

The Spreading Cancer of Counterfeit Drugs

Pharmaceutical Fakery Metastasizes
from Lifestyle to Lifesaving Medicines

By: Peter J. Pitts
Former FDA Associate Commissioner
President, Center for Medicine in the Public Interest

October 2020

Introduction

Just as the coronavirus mutates to survive and thrive, so do the purveyors of counterfeit medicines – with their high-speed “host” being the digitization of patient care. The future is now. So, how do we balance moving forward with user-friendly digitization, telemedicine and virtual healthcare delivery while simultaneously recognizing the unintended consequences of the innovative criminal mind? The first step is to recognize there’s a problem.

Counterfeit Medicines: A Moveable Feast

Once upon a time, at the beginning of the new millennium, counterfeit medicines in the United States were largely “lifestyle” products such as erectile dysfunction drugs – Viagra being the poster child of the problem.ⁱ Other categories of fake pills included treatments for depression.ⁱⁱ The common denominator was patient shame and embarrassment. Ordering from seemingly benign (i.e., “from Canada”) websites seemed like a safe and anonymous way to address their conditions without having to visit either a physician, mental health professional or pharmacist. A second category of counterfeit prey were people seeking higher risk drugs (opioids, steroids, etc.) to facilitate a more dangerous lifestyle. The rationale for this second group was easier access to more dangerous (often controlled) substances.ⁱⁱⁱ

To respond to this emerging threat, the FDA formed a Counterfeit Drug Task Force in July 2003.^{iv} As a former FDA Associate Commissioner, I was proud to serve as a member of that task force. We received extensive comment from security experts, federal and state law enforcement officials, technology developers, manufacturers, wholesalers, retailers, consumer groups and the general public on a very broad range of ideas for deterring counterfeiters. Those comments reinforced the need for the FDA to take action in multiple areas to create a comprehensive system of modern protections against counterfeit drugs.

At the FDA we discussed those ideas and developed a framework for a 21st-century pharmaceutical supply chain that would be more secure against modern counterfeit threats.

The specific approach to assuring that Americans are protected from counterfeit drugs includes the following eight elements:

- (1) Implementation of new technologies to better protect our drug supply.
- (2) Adoption of electronic track and trace technology.
- (3) Adoption and enforcement of strong, proven anticounterfeiting laws and regulations by individual US states.
- (4) Increased criminal penalties to deter counterfeiting and more adequately punish those convicted.
- (5) Adoption of secure business practices by all participants in the drug supply chain.
- (6) Development of a system that helps ensure effective reporting of counterfeit drugs to the FDA and which strengthens the agency's rapid response to such reports.
- (7) Education of consumers and health professionals about the risks of counterfeit drugs and how to protect against them.
- (8) Collaboration with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally.

According to that report, “Although the safety and security of the U.S. pharmaceutical supply is high, FDA’s investigations show that counterfeiting of legitimate drug products poses a significant and growing problem. A multi-prong anti-counterfeiting strategy is necessary to protect consumers by preventing the introduction of counterfeit drugs, facilitating the introduction of counterfeit drugs, and minimizing the risk and exposure of consumers to counterfeit drugs.”^v

Congress also stepped in with legislation, including the Drug Safety and Accountability Act of 2010 and the FDA Globalization Act.^{vi}

The FDA adopted a global strategy for assuring the safety of the U.S. supply chain that included creation of an office to oversee import safety, with stepped-up powers to interdict incoming drug shipments into the United States, collaborate with regulatory agencies in other countries and

order recalls of unsafe products. The agency also called on manufacturers to improve their own screenings of raw materials produced outside the United States — and began ranking more than 1,000 active drug ingredients to assess their “respective risk of economically motivated adulteration,” according to then FDA Commissioner Dr. Margaret Hamburg.^{vii}

In a 2011 analysis of 8,000 rogue websites, the National Association of Boards of Pharmacy concluded that 96% of them were out of compliance with U.S. pharmacy laws, and 85% didn’t require a valid prescription.^{viii}

The FDA required legal distributors to keep detailed records of the sources of the medications they dispense.^{ix} But it proved to be a futile undertaking swiftly overtaken by advancing digital technologies and criminal talent. Drug counterfeiters have become so sophisticated, they can produce both drugs and packaging that cannot be differentiated from the real thing without complex, time-consuming and costly analyses. It became quickly obvious that paper “pedigrees” were next to useless – but no new strategies, tactics were forthcoming from the FDA and Congress granted the agency neither additional funding nor enhanced regulatory powers to more robustly fight medicines counterfeiting. In 2004, when the FDA claimed that counterfeit drugs were being used to fund global terrorism,^x many high-profile elected officials accused the agency of being in the pocket of Big Pharma. Today, these same politicians are strangely silent.

Sixteen years later the problem of counterfeit medicines is only getting worse.

Counterfeits Advance from Lifestyle to Life Saving Drugs

When asked why he robbed banks, the Depression Era folk hero Willie Sutton answered, “Because that’s where the money is.”^{xi} That same dynamic explains why drug counterfeiters have changed their focus from lifestyle medicines to life saving/extending treatments – particularly oncology treatments (both oral and biological). It’s where the money is. Fakes are almost impossible to identify without a sophisticated knowledge of packaging tools and techniques (see Appendix A). The digitization of healthcare has acted as an accelerant to the increased prevalence of and negative impact of counterfeit medicines.

This new and nefarious sales and marketing strategy may be good for the criminal bottom line – but it’s deadly for patients.

The FDA has always battled to, on the one hand, empower patients while, on the other, protecting the public from incorrect, exaggerated and downright phony health information and products. For the FDA, regulatory enforcement surrounding the proliferation of dietary supplements, cannabis and cannabidiol (CBD) products have, at least to-date, been the battleground.^{xii} Today the issue is the same – a lack of resources and authority to adequately fight multiple battles simultaneously, but the stakes are higher.

According to a recent FDA statement:

FDA lab tests have confirmed that at least one batch of a counterfeit version of Roche’s Altuzan distributed in the United States contains no active ingredient. Even if the identified product were not counterfeit, Altuzan (bevacizumab), an injectable cancer medicine, is not approved by FDA for sale in the United States. The only FDA-approved version of bevacizumab for sale in the United States is called Avastin, marketed by Genentech.^{xiii}

On July 17, 2020, the US Department of Justice announced the arrest of two men from Ukraine who admitted in federal court that they conspired to smuggle and distribute counterfeit cancer and Hepatitis C drugs into the United States.^{xiv} The DOJ reports that Maksym Nienadov, the owner of the Ukrainian-based company Healthy Nation, and his co-conspirator and employee – Volodymyr Nikolaienko – pleaded guilty in federal court in Houston, Texas to conspiracy, trafficking in counterfeit drugs and smuggling goods into the United States. Nienadov also admitted to introducing misbranded drugs into the United States. The investigation was conducted by Immigration and Customs Enforcement’s Homeland Security Investigations and FDA’s Office of Criminal Investigations.

The indictment^{xv} against the pair described both the nature of their crimes and how they were brought to justice. Nienadov setup Healthy Nation to market and distribute counterfeit versions of Abraxane and Keytruda, both oncology treatments, as well as Epclusa, a pill treatment for

Hepatitis C. There was evidence they were selling or planning to sell fake versions of Iclusig, a cancer treatment, according to their plea agreement.^{xvi}

After receiving a tip about Health Nation's counterfeit drug business, undercover agents began to purchase the three drugs cited in the superseding indictment. In each case, chemical analysis showed the purchased drugs were not what the defendants said they were. In its genuine form, Keytruda is a cold-chain injectable used to treat multiple types of cancer. Testing showed the Keytruda sold by Healthy Nation did not contain pembrolizumab, the correct active ingredient, but instead, it was made from a class of chemicals known as proton-pump inhibitors: specifically omeprazole and/or pantoprazole. Omeprazole is known by its over-the-counter name Prilosec, and is used to treat acid reflux and heartburn. Pantoprazole is the active ingredient in Protonix, a prescription-only medication for treating acid reflux.

To make their fake medications appear more genuine, Nienadov and Nikolaienko produced counterfeit packaging that mimicked the genuine product boxes and labels. In addition to using logos from the manufacturers of the genuine drugs, they either created fictitious lot numbers for the drugs, or copied genuine lot numbers from images of genuine drug boxes.

The same problem exists in Canada and Europe. The World Health Organization recently warned cancer patients in North America and Europe about a batch of fake drugs that contain nothing but a common painkiller. The product alert says that counterfeit medicine packaged to look like the cancer drug Iclusig, known generically as ponatinib — a targeted therapy for chronic myeloid and acute lymphoblastic leukemia — simply contains acetaminophen.^{xvii} The fakes, discovered by a Swiss wholesaler, have also been detected in Turkey and Argentina.^{xviii}

A week-long, Interpol-coordinated blitz saw authorities in 116 countries seize 500 tons of fake pharmaceuticals worth an estimated \$14,000,000. The haul included anti-inflammatory medication, birth control pills, and counterfeit treatments for HIV, Parkinson's and diabetes. (Investigators also found more than 110,000 fake medical devices like hearing aids, contact lens and syringes.) The seizures resulted in 859 arrests and the closure of 3,671 weblinks.^{xix}

Rather than attracting otherwise healthy people looking for a quick and private way to purchase low-cost Viagra (out of their own pockets), today's victims are desperately ill patients looking for a way to afford their medicines in the face of rising and perpetual insurance co-payments.^{xx} The unintended consequences of Prescription Benefit Manager (PBM) tactics such as co-pay accumulators and maximizers^{xxi} as well as Federal government regulations that preclude the use of many patient assistance programs^{xxii} have left patients with cancer and other life-threatening diseases looking for an alternative route to access. Prescription drug counterfeiters have recognized the opportunity and rushed into the breach.^{xxiii} Nature abhors a vacuum.

The Role of Specialty Pharmacy

What has made this possible and predictable is the rapid rise of "Specialty Pharmacy." Specialty pharmacy refers to distribution channels designed to handle pharmaceutical therapies that are either high cost, high complexity and/or high touch (products that require a much higher degree of personal attention and service). Specialty pharmacy requires a higher degree of complexity in terms of distribution, administration and patient management which drives up the cost of the drugs.^{xxiv}

Initially specialty pharmacy providers attached "high-touch services to their overall price tags" arguing that patients who receive specialty pharmaceuticals "need high levels of ancillary and follow-up care to ensure that the drug spend is not wasted on them." In the mid 1990s, there were fewer than 30 specialty drugs on the market, by 2008 that number had increased to 200^{xxv} and by 2018 more than 900 unique pharmacy locations received specialty pharmacy accreditation – a 25% increase from 2017.^{xxvi}

Importantly, the pharmaceutical industry, in close collaboration with specialty pharmacy, actively and aggressively drove online service and mail-order delivery. Why is specialty pharmacy relevant to the issue of the evolution of counterfeiting? Opportunity.

Specialty pharmacy creates a powerful “cover story” for criminal counterfeiters. Legitimate insurance companies and Prescription Benefit Managers are delivering legitimate medicines through the US Postal Service creating a false sense of security for patients. Two of the serious unintended consequences of using the US Mail are quality and timing problems (see below). Since patients are regularly receiving their medicines through the mail and experience the legitimate system’s lack of precision, patients accept the legitimacy of the process. As a result, patients lower their guard and open the door for all types of pharmaceutical interactions that occur virtually or through mail. This creates a dangerous and brightly lit opportunity for counterfeiters to “impersonate” specialty pharmacy and insert counterfeit medicines, via the US Postal Service, into the medicine chests of desperately ill patients. This is the same pathway of opportunity counterfeiters follow when they place a Canadian flag on their phony websites that promise “FDA-Approved Drugs at Canadian prices.” (The issue of drug importation will be addressed later in this report.)

While mailing a prescription may sound routine, many of the patients forced to wait for these services are those with complex or life-threatening conditions such as cancer. Delaying these treatments can have serious repercussions for these patients’ health and potentially lessens their outlook.

A report from *the Columbus Dispatch* in 2018 highlighted the problem, finding patients like Elvin Weir who not only had to wait for his prescription to be sent to him, but he was also sent the incorrect medication twice. Prescription Benefit Managers (PBMs) and insurers claim that specialty pharmacies help to manage care and costs, but in Mr. Weir’s case, their “care” led to a delay in his treatment and the waste of \$20,000 worth of treatments.^{xxvii}

Another 2018 report from *the Times-Picayune* in New Orleans highlighted how numerous cancer patients are forced to wait or are outright denied the medication their doctor has prescribed them, forcing them to wait for an appeal. In the instance highlighted, the patient, Connie Raborn, had to wait almost three months before she was able to take her medication.^{xxviii}

Such delays aren't the only problems facing patients using a specialty or mail-order pharmacy. Patients have reported receiving medications which were shipped at unsafe temperatures, rendering them ineffective or even dangerous.^{xxix} It is a short step from substandard medicines to counterfeit ones.

The Regulatory Limitations of Product Serialization

Serialization refers to the requirements for application of a unique identification code, a serial number or electronic product code (EPC). Serial numbers can be tracked through its entire supply chain, from production to retail distribution to final dispensation to the patient.^{xxx}

The FDA believes that counterfeiting can be reduced significantly through product serialization. Serialization requires a comprehensive system to track and trace the passage of prescription drugs through the entire supply chain. Serialization can potentially identify every product by a unique serial number in addition to the origin, shelf life and batch number for that product. This could potentially allow the product's lifecycle to be traced from production, through distribution, and finally to the patient.

But serialization is not just about generating unique serial numbers, but also creating and maintaining identification tools that provide visibility and full traceability within the supply chain. It requires collaborative action from partners throughout the supply chain for accurate recording, tracking and managing of data as the product moves from manufacturer, to distributor, to the dispensing point. It's expensive and complex proposition. That complexity creates a multitude of opportunities for criminal counterfeiters motivated by huge profits on placing their fake products into the medicine chests of American patients.

The Drug Quality and Security Act

As part of a long-term strategy, the United States has been trying to move to implementing technology and systems that would discourage the introduction and distribution of counterfeit drugs. In November 2013, President Obama signed into law the Drug Quality and Security Act

(DQSA) (H.R. 3204).^{xxx} Implicit within the DSQA is the Drug Supply Chain Security Act (DSCSA) which outlines critical steps to build an electronic, interoperable system to identify and

trace certain prescription drugs as they are distributed in the U.S. This law established requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain (H.R.3204 – Drug Quality and Security Act, 2018).^{xxx}

Full execution of Title II of the DQSA^{xxx} dictates that data will be exchanged across a very complex and diverse set of supply chain partners: in-house packaging facilities, packaging facilities of contract development and manufacturing organizations (CDMOs), third-party logistics providers (3PLs), repackagers, wholesalers, and dispensers. However, the aggregation of serialized data is not a requirement of the DQSA.

Data must have high integrity and be free of corruption for effective use by members of the pharmaceutical supply chain, and data must be protected from hackers and other cyber criminals. Serialization is, of course, meant to protect and validate the identity of a product throughout the supply chain. Therefore, it does not take much of a leap of imagination to envision how cyber-counterfeiters benefit by manipulating the identity of high-value products – at the expense of patients’ seeking lower costs due to ever-increasing co-payments driven by the costs of specialty pharmacy and the desire of PBMs to further increase their bottom-line profits.^{xxx}

Theoretically, by the end of 2023 (the deadline for full track-and-trace implementation) an enormous amount of data will be generated at operational speeds, correctly assigned to a given product, stored, and transmitted to all appropriate supply chain partners. That data will then need to flow seamlessly between clients and their Contract Development and Manufacturing Organization (CDMO) or Contract Packaging Organization (CPO).^{xxx} Theoretically. However, as the biopharmaceutical industry, its supply chain partners, PBMs (and their specialty pharmacy divisions), regulators and lawmakers continue to discuss, debate and finesse serialization in all its forms, criminal counterfeiters are exploiting the holes in the system, enhancing their false profits through savvy exploitation of technology and regulatory gaps – at the expense of patient health.

HHS Office of Inspector General Report: The Drug Supply Chain Security Act (DSCSA)

In February 2020, the US Department of Health and Human Services Office of Inspector General issued a report^{xxxvi} that stated:

Drug diversion, counterfeiting, and the importation of unapproved drugs may result in potentially dangerous drugs entering the drug supply chain, posing a threat to public health and safety. To enhance the security of this supply chain, the DSCSA requires trading partners in the drug supply chain to create a record of each drug product transaction. FDA can use these records to investigate and identify potentially harmful drug products, prevent further distribution, and facilitate efficient recalls.

According to the report, ownership of 37 of 44 selected drug products could be traced through the supply chain using drug product tracing information that the Drug Supply Chain Security Act (DSCSA) requires. Seven selected drug products could not be completely traced to manufacturers. Typically, this was because tracing documents exchanged between the wholesale distributor and manufacturer were missing or had mismatched tracing information.

In one instance, a wholesale distributor refused to provide tracing documents. When tracing information is missing or mismatched, a complete tracing record for a drug product may not always be available to support investigations of suspect or illegitimate drug products in the supply chain, which could delay investigators. Indeed, staff at the Food and Drug Administration (FDA) reported that accurate tracing information is critical to identifying a drug product quickly in the event of a recall or when removing an illegitimate drug product from the supply chain.

Additionally, for 21 of 44 selected drug products, the Inspector General found that—unlike with their ownership—they could not trace their physical movement through the supply chain using tracing information. Nor could the OIG identify the shipping locations of trading partners (e.g., manufacturers, wholesale distributors, and dispensers) or third-party logistics providers that shipped or stored the drugs on behalf of the trading partners. Although the DSCSA does not require this information, should FDA not have access to this information in case of a drug safety

emergency, FDA and other investigators would need to request additional documents, which could delay investigations and hamper FDA’s ability to identify sources of potentially harmful drugs in a timely manner.

The OIG report recommends that FDA follow up with the wholesale distributor that did not provide tracing information. The OIG also recommends that FDA offer educational outreach to trading partners about required drug product tracing information and data standardization guidelines. Lastly, the OIG recommends that FDA seek legislative authority to require information about a drug product’s complete physical path through the supply chain on tracing information. FDA concurred with all of the OIG report recommendations.

Bad Policy Ideas Have Negative Real-World Consequences

We live in a hyper-politicized environment often driven by simplistic, soundbite solutions to complex problems – such as the cost of medicines. In the case of counterfeit medicines, they can actually exacerbate the problem. A good example of this issue is Drug Importation (aka: “Drugs from Canada”).

The concept sounds easy and logical but, as HL Mencken said, “For every complex problem there is an answer that is clear, simple, and wrong.” All importation schemes offer lower cost medicines with no additional risk. The facts, however, point to neither savings – nor safety.

During a weeklong anti-counterfeiting operation Canadian officials inspected nearly 3,600 packages — and found that 87 percent contained counterfeit or unlicensed health products.^{xxxvii} A striking number of “Canadian” drugs aren’t actually from Canada. Canadian internet pharmacies regularly import drugs from less developed^{xxxviii} and less regulated countries, like Turkey. Then they slap on their own labels and ship them elsewhere.^{xxxix} One FDA operation found 85 percent of “Canadian” drugs originated in 27 different countries and more than a third of those drugs were potentially counterfeit.^{xi}

Such concerns explain why Illinois ditched its importation program, I-SaveRX, in 2009 after failing to adequately inspect foreign pharmacies. According to a state audit, “40 percent of the required inspections of the foreign entities claiming to be pharmacies were never completed, putting patients at risk” and patients were left with “no regulator to protect them.”^{xli}

Canadian regulators have warned Americans that importation could be risky. One official at Health Canada, the government agency which oversees that nation’s pharmaceutical supply^{xlii}, said the regulator “does not assure that products being sold to U.S. citizens are safe, effective and of high quality and does not intend to do so in the future.”^{xliii} Safety cannot be ignored because it is inconvenient.

Senior U.S. officials have issued similar warnings. Over the past 18 years, in both Democrat and Republican administrations, every FDA commissioner and secretary of Health and Human Services has failed to certify that importation is safe.^{xliv}

However, recently, The Department of Health and Human Services (HHS) recently floated a proposal, dubbed the Safe Importation Plan, to allow Americans to use Canada as their personal pharmacy.^{xlv} In Canada, the government dictates the market through price controls, but any drug importation scheme should give Americans pause.^{xlvi}

The so-called Safe Importation Action Plan offers two paths forward for drug importation. First, states, wholesalers or pharmacists could submit plans for demonstration projects for HHS to review outlining how they would import Health Canada-approved drugs, Second, manufacturers could import versions of existing FDA-approved drugs into the United States.

The plan sounds reasonable enough, but it’s missing one key variable — the Canadian government. Neither the Trump Administration nor any state that’s been pondering drug importation has ever consulted the Canadian government.^{xlvii} Had they done so; they’d see that our neighbors to the north have some serious concerns with the proposal.

Access to high-quality medicines is a crucial issue, but drug importation is not the answer. The Trump Administration's drug importation plan would create more problems than it would solve by jeopardizing Canada's drug supply and exposing Americans to deadly counterfeits.

The CDC and the “Epidemiology of Counterfeiting”

Through literature review, interviews, surveillance and research, discover new data about counterfeiting as a risk to public health. With a lack of information on the public safety impact of on the most at-risk populations (economically disadvantaged, elderly, under-insured), the Centers for Disease Control and Prevention (CDC) should develop and field a study on the adverse health effects of counterfeit medicines. The scope of such a project should include:

- Raising awareness of counterfeit medicines as a public health issue within CDC and among its partners.
- In-depth interviews to determine which CDC programs and partners use prescription drugs in prevention, intervention, treatment and surveillance programs, identify baseline awareness of counterfeit medicine within the same groups.
- A literature review to determine if there is existing evidence of counterfeit medicines in the peer-reviewed literature, assess the current landscape (and associated consumer harms) and identify gaps and areas for future research.
- Collect data and determine commonalities of counterfeit-related injuries, disease, identify determinants and identify further areas for prevention.
- Develop a report to summarize key findings and recommendations, including potential subject matter experts, opportunities for further collaboration, and development of a framework for additional phases of research.

Counterfeits and COVID: Problem and Opportunity

Not surprisingly, the COVID-19 pandemic has increased the public's exposure to counterfeit medical products.

According to the FDA:

The FDA advises consumers to be cautious of websites and stores selling products that claim to prevent, treat or cure COVID-19. There are no FDA-approved products to prevent COVID-19. Products marketed for veterinary use, or "for research use only," or otherwise not for human consumption, have not been evaluated for safety and should never be used by humans. For example, the FDA is aware of people trying to prevent COVID-19 by taking a product called chloroquine phosphate, which is sold to treat parasites in aquarium fish. Products for veterinary use or for "research use only" may have adverse effects, including serious illness and death, when taken by people. Don't take any form of chloroquine unless it has been prescribed for you by your health care provider and obtained from legitimate sources.

The sale of fraudulent COVID-19 products is a threat to the public health. If you are concerned about the spread of COVID-19, talk to your health care provider and follow the advice of FDA's federal partners.^{xlviii}

The FDA recognizes the threat of criminals preying on the COVID-19 fears of the American public. The agency acted quickly and aggressively issue warnings and ramp up enforcement. Perhaps, in a post-COVID environment, the FDA will pursue the threat of counterfeit medicines in a more proactive, manner.

Reinforcing the Strongest Link in the Chain

The war against counterfeiting requires robust leadership, new strategies and tactics. The Center for Medicine in the Public Interest believes the FDA is the most appropriate federal authority to lead our nation's anti-counterfeiting efforts. And the first order of business is to create a

taskforce that includes other entities from the US Department of Health and Human Services (National Institutes of Health, Centers for Disease Control), other cabinet-level departments (Justice, Commerce, Homeland Security, the White House, etc.), state-level authorities, professional and patient organizations. You can't win a war without a war room. And you cannot fight battles without precise coordination of resources and effort.

The most potent tool in the struggle against counterfeiting is product integrity. Quality is hard to maintain, and counterfeiters don't care about it. That is their Achilles Heel. Advancing and protecting quality is the most powerful weapon in the fight counterfeit medicines.

Comprehensive product quality and supply-chain security requires a multi-layer approach that includes prevention, detection, and response strategies and actions. The battle against counterfeit medicines requires a comprehensive resource that addresses areas of vulnerability in the medical product supply chain and contains recommended best practices and tools to prevent and detect substandard and falsified medical products before they reach consumers. Such a resource must also provide tools to efficiently and effectively respond to incidents involving substandard and falsified medical products.

Consider the FDA's Supply Chain Security Tool Kit announced earlier this year. The toolkit contains training materials intended to educate regulators, industry, health care professionals, and others on a particular part of the supply chain in 10 categories:

- good manufacturing practices;
- good distribution practices;
- good import/export practices;
- clinical/retail pharmacy practices;
- product security;
- detection technology;
- internet sales;
- track and trace systems;
- surveillance and monitoring; and

- single points of contact.



http://www.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf

According to the FDA, “The toolkit will be used by industry stakeholders and regulators from around the globe to adopt best practices, for training purposes, and to strengthen laws and regulations to protect consumers from unsafe and substandard drug products. APEC Training Centers of Excellence for Regulatory Science (CoE) will be established to further training and use of the toolkit.”^{xlix}

This is an important and timely effort and should be supported with more than just rhetoric. As we enter into PDUFA reauthorization discussions^l, support of this initiative should be a priority.

But the FDA can do more. As the strongest link in the chain, the FDA must also be at the forefront of stronger criminal prosecution (in close collaboration with the Department of Justice), enhanced enforcement of dietary supplement health claims (together with the FCC and the Department of Commerce), targeted education efforts to oncology professionals (physicians, nurses, pharmacists), patients, caregivers and payers (alongside the National Cancer Institute).

It is also important that the FDA not undermine its own efforts by “going soft” on ill-considered policies that support the importation of foreign prescription medicines (see above section, “Bad Policy Ideas Have Negative Real-World Consequences”). Just as the embrace of specialty

pharmacy has created an opportunity for criminal counterfeiting, so too does the patina of FDA “approval” of the importation concept. It is essential that the FDA actively avoid allowing its own words to provide cover for those who would harm the public health for their own profit. Friendly fire is often the most costly.

Moving Forward: 10 Steps to Victory

1. **Increase awareness of counterfeit threat**, particularly associated with life-extending/saving medicines, among patients and health care providers
2. **Differentiate target audiences** – Demand reduction for Patients/HCPs to prevent inadvertent purchase of suspect product. Partner with law enforcement to address willful violators.
3. **Demand reduction must be measurable** (per HHS/OIG report).
4. **Create personal serialization validation tools** to enable patient participation.
5. **Conduct a CDC “Epidemiology of Counterfeit Medicines” study** – how many patients actually die or are seriously harmed by counterfeit oncology medicines? Who are they?^{li}
6. **Enhance productive industry/government intelligence/information exchange.**
7. **Better use of existing government resources and authorities** for more effective protection of patients/citizens.
8. **Enhance Industry/Government collaboration on demand reduction.**
9. **Eliminate use of the internet as a commercial platform** by effectively educating and partnering with recalcitrant ISPs.^{lii}
10. **Increase awareness programs for the general population** of the problem and of programs that reduce co-payment costs.

Concluding Thoughts

The unfortunate reality is that urgent public health issues (such as COVID-19 and the danger of counterfeit drugs) that should be strictly non-political are being seen, first-and-foremost, as opportunities by special interest groups and many of our elected representatives to “score points.” The media, alas, swarms to cover these blood feuds, almost entirely obfuscating the scope and severity of the problem. When it comes to counterfeit drugs, the alarm bells sounded by the biopharmaceutical industry are too often waved off as an attempt to distract attention from “the high cost of drugs.” While such exhortations are tactically successful in attracting transient media coverage, it does a tremendous disservice to the public by masking the urgency of the problem.

As Scientific American reports, “In a fiercely competitive business. For those who like pharma scandals, their paper offers detailed examples, *a la* “The Constant Gardener,” of pharmaceutical companies trying to bury their problems quietly.”^{liii}

During my tenure on the FDA’s Counterfeit Drug Task Force, I witnessed first-hand the evolution of thinking within the biopharmaceutical industry. Initially, as suggested by Scientific American article, industry’s response was to address the problem but say nothing publicly for fear of counterfeit drugs tainting their own reputation. When pressed by the FDA Task Force to take a more public leadership position, industry swiftly stepped up to the plate, partnering with the FDA and other government agencies (on both the federal and state levels) to more publicly and aggressively address the problems associated with mitigating and preventing the growth of counterfeit drugs in the United States.

Per Scientific American, “Pharma shows increased recognition that openness to the problem and notification of the public is not only the appropriate response but will likely reduce their liability and is otherwise in their self-interest.”^{liv}

According to the FDA Task Force’s initial report, “Based on what it has heard to date, the Task Force believes that the most constructive approach to addressing the problem of counterfeit drugs lies in identifying vulnerabilities in the drug distribution system and addressing those vulnerabilities with a multi-pronged approach.”

It isn't the "cost of drugs" drives desperately ill patients into the arms of counterfeiters, it is, in the majority, the cost of patient co-pays. Larger and larger co-pays and out-of-pocket costs magnify the problem by creating a criminal opportunity. Better, more targeted and aggressive regulation together with more regular and robust law enforcement is key – but when patients cannot afford their co-pay for life-saving medicines, the incentive for quick fix solutions via a website that promises to provide the genuine article is almost irresistible.

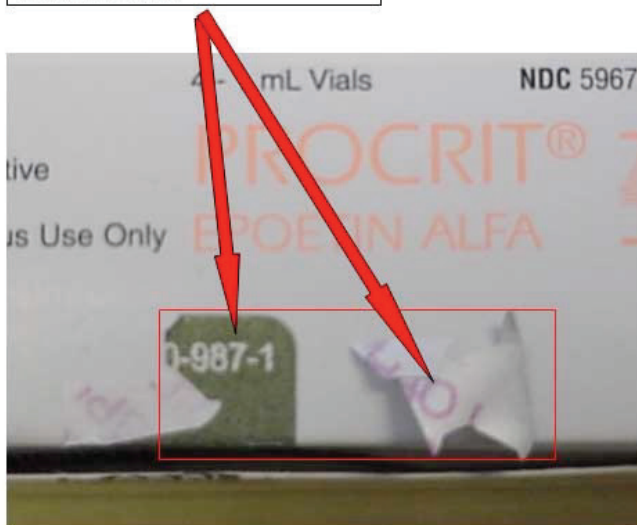
As the old Yiddish proverb reminds us, "Sometimes a bargain is too expensive." And sometimes its deadly. The time is now. Action must be taken. Attention must be paid.

###

APPENDIX A

Examples of Counterfeit Biologics Packaging

Authentic PROCRT carton P004677 and P007645. Carton closure seals are designed to breakaway and leave a residue on the box when removed. The words "OBPLP VOID" in random order should appear on the underside of the label or residue.



AMGEN



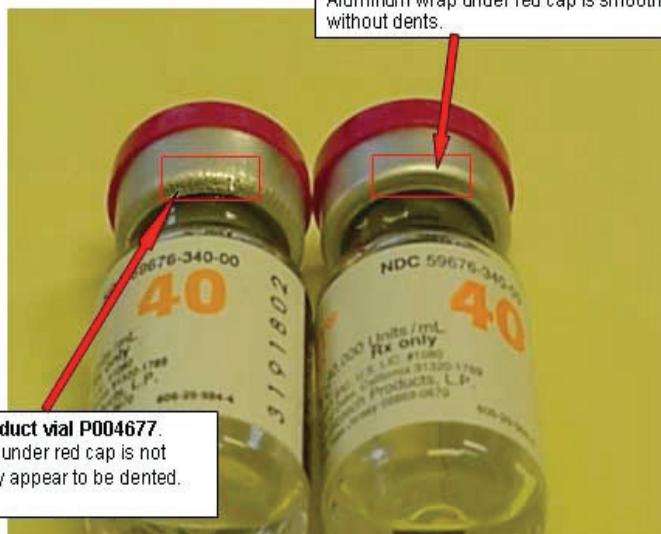
Blue Amgen logo is seen when held at waist height.

COUNTERFEIT



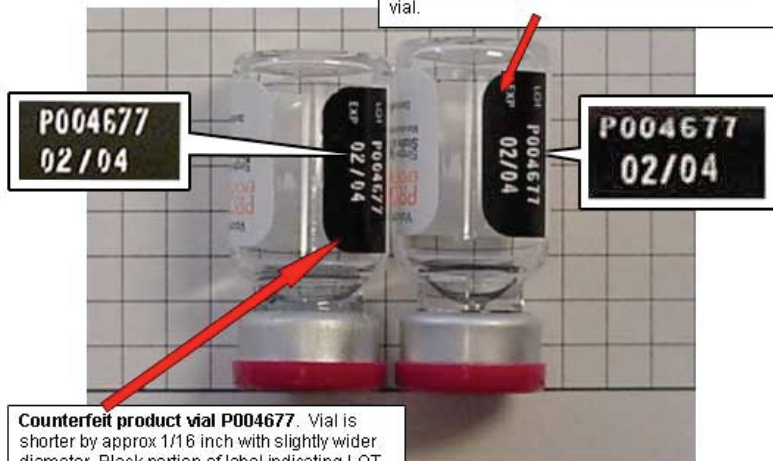
Blue Amgen logo is seen when held at waist height.

Authentic PROCIT vial P004677.
Aluminum wrap under red cap is smooth without dents.



Counterfeit product vial P004677.
Aluminum wrap under red cap is not smooth and may appear to be dented.

Authentic PROCRIT vial P004677. Vial is taller by approx. 1/16 inch with slightly smaller diameter. Black portion of label indicating LOT and EXP is secured to vial and does not appear to be pulling away. Font is larger, there is no strike-thru on number "7". Label is secured to vial.



Counterfeit product vial P004677. Vial is shorter by approx 1/16 inch with slightly wider diameter. Black portion of label indicating LOT and EXP is not secured to vial and may appear to be pulling away. Font is smaller, and there may be a strike-thru on number "7".

About the Author

Peter J. Pitts is President of the Center for Medicine in the Public Interest. A former member of the United States Senior Executive Service, Pitts was FDA's Associate Commissioner for External Relations, serving as senior communications and policy adviser to the Commissioner. His comments and commentaries on health care policy issues regularly appear in The New York Times, The Washington Post, The Wall Street Journal, the Lancet, Nature Biotechnology, among others. He is the editor of **Coincidence or Crisis**, a discussion of global prescription medicine counterfeiting, **Physician Disempowerment: A Transatlantic Malaise** and **Commonsense Healthcare Policy for Commonsense Americans**. He is a Visiting Professor at the University of Paris, Descartes Medical School, a Visiting Lecturer at the École Supérieure des Sciences Économiques et Commerciales (Paris and Singapore), and has served as an adjunct professor at Indiana University's School of Public and Environmental Affairs and Butler University.

-
- ⁱ <https://www.pharmaceutical-technology.com/features/featuretackling-counterfeit-viagra-4970635/> Last accessed June 4, 2020
- ⁱⁱ <https://www.cnbc.com/2018/08/02/antianxiety-drugs-fuel-the-next-deadly-drug-crisis-in-us.html> Last accessed June 4, 2020
- ⁱⁱⁱ <https://www.dea.gov/press-releases/2019/11/04/dea-issues-warning-over-counterfeit-prescription-pills-mexico-0> Last accessed June 4, 2020
- ^{iv} <https://www.medscape.com/viewarticle/460566> Last accessed June 4, 2020
- ^v <https://www.fda.gov/media/77086/download>
- ^{vi} <https://www.congress.gov/bill/111th-congress/senate-bill/3690> Last accessed June 4, 2020
- ^{vii} <https://www.c-span.org/video/?295894-4/margaret-hamburg-remarks-counterfeit-perscription-drugs> Last accessed June 4, 2020
- ^{viii} <https://nabp.pharmacy/newsroom/news/nabp-issues-rogue-online-pharmacy-public-health-alert/> Last accessed June 4, 2020
- ^{ix} <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1305&showFR=1&subpartNod e=21:9.0.1.1.6.3> Last accessed June 4, 2020
- ^x <https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1022&context=ijl> Last accessed June 4, 2020
- ^{xi} https://en.wikipedia.org/wiki/Sutton%27s_law Last accessed June 4, 2020
- ^{xii} <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary> Last accessed June 4, 2020
- ^{xiii} <https://www.fda.gov/drugs/counterfeit-medicine/health-care-provider-alert-another-counterfeit-cancer-medicine-found-united-states> Last accessed June 4, 2020
- ^{xiv} <https://www.justice.gov/opa/pr/ukrainian-men-plead-guilty-conspiracy-and-trafficking-counterfeit-cancer-and-hepatitis-drugs> Last accessed July 27, 2020
- ^{xv} <http://www.safemedicines.org/wp-content/uploads/2020/07/Nienadov-and-Nikolaenko-Superseding-Indictment.pdf> Last accessed July 27, 2020
- ^{xvi} <http://www.safemedicines.org/wp-content/uploads/2019/09/Nienadov-Plea-Agreement.pdf> Last accessed July 27, 2020
- ^{xvii} <https://cmlnetwork.ca/counterfeit-iclusig-ponatinib/> Last accessed June 4, 2020
- ^{xviii} <https://www.theguardian.com/society/2019/feb/12/fake-cancer-drug-made-from-paracetamol-world-health-organization> Last accessed June 4, 2020
- ^{xix} <https://www.interpol.int/News-Events/2018/N2018-123> Last accessed June 4, 2020

-
- ^{xx} <https://www.healthcarepackaging.com/markets/pharmaceutical/news/13294907/counterfeiters-move-from-lifestyle-drugs-to-lifesaving-drugs> Last accessed June 4, 2020
- ^{xxi} <https://cmpi.org/in-the-news/health-care-chutzpah-vs-health-plan-literacy> Last accessed June 4, 2020
- ^{xxii} <https://www.taftlaw.com/news-events/law-bulletins/hhs-oig-approves-narrowly-tailored-patient-assistance-program> Last accessed June 4, 2020
- ^{xxiii} <https://www.cbc.ca/news/thenational/national-today-newsletter-counterfeit-drugs-medicine-1.5014784> Last accessed June 4, 2020
- ^{xxiv} https://en.wikipedia.org/wiki/Specialty_pharmacy Last accessed June 4, 2020
- ^{xxv} https://en.wikipedia.org/wiki/Specialty_drugs_in_the_United_States Last accessed June 4, 2020
- ^{xxvi} <https://www.drugchannels.net/2019/04/the-specialty-pharmacy-boom-our.html> Last accessed June 4, 2020
- ^{xxvii} <https://www.dispatch.com/news/20180603/mail-order-pharmacy-system-delays-meds-for-some-patients> Last accessed June 25, 2020
- ^{xxviii} https://www.nola.com/entertainment_life/health_fitness/article_6ad30efb-0cca-5900-90ed-62badf5ac35b.html Last accessed June 25, 2020
- ^{xxix} <https://www.spokesman.com/stories/2018/dec/05/peoples-pharmacy-will-breast-cancer-drug-work-if-s/> Last accessed June 25, 2020
- ^{xxx} <https://www.aniglobalsource.com/blog/serialization-what-it-means-for-pharmaceutical-manufacturing> Last accessed June 4, 2020
- ^{xxxi} <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa> Last accessed June 4, 2020
- ^{xxxii} Ibid Last accessed June 4, 2020
- ^{xxxiii} <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act> Last accessed June 4, 2020
- ^{xxxiv} <https://www.newsweek.com/big-pharma-villain-pbm-569980> Last accessed June 4, 2020
- ^{xxxv} <https://www.pewtrusts.org/-/media/assets/2014/04/29/boozallenhamiltonreport.pdf> Last accessed June 4, 2020
- ^{xxxvi} <https://oig.hhs.gov/oei/reports/oei-05-17-00460.pdf> Last accessed June 4, 2020
- ^{xxxvii} <https://www.safemediines.org/2019/01/raid-in-british-columbia-canada-turns-up-a-pill-press-and-over-100-different-pill-dyes.html> Last accessed June 4, 2020
- ^{xxxviii} <https://www.safemediines.org/2015/10/5-secrets-canadian-pharmacies-dont-want-you-to-know.html> Last accessed June 4, 2020
- ^{xxxix} <https://www.nytimes.com/2004/08/11/us/vermont-will-sue-us-for-the-right-to-import-drugs.html> Last accessed June 4, 2020
- ^{xl} <https://www.safemediines.org/wp-content/uploads/FDA-Operation-Reveals-Many-Drugs-Promoted-as-Canadian-Products-Really-Originate-From-Other-Countries-captured-January-2017.pdf> Last accessed June 4, 2020
- ^{xli} <https://www.safemediines.org/2015/11/illinois-and-isavrx.html> Last accessed June 4, 2020
- ^{xlii} <https://www.canada.ca/en/health-canada/corporate/about-health-canada.html> Last accessed June 4, 2020
- ^{xliii} <http://www.safemediines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf> Last accessed June 4, 2020
- ^{xliv} <https://www.safemediines.org/2018/07/who-opposes-drug-importation-every-head-of-the-fda-and-hhs-since-2000.html> Last accessed June 4, 2020
- ^{xlv} <https://www.hhs.gov/about/news/2019/07/31/hhs-new-action-plan-foundation-safe-importation-certain-prescription-drugs.html> Last accessed June 4, 2020
- ^{xlvi} <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.20.3.92> Last accessed June 4, 2020
- ^{xlvii} Author's conversations with Canadian government officials
- ^{xlviii} <https://www.fda.gov/consumers/consumer-updates/beware-fraudulent-coronavirus-tests-vaccines-and-treatments> Last accessed June 4, 2020
- ^{xlix} <https://www.fda.gov/drugs/drug-supply-chain-integrity/fda-leads-effort-create-supply-chain-security-toolkit-medical-products> Last accessed June 25, 2020
- ⁱ <https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-fiscal-years-2018-2022> Last accessed June 25, 2020
- ⁱⁱ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6164397/> Last accessed June 4, 2020

ⁱⁱⁱ <https://www.fraserinstitute.org/sites/default/files/pharmaceutical-counterfeiting-endangering-public-health-society-and-the-economy.pdf> Last accessed June 4, 2020

ⁱⁱⁱ <https://blogs.scientificamerican.com/molecules-to-medicine/counterfeit-drugs-a-deadly-problem/> Last accessed June 4, 2020

^{liv} Ibid Last accessed June 4, 2020



The Center for Medicine in the Public Interest is a nonprofit, non-partisan 501(c)(3) organization promoting innovative solutions that advance medical progress, reduce health disparities, extend life and make health care more affordable, preventive and patient-centered. CMPI also provides the public, policymakers and the media a reliable source of independent scientific analysis on issues ranging from personalized medicine, food and drug safety, health care reform and comparative effectiveness.



Drugwonks.com is the web log of the Center for Medicine in the Public Interest (CMPI), a forum offering rigorous and compelling research on the most critical issues affecting current drug policy.