October 2011

FOOD AND DRUG ADMINISTRATION

Better Coordination Could Enhance Efforts to Address Economic Adulteration and Protect the Public Health

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Highlights

Highlights of GAO-12-46, a report to congressional requesters

Why GAO Did This Study

In recent years, the United States experienced public health crises suspected to have been caused by the deliberate substitution or addition of harmful ingredients in food and drugs—specifically melamine in pet food and oversulfated chondroitin sulfate in the blood thinner heparin. These ingredients were evidently added to increase the apparent value of these products or reduce their production costs, an activity GAO refers to as economic adulteration. The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), has responsibility for protecting public health by ensuring the safety of a wide range of products that are vulnerable to economic adulteration. This report examines (1) the approaches that FDA uses to detect and prevent economic adulteration of food and medical products and (2) the challenges FDA faces in detecting and preventing economic adulteration and views of stakeholders on options for FDA to enhance its efforts to address economic adulteration. GAO reviewed FDA documents and interviewed FDA officials and stakeholders from academia and industry, among others.

What GAO Recommends

GAO recommends that FDA adopt a working definition of economic adulteration, enhance communication and coordination of agency efforts, and provide guidance to agency centers and offices on the means of addressing economic adulteration. HHS neither agreed nor disagreed with GAO's recommendations, but cited planned actions related to adopting a definition and enhancing communication and coordination.

View GAO-12-46 or key components.
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What GAO Found

FDA primarily approaches economic adulteration as part of its broader efforts to combat adulteration in general, such as efforts to ensure the safety of imported products. Agency officials noted that the Federal Food, Drug, and Cosmetic Act does not distinguish among motives or require motive to be established to determine whether a product is adulterated. However, a senior FDA official told GAO that there is value in making a distinction between economic adulteration and other forms of adulteration to guide the agency's thinking about how to be more proactive in addressing this issue. An FDA official told GAO when the agency detects any form of adulteration that poses an adverse public health effect, it can conduct an investigation, request a recall to get the product off the market, and take enforcement action. In addition to these broader efforts, some FDA entities also have undertaken efforts that specifically focus on economic adulteration. For example, FDA's Office of Regulatory Affairs has contracted with a research center to model risk factors for improved detection of economic adulteration of food. However, FDA entities have not always communicated or coordinated their economic adulteration efforts. For example, FDA's Center for Veterinary Medicine was unaware of and did not participate in two other entities' economic adulteration efforts involving products the veterinary center regulates. In another instance, two FDA entities engaged in similar efforts but did not communicate or coordinate them, even though officials said such communication might be beneficial. Furthermore, FDA has not issued specific written guidance on how its centers and offices should approach or address their economic adulteration efforts. This is not consistent with federal standards for internal control, which require agencies to have documented policies and procedures.

FDA officials and stakeholders GAO interviewed cited several key challenges to detecting and preventing economic adulteration, including increased globalization and lack of information from industry. Globalization has led to an increase in the variety, complexity, and volume of imported food and drugs, which complicates FDA's task of ensuring their safety. In addition to globalization, an increase in supply chain complexity—the growth in the networks of handlers, suppliers, and middlemen—also complicates FDA's task, making it difficult to trace an ingredient back to its source. FDA officials and stakeholders also said that gathering information from industry, such as information on potentially adulterated ingredients, presents challenges for FDA in detecting and preventing economic adulteration due to industry's reluctance to share such information because it is proprietary. Stakeholders cited greater oversight and information sharing as options to improve FDA's ability to combat economic adulteration. Specifically, some stakeholders supported increased oversight, such as the use of technology to trace adulterated ingredients back to the point of contamination, as an option to obtain more information on supply chains. Many stakeholders also suggested that FDA increase its regulatory and enforcement actions to address economic adulteration, including in instances that may not have a large negative public health impact. Stakeholders also suggested that greater communication with industry, through such means as an information clearinghouse or more informal interactions, could enhance FDA efforts to gather information on economic adulteration.