Remarks by Mark Abdoo

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Thank you, Jeff. I'm Mark Abdoo, Associate Commissioner for Global Policy and Strategy, or OGPS, at the U.S. Food and Drug Administration. My office manages the FDA's foreign offices, functions as the point of contact for many of the FDA's bilateral exchanges and global partnerships, and is at the forefront of the collection, analysis and sharing of high-quality information – including inspection data – to advance the FDA's public health mission.

With our primary focus on global matters, OGPS ensures that global considerations are fully integrated into the FDA's policies and operational activities and are helping to shape and implement the agency's global work. Today I want to briefly outline a few aspects of our global efforts.

Advancing international harmonization is the first element of this strategy. For nearly 30 years, the IMDRF and its predecessor organization, the Global Harmonization Task Force, have emphasized the importance of regulatory harmonization, convergence, and reliance to help stretch scarce regulatory resources, ensure equitable access to medical devices and maintain the integrity of our supply chains both domestically and internationally. The FDA was a strong advocate of the IMDRF's goals from the beginning in the belief that international harmonization leads to improved efficiency in the regulatory review process, reduced time to get a product to the market, reduced patient burden through prevention of unnecessary duplication of clinical trials and postmarket clinical evaluations, and reduction of unnecessary animal testing without compromising safety and effectiveness.

The second aspect is fostering high quality standards globally. We know that some countries produce products of varying levels of quality depending on the intended market. We believe there ought to be a single high-quality standard – not one standard for the United States, Europe, and other countries with advanced regulatory systems, another standard for countries with emerging regulatory systems, and yet a third standard for less developed countries. Achieving such a standard will require continuous evolution and improvement from regulators and the adoption of a quality-focused organizational culture by industry.

Building strong partnerships, bilaterally and multilaterally is the third aspect of our global work. The FDA relies on strong domestic and international partnerships to achieve its public health mission. When a medical product shortage arises in one country, it often causes a ripple effect across the globe. Often a single regulatory authority — even one with the resources of the FDA — may lack the tools to address such issues. Therefore, public health can be better protected when we work with others — and I mean others broadly, not just the FDA's regulatory counterparts.

One important way we're building global partnerships is by providing advice and outreach to help strengthen regulatory systems across the globe, as we're doing in Africa where preparations are underway to stand up the African Medicines Agency.

A fourth aspect of the FDA's global work is combating falsified and substandard medical products. The emergence of increasingly sophisticated criminal networks means that the threat posed by the illicit trade in medical products is now too complex to be addressed by a single stakeholder. The FDA is actively working with other stakeholders, including the Organisation for Economic Co-operation and Development, on a whole of governments approach to this problem and we're working with the WHO's Member State Mechanism for Substandard and Falsified Medical Products, to develop strategies for mitigating the public health risk and harm caused by substandard or falsified medicines.

The WHO estimates that one in 10 medicines in low- and middle-income countries are substandard or falsified (SF). Many of us may know of anecdotal examples where condoms, blood glucose test strips, contact lenses and even surgical devices have been falsified. However, there is practically no data available on this problem, according to a study last year by the European Directorate for the Quality of Medicines and Healthcare, suggesting there is room for public health authorities to explore the issue of falsified medical devices in the future.

What I've outlined is admittedly a large body of work, which requires experts at our headquarters in Maryland and at the FDA's foreign offices in six countries.

Just a few months ago, the FDA marked the 15th anniversary of the opening of the FDA's first foreign office, in Beijing. The FDA foreign offices were initially conceived to manage the issues FDA was facing at the time – a boom in outsourcing of medical product and other manufacturing to India and China and an increasing reliance on produce imported from Latin America. While these factors continue, there are new challenges emerging that require an expanded FDA foreign presence for us to meet the challenges of the next 15 years. In fact, the President's FY 2025 budget released yesterday contains a request for $1 million in new funding to begin the process of expanding our foreign footprint. This ultimately will include reimagined and expanded offices in India and Latin America, an Asia regional office, a presence in Africa and changes to our Europe office to better manage the wealth of clinical trials that are conducted there.

Today I've provided a quick tour of some of the ways we are fulfilling our public health mission of promoting and protecting the health of the American people. This includes advancing international harmonization, fostering high quality standards, building strong partnerships and combating falsified and substandard products. These efforts all share a single throughput – that in today's global landscape, where many FDA-regulated products originate from outside of the United States, the FDA can't act alone, it must engage internationally to fulfill its mission. Thank you for inviting me to speak with you today.