Remarks of Mark Abdoo, Associate Commissioner for Global Policy and Strategy, U.S. Food and Drug Administration, to the Asia-Pacific Economic Cooperation (APEC) Medical Product Supply Chain Dialogue

April 25, 2023

Rockville, Maryland

Good morning, good afternoon and good evening, everyone. Before I begin, I'd like to acknowledge Susan Winckler, who has been a steadfast supporter of the FDA and of public health in her executive positions over the years. Thank you for your efforts, Susan.

I'm Mark Abdoo, the head of the FDA's Office of Global Policy and Strategy or OGPS. My office ensures that global considerations are fully integrated into the FDA policies and operational activities. We manage the FDA's foreign offices in six countries, function as the point of contact for many of the FDA's bilateral exchanges and global partnerships, and are at the forefront of the collection, analysis and sharing of high-quality information – including inspection data – to advance the FDA's public health mission.

You might say these interactions give us a front row seat to observe the many stressors buffeting the global pharmaceutical supply chain.

Certainly, for the United States, complex global supply chains have fundamentally altered our economic and security landscape and demanded a major change in the way FDA fulfills its mission to promote and protect the health of the American people. Just as public health leaders have long recognized that disease knows no borders, the FDA has learned that product safety and quality no longer begin or end at the border.

This year marks the 15th anniversary of our first foreign office in Beijing, China. It was opened in response to a series of public health tragedies in which Americans were sickened or killed by poor quality or adulterated imported products, including economically adulterated and contaminated heparin. In the years since then, our foreign offices have fulfilled a critical role, functioning as the FDA's eyes and ears in their country or region. Our staff follow regulatory and market developments, spot trends in manufacturing and product safety and quality and meet with industry and government to educate them about the FDA's regulatory requirements. Now, we're considering whether there is a need to adjust our overseas footprint to meet the challenges of the next 15 years.

The COVID-19 pandemic introduced more extreme disruptions to global supply chains. In the wake of that experience, the U.S. government commissioned studies to help us further understand these supply chain complexities. We learned that economic pressures to control health care costs encourage just in-time manufacturing and supply limited surge capacity, an overreliance on certain lower cost countries for supplies and manufacturing, contracting practices that favor single supplier contracts for lowest bidders and minimal investment in new technologies that support reliable quality over time. As next steps, the FDA helped draw up a list of 86 essential medications that will be followed more closely to ensure a stable supply. We're promoting advanced manufacturing, which can respond to supply changes more quickly and we're looking for ways to incentivize quality manufacturing.

You'll soon be hearing about the Asia Pacific Economic Cooperation's Roadmap to Promote Global Medical Product Quality and Supply Chain Security. OGPS not only embraces this approach but we're actively helping to advance it, including encouraging sufficient legal, regulatory, enforcement, and laboratory capacity at the regional, national, and global levels to help ensure integrity in the manufacturing and distribution of components and finished products in the legitimate supply chain. FDA staff meets with regulators and industry around the world to discuss pharmaceutical best practices and promote the global adoption of Good Regulatory Practice (GRP) – modern principles that embody a belief in regulations and regulatory frameworks that are transparent, predictable, and rooted in science and risk analysis.

Last year we provided technical assistance to help stand up the African Medicines Agency, dedicated to improving access to quality, safe, and efficacious medical products in Africa. And in February, I was in India, participating in a series of meetings with industry to discuss manufacturing quality just as the government was holding internal meetings to deliberate pathways to further develop robust and resilient regulatory systems.

Just like the APEC roadmap, we also encourage global regulatory convergence and standards development, recognizing that the current individual patchwork of regulations prevents comprehensive assurances of medical product safety and creates barriers to the efficient development of novel products.

I serve as a vice chairman of the Steering Committee of the WHO's Member State Mechanism for Substandard and Falsified Medical Product. The Mechanism brings together the WHO's 194 Member States to convene, coordinate, decide, and organize activities to address the public health risk caused by medicines that are falsified or of insufficient quality. One of our critical messages for the forum is that there ought to be one quality standard – not one standard for the United States, Europe, and Japan, and another for India, and yet another for Africa. Of course, we understand that assuring such standards requires continuous evolution and improvement from regulators, just as achieving it requires the same from industry.

Finally, the roadmap emphasizes the importance of having information and communication systems in place for regulators and law enforcement to share information as well as achieving global cooperation and collaboration to leverage resources between member economies. We, at FDA, are embracing these concepts as part of the Biden-Harris Administration's whole of government approach to countering illicit medical products. A couple weeks ago, on April 11th, the White House announced a strengthened whole-of-government approach to save lives by disrupting the trafficking of illicit fentanyl and its precursors into American communities. This approach builds on the President's National Drug Control Strategy and helps deliver on his State of the Union call to beat the opioid and overdose epidemic by cracking down on the production, sale, and trafficking of illicit fentanyl to help save lives, protect the public health, and improve the public safety of our communities.

OGPS and the FDA's Office of Criminal Investigations are doing their part to support this approach, including through a collaboration with the Organisation of Economic Co-Operation and Development. The emergence of increasingly sophisticated criminal networks means that the threat posed by the illicit pharmaceutical trade is too complex to be addressed by a single stakeholder. Our whole of governments approach seeks to marshal the resources of industry, regulators, public health agencies, law enforcement authorities, intellectual property and patent protection organizations; postal union, customs and border protection authorities; trade organizations, and patient and consumer groups, all working together. We held a series of meetings on this subject last year and are now working with a core group of global and regional organizations to champion concrete workstreams building on this momentum.

As you've learned, my office is broadly engaged in helping to protect the global drug supply chain. I hope these brief comments have provided a glimpse of the many issues you'll be discussing over the next two days. This looks to be an outstanding conference. I look forward to hearing from the next speakers. Thank you.