GAO Report Recommends FDA Adopt Definition of Economic Adulteration and Take Steps to Combat Independently from Other Types of Adulteration

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Responding to a request from Representatives Henry Waxman (D-CA), Frank Pallone (D-NJ), and John Dingell (D-MI), on October 24, 2011, the United States Government Accountability Office (GAO) issued a report which examines how the Food & Drug Administration (FDA) has addressed "economic adulteration" affecting the products it regulates and makes recommendations for strengthening regulatory and enforcement policies.

For purposes of the GAO evaluation and report, the GAO defined economic adulteration as "the fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e. economic gain." The GAO study highlighted two specific cases of economic adulteration as indicators of the need for stronger policies to prevent economic adulteration of FDA regulated products. First, in 2007, vegetable protein products were found to contain melamine and cyanuric acid, industrial chemicals, in order to give the products an appearance of a higher protein content. The protein products were subsequently used in pet food and caused an unknown number of illnesses and deaths to dogs and cats. Notably, the melamine contamination case helped to inspire a number of food safety policy reforms, including the enactment of the Food Safety Modernization Act on January 4, 2011, which includes mandatory HACCP-type preventive controls and establishes new safeguards to prevent intentional adulteration of food products. The second case occurred in 2008, and involved the blood thinner known as heparin, which was found to contain oversulfated chondroitin sulfate, a toxic contaminant which was later linked to multiple human illnesses and deaths.

Both of the economic adulteration cases addressed in the GAO report involved products that were imported from China to the United States. The GAO report cites increased globalization as a key factor contributing to the increased risk of economic adulteration in FDA regulated products. According to FDA documents, 10 to 15 percent of all food, 80 percent of all pharmaceutical ingredients, 40 percent of finished drugs and half of all medical devices used in the United States are imported. With these numbers expected to continue to rise, the FDA Commissioner has suggested that the FDA may need to fundamentally alter the process by which it monitors safety and quality of food and medical products. The report also references an increase in supply chain complexity as one factor complicating the regulation of economic adulteration. As products may travel through many countries for manufacturing and processing before ultimately reaching the United States, it becomes increasingly difficult to trace an ingredient back to the original source.

While the Federal Food, Drug & Cosmetic Act prohibits the introduction of any adulterated food, drug

or medical device into interstate commerce, it does not distinguish between ordinary adulteration and economically motivated adulteration. Among other things, a food is adulterated if it contains any poisonous or deleterious substance which may render it injurious to health or if any valuable constituent has been omitted, or if any damage or inferiority has been concealed.

The GAO interviewed a number of FDA officials in the course of its study and noted that the FDA currently addresses economic adulteration as part of broader efforts to combat adulteration generally. These efforts include using publicly available data to target products at risk for adulteration as part of the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT), sharing data with other federal and state agencies with authority over pet food to monitor outbreaks of illness in animals, and implementing a program allowing certain drug companies to import products on an expedited basis upon meeting certain criteria for safety.

While FDA has taken some steps specific to economic adulteration, the report found that the FDA missed opportunities for coordination and communication which would make those efforts more successful. For instance, the FDA's Office of Regulatory Affairs (ORA) and the Center for Drug Evaluation and Research (CDER) both developed models to determine which human foods and drugs were at the greatest risk for economic adulteration, but did not adequately coordinate efforts or share valuable information with the other.

The report provides three broad recommendations to the FDA in order to address economic adulteration:

- Adopt a working definition of economic adulteration as done in May 2009;
- Provide written guidance to agency centers and offices on the means of addressing economic adulteration; and
- Enhance communication and coordination of agency efforts on economic adulteration.

In its response to the draft report, the FDA explained that it viewed economic adulteration as a "subset of cases within the broader concept of adulteration, and believes that a holistic approach toward understanding and addressing adulteration is the best course forward." The FDA also noted that the Food Safety Modernization Act provided it with increased authority to promulgate broad regulations to prevent adulteration "with an enhanced focus on risk-based resource allocation." Finally, while maintaining that a holistic approach to adulteration would be best, the FDA established the Working Group on Economically Motivated Adulteration (WEMA) which held its first meeting on September 23, 2011. WEMA adopted the recommended working definition of economically motivated adulteration and will continue to hold meetings to encourage collaboration and communication to address public health issues.

The GAO report is available here.

This post was written by Donnelly McDowell.