

The Behavioral and Educational Strategies for Avoiding Falsified Medicine Exposure (BESAFE)

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Conference Report

2025 CONFERENCE ON PUBLIC HEALTH STRATEGIES TO COMBAT SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS



The BESAFE initiative is supported with funding from Pfizer Inc.



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FOREWORD

Confronting the Global Threat of Substandard and Falsified Medical Products

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The safety of the world's medicines had come under unprecedented pressure. For many years, it was widely assumed that strong regulatory systems, trusted supply chains, and scientific rigor would be sufficient to protect patients. Yet recent events revealed a far more complex reality. Substandard and falsified (SF) medical products now sit at the intersection of global public health, digital misinformation, international trade, and increasingly fragile supply chains. It was within this shifting landscape that the BESAFE Initiative was created, and why the 2025 BESAFE Conference was so important.

Countries are facing a medicine-safety environment unlike anything seen before. Devastating incidents, such as the deaths of more than 20 children in India due to toxic cough syrup, have captured global attention, yet they represented only a fraction of the broader crisis. SF medicines are estimated to contribute to nearly one million deaths each year, driving a global market valued between \$200 billion and \$431 billion. This burden ignores borders. No country is immune.

In the United States, the crisis has taken on a different but equally deadly form. In the USA alone, more than 100,000 lives are lost annually to counterfeit pills, many laced with illicitly manufactured fentanyl. Evidence of counterfeiting appeared in one-quarter of overdose deaths among adolescents. A single counterfeit ring had sold \$250 million in fake HIV medications, and falsified cancer drugs, including Keytruda, were detected within legitimate channels. Counterfeit surgical and other medical devices have also penetrated U.S. supply chains.

The rapid rise of online pharmacies further intensifies these vulnerabilities. While digital access improves convenience for consumers, it also opens wide pathways for SF medical products. According to the National Association of Boards of Pharmacy, more than 95% of online pharmacies violated U.S. public safety laws. Yet nearly half of Americans mistakenly believed that websites selling prescription drugs were approved or vetted by regulators. Many purchase medicines online without understanding the risks—an information gap that allows SF products to flourish.

This challenge is not new. The World Health Organization first recognized counterfeit medicines as a global public health threat in 1985. These products frequently contained incorrect doses, no active ingredient, or toxic contaminants. Despite progress over the years, globalization, online commerce, and increasingly sophisticated counterfeiters had outpaced existing safeguards. Strengthening regulatory systems, improving surveillance, and expanding public and provider education were widely recognized as essential. Addressing supply without addressing demand or vice versa would not be enough.



The creation of the U.S. Food and Drug Administration (FDA) in response to the 1937 mass poisoning from toxic medicine has profoundly improved drug safety and pharmacovigilance. Yet the recurrence of similar tragedies decades later raises difficult questions about how current systems have failed and what reforms are urgently needed.

Against this backdrop, the 2025 BESAFE Conference proved both timely and essential. Discussions underscored how the convergence of rapidly evolving technology, global trade, and highly organized criminal networks had heightened the risks associated with SF medicines and devices. For public health professionals, understanding the scale, complexity, and cross-sector collaboration requires confronting this challenge more critically than ever.

Over the two days, participants engaged with leading experts from across the world. Sessions explored the public health significance of SF medicines and devices, identified critical knowledge gaps, examined how to better engage HCPs (HCPs) as frontline defenders, strengthened international cooperation, and addressed the growing risks posed by online pharmacies and social-media-based drug sales. Leaders from the World Health Organization, American Medical Association, African Union Development Agency (AUDA-NEPAD), Pan American Health Organization (PAHO), Caribbean Public Health Agency (CARPHA), American Academy of Family Physicians (AAFP), American College of Preventive Medicine (ACPM), US Pharmacopeia (USP), National Association Boards of Pharmacy (NABP), Alliance for Safe Online Pharmacies (ASOP) Global, Partnership for Safe Medicines (PSM), Institute for Safe Medication Practices (ISMP), Population Services International (PSI), Pharmacy Council Jamaica, Africa Resource Center, the Gates Foundation, the Brazzaville Foundation, Concept Foundation, academic institutions, and pharmaceutical organizations contributed invaluable insights that enriched the collective understanding.

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The proceedings reflect a central conclusion: only through shared expertise, coordinated action, and a unified commitment can the global community confront the expanding threat of substandard and falsified medicines and medical devices.

Behind every statistic lies a human life, a patient who deserves safe, authentic treatment.

Thank you for your partnership, your dedication, and your collaboration as we continue this vital work.



FOREWORD

A New Era of Risks: Protecting Patients in a Digital Medicine World

Dr. Alexander Ding, MD, MS, MBA

Secretary, Board of Trustees, American Medical Association

Dr. Alexander Ding opened the 2025 BESAFE Conference with a powerful call to confront the erosion of public trust and the growing digital vulnerabilities that now shape medical safety. He emphasized that the crisis of substandard and falsified medical products (SFMPs) is not only a regulatory failure but a human one—patients who do not improve, clinicians who feel helpless, and communities whose trust in medicine is shaken. While many clinicians still assume counterfeit medicines are problems confined elsewhere or managed exclusively by regulators, Dr. Ding underscored that these products appear in U.S. exam rooms, pharmacy shelves, and online marketplaces with increasing frequency.

He highlighted how misinformation, social-media-driven demand, and affordability pressures now intertwine with criminal networks to create a digitally enabled threat landscape. Weight-loss medications, oncology products, and supplements illustrate how easily false promises and online advertising can steer patients toward illegitimate sources. Counterfeit medicines and misinformation, he argued, have become “two sides of the same coin.”

Dr. Ding stressed that clinicians remain the most trusted figures in the health system and therefore play a pivotal role in restoring confidence in healthcare. He urged the integration of suspected substandard and falsified medicines and medical devices awareness into medical and pharmacy education, simplification of reporting pathways such as MedWatch, and stronger collaboration across regulators, technologists, pharmacists, and organizations like BESAFE. He also cautioned that while Augmented Intelligence (AI) can enhance authentication and surveillance, it can equally accelerate deception, making ethical, human-centered oversight essential.

His message was clear: protecting patients in the digital age requires vigilance, partnership, and leadership from clinicians and institutions alike. “Trust in medicine starts with us,” he concluded, reminding participants that the American Medical Association’s historic mission to confront medical quackery now extends to the online world of algorithm-driven misinformation and counterfeit drug marketplaces. His keynote set the tone for a conference focused on action—uniting public health, public safety, digital governance, and global cooperation to ensure every patient receives safe and authentic treatment.

Augmented Intelligence (the term used by AMA referring to Artificial Intelligence) is reshaping both sides of the medicine-quality landscape. On one hand, AI has the potential to strengthen detection by authenticating packaging, identifying anomalies, and enhancing supply-chain traceability. On the other hand, it can also accelerate deception—facilitating fake labels, generating fraudulent data, and rapidly amplifying false health claims across digital platforms. In this evolving environment, AI is best understood as augmented intelligence: a tool that should enhance, not replace, human judgment. Ethical, human-centered oversight remains essential to ensure that technology advances medicine safety rather than undermining it.

“**Globally, the World Health Organization estimates that about one in ten medicines may be substandard or falsified. That represents not just a regulatory failure, but a human one as well, affecting patients who do not improve, clinicians who feel helpless, and communities losing faith in the promise of modern medicine.**”

Four essential actions for the health community to protect patients:

- **Educate** by integrating counterfeit-medicine awareness and pharmacovigilance into medical, pharmacy, nursing, and Nurse Practitioner and Physician Assistant training.
- **Empower** clinicians by simplifying reporting and making systems like FDA MedWatch more accessible and usable.
- **Collaborate** across disciplines and sectors—linking pharmacists, regulators, technologists, law enforcement, and organizations like BESAPE
- **Lead** by ensuring the clinician’s voice shapes policy, technology design, public-facing education, and digital-safety initiatives.



Dr. Alexander Ding, MD, MS, MBA
Secretary, Board of Trustees, American Medical Association



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EXECUTIVE SUMMARY



The 2025 BESAFE Conference outlined a comprehensive roadmap to reduce exposure to substandard and falsified medical products by strengthening regulatory and legal frameworks; empowering clinicians through education and integrated workflow supports; protecting the public through digital governance and accessible, affordable medicine pathways; and building interoperable surveillance systems that connect data across borders and sectors. The conference positioned medicine quality as a global health security priority and underscored the urgent need for unified, sustained, multi-sector action to safeguard patients worldwide.

The 2025 BESAFE Conference brought together leading experts from global health, medicine, regulatory science, cybersecurity, industry, and public policy to examine the rapidly evolving threat posed by substandard and falsified medical products (SFMPs). Over two days, participants discussed an increasingly complex global landscape in which pharmaceutical crime, digital misinformation, patient behavior, and supply chain vulnerabilities converge to undermine the safety and reliability of medicines worldwide. Speakers emphasized that the SFMPs crisis has expanded beyond traditional geographic boundaries and now affects every therapeutic category and every region, driven by rising demand for high-value medications, persistent affordability barriers, and the dramatic growth of online and informal markets. Falsified oncology injectables entering U.S. hospital systems, counterfeit semaglutide and weight-loss agents circulating through social media and encrypted apps, and diversion of cold-chain biologics illustrated how sophisticated counterfeit networks now exploit global supply chains and digital ecosystems at an unprecedented scale.



100+

Attendees shared expertise and insights



Cross-sectoral

Participation from academia, healthcare, industry and more

EXECUTIVE SUMMARY

The first section of the conference focused on the structural foundations of the crisis, regulatory capacity, clinical preparedness, and global cooperation. Discussions highlighted that national regulatory authorities (NRAs) face disparate capacity levels, limiting their ability to detect and respond to SF products without harmonized frameworks. Regional bodies such as the Caribbean Regulatory System and the African Medicines Agency showcased promising models of pooled surveillance and coordinated enforcement, yet also underscored the persistent challenges of laboratory shortages, fragmented reporting, and informal market reliance in many regions. Clinicians and pharmacists were repeatedly identified as the frontline of detection, yet most receive little formal education on SFMPs risks. Their encounters with poor-quality products often occur only after patient harm.

Speakers stressed the need to integrate SFMPs content into medical, nursing, and pharmacy curricula, supported by accreditation bodies and national transformation efforts. Technology was presented as a valuable but insufficient tool; effective detection requires strong governance, aligned standards, and integrated surveillance systems connecting pharmacovigilance data, customs intelligence, and procurement oversight.

The second section of the conference expanded the lens to public behavior, digital vulnerability, and the rapidly growing influence of online marketplaces and social media platforms. Participants described how consumers, often driven by cost pressures, drug shortages, or persuasive social media content, frequently turn to online sellers without understanding the associated risks.

Illegal online pharmacies professionally designed fraudulent websites, influencer-promoted weight-loss and aesthetic products, and algorithm-driven advertising all contribute to unprecedented levels of digital exposure.

Experts in cybersecurity and digital policy explained how counterfeiters operate through decentralized networks of website designers, affiliate marketers, payment processors, and global shippers, making traditional enforcement alone inadequate. Effective solutions require meaningful collaboration with technology companies, domain registrars, and payment networks, as well as new governance frameworks capable of assigning accountability when unsafe medical products are promoted or sold online.

Across both days, several themes emerged as central to a coordinated global response. Public trust is foundational: trust in clinicians, regulatory institutions, pharmaceutical manufacturers, digital information sources, and verified pharmacies determines whether individuals choose safe or unsafe channels. Surveillance systems must evolve beyond siloed reporting into interconnected platforms capable of identifying early warning signals across regulatory, clinical, customs, and digital domains. Clinician preparedness remains one of the weakest links, requiring both curricular reform and workflow-integrated tools that enable providers to counsel patients effectively within the constraints of routine care. And finally, meaningful progress requires cross-border and cross-sector partnerships, linking global institutions, national regulators, health systems, law enforcement, technology firms, and community organizations.



1. EMERGING THREATS, REGULATORY ALIGNMENT, AND FRONTLINE PREPAREDNESS

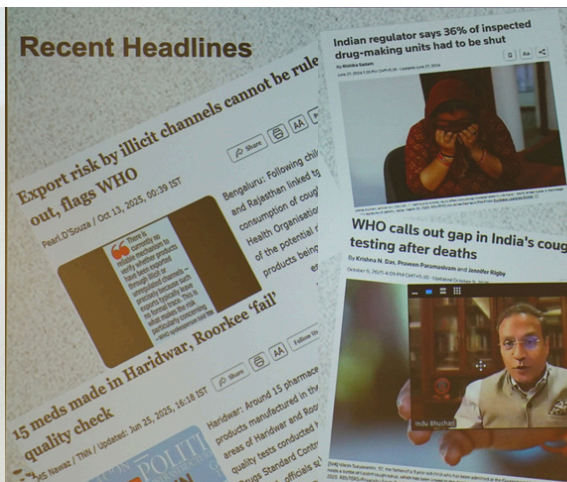
Over seven hours of panel discussions and case-driven presentations, participants described a landscape defined by rapidly expanding online marketplaces, increasingly sophisticated counterfeit operations, persistent affordability barriers, and uneven regulatory capacity across regions. The discussions emphasized five major themes: emerging threats shaped by global digital ecosystems; regulatory harmonization efforts across WHO, the Caribbean, and the African continent; the critical role of HCPs as frontline defenders; widening provider knowledge gaps; and the urgent need for curriculum reform in medicine, pharmacy, and nursing.

Case examples from North America, Africa, South America, and the Caribbean highlighted the human and economic consequences of SF medicines. Cross-cutting insights emphasized trust, surveillance integration, technology's role as an enabler, the persistence of informal markets, and the unpreparedness of clinicians.

The key recommendations included strengthening regulatory systems, expanding clinician training, modernizing pharmacovigilance, regulating online pharmacies, improving affordability, and investing in global surveillance and data systems.

1. EMERGING THREATS, REGULATORY ALIGNMENT, AND FRONTLINE PREPAREDNESS

1.1 THE STATE OF SFMPs: THE 2025 LANDSCAPE



Tony P. Nguyen, PharmD, MBA
US Patient Safety & Pharmacovigilance Head, Novartis

Karin Tollefson, PharmD
Chief Oncology Medical Officer, Pfizer

The 2025 environment reflects a convergence of structural vulnerabilities and evolving criminal dynamics. Speakers described an illicit market estimated between US\$200–431 billion annually, contributing to nearly a million deaths each year. While historically associated with low- and middle-income countries, SFMPs now pose substantial risks in high-income countries as well, driven by online pharmacies, supply chain disruptions, misinformation, and high-demand therapeutics such as oncology injectables, GLP-1 agonists, weight-loss medications, and aesthetic compounds.

Participants noted that counterfeit operations have scaled in sophistication. Investigations have revealed falsified oncology injectables with no active ingredient entering hospital procurement channels through unfamiliar distributors. Cold-chain products are increasingly diverted, repackaged, and reintroduced into markets without proper handling, undermining the stability of biologics. In this context, healthcare providers have a critical role to play at the point of care:

“**If you know that your patient did receive a medicine from an online source, please make sure to ask them to confirm whether that is a genuine online pharmacy. You can also look at the packaging for any spelling errors or issues with appearance. If the patient has been on the medicine before, they can compare it with previous packaging. Check whether the tablet is cracked and whether the quality of the tamper-evident features on the package is intact. There are physical attributes you can verify if you have the medicine in hand.** Karin Tollefson, PharmD, Chief Oncology Medical Officer, Pfizer

Counterfeiters target high-profit branded medicines, exploiting shortages and demand surges, while over 95 percent of online pharmacies operate illegally and appear legitimate. Regulations are currently built for brick-and-mortar pharmacies and must be extended to online platforms to ensure accountability.

“**Our regulations are originally made for brick-and-mortar pharmacies, and there is accountability attached to that. The regulations now need to be moved to online pharmacies so that they can be accountable for the products they are providing. And of course, there is potential for people to find loopholes, but we cannot give up!**”



Indu Bhushan, PhD, MHS, Ex-Director General, Asian Development Bank (ADB)

1. EMERGING THREATS, REGULATORY ALIGNMENT, AND FRONTLINE PREPAREDNESS

1.2 EMERGING THREATS

The discussions on emerging threats emphasized that digital ecosystems now shape the sub-standard and falsified medical products crisis. Fraudulent online pharmacies proliferate quickly, reappearing within hours after shutdowns. Social media platforms amplify unverified and misleading health information, driving consumers toward unsafe treatments and counterfeit products. Panelists described cases including falsified GLP-1 injectables circulating in multiple regions and a surge in counterfeit M30 oxycodone in North America contributing to severe poisonings. These examples illustrated the expanding reach of counterfeiters and underscored the need for coordinated digital governance approaches.

1.3 REGULATORY HARMONIZATION EFFORTS

The WHO and the Caribbean Regulatory System (CRS) presented complementary models for regulation and cooperation, which also could be a learning opportunity for the newly established African Medicines Agency. CRS supports 26 Caribbean nations with e-reporting platforms, shared alerts, and newly expanded surveillance of nutraceuticals and medical devices. In the case of

Africa, participants discussed the African Medicines Agency's long-term harmonization efforts, including the African Union Model Law, regional working groups, and proposals for an African Pharmaceutical Crime Convention. These systems create pathways for coordinated surveillance, joint enforcement, and standardized quality assurance. However, disparities in laboratory capacity, uneven regulatory maturity, fragmented reporting systems, and persistent informal markets continue to challenge progress.

Anthony Kapeta, LLM, Legal Officer, African Medicines Regulatory Harmonization Program (AMRH), African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD)



Strengthening regulatory systems is absolutely not optional. It is the single most effective way to fight SFMPs while ensuring access to safe and quality medicines. Patients and end users do not have the ability or the responsibility to determine whether a product is safe, effective, and of the right quality. That responsibility lies with strong regulatory systems that safeguard public health and build trust, because once trust is lost, it is very difficult to regain.

Pernette Bourdillon Esteve, Ph.D., Technical Officer Incidents and substandard/falsified medical products, WHO



Pernette Bourdillon Esteve (left), PhD, Technical Officer, Incidents and Substandard/Falsified Medical Products, WHO; and Chantelle Bailey (right), PhD, PGCert, Program Manager, Caribbean Regulatory System (CRS), Caribbean Public Health Agency (CARPHA).

1. EMERGING THREATS, REGULATORY ALIGNMENT, AND FRONTLINE PREPAREDNESS



From left to right: Rita K. Jew, PharmD, MBA, President, Institute for Safe Medication Practices (ISMP); Henry Michtalik, MD, MPH, MH, Assistant Professor of Medicine, Johns Hopkins University School of Medicine (BESAFE-BSPH); Margot Savoy, MD, MPH, FAAFP, Chief Medical Officer, American Academy of Family Physicians

1.4 HEALTHCARE PROFESSIONALS AS FRONTLINE DEFENDERS

Clinicians and pharmacists can play a critical role in detecting SF medicines, yet they often lack tools and training.

Participants described scenarios where clinicians encounter unexpected medication failures, inconsistent therapeutic effects, or unusual adverse events, potential indicators of SFMPs, but may not recognize these patterns. Practical cues such as unusual smell, taste, or appearance of medicines; tamper-evident packaging failures; missing batch numbers; or unexpected patient benefit can be early warning signs.

Pharmacists highlighted barriers in verifying products, particularly when suppliers fall outside established networks. The limited feedback clinicians receive from reporting systems further dampens reporting motivation.

“

If your patient is receiving a medication that you're not getting the intended effect, that should be a red flag. If the patient is getting an adverse reaction that is unexpected, that should also be another red flag.

Rita K. Jew, PharmD, MBA, President, Institute for Safe Medication Practices (ISMP)

1. EMERGING THREATS, REGULATORY ALIGNMENT, AND FRONTLINE PREPAREDNESS

1.5 MIND THE GAP: PROVIDER KNOWLEDGE GAPS

Speakers highlighted widespread gaps in both pre-service and in-service training related to SFMPs. Most U.S. medical schools lack structured content on medicine quality and falsification, and one in three pharmacy schools report no targeted instruction on counterfeit detection or supply-chain risk. As a result, many clinicians enter practice without the tools needed to anticipate or identify SFMP threats.

“ I don’t even think people are fully aware of the magnitude of what you’re describing. That big, huge magnitude of what’s going on is not at all perceived in the office. No one thinks their patients are getting that many prescriptions from outside of a standalone pharmacy. No one thinks that those prescriptions are odd.

Dr Margot Savoy, MD, MPH, FAAFP, Chief Medical Officer, American Academy of Family Physicians (AAFP)

“ ——— What we find is really astonishing. Fifty eight percent of the key starting materials (KSMs) for U.S. APIs are sourced from a single country. As we go further upstream, particularly with KSMs, that level of concentration creates a great deal of vulnerability.

Dr. Jude Nwokike, PhD, MSc, MPH, Vice President, Supply Chain Resilience. US Pharmacopeia (USP)

In the United States, gaps in clinician preparedness are compounded by structural and regulatory limitations across the pharmaceutical supply chain. Although the U.S. Drug Supply Chain Security Act (DSCSA) was designed to strengthen medicine traceability, its tools and data remain largely inaccessible to frontline clinicians, limiting their usefulness in everyday clinical decision-making. As a result, downstream clinical risks often surface only after patients experience adverse outcomes, reflecting a reactive rather than preventive approach to medicine safety.



From left to right: Steph Tan, MPH, Policy Analyst, US Pharmacopeia (USP); Paul Baffoe-Bonnie, PharmD, MHS, Research Associate, Trident Health Law; Jude Nwokike, PhD, MSc, MPH, Vice President, Supply Chain Resilience, USP; Sachiko Ozawa, PhD, MHS, Associate Professor, University of North Carolina; Brian A. Smith, JD, MPH, Founder & Principal Attorney, Trident Health Law

1. EMERGING THREATS, REGULATORY ALIGNMENT, AND FRONTLINE PREPAREDNESS

1.6 CURRICULUM REFORM

The discussion on curriculum reform underscored opportunities to embed SFMPs content within existing accreditation and competency frameworks. Presenters recommended incorporating SFMPs-related skills under Systems-Based Practice competencies within ACGME and AAMC frameworks. Several national initiatives, including the American Medical Association's 10-year medical education transformation and residency redesign, present near-term opportunities to integrate SF content. Evidence from short learning modules showed significant improvement in student knowledge, suggesting that integration need not be burdensome. Partnerships with organizations such as WHO, International Pharmaceutical Federation (FIP), and American Medical Association EdHub can support scalable training development.



From left to right: Dr. Damon Green, MD, MS, MBA, Public Health and General Preventive Medicine Specialist; Ana Carolina da Silva Macareno, PharmD, MPH, Risk Management Product Lead, Pfizer; Lynn Jeffers, MD, MBA, Member, Board of Trustees, American Medical Association, and current Trustee, American Society of Plastic Surgeons

1.7 CASE EXAMPLES AND ILLUSTRATIVE FINDINGS

Speakers referenced case examples illustrating the breadth of SFMPs challenges:

- U.S. hospitals inadvertently dispensing falsified oncology injectables obtained through unfamiliar distributors.
- More than 30 individuals hospitalized after receiving falsified Botox, including multiple ICU admissions.
- Global circulation of counterfeit semaglutide products and other GLP-1 agonists frequently purchased online.
- Counterfeit M30 oxycodone contributing to widespread poisonings during the North American opioid crisis.
- Ghana's estimated USD 32 million annual economic burden from substandard co-amoxiclav alone.
- Abortion medications, erectile dysfunction drugs, antibiotics, and weight-loss agents appearing frequently in informal markets.
- Cold-chain diversion cases revealing that improperly stored biologics re-enter formal supply chains.

These examples underscored the human, economic, and systemic consequences of SF medicines, while demonstrating how counterfeiters target both high-value therapeutics and medicines serving unmet health needs.

1. EMERGING THREATS, REGULATORY ALIGNMENT, AND FRONTLINE PREPAREDNESS

1.8 CROSS-CUTTING INSIGHTS (SUMMARY)

The Day 1 discussions surfaced several overarching insights. First, **trust** remains a foundational element of medicine quality—trust in clinicians, in regulatory systems, pharmaceutical manufacturers, and in the broader supply chain. Second, **surveillance systems** must integrate data streams across pharmacovigilance, customs, law enforcement, procurement, and manufacturing. Third, **technology** can enhance detection through AI authentication tools, advanced QR codes, microbioprinting, and chemical fingerprinting, but only when supported by strong governance and enforcement. Fourth, **informal markets** in both LMICs and high-income countries reflect systemic gaps—ranging from affordability to access—and cannot be addressed solely through punitive measures. Finally, **clinician preparedness** remains a critical weakness, as many healthcare workers lack awareness, tools, or confidence to detect and report SF medicines.

1.9 RECOMMENDATIONS EMERGING FROM SECTION I

Several recommendations emerged across the seven hours of discussion:

1. Strengthen regulatory and legal frameworks.

Participants emphasized the need for expanded laboratory capacity, harmonized national and regional regulations, stronger enforcement mechanisms, and cross-border collaboration. Proposals included enhanced customs intelligence, multi-country investigations, and continental-level legal instruments such as the proposed African Pharmaceutical Crime Convention.

2. Advance healthcare professional education.

Speakers called for integrating SFMPs content into medical, pharmacy, and nursing curricula; establishing national competencies; and creating accessible CME pathways. Practical training should equip clinicians to identify signs of product quality failure and understand reporting processes.

3. Modernize pharmacovigilance systems.

Participants stressed simplifying reporting

procedures, incorporating digital tools, and ensuring feedback loops to clinicians.

Leveraging big data, from EHRs to social media, can strengthen early signal detection.

4. Strengthen oversight of online pharmacies.

Coordinated engagement with search engines, payment processors, industry, and global security partners is needed to reduce consumer exposure to illegal sellers and increase visibility of verified sources.

5. Improve affordability and access.

Speakers highlighted the importance of expanding patient assistance programs, raising awareness of cost-saving alternatives, and ensuring supply chain resilience during shortages to reduce dependence on unsafe channels.

6. Invest in research and surveillance.

Prevalence studies, economic modeling, standardized methodologies, and cross-border data-sharing agreements are essential for building an evidence-based global response.



2. BUILDING A SAFER DIGITAL AND PUBLIC HEALTH ECOSYSTEM

The second day of the 2025 BESAFE Conference expanded the scope of discussion from clinical, regulatory, and system-level responses toward public-facing strategies, digital governance, social media enforcement, and multi-sectoral collaboration. Speakers emphasized that preventing exposure to SFMPs requires an ecosystem approach: empowering the public, strengthening the roles of HCPs in prevention and early detection, aligning global regulatory actors, leveraging cross-sector partnerships, and addressing cyber-enabled crime occurring across online pharmacies, social media platforms, and encrypted digital marketplaces.

The day's sessions underscored three overarching messages. First, public exposure to SF medicines is shaped as much by patient behavior, digital navigation, and affordability pressures as by regulatory gaps. Second, HCPs require expanded support to serve as educators, advisors, and advocates for safe medicine use. Third, cross-sector solutions—including collaboration with technology firms, cybersecurity teams, customs agencies, global intelligence networks, and patient safety organizations are essential to restoring public trust and limiting exposure to illegal supply chains.

2. BUILDING A SAFER DIGITAL AND PUBLIC HEALTH ECOSYSTEM



From left to right: Katharine Briggs, Ph.D., Research Associate, Department of Pharmaceutical Sciences, University of Maryland; Foulo BASSE, President and CEO, Brazzaville Foundation; Ilisa Bernstein, PharmD, JD, President, Bernstein Rx Solutions

2.1 REACHING THE PUBLIC AND PREVENTING EXPOSURE

The opening session of Day 2 centered on a central challenge: how to reduce consumer exposure to SF medicines in an era where drug purchasing behavior increasingly bypasses traditional pharmacies. Panelists from ASOP, PAHO, ARC, and academic institutions described major vulnerabilities in public knowledge, digital navigation, and affordability.

Speakers emphasized that most consumers cannot differentiate legitimate online pharmacies from illegal ones, and that even highly educated patients are susceptible to professionally designed fraudulent sites. Search engine algorithms further amplify risk by elevating illegal sellers, an issue repeatedly highlighted across Day 1 and Day 2.

The panel described a landscape where illegal actors flood social media with advertisements for high-demand medications, particularly GLP-1 agonists, weight-loss drugs, aesthetic products, and sexual health medications.

Panelists also underscored that affordability continues to be among key drivers of unsafe purchasing behaviors. High out-of-pocket costs push patients toward low-cost alternatives advertised online, particularly in therapeutic areas where insurance coverage is limited. Speakers argued for expanded public awareness of safer options, especially manufacturer-sponsored patient assistance programs (PAPs), which provide authentic products through direct distribution pathways. However, evidence presented showed that PAPs remain underutilized, despite being a major protective factor against SF exposure for oncology patients.

The session emphasized that public education must address practical skills: recognizing verified online pharmacies, identifying red flags in packaging, understanding risks of social media-promoted products, and seeking clinical guidance when sourcing medicines. Speakers called for a coordinated public communication strategy led jointly by regulators, professional associations, and digital safety coalitions.

2. BUILDING A SAFER DIGITAL AND PUBLIC HEALTH ECOSYSTEM

2.2 STRENGTHENING HEALTHCARE PROFESSIONALS' ROLES

The discussions on evolving role of HCPs in mitigating SFMPs exposure were moderated by global and U.S. experts from WHO, ACPM, UCL, and UNC. The discussion emphasized that HCPs play a central role not only in detection but also in prevention.

Speakers described HCPs as educators who can guide patients toward safe sources, advisors who can interpret risk signals, and advocates who can elevate system-level concerns. Yet clinicians and pharmacists often face significant barriers: limited time with patients, lack of training, and minimal awareness of reporting mechanisms. Participants discussed the realities of clinical workflow highlighted in transcript remarks where clinicians described limited patient interaction time and questioned how SFMPs education could be integrated within tight time constraints. Speakers argued that interventions must therefore be practical, brief, and embedded into existing clinical encounters without adding undue burden.

Panelists outlined key competencies that clinicians need: the ability to counsel patients on safe purchasing channels; knowledge of risk categories and common product targets; familiarity with public alerts and regulatory notices; and awareness of how to report suspected incidents to FDA or national health authorities. Several speakers reinforced that clinicians need clearer guidance and structured tools, such as EHR-integrated checklists or brief counseling scripts, to efficiently support patient decision-making.

“ HCPs are involved in the prevention, detection, and response to substandard and falsified medical products, which are the three main pillars of WHO’s work. Under prevention, we expect HCPs to be aware and vigilant, and to support quality systems... They also influence supply chain decisions, so that these are not based only on price, but also on considerations of quality, safety, and efficacy, ensuring that substandard and falsified medical products do not reach the market, including through educating patients about their scope, scale, and harm.

Rutendo Kuwana, Team Lead , Incidents and Substandard and Falsified Medical Products, WHO



From left to right: Rutendo Kuwana, Team Lead, Incidents and Substandard and Falsified Medical Products, WHO; Jean Christophe Rusatira, MD, PhD, MPH, Sr. Program Officer, BESAFE, Johns Hopkins Bloomberg School of Public Health; Dr. Peter Rumm, MD, MPH, FACPM, Director, Policy, American College of Preventive Medicine (ACPM); Michael Stepanovic, PharmD, MS, Assistant Professor, UNC Eshelman School of Pharmacy

2.3 BUILDING CROSS-SECTOR AND GLOBAL SOLUTIONS

The late morning session explored the necessity of cross-sector collaboration, bringing together representatives from the Gates Foundation, Concept Foundation, University of Maryland, and African Union Development Agency – New Partnership for Africa's Development (AUDA-NEPAD). The discussion illustrated that SFMPs prevention cannot be achieved through health sector action alone.

Panelists described the importance of linking regulatory systems with law enforcement, technology platforms, customs, and global intelligence networks. Speakers from leading organizations including Pharmaceutical Security Institute (PSI), University College London (UCL), Pharmacy Council, Jamaica and University of California San Diego shared insights into how cyber-enabled crime evolves across borders, with counterfeiters exploiting global shipping pathways, lax digital enforcement, and anonymity tools.

Speakers emphasized that solutions must integrate early-warning systems across multiple data streams, pharmacovigilance, customs seizures, manufacturing anomalies, procurement irregularities, and social media monitoring.

In addition to strengthening data interoperability and surveillance systems, speakers highlighted the importance of advancing product-level detection technologies. Prof. Bruce Yu presented Water Nuclear Magnetic Relaxometry (wNMR), a non-invasive measurement technology capable of analyzing intact liquid medicines without opening the primary container.

By integrating measurement science with data science, this approach seeks to enable earlier identification of substandard and falsified medical products before safety signals emerge, a model described as preventive pharmacovigilance. Preliminary applications demonstrate the ability to detect defects such as freeze damage, expiration-related degradation, and API concentration deviations, as well as to differentiate highly similar vaccines and biologics through molecular fingerprinting.

Ongoing FDA-supported work is focused on developing standardized fingerprint databases and exploring deployment pathways for national control laboratories and, ultimately, point-of-care use. The discussion reinforced that scalable detection tools will be critical complements to surveillance, regulatory coordination, and cross-border enforcement efforts.

2. BUILDING A SAFER DIGITAL AND PUBLIC HEALTH ECOSYSTEM

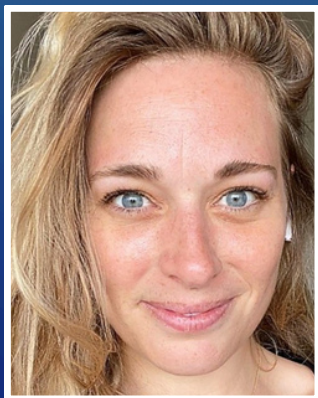
The panelists emphasized that improved interoperability across these datasets can allow earlier identification of SFMP clusters before they escalate into public health emergencies.

Participants also discussed the role of regional regulatory bodies, including the African Medicines Regulatory Harmonization program and the Caribbean Regulatory System, noting that cross-border coordination is essential for countries with limited laboratory capacity or resource constraints.

“

The Foundation has been involved in regulatory systems work for over a decade, but it's only in the last couple of years that we've focused more on substandard and falsified medical products. One of the main reasons is that we've been hearing from countries with limited regulatory systems that this is one of the most pressing regulatory issues they face. We've been able to put together a strategy and dedicated funding to sustainably reduce the prevalence of substandard and falsified medical products, while strengthening national regulatory authorities, particularly market control and surveillance.

Charlie Preston, MD, MPH Senior Program Officer, Regulatory Affairs, Gates Foundation



From left to right: Petra Procter, MSc, Senior Program Manager, Concept Foundation; Charlie Preston, MD, MPH, DipABPM, DipABLM, Senior Program Officer, Regulatory Affairs, Gates Foundation; Bruce Yu, Ph.D., Professor of Pharmaceutical Sciences, University of Maryland

2. BUILDING A SAFER DIGITAL AND PUBLIC HEALTH ECOSYSTEM

2.4 SAFEGUARDING CONSUMERS FROM ONLINE PHARMACY RISKS

The session “A Cautious Click” addressed the expanding digital threat environment. Cybersecurity experts, global intelligence analysts, and regulatory leaders described illegal online pharmacies as one of the fastest-growing vectors of SFMPs exposure.

The speakers highlighted the dramatic growth in online medicine purchasing, driven by convenience, social media influence, and affordability. They described a digital ecosystem where illegal sellers often appear legitimate, host professional-looking websites, and exploit search engine marketing tools.

“**We can do all that investigation we were talking about before, put all those dealer resources into it, identify a website, have it removed, and that same seller can pop up in the next day or two ... Unfortunately, if we don't get to the demand side, we're going to be playing this whack-a-mole issue for decades, like we already have.**

Timothy Mackey, Ph.D., Professor, UC San Diego; & Director, Global Health Policy Institute



From left to right: Jillian K. Brady, MS, Advisor, ASOP; Timothy Mackey, PhD, Professor, UC San Diego, and Director, Global Health Policy Institute; Ernestine Watson, PharmD, Chairperson, Jamaica Pharmacy Council; Peter York, Director of Global Intelligence, Pharmaceutical Security Institute

“**There's no solution. There are only layers of defense that you can put up. Disruption activities, investigations, and takedowns can be effective, but the penalties aren't harsh enough, so we see recidivists come back into the business. And lastly, we have to raise awareness. You've got to get to healthcare providers and patients. The only thing you can do is try to reach those that you can reach.**

Peter York, Director of Global Intelligence, Pharmaceutical Security Institute (PSI)

The session emphasized that cyber-enabled counterfeit networks are agile, rapidly shifting domains, mimicking regulatory logos, and using encrypted payment methods. Participants highlighted the “cat-and-mouse” dynamic where websites reappear shortly after takedowns. Social media platforms increasingly serve as advertising ecosystems for counterfeit medicines, with high engagement for weight-loss and aesthetic drugs.

Panelists stressed that public health actors must collaborate directly with tech companies, search engines, domain registrars, and payment processors. Without such partnerships, criminal networks retain major structural advantages.

2. BUILDING A SAFER DIGITAL AND PUBLIC HEALTH ECOSYSTEM

2.5 TACKLING THE SALE OF FALSIFIED MEDICINES ON SOCIAL MEDIA

The final panel explored how social media platforms have become major conduits for illegal medicine promotion. Representatives from anti-counterfeiting programs, legal enforcement, and industry described the surge in promotions for weight-loss medications, lifestyle drugs, and aesthetic products. Speakers noted that social media advertising exploits algorithmic amplification: products with high engagement, especially for weight-loss or cosmetic use, gain visibility quickly, spreading misinformation and unsafe promotional claims. Counterfeiters also take advantage of influencer-driven markets, where endorsements may not be evidence-based or may be posted by unidentified accounts.

Legal experts emphasized that enforcement across social media is particularly challenging. Platforms span jurisdictions, content is ephemeral, and sellers use evasive tactics such as coded language, disappearing stories, and redirection to encrypted messaging apps. Participants argued for new legal frameworks and global agreements that assign clear accountability for online harms.

2.6 CASE EXAMPLES AND ILLUSTRATIVE FINDINGS

The discussions offered compelling real-world cases illustrating the complexity of reaching the public and curbing digital exposure risks. Examples included:

- Social media-driven clusters of falsified semaglutide use leading to severe hypoglycemia.
- Illegal sellers on messaging apps distributing falsified antibiotics and sexual health medications.
- Cold-chain failures in diverted biologics purchased through unauthorized channels.
- Counterfeiters using identical labeling and QR codes to infiltrate hospital systems.
- Online pharmacy investigations revealing coordination between global producers and U.S.-based distribution hubs.
- Consumer-targeted scams where patients received saline, sub-potent doses, or mislabeled actives.

2.7 CROSS-CUTTING INSIGHTS

The Day 2 discussions repeatedly emphasized the need for integrated strategies across health systems, regulators, clinicians, tech companies, and global institutions. Several insights emerged: public education requires combining digital literacy with medicine safety guidance; clinicians need streamlined tools to advise patients within limited time; social media, online pharmacies, and encrypted marketplaces now form a unified risk ecosystem; and global interoperability across surveillance systems is essential for early detection. Above all, speakers highlighted that tech company collaboration is now a structural requirement for protecting public health.

2. BUILDING A SAFER DIGITAL AND PUBLIC HEALTH ECOSYSTEM



2.8 RECOMMENDATIONS EMERGING FROM DAY 2

Key recommendations included

- Launching coordinated awareness campaigns for healthcare providers and the public
- Expanding clinician training to include patient counseling strategies
- Strengthening partnerships with tech companies, search engines, and payment processors
- Developing global accountability frameworks for social media platforms
- Supporting regional initiatives such as Caribbean Regulatory System and African Medicines Regulatory Harmonization
- Integrating digital surveillance and customs data
- Enhancing affordability programs to reduce reliance on unsafe channels

“

Preventing exposure to SFMPs requires whole-of-society action. Regulators, clinicians, technologists, law enforcement, global institutions, and community organizations must act in concert. Protecting the public demands both structural reforms and practical tools that empower individuals to make safe choices.

Professor Saifuddin Ahmed, MBBS, PhD, Johns Hopkins Bloomberg School of Public Health (BSPH)

KEY NEXT STEPS FOR COORDINATED ACTION

HCPs Empowerment

1. Integrate SFMPs competencies into medical, nursing, pharmacy, and nurse practitioner and physician assistant curricula and continuing medical education programs.
2. Deploy workflow-integrated tools (electronic health record prompts, sourcing questions, visual inspection cues, one-click reporting).
3. Integrate the **4Ps into everyday practice**:
 - **Pause** – Quick safety check and packaging inspection.
 - **Probe** – Ask where medicines were obtained and use National Association of Boards of Pharmacy (NABP) verification tools.
 - **Protect** – Teach and reinforce three red flags (misspellings, pill changes, tampering).
 - **Pass It On** – Streamline MedWatch/online-pharmacy reporting and close feedback loops.

Digital Safety & Public Protection

1. Develop a Digital Exposure Risk Index to quantify online and social-media vulnerabilities.
2. Strengthen mechanisms to detect and limit illegal online pharmacies and social-media-based drug promotion.
3. Establish a BESAFE-Tech consortium involving Tech companies such as Google, Meta, TikTok, domain registrars, and payment processors.
4. Advocate for new accountability frameworks assigning responsibility to platforms that host or amplify SFMPs content.
5. Launch a national campaign to promote safe purchasing behaviors.
6. Provide consumer tools: Safe Online Pharmacy Checklist, red-flag packaging guide, Patient Assistance Program (PAP) navigation resource.
7. Expand digital literacy and medicine-safety education through libraries, schools, community centers, and patient organizations.

System & Regulatory Strengthening

1. Build interoperable surveillance systems linking safety alerts, pharmacovigilance (PV) data, customs, procurement, and digital monitoring.
2. Expand laboratory capacity and support regional pooled testing (African Medicines Agency, Caribbean Regulatory System, Pan American Health Organization).
3. Strengthen affordability pathways (PAP directories, patient support programs) to reduce unsafe purchasing.
4. Enhance cross-border collaboration with INTERPOL, customs, cybercrime units, and manufacturers on serial verification and tamper-evident features.



From the top left to right: Prof. Saifuddin Ahmed, Mr. Lev Kubiak, Dr. Jean Christophe Rusatira, Dr. Patrick Caubel, Dr. Henry Joseph Michtalik, Dr. Reema Mehta, Ms. Eishita Pal, Mr. Angel M. Melendez, Dr. Jean Berchmans, Mr. Michael Comeaux, Ms. Ayesha Khan, Dr. Nishith Jobanputra, Ms. Sharon J. Castillo, Ms. Manuela Dorado Novoa, Ms. Tess Morgan, Mr. Cameron Persaud, and Dr. Ana Macarenco.

ACKNOWLEDGMENT

The authors would like to thank all the speakers, presenters, and participants of the 2025 Conference on Public Health Strategies to Combat Substandard and Falsified Medical Products, held on October 22–23, 2025, 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 Johns Hopkins University (JHU) in close collaboration with a team from Pfizer Inc.

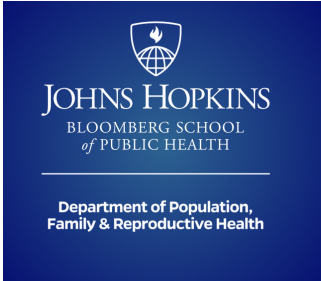
JHU BESAFE TEAM

- Saifuddin Ahmed
- Henry Joseph Michtalik
- Jean Christophe Rusatira
- Eishita Pal
- Jean Berchmans Uwimana
- Ayesha Khan
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Pfizer TEAM

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BESAFE WEBSITE

www.fakemedicinenomore.org

The conference, part of the BESAFE initiative, is supported with funding from Pfizer Inc.

FULL KEYNOTE ADDRESS

Dr. Alexander Ding, MD, MS, MBA.
Secretary, Board of Trustees, American Medical Association

“

Good morning, everyone. It is an honor to join you on behalf of the American Medical Association to open this important convening.

The BESAFE Conference sits at the intersection of public health, public safety, medicine, and global trust. It reminds us that the safety of our medicines is not guaranteed by chemistry alone—but by vigilance, collaboration, and shared responsibility.

Let me begin with a familiar clinical story. A patient comes in after weeks of treatment that simply isn't working. You check adherence, dosage, interactions, comorbidities—everything seems right. And then you realize the problem may not be clinical at all, but chemical: a medication that is not what it claims to be. That moment, when confidence in medicine itself feels fragile, is what this conference exists to address.

We all recognize that we are practicing in an era of declining public trust in institutions, in science, and in professionals, including physicians. Misinformation, political polarization, inequities in access, and the legacy effects of historical injustices have created a climate where doubt spreads faster than data. For clinicians, this means every encounter is more complex. Our expertise is questioned, our recommendations are compared against last night's search results, and our patients often arrive armed with misinformation, sometimes even with products purchased from online pharmacies or promoted by influencers.

For patients, diminished trust leads to hesitancy, fragmented care, and vulnerability to deception. And when substandard or falsified medicines are added to the equation, the consequences become even more severe.

Globally, the World Health Organization estimates that roughly one in ten medicines may be substandard or falsified. That statistic is not just a regulatory failure; it is a human one. It represents a patient who does not improve, a clinician who feels helpless, and a community that loses faith in the promise of modern medicine.

Yet many clinicians do not recognize this issue as part of their professional role. Most assume that problems with counterfeit or substandard products belong to the FDA, to pharmacies, or to law enforcement, not something that appears in their own exam rooms. But they do. And few physicians know how to identify the warning signs or how to report suspected issues through systems like FDA MedWatch.

This is precisely the gap that BESAFE seeks to close.

FULL KEYNOTE ADDRESS (CONT.)

What is new is how digitally enabled this problem has become. Fake medicines no longer circulate in back-alley markets, they circulate through social media, online forums, influencer marketing, and digital advertising. The same algorithms that connect people to health information can just as easily connect them to health misinformation. Demand generated by false promises, particularly during drug shortages or when treatments are costly or stigmatized, creates opportunity for illegitimate products to fill the void.

Misinformation and counterfeit products are not separate problems; increasingly, they are two sides of the same coin. Consider weight-loss medicines: Social media fuels demand for GLP-1 agonists. When legitimate supply is constrained, patients turn to compounded or online versions, some legitimate, others dangerously inconsistent. Or consider oncology, where desperation can push patients outside regulated supply chains. Even small quality lapses can be life-threatening. And in the supplement industry, where oversight is limited, mislabeling and contamination are widespread.

The AMA has extensively studied these dynamics through its Council on Science and Public Health. We have reaffirmed the need for strong physician reporting, FDA oversight, and transparency through the Drug Supply Chain Security Act. But vigilance must now extend to the digital marketplace, where misinformation has become a contaminant of care.

This isn't a new struggle for the AMA. When our association was founded in 1847, one of its first missions was to combat medical quackery. Today, the storefronts have moved online, and the false cures appear through TikTok ads, AI-generated testimonials, and counterfeit online pharmacies. But the mission, to protect patients from deception, remains the same.

Physicians and HCPs are uniquely positioned to meet this moment, not because we can inspect every vial, but because we hold something more powerful: the public trust. We must pair that trust with awareness, training, and partnership. We must serve as educators, helping patients distinguish evidence from marketing; as sentinels, identifying signs of poor-quality medicines and reporting them; as advocates for oversight and transparency; and as collaborators, working with pharmacists, regulators, technologists, and organizations like BESAFE.

AI reshapes both sides of this challenge. It can strengthen detection of anomalies, authenticate packaging, and enhance supply-chain traceability. But it can also make deception easier, enabling fake labels, fraudulent data, and rapid dissemination of false health claims. This is why the AMA uses the term augmented intelligence: technology must enhance, not replace, human judgment. Our ethical compass must guide how we apply these tools.

FULL KEYNOTE ADDRESS (CONT.)

We also recognize that systemic challenges compound these risks: workforce reductions at the FDA, increasing drug shortages, global manufacturing disruptions, and affordability pressures. When legitimate medications are scarce, patients look online, and the risk of encountering counterfeit or substandard products increases.

So how do we rise to this moment?

- Educate by integrating counterfeit-medicine awareness and pharmacovigilance into medical and pharmacy training.
- Empower clinicians by simplifying reporting and making systems like MedWatch more accessible.
- Collaborate across disciplines and sectors, partnering with pharmacists, regulators, technologists, and organizations like BESAFE.
- Lead by ensuring the clinician's voice shapes policy, technology, and public-facing education.

Because trust in medicine starts with us.

From fighting 19th-century snake oil to confronting 21st-century misinformation, the AMA's mission has remained constant: to safeguard truth in medicine and protect the patients who depend on it. By confronting misinformation, strengthening partnerships, and using technology wisely, we can rise to this challenge together.

Thank you for the opportunity to join you today. Welcome to BESAFE 2025. I look forward to an engaging and collaborative conference.”



Dr. Alexander Ding, MD, MS, MBA

Secretary, Board of Trustees, American Medical Association



JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Department of Population,
Family & Reproductive Health
BESAFE

AGENDA

October 22 -23, 2025

THE 2025 SYMPOSIUM ON PUBLIC HEALTH STRATEGIES FOR COMBATING SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS

JOHNS HOPKINS UNIVERSITY BLOOMBERG CENTER
555 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20001



THE BESAFE INITIATIVE IS SUPPORTED WITH FUNDING FROM PFIZER INC.

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MORNING

8:00-9:00 AM	Registration, Coffee, and Badge Pick-up
9:00-9:15 AM	Welcome Address Saifuddin Ahmed , Professor, Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health
9:15-9:30 AM	Keynote Speaker Alexander Ding, MD, MS, MBA , Secretary, Board of Trustees, American Medical Association (AMA)
9:30-10:15 AM	Panel: Emerging threats and the rapidly changing landscape of SFMPs Chair: Henry Michtalik, MD, MPH, MH , Assistant Professor of Medicine, Johns Hopkins University School of Medicine (BESAFE-BSPH) Panelists: <ul style="list-style-type: none"> • Karin Tollefson, PharmD, Chief Oncology Medical Officer, Pfizer • Tony Nguyen, PharmD, MBA, US Patient Safety & Pharmacovigilance Head, Novartis • Indu Bhushan, PhD, MHS, Ex-Director General. Asian Development Bank (ADB)
10:15-10:30 AM	Coffee break
10:30-11:15 AM	Panel: Combating SF and improving timely access to quality medicines through regulatory optimization and harmonization Chair: Ilisa Bernstein, PharmD, JD , President, Bernstein Rx Solutions Panelists: <ul style="list-style-type: none"> • Rutendo Kuwana, Team Lead & Pernette Bourdillon Esteve, Ph.D., Technical Officer, Incidents and substandard/falsified medical products, World Health Organization (WHO) • Chantelle Bailey, PhD, PGCert, Program Manager, Caribbean Regulatory System (CRS), Caribbean Public Health Agency (CARPHA) • Anthony Kapeta, LLM, Legal Officer, African Medicines Regulatory Harmonization Program (AMRH), African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD)
11:15 AM-Noon	Panel: Healthcare Professionals as Frontline Defenders Chair: Reema Mehta, PharmD, MPH , Head of Risk Assessment and Management Pfizer Panelists: <ul style="list-style-type: none"> • Henry Michtalik, MD, MPH, MH, Assistant Professor of Medicine, Johns Hopkins University School of Medicine (BESAFE-BSPH) • Rita K. Jew, PharmD, MBA, President, Institute for Safe Medication Practices (ISMP) • Margot Savoy, MD, MPH, FAAFP, Chief Medical Officer American Academy of Family Physicians • Oksana Pyzik, MPharm, Associate Professor, University College London (UCL) School of Pharmacy
Noon-1:00PM	Lunch Break & Networking

AFTERNOON

1:00-2:45 PM	<p>Panel: Mind the Gap—What Providers Know (and Don't Know) About SF Medicine</p> <p>Chair: Brian A. Smith, JD, MPH, Founder & Principal Attorney, Trident Health Law</p> <p>Panelists:</p> <ul style="list-style-type: none">• Sachiko Ozawa, PhD, MHS, Associate Professor, University of North Carolina (UNC)• Jude Nwokike, PhD, MSc, MPH, Vice President, Supply Chain ResilienceUS Pharmacopeia (USP)• Paul Baffoe-Bonnie, PharmD, MHS, Research Associate, Trident Health Law• Josh Bolin, Associate Executive Director, Government Affairs and Innovation, National Association of Boards of Pharmacy (NABP)• Alem Zekarias, MSPS, Senior Pharmacovigilance Scientist, Uppsala Monitoring Centre (UMC)• Steph Tan, MPH, Policy Analyst International Government & Regulatory Affairs, US Pharmacopeia (USP)
2:45-3:00 PM	<p>Coffee Break</p>
3:00-3:45 PM	<p>Panel: Curriculum Reform: Integrating SF Medical Products Content into Pre-Service and In-Service Training</p> <p>Chair: Ana Carolina da Silva Macareno, PharmD, MPH, Risk Management Product Lead, Pfizer</p> <p>Panelists:</p> <ul style="list-style-type: none">• Lynn Jeffers, MD, MBA, Member of the Board of Trustees of the American Medical Association (AMA) and current Trustee of the American Society of Plastic Surgeons (ASPS)• Dr. Damon Green, MD, MS, MBA, American College of Preventive Medicine (ACPM)
3:45-4:00PM	<p>Recap and Q&A: Henry Michtalik, MD, MPH, MH, Assistant Professor of Medicine, Johns Hopkins University School of Medicine (BESAFE-BSPH)</p>



MORNING

8:00-9:00 AM	Registration, Coffee, and Badge Pick-up
9:00-9:30 AM	Welcome Address Saifuddin Ahmed , Professor, Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health
9:30-10:15 AM	Panel: Reaching the Public and Preventing their Exposure Chair: Katharine Briggs, Ph.D. , Research Associate, Department of Pharmaceutical Sciences, University of Maryland Panelists: <ul style="list-style-type: none"> • Libby Baney, JD, Senior Advisor, Alliance for Safe Online Pharmacies (ASOP) • Edgar Robin Rojas, MPH, Technical Officer, Safe Use of Pharmaceuticals, Biologicals and Vaccines Pan American Health Organization (PAHO) • Neelaveni Padayachee, Ph.D., Associate Professor Pharmacy Practice, University of the Witwatersrand • Ilisa Bernstein, Ph.D., President, Bernstein Rx Solutions • Ibnou Khadim Diaw, MD, MPH, CEO, Africa Resource Centre (ARC)
10:15-10:30 AM	Coffee Break
10:30 -11.15 AM	Panel: Strengthening roles of Healthcare Professionals in fighting SFMPs Chair: Foulo BASSE , President and CEO, Brazzaville Foundation Panelists: <ul style="list-style-type: none"> • Rutendo Kuwana, Team Lead & Leticia Megias Lastra, MPharm, MSc Global Health, Technical Officer, Incidents and Substandard and Falsified Medical Products, WHO • Jean Christophe Rusatira, MD, Ph.D., MPH, Sr. Program Officer, BESAFE, Johns Hopkins Bloomberg School of Public Health • Dr. Peter Rumm, MD, MPH, FACPM, Director, Policy, American College of Preventive Medicine (ACPM) • Michael Stepanovic, PharmD, MS, Assistant Professor, UNC Eshelman School of Pharmacy
11:15 -Noon	Panel: Building Collaborative and Cross-Sector Solutions Chair: Anthony Kapeta, LLM , Legal Officer, African Medicines Regulatory Harmonization Program (AMRH), African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD) Panelists: <ul style="list-style-type: none"> • Charlie Preston, MD, MPH, DipABPM, DipABLM, Senior Program Officer, Regulatory Affairs, Gates Foundation • Shabbir Imber Safdar, Executive Director, Partnership for Safe Medicines (PSM), USA • Bruce Yu, Ph.D., Professor of Pharmaceutical Sciences, University of Maryland • Petra Procter, MSc, Senior Program Manager, Concept Foundation
Noon-1:00 PM	Lunch & Networking

AFTERNOON

1:00-2:00 PM	<p>Panel: A Cautious Click: Safeguarding Consumers from Online Pharmacy Risks Chair: Anthony Zook, Ph.D., Associate Vice President, Global Security, Merck & Co., Inc.</p> <p>Panelists:</p> <ul style="list-style-type: none">• Timothy Mackey, Ph.D., Professor, UC San Diego; & Director, Global Health Policy Institute UC San Diego• Jillian K. Brady, M.S., Advisor, Alliance for Safe Online Pharmacies (ASOP)• Peter York, MSc, Director of Global Intelligence Pharmaceutical Security Institute (PSI)• Dr Ernestine Watson, PharmD, Chairperson Pharmacy Council, Jamaica
2:00-3:00 PM	<p>Spotlight Talk: Tackling the Sale of Falsified Medicines on Social Media Chair: Michael K. Comeaux, Director Product Integrity, Pfizer Corporate Compliance and Risk, Global Security</p> <p>Panelists:</p> <ul style="list-style-type: none">• Silvia Helena Montoya Borrás, Director, Anti-Counterfeiting ProgramThe Asociación Nacional de Empresarios de Colombia (ANDI)• Kendra Ervin, J.D., Vice President, Head of Global Litigation and Enforcement, IP House
3:00-3:15 PM	<p>Recap and Q&A: Saifuddin Ahmed, Professor, Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health</p>



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SPEAKER BIOS



Saifuddin Ahmed, Professor, Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health

Dr. Saifuddin Ahmed is a distinguished physician, demographer, and epidemiologist, and serves as the Principal Investigator of the BESAFE Initiative – Behavioral and Educational Strategies for Avoiding Falsified Medicine Exposure. A professor at the Johns Hopkins Bloomberg School of Public Health, Dr. Ahmed has dedicated his career to advancing global health through rigorous research, policy engagement, and evidence-based program design.

He has served as a technical advisor to the World Health Organization and numerous international agencies, contributing to the development of frameworks aimed at strengthening health systems and ensuring the quality and safety of medicines. His pioneering research has significantly influenced maternal health, family planning, and health systems strengthening, and more recently, the global response to substandard and falsified medical products.

Dr. Ahmed’s scholarly impact is exceptional—he has authored over 190 peer-reviewed publications in leading scientific journals such as *The Lancet*, *The Lancet Global Health*, and *BMJ Global Health*, collectively garnering more than 15,000 citations. His mentorship, scientific rigor, and commitment to translating research into policy and practice continue to inspire a new generation of global health leaders working toward safer, more equitable access to medicines worldwide.



Alexander Ding, MD, MS, MBA, Secretary, Board of Trustees, American Medical Association (AMA)

Dr. Alexander Ding is a board-certified diagnostic and interventional radiologist and the enterprise Deputy Chief Medical Officer at Humana and CenterWell. In this role, he leads efforts to advance physician engagement, advocacy, wellness, value-based care, and clinician recruitment and retention. A fellow of the American College of Radiology, he serves as associate professor at the University of Louisville School of Medicine and mentors students through the University of Louisville Bluegrass Biodesign and Stanford Clinical Informatics and Management programs. Previously, Dr. Ding was Managing Partner at California Advanced Imaging, Vice Chief of Staff at San Mateo County Medical Center, and Chief of Radiology and Medical Director of Imaging at Sutter Health. He represents the AMA on the Association for the Advancement of Medical Instrumentation’s AI Committee and serves on the HL7 DaVinci Project steering committee.

Dr. Ding advises several health technology companies, innovation funds, and the FDA’s Total Product Life Cycle Advisory Program. He serves on the AMA Board’s Finance and Audit Committees and co-vice chairs the Firearm Injury Prevention Task Force.

He earned degrees from UC Berkeley, UCSF, and the Wharton School, completing residency and fellowship at Massachusetts General Hospital and Harvard Medical School. A U.S. Navy veteran, Dr. Ding lives in Louisville, Kentucky, with his wife and two sons.

SPEAKER BIOS



Karin Tollefson, PharmD, Chief Oncology Medical Officer, Pfizer Karin Tollefson, PharmD, is the Chief Oncology Medical Officer at Pfizer and leads the Oncology Global Medical Affairs Division. Prior to joining Pfizer, Karin was the Senior Vice President and Head of Global Medical Affairs at Seagen Inc. where she led the medical organization through the successful launches of three practice-changing medicines and established a global medical affairs organization. Dr. Tollefson has 30 years of experience in the pharmaceutical industry spending much of her early career at Eli Lilly and Company serving in progressive leadership roles in clinical operations, clinical development, portfolio & program management, and global medical affairs. She supported Lilly's acquisition and integration of ImClone Systems in 2008 and was part of the Oncology Business Unit Leadership team until her retirement in 2017. During her career, she has been involved in the launch of eight new medicines and numerous additional indications in the U.S. and international markets, serving patients in over 10 tumor and therapeutic areas. Dr. Tollefson currently serves as an Independent Director on the Board for Verastem Oncology, and has served on the philanthropic boards of the American Lung Association and the Leukemia and Lymphoma Society Indiana Board of Trustees. She started her undergraduate studies at Kansas State University and earned her Doctor of Pharmacy from the University of Kansas.



Tony P. Nguyen, PharmD, MBA, US Patient Safety & Pharmacovigilance Head, Novartis

Dr. Tony P. Nguyen is the US Patient Safety & Pharmacovigilance Country Head at Novartis, based in East Hanover, NJ. In his current role, Tony leads the development and implementation of local US pharmacovigilance strategies, oversees safety policies and procedures to ensure regulatory compliance, and provides strategic direction for risk management. He is responsible for the collection, evaluation, and reporting of adverse event data, and drives continuous improvement in pharmacovigilance systems and processes. He led new brands launches and supported major company acquisitions across pharmaceutical, consumer health, medical device, and digital health sectors.

Actively engaged in advancing medication safety and regulation, he has been published in peer-reviewed journal on safety considerations for dietary supplement manufacturers in the United States. Tony has served as a Stakeholder Council Member of the Botanical Safety Consortium and contributed to the CDC's PROTECT Initiative, which focuses on preventing overdoses and treatment errors in children. He was also an active member of the Consumer Healthcare Products Association (CHPA) Dietary Supplement Safety Workgroup and Self Harm Committee, and participated in the Council for Responsible Nutrition (CRN) CBD Working Group Taskforce. Through affiliations, Tony collaborates with industry, regulatory, and scientific partners to address emerging threats and promote best practices in product safety.

Tony holds a Doctor of Pharmacy (Pharm.D.) from Rutgers University and an MBA focused on strategic leadership. He is certified as a Project Management Professional (PMP®), Certified Manager of Quality/Organizational Excellence (CMQ/OE), and Board Certified Medical Affairs Specialist (BCMAS), and has completed Executive Leadership program at Cornell University.

On a personal note, Tony is passionate about mentoring and professional development, volunteering with Rutgers University's mentoring programs. He also enjoys cooking and barbecuing with families and friends on a nice sunny day.

SPEAKER BIOS

Indu Bhushan, PhD, MHS, Ex-Director General, Asian Development Bank (ADB)

Dr. Indu Bhushan is a Senior Associate at the Bloomberg School of Public Health, Johns Hopkins University, and Senior Advisor for the Asia Pacific region with the Boston Consulting Group (BCG). He also serves on the boards of several corporate and not-for-profit organizations. A former Indian Administrative Service (IAS) officer (1983 batch), Dr. Bhushan was the founding Chief Executive Officer (CEO) of the National Health Authority (NHA) and architect of the Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (AB-PMJAY), India's landmark health assurance program. Under his leadership, the scheme rapidly expanded to provide financial protection to more than 500 million people. He also spearheaded the launch of the National Digital Health Mission, later renamed the Ayushman Bharat Digital Mission, which laid the foundation for India's digital health ecosystem.

Dr. Bhushan holds a PhD in Health Economics and a Master of Health Sciences from Johns Hopkins University. He earned his B.Tech from IIT-BHU and a Postgraduate Diploma from IIT Delhi, and is also a Chartered Financial Analyst (CFA). Before returning to India, Dr. Bhushan held several senior leadership roles at the Asian Development Bank (ADB), including Director General of the East Asia Department, where he oversaw ADB's engagement with major Asian economies such as China, and Director General of the Strategy and Policy Department. He has been recognized globally for his contributions, receiving the Johns Hopkins Alumni Global Achievement Award, the Government of India's E-Governance Gold Medal, and the Population Award from the Government of Vietnam.

For more information, visit indubhushan.com

Pernette Bourdillon Esteve, Ph.D., Technical Officer, Incidents and substandard/falsified medical products, World Health Organization (WHO)

Pernette Bourdillon Esteve is a Technical Officer Market Surveillance and Control (MSC) team at the World Health Organization (WHO). She leads strategic initiatives to strengthen global surveillance and response systems for SF medical products, managing the Global Surveillance and Monitoring System database and guiding policy development through data analysis.

With over 15 years of international public health experience, Pernette has worked across global policy and technical domains. Her expertise spans incident management, strategy design, data interoperability, and training. Prior to WHO, she held roles at the United Nations Office against Drugs and Crime, UNITAID, the French Ministry of Foreign Affairs, and in the private sector, consistently focusing on global health.

She holds a Bachelor's degree in public health, a Masters in Political Science and is currently pursuing a PhD in global health, focusing on the interoperability of datasets linking SF medical products, diseases, and populations.

SPEAKER BIOS



Chantelle Bailey, PhD, PGCert, Program Manager, Caribbean Regulatory System (CRS), Caribbean Public Health Agency (CARPHA)

Dr. Bailey recently started her position as Programme Manager at the Caribbean Regulatory System (CRS) within the Caribbean Public Health Agency (CARPHA). She has fifteen years' international technical experience in leading, conducting and publishing several projects which primarily focused on regulation development, monitoring and evaluation to inform strategic policy for health systems. Furthermore, she has substantial expertise in the roles of regulatory frameworks on pharmacovigilance and post-market surveillance initiatives within acute care and primary care settings and clinical audits of health technologies at the drug-medical device interface. Currently, she is investigating intersectoral strategies for addressing the entry of substandard, falsified and unlicensed medical products into legitimate supply chains in the Caribbean.

She holds a PhD in Pharmacy and Pharmaceutical Sciences from the University of Manchester, a CIHR Postdoctoral Research Fellowship in Emergency Medicine undertaken at the University of British Columbia and a CIHR-MITACS Health System Impact Fellowship in Public Policy undertaken at the University of Toronto. Furthermore, she has received specialist training in Regulatory Affairs (PGCert) which focused on the implementation of quality management systems in pharmaceutical and chemical manufacturing.



Anthony Kapeta, LLM, Legal Officer, African Medicines Regulatory Harmonization Program (AMRH), African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD)

Anthony B. Kapeta works as a Legal Officer for AUDA-NEPAD (African Union Development Agency). He supports health-related programs and leads the activities of the Technical Committee on Medicines Policy and Regulatory Reforms under the African Medicine Regulatory Harmonization Programme (AMRH). Anthony also coordinates the AUDA-NEPAD's interventions against substandard and Falsified medical products and is the focal person for the development of the Continental plan against SF medical products. In addition, Anthony B. Kapeta provides expertise to support the development of pooled procurement mechanisms of medicines within the African continent and coordinates AUDA-NEPAD's country interventions to support development or the review of legislations on medicines and related substances (including legislation on SF). He was part of the drafting team of the Reference Manual on legislation of SFMP, under the European Union Project Medisafe. Prior to AUDA-NEPAD, Anthony B. Kapeta has worked as Legal Advisor for Doctors Without Borders (MSF) Canada in Cameroon, Legal Associate for the African Union Commission (Office of the Legal Counsel) in Ethiopia, and as a Registered Lawyer at the Kinshasa Bar in Congo (Democratic Republic).

SPEAKER BIOS



Henry Michtalik, MD, MPH, MH, Assistant Professor of Medicine, Johns Hopkins University School of Medicine (BESAFE-BSPH)

Dr Michtalik is an Assistant Professor of Medicine at the JHU-SOM. He is an academic fellowship trained researcher and hospitalist with research interests in patient safety issues, quality improvement, and systems management. Through multi-disciplinary collaboration, he identifies common problems in healthcare, works with front-line staff, and uses mixed-methods approaches with academic rigor to create, educate and implement, evaluate, disseminate, and sustain potential solutions. As part of the Collaborative Internal Medicine Service of hospitalists, the largest hospitalist group within the Johns Hopkins Health System with over 100 medical professionals, the clinical footprint is widespread and represents a diverse set of hospitals (community, academic, tertiary care) and hospitalist program structures (variable scheduling and compensation models; advanced care practitioner, attending-only, teaching or combined service models).

Dr. Michtalik has received multiple local and national grants examining hospitalist workload and burnout, resiliency, and clinical topics such as Parkinson's Disease, preventing hospital acquired infections, and optimal use of cardiac synchronization therapy, with formal recommendations to stakeholders and federal agencies such as the FDA, AHRQ, and DHHS. He serves as the PI for the international Hospitalist Morale Index study and led a national project for decolonization of hospital patients with indwelling medical devices, and he also has served as co-investigator on several AHRQ Topic Refinement and Systematic Review task orders for the JHU Evidence-Based Practice Center examining cardiac resynchronization therapy.

Dr. Michtalik's work bridges research with clinical processes to develop and implement front-line solutions, now focused on public health strategies for combating substandard and falsified medical products.



Rita K. Jew, PharmD, MBA, President, Institute for Safe Medication Practices (ISMP)

Rita K. Jew is President at the Institute for Safe Medication Practices (ISMP) where she provides leadership in advocacy of ISMP's mission and vision to stakeholders and develops and implements strategic goals. She also provides oversight and actively participates in consultation, education, publications, alerts and error reporting programs and oversees the development of new guidelines, programs, products and services. Prior to joining ISMP, Dr. Jew held various leadership positions including Director of Pharmacy at UCSF Health, Executive Director of Pharmacy & Clinical Nutrition Services at CHOC Children's and Clinical Manager at Children's Hospital of Philadelphia. Her 25 plus-year tenure in hospital pharmacies encompassed broad experiences in pharmacy leadership, clinical pharmacy services, formulary management, medication safety, pharmacy operations, centralized pharmacy services, pediatric pharmacy services, healthcare technology and automation, sterile & non-sterile compounding, finance and revenue-cycle, 340B program, CQI/lean, clean room and pharmacy construction, emergency preparedness and establishing pharmacy residency programs.

Dr. Jew presented and published extensively on clinical topics in pediatrics, extemporaneous compounding, vaccines, healthcare technology and automation as well as various topics on pharmacy operations and medication safety. She held adjunct faculty appointments at various Schools of Pharmacy and School of Nursing. She has received numerous awards and accolades from professional organizations.

Dr. Jew received her Pharm.D. from University of California at San Francisco, completed an ASHP-Accredited Residency in Clinical Pharmacy at Thomas Jefferson University Hospital and received her MBA from the Wharton School, University of Pennsylvania. She is a Board-Certified Pediatric Pharmacy Specialist (BCPPS).



Margot Savoy, MD, MPH, FAAFP, Chief Medical Officer, American Academy of Family Physicians



Margot Savoy is Chief Medical Officer for the American Academy of Family Physicians, Associate Professor of Family & Community Medicine and Urban Bioethics & Population Health at the Lewis Katz School of Medicine. Dr. Savoy's portfolio includes family physician education, the AAFP accreditation system, journal media, health of the public and science, Centers for Diversity & Health Equity and Women's Health and physician well-being.

Dr. Savoy graduated from the University of Maryland School of Medicine in 2002, completed Family Medicine Residency Program at the Crozer-Keystone Family Medicine Residency Program (Springfield, PA) in 2005 and graduated from the University of North Carolina Chapel Hill Gillings School of Global Public Health in 2008 with a Masters degree in Public Health Leadership with a focus on Public Health Practice. She is certified by the American Board of Family Medicine, the Certifying Commission in Medical Management, the American Board of Medical Quality and is a Fellow of the American Academy of Family Physicians, American Association of Physician Leaders and the Advisory Board Company. .

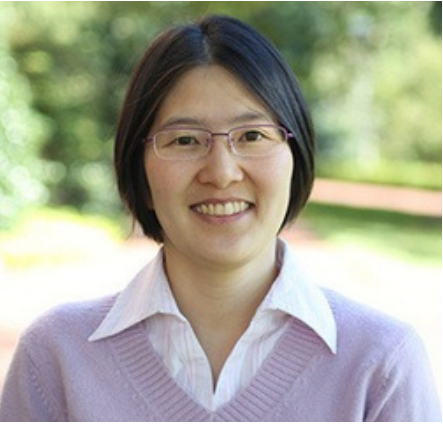
Oksana Pyzik, MPharm, Associate Professor, University College London (UCL) School of Pharmacy



Oksana Pyzik is an Associate Professor of Pharmacy Practice and Policy at the UCL School of Pharmacy, and is a UK licensed Pharmacist. Oksana is also the Founder of the UCL Fight the Fakes Collaborating Centre and Academic Chair & Executive Board Member of the Fight the Fakes Alliance. Her teaching, research and global engagement portfolio spans across global health topics including health and humanitarian emergencies, pandemic preparedness, and medicines quality with a focus on substandard and falsified medical products prevention and education.

As a global health expert, she is also a regular commentator in the media and advises Governments, NGOs, and social impact startups on public health issues and was awarded the Association of British Science Writers (ABSW) Media Fellowship in 2023 writing for The Guardian. In 2017, Oksana was elected to the Board of Trustees of the Commonwealth Pharmacists Association and serves on the Editorial Board of The Medicine Access Journal. Oksana was awarded the " UK Top 35 Women Under 35" Prize by Accenture and Management Today in 2020 for her work in global health and is a Fellow of the UK Higher Education Academy.

SPEAKER BIOS



Sachiko Ozawa , PhD, MHS, Associate Professor, University of North

Carolina Sachiko (Sachi) Ozawa is an Associate Professor at the University of North Carolina at Chapel Hill Eshelman School of Pharmacy and an Adjunct in Maternal and Child Health at UNC Gillings School of Global Public Health. She is a health economist whose work focuses on generating evidence to improve access to vaccines and quality-assured medicines, working at the interface between pharmacy and public health. She has published nearly 100 articles in peer-reviewed journals conducting research on the value of vaccines, the economic impact of substandard and falsified medicines, and the threat of illegitimate online pharmacies. Her work has been presented at the National Press Club, became Health Affairs' top 10 most read articles, cited by the Prime Minister of Canada, and was tweeted by Bill Gates. Her research has been reported by the Washington Post, Forbes, CNN Business, Reuters, National Public Radio (NPR), and other news media.



Jude Nwokike, PhD, MSc, MPH, Vice President, Supply Chain ResilienceUS Pharmacopeia (USP)

Dr. Jude Nwokike brings over 20 years of leadership in medical products development, quality assurance, regulatory systems strengthening, and pharmaceutical systems. As Vice President at USP, he has led global initiatives to ensure the quality and safety of medicines and promoted the adoption of manufacturing standards and regulatory frameworks across nearly 60 countries, removing barriers to accelerate access to life-saving medicines and vaccines.

Before joining USP, Dr. Nwokike served as the U.S. FDA liaison to the Center for Drug Evaluation and Research, supporting the PEPFAR antiretroviral drugs program. He coordinated with pharmaceutical companies to streamline participation in the FDA's expedited review process for ARVs and collaborated with the World Health Organization (WHO) to enhance reliance and timely access to FDA-approved ARVs for global health programs.

Earlier, he held global technical leadership roles advancing product quality assurance, regulatory harmonization, and pharmaceutical supply systems strengthening. His decade in the pharmaceutical industry refined his expertise in product development, manufacturing standards, and delivering quality pharmaceuticals to global markets. Dr. Nwokike chairs WHO's Global Steering Group for the Coalition of Interested Parties (CIP) Network and received the 2020 IPS Medal Award from the International Pharmaceutical Federation (FIP). A mentor to thousands of experts, he continues to build high-performing teams that drive excellence in global health.



Paul Baffoe-Bonnie, PharmD, MHS, Research Associate, Trident Health Law

Paul Baffoe-Bonnie is a Ghanaian pharmacist and global health economist dedicated to advancing equitable access to health care. He has a MHS in Global Health Economics from Johns Hopkins University and a PharmD, and his work bridges clinical knowledge and economic policy.

Paul has contributed to national health financing reforms in Ghana, including the National Health Accounts and Health Labor Market Analysis, helping policymakers address critical funding and workforce challenges. His research spans cost-effectiveness modeling, health systems analysis, and U.S. pharmaceutical policy, with a particular focus on addressing disparities in treatment access.

Currently a Global Health Financing and Governance Fellow with the Health Diplomacy Alliance, and a Research Assistant with Trident Health Law, Paul seeks to strengthen the link between economic evidence and health diplomacy, ensuring that financing strategies reflect the realities of vulnerable populations and support progress toward universal health coverage.

SPEAKER BIOS



Alem Zekarias, MSPS, Senior Pharmacovigilance Scientist, Uppsala Monitoring Centre (UMC)

Alem Zekarias, MS in Pharmaceutical Sciences or (MSPS), Senior Pharmacovigilance Scientist, Uppsala Monitoring Centre (UMC). Alem Zekarias is a Senior Pharmacovigilance Scientist working at the Uppsala Monitoring Centre in Uppsala, Sweden. She is the key person responsible for medication error-related activities at the organization. Alem is a pharmacist by training with a Master's Degree in Drug Discovery and Development from Uppsala University. She has been working in global pharmacovigilance, including signal management, research and method development, education and training—for more than 10 years. She has actively engaged with the International Society of Pharmacovigilance (ISoP) and has led several international collaborative projects aimed at strengthening pharmacovigilance practices worldwide.

Before joining UMC, she worked as a pharmacy manager and in clinical trials.



Steph Tan, MPH, Policy Analyst International Government & Regulatory Affairs, US Pharmacopeia (USP)

Steph Tan is a New Zealand-born public health professional dedicated to translating scientific evidence into policies and interventions that improve US and global health. She currently is an International Government Policy Analyst at the U.S. Pharmacopeia (USP). Until March 2025, Steph Tan served at the U.S. Food and Drug Administration (FDA) in the Office of Economics and Analysis and the Office of Global Policy and Strategy, where she advanced evidence-to-policy initiatives and represented the United States as a delegate to the World Health Organization's (WHO) Member State Mechanism for Substandard and Falsified Medical Products. In that role, she also supported the WHO Informal Markets workgroup, contributing to global discussions on the quality and safety of medicines illegally distributed through unregulated channels.

Steph Tan's contributions have been recognized through numerous distinctions, including a FDA Special Recognition Award for informing HIV drug procurement strategies to support manufacturing capacity in Africa, and the U.S. EB-1A Green Card for "Extraordinary Ability" for sustained international contributions to public health and science. She has been featured 50+ times in news media outlets, including The Wall Street Journal, and has published first-author research in The Lancet and the WHO Bulletin that has informed government pandemic responses across the U.S., U.K., Italy, and New Zealand.

Prior to the FDA, Steph Tan served as a Technical Expert on the White House and Rockefeller Foundation's COVID-19 Testing Panel and advised the New Zealand government on establishing novel saliva testing during the pandemic.

Steph Tan holds a Master of Public Health (MPH) from Yale University and completed undergraduate studies in Nutritional Sciences and Dietetics at Cornell University.

SPEAKER BIOS



Lynn Jeffers, MD, MBA, Member of the Board of Trustees of the American Medical Association (AMA) and current Trustee of the American Society of Plastic Surgeons (ASPS)

Dr. Jeffers was elected to the American Medical Association (AMA) Board of Trustees in June 2024. She is a past chair of the AMA Council on Medical Service and the AMA Section on Plastic, Reconstructive, and Maxillofacial Surgery, and a past president and current trustee of the American Society of Plastic Surgeons (ASPS). A fellow of the American College of Surgeons, she practices in southern California and serves as chief medical officer of St. John's Regional Medical Center and St. John's Hospital Camarillo, medical director of St. John's Integrated Breast Center, and a plastic surgeon in private practice.

Her 30-year career in organized medicine spans numerous leadership roles and recognitions, including the AMA Glaxo Achievement Award, AMA Foundation Excellence in Medicine Leadership Award, ASPS Presidents' Award, and the 2023 AMA Foundation Dr. Edmond and Rima Cabbabe Dedication to the Profession Award. As ASPS president and chief medical officer during the pandemic, she led national and institutional responses, with ASPS recognized by the White House and the surgeon general for sourcing millions of masks for hospitals. Dr. Jeffers earned her BS and MD from the University of Michigan, where she also completed her integrated plastic surgery residency, and later obtained an MBA from the Ross School of Business. She continues to advance leadership, innovation, and medical education through ASPS and academic partnerships.

SPEAKER BIOS



Dr. Damon Green, MD, MS, MBA, Public Health & General Preventive Medicine specialist, American College of Preventive Medicine (ACPM)

Dr. Green completed his undergraduate education at Howard University earning a Bachelor of Science as a Physician Assistant; completed a Doctor of Medicine and a Masters of Epidemiology at the University of Maryland; a Master of Business Administration at St. Joseph's University in Philadelphia, PA; and a MA in Biblical Studies at Lancaster Bible College. As a Fellow of the American College of Preventive Medicine, he plans to continually use the breadth of his education and experience to serve his local community.



Libby Baney, JD, Senior Advisor, Alliance for Safe Online Pharmacies (ASOP)

Libby embraces "Love What You Do." A partner at Faegre Drinker LLP, Libby works on drug safety, pharmacy, supply chain, online pharmacy, and direct-to-consumer healthcare issues. Libby represents the Alliance for Safe Online Pharmacies (ASOP Global), the ASOP Global Foundation, and other nonprofit and corporate entities. She has built trusted relationships with U.S. and international agencies. Clients hire Libby for her strategic insight, collaborative approach, and tenacious, results-oriented work product. In addition to advising clients, Libby serves as part of Faegre Drinker's Board. Outside of work, Libby enjoys early morning workouts, scuba, cycling through Washington, D.C., and spending quality time with her family.

SPEAKER BIOS



Edgar Robin Rojas, MPH, Technical Officer, Safe Use of Pharmaceuticals, Biologicals and Vaccines, Pan American Health Organization (PAHO)

Robin Rojas Cortés is a Colombian pharmaceutical chemist and a leading voice in the international field of drug safety. With over a decade of experience at the Pan American Health Organization (PAHO) — the regional office of the World Health Organization (WHO) — he has played a pivotal role in advancing strategies to ensure the safe use of medicines, vaccines, and biological products across the Americas.

Based in Washington, D.C., Mr. Rojas leads regional cooperation initiatives that strengthen national pharmacovigilance systems and safeguard public health in Latin America and the Caribbean. He also serves as a key liaison between the Americas and WHO's global surveillance mechanisms in Geneva, contributing his expertise through participation in international technical committees and high-level conferences. Throughout his career, he has been deeply committed to promoting the responsible use of health technologies and combating falsified medical products, issues that remain central to global health security.



Neelaveni Padayachee, Ph.D., Associate Professor Pharmacy Practice, University of the Witwatersrand

Prof. Neelaveni Padayachee is an Associate Professor in Pharmacy Practice at the University of the Witwatersrand, with over 19 years of experience spanning academia, pharmaceutical policy, and public health. She holds a PhD in Pharmacy, with her research focusing on the utilisation of over-the-counter medicines in South Africa.

Prof. Padayachee has published extensively in the areas of pharmacovigilance, access to medicines, and medicine safety, and has supervised more than 35 postgraduate students to completion. She currently serves as Vice-Chair of the AUDA-NEPAD Substandard and Falsified Medicines Committee and Chair of the Education and Awareness Subcommittee of South Africa's National Action Plan on Substandard and Falsified Medicines, a collaborative initiative with SAHPRA and the World Health Organization (WHO). In addition, Prof. Padayachee has served as a South African Pharmacy Council (SAPC) inspector for over 18 years, bringing extensive auditing expertise to ensure that pharmacies across South Africa uphold the highest standards of Good Pharmacy Practice (GPP). Her work continues to strengthen medicine safety, ethical practice, and pharmaceutical governance across the African continent.

SPEAKER BIOS



Ilisa Bernstein, Ph.D., President, Bernstein Rx Solutions Ilisa Bernstein, PharmD, JD, FAPhA, is President of Bernstein Rx Solutions, LLC, where she advises clients on navigating drug and pharmacy regulatory policy, compliance, and advocacy. With over 35 years of experience across government, non-profit, and private sectors, she has advanced innovation and policy solutions in healthcare. Dr. Bernstein previously served nearly five years at the American Pharmacists Association (APhA), including a 13-month tenure as APhA's 14th CEO and Executive Vice President—the first woman to lead the association in its 172-year history. She oversaw strategic operations for APhA, the Board of Pharmacy Specialties, and the APhA Foundation. Her public service includes more than 30 years at the U.S. Food and Drug Administration, where she held senior leadership roles in the Office of Compliance and the Office of the Commissioner, shaping national drug policy, enforcement, and safety. Dr. Bernstein serves on the Board of Trustees of the United States Pharmacopeia and previously held board positions with ASOP, PQA, and APhA. She earned her PharmD from the University of Michigan and her JD from American University.



Ibnou Khadim Diaw, MD, MPH, CEO, Africa Resource Centre (ARC) Ibnou Khadim Diaw is Co-Executive Director of the Africa Resource Center (ARC), where he has been leveraging his extensive expertise in implementing public health development projects and transforming health supply chains since 2015. With extensive experience building strong partnerships, he has collaborated with United Nations agencies such as WHO, UNICEF, and UNFPA, as well as technical and financial partners, including GAVI, the Global Fund, USAID, the World Bank, the Bill & Melinda Gates Foundation, PATH, INTRAHEALTH, Belgium Corporation, LuxDevelopment agency, and FHI 360, on the African continent and beyond. He also benefited from more than 15 years of hospital experience after graduating from the Faculties of Science and Medicine (1992 FMPOS) of Cheikh Anta Diop University of Dakar, Laval (1994 Molecular Biology) and Paris Diderot, France (2003 Public Health). He was at the forefront of fundamental research into HIV and HPV as Director of the national STD/AIDS reference laboratory of Senegal, where he was responsible for the Dakar cohort for the natural history of HIV/AIDS infection in collaboration with the universities of Tours, Limoges (France) and Harvard (Cancer Biology Boston MA) with the team of Max Essex and P. Kanki. He has supported several international initiatives on vaccination, notably with the Optimize project (WHO, BMGF and PATH), the evaluation of vaccine quality, the mapping of storage temperatures and the study of CTC costs of MenAfrivac in Togo. With the advent of structural adjustment and the programmatic approach at the end of the 1990s, he supported several countries (16 founded by World Bank) in the development of their national health development program and the strengthening of primary health care, before gradually embracing the Supply chain of health products with Roche Diagnostics Laboratories (Mannheim). Since then, he has been fully active in the formulation of development policies for the resilience of health systems and the integration of supply chains to make the right to health a reality on the African continent.

SPEAKER BIOS



Rutendo Kuwana, Team Lead, Incidents and Substandard and Falsified Medical Products, WHO Rutendo Kuwana is the Team Lead of the Market Surveillance and Control (MSC) team, within the Regulation and Prequalification (RPQ) department, at the World Health Organization (WHO). His work focuses on strengthening country capacity to prevent, detect, and respond to substandard and falsified medical products.

Prior to this role, Rutendo coordinated WHO's prequalification activities for medicines quality control laboratories, and provided technical assistance to national regulatory authorities, manufacturers, and laboratories. His expertise includes Good Manufacturing Practice, marketing authorisation, quality assurance, and post-market surveillance.

Before joining WHO, Rutendo spent 15 years at the Medicines Control Authority of Zimbabwe. He holds a pharmacy degree from the University of Zimbabwe and specialises in medical product regulatory control.

Jean Christophe Rusatira, MD, Ph.D., MPH, Sr. Program Officer, BESAFE, Johns Hopkins Bloomberg School of Public Health



Dr. Jean Christophe Rusatira is a physician, epidemiologist, and population health researcher with over 15 years of experience in public health research, policy, and program implementation. He holds a Medical Degree from the National University of Rwanda and both an MPH and a PhD from the Johns Hopkins Bloomberg School of Public Health. His work focuses on population health, safe medicines, road safety, and regulatory affairs, emphasizing evidence-based policy and program innovation in the U.S. and Sub-Saharan Africa. He led the development of the Demographic Dividend Effort Index (DDEI) across six African countries and the BESAFE initiative on falsified medicines at Johns Hopkins. Dr. Rusatira has consulted for the World Health Organization, Gates Foundation and the World Bank. He founded Healthy People Rwanda, co-founded the International Youth Alliance for Family Planning (IYAFFP), and founded Matriarch Coffee, a social-impact company connecting his family's Rwandan coffee farms to the U.S. market.



Dr. Peter Rumm, MD, MPH, FACPM, Director, Policy, American College of Preventive Medicine (ACPM)

Peter D. Rumm MD, MPH, FACPM is currently the CEO of Executive Healthcare Coaching and Career Services and a consultant on healthcare policy, FDA regulations and AI. In the Army he commanded two international health facilities and was a theater epidemiologist. He then had senior level positions at the VA, FDA, the Office of the Surgeon General and the State of Wisconsin Division of Public Health. At FDA he was the deputy director of large pre-market device divisions and also had a senior role in generic drugs. In academia he has been a center director and currently is an associate adjunct professor at USUHS medical school and Augusta University SPH in health policy areas.

SPEAKER BIOS



Michael Stepanovic, PharmD, MS, Assistant Professor, UNC Eshelman School of Pharmacy Michael Stepanovic is an assistant professor, specializing in Health-System Pharmacy Administration. His research focuses on medication quality, pharmacy leadership, and expanding non-clinical pathways for students. He is a passionate advocate for leveraging technology to enhance health care delivery.

Stepanovic's academic background includes a PharmD from Purdue University, followed by a MS in Health-System Pharmacy Administration from the School. He completed clinical training with a PGY1 Acute Care Residency and PGY2 Health-System Pharmacy Administration Residency at the Hospital of the University of Pennsylvania. His professional career has been marked by roles at AstraZeneca, The Johns Hopkins Hospital, and prominent research institutions such as Rush University Medical Center and the University of Chicago Medical Center.

An innovator, Stepanovic founded MedTrak, LLC to improve medication tracking and patient safety. He has completed several technology commercialization programs, including the NSF and NIH I-CORPS fellowships. He is also actively involved in pharmacy organizations such as the ASHP and FIP, contributing to global pharmacy standards and leadership initiatives.

SPEAKER BIOS



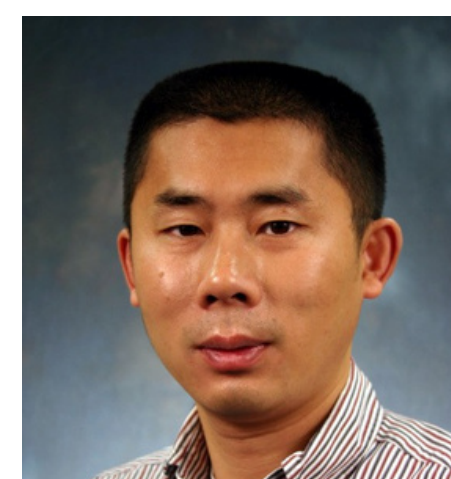
Charlie Preston, MD, MPH, DipABPM, DipABLM, Senior Program Officer, Regulatory Affairs, Gates Foundation

Charles Preston is a senior program officer at the Gates Foundation working on the regulatory systems team within the global health division. He has worked on regulatory strengthening in roles at US FDA, WHO/PAHO, and now Gates for the past 15 years. He is a public health physician and did his MPH and public health residency training at Hopkins.



Shabbir Imber Safdar, Executive Director, Partnership for Safe Medicines (PSM), USA

Shabbir Imber Safdar has served as the Executive Director of the Partnership for Safe Medicines since 2017. Before that he served as a consultant to PSM for nearly a decade. 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. The Partnership for Safe Medicines, 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. Today Shabbir leads the Partnership for Safe Medicines team from San Francisco, CA where he lives with his wife and two children. He teaches archery to adults and youth in his spare time.



Bruce Yu, Ph.D., Professor of pharmaceutical sciences, University of Maryland

Dr. Bruce Yu is a professor at the University of Maryland School of Pharmacy and a fellow of the Institute for Bioscience and Biotechnology Research. He was appointed as an Inaugural MPower Professor from 2021 to 2024 by the University of Maryland and served as the director of its Bio- and Nano-technology Center from 2015 to 2024. Dr. Yu has conducted research on biophysics, imaging agents and biomaterials. His current focus is on noninvasive analytic technologies for pharmaceutical manufacturing and quality control. He received the 2004 Kimmel Scholar Award and the 2005 US Presidential Early Career Awards for Scientists and Engineers. Dr. Yu has a Ph.D. in molecular biophysics from the Johns Hopkins University.

SPEAKER BIOS



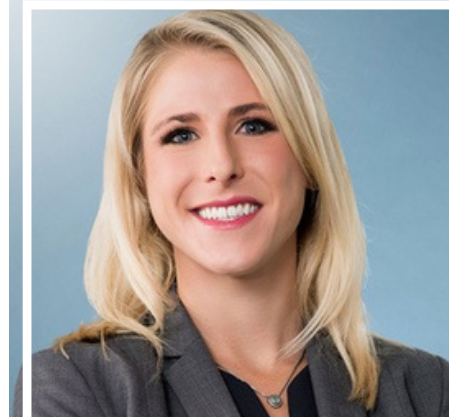
Petra Procter, MSc, Senior Program Manager, Concept Foundation

Petra Procter studied Biomedical Sciences with Pharmacology followed by a Masters in Clinical Pharmacology, Drug Development and Biobusiness, at the University of Aberdeen. After her studies, she moved straight from a voluntary Internship at WHO in the Pharmacovigilance department to her first role at CF in 2011. In her 12 years at CF, she has supported CF's work on Quality of SRH medicines, Access to Family Planning, managing CF's work on increasing access to Injectable Contraception before moving to Programme Manager of CF's Manufacturing and Development programmatic pillar. As Senior Programme Manager she now supports projects across CF's programmatic pillars and thematic areas, bringing over a decade of knowledge and experience in access to Quality Assured SRH medicines and technologies in LMICs.



Timothy Mackey, Ph.D., Professor, UC San Diego; & Director, Global Health Policy Institute UC San Diego

Tim Ken Mackey is a Professor in the Global Health Program at UC San Diego and is also the CEO and co-founder of S-3 Research, a public health data science company that conducts online monitoring and investigation work to address illicit online markets. He is also the Director of the Global Health Policy and Data Institute and the Editor-in-Chief of JMIR Infodemiology. He holds a BA in Political Science-International Relations, a Master's Degree in Health Policy & Law, and also earned his PhD in Global Public Health from the joint doctoral program at UC San Diego - San Diego State University. He has co-authored over 270 manuscripts on topics including global health, technology, data science, substance use disorder, and health policy. Dr. Mackey is a successful entrepreneur and scientist and has been featured in numerous media outlets (NY Times, The Today Show, NBC News, etc.), and has acted as a consultant for several domestic and international organizations including the Department of Justice, World Health Organization, and others.



Jillian K. Brady, M.S., Advisor, Alliance for Safe Online Pharmacies (ASOP)

Jillian Brady is an ASOP Global Foundation advisor and a Manager at Faegre Drinker Consulting. She provides strategic and project management support to consortia clients, comprised of representatives from the pharmaceutical industry, United States regulatory agencies and academia. A number of these consortia focus on joint technology development and data-sharing initiatives, where Jillian utilizes her experience in scientific research to help clients overcome a wide range of technical and regulatory challenges

SPEAKER BIOS

Peter York, MSc, Director of Global Intelligence Pharmaceutical Security Institute (PSI)

Peter York serves as Director of Intelligence at the Pharmaceutical Security Institute (PSI), where he has been a key figure in pharmaceutical crime analysis since 2003. As the principal author of PSI's Global Situation Report, he collaborates with investigators from 40 member companies, law enforcement agencies, and drug regulators worldwide. Mr. York is particularly knowledgeable about pharmaceutical counterfeiting and diversion networks in Turkey and Russia. Prior to joining PSI, he worked for a U.S. Department of State contractor in Washington, D.C. He holds a Master of Public and International Affairs from the University of Pittsburgh.

Dr Ernestine Watson, PharmD, Chairperson, Pharmacy Council, Jamaica

Dr. Ernestine Watson is a passionate, creative, and committed pharmacist, international speaker, and team leader who values collaboration and relationship building. A graduate of the College of Science and Technology (CAST) and the University of Technology (UTECH), Jamaica, she earned a Bachelor of Pharmacy (First Class Honours) and later completed a Doctor of Pharmacy (Magna Cum Laude) at the University of Florida (UF). She also holds a Certificate in Practical Theology from the International Seminary, Florida, and was certified in 2016 as a Women Innovators Network Caribbean Woman Entrepreneur.

Dr. Watson currently serves as General Manager of Everybody's Pharmacy and a part-time lecturer at both UTECH and the University of the West Indies. She is also a Director of Cycle Sports and Equipment, Everybody's Café, and S&E Enterprises, and has served as President of the Pharmaceutical Society of Jamaica (2018–2020), Chairman of the Pharmacy Council of Jamaica, and on several national and regional boards.

Her numerous awards include Caribbean Pharmacist of the Year, PSJ Pharmacist Primus, and Outstanding UTECH Alumni (2019). Deeply committed to service, Dr. Watson has led outreach initiatives through the National Council on Drug Abuse, UTech, and the Rotary Club, raising over J\$2 million for health and wellness charities.

An elder at Webster Memorial United Church, Dr. Ernestine Watson balances her professional achievements with faith, family, and her love for exercise, gardening, interior design, and writing

SPEAKER BIOS



Silvia Helena Montoya Borrás, Director, Anti-Counterfeiting Program, The Asociación Nacional de Empresarios de Colombia (ANDI)

Silvia Helena Montoya Borrás is a seasoned lawyer with over 20 years of experience in intellectual property protection, specifically in counteracting counterfeiting and illegal pharmaceutical commercialization. Since January 2013, she has served as the Manager of the Project Against Counterfeiting at ANDI - National Business Association of Colombia in Bogotá. In this role, she leads a program that was established in 1998, focusing on the prevention of counterfeiting, contraband, and other criminal activities affecting the legal markets of pharmaceuticals, liquors, food, personal care, and agrochemicals. Her achievements include close collaboration with public forces to dismantle criminal organizations, along with extensive work on training programs designed to equip authorities with the skills to identify authentic products and uphold legal practices both nationally and internationally.

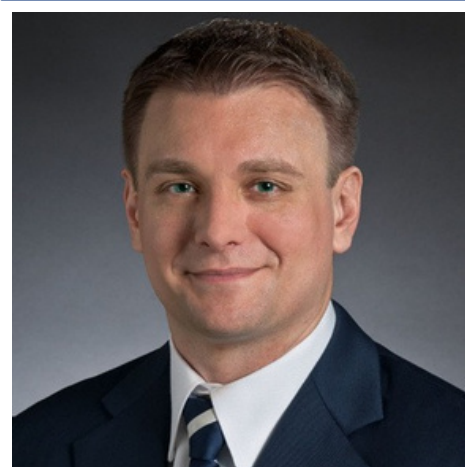
Previously, from December 2005 to December 2012, Silvia worked as a Prosecutor in the Intellectual Property Crime Unit at the Office of the Attorney General in Bogotá, where she prosecuted cases involving intellectual property crimes, contributing to the integrity of intellectual property rights. Prior to this, from October 2004 to November 2005, she was with TRADE MARK PROTECTION S.A. in Bogotá, specializing in trademark protection and enforcement, ensuring robust protection of trademark laws and intellectual property rights.



Kendra Ervin, J.D., Vice President, Head of Global Litigation and Enforcement, IP House

Kendra Ervin is the Vice President & Head of Global Litigation and Enforcement at IP House where she formulates high-impact litigation and IP enforcement strategies for companies worldwide; advises clients on anti-counterfeiting, anti-piracy, and other IP enforcement efforts; and works proactively with government and law enforcement officials to combat IP infringement. Prior to joining IP House, Ms. Ervin served as the Deputy Chief for IP in the Computer Crime & Intellectual Property Section (CCIPS) of the U.S. Department of Justice. In her fourteen years with CCIPS, Ms. Ervin prosecuted large-scale, multi-jurisdictional IP crimes; participated in domestic and international IP enforcement training and outreach; and helped to develop legislative and policy initiatives addressing all facets of IP crime. Prior to CCIPS, Ms. Ervin specialized in patent litigation at Williams & Connolly, and clerked on the United States Court of Appeals for the Federal Circuit. She earned her J.D. from the University of Virginia School of Law, and her undergraduate degree from Emory University.

CHAIR: FACILITATOR BIOS



Henry Michtalik, MD, MPH, MHS, Assistant Professor of Medicine, Johns Hopkins University School of Medicine (BESAFE-BSPH) Dr Michtalik is an Assistant Professor of Medicine at the JHU-SOM. He is an academic fellowship trained researcher and hospitalist with research interests in patient safety issues, quality improvement, and systems management. Through multi-disciplinary collaboration, he identifies common problems in healthcare, works with front-line staff, and uses mixed-methods approaches with academic rigor to create, educate and implement, evaluate, disseminate, and sustain potential solutions. As part of the Collaborative Internal Medicine Service of hospitalists, the largest hospitalist group within the Johns Hopkins Health System with over 100 medical professionals, the clinical footprint is widespread and represents a diverse set of hospitals (community, academic, tertiary care) and hospitalist program structures (variable scheduling and compensation models; advanced care practitioner, attending-only, teaching or combined service models).

Dr. Michtalik has received multiple local and national grants examining hospitalist workload and burnout, resiliency, and clinical topics such as Parkinson's Disease, preventing hospital acquired infections, and optimal use of cardiac synchronization therapy, with formal recommendations to stakeholders and federal agencies such as FDA, AHRQ, and DHHS. He serves as the PI for the international Hospitalist Morale Index study and led a national project for decolonization of hospital patients with indwelling medical devices, and he also has served as co-investigator on several

AHRQ

Topic Refinement and Systematic Review task orders for the JHU Evidence-Based Practice Center examining cardiac resynchronization therapy. Dr. Michtalik's work bridges research with clinical processes to develop and implement front-line solutions, now focused on public health strategies for combating substandard and falsified medical products.



Ilisa Bernstein, PharmD, JD, President, Bernstein Rx Solutions

Ilisa Bernstein is President of Bernstein Rx Solutions, LLC, where she advises clients on navigating drug and pharmacy regulatory policy, compliance, and advocacy. With over 35 years of experience across government, non-profit, and private sectors, she has advanced innovation and policy solutions in healthcare.

Dr. Bernstein previously served nearly five years at the American Pharmacists Association (APhA), including a 13-month tenure as APhA's 14th CEO and Executive Vice President—the first woman to lead the association in its 172-year history. She oversaw strategic operations for APhA, the Board of Pharmacy Specialties, and the APhA Foundation.

Her public service includes more than 30 years at the U.S. Food and Drug Administration, where she held senior leadership roles in the Office of Compliance and the Office of the Commissioner, shaping national drug policy, enforcement, and safety.

Dr. Bernstein serves on the Board of Trustees of the United States Pharmacopeia and previously held board positions with ASOP, PQA, and APhA. She earned her PharmD from the University of Michigan and her JD from American University

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Reema Mehta, PharmD, MPH, Head of Risk Assessment and Management, Pfizer Dr. Reema Mehta is Vice President and Head of Risk Assessment and Management within Pfizer's Worldwide Safety organization. She leads global efforts to strengthen benefit–risk evaluation, medication-error prevention, and risk-minimization strategies across the product lifecycle. With more than 15 years of combined regulatory and industry experience, Dr. Mehta previously served in the U.S. Food and Drug Administration's Office of Medication Error Prevention and Risk Management, where she helped develop national policies on Risk Evaluation and Mitigation Strategies (REMS). Before joining Pfizer, she held pharmacovigilance and safety leadership roles at Johnson & Johnson. Dr. Mehta earned her Doctor of Pharmacy (PharmD) from Rutgers University and Master of Public Health (MPH) from the Johns Hopkins Bloomberg School of Public Health. A recognized thought leader in drug safety science, she continues to champion collaborative, data-driven approaches to ensure patient safety and promote public confidence in medicines globally.



Brian A. Smith, JD, MPH, Founder & Principal Attorney, Trident Health Law

Brian A. Smith is the Founder and Principal of Trident Health Law, a boutique firm dedicated to advancing health equity, regulatory clarity, and operational excellence across the healthcare ecosystem. His career spans federal government, academia, the nonprofit sector, bringing a uniquely integrative perspective to health law and policy.

Before founding Trident, Brian served as a Presidential Management Fellow and attorney with the U.S. Department of Health and Human Services and the Centers for Disease Control and Prevention (CDC), where he advised on organ transplantation policy, data use, and national initiatives to reduce drug overdose deaths. He also supported agency communications and congressional testimony.

Brian's legal training includes externships at a Fortune 500 health products company and the CDC's Public Health Law Program. He earned his JD from the University of Illinois, MPH from the Johns Hopkins Bloomberg School of Public Health, and BA in Neuroscience from Amherst College.

A frequent speaker on health law and policy, Brian has presented at leading institutions, including Johns Hopkins, NIH, and the FDA. At Trident, he leads a mission-driven practice that bridges law, science, and policy to build a more equitable and effective healthcare system.



Ana Carolina da Silva Macarencio, PharmD, MPH, Risk Management Product Lead, Pfizer

Dr. Ana Carolina da Silva Macarencio is an accomplished pharmaceutical safety leader and serves as Risk Management Product Lead within Pfizer's Worldwide Safety organization. In this role, she oversees the design and implementation of comprehensive global risk-management strategies across therapeutic areas, ensuring that benefit–risk frameworks, post-market surveillance, and risk-minimization measures meet the highest scientific and regulatory standards. Dr. Macarencio has extensive expertise in pharmacovigilance, regulatory science, and product lifecycle management, with a focus on integrating data-driven approaches to enhance patient safety and compliance worldwide. She holds a Doctor of Pharmacy (PharmD) and a Master of Public Health (MPH) and has contributed to multiple cross-functional initiatives advancing safety governance and regulatory harmonization. Dr. Macarencio's leadership reflects a deep commitment to advancing a culture of safety, scientific excellence, and collaboration across global markets to strengthen confidence in the quality and integrity of medicines.

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Katharine Briggs, Ph.D., Research Associate, Department of Pharmaceutical Sciences, University of Maryland Katharine Briggs earned her Ph.D. in biological sciences from the University of Maryland, College Park. She is a Research Associate in the Department of Pharmaceutical Sciences at the University of Maryland Baltimore, School of Pharmacy. In the lab of Prof. Bruce Yu, she is exploring time-domain NMR as a noninvasive analytical tool for use in the pharmaceutical industry and beyond. Her research develops benchtop NMR methods applicable to drug substance research and development, quality control for biomanufacturing, and pharmacovigilance at the point of care. To date, these methods have proven capable of detecting many substandard quality indicators (e.g., mAb aggregation, changes in insulin pen content, aluminum adjuvant agglomeration, etc.).

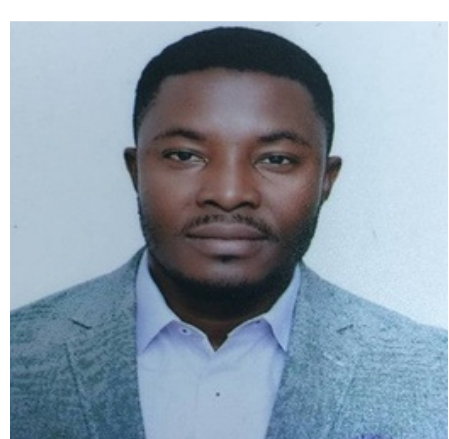
Foulo BASSE, President and CEO, Brazzaville Foundation

Foulo Basse has a rich experience acquired in the public service, in the academic field and in the private sector in Europe and numerous expert missions in Africa. He has held senior positions at the Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail (A.N.S.E.S.), from coordinating the European Med-Vet-Net network to managing the administration of laboratories. Mr Basse was also Director General of Services at the University of Evry-Val d'Essonne for 8 years. He has led a number of conferences, particularly on high-impact subjects. He is the founder of Foulo Basse Conseil, a consulting company specialising in responsible strategy, the development of sustainable products, services and policies, extra-financial reporting, quality management and change management. Foulo Basse has been a volunteer member of a number of NGOs, as well as a member of Think Tanks on social issues (gender, sustainable development, global warming, etc.).



Anthony Kapeta, LL.M., Legal Officer, African Medicines Regulatory Harmonization Program (AMRH), African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD)

Anthony B. Kapeta works as a Legal Officer for AUDA-NEPAD (African Union Development Agency). He supports health-related programs and leads the activities of the Technical Committee on Medicines Policy and Regulatory Reforms under the African Medicine Regulatory Harmonization Programme (AMRH). Anthony also coordinates the AUDA-NEPAD's interventions against substandard and falsified medical products and is the focal person for the development of the Continental plan against SF medical products. In addition, Anthony B. Kapeta provides expertise to support the development of pooled procurement mechanisms of medicines within the African continent and coordinates AUDA-NEPAD's country interventions to support development or the review of legislations on medicines and related substances (including legislation on SF). He was part of the drafting team of the Reference Manual on legislation of SFMP, under the European Union Project Medisafe. Prior to AUDA-NEPAD, Anthony B. Kapeta has worked as Legal Advisor for Doctors Without Borders (MSF) Canada in Cameroon, Legal Associate for the African Union Commission (Office of the Legal Counsel) in Ethiopia, and as a Registered Lawyer at the Kinshasa Bar in Congo (Democratic Republic).



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Anthony Zook, Ph.D., Associate Vice President, Global Security, Merck & Co., Inc.

Tony serves as Merck's Associate Vice President of Global Security and head of Merck's global Product Integrity program. This includes responsibility for the development and execution of the Company's strategy that protects Merck products from illicit actions, including counterfeiting, diversion, tampering, and theft. His work focuses on securing the supply chain, investigation and enforcement of illicit activity, and building stakeholder awareness to this growing threat to public safety. He is particularly interested in investigations and forensic analysis of counterfeit medicines, applications of advanced intelligence analytics to support these investigations, and collaborative relationships with regulatory and enforcement agencies who can best mitigate risks to patients.

Michael K. Comeaux, Director Product Integrity, Corporate Compliance and Global Security, Pfizer

Michael Comeaux brings extensive experience in corporate compliance and market access in the pharmaceutical industry. Currently serving as Director of Product Integrity Corporate Compliance Global Security at Pfizer since December 2023, Michael has previously held leadership roles at Seattle Genetics, where responsibilities included overseeing Global Market Access, Distribution, and Product Integrity from April 2011 to December 2023. Prior to Seattle Genetics, Michael was Corporate Accounts Director at Allos Therapeutics, Inc. and Regional Director at Novartis Oncology. Michael's educational background includes a Bachelor of Science in International Relations and Engineering from the United States Air Force Academy, an MBA in Management from Golden Gate University, and executive education in Medical Marketing from UCLA Anderson School of Management, along with executive leadership training from Vanderbilt University - Owen Graduate School of Management



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