

Remarks of Mark Abdo
FDA Associate Commissioner for Global Policy and Strategy
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Introduction

Good morning, everyone. I am delighted to be here this morning. First, I'd like to thank the organizers and the local host committee for inviting me to be with you today. I also appreciate having heard about the close relationship FDA has with DOJ from the first keynote speaker, Arun Rao. I'm Mark Abdo, Associate Commissioner for Global Policy and Strategy at the U.S. Food and Drug Administration, and my office helps ensure global considerations are integrated into the FDA's policies, regulations, programs, and strategies.

Today I am going to provide my perspective on "the FDA in the world," which is a big topic.

The FDA began engaging globally well before the rapid increase in imports caused by the efforts of manufacturers and producers regulated by the FDA to lower costs and improve productivity, fueling a cycle in which the quest for efficiency led to increased production abroad and higher volumes of imported products for the FDA to regulate.

And we did so for a few reasons:

First, to become more effective and efficient. Globally aligning approaches to common problems allows us to be more effective in mitigating or managing them and relying on data and information collected by foreign regulators to support the FDA's oversight activities generates efficiencies so we can focus our own resources in areas of greater risk.

Second, to benefit patients and consumers ... and industry too. International harmonization is a good example. 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.

Third, and perhaps most significantly, to keep Americans safe, which often has the collateral benefit of improving safety in other jurisdictions as well. Complex global and regional supply chains fundamentally altered the United States' 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 knows product safety and quality no longer begin or end at the border.

Over the last few decades economic considerations — such as lower wages and investment-friendly industrial policy — prompted a boom in outsourcing of manufacturing to India and

China and an increasing reliance on produce imported from Latin America. As international legal practitioners in the life sciences, you probably know that FDA-regulated products account for about 20 cents of every dollar spent by consumers. You also probably know many of these products originate from outside of the United States — such as produce from Mexico, seafood from Indonesia, drugs from India, and medical devices from China. And sometimes the regulatory frameworks of the countries from which they originate are outdated and provide insufficient oversight creating risks for U.S. patients and consumers that led to expansion of the FDA’s oversight and modernization of our mission delivery.

Given this global landscape, the FDA must engage internationally to fulfill its mission. To give you a more in-depth perspective of “FDA in the world,” let’s consider the work of my office, the Office of Global Policy and Strategy, or OGPS. Among other things, OGPS manages the FDA’s foreign offices, two of which focus on products from a single country — in Beijing, China and New Delhi, India — one focused on products from the 44 countries of Latin America and the Caribbean, and one focused on cooperation with the mature regulators of Europe and the less developed regulators of Central Asia. This year marks the 15th anniversary of the opening of FDA’s first foreign office, in Beijing, and we are currently in the process of considering whether we need to adjust our overseas footprint to meet the challenges of the next 15 years. We opened these offices in response to a series of public health tragedies in which Americans were sickened or killed by poor quality or adulterated imported products, such as diverted and counterfeit glucose monitor test strips, adulterated heparin, and cantaloupes contaminated with salmonella.

Our foreign offices fulfill a critical role — they function as FDA’s eyes and ears in the country or region where they are located. 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 FDA’s regulatory requirements, building relationships that simply wouldn’t be possible by engaging from afar. And yes, our staff also conducts inspections of manufacturing facilities in their host countries.

I am going to speak next about a few of the important approaches the FDA uses to fulfill its mission: global partnerships, collection, analysis, and dissemination of high-quality information, and policy coherence. I’ll provide examples of each approach and will also mention a few ways FDA’s authorities have changed in response to global developments. Let me start with FDA partnerships.

Partnerships

The FDA relies on strong domestic and international partnerships to achieve its public health mission. When a medical product shortage or a food safety problem 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.

Nothing makes this clearer than public health emergencies, during which collaboration with our partners is essential. Last year, to build immediate relief into the infant formula supply chain, The FDA engaged with U.S. Government and international partners that had specialized supply chain authorities, expertise, and influence. At the peak of the crisis, the FDA expanded access to infant formula by temporarily exercising enforcement discretion for certain infant formula

requirements on a case-by-case basis. FDA supported Operation Fly Formula to arrange for emergency transport of the essential product from outside the U.S. Between May and September 2022, the operation facilitated over 70 shipments from Europe, Asia, and North America that imported over 6 million pounds of infant formula into the United States. These partnerships — across multiple government agencies, regulators, and industry — helped the United States to address this shortage.

Another good example comes from the work of our India office, which builds coalitions and partnerships with in-country regulatory authorities, industry, academia, multilateral organizations, and nongovernmental organizations. In response to medical products with quality issues linked to manufacturing in India, our India Office devoted much of February to meet with regulators and industry to emphasize the importance of instilling a culture of quality in drug manufacturing. The FDA repeatedly emphasized that Indian manufacturing shouldn't have one quality standard for products bound for countries with stringent regulatory authorities and another lower standard for its domestic market or countries in Africa and other locations with lower-resourced regulators. The FDA also encouraged India to set aside more resources to support its regulatory system. In turn, the Government of India hosted a series of internal meetings to deliberate pathways for developing more robust and consistent oversight for pharmaceutical manufacturing. Such engagement from the FDA benefits patients in the United States and, importantly, also benefits other countries that rely on drugs manufactured in India.

Over the longer term, the FDA has an interest in strengthening new regulatory partnerships. Africa is becoming a region of greater interest for the FDA, where attention to public health regulations and prioritization for Africa's regulatory capacity has increased because of the pandemic. The FDA, through OGPS, is considering how best to help in standing up the African Medicines Agency — or AMA — dedicated to improving access to quality, safe, and effective medical products in Africa. We are working to support operationalization of AMA because it is the right thing to do, and, importantly, down the road a strong, well-functioning AMA will support manufacturing in Africa that could eventually contribute to resiliency and redundancy in supply chains for products Americans rely on.

Information Sharing

Every one of our foreign offices serves as a critical hub where information is collected, analyzed, and transmitted back to FDA headquarters to inform the agency's decision-making. Not only does the agency use information-sharing to inform its Centers' longer-term regulatory policies on drugs, food, devices, and biologics, but also shares information to cope with emergencies.

An important way the FDA gathers high-quality information is through confidentiality commitments and mutual recognition agreements. A confidentiality commitment is a legal framework for the agency to share certain kinds of non-public information with our counterparts in foreign countries. The FDA signed its first confidentiality commitments with the European Medicines Agency or "EMA" 20 years ago. In the years since, the EMA and the FDA have established more than 30 technical expert groups that meet regularly for regulatory and technical discussions. These groups cover a wide range of topics, from oncology to patient engagement, to vaccines.

Under the Food and Drug Administration Safety and Innovation Act, enacted in 2012, the FDA received the authority to enter into agreements to recognize drug inspections conducted by

foreign regulatory authorities. Mutual Recognition Agreements between countries allow drug inspectors to rely upon information from inspections conducted by other countries, if the FDA determined those countries' authorities can conduct inspections that meet U.S. requirements. There is much to be gained by collaborating with other regulators to reduce duplicative efforts and maximize inspection resources. In January 2023, we established an agreement with Switzerland and its drug regulator, Swissmedic. This kind of information sharing with our foreign colleagues has proven to be especially vital during global public health crises, like the pandemic, when we were unable to conduct foreign inspections and needed to rely on the authorities in the EU and UK for information to inform our decisions.

Related to information sharing, the legal landscape across the world is changing in important ways. My office is monitoring laws in Europe and China that could affect the FDA's collection and sharing of information. Some countries have data laws that impede sharing of medical and health care data or facilitate foreign access to data on people in the United States. In 2018, the European Union enacted a law requiring that organizations put in place certain measures if they collect, use, or store personal data originating in the European Economic Area. This law intended to ensure that the data is protected, even if transferred out of the area, and resulted in Europe's General Data Protection Regulation or "GDPR".

The FDA's Europe Office has been closely following the potential impact of the GDPR on our public health activities. So far, the FDA's bioresearch monitoring program, which oversees the conduct and reporting of FDA-regulated research, has been most impacted by the law. There have been instances in which FDA investigators have been unable to complete in-person inspections due to data sharing policies, such as GDPR. While data sharing policies are only one challenge in conducting inspections, lack of clarity around GDPR impeded the FDA's ability to review data remotely during the pandemic.

China's laws go even further. A 2019 report prepared for the U.S.-China Economic and Security Review Commission noted that China's laws prevent the export of information about Chinese people and require a permit for research use of genomic information. Chinese law also authorizes the central government to access private sector data, but with limited protections. The law is vague about information oversight that could allow collection of health information to go unchecked and may have not just privacy and public health implications, but also national security implications for the United States.

Policy Coherence

I'm going to turn, now, to a discussion of policy coherence — what it is, and how FDA contributes to it as part of our public health mission. The Organisation for Economic Co-operation and Development or "OECD" describes policy coherence as strengthening the capacity of governments to design, implement, and monitor coherent policies for sustainable development. This entails activities such as fostering synergies across economic, social, and environmental policy areas, as well as reconciling domestic and international objectives. This is a concept that has long been recognized in global development circles and is also relevant for some of our global work. The FDA promotes this concept by helping other countries or institutions like the World Health Organization, or WHO, think through how best to prevent one policy interest, such as reducing cost, from undermining another policy interest, like assuring safety.

A good example is our work with the WHO on substandard and falsified medicines. The WHO estimates that more than one in 10 medicines in low- and middle-income countries are substandard or falsified. The reasons for this are varied — porous borders, lax oversight, pressure to reduce cost, and distribution of medical products through informal markets. And the effects are significant: adverse events, including death; increased out-of-pocket and government expenditure on healthcare; and loss of economic productivity and social mobility. In 2012, the World Health Assembly — the supreme governing body of the WHO — established the WHO Member State Mechanism on Substandard and Falsified Medical Products to consider ways to reduce the public health risk and harm caused by substandard or falsified medical products.

Within this governance structure, the United States has spearheaded a workstream to better understand the complex drivers of distribution of drugs through informal markets to help develop coherent risk management and policy options that deconflict what could be competing interests: regulation of drug distribution, assurance of high-quality medicines, lower costs for consumers, and high level of access, including for rural and underserved populations, so countries can more effectively protect public health. Again, this work is not purely altruistic. By helping think through how countries can manage their own distribution systems, the FDA benefits U.S. patients and consumers who travel across borders and purchase drugs they believe to be legitimate in unregulated, informal markets.

Another example is the “whole-of-governments” approach to combating illicit pharmaceutical trade that we’ve been working on with a variety of stakeholders. In some instances, there may be incoherence between policies that reward innovation and policies that promote access. Increasingly sophisticated criminal networks exploit this incoherence by facilitating access to lower cost products of dubious origin and quality. The policy tools necessary to combat the problem reside in multiple government departments and agencies (ministries in parliamentary systems), which means no single stakeholder can effectively address the threat. Our office co-hosted a series of workshops in 2022, culminating in a large two-day in-person event that brought together more than 110 representatives from government, multilateral international organizations, and industry. This initiative was groundbreaking in that it brought together relevant communities that sometimes inadvertently operate in silos: public health institutions, regulatory agencies, law enforcement authorities, intellectual property organizations, postal unions, customs authorities, trade organizations, industry stakeholders, and consumer groups. The event allowed participants from all over the world to openly discuss trends they have been seeing with respect to illicit pharma products, and what strategies have worked best.

Supply Chain Challenges

Before I conclude I’d like to touch on one of the major global public health issues confronting us today — supply chain disruptions. Our overseas offices give us a front row seat to observe the many elements buffeting the world’s supply chains of the products we regulate — from drugs to medical devices and infant formula. The fact is, every industry we regulate is at risk from supply chain issues, deeply embedded in “just in time” manufacturing methodology and sole sourcing to maximize profit, leading to low inventories, and offshoring of key elements to reduce costs. In the face of international strife and economic distortions, these risks have resulted in real-world consequences, affecting, for example, the availability of certain drug products and infant formula. The FDA has authorities that are helpful, and which Congress has expanded over the last few years, but they don’t match public expectations. As we’ve learned in the past few years,

supply chains can be disrupted by quality defects, public health emergencies, weather events, transportation disruptions, changes in how healthcare is provided, or simply changes in consumption habits. The result of such disruptions is often shortages of critical products.

The havoc that the COVID-19 pandemic played with medical product and food supply chains started a shift in how the agency evaluates the effects of manufacturing conditions on shortages and product availability. This relationship between manufacturing quality and product availability was brought into sharper focus during the nationwide shortage of infant formula due to the adulteration of formulas produced at one specific manufacturing facility. For the next few minutes, I'm going to speak about how some of FDA's authorities and agency programs have evolved to help manage supply chain risks.

In March of 2020, Congress passed the bipartisan Coronavirus Aid, Relief, and Economic Security (CARES) Act. The CARES Act provided the FDA with new authorities intended to identify and mitigate shortages of medical products by, among other things, enhancing FDA's visibility into drug and medical product supply chains. The Act requires certain manufacturers of drugs or active pharmaceutical ingredients to create and implement a manufacturing facility-specific risk management plan which evaluates the risks to the supply of the drug for that establishment. FDA's draft guidance for industry on Risk Management Plans to Mitigate the Potential for Drug Shortages was published in May of 2022.

In January of this year, as part of the Consolidated Appropriations Act, Congress passed the Food and Drug Omnibus Reform Act (FDORA) of 2022. FDORA includes a host of interesting new authorities and requirements for FDA, some of which strengthen our oversight and understanding of critical supply chains. On the foods side, the Act includes a provision requiring that critical food manufacturers put in place a risk management plan that will be subject to review during inspection. It also requires the agency to create a new Office of Critical Foods that will be responsible for oversight and coordination related to the supply of products such as infant formula.

With respect to medical devices, the FDA developed a Resilient Supply Chain Program, which has enhanced the agency's capacity to prevent and mitigate supply chain interruptions and promote resiliency and redundancy. The program's goals include identifying supply chain risks and developing strategies to prevent and mitigate medical device shortages. Despite all of the efforts the FDA has put into supply chain oversight and resiliency, the FDA cannot work in a vacuum. To further strengthen supply chains, we partner with other agencies within the U.S. Government, and with foreign counterparts.

The United States needs resilient, diverse, and secure supply chains to ensure our economic prosperity and national security. Coordination across the Federal government and with partner governments is one step toward implementing policy frameworks that support a resilient supply chain, build redundancy, and address risks. Resilient American supply chains can also revitalize and rebuild domestic manufacturing capacity.

Conclusion

So, where do we go from here? The same economic forces I mentioned earlier — such as lower wages and investment-friendly industrial policy that spurred manufacturers to open facilities in India and China in the 1990s — are now pushing some manufacturing toward Southeast Asia and parts of Latin America. The demographic and economic profile of Southeast Asian nations

— large, young populations of educated labor — indicate likely continued growth in manufacturing. Similarly, in Latin America, Mexico has emerged as a powerhouse for Class I and II medical device manufacturing with continued growth projected in the region.

These economic forces and other market trends will continue to shape our regulatory future. As a result of supply chain vulnerabilities exposed during the pandemic, leaders continue to push for critical supply chains to have multiple scalable sources for producing foods, drugs, vaccines, and medical devices. This global push is catalyzing investment in manufacturing and in regulatory oversight in places that have historically not had a large export industry. These investments will likely require FDA to mitigate risks of new products entering the U.S. market and present opportunity to shape regulatory frameworks in countries where they are being developed.

Today I've touched on many issues, including changing legal landscapes in Europe and China, and how they relate to us in the United States. I've shared how FDA's partnerships, information sharing, and policy coherence efforts support the United States in navigating international market forces. In keeping with my charge, these are among the prominent challenges and opportunities for "the FDA in the world." I hope my remarks have provided you with some insight that supports your global interests and endeavors to assist the legal community, influence the development of international law reform, and shape the future of the legal profession.

Thank you.