Virtual Remarks by Mark Abdoo

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USP Convention Africa First Chapter Meeting

Second Session Opening Comments: "Standards Ensure Regulatory Compliance Throughout the Medicinal Product Life Cycle"

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Distinguished leaders and colleagues from the African Union (AU), World Health Organization (WHO), regional and national regulatory authorities, civil society, academia, industry, panel members, and all protocol observed. Good morning, good afternoon, and good evening to all of you. Warm greetings from the U.S. Food and Drug Administration (FDA). Congratulations to USP for today's launch of the Africa Regional Chapter. Thank you for inviting the FDA to be part of the important event. I'm delighted to be part of the "USP Africa First Chapter Meeting" and share opening comments during this afternoon session on regulatory compliance.

I'm Mark Abdoo, Associate Commissioner for Global Policy and Strategy at the U.S. FDA. My office helps ensure that, in addition to our domestically focused role assuring the products American patients and consumers use are safe, effective, and secure, the FDA maintains a strong focus on global public health objectives. We manage the FDA's foreign offices in Asia, Europe, Latin America, and, in the near future, Rwanda. Our office serves as the point of contact for many of the FDA's global partnerships like the USP Africa Regional Chapter. We are at the forefront of the collection, analysis, and sharing of high-quality information – including inspection data as appropriate – to advance the FDA's global public health mission.

I would like to start with an overview of some of FDA's global work with examples from topics of interest today such as supply chains and falsified and substandard medical products. I will end by speaking about some of our historic, current, and future work in Africa. It is important to the FDA and me personally that our future work is guided by you. Building upon the remarkable achievements by so many of you present today, our work in Africa will continue with you. This

underscores the importance of today's meeting and our shared appreciation of the critical regulatory foundation needed to assure quality, safe, and effective medical products, and self-reliance across Africa.

I unfortunately can be available for a limited time today. My colleagues are also on the line and happy to follow up after the meeting. We are also here to listen and learn.

Today, products can travel from country to country in an increasingly complex path from raw source materials to finished products. In the United States, for example, about 82% of active pharmaceutical ingredient manufacturers are located outside of the U.S. and about 47% of the medical devices used in the U.S. are imported.

Risks can arise at any step in the supply chain from sourcing the raw materials or components used to make a product, through its manufacture, storage, transit, sale, and distribution. Moreover, industries face inherent challenges and risks. These include timely response to emergent needs that may be presented by a pandemic and manufacturing methodology pressured by economic realities that may have real-world consequences impacting inventories and availability of certain drug products.

Supply chain shortages were accentuated by the COVID-19 pandemic when personal protective equipment, diagnostic tests, and medicines were all in short supply. Inequities in vaccine access are appreciated by all of us here today. While notable vaccination rates were being achieved during the pandemic in many areas of the world including the U.S., many countries in Africa had vaccinated only a small percentage of their populations. We must learn from the COVID-19 pandemic and work together to do better.

Manufacturing and quality issues – including poor compliance with good manufacturing practices - are by far the most cited reason for shortages. Some manufacturers may produce products of varying levels of quality depending upon the intended destination. A worst-case scenario was tragically seen in 2022 when some children lost their lives from acute kidney injury after ingesting imported adulterated cough syrups. This underscores how important this

meeting is, and many of your efforts are, in assuring the regulatory infrastructure is in place to protect the public health.

Adulterated cough syrup may be an extreme example of the challenges posed by substandard and falsified medical products, but an astounding 1 in 10 medicines in low- and middle-income countries are substandard or falsified, according to the World Health Organization. The reasons for this are varied, including limited resources for oversight, need for affordable medicines, and distribution of medical products through informal markets. But certainly, the public health impact is significant. Falsified and substandard products can lead to adverse events, including death; discourage the use of lifesaving products; increase health care costs; and lead to lower economic productivity.

We have confronted our own problems in the U.S. and at the FDA with falsified and substandard products, most notably 15 years ago when Americans were sickened or killed by poor quality or adulterated imported products, including counterfeit glucose monitor test strips and adulterated heparin.

These events demonstrated to our leadership that complex global supply chains had fundamentally altered the United States' economic and security landscape, demanding a major change in the way the FDA fulfills its mission to protect the health of the American people.
As a priority for regulatory authorities across the globe and relevant to today's discussion, I would like to speak a bit further on falsified and substandard medical products. The FDA is actively involved in the WHO's Member State Mechanism on Substandard and Falsified Medical Products, established in 2012 to consider ways for global regulators to reduce the public health risk and harm caused by such products. Today we're spearheading a couple of working group under the MS Mech. One is seeking to better understand the complex drivers of distribution of drugs through informal markets such as small retail shops where medicines are sold. We're trying to help develop coherent risk management and policy options to support regulators and other stakeholders. The other working group is seeking to address the quality of excipients to help prevent another tragedy like the syrups one I mentioned a moment ago.

I am proud that the Chair of the World Health Organization Member State Mechanism has transitioned to the Africa region, specifically the Rwanda Food and Drug Authority under the strong direction of Director General Bienvenu. I believe the USP Africa Regional Chapter has a valuable role in supporting the success in combating falsified and substandard medical products. We look to partner with you.

Separately, we're involved in a "whole-of-governments" approach to combating illicit pharmaceutical trade that we've been working on with a variety of stakeholders. We have aimed to bring together a range of stakeholders, all with important skills that sometimes inadvertently operate in silos, including public health institutions, regulatory agencies, law enforcement authorities, intellectual property organizations, postal unions, customs authorities, trade organizations, industry stakeholders, and consumer groups.

I would like to recognize the national regulatory authorities that have achieved Maturity Level 3 under the WHO Global Benchmarking Tool. Congratulations to Egypt, Ghana, Nigeria, South Africa, and Tanzania. Many of you are striving for operations at an advanced level of performance and continuous improvement. You also serve as Regional Centers of Excellence. The FDA appreciates the World Health Organization for their continued leadership and introduction of the WHO Listed Authority or WLA. In reminder to us all, a WHO Listed Authority replaces the Stringent Regulatory Authority classification, which was based on politics. A WHO Listed Authority is a regulatory authority or a regional regulatory system that complies with all the relevant indicators and requirements specified by WHO for regulatory capability as defined by an established benchmarking and performance evaluation process.

Last month, the FDA was honored to join 33 regulatory authorities in receiving the WHO Listed Authority (WLA) designation. The FDA supports the WLA approach because it sets common standards and thus furthers international regulatory harmonization and convergence that will facilitate access to products and maintains the integrity of our supply chains both domestically and internationally. These are "best regulatory practices" common to discussions today. The USP Africa Regional Chapter may play an important role in supporting national regulatory authorities in advancing their capacity as evaluated under the Benchmarking Tool. It is not too

early to work together in planning to see the African Medicines Agency graduate through maturity level steps and ultimately achieve WHO Listed Authority status.

There is a lot I more that I would like to discuss with you. In appreciation of time and my colleagues also speaking, I will begin wrapping up by mentioning some of our work in Africa. The FDA is proud of our long-standing regulatory systems strengthening support in Africa through multilateral partners including the World Health Organization, African Union, regional economic communities and, at times, national regulatory authorities. Some examples of our early support include partnering with WHO to advance regulatory systems strengthening as part of global benchmarking, joining many of you early in development of the African Vaccines Regulatory Forum (AVAREF) and the African Union Smart Safety Surveillance (AU-3S) program, and early participation in the International Medical Device Regulators Forum (IMDRF)/African Medical Devices Forum (AMDF). Much of this work was before more formal inclusion of these activities in the African Medicines Regulatory Harmonization (AMRH) technical committee structure. Again, with appreciation to the AU, WHO, and several national regulatory authorities present today, both AVAREF and AU-3S were valuable assets during COVID-19 and will continue play important roles in the future. The IMDRF is also a success story we are proud to be part of.

Last November in Nairobi, we were pleased to join many of you at the African Medical Devices Forum meeting where we held a joint AMDF/FDA workshop on capacity building and regulatory convergence for medical devices. The workshop's objectives were to support the forum's five-year strategic plan, to support its successful application as a Regional Harmonization Initiative of the IMDRF, to strengthen the infrastructure of medical device regulatory frameworks on the continent, to incorporate global lessons learned from the COVID-19 pandemic, to prevent the implementation of unnecessary regulatory barriers to medical technologies, and to encourage adoption of good regulatory practices in the area of medical device regulation. Since this workshop, Kenya, Tanzania, Ethiopia, and South Africa have become IMDRF affiliate members.

More recently, at the regional level, we worked within our government in partnership with the U.S. Trade and Development Authority to support regional regulatory system strengthening with a focus on good regulatory practices. The FDA moderated and participated on panels for

the USTDA Workshop on Regulatory Convergence for Healthcare Products in East Africa, as well as a separate workshop on the same topic in South Africa. The FDA plans to participate in the upcoming program on Regulatory Convergence for Healthcare Products in West Africa. It was a pleasure to meet many of you in several of these meetings and learn from your experiences and recommendations.

In partnership with many of in the audience and expert panel members today, we've more recently increased our engagements with an overarching goal to support operationalization and success of the African Medicines Agency (AMA). One important example is our work with both AMRH and Good Manufacturing Practices (GMP) technical committee leadership to support ongoing GMP trainings reaching hundreds across Africa. We are also having discussions about providing more long-term training support as future plans are developed. Another critical area is pharmacovigilance. I'm particularly excited to see discussions proceed on how we can best support your technical committee needs here. We've recently started discussions with AUDA-NEPAD around potential confidentiality commitments and mutual recognition agreements. Such discussion may result in a legal framework for the FDA to share certain kinds of nonpublic information, thereby expediting regulatory reviews and processes. These discussions could have more long-term benefit and serve as a framework for future discussion between the FDA and the AMA.

In speaking of the AMA and deepening our engagements, I would like to express the FDA's commitment to supporting the operationalization and long-term success of the AMA. We were proud to convey that in person at the FDA during a high-level visit that included several of you. I would like to repeat that commitment again today. We all are eager to see the AMA become active. As that time comes, I would like to recognize the remarkable depth and breadth of technical capacity and regulatory infrastructure that has been developed by many of you under AMRH and elsewhere. The products of your ongoing hard work will truly benefit the AMA. Reflecting our steadfast commitment and as mentioned in my initial comments, I am proud that the FDA is opening an office at our U.S. Embassy in Kigali to provide direct support to AMA. We are doing so with appreciated support from the U.S. President's Emergency Plan for AIDS Relief

(PEPFAR) program. We, like so many of you, value PEPFAR's commitment – and that of Ambassador Nkengasong himself – to see regional manufacturing succeed. We will continue deepening our support to PEPFAR as well.

It would be great to spend more time speaking with you. Importantly, the FDA wants to hear you and support you. We want to move forward in a manner that best supports your ongoing and future efforts. While time is limited today, I hope to meet several of you in person and speak further in a few weeks in Kigali at the Bill & Melinda Gates 2024 Global Health Regulatory Team meeting. Please feel free to reach out through USP and the Africa Regional Chapter as you would like.

In closing, I would like to first acknowledge USP. The U.S. Pharmacopeial Convention (USP) and its consortium of partners have a long history of providing regulatory and health systems support to countries across the globe. I applaud USP for their contributions and a common, shared vision with all in the audience to increase equitable access to quality-assured medical products. In addition to being neighbors in the Washington, D.C. area, we are friends with a long history of working together. Many of us worked together in an earlier, international office before my office and across the FDA. We work together on several lines of effort. With several already mentioned, I am sure we will find more.

I end by conveying my gratitude to the newly launched USP Africa Regional Chapter and to each of you for all you do in effort to assure access to quality, safe, and efficacious medical products in Africa. Thank you again.