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FOOD AND DRUG ADMINISTRATION

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

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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. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov, or Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

FOOD AND DRUG ADMINISTRATION

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

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.

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Abbreviations

API	active pharmaceutical ingredient
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CFSAN	Center for Food Safety and Applied Nutrition
CVM	Center for Veterinary Medicine
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
ORA	Office of Regulatory Affairs
PREDICT	Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
USP	United States Pharmacopeia

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G A O

Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

October 24, 2011

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable John D. Dingell
House of Representatives

In recent years, the United States experienced two crises suspected to have been caused by the deliberate substitution or addition of harmful ingredients in food and drugs. These ingredients were evidently added to increase the apparent value of these products or reduce their production costs, an activity we refer to as “economic adulteration.” Specifically, in 2007, vegetable protein products imported to the United States from China were found to contain melamine, an industrial chemical, which later investigation suggested had been added to give the appearance of higher protein content. The products were used as ingredients in pet food, sickening and killing an unknown number of dogs and cats.¹ In 2008, heparin—a commonly used blood thinner—was imported from China and found to contain oversulfated chondroitin sulfate, a toxic contaminant that mimics heparin. The contaminated heparin was linked to a number of serious allergic reactions and deaths in the United States. In addition to harming public health, such incidents can undermine confidence in the safety of the nation’s food and medical products and have significant economic consequences for industry. For example, the melamine incident prompted pet food manufacturers to recall over 150 brands of dog and cat

¹According to FDA officials, the imported vegetable protein products also contained cyanuric acid, a melamine-related compound. Melamine and cyanuric acid individually are relatively nontoxic. However, when combined, they produce crystals, which can lead to kidney failure. For purposes of this report, we use the term melamine to mean melamine and its related analogs (e.g., melamine and cyanuric acid).

food across the United States, and the heparin crisis prompted 16 drug and device firms to recall at least 11 drug products and 72 heparin-containing medical devices.

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 food and medical products (drugs, medical devices, and biologics²) that are vulnerable to, among other things, economic adulteration. With increasing globalization of food production and medical product manufacturing, the volume of imported goods regulated by FDA has more than doubled in the last decade. As a result, according to FDA documents, from 10 to 15 percent of all food consumed in the United States is now imported, as are about 80 percent of the active pharmaceutical ingredients in drugs, nearly 40 percent of finished drugs, and half of all medical devices. FDA expects the growth in imports to continue. The FDA Commissioner has said that globalization presents huge and growing challenges and that economic adulteration remains a public health threat. She indicated that another public health crisis like heparin or melamine seems inevitable unless FDA is able to forge changes in how it ensures the safety and quality of food and medical products. In part due to regulatory challenges posed by increased globalization, we included federal oversight of both food and medical products in our 2011 list of federal programs at high risk for waste, fraud, abuse, or mismanagement that warrant attention by Congress and the executive branch.³ We first added federal oversight of food safety to our High-Risk list in January 2007 and federal oversight of medical products in January 2009.⁴

This report responds to your request that we review how FDA oversees the safety of food and drugs in order to prevent and respond 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, if any, FDA faces in detecting and preventing

²Biologics are generally materials—such as vaccines—derived from living sources, such as humans, animals, and microorganisms, as well as materials produced by biotechnology methods. See 42 U.S.C. § 262(i); 21 C.F.R. § 600.3(h).

³GAO, *High-Risk Series: An Update*, [GAO-11-278](#) (Washington, D.C.: February 2011).

⁴GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007); and *High-Risk Series: An Update*, [GAO-09-271](#) (Washington, D.C.: January 2009).

economic adulteration and stakeholder views on options for FDA to enhance its efforts to address economic adulteration.

For purposes of this report, we define 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., for economic gain. [It] includes dilution of products with increased quantities of an already-present substance (e.g., increasing inactive ingredients of a drug with a resulting reduction in strength of the finished product, or watering down of juice) to the extent that such dilution poses a known or possible health risk to consumers, as well as the addition or substitution of substances in order to mask dilution.” This definition is the same as the working definition of “economically motivated adulteration” that FDA developed for a May 2009 public meeting⁵ to raise awareness and solicit input on the topic.⁶

To determine the approaches FDA uses to detect and prevent economic adulteration, we interviewed FDA officials about the agency’s efforts to address economic adulteration and reviewed relevant FDA documents. We also reviewed our previous reports on FDA’s oversight of food and medical products, as well as the agency’s strategic planning efforts. We compared FDA’s efforts to address economic adulteration with federal standards for internal control. To determine the challenges FDA faces in detecting and preventing economic adulteration, we interviewed FDA officials and stakeholders, including former FDA officials and some representatives from academia, industry, and consumer groups who made presentations at FDA’s May 2009 meeting on economically motivated adulteration. We also interviewed the stakeholders to obtain their views on options for FDA to enhance its efforts to address economic adulteration. The views of these stakeholders are not representative of and cannot be generalized to all stakeholders. Appendix I contains a detailed discussion of the scope and methodology of our review.

We conducted this performance audit from September 2010 to October 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to

⁵See 74 Fed. Reg. 15498 (Apr. 6, 2009).

⁶For the purposes of this report, we are using the term “economic adulteration” to mean “economically motivated adulteration.”

obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

FDA is responsible for protecting public health by ensuring the safety and efficacy of medical products marketed in the United States—including drugs, medical devices, and biologics—and the safety of nearly all food products other than meat and poultry,⁷ regardless of whether they were manufactured domestically or overseas. The agency's responsibilities for overseeing food and medical products are divided among the following five FDA product centers, each responsible for specific types of products:

- The Center for Biologics Evaluation and Research (CBER) is responsible for regulating biologics for human use, such as blood, blood products, vaccines, and allergenic products, and ensuring that biologics are safe and effective.
- The Center for Devices and Radiological Health (CDRH) is responsible for regulating firms that manufacture and import medical devices and for ensuring that radiation-emitting products, such as lasers and x-ray systems, meet radiation safety standards.
- The Center for Drug Evaluation and Research (CDER) is responsible for regulating over-the-counter and prescription drugs for human use, including generic drugs.
- The Center for Food Safety and Applied Nutrition (CFSAN) is responsible for ensuring the safety of most foods for humans (except meat and poultry and processed egg products, which are regulated by the U.S. Department of Agriculture), including dietary supplements.
- The Center for Veterinary Medicine (CVM) is responsible for regulating the manufacture and distribution of drugs, devices, and food given to, or used by animals.

⁷The United States Department of Agriculture is responsible for ensuring the safety of meat and poultry products.

Among other things, the centers monitor the safety and effectiveness of marketed medical products and the safety of food, formulate regulations and guidance, conduct research, communicate information to industry and the public, and set their respective program priorities.

In addition to the work of the five centers, FDA's Office of Regulatory Affairs (ORA) conducts field work for the product centers to promote compliance with agency requirements and applicable laws. ORA field activities include inspecting domestic and foreign manufacturing facilities, examining products offered for import, collecting and analyzing samples, and taking enforcement action.⁸ ORA's Office of Criminal Investigations is responsible for investigating potential criminal violations involving FDA-regulated products and may refer cases to the Department of Justice for prosecution.

FDA's Office of the Commissioner is responsible for providing leadership and direction to the product centers and ORA. FDA's Office of International Programs is responsible for leading, managing, and coordinating all of FDA's international activities and its recently established overseas offices.

In July 2011, FDA created "directorates" that align similar functions under common leadership within the Office of the Commissioner—the Office of Medical Products and Tobacco, which oversees CBER, CDER, and CDRH, as well as the Center for Tobacco Products; the previously established Office of Foods, which oversees CFSAN and CVM; and the Office of Global Regulatory Operations and Policy, which oversees ORA and the Office of International Programs.

In recent years, we have reported on a variety of concerns related to FDA's resource management, strategic planning, and internal communications and coordination. Specifically, in June 2009, we found that FDA was unable to provide complete and reliable estimates of its

⁸According to FDA's Office of Chief Counsel, formal enforcement actions available to FDA include initiating a seizure of an adulterated product, seeking an injunction to stop a company from engaging in certain behavior, or referring a firm for criminal prosecution. FDA can also issue warning letters, which are intended to prompt companies to voluntarily correct violations of regulatory significance.

resource needs for its medical products.⁹ In February 2010, we reported on management challenges the agency faces and FDA's difficulties in using practices for effective strategic and workforce planning.¹⁰ Coordinating internally among its centers and offices and externally with outside experts were among the agency's major management challenges. Also, in September 2010, we reported on FDA's overseas offices and the need for better coordination among the centers.¹¹ For a list of these and other related reports, see Related GAO Products at the end of this report.

Federal Law on the Adulteration of FDA-Regulated Food and Medical Products

The Federal Food, Drug, and Cosmetic Act prohibits the introduction of adulterated food, drugs, and medical devices into interstate commerce. However, the act does not define or use the term "economic adulteration" or "economically motivated adulteration." The act includes, but is not limited to, the following:

- A food is deemed to be adulterated if, among other circumstances, it bears or contains any added poisonous or deleterious substance that may render it injurious to health. A food is also deemed to be adulterated (1) if any valuable constituent has been omitted in whole or in part, or (2) if any substance has been substituted wholly or in part, or (3) if damage or inferiority has been concealed in any manner, or (4) if any substance has been added so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.
- A drug is deemed to be adulterated if it purports to be a drug whose name is recognized in an official compendium¹² and its strength differs from, or its quality or purity falls below, the standards set forth

⁹GAO, *Food and Drug Administration: FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs*, [GAO-09-581](#) (Washington, D.C.: June 19, 2009).

¹⁰GAO, *Food and Drug Administration: Opportunities Exist to Better Address Management Challenges*, [GAO-10-279](#) (Washington, D.C.: Feb. 19, 2010).

¹¹GAO, *Food and Drug Administration: Overseas Offices Have Taken Steps to Help Ensure Import Safety, but More Long-Term Planning Is Needed*, [GAO-10-960](#) (Washington, D.C.: Sept. 30, 2010).

¹²The official drug compendium of the United States is the *United States Pharmacopeia/National Formulary*, published by the United States Pharmacopeial Convention, a non-governmental, standard-setting authority.

in such compendium. If a drug does not purport to be a drug listed in an official compendium, it is deemed to be adulterated if its strength differs from, or its purity or quality falls below, that which it purports to possess. A drug is also deemed to be adulterated if, among other circumstances, any substance has been (1) mixed or packed with it so as to reduce its quality or strength or (2) substituted wholly or in part.

- A device is deemed to be adulterated if it is, or purports to be or is represented as, a device which is subject to a performance standard established or recognized under the act unless such device is in all respects in conformity with such standard. It is also deemed adulterated if, among other circumstances, the device was not manufactured, packed, stored, or installed in conformity with good manufacturing practices.

Economic Adulteration

Economic adulteration is not a new problem and ranges from simple actions, such as adding material to increase a product's weight, to more sophisticated substitutions or additions that are designed to avoid detection by tests known to be used to authenticate ingredients or products. Economic adulteration differs from other forms of intentional adulteration, such as bioterrorism or sabotage, whose primary purpose is to cause harm. Because economic adulteration is intentional, it also differs from unintentional adulteration, such as adulteration through failure to follow good manufacturing practices.

Although the primary driver of economic adulteration is financial gain rather than causing harm, it can pose a variety of public health risks. The actual risks will vary depending on the adulterant used, the person who consumes the product, and the length of use or exposure. There is a direct and immediate threat to public health when the adulterant is a toxic or lethal substance, as was the case in the melamine and heparin incidents. There are also risks that arise as a result of long-term, low-dosage exposure to a contaminant or as a result of using a product whose nutritional value or efficacy has been compromised by an adulterant. Certain populations, such as infants, the elderly, and persons with compromised immune systems are particularly vulnerable to these risks. In some cases, an adulterant may only pose a public health risk for those who are allergic to it, such as fish substituted with a less expensive fish to which a person is allergic. Furthermore, economic adulteration that poses no known health risk may expose a vulnerability in the supply chain—the network of handlers, suppliers, and middlemen involved in the production of food and drugs—that could be further exploited in the future, with serious consequences.

Following the melamine and heparin incidents, FDA formed an internal work group focused on predicting and addressing what the agency referred to as “economically motivated adulteration.” The work group, comprising representatives from FDA’s food and medical product centers and ORA, held a May 2009 public meeting on the topic. For purposes of the meeting, FDA developed a working definition of economically motivated adulteration. The meeting, attended by representatives of academia, industry, and consumer groups, was designed to raise awareness about the potential for this problem and gather information on how to better predict, prevent, and address it. According to FDA officials, the work group stopped meeting shortly after the public meeting was held. FDA made a transcript of the meeting publicly available, but issued no report.

FDA Has Many Efforts to Address Economic Adulteration but Has Missed Opportunities to Communicate and Coordinate

FDA primarily approaches economic adulteration as part of its broader efforts to detect and prevent adulteration of food and medical products in general. In addition, CDER, ORA, CFSAN, and CBER have undertaken efforts specific to economic adulteration, while CVM and CDRH have not. However, agency entities have missed opportunities to communicate and coordinate efforts specifically directed at economic adulteration and identify potential public health risks.

FDA Primarily Approaches Adulteration Broadly, but Some Centers and ORA Have Undertaken Efforts Specific to Economic Adulteration

According to FDA officials, the agency primarily approaches economic adulteration as part of its broader efforts to combat adulteration in general. Such efforts include, for example, the agency’s actions to ensure the safety of imported products. According to FDA officials, these broad efforts to combat adulteration could also combat economic adulteration. 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. FDA adopted a working definition of economically motivated adulteration for the purposes of discussing the topic at its May 2009 public meeting. In its written comments on our draft report, HHS told us that the recently formed FDA Working Group on Economically Motivated Adulteration will use the working definition proposed at the public meeting, enabling FDA centers to focus their discussions and encouraging communication and collaboration. According to an FDA official, the agency generally does not expend resources to distinguish between economic and other motives for

adulteration. Rather, 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. A senior FDA official told us 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.

Examples of broader FDA efforts to address adulteration include:

- *ORA's Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT)*. This tool generates a numerical risk score for all FDA-regulated products by analyzing importers' shipment information using sets of FDA-developed risk criteria based in part on publicly available information,¹³ which may indicate opportunities for economic adulteration. PREDICT then targets for examination products that have a high risk score. As of September 2011, PREDICT was operating in ports of entry in 13 of 16 FDA districts, and FDA officials said the agency expects PREDICT to be operational in all ports of entry by the end of 2011.
- *CVM's Pet Event Tracking Network (PETNet)*. In August 2011, CVM launched PETNet, a secure, Internet-based network comprised of FDA and other federal and state agencies with authority over pet food that would allow them to exchange real-time information about outbreaks of illness in animals associated with pet food and other pet food-related incidents. PETNet members can elect to receive alerts about pet food incidents and create alerts when they are aware of a pet food incident within their jurisdiction. According to FDA, the information would be used to help federal and state regulators determine how best to use inspectional and other resources to either prevent or quickly limit the adverse events caused by adulterated pet food. Use of the system is voluntary.
- *CDER's Secure Supply Chain Pilot Program*. This program, which is in the process of being implemented, is intended to help the agency ensure the safety of imported drugs by enabling it to focus its

¹³For more information on PREDICT, see *Food Safety: FDA Has Begun to Take Action to Address Weaknesses in Food Safety Research, but Gaps Remain*, [GAO-10-182R](#) (Washington, D.C.: Apr. 23, 2010).

resources on preventing the importation of drugs that do not comply with applicable FDA requirements. The program is intended to allow a limited number of drug companies to import their products on an expedited basis if, among other things, they can meet FDA criteria showing that they maintain control over their products from manufacture through entry into the United States. FDA expects to announce the date on which it will begin accepting applications for the pilot by the end of 2011.

In addition to these broader efforts, some FDA entities have undertaken efforts specific to economic adulteration. For example, in the aftermath of the melamine and heparin incidents, CDER, ORA, CFSAN, and CBER have taken the following steps to specifically address economic adulteration:

- CDER has developed a model to rank the 1,387 active pharmaceutical ingredients (API) known to be in current use according to their susceptibility to economic adulteration.¹⁴ According to CDER officials, the ranking model incorporates various risk factors, such as estimates for volume of use, cost per unit of the API, and reliance on testing methods to check quality that are known to be less accurate than more modern methods developed for other APIs. CDER officials told us the center sampled and tested 20 of the 77 higher-ranked APIs in 2010 and found no evidence of any significant contamination suggesting intentional adulteration. According to agency officials, after this pilot program is completed, FDA will determine if the program was valuable and, if so, whether the model's risk factors may need to be adjusted.
- CDER is leading efforts to work with United States Pharmacopeia (USP) to focus on the vulnerability of drugs to economic adulteration. USP is a nonprofit organization that sets standards for medicines, food ingredients, and dietary supplements. USP's drug standards are enforceable under the Federal Food, Drug, and Cosmetic Act. Actions CDER officials say they have taken include selecting 20 USP standards¹⁵ for updating that include certain over-the-counter drugs,

¹⁴API refers to any component that is intended to provide pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease.

¹⁵These standards are in the form of monographs—written standards that describe a substance or product, including information on tests needed to ensure that the substance is of the appropriate strength, quality, and purity.

inactive ingredients used in high volume, and APIs that use outdated technology or for which there are no procedures to identify impurities. The goal of this modernization effort is to replace outdated USP standards with more modern, accurate, and specific ones. CDER has also worked closely with USP in revising the heparin testing standard and the standards for glycerin and five other similar drug product ingredients to prevent economic adulteration with diethylene glycol, a cheaper, but deadly ingredient often substituted for glycerin.

- ORA, along with the Department of Homeland Security and the Department of Agriculture's Food Safety and Inspection Service, contracted in 2010 with the University of Minnesota's National Center for Food Protection and Defense to model risk factors for improved detection of economic adulteration.¹⁶ The contract consists of three phases: (1) a survey of U.S. companies to collect information on prior or potential economic adulteration experiences and identify characteristics of potential targets of economic adulteration; (2) the development of strategies to group test methods to identify those methods that pose the greatest potential risk for economic adulteration, including the level of technical sophistication required to exploit the test method; and (3) the development of supply chain models in order to identify shifts in these supply chains that may indicate the potential for economic adulteration.
- CFSAN formed a work group on the economic adulteration of food, which started meeting in February 2008. CFSAN officials said the group, which includes representatives from CVM and ORA, generally meets monthly and is looking at the impact of economic adulteration on food safety and whether there is other work that FDA could undertake to mitigate that impact. Among other things, the group has proposed creating a page on FDA's website on economic adulteration, and it has developed a methodology for the testing of pomegranate juice, which officials said they chose to focus on because it is expensive and because its health benefits have been widely touted. CFSAN officials said the group is also looking at ways to make industry more comfortable with providing information to FDA on possible economic adulteration.

¹⁶The National Center for Food Protection and Defense is a research consortium that addresses the vulnerability of the nation's food system to attack through intentional contamination with biological or chemical agents.

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- CFSAN has a number of efforts under way to develop analytical tests and tools for detecting economic adulteration. For example, the center has developed a method for analyzing nitrogen-containing compounds similar to melamine that might be used to boost apparent nitrogen content in milk and other protein products. CFSAN's research office has a project to develop methods to detect the adulteration of powdered milk products and fruit juices. One element of this project involves the creation of a library of powdered milk signatures, against which new samples can be compared (and adulterants identified) using modern statistical methods. This project is slated for completion over the next 2 years.
 - CBER established a process in late 2008 to extract relevant product component information from regulatory applications and input this data into a database. The center has since expanded its process of extracting product component information from applications to include, for example, ingredients that may be subject to contamination. The database includes nonproprietary, unique ingredient identifiers and other information designed to facilitate faster identification of products made from components suspected of being economically adulterated.

In contrast to the other entities, senior CVM officials we spoke with said that although the center has broad initiatives designed to prevent and detect adulteration in general (i.e., PETNet), CVM has undertaken no efforts targeted to economic adulteration and has no plans to do so.¹⁷ Officials said that the melamine incident gave them greater awareness that products with high-value ingredients could be susceptible to economic adulteration and that this was the only lesson they learned from the melamine incident. Officials said they recognize that CVM-regulated products may be vulnerable to economic adulteration because they are composed of numerous byproducts, any one of which could be adulterated. Nevertheless, they said that they do not believe economic adulteration is a growing problem because of industry's overall awareness of its supply chain through efforts such as verifying certificates of analysis of ingredients from suppliers.

¹⁷While CVM has not undertaken any efforts exclusively targeting economic adulteration, in its written comments on our draft report, HHS noted that CVM is participating in an FDA Monograph Modernization Task Group to help USP prioritize monographs in need of modernization, which includes reduction of economic adulteration.

Officials from CDRH told us that, other than its broader efforts to combat adulteration in general, the center had no initiatives specifically directed at addressing economic adulteration, but indicated they are responsible for products that are vulnerable to economic adulteration. For example, CDRH officials said that they have found that a manufacturer of imported sunglass lenses may have been substituting inferior material. However, center officials were unaware of any actual cases of economic adulteration involving products for which they are responsible.

Agency Entities Have Not Communicated or Coordinated on Economic Adulteration Efforts

We found two instances in which CVM did not know about or participate in efforts on economic adulteration that involved CVM-regulated products. First, the director of the University of Minnesota's National Center for Food Protection and Defense told us that, as part of the center's contract with ORA, it will be drafting a list of foods at high risk of economic adulteration and that the list will likely include foods that are also used as animal feed ingredients. The director noted that, with the exception of certain kinds of fats, the global supply chain for animal food and feed is the same as that for human foods. The director said that, for this reason, his center had considered finding ways to make its work for FDA even more applicable to animal feed. Although CVM provided developmental input, direction, and technical support with regard to the contract, CVM officials said they were not aware of the center's work under the contract to develop this list of high-risk foods. Second, CFSAN has a research project that focuses primarily on developing methods for authenticating protein-based foods and ingredients, detecting the presence of adulterants, and identifying chemical hazards in protein-based products. Among other things, this project is to develop methods for screening skim milk powder, which can be found in both food and animal feed, for the presence of soy or other vegetable protein. Senior CVM officials said they were unaware of this research project, but they stated that CVM has been involved in developing methods to identify contaminants of protein-based ingredients.

We also found an instance where FDA entities engaged in similar efforts on economic adulteration but did not communicate or coordinate about those efforts. Specifically, as we mentioned earlier, ORA and CDER are engaged in similar efforts to determine which human foods and drugs, respectively, are at greatest risk for economic adulteration. However, according to ORA and CDER officials, they have not coordinated those efforts or communicated about them, even though they are using some of the same risk factors in their efforts—including price fluctuations and

reliance on less specific test methods. Officials from both entities said that such communication and coordination could be beneficial to both efforts.

In addition, we have previously identified internal coordination—among FDA’s centers and offices—as one of the agency’s major management challenges based on a review of evaluations of FDA by HHS and the FDA Science Board, among others.¹⁸ Also, in our 2009 survey of FDA managers, 70 percent reported that better internal coordination and communication would greatly improve their ability to contribute to FDA’s goals and responsibilities, though 28 percent reported that FDA was making great progress in this area. Furthermore, we asked FDA managers in our survey to identify the top priorities that FDA leadership should address to achieve agency goals and responsibilities, and the second most commonly identified issue was improving coordination within FDA. In detailed written responses in our survey, some managers noted that better coordination among FDA’s centers could increase effectiveness and decrease redundancy.

Furthermore, a recommendation made by FDA’s work group on economic adulteration in August 2009 related to communication—that FDA designate a lead office and develop standard operating procedures for information sharing—was not implemented. A senior FDA official told us that there has been some work across FDA centers on economic adulteration but that the centers did not see a lot of value in additional coordination because of the differences between the products each center oversees. However, the issue of economic adulteration cuts across the agency, and without communicating about and coordinating on economic adulteration efforts, FDA may not be making the best use of scarce resources.

In August 2011, FDA officials told us that the agency’s Compliance Policy Council, which consists of senior representatives of ORA and the FDA centers, met in July 2011 and discussed whether and how the agency should coordinate work on economic adulteration. The council directed risk management staff from ORA and the centers to form a group to discuss opportunities to share intelligence and approaches to economic adulteration and then report back to the council. According to FDA officials, the proposed agenda included discussion about the

¹⁸[GAO-10-279](#).

development of standard operating procedures. In its written comments on our draft report, HHS told us that the work group held its first meeting on September 23, 2011, while our report was at the agency for comment.

The Commissioner and other senior FDA officials have often spoken publicly about the threat posed by economic adulteration. In its July 2011 report entitled *Pathway to Global Product Safety and Quality*,¹⁹ FDA stated that globalization has fundamentally altered the economic and security landscape, requiring FDA to transform itself into a global agency prepared to regulate in an environment in which product safety and quality know no borders. The report also called economically motivated harms perhaps the most serious challenge on the horizon for the agency and noted that the heparin and melamine incidents underscore how serious the potential danger can be. The report also noted that FDA needs to move beyond its current efforts and think strategically across the agency. However, FDA officials told us that the Office of the Commissioner has not issued specific written guidance on how FDA centers and offices should approach or address their economic adulteration efforts. The Office of the Commissioner's role is to provide policy making, program direction, coordination, liaison, and expert advice for agency programs. According to federal standards for internal control, agencies should have documented policies and procedures in place to carry out management's directives.²⁰ This documentation should be readily available for examination in management directives, administrative policies, or operating manuals in paper or electronic form. In addition, the federal standards call for effective communication, with information flowing down, across, and up the organization.

¹⁹Department of Health and Human Services, U.S. Food and Drug Administration, *Pathway to Global Product Safety and Quality* (Washington, D.C.: July 2011).

²⁰GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999).

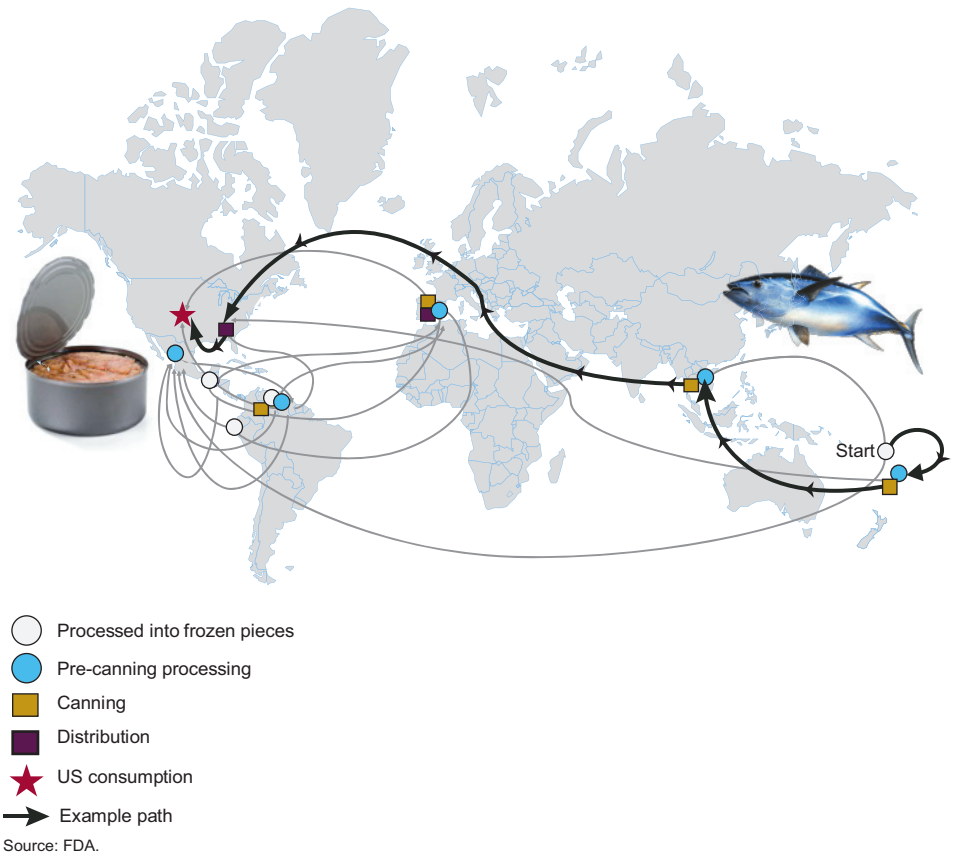
FDA Faces Challenges in Addressing Economic Adulteration, and Stakeholders Identified Options That May Help Agency Efforts

FDA officials and stakeholders we interviewed cited several key challenges the agency faces in detecting and preventing economic adulteration, and stakeholders identified options for enhancing the agency's efforts to address economic adulteration.

Key Challenges Include Increased Globalization and Lack of Information from Industry

FDA officials and stakeholders told us that responding to increased globalization and the expanding complexity of the supply chains for both food and medical products is a key challenge in addressing economic adulteration. 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. According to FDA, the market for outsourcing portions of pharmaceutical production has more than doubled in the past 9 years. FDA noted in its July 2011 *Pathway* report that more products are following increasingly complex paths through multi-step supply chains before reaching the United States. Figure 1 illustrates the complex supply chain of a single commodity, canned tuna. As the figure shows, after the tuna is caught in East Asia, it can travel through many countries for processing and canning before the finished product finally reaches store shelves in the United States.

Figure 1: Illustrative Supply Chain for Canned Tuna



FDA officials gave several reasons that this increasing complexity poses a challenge. For example, CFSAN officials told us that food companies can change ingredients and suppliers at will without having to notify FDA of those changes, making it difficult to track or trace an ingredient back to its source or supplier. However, many food manufacturers are required to keep records of the immediate previous sources of all foods received. Similarly, CDER officials said that it is increasingly difficult to trace ingredients through drug supply chains due to the increasing number of parties involved and the increase in transfers between parties in other countries. Stakeholders from associations representing the food and medical product industries agreed that the large number of imported ingredients and foreign establishments, as well as the difficulties related to tracking an ingredient back to the original source, are of particular concern.

FDA officials and stakeholders said that obtaining information on potential instances of economic adulteration is critical to addressing the problem, but they also agreed that the agency faces challenges in gathering such information from industry. Industry may be a source of information on potential incidents of adulteration because companies regularly test ingredients from suppliers. The responsible party for a firm that introduces into commerce an article of food containing an adulterated ingredient that could cause serious adverse health consequences or death must report this information to FDA through the Reportable Food Registry. However, agency officials and industry representatives said industry is often reluctant to share such information when an adulterated ingredient has not entered into commerce. For example, a company may be concerned that it could provoke a lawsuit if it reported a supplier for intentionally adulterating products and the accusation was subsequently determined to be unfounded. They said that a wrongful accusation can have serious consequences, such as compromising the integrity of the company's brands and products if certain information became public.

In addition to a need for more information about industry suppliers, FDA officials told us that they need more information about substances that could be used to adulterate products. These officials said that new, more precise testing methods need to be developed to detect these adulterants because some current tests are outdated or insufficiently specific. Recent cases of melamine contamination in pet food illustrate the need for such tests. The presence of melamine in pet food was not initially discovered by the standard test for protein because that test was designed to detect nitrogen and could not distinguish between protein and melamine. The contamination was ultimately discovered when FDA scientists developed a specific test to identify melamine. FDA and others determined that melamine was apparently selected as an adulterant to evade the original testing and increase the apparent protein content.

CDER officials also told us that it is difficult to detect instances of economic adulteration because the potential adulterant is often unknown or has not yet been identified. For example, during the heparin incident, the available test methods for heparin were not able to detect the contaminant oversulfated chondroitin sulfate. FDA collaborated with scientists outside the agency to identify the contaminant and develop new tests to detect it. Industry may be the best source of tests to detect adulteration because companies develop such tests to monitor the products they receive from their suppliers; however, industry officials indicated that they are often reluctant to share such information because it is proprietary.

Stakeholders cited additional challenges that FDA faces in addressing economic adulteration, including its legal authorities. For example, one stakeholder said that FDA does not have the authority to accredit, or approve third parties to inspect establishments that make drugs; the stakeholder said that if FDA did have that authority, such inspections may help decrease FDA's inspection workload and could increase the total number of facilities inspected. FDA recently received authority to recognize, in certain situations, accreditation bodies that may then accredit qualified third parties to inspect food establishments. The FDA Food Safety Modernization Act provides that, no later than January 2013, FDA is to establish a program to recognize these accreditation bodies. It is worth noting, though, that FDA has had the authority to accredit third parties to conduct inspections of certain domestic and foreign medical device manufacturing establishments since 2002. FDA implemented its accreditation programs, permitting eligible establishments to voluntarily request inspections from third-party organizations, but relatively few establishments have chosen to take advantage of this program.²¹

Some stakeholders also told us that FDA's limited resources, including staffing, present a challenge. Specifically, they said FDA has limited ability to investigate potentially economically adulterated products because such investigations are resource-intensive. They also told us that FDA does not have the range of expertise among staff that is needed to address economic adulteration, in particular staff with a background in intelligence gathering or law enforcement. We have previously reported on FDA's own concerns about its staffing levels and oversight responsibilities for certain activities, such as its oversight of medical devices and inspections of establishments that manufacture approved drugs.²²

²¹GAO, *Medical Devices: Shortcomings in FDA's Premarket Review, Postmarket Surveillance, and Inspections of Device Manufacturing Establishments*, [GAO-09-370T](#) (Washington, D.C.: June 18, 2009).

²²[GAO-09-581](#), and GAO, *Food and Drug Administration: Effect of User Fees on Drug Approval Times, Withdrawals, and Other Agency Activities*, [GAO-02-958](#) (Washington, D.C.: Sept. 17, 2002).

Some Stakeholders Cited Greater Oversight and Information Sharing as Options to Address Economic Adulteration

Some stakeholders supported increased oversight by FDA, in particular, as an option to obtain more information on supply chains—information that is useful in tracing the source of economic adulteration. For example, one stakeholder suggested that the use of track-and-trace technology—such as using standard numerical identifiers on prescription drug packages—could facilitate FDA’s oversight of the supply chain by making it easier for FDA and industry to trace adulterated ingredients back to the point of contamination. Under the new FDA Food Safety Modernization Act, the Secretary of HHS, acting through FDA, is directed to establish a system that will improve its ability to rapidly track and trace both domestic and imported foods. Similarly, the Food and Drug Administration Amendments Act of 2007 required FDA to develop a unique device identifier system to adequately identify a medical device through distribution and use. According to FDA officials, the agency expects to publish a proposed rule on the establishment of this system by the end of 2011.²³

Many stakeholders also suggested that FDA increase its regulatory and enforcement actions to address economic adulteration. These stakeholders said that public health risk should be FDA’s priority in taking such actions, but many also told us that FDA should pursue those who adulterate for economic gain, including in instances that may not have a large negative public health impact. For example, some stakeholders suggested building criminal cases against those who adulterate for economic gain and prosecuting them swiftly and visibly to help ensure that companies are complying with laws and regulations. In addition, these stakeholders said that, even when the adulteration has little health impact, such actions could help protect public health by deterring future instances, some of which may pose a significant health threat. Depending on the circumstances, such as the type of violation and product involved, a range of enforcement actions or penalties could be pursued. However, in February 2009, we reported that FDA has taken few actions in pursuing instances of economic fraud in seafood.²⁴ In that report, we found that FDA did not issue any regulatory letters to companies regarding seafood

²³GAO, *Medical Devices: FDA Should Enhance Its Oversight of Recalls*, [GAO-11-468](#) (Washington, D.C.: June 14, 2011).

²⁴GAO, *Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Prevention and Detection*, [GAO-09-258](#) (Washington, D.C.: Feb. 19, 2009).

fraud from 2005 through 2008, and according to a senior FDA official, the agency had not taken any enforcement actions for seafood fraud since 2000.

Even with the challenges related to the disclosure of proprietary information, stakeholders also suggested that greater communication with industry could enhance FDA efforts to gather information on economic adulteration. One option for greater communication that several stakeholders identified was the creation of an information clearinghouse, through which companies could anonymously share information on adulterated ingredients with FDA and other companies. Stakeholders noted that the clearinghouse could enhance FDA's ability to disseminate information on adulterated products quickly, facilitate secure information sharing across industries, and enable FDA and industry to respond more rapidly to potential instances of adulteration. For example, they said that a clearinghouse could allow the sharing of information, such as information on market price fluctuations, environmental disasters, or other macroeconomic factors. In the view of these stakeholders, this type of information may help both industry and FDA better target their efforts to detect and prevent economic adulteration. One stakeholder said that such a clearinghouse was an opportunity for industry and FDA to share information from various sources in a central location, which would help them draw conclusions about the authenticity of ingredients or raw materials. This stakeholder suggested that if an information clearinghouse had existed prior to the heparin incident, it could have contained critical information—such as the sudden increase or decrease in the price of ingredients for food or drugs—to alert FDA and industry to the potential for adulteration.

One stakeholder noted that because some of the industries affected by economic adulteration are small, some companies might easily be identified by the information reported, even if they reported it anonymously. Consequently, some stakeholders suggested engaging a neutral third party to operate the information clearinghouse, thus helping to ensure that the information shared was free of specific company identifiers. FDA officials said that they are examining various ways to facilitate information sharing with industry and have discussed the idea of a clearinghouse, but they have no plans to develop one.

In addition to formal information sharing, some stakeholders suggested more informal interaction between industry and FDA. Stakeholders noted that increased dialogue could provide opportunities for FDA to communicate to industry its overall strategy on economic adulteration.

Some stakeholders told us that FDA's communication during adverse public health events was clear and timely but that at other times they were unsure what FDA was doing to address potential economic adulteration. Some stakeholders expressed a willingness to work with FDA on the issue but said that they need to better understand FDA's expectations of industry. For example, one stakeholder suggested a forum where FDA officials can talk to industry directly and engage in dialogue to clarify the agency's strategy.

Some stakeholders from food industry groups also said that they believe the recent passage of the FDA Food Safety Modernization Act provides new opportunities for both FDA and industry to address economic adulteration. One stakeholder noted that the new law may give FDA more opportunities to include economic adulteration in its inspection program. In addition, stakeholders told us that they believe the law provides a science- and risk-based approach for companies to verify their ingredient suppliers, including multiple ways of assuring the public and FDA that industry has processes in place to detect economic adulteration. Specifically, under the act, certain facilities are required to identify reasonably foreseeable hazards and to prepare written control plans that illustrate reasonable approaches to looking for intentional adulteration.

Lastly, one stakeholder said that FDA may need additional authority to require the drug industry to provide the agency with information critical to securing the medical product supply chain. Additional authority may include, for example, allowing FDA to require enhanced documentation from industry on its supply chains to increase transparency. In its comments on one of our recent reports, HHS also mentioned legislation previously under consideration by Congress that it believed would, if enacted, provide FDA with helpful tools to further secure the nation's drug supply chain.²⁵ For example, according to the agency, the proposed legislation would have provided FDA authority to require foreign and domestic drug manufacturers to implement quality systems and adopt plans to identify and mitigate hazards. In its comment letter, FDA said that such legislation could ensure that the agency can hold industry accountable for the security and integrity of its supply chains and quality control systems.

²⁵[GAO-11-95](#).

Conclusions

Economic adulteration is not a new problem. It can undermine confidence in the safety of the nation's food and medical products and have significant economic consequences for industry. The recent crises involving the contamination of pet food with melamine and the adulteration of heparin with oversulfated chondroitin sulfate showed that economic adulteration continues to be a problem and can have serious public health consequences. Senior FDA officials, including the Commissioner, have often spoken publicly about the threat posed by economic adulteration. However, FDA does not have a definition of economic adulteration. Without such a definition, when FDA detects adulteration, it is more difficult for the agency to make a distinction between economic adulteration and other forms of adulteration to guide the agency's thinking about how to be more proactive about this issue. In addition, FDA has not provided guidance to its centers and offices on how they should approach or address their economic adulteration efforts. This is not consistent with federal standards of internal control, which state that agencies should have documented policies and procedures in place to carry out management's directives. Some entities have undertaken efforts that specifically focus on economic adulteration, but they have not always communicated or coordinated their efforts with other FDA entities. Without such communication and coordination, in these times of economic uncertainty, FDA may not be making the best use of its scarce resources. As food and medical product supply chains become increasing global and complex, economic adulteration will continue to remain a threat.

Recommendations for Executive Action

To enhance FDA's efforts to combat the economic adulteration of food and medical products, we recommend that the Commissioner of FDA take the following three actions:

- adopt a working definition of economic adulteration,
- 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.

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for review and comment. We received written comments from HHS, which are reproduced in appendix II. HHS neither agreed nor disagreed with our recommendations. In its comments, HHS stated that FDA views the term “economically motivated adulteration” as describing a subset of cases within the broader concept of adulteration, and believes that a holistic approach toward understanding and addressing adulteration generally is the best course forward. HHS also said that this approach will best serve the agency as it strives to protect the health and well-being of the American people by preventing, detecting, and taking appropriate responses to all adulterations of food and medical products. As we note in our report, however, agency entities have missed opportunities to communicate and coordinate efforts specifically directed at economic adulteration and identify potential public health risks. At the same time, FDA said that it recognizes the importance of sharing and leveraging information relevant to economically motivated adulteration and the utility of a mechanism for facilitating such sharing and collaboration at FDA. The department provided additional information in its written comments on planned actions of FDA’s Working Group on Economically Motivated Adulteration that are consistent with two of the three recommendations we made in our draft report. The additional comments related to our recommendations that FDA adopt a working definition of economic adulteration and enhance communication and coordination of agency efforts on economic adulteration are as follows:

- *Adopt a working definition of economic adulteration.* HHS stated that the Working Group on Economically Motivated Adulteration will use the working definition of economically motivated adulteration that FDA proposed at its May 2009 public meeting on the topic.
- *Enhance communication and coordination of agency efforts on economic adulteration.* HHS stated that FDA expects the efforts of the working group will result in enhanced collaboration and communication at FDA on ways to approach and address situations of economically motivated adulteration.

We have included this additional information in our report.

HHS also provided technical comments, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the Commissioner of the Food and Drug Administration, and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov or Marcia Crosse at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.



Lisa Shames
Director, Natural Resources and Environment



Marcia Crosse
Director, Health Care

Appendix I: Objectives, Scope, and Methodology

This report examines (1) the approaches the Food and Drug Administration (FDA) uses to detect and prevent economic adulteration of food and medical products, and (2) the challenges, if any, FDA faces in detecting and preventing economic adulteration and stakeholder views on options for FDA to enhance its efforts to address economic adulteration. For this report, we define 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., for economic gain. [It] includes dilution of products with increased quantities of an already-present substance (e.g., increasing inactive ingredients of a drug with a resulting reduction in strength of the finished product, or watering down of juice) to the extent that such dilution poses a known or possible health risk to consumers, as well as the addition or substitution of substances in order to mask dilution.” Our definition of economic adulteration is the same as the working definition of “economically motivated adulteration” that FDA developed for a May 2009 public meeting to raise awareness and solicit input on the topic. We did not include counterfeiting of a finished product because counterfeiting concerns the unauthorized use of intellectual property rights.

To determine the approaches FDA uses to detect and prevent economic adulteration of food and medical products, we interviewed officials from the five FDA centers responsible for food and medical products, including the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research, as well as FDA’s Office of Regulatory Affairs, Office of International Programs, and Office of the Commissioner. We also interviewed former FDA officials and representatives of organizations that have been assisting FDA in its efforts to detect and prevent economic adulteration, including the United States Pharmacopeia, the University of Minnesota’s National Center for Food Protection and Defense, and New Mexico State University’s Center for Animal Health, Food Safety and Bio-Security. We reviewed relevant FDA documents, including regulations, compliance manuals and inspection guides, sampling surveillance results, statements and presentations by agency officials, a contract to fund a research project at the National Center for Food Protection and Defense, and communications with industry and the public. We also reviewed published information from FDA, including its *Strategic Priorities 2011-2015* report, its *Pathway to Global Product Safety and Quality* report, and *Federal Register* notices. We also reviewed previous GAO reports and recommendations on FDA’s oversight of food and medical products, as

well as the agency's strategic planning efforts. We compared FDA's efforts to address economic adulteration with federal standards for internal control.¹

To determine the challenges FDA faces in detecting and preventing economic adulteration, we interviewed and obtained the views of FDA officials and stakeholders about the challenges the agency faces in addressing economic adulteration. Stakeholders included members of academia and representatives of industry and consumer groups who made presentations at FDA's May 2009 meeting on economically motivated adulteration, as well as former FDA officials who were involved in agency efforts that led to that meeting. We also interviewed and obtained the views of the stakeholders on options for FDA to enhance its efforts to address economic adulteration. The views of these stakeholders are not representative of and cannot be generalized to all stakeholders. In addition, we reviewed FDA and stakeholder documents related to challenges and options, as well as portions of the FDA Food Safety Modernization Act.

We conducted this performance audit from September 2010 to October 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

¹GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999).

Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

Lisa Shames, Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

OCT 07 2011

Dear Ms. Shames:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled, "FOOD AND DRUG ADMINISTRATION: Better Coordination Could Enhance Efforts to Address Economic Adulteration and Protect the Public Health" (GAO-12-46).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in black ink that reads "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

cc: Marcia Crosse
Director, Health Care

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD AND DRUG ADMINISTRATION: BETTER COORDINATION COULD ENHANCE EFFORTS TO ADDRESS ECONOMIC ADULTERATION AND PROTECT THE PUBLIC HEALTH" (GAO-12-46)

The Department appreciates the opportunity to comment on this draft report.

More and more of the foods and medical products that the Food and Drug Administration (FDA) regulates are produced overseas, by hundreds of thousands of firms, and the paths by which these products reach our borders and travel on to our grocery stores, hospitals, pharmacies and doctors' offices are increasingly long and complex. The global nature of the U.S. marketplace presents formidable challenges to the FDA as it works to ensure the safety of these foods and medical products. The sheer number of firms and complexity of these supply chains provide myriad opportunities for many forms of adulteration, any of which poses risk to the health and well-being of the American people. For example, FDA has grappled with adulteration of food and medical products arising from deficient manufacturing practices, including insufficient attention to the sources and supply chains for ingredients; cargo theft; counterfeiting; and apparent economic motivation. It is also conceivable that FDA-regulated products could be used as a vehicle for terrorists.

FDA's first priority is to protect the American public by enhancing its capacity to prevent, detect, and respond to all adulterations that may harm American consumers and patients. The adulteration of pet food with melamine, and heparin with oversulfated chondroitin sulfate, serve as compelling illustrations of the challenges that FDA faces in securing our food and pharmaceutical supply chains. These incidents demonstrate the increasing opportunities that extended and fractured supply chains present to those who, for economic gain or to intentionally harm people, are willing to adulterate foods and drugs. The melamine and heparin contamination incidents are not the first such examples, and they may not be the last. They are clarion calls to the agency, and anyone with an interest in promoting the public health, to improve controls on quality in, and collect better information about, the supply chains of products, and to develop tools for anticipating, preventing, and taking actions to address the adulteration. These iconic incidents have served to heighten the efforts across the FDA to address these challenges.

FDA views the term "economically motivated adulteration," as describing a subset of cases within the broader concept of adulteration, and believes that a holistic approach toward understanding and addressing adulteration generally is the best course forward. Securing the supply chains of FDA-regulated goods will help the agency to minimize opportunities for contamination and adulteration--whether intentional or otherwise. In terms of motivation or intention, often it is the ignorance, indifference or recklessness of someone downstream in the supply chain that provides opportunities for intentional adulteration by someone up-stream. Only a holistic, quality systems approach toward securing these supply chains will effectively constrain opportunities for adulteration, regardless of motivation. In addition, the agency believes that in responding to instances of adulteration, its first focus must be to identify the adulterated product and remove it from the supply chain so that it is not circulating in the market place where it can harm consumers or patients, regardless of the reason or motivation for the adulteration.

Prompted by the ever-changing and unpredictable global environment that threatens the safety of pharmaceutical and food supply chains, FDA has developed a strategy, articulated in FDA's *Pathway to Global Product Safety and Quality*, that fundamentally changes its posture from intercepting adulterated product to anticipating and preventing conditions and actions that could threaten the health and safety of the American people. Although this particular GAO study focuses specifically on what it calls "economic adulteration," and GAO would have the agency focus on discerning whether adulteration is economic or not, FDA emphasizes its strategy to address the increasingly complex and unpredictable global

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD AND DRUG ADMINISTRATION: BETTER COORDINATION COULD ENHANCE EFFORTS TO ADDRESS ECONOMIC ADULTERATION AND PROTECT THE PUBLIC HEALTH" (GAO-12-46)

environment through a holistic approach that recognizes and adapts to the broad challenges of globalization and the numerous opportunities it provides for all forms of adulteration. As explained in the *Pathway to Global Product Safety and Quality*, FDA's approach is to transform itself fully into a global regulatory agency with an "international operating model that relies on enhanced intelligence, information sharing, data-driven risk analytics, and the smart allocation of resources through leveraged partnerships." This approach will best serve the agency as it strives to protect the health and well-being of the American people by preventing, detecting, and taking appropriate responses to all adulterations of food and medical products.¹

The Food Safety Modernization Act of 2011 (FSMA) charged FDA with building a modern, prevention-oriented food safety system suited for today's globalized food supply. Specifically, FSMA provided FDA with new authority to promulgate a wide range of regulations, with an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize hazards from farm-to-table. Many of FDA's new authorities under FSMA enhance FDA's ability to prevent adulteration, including economically motivated adulteration. These authorities include requirements for a system of hazard analysis and risk-based preventive controls in most food facilities, new standards for produce safety, mandatory recall authority, administrative detention, requirements to specifically protect against the intentional adulteration of high-risk foods, enhanced tracking and tracing of food and new recordkeeping requirements, enhanced authority to inspect foreign food facilities, and the development of a foreign supplier verification program.

Similarly, obtaining new drug safety regulatory authorities directed toward an increasingly complex and globalized world may help ensure the security and integrity of drug supply chains and the systems used to produce pharmaceutical products for the American people. Such new authorities, if enacted, could help to level the playing field between domestic and foreign drug manufacturers, ensure drug product safety, and provide FDA with the information it needs to protect consumers. Those authorities may include

- Refusal of drug product admission to the United States if inspection of the manufacturing facility is delayed, limited, or denied;
- Requirement of information or other assurance of compliance with applicable standards or requirements as a condition of importation;
- Quality management systems to place greater responsibility on manufacturers to account for the quality and provenance of the materials that go into their products;
- Mandatory recall authority;
- Administrative destruction at the border;
- Administrative detention;
- Enhanced criminal and civil penalties for foreign and domestic suppliers;
- Modernization of drug registration and listing;
- Notification to FDA from foreign and domestic companies of complete information on threats such as counterfeiting, theft, non-compliance with regulatory standards, mislabeling or misbranding, or other threats to the security of the drug supply chain;

¹ In addition, in September 2011 FDA issued for comment a draft FDA Foods and Veterinary Medicine Program Strategic Plan for 2012-2016. The draft Strategic Plan identifies "intentional contamination" as a growing concern in the food and veterinary medicine program areas and indicates that key initiatives in coming years include setting preventive control standards for intentional contamination.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD AND DRUG ADMINISTRATION: BETTER COORDINATION COULD ENHANCE EFFORTS TO ADDRESS ECONOMIC ADULTERATION AND PROTECT THE PUBLIC HEALTH" (GAO-12-46)

- Unique facility identifiers as a condition of registration and importation to help FDA to follow threats up the supply chain and to properly cross-reference;
- Authority to share certain non-public information with other regulatory agencies and foreign governments in order to allow FDA to share certain information that could lead to timely identification, prevention, and resolution of emerging threats; and
- The requirement of a cost-effective track-and-trace system for all drug products throughout the supply chain to improve the security and integrity of the drug supply and ensure transparency and accountability of product manufacturing and distribution, whether the product is manufactured domestically or internationally.

Within this broad strategic framework to address the challenges of globalization, FDA recognizes the importance of sharing and leveraging information relevant to economically motivated adulteration and the utility of a mechanism for facilitating such sharing and collaboration at FDA. To that end, FDA recently established the Working Group on Economically Motivated Adulteration (WEMA). Comprised of staff from all of the Centers, ORA, and Office of the Commissioner, including risk managers, economists, regulatory counsel, and policy analysts, WEMA seeks to encourage information sharing across FDA on issues relevant to economically motivated adulteration. Because such threats have common risk factors, FDA can benefit from sharing intelligence, experiences, data, models, and strategies. This collaboration may include the development of approaches to prevent economically motivated adulteration and processes for information sharing.

To identify topics of broad FDA interest, the WEMA will use the working definition proposed at the May 1, 2009 Public Meeting on economically motivated adulteration:

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., for economic gain. EMA includes dilution of products with increased quantities of an already-present substance (e.g., increasing inactive ingredients of a drug with a resulting reduction in strength of the finished product, or watering down of juice) to the extent that such dilution poses a known or possible health risk to consumers, as well as the addition or substitution of substances in order to mask dilution.

This working definition has been used to generate dialogue between the FDA, the regulated community, and advocacy groups. It has gained traction as a practical working definition, and although it does not serve as a legal definition or require conformance or uniform acceptance, it is a functional and adaptable means of identifying situations of economically motivated adulteration that may concern multiple Centers, enabling them to focus their discussions and encouraging communication and collaboration.

Organized by the Office of Regulatory Affairs' Risk Management Staff, the WEMA held its first meeting on September 23, 2011, with plans to meet regularly to accomplish its goals. The WEMA will facilitate discussion and recommendations on the exchange of information and intelligence related to economically motivated adulteration. FDA expects that the work group's efforts will result in enhanced collaboration and communication at FDA on ways to approach and address these important public health issues.

Appendix III: GAO Contacts and Staff Acknowledgments

GAO Contacts

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Staff Acknowledgments

In addition to the contacts named above, Jose Alfredo Gomez (Assistant Director), Geraldine Redican-Bigott (Assistant Director), Cheryl Williams (Assistant Director), Kevin Bray, Mollie Hertel, Sherrice Kerns, Susan Malone, Michael Rose, Cynthia Saunders, Ben Shouse, and Kiki Theodoropoulos made key contributions to this report.

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