

Combatting Substandard and Falsified Medicines



ISSUE: Substandard and falsified medicines—drugs that are of poor quality or “fake”—pose a grave global health threat, causing more than a million patient deaths a year,¹ reducing the effectiveness of medical treatment, contributing to drug resistant infections,² depleting national health resources, and posing a threat to domestic security.

POSITION

USP⁴ supports a comprehensive public policy framework to combat substandard and falsified medicines,⁵ including advancing stewardship of quality pharmaceutical products and practices, and building the capacity to prevent, detect, and respond to threats.

Key elements include awareness; better data; compliance with quality standards; strengthening regulatory and quality systems; increasing resources for regulatory agencies responsible for oversight and enforcement; and enhancing the ability to approve, bring to market, and maintain the availability of quality drug therapies, through appropriate incentives and investment.

- 1. Raise awareness** of the problem of substandard and falsified medicines, elevating the issue for practitioners, patients, and policymakers through outreach campaigns about risks and possible responses.^{6,7}
- 2. Develop better data and rigorous research** to inform evidence around the scope, scale, and harm of substandard and falsified medicines and drive implementation of solutions.^{8,9}
- 3. Ensure that medicines meet quality standards.** Quality standards of pharmacopeias around the world¹⁰ help ensure the identity, strength, quality, and purity of a medicine, providing a measure to which to test—helping to keep substandard and falsified medicines out of the market and assisting manufacturers in ensuring compliance with Good Manufacturing Practices (GMPs) and other available standards.

- 4. Enhance the capacity of regulatory authorities, manufacturers, and other stakeholders,** especially in low-income countries, to help ensure quality, safe and beneficial medicines and establish a strong framework to prevent, detect, and respond¹¹ to threats of substandard and falsified products in order to secure the supply chain.¹²
- 5. Support increased resources for regulatory and enforcement oversight authorities.** Encourage greater funding and international cooperation to secure supply chains and identify and prosecute illegal activity.¹³ Successful approaches include:
 - Advancing training to build skills and knowledge of enforcement agencies,¹⁴
 - Building partnerships across the globe,¹⁵ and
 - Implementing strategies with respect to use of informational tools.¹⁶
- 6. Advance market incentives and investment to encourage the development and continued availability of safe, effective and quality medicines by legitimate manufacturers,** including facilitating regulatory access and ensuring adequate payment mechanisms. Shortages in quality-assured medicines hinder treatment and create an environment for substandard and falsified medicines to flourish.¹⁷ Potential solutions include:
 - Financial or other economic incentives for product innovation and quality,¹⁸
 - Making investment in high-quality manufacturing, including possible payer-based incentives,¹⁹
 - Making use of prequalification programs to identify high quality medicines for procurers,²⁰ and
 - Facilitating streamlined regulatory agency approval of medicines that have been prequalified.²¹



BACKGROUND

I. What are Substandard or Falsified Medicines?

A number of terms have been used to describe medicines that are poor quality or “fake.” The Institute of Medicine (IOM) uses the term “**falsified and substandard drugs**,”²² the WHO previously used the term “**substandard/spurious/falsely labeled/falsified/counterfeit (SSFFC) medical products**” but recently adopted similar nomenclature to the IOM.²³

The U.S. FDA has spoken about the problem of **counterfeit and substandard drugs, stolen or diverted product, expired products, adulterated products, or unapproved or otherwise substandard products**.²⁴

A substandard or falsified medicine frequently may contain no active ingredients, less than the required amount of active ingredients, too much of the active ingredients, or ingredients not described on the package label.^{25,26} **Both types of products may have ingredients that are toxic (e.g., boric acid, leaded road paint, floor and shoe polish, talcum powder, chalk, brick dust, and nickel).**^{27,28}

II. Why Should We Be Concerned?

Substandard and falsified medicines are a global “pandemic,”²⁹ an “urgent threat,”³⁰ and “an unacceptable risk to public health,”³¹ affecting every region and encompassing a wide range of medicines, including vaccines and diagnostics.³² Substandard and falsified medicines can cause adverse and fatal side effects or death³³ and can increase the risk of antimicrobial resistance (AMR), for example, drug resistant tuberculosis (TB) or malaria.³⁴

Facts
 Globally:
Roughly 10% of medicines worldwide are falsified; ³⁵ in some countries, falsified pharmaceuticals account for 70 percent of all drugs in the supply chain. ³⁶ It is estimated that one third of malaria medicines used in East Asia and sub-Saharan Africa are fraudulent. ³⁷
Substandard and falsified medicines for TB and malaria contribute to 700,000 deaths per year globally. ³⁸
A 2015 review of 17,000 drug samples, including anti-malarials, anti-tuberculosis medicines, and antibiotics, found that up to 41% failed to meet quality standards. ³⁹
90% of medicines used to treat post-partum hemorrhage in Ghana failed tests for quality. ⁴⁰

In just one year, a projected 122,000 children under the age of five from 39 sub-Saharan African countries lost their lives as a result of counterfeit anti-malarials alone. ⁴¹
In 2012, more than 200 patients in Pakistan died and around 1000 became seriously ill after receiving heart medication that had been accidentally contaminated with large quantities of an antiparasitic drug during the manufacturing process. ⁴²
IN THE UNITED STATES:
In 2007 and 2008, dozens of patients in the U.S. suffered adverse events and several lost their lives due to intentionally adulterated heparin (a blood thinner) imported from China that had entered the Chinese heparin supply purporting to be pure heparin. ⁴³
In 2012, contaminated injectable compounded sterile preparations caused a fungal meningitis outbreak: more than 70 people died and over 750 cases of infection were reported in 20 states. ⁴⁴ That same year, 43 patients developed fungal eye infections from contaminated compounded sterile ophthalmic drug products. At least 29 suffered vision loss. ⁴⁵
1,400 adverse reactions to falsified drugs have been reported to the U.S. FDA since 2010. ⁴⁶
750,000 jobs have been lost in the U.S. due to falsified medicines, and American companies have incurred more than \$200 billion in annual losses. ⁴⁷
Falsified medicines containing fentanyl, a powerful opioid, as a hidden ingredient are killing people all over the U.S., according to the U.S. Drug Enforcement Agency (DEA), raising serious national security as well as public health concerns. ⁴⁸
In March 2016, law enforcement officers in Ohio seized 500 pills that were marked as oxycodone but instead contained the research chemical U-477, a dangerous synthetic opioid not studied for human use. ⁴⁹

III. The Global Supply Chain

A. Situation

Medicines and ingredients are part of a complex global supply chain: before a product even reaches the patient, multiple ingredient manufacturers, suppliers, and distributors from different parts of the world have participated in making, storing, and handling the product.⁵⁰ Nearly 40% of U.S. drugs are made overseas; approximately 80% of active ingredients are also imported.⁵¹ The increasingly interconnected world has accelerated this trend.⁵²

While the U.S. drug supply chain remains one of the safest in the world, this complex supply chain can potentially result in ineffective or unsafe drugs entering U.S. distribution. Threats include counterfeiting/false drugs, diversion, cargo theft, and importation of unapproved or otherwise substandard drugs.⁵³

Outside the U.S., the problem is compounded in low-and middle income countries that have weak or under-resourced infrastructures for regulating medicines—opening the door for the distribution of substandard and counterfeit medicines—including attenuation of drugs through weak supply chains (for example, degradation of a heat-sensitive product by the time it reaches the patient).

Poor quality encompasses a range of issues, including expired medicines or products that are not fully efficacious. For example, in many African countries, regulatory systems are not fully equipped to detect substandard and falsified drugs, and policies preventing the sale and distribution of such medicines are either lacking or not followed.

In the U.S. and abroad some consumers seeking to save money on prescriptions or who lack adequate coverage have turned to online pharmacies. While there are legitimate online pharmacies, patients are at risk of purchasing dangerous poor-quality, or falsified medicines.⁵⁴ According to some estimates, 96% of online prescription drug sellers are not in compliance with pharmacy laws and safety standards.⁵⁵

B. Global Approaches

Around the world, governments and industry are implementing programs to advance quality and combat substandard and falsified medicines, including:

1. Prevention, Detection, and Response Framework

Regulators such as US FDA^{56, 57} and WHO⁵⁸ are advancing frameworks pointing to prevention, detection, and response strategies. Elements include prevention (reducing manufacture of substandard and falsified products and improving supply chain integrity); detection (improving surveillance, effective investigation, effective confirmation of suspect products); and response (increased notification, improved removal from market, containment, and enforcement).⁵⁹ A key element is collaboration, sharing information, and working regionally and multilaterally.⁶⁰

2. Compliance with Quality Standards

Standards for the identity, strength, quality, and purity of medicines are important constituents of a comprehensive prevention, detection, and response framework. Medicine

quality can be defined as “a balanced, risk-based set of characteristics, systems, and requirements that consistently ensure a medicine’s delivery of stated and implied clinical outcomes for patients.”⁶¹ Medicines that do not meet applicable quality standards, whether inadvertently or intentionally, are compromised in identity and/or integrity, leading to adverse events, inadequate treatment, therapeutic failure, drug resistance, and reduced patient trust.

Pharmacopeial⁶² quality standards (e.g., those of USP and other world pharmacopeias) help manufacturers ensure their products are safe and reliable for patients and consumers — serving to assess the quality of a medicine through its entire lifecycle, from production to consumption, including:

- The quality of raw materials used to make the medicine, including active pharmaceutical ingredients and excipients (the nonactive part of the medicine)
- The manufacture of the finished product
- General standards that ensure the proper dosage, control of impurities, toxins, etc. (including for compounded preparations).

Quality standards are a key part of the adulteration and misbranding provisions of the Federal Food, Drug, and Cosmetic Act (FDCA). Under the FDCA, drugs and ingredients imported into or marketed in the United States must comply with applicable *United States Pharmacopeia-National Formulary (USP-NF)* standards for identity, strength, quality, and purity, and those requirements are enforceable by US FDA.⁶³ Such quality standards are also part of the effort to help ensure compliance with GMPs and various other provisions that help ensure good quality medicines and monitor for falsified and substandard products.

3. Quality Assurance, Regulatory Systems Strengthening, and Surveillance

Countries with a higher incidence of substandard and falsified medicines generally lack appropriate product registration; good laboratories that can test product quality; a mechanism for surveillance and monitoring; and appropriate oversight, compliance and enforcement to remove compromised products from the market.⁶⁴

It is critical to invest in and build strong, sustainable quality assurance systems and robust post market quality surveillance as part of an overall prevention, detection, and response framework for medicines. Building local capacity and introducing innovative safeguards (i.e., surveillance technologies) helps to eliminate substandard and falsified



products. *Publicly available test specifications supported by acceptable procedures and reference materials are key to the implementation of surveillance programs, serving as an important adjunct to other methods, such as visual inspection.*

The United States Agency for International Development (USAID) funds and USP administers⁶⁵ an effort to improve the supply and availability of quality-assured essential medicines and medical products by strengthening regulatory systems and building manufacturing capacity in low-and middle-income countries, including building product quality surveillance systems and helping to detect substandard and falsified products. Other Initiatives exist through the WHO,⁶⁶ the World Bank,⁶⁷ and other organizations.

The U.S. Department of Health and Human Services (HHS) is working globally to help expand regulatory frameworks, believing that “effective regulatory frameworks, transparent and accountable manufacturing and supply chain systems, and strong regulatory and procurement authorities are central to assuring the safety, quality, and availability of food and medical products in an effective public health system. Global manufacturing and supply chains are complex networks, with many potential vulnerabilities and risks.”⁶⁸

4. Solutions to Address Online Pharmacies

Illegitimate online pharmacies can expose patients to the risk of purchasing bad and even dangerous medicine. A number of solutions have been proposed:

- In the United States, the National Association of Boards of Pharmacy (NABP) runs the Verified Internet Pharmacy Practice Sites (VIPPS) accreditation program⁶⁹ to recognize safe online drug stores. Accredited online pharmacies comply with state licensing requirements for both the state that the pharmacy is in and all the states in which it sells, including authentication of prescriptions, observance of quality-assurance standards, and submission to regular state inspection.
- The “.Pharmacy” Verified Websites program, also spearheaded by NABP, identifies pharmacy-related websites around the world that are safe and legitimate and allows them to use a special “.Pharmacy” Internet domain so customers know to look for them.⁷⁰ Applicants must meet specified core standards to be eligible.⁷¹
- The Alliance for Safe Online Pharmacies⁷² works globally to support measures to combat illegal online pharmacies and promote those that are legitimate, including through use of the NABP accreditation program and “.Pharmacy.”

- LegitScript operates a site to help determine whether Internet pharmacies, supplement sellers, and other online merchants are legitimate.⁷³

USP’s Role

USP is a public health organization committed to quality, including supporting a prevention, detection, and response framework for medicines globally.

The organization is an independent, science-based nonprofit founded in 1820 that safeguards the public’s health globally through quality standards for medicines, dietary supplements, food ingredients, and healthcare quality. USP standards describe specifications and tests for identity, strength, quality, and purity.

USP’s standards are developed through a network of independent experts⁷⁴ in a transparent scientific process with input from stakeholders and Federal agencies such as the U.S. FDA. They are enforceable by U.S. FDA for medicines and their ingredients imported into or marketed in the United States, and have been used in more than 140 countries globally. Such standards also assist industry in the development and testing of medicines, increasing quality of manufacturing and furthering good distribution practices.

USP participates in and helps to advance cross sector partnerships that support pharmaceutical quality and build regulatory and surveillance capacity. USP offers resources in under-resourced countries to help combat substandard and falsified drugs; USP works closely with USAID, WHO, and others globally to strengthen monitoring and surveillance systems—building a body of evidence and serving as a rapid alert to identify problems.

The Promoting the Quality of Medicines (PQM)⁷⁵ program is a United States Agency for International Development (USAID) funded initiative implemented by USP, working with medicines regulatory authorities, manufacturers, quality control professions and others in over 35 countries across 4 continents to improve public health by building local capacity to ensure quality medicines.

Regulatory System Building and Strengthening & Working with Manufacturers to Increase the Supply of Quality Medicines:

USP supports the development of local, sustainable quality assurance systems by helping local governments, regulators and manufacturers in low-and



middle-income countries to ensure quality medicines—offering education, outreach, and technical assistance. USP offers these services in partnership with, among others: USAID, national regulatory authorities, WHO, the Global Fund, the World Bank, and the New Partnership for Africa's Development (NEPAD). USP works closely with manufacturers to improve compliance with applicable standards and facilitate approvals for new antimicrobial drugs.

Surveillance: USP establishes and supports countries to build capacity for surveillance programs in Africa, Asia and South America to identify substandard and falsified medicines and take these products out of circulation. As part of that effort, USP also maintains the **Medicines Quality Database**,⁷⁶ a free, publicly available tool that monitors the quality of drugs in over 30 low-and middle-income countries and evaluates the capabilities of medicine quality screening technologies; the organization is engaged in work around large-scale sampling and statistical analysis.

Quality in the Supply Chain: To help secure medicine quality throughout the entire lifecycle and across the supply chain, integrate knowledge and best practices, and promote international cooperation and communication, USP is piloting an effort with the Asia Pacific Economic Cooperation (APEC), a regional economic forum—supporting a center of excellence within APEC that is raising awareness about quality and making tools available to improve quality.

Awareness: USP is a longstanding proponent of raising awareness and taking action to improve medicine quality. Recognizing the key role that quality standards play in improving public health outcomes, USP is steadfast in its commitment to be a leading advocate for the use of quality standards throughout the world.

Convening: USP works to convene stakeholders—for example, bringing together representatives of NGOs and others at the 2017 World Health Assembly to identify the role of medicine quality in AMR. USP also recently convened stakeholders in India to identify options to improve medicine quality.

To learn more about what USP is doing to help prevent substandard and falsified medicines, please go to usp.org/global-health-programs.

1 Insight Crime, “Counterfeit Drugs Kill 1 Mn People Annually: Interpol.” <http://www.insightcrime.org/news-briefs/counterfeit-drugs-kill-1-million-annually-interpol>.

2 Id.

3 See “Countering the Problem of Falsified and Substandard Drugs,” Committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products, Institute of Medicine (IOM), <https://www.nap.edu/read/18272/chapter/1> (2013).

4 USP is an independent public health organization established in 1820. USP develops transparent standards of quality for medicines, dietary supplements and foods, working with a network of independent experts. USP collaborates with the U.S. Food and Drug Administration (FDA) and other Federal agencies; USP standards for drug quality have been recognized in Federal law since 1906 and are enforceable by FDA.

5 Internationally, the phrase “medical products” is sometimes used in lieu of “medicines”: this paper uses “medicines” throughout as a shorthand.

6 FDA, “Counterfeit Drugs: Fighting Illegal Supply Chains,” testimony of Howard Sklamberg, Deputy Commissioner for Global Regulatory Operations and Policy, Food and Drug Administration, before the Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, U.S. House of Representatives, February 27, 2014, <https://www.fda.gov/newsevents/testimony/ucm387449.htm> (FDA is educating consumers and the healthcare community, including through public awareness campaigns, about the risks of counterfeit and substandard drug products).

7 Efforts to build awareness include Fight the Fakes, <http://fightthefakes.org/>, which encourages organizations and individuals around the world to help spread the word about the problem of counterfeit and substandard medicines.

8 In 2013 the World Health Organization (WHO) launched a global surveillance and monitoring system to encourage Member States to report incidents of substandard and falsified medicines in order to develop a more accurate and validated assessment of the scope, scale, and harm caused by these products. Products have so far been reported representing all main therapeutic categories and representing both innovator and generic medicines. WHO, fact sheet, Substandard, spurious, falsely labeled, falsified, and counterfeit (SSFFC) medical products, <http://www.who.int/mediacentre/factsheets/fs275/en/>; WHO, SSFFC: Frequently asked questions, http://www.who.int/medicines/regulation/ssffc/faq-ssffc_1-10/en/.

9 Global Medicines Integrity: Landscape Assessment of Current Progress and Future Ambitions, Development Finance International, Inc., 2015 (“data is not robust enough to galvanize public consciousness and political will. Awareness of the problem is uneven across geographies, and not yet at a ‘tipping point,’ and the data on public health impact, which is essential to heighten awareness, is deficient.”) See also, Counterfeit or substandard antimicrobial drugs, a review of the evidence, J Antimicrob Chemother (2007) 60 (2): 214-236 (“to implement effective countermeasures against counterfeit and substandard drugs, there is a need for more data...”), <https://academic.oup.com/jac/article/60/2/214/710135/Counterfeit-or-substandard-antimicrobial-drugs-a>.

10 E.g., USP, www.usp.org; the European Pharmacopoeia (EP), <https://www.edqm.eu/en/european-pharmacopoeia-background-50.html>; British Pharmacopoeia (BP), <https://www.pharmacopoeia.com/>; Japanese Pharmacopoeia (JP), <http://www.pmda.go.jp/english/rs-sb-std/standards-development/ip/0005.html>, and other world pharmacopoeias.

11 WHO, slide presentation (2015) on Substandard, Spurious, Falsely Labeled, Falsified and Counterfeit (SSFFC) Medical Products, http://www.who.int/medicines/technical_briefing/tbs/TBS2015_SSFFC.pdf?ua=1 (slide on Prevent-Detect-Respond Strategy).

12 See Global Medicines Integrity, Landscape Assessment, above.

13 Global Medicines Integrity, Landscape Assessment, above (“Enhanced efforts, in recent years, including coordination, have achieved tangible results in arresting criminals and seizing falsified and substandard products from the market.”)

14 See Interpol, Pharmaceutical crime, <https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime>.

15 See Interpol, Partnerships, <https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Partnerships>.

16 E.g., WHO global surveillance and monitoring system, above.

17 Malaria Journal (2016), combatting poor-quality anti-malarial medicines: a call to action (a shortage of medicines can lead to a reliance on unknown suppliers and illicit/uncontrolled supply chains, where the risk of poor-quality medicines may be greater); <https://malariajournal.biomedcentral.com/articles/10.1186/s12936-016-1357-8>.

18 See WHO, Essential medicines and health products, <http://www.who.int/medicines/innovation/en/> (WHO works to promote research and development and equitable access by stimulating innovation for health products to treat diseases that predominantly affect the poor by seeking innovative financing systems to fund such research).

19 See, for example, FDA, Strategic Plan for Preventing and Mitigating Drug Shortages (2013) (Actions for Other Stakeholders to Consider, Manufacturing Incentives), <https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf>.

20 WHO, Essential medicines and health products, Medicines Quality Assurance, http://www.who.int/medicines/areas/quality_safety/quality_assurance/en/.

21 WHO, Accelerated Registration of Prequalified FPPs (finished pharmaceutical products), <https://extranet.who.int/prequal/content/collaborative-registration-faster-registration>.

22 IOM, above.



23 WHO, Seventieth World Health Assembly update, 29 May 2017 news release, <http://www.who.int/mediacentre/news/releases/2017/dementia-immunization-refugees/en/> (substandard and falsified medical products).

24 FDA, Protecting Patients from Counterfeit and Other Substandard Drugs/Supply Chain Threats, Connie Jung, RPh, Ph.D., and Jeanne McCue, Office of Drug Security, Integrity, and Recalls, Office of Compliance/Center for Drug Evaluation and Research, <https://www.fda.gov/downloads/ForHealthProfessionals/UCM330640.pdf>.

25 CDC, Counterfeit and Substandard Antimalarial Drugs, https://www.cdc.gov/malaria/malaria_worldwide/reduction/counterfeit.html.

26 IOM, above.

27 IOM, above.

28 International Business Times, (2012) Counterfeit Drug Sales Becomes \$75 billion business, <http://www.ibtimes.com/counterfeit-drug-sales-become-75-billion-business-414654>.

29 Washington Post, "Why researchers say fake and low-quality drugs are a "global pandemic," https://www.washingtonpost.com/news/to-your-health/wp/2015/04/20/why-researchers-say-fake-and-low-quality-drugs-are-a-global-pandemic/?utm_term=.acf676324462

30 IOM, above.

31 WHO, fact sheet, "Substandard, Spurious, Falsely labeled, Falsified and counterfeit (SSFFC) medical products," above.

32 Id.

33 CDC, above.

34 Roger Bate (2012), "Substandard medicines huge threat to health in developing world," <http://www.aei.org/publication/substandard-medicines-huge-threat-to-health-in-developing-world/>.

35 Blackstone, Erwin. The Health and Economic Effects of Counterfeit Drugs. (American Health and Drug Benefits, June 2014).

36 National Crime Prevention Council, Counterfeit Drugs, Fake Drugs are Bad Medicine, <http://www.npcp.org/topics/intellectual-property-theft/counterfeit-drugs-1/>

37 United Nations Office on Drugs and Crime, Counterfeit goods, Quick Facts, <http://www.unodc.org/toc/en/crimes/counterfeit-goods.html>

38 International Policy Network, Fake drugs kill over 700,000 people every year, <http://archive.is/ipW8i>

39 National Institutes of Health. News release: Global pandemic of fake medicines poses urgent risk, scientists say. (2015), <https://www.nih.gov/news-events/news-releases/global-pandemic-fake-medicines-poses-urgent-risk-scientists-say>

40 Ghana FDA and Promoting the Quality of Medicines, 2013 Surveillance on Uteronics, http://pdf.usaid.gov/pdf_docs/PA00MRZX.pdf

41 Renschler et al. "Estimated under-five deaths associated with poor-quality antimalarials in sub-Saharan Africa," American Journal of Tropical Medicine and Hygiene, April 2015.

42 WHO, Deadly medicines contamination in Pakistan, http://www.who.int/features/2013/pakistan_medicine_safety/en/

43 House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, hearing memo, "Counterfeit Drugs, Fighting Illegal Supply Chains," memorandum, February 25, 2014, <http://docs.house.gov/meetings/IF/IF02/20140227/101804/HHRG-113-IF02-20140227-SD002.pdf>

44 CDC, Multistate Outbreak of Fungal Meningitis and Other Infections-Resources for Clinicians, <https://www.cdc.gov/hai/outbreaks/clinicians/index.html> (last updated October 30, 2015); Boston Globe, CDC investigator says fungal meningitis outbreak rivaled Ebola epidemic, January 10, 2017, <https://www.bostonglobe.com/metro/2017/01/10/cdc-investigator-says-fungal-meningitis-outbreak-rivaled-ebola-epidemic/JnvGbXIZ90MFr1z1bOr6M/story.html>

45 FDA, Testimony of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, May 23, 2013, <https://www.fda.gov/NewsEvents/Testimony/ucm353654.htm>

46 Joe Eaton, Counterfeit Drugs are Flooding the Nation's Pharmacies and Hospitals, AARP Bulletin, May 2016.

47 Blackstone, Erwin. Above.

48 DEA Intelligence Brief, Counterfeit Prescription Pills Containing Fentanyl: a Global Threat (July 2016), <https://www.dea.gov/docs/Counterfeit%20Prescription%20Pills.pdf>

49 Id.

50 USP Plans Standards on Good Distribution Practices, Desmond Hunt, (November 2013) BioPharm International, Volume 26, Issue 11. <http://www.biopharminternational.com/usp-plans-standards-good-distribution-practices-0>

51 US House of Representatives, hearing memo, above.

52 WHO, SSFFC Medical Products, Background, <http://www.who.int/medicines/regulation/ssffc/background/en/>.

53 <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm>

54 BBC, (2017) "Buying medications online 'can put health at risk,'" <http://www.bbc.com/news/health-39134061>

55 Alliance for Safe Online Pharmacies, Key Data About Online Sales of Prescription Medicines, <http://www.multivu.com/players/English/7843951-asop-csjp-ncl-fake-prescription-drugs/docs/data-about-illegal-online-pharmacies-patient-case-studies-and-law-enforcement-actions-269296036.pdf>

56 Sklamberg testimony, above.

57 The Food and Drug Administration Amendments Act of 2007 (FDAAA, P.L. 110-85) required the Secretary to "develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs." In 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA, P.L. 112-144) provided FDA with the authority to administratively detain drugs believed to be adulterated or misbranded and to destroy certain adulterated misbranded, or counterfeit drugs offered for import; and expanded registration and reporting requirements, including requiring foreign and domestic companies to provide complete information on threats to the security of the drug supply chain. In 2013, the Congress enacted the Drug Quality and Security Act (DQSA), which contained Title II, the Drug Supply Chain Security Act, to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed into the United States. 10 years after enactment the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain FDA, Drug Supply Chain Security Act, <https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/>.

58 WHO slide presentation, above.

59 FDA, Roadmap to Global Medical Product Quality & Supply Chain Security, Ilisa B.G. Bernstein, Pharm.D., J.D, U.S. Food and Drug Administration, Presented at USP APEC Center of Excellence Pilot Program, March 28, 2017.

60 Id.

61 Ron Piervincenzi, Ph.D., Promoting a Quality Culture in the Supply Chain, Presented at USP APEC Center of Excellence Pilot Program, March 28, 2017. Slide: What is Quality.

62 See What is a Pharmacopeia, <https://www.youtube.com/embed/i4TrcwOfAZY?rel=0>

63 FDCA Sections 501(b) and 502(e)(3)(b); see also 21 C.F.R. Section 299.5

64 Popular Science, 2017, Counterfeit drugs are putting the whole world at risk, <http://www.popsci.com/what-can-we-do-to-stop-fake-medicines>.

65 USP administers, with funding from USAID, the Promoting the Quality of Medicines Program; Promoting the Quality of Medicines (PQM) FY 2016 Annual Report, Submitted to the United States Agency for International Development (USAID) January 2017 (an initiative funded by USAID and implemented by USP), http://pdf.usaid.gov/pdf_docs/pa00mk28.pdf. USP also receives support from the WHO and the Global Fund to Fight AIDS, Tuberculosis, and Malaria (the Global Fund) to detect and combat substandard and falsified medicines.

66 WHO, <http://www.who.int/medicines/regulation/ssffc/capacity-building/en/>

67 World Bank, <http://projects.worldbank.org/P075056/food-drugs-capacity-building-project?lang=en&tab=overview>

68 The Global Strategy of the U.S. Department of Health and Human Services (2012) (Objective 4: Increase the Safety and Integrity of Global Manufacturing and Supply Chains); <https://www.hhs.gov/sites/default/files/hhs-global-strategy.pdf>.

69 NABP, Verified Internet Pharmacy Practice Sites Program, (VIPPS), <https://nabp.pharmacy/programs/vipps/>.

70 <https://www.safe.pharmacy/>

71 <https://www.safe.pharmacy/standards-policies/program-standards/>

72 Alliance for Safe Online Pharmacies, <https://buysafexr.pharmacy/>

73 <https://www.legitscript.com/>

74 <http://www.usp.org/expert-committees/compounding-expert-committee-work-plan>

75 <http://www.usp-pqm.org/>

76 <http://www.usp.org/global-health-programs/medicines-quality-database-mqdb>