REPORT

THE 2023 SYMPOSIUM ON PUBLIC HEALTH STRATEGIES FOR COMBATING COUNTERFEIT DRUGS

JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

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BE SAFE

The symposium, part of the BESAFE project, is supported with funding from Pfizer Inc.

A WORD FROM BESAFE TEAM

Thank you for your interest in this report.

It was our distinct honor to be the host of the first-ever Symposium on Public Health Strategies to Combat Counterfeit Drugs. This symposium was a unique opportunity to confront the escalating burden of counterfeit drugs globally.

As the host of this symposium, we recognize the gravity of the challenge we face, a challenge that extends beyond the realms of healthcare, touching the lives of millions and threatening the very fabric of public trust in pharmaceuticals.

This symposium provided a platform for collective expertise to dissect the multifaceted dimensions of this issue, aiming not only to comprehend the current burden but, more importantly, to chart a collective course toward tangible solutions from law enforcement, drug manufacturers, healthcare providers, policymakers, public health research, academia, etc. The detailed agenda and bios of our distinguished speaker are provided as annexes to this report.

Together, let us harness our efforts, knowledge, experience, and dedication to alleviate the burden of counterfeit drugs and build a future where the integrity of medications remains unwavering and patients are not exposed to substandard and falsified drugs.

Sincerely,

SAIFUDDIN AHMED, MBBS, PhD

PROFESSOR
PRINCIPAL INVESTIGATOR - BESAFE
POPULATION, FAMILY AND REPRODUCTIVE HEALTH, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

Note

The symposium used the term "counterfeit" to encompass a broad range of drug quality issues as used by the World Health Organization for poor-quality medicines: Substandard, Spurious, Falsely-labelled, Falsified, and Counterfeit (SSFFC), including unregistered/unlicensed medical products. We recognize intellectual property and trademark infringement issues associated with the counterfeit term but used it here for wider recognition of the term and viewed through a public health lens to cover all "substandard and falsified" drugs.

A GLOBAL HEALTH THREAT THAT REQUIRE A MULTIFACETED APPROACH

CYNTHIA SCHAFFER MINKOVITZ, MD, MPP

WILLIAM H. GATES, SR. PROFESSOR AND CHAIR, DEPARTMENT OF POPULATION, FAMILY AND REPRODUCTIVE HEALTH, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

More than 100,000 deaths from drug overdose with counterfeit pills take place each year in the US and that's just the tip of the iceberg. Counterfeit medicines and drugs represent a multifaceted threat that transcends all of our borders, affects both rich and poor countries, and urgently demands our unified response.

We are at a juncture where the intersection of technology, global trade, and the growing sophistication of counterfeiters has escalated the risks associated with counterfeit medicines as public health professionals. It's important that we appreciate the scale of this issue and collaborative efforts are needed to address it.

Counterfeit drugs are not just a health hazard. They mark an incredible set of health inequities, injustices, and gaps in our healthcare systems. They challenge the very framework of trust that health systems are built upon, and they exploit the vulnerabilities of the uninformed and the unprotected.

We are required to use our experiences to deepen our understanding of the risk posed by counterfeit drugs to catalyze action, drive policy, and change and inspire innovative solutions that resonate globally.

"Behind every statistic about counterfeit drugs, there is a deep and sad human story, a life that could be saved, or a life that was lost"

Dr. Cynthia Schaffer Minkovitz

"Counterfeit medicine containing no active ingredients may be just as dangerous as those containing contaminants."

Dr. Aida Habtezion
Chief Medical Officer
Head of Worldwide Medical & Safety
Pfizer

Although the burden of counterfeit drugs is often framed as a concern for developing nations, this global challenge involves both rich and poor regions of the world. Counterfeit Medicine proliferation is a significant public health threat. This poses a significant and serious risk to patient safety in the world. It has been reported that up to 500,000[1] people are killed by fake medicines in sub–Saharan Africa every year.

According to a report by the Guardian from the UK, fake drugs kill more than 250,000[2] children a year. The substances found in some of these drugs sold to treat life-threatening diseases and illnesses included substances such as printer ink, paint, and arsenic.

Several specific cases of counterfeited drugs have been reported which unfortunately threaten the lives of millions. A recent case of falsified Meronem (Meropenem trihydrate injection) was reported in Nigeria following an incident report received through a patient notification platform, concerning a suspicious Meronem which is a broad-spectrum, beta-lactam antibiotic used for complicated bacterial infection. Unfortunately, the patient did not have clinical improvement and ultimately passed away. Meronem, taken by the patient, was brought to this medical center and was obtained from an unknown source.

During investigation, a gel-like solution was found, instead of the usual Meronem solution. This case was one of many other cases of the same drug that were reported to the National Agency for Food and Drug Administration and Control (NAFDAC) which is also related to a recent Public Alert No. 036/2023 – Alert on Counterfeit Meronem 1g Injection circulating in Nigeria that was issued on November 19, 2023.[3]

Alarming Features Found [3]:

- The crimp code did not match the code reported on the production documentation batch of 2A21F11 which is the semi-finished batch used for 4A21I17. This did not meet with the Pfizer's specifications.
- The batch number and expiry date matched an authentic batch of Meronem 1g injection intended for distribution in the Egyptian market.
- The vial label compared favorably to the purported artwork version

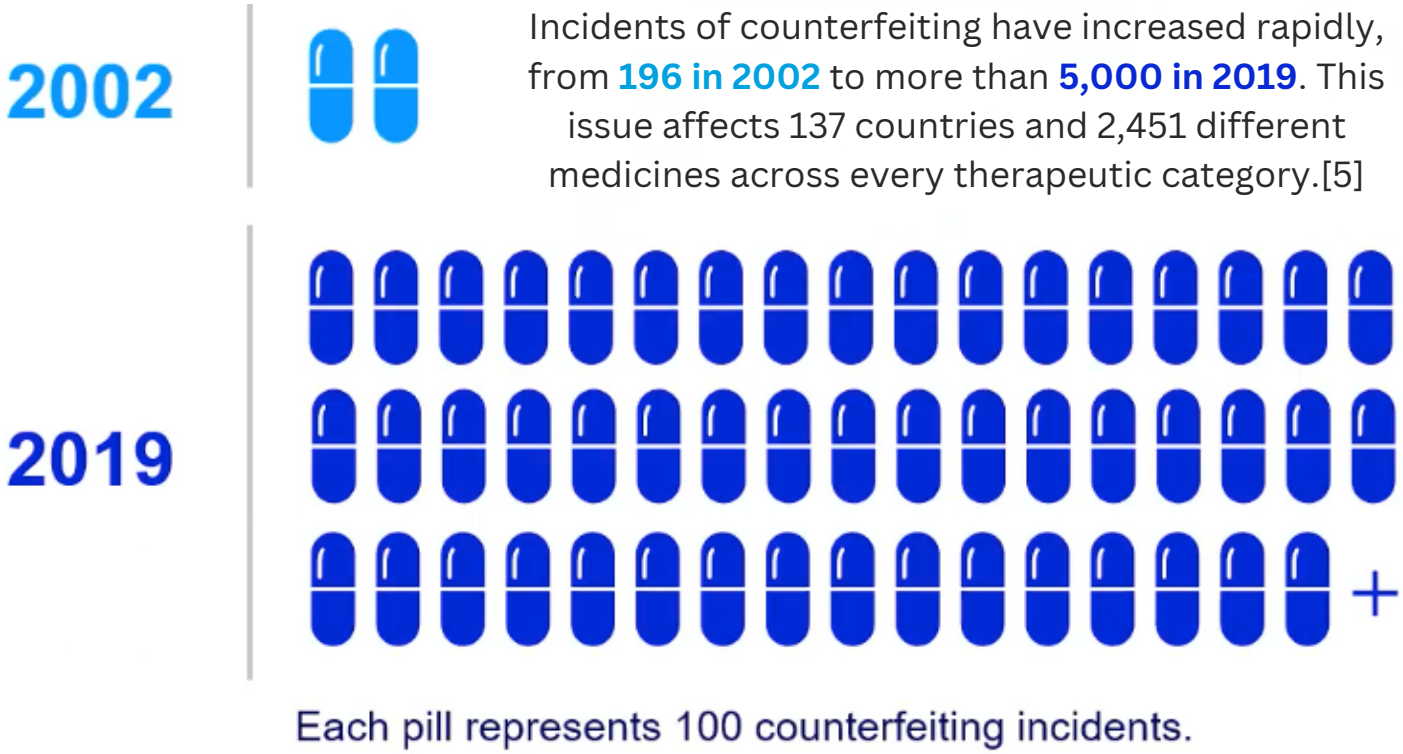
Image from the Nigeria National Agency for Food and Drug Administration and Control (NAFDAC) Public Alert - No. 036/2023

4.7%

Evidence of counterfeit pill use increased to 4.7% in the US by the end of 2021, up from 2% in 2019.[4]

33,250

There are roughly about 35,000 active online pharmacies and 33,250 (95%) of them operate in the US. A challenge to law enforcement although counterfeit pills have been seized by law enforcement agencies in every U.S. state in unprecedented quantities.[5]



Incidents of counterfeiting have increased rapidly, from **196 in 2002** to more than **5,000 in 2019**. This issue affects 137 countries and 2,451 different medicines across every therapeutic category.[5]

Pfizer

IMPACT OF COUNTERFEIT MEDICAL PRODUCTS

ECONOMIC IMPACT

- Economic loss
- Wasted resources
- Increased out-of-pocket spending

HEALTH IMPACT

- Increased mortality and morbidity (Adverse effects)
- Loss of confidence

SOCIOECONOMIC IMPACT

- Loss of productivity
- Loss of income
- Lack of social mobility
- Increased poverty

Source: WHO. A study on the public health and socioeconomic impact of substandard and falsified medical products.[5]

"We must come together as a community to support, educate and protect patients and providers from the devastating life-changing impact of counterfeit medicines"

Dr. Aida Habtezion, Chief Medical Officer , Head of Worldwide Medical & Safety, Pfizer

Counterfeit drugs have profound economic, socio-economic, and health ramifications, creating a multifaceted impact on both national and global scales. The production and distribution of counterfeit pharmaceuticals undermine the legitimate pharmaceutical industry, resulting in revenue losses and decreased investments in research and development. This economic strain not only stifles innovation but also compromises the availability of safe and effective medications.

Governments face increased healthcare costs as a consequence of treating patients with ineffective or harmful counterfeit drugs, exacerbating the financial burden on public health systems. Furthermore, the illicit trade of counterfeit drugs contributes to the growth of an underground economy, fostering criminal networks and corruption.

Further, the erosion of trust in healthcare systems also hampers economic development, as individuals may become hesitant to seek medical attention or comply with prescribed treatments due to concerns about the authenticity of pharmaceuticals.

The socio-economic impact of counterfeit drugs extends beyond monetary losses, influencing the well-being of individuals and communities. Substandard and falsified medications can lead to treatment failure, worsening health conditions, and increased mortality rates. Vulnerable populations, particularly those in developing countries with limited access to healthcare resources, bear the brunt of these consequences. The prevalence of counterfeit drugs perpetuates health inequalities, as disadvantaged communities are disproportionately affected.

In terms of health impact, the consequences of counterfeit drugs are dire and far-reaching. Individuals who unknowingly consume substandard or falsified medications face serious health risks, including treatment failure, the development of drug-resistant diseases, and adverse reactions. Ineffective treatments can exacerbate the progression of illnesses, leading to prolonged suffering and increased morbidity rates.

The global threat of counterfeit drugs also jeopardizes public health efforts, such as disease eradication campaigns and vaccination programs, as the distribution of fraudulent pharmaceuticals undermines the effectiveness of these initiatives. Ultimately, the health impact of counterfeit drugs extends beyond the immediate consequences for individuals, contributing to the global burden of disease and hindering progress in public health.

"Combating counterfeit drugs will not be successful in isolation. There is a need to further strengthen cooperation between all actors in this area."

Dr. Kunio Mikuriya
Secretary General
World Customs Organization (WCO)

Criminal organizations exploit vulnerabilities at borders by engaging in illicit trade, including sub-standard and falsified medical products, and attempting to make a huge illegal profit. During the COVID-19 pandemic, while the world experienced an unprecedented health crisis, criminal organizations have been taking advantage by engaging in fraudulent activities, thereby putting the health and safety of the world's population at serious risk. Compared with other types of illicit trade, including opioids, explosives, and revenue fraud, counterfeit medicines provide a low-risk and high-profit business opportunity. Indeed, they exploit regulatory weaknesses where Customs are not sufficiently empowered, and judiciary authorities are often less inclined to pursue the legal cases, because of the light penalties.

One of the strategies that the World Customs Organization (WCO) has implemented was to identify essential medicines and medical goods to facilitate their cross-border movement and train Customs officers around the world to identify unauthorized and falsified medicines, vaccines, and medical goods at borders. The adversary impact of counterfeit medicines on public health is well understood among experts like you, but there are also significant economic implications on individuals who might lose their employment and on governments, both in reduced tax revenue and additional expenditure for health care.

It is crucial to look at how to manage trade at borders and where supply chain vulnerabilities are found. When containers cross borders, commercial data on goods, traders, and routes among others, is generated. Customs uses this data as the basis to analyze the risks represented by each container. Commercial data, usually in the form of advanced electronic data, supplemented by the specific information and intelligence offered from both the private and public sectors are also used for non-intrusive and secondary inspections of containers.

Therefore, having access to the necessary data along the supply chain, from suppliers at the origin through intermediaries and buyers, is fundamental for Customs to secure supply chains with trusted traders, supported by the Authorized Economic Operators (AEOs) scheme to establish trust between Customs and businesses. This system is not free from vulnerability as organized crime tries to infiltrate the port areas, and this challenge calls for enhanced collaboration between the stakeholders.

Free trade zones are also vulnerable areas, and governments are urged to empower Customs to have better control of these zones while respecting 'operators' exemptions from Customs duties and tax obligations. E-commerce, which has shown exponential growth during and after the pandemic, is more vulnerable along the supply chain than traditional container trade, because of the lack of quality data in a timely manner.

Unlike container trade, those involved in e-commerce as online vendors and buyers are often consumers and micro, small, and medium-sized enterprises, who do not know how to comply with Customs requirements for data, health, and safety regulations. In line with the WCO Framework of Standards on cross-border e-commerce, many Customs administrations are exploring new legislative measures to get access to data for better risk management with regard to public health and revenue leakage among other risks.

KEY LESSONS FROM THE WORLD CUSTOMS ORGANIZATION (WCO)

E-commerce requires urgent action

To tackle the growing online conduits of illicit trafficking of medicine

Expertise and information are essential

To foster collaboration between researchers, medical manufacturers and supplies

Tackling upstream trafficking is important

To facilitate collaboration with judiciary authorities

Consumer education is critical

To address the challenges related to the demand of drugs

Since 2020, the WCO has organized a series of STOP Operations as an immediate response to the illegal trafficking of medical products, linked to the COVID-19 pandemic, with the support of the WHO, UNODC, INTERPOL, EU institutions and Japan, but also with the input from medical suppliers. While Operations STOP resulted in a huge number of seizure of counterfeit and illicit medicines, it has raised awareness on public health risks with some lessons learned.

Firstly, e-commerce has become one of the major conduits for illicit trafficking of medicine. The WCO is exploring collaboration with intermediary in e-commerce supply chain, including online platforms for a better access to data. Secondly, cooperation with public health researchers, medical manufacturers and suppliers is indispensable in getting necessary expertise and information.

The WCO invites right holders for pre-operation training sessions, and it also organizes an annual right holder meeting to have dialogue with the stakeholders to explore more avenue for cooperation. Thirdly, collaboration with judiciary authorities is necessary to tackle the upstream of illicit trafficking of medicines. Fourthly, consumer education is necessary to address the issue not only from the supply side, but also from the demand side of illicit medicines. Finally, capacity building is necessary for all actors in this field by sharing information and necessary resources.

In brief, the key path to successfully addressing counterfeit drugs will be to strengthen cooperation between all actors.

"Preventing economic loss and protecting the health and safety of the people"

Mr. John P. Leonard
Deputy Executive Assistant Commissioner, Customs and Border Protection (CBP) Office of Trade, USA

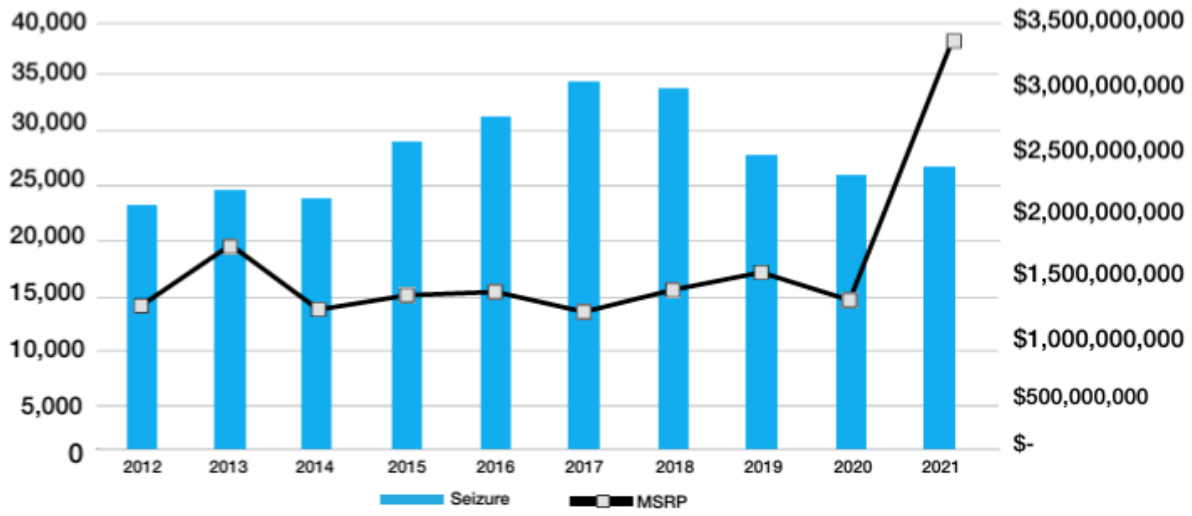
The Office of Trade, U.S. Customs and Border Protection (CBP), partners with both the private sector and partner government agencies all around the world. CBP is America's unified border agency that looks after all the migration and travel as well as traditional customs trade issues. The work of the Office of Trade is to keep our country safe while facilitating legitimate and compliant trade to power our economy." The mission for keeping counterfeits, and in particular, counterfeit medicines, out of the country is a priority and the problem has been growing during and after the COVID-19 pandemic.

Currently, over 2 million small packages come into the US per day from foreign countries, mostly as a result of e-commerce purchases from individuals and families. Though much of it is compliant, some is illicit and counterfeit, with a growing number in the pharmaceutical area, which is very concerning. The big question is how do you find that needle in the haystack? How do we target and select the packages to be inspected and/or seized that are counterfeits? The challenge is limited personnel bandwidth at the port of entry combined with a staggering volume of freight. Addressing counterfeit drugs at the border requires officer knowledge, focus, artificial intelligence, machine learning, and more advanced data which may require legislation.

Though the 40-foot container is still a mainstay of international trade, the small packages arriving by air have transformed our trade landscape. In the case of pharmaceuticals, it is the direct-to-consumer online transactions that expose the public who purchase counterfeit products online thinking that they're getting legitimate medicines. Another challenge to this is that the websites are more and more sophisticated and deceptive. The supply chains are also quicker to get goods into the hands of consumers. These developments require government agencies and their partners to become nimbler. In addition, to tackle this problem, public and private partnerships are critical. In the USA, these partnerships include the U.S. Chamber of Commerce and its members such as Pfizer, sharing counterfeit data and information with CBP.

Last year alone, CBP seized well over 1.5 million individual units in pill form of pharmaceuticals to the tune of $100M USD at manufacturer's suggested retail price. Overall, pharmaceuticals are in the top 10 seized products (currently number 6) of counterfeit items that CBP seizes. Some of the countries of origin of those interdicted shipments are India, followed by Singapore, China, and United Arab Emirates. Of note, India is by far the largest for pharmaceuticals.

INTELLECTUAL PROPERTY RIGHTS (IPR) INCREASING SEIZURES
10 YEAR TOTALS



Extracted from the FY 2021 IPR Seizure Statistics Book, Customs and Border Protection

INNOVATION & COLLABORATION: THE CASE OF "OPERATION BLUE PIGEON"

The cooperation between customs administrations and the private sector working together worldwide is crucial. The enforcement effort called " **Operation Blue Pigeon**" between the US and Singapore was a demonstration of a successful collaboration implemented to address counterfeit Viagra coming in from India, sent through Singapore and then onward to United States. (The operation name of "Blue Pigeon" was based on the fact that the pills were blue and they flew in the air.)

With the help of Singapore Customs, the strategy involved targeting and segregating counterfeit shipments in Singapore's Changi International Airport.

For legal reasons, the seizures could not happen in Singapore, but Singapore Customs' help was invaluable in staging and identifying those counterfeit packages when they arrived in Miami and Cincinnati. Our CBP personnel on the ground were able to make hundreds of seizures of counterfeit Viagra. This is an example of great cooperation between customs administrations and the private sector on both sides of the planet, working together to achieve results to protect our citizens and the economy.

"The issue of sub-standard, falsified, and unregistered drugs is a cross-cutting issue and a cross-cutting issue means a multi-stakeholder approach."

Ms Pernette Bourdillon-Esteve, Regulation, safety, and quality of medical products at World Health Organization

A RISING THREAT IN LOW- AND MIDDLE-INCOME COUNTRIES (LMICS)

Substandard, falsified, and unregistered medical products are increasingly causing deaths and economic losses in low- and middle-income countries (LMICs). Falsified products are those that deliberately or fraudulently misrepresent their identity, their composition, or source. Sub-standard products are those that have lost their attributes of quality and have become out of specification but there has been no deliberate intent to make them defective. Unregistered products are those that have not been authorized by the competent authority for the market in which it is circulating but may not necessarily mean that the quality and safety are compromised. The effects of these products require urgent attention.

286,000

Annual deaths for childhood pneumonia and malaria in Africa

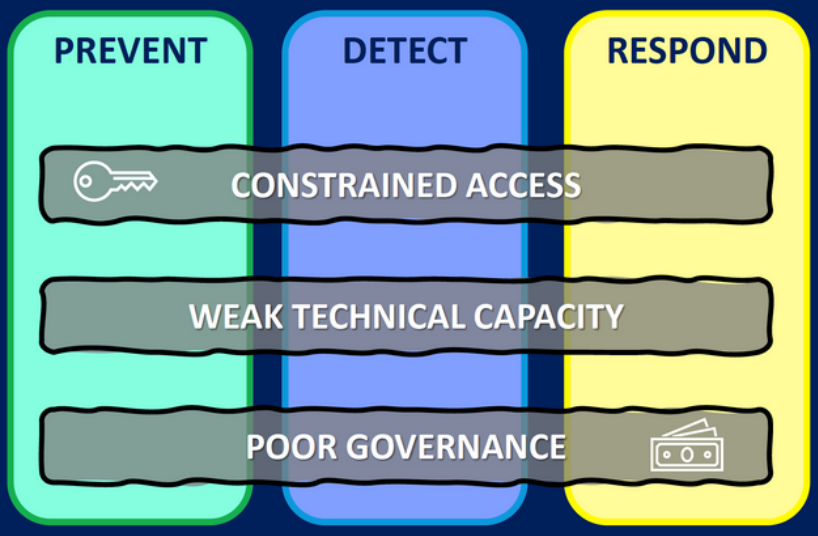
10.5%

Failure rate of medicines in LMICs

US$ 30.5 BILLION

Est. annual spending on sub-standard and falsified medicines in LMICs

WORLD HEALTH ORGANIZATION (WHO) RESPONSE



The WHO has a three-pillar response strategy which is prevention, detection, and response and these three pillars address the three main driving forces. The first force is constrained access which covers acceptability and availability and affordability. The first major component of the prevention pillar is ensuring that people demand quality at all levels of the supply chain. The second driving force is related to weak technical capacity and the third is about addressing poor governance.

APPROACHES TO ADDRESSING SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS (SFMP) IN LOW- AND MIDDLE-INCOME COUNTRIES

CHARLIE PRESTON, MD, MPH

SENIOR PROGRAM OFFICER AT BILL & MELINDA GATES FOUNDATION

The Bill and Melinda Gates Foundation (BMGF) has been involved in regulatory system strengthening for over a decade and made significant investments in regulatory systems as a key enabler of getting technologies to patients in low- and middle-income countries. The BMGF's strategy on substandard and falsified medical products (SFMP) is grounded in its regulatory systems strengthening work, and structured around three pillars.

The first pillars focus on supporting countries to develop national plans for substandard and falsified medicines. In this process, the country's regulatory agencies take the lead because they manage critical functions before marketing authorization and make sure that products are tested and monitored when they're in the markets. This is crucial in preventing and controlling any suspected substandard and falsified products. National plans are sustainable because they are country-owned.

The second pillar focuses on providing continental and global support to foster local institutional ownership and develop trusted mechanisms including a Global Surveillance and Monitoring System, product safety alerts, a national plan handbook , etc.

This support is provided in collaboration with continental and global partners such as the African Union, the World Health Organization, and the African Union Development Agency-NEPAD (AUDA-NEPAD). The third pillar focuses on supporting the technologies that contribute to the fight against substandard and falsified medical products.

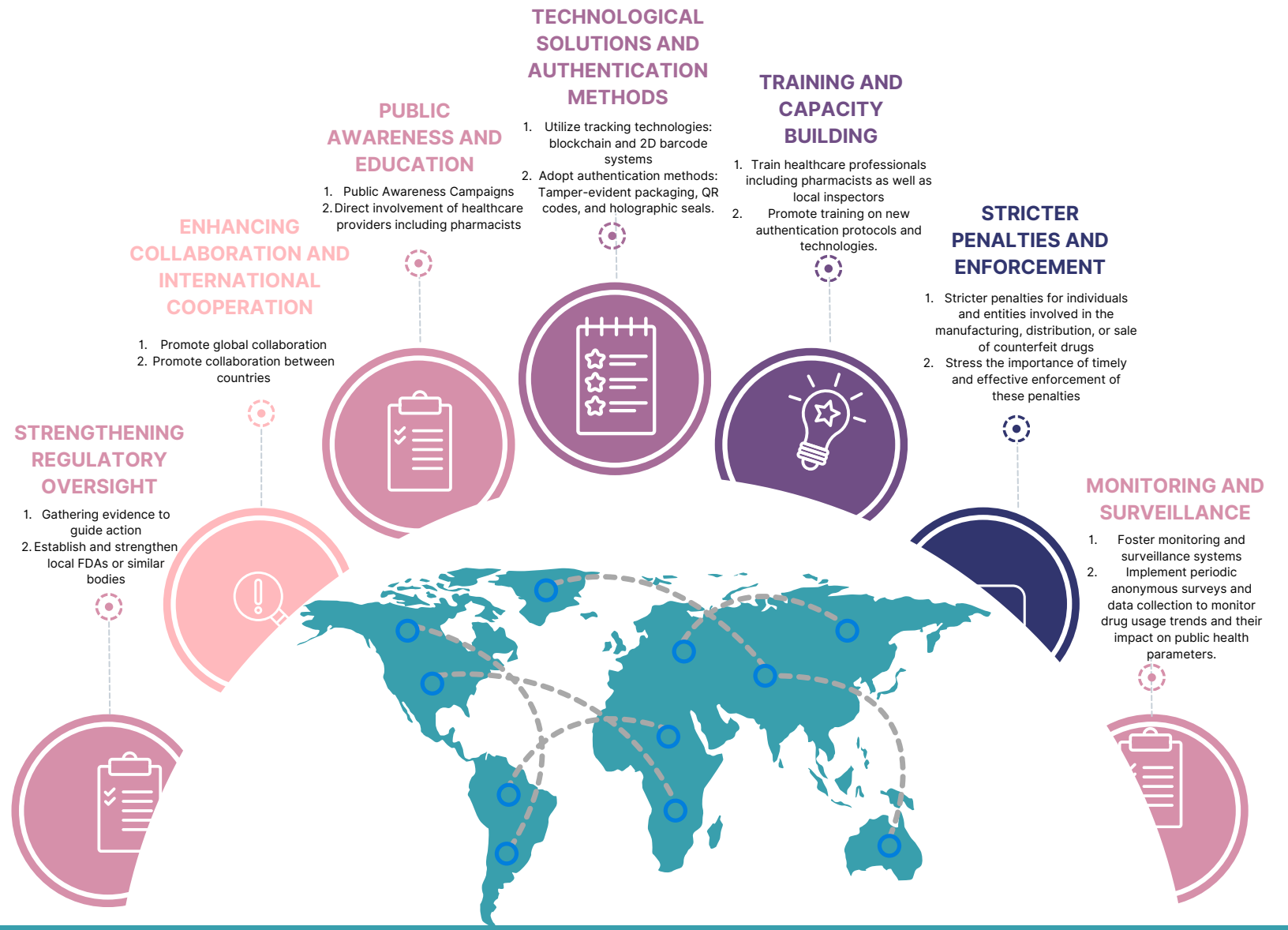
Overall, the BMGF envisions contributing to creating stronger regulatory systems through an intersectoral approach which will ensure that quality products predominate LMICs' markets and ultimately reduce the prevalence of SF products, stimulate better health outcomes, and guarantee fewer tragedies.

"Wherever you have a limited regulatory system, you tend to have higher prevalence of substandard and falsified medical products. So I think that's an important correlation to keep in mind."

Dr. Charlie Preston

PUBLIC HEALTH RESPONSES TO COUNTERFEIT DRUGS

The current 84% increase in the proliferation of counterfeit drugs signals a pressing need for effective solutions. Among the key challenges to effective response are the knowledge gaps among healthcare providers including pharmacists. Healthcare providers are frequently unaware of counterfeit drugs within the supply chain and are hesitant to implement necessary changes. The ramification of this challenge is that patient counseling remains inadequate and ultimately reflects a need for improved communication and education efforts. In particular, consumers are at risk as they may unknowingly use unsafe medical products obtained increasingly from online resources.



Adapted from the findings from Scoping review conducted as part of the Behavioral and Educational Strategies for Avoiding Falsified Medicine Exposure (BESAFE) project implemented by a team at Johns Hopkins University in collaboration with Pfizer

PUBLIC HEALTH RESPONSES TO COUNTERFEIT DRUGS

From the left to the right: Dr. Caleb Alexander, MD, Associate Professor, Co-Director, Center for Drug Safety and Effectiveness, Johns Hopkins University School of Medicine; Mr. Rutendo Kuwana, Team Lead, Incidents and Substandard/Falsified medical products, WHO (Virtual); Sangeeta V. Chatterjee, PharmD, Deputy Director, Office of Drug Security, Integrity, and Response (ODSIR), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA); Mr. Josh Bolin, Associate Executive Director, Government Affairs and Innovation, National Association of Boards of Pharmacy (NABP); Dr Ilisa Bernstein, PharmD, JD, FAPhA, Senior Vice President of Pharmacy Practice and Government Affairs, American Pharmacists Association (APhA)

In addition, addressing drug shortages is critical, as patients will seek alternatives when medications are not available, potentially leading to the use of counterfeit drugs from various avenues which makes the role of pharmacists critical. Effective prevention requires effective pharmacovigilance and education for the patients. Among the important steps made in pharmacovigilance is the global drug serialization and safety. This step potentially extends the role of pharmacists to allow them to verify drug serialization to prevent the circulation of counterfeit drugs which is critical for quality control. For example in the case of the USA, among the key players facilitating the pharmacists' response is the National Association of Boards of Pharmacy (NABP) in the US.

The FDA oversees federal requirements that apply to the prescription drug supply chain in the U.S., including serialization and tracing of products to ensure authenticity and detect counterfeits. This effort utilizes the Drug Supply Chain Security Act (DSCSA) which requires trading partners to maintain control over their serialized data and respond to requests from regulators for information on suspect or illegitimate products.

The DSCSA directs the FDA to establish national licensure standards for wholesale distributors and third-party logistics providers and requires these entities to report licensure and other information to the FDA annually.

In its effort to protect consumers from unsafe medications, the FDA plays a key role as a regulatory body and conducts outreach efforts to educate healthcare professionals and consumers about purchasing medications safely. The Office of Drug Security, Integrity, and Response (ODSIR) mission is to shield patients from poor quality, unsafe, and ineffective drugs through proactive compliance strategies and risk-based enforcement action. The FDA takes a holistic approach to this approach, involving various agencies of the government and establishing private-public collaborations to protect the public. To address the issue of the illegal sale of unapproved and misbranded drugs online, the FDA has issued warning letters, held online Controlled Substances Summits, collaborated with various stakeholders to conduct various investigations, and produced education and outreach campaigns.

PUBLIC HEALTH RESPONSES TO COUNTERFEIT DRUGS

In many countries as well as in the US, government agencies and their partners are focusing on counteracting the drivers that promote the proliferation of sub-standard and falsified medical products. However, the alarming issue remains that a lot of healthcare professionals lack the confidence to determine the difference between a genuine and a substandard falsified medical product. This ultimately has an impact on the number of reports that can be expected. Nevertheless, platforms must be provided for people to be able to report any suspected products. One example of such technologies is the FDA's MedWatch (https://www.accessdata.fda.gov/scripts/medwatch/) which allows for product safety reporting for health professionals, patients, and consumers. There is a great opportunity to utilize technology given the high adoption of smartphones globally.

FDA's page that contains warning letters to online pharmacies and contact details for FDA Internet Pharmacy Task Force that can be reached at FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov.

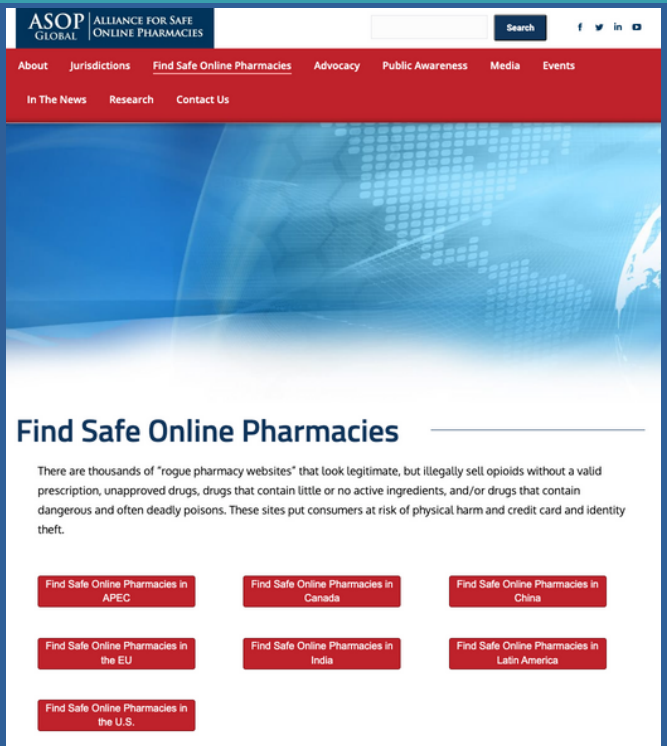
"Given the high penetration of smartphones that ranges between 80-100% in most countries, including lots to middle-income countries, we have the opportunity to embrace the use of smartphone apps to increase the reporting either at the patient level or healthcare professional level to report on substandard and falsified medical products."

Mr. Rutendo Kuwana
Team Lead, Incidents and
Substandard/Falsified medical products
World Health Organization

In addition, there is no single directory within the prescription drug supply chains to be able to identify trading partners and connect those trading partners. In this regard, the NABP is launching a platform referred to as "PULSE by NABP". This platform serves as a directory for the prescription drug supply chain and enables communication between state regulators and trading partners. It also allows for communication among trading partners themselves because they have obligations. This platform reflects how the DSCSA is structured and is meant to be implemented.

PHARMACISTS ARE PIVOTAL

Pharmacists are in a unique position to help consumers avoid substandard and falsified drugs. In the USA, a patient sees their pharmacists 13 times a year on average, and 90% of the people live within 5 miles of a pharmacy. These are teachable moments where a healthcare professional and provider can be working with and/or teaching patients. However, pharmacists also need crucial resources to be able to identify various red flags that may indicate substandard and falsified drugs. The American Pharmacists Association plays an important role in facilitating access to various resources in particular those provided by FDA and other partners. The Alliance for Safe Online Pharmacies (ASOP) also provides resources, research, and advocacy on combating substandard and falsified drugs on the internet and other platforms. Given the increasing use of online pharmacies platforms such as ASOP will continue to be more crucial in combating sub-standard and falsified drugs.



A PUBLIC HEALTH PERSPECTIVE ON COUNTERFEIT DRUGS

JOSHUA M. SHARFSTEIN, MD, DISTINGUISHED PROFESSOR OF THE PRACTICE
VICE DEAN FOR PUBLIC HEALTH PRACTICE AND COMMUNITY ENGAGEMENT, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

The global phenomenon of counterfeit drugs poses a major threat to public health. That's because millions of people are purchasing medications that are harmful or don't work and are missing the opportunity to receive effective treatment. In some circumstances, the use of substandard medications leads to antibiotic resistance, making health problems worse for everyone.

The challenge of counterfeit drugs also reflects deeper problems affecting public health. An economic incentive to counterfeit drugs is present any time people cannot afford or cannot purchase legitimate medications. Ineffective health systems, or inaccessible pricing from companies, leads to desperation among patients. This desperation is what helps counterfeiting thrive.

It's important, therefore, for there to be a balanced approach to counterfeit drugs, addressing both the supply of and demand for these products. The supply-side strategy relates to effective regulation and enforcement, as we've heard today. The companion demand side approach seeks to make sure that people have ready access to the essential, effective medications they need.

There are additional benefits to a balanced approach. With improved access to care, more people will have access to medications essential to reducing the spread of infectious disease and countering common non-communicable diseases.

Expanding access to care need should be embraced by the pharmaceutical industry. Companies can earn greater revenue from larger volumes of sales, even in the setting of lower unit prices.

Given that counterfeit drugs are a particular scourge in low and middle income countries, addressing this challenge will close equity gaps – especially if accomplished in a way that expands access to effective treatment.

"Our response to counterfeit drugs should be balanced – greater regulation and enforcement, as well as enhanced access to effective health care."

Dr. Joshua M. Sharfstein
Johns Hopkins Bloomberg School of Public Health

KNOWLEDGE AND PRACTICE OF HEALTHCARE PROVIDERS FOR COMBATING COUNTERFEIT DRUG-USE

Alain Koffi, MD, PhD, MS, BESAFE Co-Principal Investigator
Johns Hopkins Bloomberg School of Public Health

The preliminary findings from an ongoing online survey of healthcare providers about Counterfeit Medicines or Drugs were presented. This survey is part of the Behavioral and Educational Strategies for Avoiding Falsified Medicine Exposure (BESAFE). The project's goal is to assess the knowledge of healthcare providers about current practices, challenges, and other important issues related to counterfeit medicines. Specifically, the study had three objectives. First, to understand gaps in knowledge of counterfeit medicines and illicit online pharmacies among healthcare providers (HCPs). Second, to access providers' experience in dealing with patient's exposure to counterfeit medicines and their reasons for purchasing from online pharmacies. Third, to explore their perceived roles in combating the use of counterfeit drugs by counseling patients and encouraging them to purchase drugs from authorized pharmacies. The target sample size was 400 respondents from both study countries namely South Africa and USA, at the time of the symposium, the preliminary results presented were from 191 respondents.

Key preliminary findings included that overall, 9% of respondents in the USA and South Africa responded that they did not know how to define what is considered counterfeit medicine, 52% of respondents in the USA and 32% of respondents in South Africa reported that they did not know which therapeutic drug categories are most impacted by counterfeiting. Similarly, 86% of respondents in the USA reported not knowing specific actions to undertake to prevent counterfeit medicine and this proportion was 56% in South Africa. These preliminary findings are alarming and require urgent action.

In response to the COVID-19 pandemic's shift towards telehealth, APCO crafted a strategy and framework to understand how patients obtained their medication, risks to purchasing medicine online and proactive communications healthcare providers and pharmacists share to ensure safe access to prescription medicines. APCO facilitated seven focus group discussions with the objective to use this knowledge to enhance messaging to the public and ensure patient safety during prescription fulfillment.

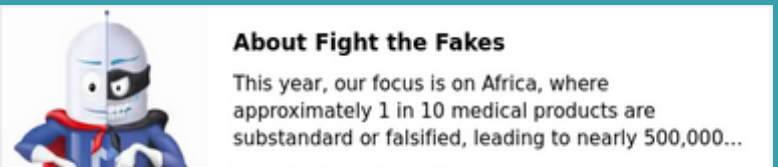
The effort yielded practical insights: First, individuals require straightforward solutions to identify reputable sources of accurate information and affordable medication. Second, patient safety and medication efficacy are paramount, necessitating the promotion of these reputable sources that not only share the risks of counterfeit medicine but the importance of using legitimate online pharmacies. Lastly, understanding patient and consumer viewpoints in the drug development process is crucial in building and maintaining trust between the public and pharmaceutical companies.

Mackenzie Allen, Senior Associate Director, APCO Worldwide

INTERVENTION STRATEGIES FOR CONSUMERS AND PATIENTS

From the left to the right: Dr. John Hertig, Associate Professor, Butler University College of Pharmacy and Health Sciences ; Dr. Anita Sands, Technical Officer - Incidents and Substandard/Falsified Medical Products Team (virtual); Pedro (Pete) Álvarez, Senior Director, Identification and Master Data, Healthcare; Mr. Shabbir Safdar, Executive Director, Partnership for Safe Medicines (virtual) ; Mr. Christopher Goetz, Executive VP and General Manager, International Federation of Pharmaceutical Wholesalers IFPW

The complexity of the problem of substandard and falsified drugs requires interoperability and multi-prong strategies for consumers and patients. To foster interoperability, it is crucial to promote standardization in the pharmaceutical industry by utilizing tools such as the Global Language Model (GLM) and barcode/RFID tags as key components of interoperability. Other various strategies should include educational initiatives, monitoring enhancement, supply chain oversight, professional empowerment and incentivization, broad-based prevention tactics, and promotion of behavioral change initiatives. One of the example of such initiative is the “Fight the Fakes”, a global grassroots awareness-raising campaign that was launched in 2013. From social media tiles and messages, infographics, videos, and stories from victims of fake medicines, this initiative makes sure that everyone understands the dangers of falsified and substandard medicines. Its messages are echoed by the different members, allies and the public.



The healthcare empowerment efforts must go together with the development of protocols and systems for the identification and reporting of counterfeit drugs, an essential step in safeguarding patient health and maintaining trust in healthcare systems. For instance, in the case of vaccines, to effectively strengthen the vaccine supply chain one has to work on the critical aspect of vaccine distribution, ensuring a robust and secure supply chain which is vital for effective delivery of vaccines. This approach is the cornerstone of public health initiatives and pandemic response strategies.

Nonetheless, patient safety concerns remain. For instance, in the US, there is a growing trend of doctors recommending Canadian websites for drug purchases, which could potentially lead patients to access counterfeit drugs. Proactive countermeasures are required to address this problem. One essential proactive measure is to foster collaboration among brand protection teams to combat the spread of counterfeit drugs, ensuring that the focus remains on curtailing the availability and distribution of illegitimate medications. The formation of such teams should focus on ensuring that the team's efforts are focused on public safety and health rather than profit motives.

SPOTTING ILLEGITIMATE PRODUCT CAN BE AS SIMPLE AS SCANNING A BARCODE

(01)09504000059101
(21)19067811811
(10)563GS1
(17)200331

Example: Use of GS1 standards for the identification of products using a GS1 DataMatrix

GTIN: (01)09504000059101
S/N: (21)19067811811
Batch / lot: (10) 563GS1
Expiry: (17) 200331

Substandard and falsified medicines are a global threat, but we can push back by acting together. Everyone involved in healthcare, in any capacity, should be concerned about the problem. The pharmaceutical supply chain is incredibly complicated, and each of its many points across the global supply chain presents an opportunity for infiltration by counterfeit products.

One important method of preventing falsified medicines from endangering people's health and wellbeing is robust product identification. GS1 Healthcare wants to make sure that every single drug is uniquely identified, and that the data are easy to share. By using GS1 global standards for identification and traceability, spotting an illegitimate product would become as simple as scanning a barcode.

GS1 standards are the most widely used standards for identification and traceability for healthcare products worldwide. More than 70 regulations for medicines traceability across the world today are based on these standards and using them is a way to ensure global harmonization and interoperability for the improvement of supply chain efficiency and patient safety. Below is an illustration of the barcode and identification these regulations have in common.

Patients are also empowered to ensure they are using the medicine in a safe way by scanning their medicine's DataMatrix barcodes to access online information, such as how to take the medicine, and what its likely side effects may be. Just as every member of the pharmaceutical supply chain is a partner in solving these issues, so too are the patients themselves.

How GS1 can help tackle counterfeit products?

Better Search Experience

Make product information search engine friendly

Improved Product Information

Create and deliver reliable, accurate product information

Optimized Consumer Fulfillment

Greater inventory visibility to better match inventory with consumer demand

Smarter Analytics

Understand your customers

Safer Products

Reduced confusion from counterfeit products

Source: GS1. [7]

INTERVENTION STRATEGIES FOR PHARMACY SERVICES AND FOR HEALTHCARE PROVIDERS

From left to the Right: Connie Jung, RPh, PhD, Senior Advisor for Policy, ODSIR, FDA; Dr Ilisa Bernstein, PharmD, JD, FAPhA, Senior Vice President of Pharmacy Practice and Government Affairs, American Pharmacists Association (APhA); Lubna Merchant, M.S., Pharm.D., Risk Management Product Lead, Pfizer; Mr. Josh Bolin, Associate Executive Director, Government Affairs and Innovation, National Association of Boards of Pharmacy (NABP)

Pharmacy services and healthcare providers require specific resources and tools to effectively contribute to the fight against substandard and falsified drugs. In the US, the core tenet is the Drug Supply Chain Security Act (DSCSA). This Act is pivotal in the FDA's efforts to protect the integrity of the drug supply chain in the US. It ensures that patients receive medications that are safe, effective, and of the highest quality. The DSCSA mandates compliance from manufacturers, repackagers, wholesale distributors, and dispensers through four critical measures namely product tracing, verification, product Identifier, and authorized trading partner. Notably, critical product identifiers are required to be encoded on prescription drugs distributed in the U.S. and include the Global Trade Identification Number (GTIN) (which contains the National Drug Code (NDC)), package-specific serial number, lot number, and expiration date. This information will be used for enhanced product tracing and verification under the DSCSA.

To improve supply chain integrity, all trading partners namely manufacturers, repackagers, wholesale distributors, and dispensers have to be authorized (registered or licensed as applicable). All pharmacies have to ensure that they have policies and procedures in place to ensure that they are verifying the licenses of their trading partners and to ensure traceability and appropriate reporting. These requirements make the use of technology paramount and the NABP's Pulse platform is an example of such technologies. It facilitates seamless communication and connection within the supply chain, thereby streamlining operations and compliance while safeguarding population health.

Specific to pharmacy services, a three-pronged intervention model could be utilized. First, prevention through education to minimize drug-related risks. Second, vigilant detection of drug safety and authenticity. Third, a responsive educational approach to equip patients and healthcare providers in identifying counterfeit drugs. This model fosters regulatory compliance with safety protocols and verification processes that are crucial to ensure the integrity of FDA-approved pharmaceuticals. Further, effective use of educational resources to support the Drug Supply Chain Security Act is essential. These include the dscsa.pharmacy which is a unique educational resource available for pharmacies and other trading partners. Essentially in the current era when many people are relying on online pharmacy services, it is critical to utilize reliable online pharmacy resources such as the BeSafeRx campaign and the Alliance for Safe Online Pharmacies.

Furthermore, because of the high burden of counterfeit drugs, there is an urgent necessity for training amendments to ensure that pharmacy, medical, and health sciences education encompasses training on preventing and managing substandard drugs, thus arming future health professionals with essential professional competencies. Current resources for such amendments include a curriculum guide and competency framework developed by the International Pharmaceutical Federation and the compliance tool developed by the Asia Pacific Economic Cooperation (APEC).

KEY TAKEAWAYS

The symposium provided a unique opportunity for discussions and mutual learning among leaders, experts, professionals, and students. The speakers and participants expressed an urgent need for more efforts to catalyze transformational partnerships and collaborations between public health researchers, drug manufacturers and suppliers, regulatory and law enforcement agencies, policymakers, and program implementers to stop counterfeit medicine. The growing burden of counterfeits and falsified drugs has been felt across levels, by individuals, households, communities, and nations. The Symposium provided a unique space to explore existing and novel strategies for collaborative efforts to ensure public safety and well-being.

The symposium featured insightful and engaging research and panel discussions that were led by global experts in the field. These discussions specifically addressed the status of the global burden of substandard and falsified drugs, public health responses, intervention strategies for consumers and patients, intervention strategies for pharmacy services, intervention strategies for health care providers, and intervention strategies for policy makers. Moving forward, it will be crucial to leverage currently available resources from global organizations, governments, drug manufacturers and suppliers, professional organizations, and academic institutions. In addition to institutional collaborative efforts, specific actions are urgently needed to raise awareness and garner more data to inform policy and programs to address falsified, substandard, and counterfeit drugs.

Over the last few years, a few health communication and behavioral change initiatives have been implemented but many gaps remain. There are still opportunities for collaborative health communication interventions to increase the awareness of people regarding counterfeit medicines and risks associated with purchasing drugs from unauthorized Internet sites, educate consumers about the associated risks and how to verify the authenticity of purchased drugs to enable them to make informed choices and promptly report suspicious products. Moreover, such efforts should be complemented with programs intended to strengthen the capacity and skills of regulatory bodies as well as healthcare personnel to recognize, assess, and respond to the threats posed by substandard, falsified, and counterfeit drugs.

Lastly, there are technology-based solutions that have been developed and more are still needed. The NABP's PULSE platform is an example of potential transformative technology solutions. Information, data analytics, and computational intelligence should be explored further to develop robust monitoring and surveillance platforms to measure the burden of substandard and falsified medical products and track changes in the trends to inform public health policy and practice. There is an urgent need to capture consumer behaviors, counterfeiting patterns, and trends through consumer and healthcare personnel surveys and machine learning applications. These data sources could become key resources for real-time data to identify high-risk individuals, populations, and regions which is a key step to proactively protect population health.

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From the left to the right: Dr. Alain Koffi, Dr. Lubna Merchant, Dr. Patrick Caubel, Dr. Jean Christophe Rusatira, Dr. Saifuddin Ahmed, Dr. Henry Joseph Michtalik, Ms. Eishita Pal, Ms. Tiffany Dominic

ACKNOWLEDGMENT

The authors would like to thank all the speakers, presenters, and participants of the 2023 Symposium on Public Health Strategies for Combating Counterfeit Drugs held on Friday, December 1, 2023, at the Johns Hopkins University Bloomberg Center, 555 Pennsylvania Avenue NW, Washington, D.C. 20001. The symposium was hosted by the Behavioral and Educational Strategies for Avoiding Falsified Medicine Exposure (BESAFE) team at the Johns Hopkins University(JHU) in close collaboration with a team from Pfizer Inc.

JHU BESAFE TEAM

Saifuddin Ahmed
Alain Koffi
Henry Joseph Michtalik
Jean Christophe Rusatira
Eishita Pal

PFIZER TEAM

Patrick Caubel
Lubna Merchant
Reema Mehta
Lev Kubiak
Angel M. Melendez
Tiffany Dominic

Corresponding author: Jean Christophe Rusatira, jcrusatira@jhu.edu

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BESAFE

The symposium, part of the BESAFE project, is supported with funding from Pfizer Inc.

AGENDA

Friday, December 1, 2023

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SYMPOSIUM ON PUBLIC HEALTH STRATEGIES FOR COMBATING COUNTERFEIT DRUGS

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MORNING

8:00-9:00 AM	**Registration & Coffee & Badge Pick-up**
9:00-9:15 AM	**Welcome Message** **Cynthia Schaffer Minkovitz, MD, Professor,** Chair of the Department of Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health
9:15-9:30 AM	**Welcome Message** **Aida Habtezion, M.D., MSc, FRCPC, AGAF,** Chief Medical Officer and Head of Worldwide Medical & Safety, Pfizer
9:30-10:15 AM	**Panel: Global burden of counterfeit drugs** **Facilitator: Henry Joseph Michtalik, MD, MHS, MPH.,** Assistant Professor of Medicine, Johns Hopkins Medicine **Panelists:** • **Dr. Kunio Mikuriya**, Secretary General of the World Customs Organization (WCO)- *Topic: Public Health Impact and Economic Consequences (10 min) (Recorded)* • ***Mr. John P. Leonard,*** Deputy Executive Assistant Commissioner of the Office of Trade - *Topic: CBP's mission to keep counterfeit pharmaceuticals out of the U.S. and related border agency international cooperation (10 min)* • **Ms Pernette Bourdillon-Esteve,** Regulation, safety, and quality of medical products at World Health Organization (10 min) (Virtual) • **Dr. Charlie Preston,** Senior Program Officer at Bill & Melinda Gates Foundation - *Topic: Approaches to addressing substandard and falsified medicines in low and middle income countries (10 min)*
10:15-10.30 AM	**Plenary: Scoping review: Behavioral and Educational Strategies for Avoiding Falsified Medicine Exposure (BE SAFE)** **Saifuddin Ahmed, MBBS, PhD**, Professor, Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health
10.30-10:45 AM	**Coffee break**
10:45-11.45 AM	**Panel: Public health responses to counterfeit drugs** **Facilitator: Professor Caleb Alexander, MD, Associate Professor,** Co-Director, Center for Drug Safety and Effectiveness, Johns Hopkins University School of Medicine **Panelists:** • **Mr. Rutendo Kuwana,** Team Lead, Incidents and Substandard/Falsified medical products, WHO - Topic:Technological Solutions (10 min) (Virtual) • **Dr Ilisa Bernstein, PharmD, JD, FAPhA,** Senior Vice President of Pharmacy Practice and Government Affairs, American Pharmacists Association (APhA) - *Topic: pharmacy response (10 min)* • ***Mr. Josh Bolin,*** Associate Executive Director, Government Affairs and Innovation, National Association of Boards of Pharmacy (NABP) - *Topic: Regulatory Frameworks and Enforcement (10 min)* • **Sangeeta V. Chatterjee, PharmD**, Deputy Director, Office of Drug Security, Integrity, and Response (ODSIR), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA), U.S. FDA - *Topic: Strategies to Protect Patients from Unsafe Drugs (10 min)*
11.45-12:00 PM	**Interactive session: Identifying the challenges and gaps** **Jean Christophe Rusatira, MD, MPH, PhD Candidate,** BE SAFE Co-investigator, Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health
12:00-1:00 PM	**Lunch & Networking**

AFTERNOON

1:00-1:15 PM	**Plenary: Public Health Practice and Challenges** • **Joshua M. Sharfstein, MD, Distinguished Professor of The Practice**, Vice Dean for Public Health Practice and Community Engagement, Johns Hopkins Bloomberg School of Public Health (15 min)
1:15-1:45 PM	**Plenary: Knowledge and practice of healthcare providers for combating counterfeit drug use** **Plenarists:** • **Alain Koffi, MD, PhD, MS,** BE SAFE Co-Principal Investigator, Johns Hopkins Bloomberg School of Public Health (10 min) • **Mackenzie Allen**, Senior Associate Director, APCO Worldwide (10 min)
1.45-2:45 PM	**Panel: Intervention strategies for consumers and patients** **Facilitator: Mr. John Hertig,** Associate Professor, Butler University College of Pharmacy and Health Sciences **Panelists:** • **Mr. Christopher Goetz,** Executive VP and General Manager, International Federation of Pharmaceutical Wholesalers IFPW **-** *Topic: Public Awareness and Education (10 min)* • ***Dr Anita Sands,*** *Technical Officer - Incidents and Substandard/Falsified Medical Products Team, WHO - Topic: Interventions & Technological solutions (10 min)* • **Mr. Shabbir Safdar,** Executive Director, Partnership for Safe Medicines -*Topic: Online marketplace threats to the legitimate supply chain (Virtual) (10 min)* • **Pedro (Pete) Álvarez, Senior Director,** *I*dentification and Master Data*, Healthcare, Topic - How GS1 standards help fight the fakes (10 min)*
2:45-3:00 PM	**Coffee break**
3:00-4:00 PM	**Panel: Intervention strategies for pharmacy services and for healthcare providers** **Facilitator: Lubna Merchant, M.S., Pharm.D.,** Risk Management Product Lead, Pfizer **Panelists:** • **Dr Ilisa Bernstein***,* PharmD, JD, FAPhA, Senior Vice President of Pharmacy Practice and Government Affairs, American Pharmacists Association (APhA) - *Topic:perspective on pharmacist and patient education (10 min)* • ***Mr. Josh Bolin,*** Associate Executive Director, Government Affairs and Innovation, National Association of Boards of Pharmacy - *Topic: Enhanced Authentication and Verification Protocols (10 min)* • **Connie Jung, RPh, PhD,** Senior Advisor for Policy, ODSIR, FDA - *Topic:Perspectives on Supply Chain Security for Prescription Drugs (10 min)*
4.00-4.15M	**Closing Notes** **Saifuddin Ahmed, MBBS, PhD, Professor,** Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health

SPEAKER BIOS

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SPEAKER BIOS

Cynthia Schaffer Minkovitz, MD, MPP, William H. Gates, Sr. Professor and Chair, Department of Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health

Cynthia Minkovitz, MD, MPP, is the William H. Gates, Sr. Professor and Chair of the Department of Population, Family and Reproductive Health at Johns Hopkins Bloomberg School of Public Health, and a Professor of Pediatrics in the School of Medicine. Her research focuses onenhancing systems of care and the quality of preventive services for children and families. She co-leads the Resource and Coordinating Center for ENRICH, a clinical trial to test the effectiveness of strategies in home visiting to promote cardiovascular health for mothers and their young children and reduce related disparities. Dr. Minkovitz leads the Johns Hopkins MCH Center of Excellence in Education, Science and Practice and is the recipient of multiple mentoring and teaching awards as well as the Academic Pediatric Association's Research Award.

Aida Habtezion, M.D., MSc, FRCPC, AGAF, Chief Medical Officer and Head of Worldwide Medical & Safety, Pfizer

As Chief Medical Officer of Pfizer, Aida Habtezion leads Pfizer's Worldwide Medical & Safety organization responsible for ensuring that patients, physicians, and regulatory agencies are provided with information on the safe and appropriate use of Pfizer medications. Her organization is responsible for monitoring the benefit risk profile and safety of Pfizer's portfolio of products from the first person that receives an investigational medicine or vaccine to the millions of patients that rely on these marketed therapies every day. She also leads Pfizer's Institute of Translational Equitable Medicine (ITEM), an initiative spanning research, development, and medical activities to close gaps in health disparities. The Institute leverages science, data, and translational expertise to integrate equity across Pfizer's end-to-end development pipeline.

Prior to joining Pfizer, she was a practicing physician, scientist, a tenured and endowed Professor of Medicine, at Stanford University. She led a large translational research lab funded by multiple NIH, DOD, and foundation grants focused on understanding disease mechanisms in pancreatic and intestinal inflammatory diseases and authored over a hundred high impact publications in top peer-reviewed journals. She also served as an Associate Dean for Academic Affairs in the School of Medicine, a faculty member in Stanford's Immunology Ph.D. program, Neuroscience Institute, Cancer Institute, Bio-X interdisciplinary biosciences institute, Maternal & Child Health Research Institute, and faculty fellow at Stanford's ChEM-H (Chemistry, Engineering & Medicine for Human Health). She served in multiple national, NIH, and international scientific study sections and editorial boards.

She is a Fellow of the American Gastroenterological Association, an Allen Distinguished Investigator, the American Pancreas Association past President, an elected member of the American Society for Clinical Investigation (ASCI) and the Association of American Physicians (AAP).

SPEAKER BIOS

Dr. Kunio Mikuriya, Secretary General of the World Customs Organization (WCO)
Dr. Kunio Mikuriya has been Secretary General of the World Customs Organization (WCO) since 1 January 2009. He provides leadership and executive management for the global Customs community's priorities, including developing global Customs instruments, standards, and tools; securing and facilitating global trade; realizing revenues; building Customs business partnerships; and delivering capacity building in support of Customs reform and modernization. Prior to joining the WCO, he worked for Japan's Ministry of Finance for 25 years. During his career with the Ministry, Dr. Mikuriya occupied a variety of senior posts, which have given him broad experience and knowledge in Customs, trade, development, budget, and financial policies. He served as Director of Enforcement where he led efforts to fight illicit trade, then as Director of Research and International Affairs, paving the way for the conclusion of Japan's first regional trade agreement, and then as a Counsellor in the Tariff and Customs Bureau. Dr. Mikuriya has a degree in law from the University of Tokyo (Japan) and a PhD in international relations from the University of Kent (United Kingdom).

Mr. John P. Leonard, Deputy Executive Assistant Commissioner of the Office of Trade
John P. Leonard serves as Deputy Executive Assistant Commissioner for the Office of Trade, U.S. Customs and Border Protection (CBP), overseeing a diverse portfolio of trade enforcement, security, and facilitation to enable legitimate trade, contribute to American economic prosperity, and protect against risks to public health and safety. With more than 30 years' experience at CBP and the former U.S. Customs Service, he began as an Import Specialist in Boston, Massachusetts before serving as the Area Port Director of San Francisco and the CBP Attaché to Singapore. DEAC Leonard holds a bachelor's degree from the University of Massachusetts at Amherst, a master's degree in International Commerce and Policy from George Mason University and is a graduate of the Harvard University John F. Kennedy School Senior Executive Fellows program.

Ms Pernette Bourdillon-Esteve, Regulation, safety, and quality of medical products atWorld Health Organization
Pernette Bourdillon Esteve has 15 years' international public health experience, at both global policy and technical levels. Her technical expertise is strategy development, data analysis, incident management, and training. Operational expertise is programme administration and human management.
At WHO she operates the Global Surveillance and Monitoring System on substandard-falsified (SF) medical products, with emphasis on database design and management. She analyses qualitative and quantitative data to identify country needs to prevent-detect-respond to SF medical products. These insights inform strategic policy decisions.
Before WHO, Pernette worked for the UN Office against Drug and Crime, UNITAID, French Foreign Affairs, and private sector. In addition to a public health Bachelors (management of health structures, epidemiology) and a political science Masters' (development economics), she is currently completing a global health PhD, focused on interoperability of datasets between SF medical products, diseases, and populations. She is fluent in French and English, intermediate in Spanish.

SPEAKER BIOS

Dr. Charlie Preston, Senior Program Officer at Bill & Melinda Gates Foundation
Charles “Charlie” Preston is a public health physician with experience in regulatory systems strengthening and access to quality medicines in low-and-middle-income countries. His career spans the US Food and Drug Administration, the World Health Organization/Pan American Health Organization (WHO/PAHO), and now the Bill and Melinda Gates Foundation. He is currently a senior program officer working across the foundation’s regulatory team, with a focus on major grants to WHO for regulation and prequalification, and the development of strategy and grants to address substandard and falsified medicines in Africa. He holds an MD from the University of Pennsylvania, an MPH from Johns Hopkins, and completed a preventive medicine residency at Johns Hopkins.

Saifuddin Ahmed, MBBS, PhD, Professor, Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health
Dr. Ahmed is a physician, demographer and epidemiologist. He teaches advanced statistical courses and he published more than 180 papers in high impact journals like the Lancet, Lancet Global Health, and BMJ Global Health, which have more than 13,000 citations. He is the principal investigator of the BE SAFE – Behavioral and Educational Strategies for Avoiding Falsified Medicine Exposure – project. He has served as a technical advisor to the World Health Organization.

Mr. Rutendo Kuwana, Team Lead, Incidents and Substandard/Falsified medical products,WHO - Topic: Technological Solutions
Rutendo leads the World Health Organization (WHO) Incidents and Substandard/Falsified (ISF) medical products team based at Geneva, Switzerland. He has been in this position since June 2021. The ISF team is part of the WHO Access to Medicines and Health Products (MHP) division. Since joining WHO in 2009, Rutendo has held various roles including being responsible for the initiation, coordination and conduct of activities related to prequalification of medicines quality control laboratories in priority regions and countries. He was also involved in provision of technical assistance and capacity building for quality control laboratories, medicine manufacturers and national medicines regulatory authorities. In his current role, he leads the WHO team that provides global coordination and support to national regulatory authorities with mandates or oversight to prevent, detect and respond to substandard and falsified medical products. He has 30 years’ experience in review of quality data for medicines submitted for prequalification with WHO, conduct of Good Manufacturing Practice inspections, benchmarking of national medicines regulatory authorities focusing on market control and surveillance.

SPEAKER BIOS

Dr Ilisa Bernstein, PharmD, JD, FAPhA, Senior Vice President of Pharmacy Practice and Government Affairs, American Pharmacists Association (APhA)

Ilisa Bernstein, PharmD, JD, FAPhA, is Senior Vice President for Pharmacy Practice and Government Affairs at the American Pharmacists Association (APhA). She is responsible for responsible for leading the development and implementation of APhA's strategies, policies, and programs related to pharmacy practice, advocacy, and government affairs, and guiding APhA as the voice of pharmacists in all practice settings. She joined APhA in 2019. From June 2022 to July 2023, Dr. Bernstein was Interim CEO and Executive Vice President at APhA, the first female to lead as CEO in the 170-year history of APhA.

She has over 30 years of experience advocating for pharmacy and patients at the U.S. Food and Drug Administration (FDA), where she has held several senior leadership positions. Prior to joining APhA, Dr. Bernstein was deputy director of FDA's Office of Compliance in the Center for Drug Evaluation & Research, leading policies, compliance, and enforcement in areas including drug compounding, supply chain security, drug manufacturing and quality, drug shortages, and post-market drug safety. Dr. Bernstein also served as director of pharmacy affairs for FDA and senior advisor for regulatory policy in the Office of the Commissioner. She started at FDA as clinical pharmacology reviewer of investigational and new drug applications.

Previously, Dr. Bernstein was senior associate director of worldwide regulatory affairs for Pfizer and completed a post-doctoral clinical residency at the National Institutes of Health. She earned her Doctor of Pharmacy from the University of Michigan College of Pharmacy and her Juris Doctor from American University Washington College of Law.

Joshua M. Sharfstein, MD, Distinguished Professor of The Practice, Vice Dean for Public Health Practice and Community Engagement, Johns Hopkins Bloomberg School of Public Health

Dr. Sharfstein is Vice Dean for Public Health Practice and Community Engagement, director of the Bloomberg American Health Initiative, and Professor of the Practice in Health Policy and Management. Previously, he served as the Secretary of the Maryland Department of Health and Mental Hygiene, the Principal Deputy Commissioner of the U.S. Food and Drug Administration, as Commissioner of Health for Baltimore City, and as health policy advisor for Congressman Henry A. Waxman. He is an elected member of the National Academy of Medicine and the National Academy of Public Administration.

SPEAKER BIOS

Sangeeta V. Chatterjee, PharmD, Deputy Director, Office of Drug Security, Integrity, and Response (ODSIR), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)

Dr. Sangeeta V. Chatterjee is the Deputy Director of the Office of Drug Security, Integrity, and Response (ODSIR) within the Center for Drug Evaluation and Research's Office of Compliance at the U.S. Food and Drug Administration (FDA). She oversees a wide range of efforts to protect U.S. consumers from unsafe, ineffective, and poor-quality drugs by directing precedent-setting compliance strategies, raising public awareness of breaches and vulnerabilities in the U.S. drug supply chain, and encouraging voluntary compliance by industry. She has also spearheaded innovative collaborations with international stakeholders, federal partners, and the private sector to address significant public health threats, including substandard and falsified medicines and the opioid crisis.

Before joining ODSIR, Dr. Chatterjee served as a Branch Chief within the Office of Compliance and Enforcement of the Center for Tobacco Products at FDA where she championed novel enforcement strategies to address violations related to the promotion of tobacco products. She also served as a Team Leader within the Office of Medical Policy's Office of Prescription Drug Promotion (formerly known as the Division of Marketing, Advertising, and Communications) where she directed compliance actions and policy development for prescription drug advertising. Prior to her career at FDA, Dr. Chatterjee held positions at Bristol-Myers Squibb in Global Regulatory Strategy for oncology drugs and in Promotion Compliance.

Dr. Chatterjee earned her Doctor of Pharmacy Degree from the University of the Sciences in Philadelphia, PA. She completed the Visiting Scientist Fellowship Program in Regulatory Affairs at Eli Lilly and Company during which she was also an adjunct professor at Butler University. She holds a certificate in Executive Leadership from Northwestern University's Kellogg School of Management. Dr. Chatterjee has also received prestigious accolades in recognition of her outstanding work to protect public health, including the Journal of Medical Regulation Award for Excellence in Editorial Writing (2018) and FDA Commissioner's Special Citations.

Alain Koffi, MD, PhD, MS, BE SAFE Co-Principal Investigator, Johns Hopkins Bloomberg School of Public Health

Dr. Alain Koffi is a population health researcher with a multidisciplinary background in Medicine, epidemiological maternal and child health and mortality, community primary health care and more recently, in data analytics/ data science. Current research areas include operations and implementation research in community-based primary health care and nutrition services, community-based surveillance approaches for health systems strengthening, either through "real time" monitoring of vital events and reproductive health behaviors or measuring the causes and determinants of neonatal and child mortality.

SPEAKER BIOS

Mackenzie Allen, Senior Associate Director, APCO Worldwide

Ms. Allen is a senior associate director at APCO Worldwide and is based in Chicago. She assists clients in building and executing integrated communications plans and campaigns to engage audiences and meet their organizational goals in today's complex media and business environment. Ms. Allen has extensive experience working within health care, food and nutrition, and association management.

Pedro (Pete) Alvarez, Senior Director, Identification and Master Data, Healthcare, GS1 Global Office

Pete is part of the GS1 Global Office healthcare team and has been with GS1 since 1999. He is a subject matter expert on GS1 standards for Automatic Identification and Data Capture (AIDC), master data and data quality, the Global Data Synchronisation Standard (GDSN), product classification standards, and the GS1 Digital Link standard in the healthcare sector. He is passionate about the work GS1 is doing to improve patient safety, medical outcomes and supply chain efficiency.

Mr. Christopher Goetz, Executive VP and General Manager, International Federation of Pharmaceutical Wholesalers IFPW

Mr. Goetz has served IFPW for over 28 years, in roles of increasing responsibility, and led IFPW Foundation since its inception in 2012. Today he oversees all the day-to-day operations of both not-for-profit organizations; establishes and manages their respective strategies and budgets; develops new opportunities for the global wholesale industry – particularly in Global Health initiatives and coordinates the activities of IFPW's 7-person team from IFPW's headquarters in the Washington, D.C. area. In addition, for IFPW Foundation, Chris serves as the lead on the Foundation's three primary activities namely a collaboration with Gavi since 2015 (around supply chain and human resource strengthening in eligible countries), supporting the Fight the Fakes Alliance and lastly supporting the African Pharmaceutical Distribution Association (APDA) as a platform for improving access to medicines and supply chain security.

SPEAKER BIOS

Dr Anita Sands, Technical Officer - Incidents and Substandard/Falsified Medical Products Team, WHO

Dr Sands serves as laboratory scientist with specialty in quality management systems for laboratory and point-of-care testing services, and quality assurance of IVDs. Dr Sand specializes in managing incidents/complaints of substandard/falsified medical devices including IVDs, supporting device manufacturers to conduct post-market surveillance, supporting device regulators to conduct market surveillance, and conducting technical and quality assessments for IVDs. She also supports procurement for IVDs and related laboratory equipment and commodities, including selection and use and the implementation of national traceability systems for medical products, and selection and use of detection technologies.

Mr. Shabbir Safdar, Executive Director, Partnership for Safe Medicines

Shabbir Imber Safdar has been at the Partnership for Safe Medicines for over a decade and was tapped to lead it in 2017. The Partnership, founded in 2003, is a not for profit focused entirely on researching the danger of counterfeit drugs in America and educating the public about how to stay safe from them. Shabbir is passionate about patient safety and the dangers of counterfeits, having seen them firsthand the dangers of counterfeits in countries around the world where a closed, secure drug supply chain doesn't exist.

Mr. Josh Bolin, Associate Executive Director, Government Affairs and Innovation, National Association of Boards of Pharmacy (NABP)
Josh Bolin serves as the Associate Executive Director for Federal Affairs and Strategy for the National Association of Boards of Pharmacy (NABP).

Since joining NABP in 2005, Josh has worked on development of PMP InterConnect, multiple pharmacy accreditation and inspection programs, including accreditation programs for durable medical equipment and specialty pharmacy, and inspection programs for the prescription drug supply chain, sterile and nonsterile compounding and nuclear pharmacy. Josh also worked with NABP's member boards of pharmacy to develop NABP's Universal Inspection form and Multistate Inspection Blueprint, which are tools to assist the boards of pharmacy in conducting uniform inspections of sterile compounding facilities. Josh is currently working with NABP member boards of pharmacy on uniform processes and tools with respect to the DSCSA.

Connie Jung, RPh, PhD, Senior Advisor for Policy, ODSIR, FDA - Topic: Perspectives on Supply Chain Security for Prescription Drugs

Dr. Jung is currently Senior Advisor for Policy in the Office of Drug Security, Integrity, and Response (ODSIR) in FDA's Center for Drug Evaluation and Research, Office of Compliance. Her work focuses on development of policy and regulatory strategies to improve the security and integrity of the U.S. drug supply to protect patients from counterfeit or stolen product. She received her B.S. in Pharmacy from The Ohio State University and her Ph. D. in Pharmaceutical Sciences from the University of Cincinnati. Dr. Jung joined the FDA in 1999 as a toxicology researcher in the Center for Food Safety and Applied Nutrition, and later served as a Regulatory Reviewer of bioequivalence studies in the Office of Generic Drug before working on supply chain issues.

FACILITATOR BIOS

Henry Joseph Michtalik, MD, MHS, MPH., Assistant Professor of Medicine, Johns Hopkins Medicine

Dr. Michtalik is an Assistant Professor of Medicine at the Johns Hopkins University School of Medicine and a hospital medicine physician and researcher dedicated to providing wellness, patient safety, and quality improvement. He has experience in quantitative data analyses (including provider outcomes), qualitative methods (including developing and analyzing survey tools for hospital employees), and stakeholder engagement (including "white papers" of workload and healthcare coverage recommendations). He has also successfully collaborated with the Johns Hopkins Clinical Research Network, a network of over 25 hospitals within Maryland, Washington D.C, Pennsylvania, and Virginia and served as co-investigator on several AHRQ task orders to review evidence for best practices and provide formal recommendations for government stakeholders. With his clinical, research, systematic review, and stakeholder engagement skills, he will help lead and analyze the provider survey on the knowledge, attitude, and practice toward counterfeit medicines.

G. Caleb Alexander, MD, Professor of Epidemiology and Medicine, Center for Drug Safety and Effectiveness, Johns Hopkins Bloomberg School of Public Health

Dr. Alexander is a Professor of Epidemiology and Medicine at the Johns Hopkins Bloomberg School of Public Health, where he serves as founding co-Director of the Center for Drug Safety and Effectiveness and founding Principal Investigator of the Johns Hopkins-FDA Center of Excellence in Regulatory Science and Innovation (JH-CERSI). He is a practicing general internist and pharmacoepidemiologist and is internationally recognized for his research examining prescription drug utilization, safety and effectiveness. The author of over 425 scientific articles and book chapters, many of which have focused on the epidemiology of the opioid epidemic, he has published regularly in leading scientific journals and testified in front of expert bodies including the U.S. House of Representatives and U.S. Senate. Dr. Alexander also serves on several editorial and advisory boards and is a frequent speaker on pharmaceutical utilization and policy. He received his B.A. cum laude from the University of Pennsylvania, an MD from Case Western Reserve University, and a Master of Science from the University of Chicago.

FACILITATOR BIOS

John B. Hertig, PharmD, MS, CPPS, FASHP, FFIP is Chair and an Associate Professor of Pharmacy Practice in the Butler University College of Pharmacy and Health Sciences
Dr. Hertig lectures around the world and publishes on a variety of patient safety, leadership, administration, health policy topics. He serves as an Associate Editor for the Journal of Medicine Access, and his extensive research program is designed to enhance the safety of the medication use process, while using evidence to inform patient advocacy efforts. Dr. Hertig is a Member of the United States Food and Drug Administration Drug Safety and Risk Management Advisory Committee. He holds other national and international appointments, including with the International Pharmaceutical Federation, where he is Treasurer for the Hospital Pharmacy Section, and as Past-President of the Board of Directors for the Alliance for Safe Online Pharmacies – Global (ASOP), where he leads efforts to reduce the patient safety impact of illegal and counterfeit online drug distribution worldwide. He was awarded the ASOP Global Patient Safety Champion Award in 2018. Dr. Hertig received his Bachelor of Science in Pharmaceutical Sciences and Doctor of Pharmacy degrees from Purdue University (USA). He completed a PGY1 pharmacy practice and PGY2 health-system pharmacy administration residency at The Ohio State University Medical Center while also obtaining a Masters degree in Health-System Pharmacy Administration from The Ohio State University (USA).

Lubna Merchant, M.S., Pharm.D., Risk Management Product Lead, Pfizer
Dr. Merchant is a Director in the Risk Management Center of Excellence at Pfizer, Inc., where she is responsible for the strategy and implementation of risk management plans globally. Dr. Merchant provides global leadership in delivering innovative and strategic risk management excellence, regulatory compliance, effectiveness evaluation, and operational excellence for Pfizer's portfolio of drug products with risk management programs. Prior to joining Pfizer, Dr. Merchant was the Deputy Director of the Office of Medication Error Prevention and Risk Management in FDA's Center for Drug Evaluation and Research's (CDER) where she was responsible for the Center's programs in risk management and medication error prevention. She provided expertise on development and implementation of programs and initiatives to support the Center's policies related to Risk Evaluation and Mitigation Strategies (REMS). She also served as an expert/scientific advisor on medication errors associated with drug and biological products within the Center and outside agencies.