outside of a licensed pharmacy are illegal, dangerous, and potentially lethal”

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