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FOOD AND DRUG ADMINISTRATION

Response to Heparin Contamination Helped Protect Public Health; Controls That Were Needed for Working With External Entities Were Recently Added

GAO Highlights

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Highlights of GAO-11-95, a report to the Ranking Member, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

In early 2008, the Food and Drug Administration (FDA) responded to a crisis involving the contamination of heparin, a medication used to prevent and treat blood clots, when the agency received multiple reports of adverse events involving severe allergic reactions. The crisis took place from January 2008 through May 2008, during which time FDA took several actions in its response to the crisis.

GAO was asked to review FDA's management of the heparin crisis. This report examines (1) how FDA prevented additional contaminated heparin from reaching U.S. consumers, (2) how FDA coordinated its response to the contaminated heparin crisis, and (3) FDA's monitoring and analysis of adverse events associated with heparin.

To conduct this review, GAO reviewed relevant FDA documents, regulations, and guidance; analyzed FDA data; and interviewed FDA officials and other experts involved in the crisis and knowledgeable about drug quality standards.

View GAO-11-95 or key components.
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What GAO Found

In its response to the heparin crisis, FDA took several actions related to its responsibility to protect the public health by ensuring the safety and security of the nation's drug and medical device supplies. FDA increased its activities related to oversight of heparin firms by conducting inspections and investigations and monitoring heparin imports, and worked with drug and device manufacturers to recall contaminated products while ensuring that an adequate supply of uncontaminated heparin was available. With the help of external entities, FDA identified the unknown contaminant and developed tests to screen all heparin products. Additionally, the agency reached out to its international regulatory partners during the crisis. However, FDA faced some limitations in its efforts to inspect heparin firms in China and collaborate internationally, and the agency was unable to determine the original source of contamination.

FDA coordinated internal and external resources to respond to the contaminated heparin crisis, but did not address risks related to working with certain external entities with ties to heparin firms. The agency has issued standards of ethics regarding collaboration with external entities and governmentwide standards apply to the acceptance of services provided free of charge. Despite these existing standards, FDA did not have processes in place to ensure that it considered or applied them when it accepted assistance from external entities with ties to heparin firms on a voluntary basis during the heparin crisis. Not adequately addressing these risks could have affected the public's confidence in FDA's response efforts and in its other activities related to the regulation of heparin products and also left FDA open to claims for payment for services that these external entities provided to FDA.

FDA monitored trends in the number of reports of adverse events associated with heparin drug products and heparin-containing medical devices that it received before, during, and after the crisis. FDA also conducted analyses of adverse events, including deaths, associated with heparin drug products and heparin-containing medical devices. However, FDA was unable to determine if any of the adverse events or deaths were linked to contaminated heparin because of data limitations and confounding factors regarding the individual patients, such as the natural course of the underlying disease or condition.

In the draft report we provided to the Department of Health and Human Services for comment, we recommended that FDA develop adequate controls to help avoid exposure to risks when working with external entities in future situations similar to the heparin crisis. In response, FDA issued guidance on October 15, 2010, for FDA staff to follow when working with external scientific and other experts in emergency situations when the services are provided on a gratuitous basis. FDA also stressed the unprecedented nature of the heparin crisis and noted various actions it took in response to the crisis.