FROM A GLOBAL PERSPECTIVE

A Conversation with FDA Associate Commissioner Mark Abdoo

Whether it is generic drugs from India, fruits and vegetables from Mexico, or life-saving medical devices from Europe, there's a good chance these and other products Americans use every day originated from outside of the United States.

In fact, more than 136,400 foreign facilities export FDA-regulated products to the United States every year. Many of these products are entering from developing countries, emerging markets, or via multinational supply chains. Navigating through such complexity to ensure that U.S. imports have been properly manufactured, handled and stored is a significant challenge for FDA. This is made all the more difficult because there are 150 plus countries that export to the U.S. and each has its own laws and standards.

These are issues that the FDA's Office of Global Policy and Strategy (OGPS) confronts on a daily basis as it strives to protect and promote the public health in a global marketplace. If this office doesn't sound familiar that's because it's new. It was established on March 31, as part of a broader reorganization of the Office of the Commissioner which created a free-standing Office of Regulatory Affairs and the new OGPS (an augmented and redesigned Office of International Programs) within FDA's Office of Policy, Legislation and International Affairs. In this inaugural issue of From a Global Perspective, Mark Abdoo, Associate Commissioner for Global Policy and Strategy talks about his vision for the new office.

Mr. Abdoo joined FDA in 2013 as the first director of the Office of Public Health and Trade (OPHT) in the Office of International Programs. Prior to joining FDA, Mr. Abdoo served in other senior positions in the Federal government, including Senior Advisor for Food Security and Agricultural Economics at the U.S. Agency for International Development; Director for Global Health and Food Security at the National Security Council staff at the White House; and, in various positions in the Office of the Secretary of Health and Human Services, including Director and Acting Deputy Director for Multilateral Affairs in the Office of Global Affairs, where he was responsible for the Department's engagement with the Agencies of the United Nations System, the Organization for Economic Cooperation and Development, and other organizations. He speaks fluent Mandarin.

Let's begin by talking about the new office that you lead. Can you explain how our international work was reorganized into OGPS and why?

As the Commissioner's office reorganized in order to make it more efficient and more effective in the 21st century, it seemed to me that the international office had three big buckets of activities that were increasingly dominant. Those included partnerships and multilateral diplomacy, operating and maintaining our foreign offices and the policy planning and evaluation work that goes along with that, and finally issues related to the trade of regulated products.

Each of those big buckets of activities - partnership and multilateral diplomacy, global operations, and trade - fit naturally into a sub-office structure.

FDA isn't ordinarily thought of in terms of trade. Why is it important to have a sub-office at FDA that focuses on trade?

FDA's regulatory remit is so broad that many parts of a trade agreement affect us. That means we have a defensive need to ensure that nothing in the agreement could potentially undermine our regulations or authorities. We also take a proactive stance to trade agreements, figuring out how they can be leveraged to advance FDA's regulatory framework that requires that measures be transparent; science and risk-based; and predictable. The trade office makes sure that this framework is accounted for in a trade agreement and it strives to do so with some nuance, so we are not inadvertently creating a one-size situation that doesn't work for us given the complexity of our statutes and regulations.

Following up. Why is the trade office also tasked with work on mutual recognition agreements?

Many governments view a mutual recognition agreement as a trade facilitative mechanism, as opposed to a mechanism for regulatory cooperation, so often the authority or the impetus for entering into an MRA comes from a trade or economic ministry. That's true for the EU, Switzerland and other jurisdictions and, in fact, it's also true for the United States. The Trade Act of 1974 gives the U.S. Trade Representative the right to enter into an MRA and this has led to a whole range of those umbrella agreements. That's why work on trade issues and on MRAs go hand in hand.

FDA has foreign posts in six locations around the world – Brussels, Chile, China, Costa Rica, India and Mexico and has a staff member embedded in the European Medicines Agency in the Netherlands. Why are they there? Why is that important?

In the most general terms, FDA maintains foreign offices to ensure that we have the right people, at the right place, at the right time for foreign inspections to best assure the safety and quality of products coming into the U.S. That's especially important in China and India. We're also leveraging a different type of boots on the ground with our international relations specialists who are tasked with building relationships with regulatory authorities in the countries where we have offices. In India that means working not only with officials at the federal level but also the state level where much authority for regulation of medical products is devolved. As a result of this work, we are able to actually raise everyone's standards, helping our regulatory partners move towards global norms through harmonization and to achieve greater transparency in their regulatory decision making. Thanks to such relationship building we are likely to have a better understanding of how officials in these countries make decisions which allows us to create stronger partnerships.

Can you provide an example of how having an FDA office in a foreign country has been beneficial to public health?

Sure. One recent example is the role our India Office (INO) played in the safety issue surrounding Angiotensin II Receptor Blockers (ARBs) used for treating elevated blood pressure and heart failure. In the summer of 2018, FDA learned that some generic versions of this drug contained probable cancer-causing impurities called nitrosamines that may occur when specific chemicals and reaction conditions are present in the manufacturing process for an active pharmaceutical ingredient, or if raw or starting material has been contaminated.

The INO played an instrumental role in the investigation, conducting inspections at API manufacturing facilities in India, providing observations which resulted in multiple Warning Letters, Regulatory Meetings and Import Alerts. Due to its local presence, INO inspectors were able to rapidly mobilize to collect samples from multiple manufacturers, including samples urgently needed due to discrepant test results. Our foreign office staff routinely tracks local market trends in addition to conducting inspections and as a result were made aware of the emergence of the industry's use of solvent recovery plants in India as a cost-effective measure to "recycle" solvents previously used in drug manufacturing processes. This knowledge led to for-cause inspections of these recovery plants and the identification of nitrosamines in solvents being used to make API for ARB drugs. Without having the right people on the ground at the right time we wouldn't have recognized this trend. Since that discovery, considerations of these practices have been incorporated into inspection assignments and general inspection considerations across all drug manufacturing processes.

As you can see from the India example, time is of the essence in for-cause work in that country, just as it is in China. Therefore, it's essential to have somebody who is already prepositioned in those countries, who is prepared to go out, without notice, to inspect a facility in order to best assess quality concerns.

I understand that one of your strategic priorities for the office is policy coherence. Can you explain what you mean by that and why it is important?

Policy coherence occurs when policy and programmatic decisions are mutually reinforcing to achieve a certain outcome. It is particularly important when dealing with large complex bureaucracies. If one takes a narrow aperture and only sees their little area, an action one does could inadvertently undermine or dilute the actions that might be taken by another part of the organization. If we are really able to achieve the vision of having global considerations fully integrated into our policy strategies and programs, there may be opportunities to ensure that FDA is better coordinated so that policy levers are being used in concert. That's something we intend to address.

You have two other strategic priorities for the office besides policy coherence. What are they?

One is to make better use of high-quality information for decision making. I think we've got a tremendous opportunity to really expand the way the agency uses data that we collect to better inform our decision making. We collect a broad range of information - regulatory information, safety signals, geopolitical information - and all of this needs to be transformed into a format that can be useable by the agency. We've not been as good as we can be in aggregating this information but looking ahead, I see tremendous opportunity in data collection and dissemination. Data collection can be important in the trade world. If we know that aquaculture shipments from China are on Import Alert, we could leverage export data collected in other markets, and if we identify spikes in exports, we may be able to better understand relationships, and this might be information that our Office of Regulatory Affairs might be able to use.

The other priority, our third one, is to build and leverage global partnerships. This has historically been a known aspect of our international work such as participation in the Pan American Health Organization and the United Nations. We have opportunities to build partnerships and leverage activities with partners that we don't normally think of. For example, our work on food safety systems at the World Bank is not aimed at food regulators but aimed at heads of state and ministries of finance who are the real players because they hold the policy and purse strings.

These are all ambitious goals and yet your office is understaffed, which could make it more difficult for you to achieve these goals. What is being done to address your hiring issues?

Well, you could say we have a "small but mighty footprint." But seriously, we imposed a hiring freeze two years ago at the beginning of the reorganization process. Now we want to be smart as we go about rebuilding. As you may know, before my government service I was an entrepreneur for 10 years in East Asia. I learned from that experience the importance of being able to assess opportunities to bring them into reality and to build coalitions. Assessing context from a variety of lenses is critical, to understand when an opportunity is ripe and when it's not.

From that experience I know it takes a different type of person for our international work and consequently it will take time to get candidates who have the right background, who can think outside the box and understand the global context.

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