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Health Industry Alert

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FDA Announces Import Staffing Change at International Mail Facilities

Earlier this month, *The Washington Post* reported that Food and Drug Administration (FDA) Commissioner Scott Gottlieb announced that he was reallocating three dozen employees to international mail facilities (IMF), as well as the FDA'scybercrime and forensic chemistry units, to focus on suspicious shipments that may contain illegal food and medical products.[1] Commissioner Gottlieb indicated that the deployment will be funded through existing FDA resources, but he did not indicate how the deployment will affect the processing of imports at express consignment carrier facilities or other ports of entry.

The initiative is the first major announcement by the new FDA Commissioner on FDA import enforcement. It shows that Commissioner Gottlieb is aware of the sharp and continuing increase in the volume of imports that the FDA oversees, but it also demonstrates the trade-offs and challenges that the FDA faces in dealing with this volume.

The number of imports that the FDA has overseen has increased from 15 million shipments in fiscal year (FY) 2006 to 36.9 million shipments in FY 2016. Currently, 40 percent of listed finished drugs, 35 percent of medical devices, 50 percent of fresh fruit and 80 percent of seafood on the U.S. market are imported foreign goods. Working with U.S. Customs and Border Protection (CBP) and others, the FDA screens imports at ports of entry (such as seaports, land border crossings and airports), IMFs (where international packages sent through the U.S. Postal Service are screened) and express courier hubs (where packages sent through private courier services are screened). The volume in all of these facilities has increased significantly over the past decade. In order to identify potentially illegal imports, the FDA uses portable screening devices to examine suspicious items and then sends many to its Forensic Chemistry Center for further analysis and refers some to its Office of Criminal Investigation.

The FDA's announcement focuses exclusively on identifying illegal imports through a specific facility–IMF. IMFs have recently been the focus of drug interdiction programs, since postal shipments are not subject to the same rigorous reporting and screening requirements as shipments entering through traditional ports of entry or express courier hubs. Furthermore, FDA inspectors also have limited authority to open and inspect postal packages, as opposed to packages imported by private express consignment carriers.

Given the potentially limited impact of the personnel shift, the announcement raises the question of the staffing and resourcing of FDA operations at ports and courier hubs for the screening of legal products. Commissioner Gottlieb states that he is redeploying existing resources to IMFs. The work of the FDA's import personnel is a specialty, which limits the FDA's ability to shift existing personnel from outside the

[1] *See* https://www.washingtonpost.com/news/to-your-health/wp/2017/08/04/fda-to-step-up-fentanyl-targeting-at-postal-facilities/?utm_term=.ce3919fe29b6#comments

import field to import operations. For example, the FDA could not easily redeploy someone who conducts inspections of drug manufacturing facilities to an IMF. Without a funding increase and changes to the reporting requirements for postal shipments, an emphasis on IMFs may place pressure on staffing resources at ports and courier hubs, which have personnel with the skills to work at IMFs.

In the past, the FDA has used several means to grapple with the pressure caused by the growing volume of imports.

First, it has sought and used new statutory tools and additional funding. For example, with administration support, Congress passed the FDA Food Safety and Modernization Act (FSMA) in 2011. The FDA used authority under FSMA to create a Voluntary Qualified Importer Program (VQIP), which expedites FDA review for food importers who have a strong food-safety record. VQIP is analogous to Global Entry's expedited screening process for trusted travelers. The FDA also received additional appropriations from Congress to implement FSMA's import provisions. Outside of food, the FDA has launched a Secure Supply Chain Pilot Program for drugs and is in the process of working with the CBP to develop a trusted trader program. The FDA announced the latter effort in 2014.

Second, the FDA has used information technology to focus its resources on higher-risk products and to become more efficient. It has increased the use of the Predictive Risk-based Evaluation for Dynamic Compliance Targeting ("PREDICT") system to expedite screening of lower-risk imports. Last year, the CBP worked with the FDA and other agencies to implement the Automated Commercial Environment/International Trade Data System, which created a single portal through which importers could submit data.

Even with these steps, the increase in volume has far exceeded the resources devoted to screening imports.

Commissioner Gottlieb's announcement shows that the FDA continues to adjust its priorities for the screening and enforcement of imports that it regulates. As the FDA increases resources at IMFs, it may take steps, such as expanding its use of trusted importer programs like VQIP, further refining how it identifies high-risk products and seeking additional resources. Some of these steps might call for public comment. Industry should remain aware of this ever-changing environment and of the need to ensure that increasing volume does not delay shipments of FDA-regulated commerce. Industry should provide input as the FDA considers new programs.

Contact Information

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