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PRESCRIPTION DRUGS

State and Federal Oversight of Drug Compounding by Pharmacies

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Highlights

Highlights of GAO-04-195T, a testimony to the Committee on Health, Education, Labor, and Pensions, U.S. Senate

Why GAO Did This Study

Drug compounding—the process of mixing, combining, or altering ingredients—is an important part of the practice of pharmacy because there is a need for medications tailored to individual patient needs. Several recent compounding cases that resulted in serious illness and deaths have raised concern about oversight to ensure the safety and quality of compounded drugs. These concerns have raised questions about what states—which regulate the practice of pharmacy—and the Food and Drug Administration (FDA) are doing to oversee drug compounding. GAO was asked to examine (1) the actions taken or proposed by states and national pharmacy organizations that may affect state oversight of drug compounding, and (2) federal authority and enforcement power regarding compounded drugs.

This testimony is based on discussions with the National Association of Boards of Pharmacy (NABP) and a GAO review of four states: Missouri, North Carolina, Vermont, and Wyoming. GAO also interviewed and reviewed documents from pharmacist organizations, FDA, and others involved in the practice of pharmacy or drug compounding.

www.gao.gov/cgi-bin/getrpt?GAO-04-195T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Janet Heinrich at (202) 512-7119.

What GAO Found

A number of efforts have been taken or are under way both at the state level and among pharmacy organizations at the national level that may strengthen state oversight of drug compounding. Actions among the four states reviewed included adopting new regulations about compounding and conducting more extensive testing of compounded drugs. For example, the pharmacy board in Missouri is starting a program of random testing of compounded drugs for safety, quality, and potency. At the national level, industry organizations are working on standards for compounded drugs that could be adopted by the states in their laws and regulations, thereby potentially helping to ensure that pharmacies consistently produce safe, high-quality compounded drugs. While these actions may help improve oversight, the ability of states to oversee and ensure the quality and safety of compounded drugs may be affected by state-specific factors such as the resources available for inspections and enforcement.

FDA maintains that drug compounding activities are generally subject to FDA oversight, including its authority to oversee the safety and quality of new drugs. In practice, however, the agency generally relies on states to regulate the limited compounding of drugs as part of the traditional practice of pharmacy. In 1997, the Congress passed a law exempting drug compounders that met certain criteria from key provisions of the Federal Food Drug and Cosmetic Act (FDCA), including the requirements for the approval of new drugs. These exemptions, however, were nullified in 2002 when the United States Supreme Court ruled part of the 1997 law to be an unconstitutional restriction on commercial speech, which resulted in the entire compounding section being declared invalid. Following the court decision in 2002, FDA issued guidance to indicate when it would consider taking enforcement actions regarding drug compounding. For example, it said the agency would defer to states regarding “less significant” violations of the Act, but would consider taking action in situations more analogous to drug manufacturing.