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DIA Roundtable
Innovating Together: Tackling Global Challenges in Developing, Manufacturing, and Distributing Safer, High-Quality Medicines
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Hello, I'm Mark Abdoo, FDA Associate Commissioner for Global Policy and Strategy. Thanks to Marwan, Zili, and the DIA team for bringing us together today. The fact that we are all making time today is testament to the significance of the topic. I'd also like to welcome Minister Bi. I wish I could have been there in person to greet you.

As most of you know, my office, among other things, manages the FDA's foreign offices in six countries, including China, our largest and oldest office, established in late 2008.

Each foreign office serves as a critical hub where information is collected, analyzed, and transmitted bi-directionally – with HQ including our product centers, to inform policy and risk-based decision making. Our staff closely follow regulatory and market developments, accumulating vital expertise over time. They spot trends in manufacturing and product safety and quality. They meet with industry and government, educating them about the FDA's regulatory requirements, and building relationships that simply wouldn't be possible by engaging from afar, critical to driving regulatory coherence and harmonization. And yes, our staff also conducts inspections of manufacturing facilities in their host countries.

Today we're considering how we can coordinate work to address the global challenges we all face in developing, manufacturing, and distributing safer, high-quality medicines. I'm going to focus my remarks on two critical and interrelated issues – substandard and falsified medical

products and assuring quality. My office, and I would venture to say the FDA more broadly, has a vision –one in which innovative partnerships advance a global marketplace that consistently offers high-quality options for consumers and patients regardless of where they live or their socioeconomic status, underpinned by consistent regulatory frameworks and close collaboration among relevant stakeholders, and particularly regulatory authorities. I'll cut to the chase and give you my bottom lines up front:

First, we need more coordination globally to improve technical capacity, so more countries have a strong and qualified regulatory workforce that is trained in the requisite tools and methods to prevent, detect, and respond to SF medical products.

Second, we collectively need to foster a culture of quality that carries all the way through the supply chain. And when I speak of quality, I don't mean only manufacturing quality. I am also speaking of quality in the clinical studies that underpin product approvals, including through assuring the integrity of the data and upholding the ethical imperatives for human subjects in medical research by requiring truly informed consent, particularly for minority and vulnerable populations.

Okay, now that's out of the way I am going reflect on our mutual experience, the market risks we all face, and then how we can address these challenges. Given Minister Bi's presence, many of my examples will focus on FDA's cooperation with China. The FDA decided to open an office in China because even then it was an important supplier of drugs and other products to the United States, a trend which continues to this day. As of FY 2022, China ranked third among countries that export drugs and biologics to the United States by FDA cleared import line,

defined as a distinct regulated product within a customs entry. Approximately 85% of these import lines from China were human finished dosage forms. China's share of drug and biologic imports to the United States is growing, increasing 9% to 12% in the period from 2015 to 2019, measured by import lines.

Not surprisingly, China also ranks third for number of FDA-registered manufacturing facilities after the U.S. and India. The FDA uses a risk-based model to inspect these facilities, employing a combination of announced, short-announced, and unannounced inspections. When we inspect, we expect access to the facility, manufacturing records, standard operating procedures, databases, and other records such as recalls and complaints. Limiting access can result in regulatory actions such as a warning letter or an import alert.

In today's global marketplace, products travel from country to country in an increasingly complex path from raw source materials to finished products. Risks can arise at any step in the supply chain. Whether it's the sourcing of active pharmaceutical ingredients, key starting materials, or other components used to make a product, the manufacture, storage, transit, sale, and distribution of medical products involve numerous entities. When unexpected medical product shortages or safety problems arise in one manufacturer, country, or region, its cascading impacts can be felt around the world. Additionally, industries face increasing economic pressure to grow output and/or reduce costs, which often happens at the expense of quality controls.

Pressures also include the need for a timely response to emerging public health needs as well as the need to keep up with changes in how products are being made. As industry practices adapt

to meet the demands of an evolving world, the traditional model of batch manufacturing drugs is slowly being phased out in favor of new advanced manufacturing technologies. Moreover, too much of the world faces profound challenges from substandard and falsified products pouring across borders, while low- and- medium income countries find themselves being sold lower quality products.

These changes open new opportunities and risks for the safety and availability of drug and vaccine products. And it further underscores the need for international coordination to protect public health and respond quickly and effectively to risks to medical product safety and availability.

No regulatory authority can do everything on its own. That is why the FDA seeks to develop innovative partnerships with regulatory counterparts and international organizations. Working collaboratively enables public resources to be used more effectively in the oversight of products we regulate, helps promote more equitable access to medical products, and maintain the integrity of our supply chains, both domestically and internationally. These partnerships better position the FDA and our counterparts to mitigate the numerous risks that could impact access to high-quality medicines and vaccines.

One example of regulatory authorities coming together is the Member State Mechanism on Substandard and Falsified Medical Products. This collaboration brings countries together to address the public health impacts of substandard and falsified products and by doing so, ultimately helps countries around the globe better protect their patients.

The FDA collaborates with China in various ways. A year before the FDA China Office opened, the U.S. and China signed a memorandum of understanding that created a formal structure for information sharing and collaboration on drug and medical device safety. This MOU set the stage for annual bilateral meetings and other in-country engagements, now with China's National Medical Products Administration, or NMPA. This relationship has proved vital, for example, when NMPA was able to help address a cancer drug shortage in the United States.

During the latest bilateral, in June, we discussed the FDA's long-term vision to achieve a global marketplace which consistently offers high-quality medical products for consumers and patients regardless of their location. And we invited NMPA to work with us in pursuing the public health priorities of improving the quality, safety, and effectiveness of medical products, counteracting the marketing of substandard and fraudulent products, and increasing international regulatory harmonization.

Because of the complex nature of the production and distribution of the products we regulate, no national regulatory authority can inspect every facility under its jurisdiction every year - or sample every imported product. Inspecting or testing our way to quality is not a feasible approach. We must all encourage a culture of quality at every stage of the global supply chain. Regulatory requirements set a floor, but a culture of quality demands adoption of best practices and a commitment to continuous improvement.

In addition, fully tackling the global challenges of developing, manufacturing, and distributing safer high-quality medicines also requires consistent, harmonized regulatory frameworks. 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 studies and postmarket clinical evaluations, and reduction of unnecessary animal testing without compromising safety and effectiveness.

China has embraced international harmonization. Today, NMPA is a member of the management committee of the International Medical Device Regulatory Forum, a regulatory member of the International Council for Harmonisation of Technical Requirements for Human Pharmaceuticals, and, in November 2023, NMPA was confirmed as an applicant for PIC/S, the Pharmaceutical Inspection Co-operation Scheme.

The U.S. and China have one other commonality, a shared priority in advancing innovation and collaboration to improve the prevention and treatment of chronic non-communicable diseases, recognizing the profound impact these efforts can have on enhancing health outcomes and quality of life for their citizens. In China, NCDs account for 90% of all deaths, with cardiovascular diseases representing nearly half of these fatalities. Similarly, in the U.S., NCDs are responsible for 77% of deaths, primarily from heart disease, cancer, and diabetes. Effective management of risk factors, such as hypertension, obesity, and smoking, is critical in both nations.

As China's pharma industry grows in size and scope, so must its role in the international community and marketplace, working with the United States and others to ensure a resilient pipeline of high-quality medical products for the world. Such challenges as falsified and substandard products and lower quality products undermine the confidence in medical products and threaten the integrity of our medical product supply chains. We must work

together to counter these risks if we wish to ensure the safety of our peoples all of whom depend upon the reliability and coherence of the global medical product marketplace.

I'd like to leave you with two questions: what more can be done to achieve a holistic, whole-of-stakeholders approach so all medical products, regardless of where they are manufactured or whether they are intended for richer or poorer countries and communities are of a high quality, and how can we collectively do more to prevent, detect, and respond to SF medical products?

Thank you.