Chairman Towns Releases GAO Studies Examining Challenges Facing the FDA in Regulating Foreign-made Pharmaceuticals and Food Consumed in America

WASHINGTON – Chairman Edolphus “Ed” Towns (D-NY) today released two reports by the Government Accountability Office (GAO) demonstrating how globalization is placing considerable demands on the Food and Drug Administration (FDA), which is responsible for ensuring that an increasingly large volume of both food and drug products originating from abroad and consumed by Americans are safe and meet U.S. standards.

One of the studies issued by GAO entitled, “FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but more Progress Is Needed,” examines FDA’s efforts to regulate and provide adequate oversight over foreign drug manufacturing firms that export drug products to the U.S. market. The review also examines whether the agency is prioritizing scarce inspection resources and making needed changes regarding how it collects important data about foreign firms that export drug products to the U.S.

GAO found that while FDA has made some progress in closing its inspection gap, the agency still conducts relatively few foreign inspections: For example, only about 11 percent of all foreign drug firms exporting to the U.S. are inspected each year.

At this rate, it would take FDA about 9 years to inspect each firm shipping drug products to the U.S. a single time.

In contrast, FDA inspects each domestic U.S. firm making a drug product for the U.S. market about once every 2.5 years.

GAO also recommended in earlier work that FDA create a risk-based inspection system to better prioritize scarce inspection resources.

The agency has yet to fully adopt that recommendation resulting in the potential misapplication of critical resources.

“Given that foreign firms are increasingly the source of many medicines now consumed by Americans, FDA needs to continue to explore way to better enhance its foreign inspection efforts, particularly for high risk products” said Chairman Towns. “It is troubling to learn that a foreign plant making a drug product for the U.S. market is inspected far less frequently than a domestic plant.”

The second GAO study released by Chairman Towns entitled, “Overseas Offices Have Taken Steps to Help Ensure Import Safety, but More Long-Term Planning is Needed,” examines efforts by the FDA to establish a series of overseas offices to enhance its ability to work with host governments to inspect and monitor food products, medical devices, and drug products sent to the U.S. Food production for the U.S. market, like for medicine, has increasingly shifted overseas over the past decade. This also has posed considerable new challenges for the agency.

GAO’s study found that while the impact of the overseas offices on the safety of imported products is not yet clear, such offices have provided other benefits which may help protect the U.S. consumer in the long run. For example, the establishment of a permanent foreign capability has allowed FDA to establish important regulatory dialogue with their foreign counterparts and has allowed the agency to gather important information about regulated products. Additionally, FDA field officials are allowing the agency to conducted more inspections and are assisting the export countries in developing their own regulatory systems.

However, GAO found that coordination of the foreign offices with other parts of FDA remains a challenge and that the agency lacks a long-term strategic plan for how these offices will continue to function. Without such a plan, GAO raised concerns that it will be difficult to assess how this program is benefitting the U.S. consumer, and whether their current setup optimizes FDA's limited inspection resources.

"With the avalanche of products consumed in America now coming from overseas, I applaud FDA's efforts to step up their foreign presence with these new offices," said Towns. "Nonethele ss, where they are strategically located and what they accomplish towards protecting the consumer should be closely monitored over the coming years to ensure their costs can be justified."

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