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DRUG COMPOUNDING

Clear Authority and More Reliable Data Needed to Strengthen FDA Oversight

GAO Highlights

Highlights of GAO-13-702, a report to congressional requesters

Why GAO Did This Study

Drug compounding is the process by which a pharmacist combines, mixes, or alters ingredients to create a drug tailored to the medical needs of an individual. An outbreak of fungal meningitis in 2012 linked to contaminated compounded drugs has raised concerns about state and federal oversight of drug compounding. GAO was asked to update its 2003 testimony on drug compounding. Specifically, this report addresses (1) the status of FDA's authority to oversee drug compounding, and the gaps, if any, between state and federal authority; (2) how FDA has used its data and authority to oversee drug compounding; and (3) the actions taken or planned by states or national pharmacy organizations to improve oversight of drug compounding. GAO reviewed relevant statutes and guidance; reviewed FDA data; and interviewed officials from FDA, national pharmacy organizations, and four states with varied geography, population, and pharmacy regulations.

What GAO Recommends

To help ensure that the entities that compound drugs have appropriate oversight, Congress should consider clarifying FDA's authority to oversee drug compounding. In addition, FDA should ensure its databases collect reliable and timely data on inspections associated with compounded drugs, and differentiate drug compounders from manufacturers. HHS's comments support the need to clarify FDA's authority, and stated that the information in its inspection database could be improved and that it would consider whether it can differentiate compounding pharmacies from manufacturers.

View GAO-13-702. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

The authority of the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), to oversee drug compounding is unclear. Two federal circuit court decisions have resulted in differing FDA authority in different parts of the country. According to FDA officials, these inconsistent decisions and the agency's limited inspection authority over pharmacies have created challenges in FDA's ability to inspect and take enforcement action against entities engaging in drug compounding. For example, from 2002 through 2012, in order to inspect some facilities engaged in drug compounding, FDA officials said they had to obtain 11 warrants to gain access to drug compounders' facilities that had challenged FDA's inspection authority. GAO also found that while FDA and national pharmacy organization officials generally agreed that states regulate the practice of pharmacy and FDA regulates drug manufacturing, there was no consensus on whether compounding drugs in large quantities—in anticipation of individual prescriptions or without prescriptions—and selling those drugs across state lines falls within the practice of pharmacy or is a type of drug manufacturing that should be overseen by FDA. This lack of consensus and differing FDA authority to oversee compounded drugs across the country has resulted in gaps in oversight of drug compounding.

FDA lacks timely and reliable information to oversee the entities that compound drugs, but has found problems through its limited oversight. Specifically, FDA's inspection database cannot identify all of the agency's inspections of compounding pharmacies, or the final classification of inspection results, for all of the inspections. Until 2013, FDA limited its inspections of compounding pharmacies to those conducted in response to complaints or adverse events. However, the agency recently inspected compounding pharmacies that it identified as posing a significant threat to public health from poor sterile drug production practices in the past and found problems, such as concerns about a lack of sterility, which resulted in recalls of compounded drugs. In addition, drug manufacturers are required to register with FDA and are subject to FDA's inspection and drug approval processes; pharmacies meeting certain requirements are generally exempt from registration. However, some compounding pharmacies may have registered with FDA to market themselves as "FDA-registered" which may lead some purchasers to assume that FDA has inspected or approved their compounded drugs; whereas, according to FDA officials, this is generally not the case.

The states GAO reviewed—California, Connecticut, Florida, and Iowa—have each taken actions to enhance their oversight of drug compounding. For example, Florida required all pharmacies—both those located in the state and out-of-state that sell drugs in Florida—to notify the board of their compounding activities. In addition, national pharmacy organizations have undertaken efforts to help states oversee drug compounding. For example, a national pharmacy organization is working with Iowa to inspect out-of-state pharmacies that ship drugs into the state. However, according to national pharmacy organizations and officials from state boards of pharmacy, some states do not have the resources to inspect pharmacies on a regular basis. Instead, these states inspect pharmacies only in response to a complaint or a reported adverse drug event.