

**GAO**

Testimony

Before the Committee on Health,  
Education, Labor, and Pensions, U.S.  
Senate

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# PRESCRIPTION DRUGS

## State and Federal Oversight of Drug Compounding by Pharmacies

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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](http://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.

## PRESCRIPTION DRUGS

# State and Federal Oversight of Drug Compounding by Pharmacies

## 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.

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Mr. Chairman and Members of the Committee:

I am pleased to be here today as you consider state and federal oversight to ensure the safety and quality of compounded prescription drugs. Drug compounding—the process of mixing, combining, or altering ingredients to create a customized medication for an individual patient—is an important part of the practice of pharmacy. Common examples of compounded drugs include tailor-made medications for patients who are allergic to an ingredient in a manufactured drug. Drug compounding is part of pharmacy education and, like other aspects of pharmacy practice, it is regulated by state pharmacy practice acts, which in turn are enforced by state boards of pharmacy. All 50 states describe drug compounding in their state laws and regulations on pharmacy practice, although specific statutes or regulations vary across states. At the federal level, the Food and Drug Administration (FDA), which oversees the introduction of new drugs into the marketplace under the Federal Food, Drug and Cosmetic Act (FDCA),<sup>1</sup> maintains that compounded drugs are generally subject to the act.

While drug compounding is an important part of ensuring that medications are available to meet individual patient needs, the quality and extent of drug compounding have surfaced as important issues in recent years. For example, several compounding cases in the past several years have resulted in serious illnesses and deaths, raising concern about oversight to ensure the safety and quality of compounded drugs. In addition, concerns have been raised by FDA and others that some pharmacies are going beyond traditional drug compounding for individual patients by, for example, compounding and selling large quantities of drugs without meeting safety and other requirements for new manufactured drugs. Because both states and the federal government have oversight responsibilities, you asked us to address (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.

My testimony today is based in part on discussions with the National Association of Boards of Pharmacy (NABP), as well as a review we conducted of four states: Missouri, North Carolina, Vermont, and Wyoming. We selected these states based on their geographic location and

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<sup>1</sup>See 21 U.S.C. § 355.

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variation in compounding regulations. Two of the states came to our attention as having taken unique steps with regard to oversight of compounded drugs, and the other two had each adopted new regulations on drug compounding. For each of the four states, we reviewed state statutes and regulations, interviewed officials from the state board of pharmacy, and reviewed relevant documents such as pharmacy inspection forms. In addition to examining state-level actions, we examined national industry efforts by interviewing officials from the American Pharmacists Association, the International Academy of Compounding Pharmacists, the American Society of Health-System Pharmacists, the National Association of Chain Drug Stores, and Professional Compounding Centers of America, which provides training to pharmacists and also sells bulk ingredients for drug compounding. We also contacted and obtained information from the United States Pharmacopeia (USP), which is a nonprofit agency that develops standards for pharmaceuticals. Finally, to examine federal authority and enforcement power, we reviewed federal statutes, FDA compliance policy guides, court decisions, and other relevant documents, and interviewed FDA officials and industry experts. We conducted our work from August 2003 to October 2003 in accordance with generally accepted government auditing standards.

In summary, efforts at the state level and among pharmacy organizations at the national level have been taken or are under way to potentially strengthen state oversight of drug compounding. Actions among the four states we reviewed included adopting new statutes and regulations about compounding, such as requirements for facilities and equipment, 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 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. For example, in three of the four states we reviewed, pharmacy board officials indicated that resource limitations affected their ability to conduct routine inspections.

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FDA maintains that drug compounding activities are generally subject to its 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 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 FDCA provisions, including safety and efficacy requirements for the approval of new drugs. However, the entire section of the law dealing with drug compounding was nullified in 2002 after the United States Supreme Court ruled that part of it was an unconstitutional restriction on commercial speech. Following the court decision in 2002, FDA issued guidance to indicate when the agency would consider taking enforcement actions regarding drug compounding. For example, it said the agency would generally defer to the states for “less significant” violations of the FDCA but would consider taking action in situations more analogous to drug manufacturing.

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## Background

For most people and many pharmacies, filling a prescription is a matter of dispensing a commercially available drug product that has been manufactured in its final ready-to-use form. This has been particularly true in the United States since the rise of pharmaceutical manufacturing companies. In addition to meeting federal safety and efficacy requirements before a new drug is marketed, the drugs manufactured by these companies are routinely tested by FDA after marketing. According to FDA, the testing failure rate for more than 3,000 manufactured drug products sampled and analyzed by FDA since fiscal year 1996 was less than 2 percent. Drug manufacturers are also required to report adverse events associated with their drugs, such as illness and death, to FDA within specified time frames.

Drug compounding, which has always been a part of the traditional practice of pharmacy, involves the mixing, combining, or altering of ingredients to create a customized medication for an individual patient. According to the American Pharmacists Association, some of the most commonly compounded products include lotions, ointments, creams, gels, suppositories, and intravenously administered fluids and medication. Some of these compounded drugs, such as intravenously administered chemotherapy drugs, are sterile products that require special safeguards to prevent injury or death to patients receiving them. For example, sterile compounding requires cleaner facilities than nonsterile compounding, as well as specific training for pharmacy personnel and testing of the compounded drug for sterility.

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The extent of drug compounding is unknown, but it appears to be increasing in the United States. While industry representatives, the media, and others have cited estimates for the proportion of prescription drugs that are compounded ranging from 1 percent to 10 percent of all prescriptions, we found no data supporting most estimates.<sup>2</sup> FDA does not routinely collect data on the quantity of prescriptions filled by compounded drugs. Similarly, we found no publicly available data, either from FDA or from industry organizations, on the amount of bulk active ingredients and other chemicals that are used in drug compounding in the United States. However, many state officials, pharmacist association representatives, and other experts we interviewed reported that the number of compounded prescriptions, which had decreased when pharmaceutical manufacturing grew in the 1950s and 1960s, has been increasing over the past decade.

Problems have come to light regarding compounded drugs, some of which resulted in death or serious injury, because the drugs were contaminated or had incorrect amounts of the active ingredient. Unlike drug manufacturers, who are required to report adverse events associated with the drugs they produce, FDA does not require pharmacies to report adverse events associated with compounded drugs. Based on voluntary reporting, media reports, and other sources, FDA has become aware of over 200 adverse events involving 71 compounded products since about 1990. These incidents, including 3 deaths and 13 hospitalizations following injection of a compounded drug that was contaminated with bacteria in 2001, have heightened concern about compounded drugs' safety and quality. In addition, a limited survey conducted by FDA's Division of Prescription Drug Compliance and Surveillance in 2001 found that nearly one-third of the 29 sampled compounded drugs were subpotent—that is, they had less of the active ingredients than indicated.

FDA and others have also expressed concern about the potential for harm to the public health when drugs are manufactured and distributed in commercial amounts without FDA's prior approval. While FDA has stated that traditional drug compounding on a small scale in response to

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<sup>2</sup>A 2001 draft report of a study contracted by FDA included an estimate that about 6 percent of all prescriptions were compounded but cautioned that there was considerable uncertainty around this estimate due to limited data. The report acknowledged that definitive statistics on compounding activities were not available. Eastern Research Group Inc., *Profile of the Pharmaceutical Compounding Industry*, draft final report prepared for the Food and Drug Administration, August 27, 2001.

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individual prescriptions is beneficial, FDA officials have voiced concern that some establishments with retail pharmacy licenses might be manufacturing new drugs under the guise of drug compounding in order to avoid FDCA requirements.

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## Actions Taken or Under Way by States and National Organizations to Strengthen State Oversight of Drug Compounding, but Affect Likely to Vary from State to State

We found efforts at the state level and among national pharmacy organizations to potentially strengthen state oversight of drug compounding. Actions among the four states we reviewed included adopting new drug compounding regulations and random testing of compounded drugs. At the national level, industry organizations are working on standards for compounded drugs that could be adopted by states in their laws and regulations. According to experts we interviewed, uniform standards for compounded drugs could help ensure that pharmacists across states consistently produce safe, quality products. 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 their available resources and their ability to adopt new standards and enforce penalties.

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## Four States Reviewed Have Taken a Variety of Approaches to Strengthen Oversight

The four states we reviewed have taken a variety of approaches to strengthen state oversight.

- *Missouri.* The pharmacy board in Missouri has taken a different approach from other states: it is in the process of implementing random batch testing of compounded drugs. No other state has random testing, according to an NABP official. Random testing will include both sterile and nonsterile compounded drugs and the board plans on testing compounded drugs for safety, quality, and potency. A Missouri pharmacy board official said testing will include random samples of compounded drugs in stock in pharmacies in anticipation of regular prescriptions, random selection of prescriptions that were just prepared, and testing of compounded drugs obtained by undercover investigators posing as patients. The official added that random testing will help to ensure the safety and quality of compounded drugs and is also intended to serve as a deterrent for anyone who might consider purposely tampering with compounded prescriptions.
- *North Carolina.* North Carolina is the only state in the country that requires mandatory adverse event reporting involving prescription drugs,

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including compounded drugs, according to an NAPB official. Regulations in North Carolina require pharmacy managers to report information to the pharmacy board that suggests a probability that prescription drugs caused or contributed to the death of a patient. This reporting system, which does not extend to incidents of illness or injury, allows the board to investigate all prescription-drug-related deaths and determine whether an investigation is warranted.

- *Vermont.* The pharmacy board in Vermont overhauled the state's pharmacy rules in August 2003 to address changes in pharmacy practice, including the increase in Internet and mail-order pharmacies, according to the pharmacy board chairman. For example, the chairman reported that prior to the adoption of the new rules, Vermont had no definition of out-of-state pharmacies and no requirements for these pharmacies to have a Vermont license to do business in the state. The board chairman said that the new rule requiring licensing for out-of-state pharmacies would provide a mechanism to monitor pharmacies that ship prescription drugs, including compounded drugs, into the state. In addition, he added that the board revised the rules for compounding sterile drugs by including specifics on facilities, equipment, and quality assurance measures.
- *Wyoming.* Prior to March 2003, Wyoming did not have state laws or rules that established specific guidelines for drug compounding, aside from a definition of drug compounding, according to a pharmacy board official. The new rules include requirements for facilities, equipment, labeling, and record keeping for compounded drugs, as well as a specific section on compounding sterile drugs. In addition, under the new rules, the official added that pharmacy technicians-in-training are no longer allowed to prepare compounded drugs, including sterile products, which is a more complex procedure requiring special equipment to ensure patient safety.

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## Efforts of National Organizations May Help States Strengthen Oversight of Drug Compounding

At the national level, industry organizations are working on uniform practices and guidelines for compounded drugs and a committee of national association representatives recently began work on developing a program that would include certification and accreditation for drug compounding that could be used for state oversight. Groups such as the NABP concluded that state oversight of drug compounding would be strengthened if the states had uniform standards and other tools that could be adopted to address the quality and safety of compounded drugs. Several experts that we spoke with said national standards for compounding drugs that could be incorporated into state laws and regulations could help to ensure the quality and safety of compounded drugs. One expert noted that an advantage to incorporating compliance

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with national compounding standards into state laws is that it would be easier for states to keep up with updated standards without going through the process of legislative changes.

NABP developed and updated a Model State Pharmacy Act that provides standards for states regarding pharmacy practice. Recently revised in 2003, the model act includes a definition of drug compounding and a section on good drug compounding practices. According to the executive director of NABP, many states have incorporated portions of the model act into their state pharmacy statutes or regulations by including similar definitions of drug compounding and components of NABP's good drug compounding practices. For example, officials in Missouri and Wyoming reported using the model act's good drug compounding practices as a guideline for developing their drug compounding regulations. In addition, USP has established standards and guidelines for compounding nonsterile and sterile drug products, both of which are being updated by expert committees. An official told us that these revisions would be completed early in 2004.

In addition, recognizing that there is no coordinated national program to oversee compounding practices and that states' oversight may vary, NABP recently began working with other national organizations, including the American Pharmacists Association and USP, to create a steering committee to develop a national program to provide a national quality improvement system for compounding pharmacies and the practice of compounding. The committee, which held its second meeting in October 2003, is developing a program that is anticipated to include (1) the accreditation of compounding pharmacies, (2) certification of compounding pharmacists, and (3) requirements for compounded products to meet industry standards for quality medications. To strengthen state oversight of drug compounding, these accreditations, certifications, and product standards, once developed, could be adopted by the states and incorporated into their requirements for compounding pharmacists and pharmacies.

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### Factors Such as Available Resources May Affect States' Ability to Oversee Compounded Drugs

Although there are several efforts by states and national organizations that may help strengthen state oversight, some states may lack the resources to provide the necessary oversight. State pharmacy board officials in three of the four states reported that resources were limited for inspections, for example:

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- The Missouri pharmacy board director reported that pharmacy inspections typically occur every 12 to 18 months; however, an increase in complaints has resulted in less frequent routine pharmacy inspections, because investigating complaints takes priority over routine inspections.
  - North Carolina has six inspectors for about 2,000 pharmacies, which the state pharmacy board director said are inspected at least every 18 months. The director added that it is difficult to keep up with this schedule of routine inspections with the available resources while also investigating complaints, which take first priority.
  - In Vermont, the pharmacy board chairman reported that, for a period of about 8 years until January 2003, pharmacy inspectors were only able to respond to complaints and not conduct routine inspections because of a shortage of inspectors. Vermont now has four full-time inspectors that cover the state's 120 pharmacies; however, in addition to routine pharmacy inspections, the inspectors are also responsible for inspecting other facilities such as nursing homes and funeral homes. The chairman added that the board would like to have pharmacies inspected annually but it is difficult to keep up with the current schedule of inspections once every 2 years.

Since drug compounding may occur in mail-order and Internet pharmacies, the compounding pharmacy may be located in a state different from the location of the patient or prescribing health professional. Three of the four states we reviewed had a large number of out-of-state pharmacies that were licensed to conduct business in those states, and inspection and enforcement activities may differ for these pharmacies. For example, Wyoming has 274 licensed out-of-state pharmacies, which is nearly twice as many as the number of in-state licensed pharmacies. The four states we reviewed said that they have authority to inspect out-of-state pharmacies licensed in their states but because of limited resources, they generally leave inspections to the state in which the pharmacy is located. Regarding enforcement authority, all four states reported having authority to take disciplinary action against out-of-state pharmacies licensed in their states.

While the pharmacy boards in all four states we reviewed can suspend or revoke pharmacy licenses or issue letters of censure, enforcement mechanisms vary. For example, Missouri and North Carolina are not authorized to charge fines for violations; however, Wyoming can fine a pharmacist up to \$2,000 and Vermont can fine a pharmacy or pharmacist \$1,000 for each violation. Further, not all state pharmacy boards have the

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authority to take enforcement action independently. For example, in Missouri when attempting to deny, revoke, or suspend a license through an expedited procedure, the pharmacy board must first file a complaint with an administrative hearing commission. Only after the commission determines that the grounds for discipline exist may the board take disciplinary action.

Pharmacy board officials reported relatively few complaints and disciplinary actions involving drug compounding. For example, of the 307 complaints received and reviewed by the board of pharmacy against pharmacies and pharmacists in Missouri in fiscal year 2002, only 5 were related to drug compounding.<sup>3</sup>

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## FDA Asserts Oversight Authority Under FDCA but Generally Relies on States to Regulate Drug Compounding

FDA maintains that drug compounding activities are generally subject to FDA oversight, including the “new drug” requirements and other provisions of the FDCA. In practice, however, the agency generally relies on the states to regulate the traditional practice of pharmacy, including the limited compounding of drugs for the particular needs of individual patients. In recent years, the Congress has attempted to clarify the extent of federal authority and enforcement power regarding drug compounding. In 1997, the Congress passed a law that exempted drug compounders from key portions of the FDCA if they met certain criteria. Their efforts, however, were nullified when the Supreme Court struck down a portion of the law’s drug compounding section as an unconstitutional restriction on commercial speech, which resulted in the entire compounding section being declared invalid.<sup>4</sup> In response, FDA issued a compliance policy guide to provide the compounding industry with an explanation of its enforcement policy, which included a list of factors the agency would consider before taking enforcement actions against drug compounders.

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<sup>3</sup>The state pharmacy board officials that we spoke with reported that most complaints and disciplinary actions cover dispensing errors related to manufactured drugs, such as incorrectly counting the number of pills for a prescription.

<sup>4</sup>*Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

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## FDA Asserts Jurisdiction to Regulate Drug Compounding Under FDCA

FDA maintains that FDCA requirements, such as those regarding the safety and efficacy requirements for the approval of new drugs, are generally applicable to pharmacies, including those that compound drugs. The agency recognized in its brief submitted in the 2002 Supreme Court case that applying FDCA's new drug approval requirements to drugs compounded on a small scale is unrealistic—that is, it would not be economically feasible to require drug compounding pharmacies to undergo the testing required for the new drug approval process for drugs compounded to meet the unique needs of individual patients. The agency has stated that its primary concern is where drug compounding is being conducted on a scale tantamount to manufacturing in an effort to circumvent FDCA's new drug approval requirements. FDA officials reported that the agency has generally left regulation of traditional pharmacy practice to the states, while enforcing the act primarily when pharmacies engage in drug compounding activities that FDA determines to be more analogous to drug manufacturing.

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## FDA Modernization Act Exempted Drug Compounders from Some FDCA Requirements but Was Declared Invalid

Federal regulatory authority over drug compounding attracted congressional interest in the 1990s, as some in the Congress believed that “clarification is necessary to address current concerns and uncertainty about the Food and Drug Administration’s regulatory authority over pharmacy compounding.”<sup>5</sup> The Congress addressed this and other issues when it passed the FDA Modernization Act of 1997 (FDAMA), which included a section exempting drugs compounded on a customized basis for an individual patient from key portions of FDCA that were otherwise applicable to manufacturers.<sup>6</sup> According to the congressional conferees, its purpose was to ensure continued availability of compounded drug products while limiting the scope of compounding so as “to prevent manufacturing under the guise of compounding.”<sup>7</sup>

In order to be entitled to the exemption, drug compounders had to meet several requirements, including one that prohibited them from advertising or promoting “the compounding of any particular drug, class of drug, or

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<sup>5</sup>S. Rep. No. 105-43, at 67 (1997).

<sup>6</sup>These portions covered “adequate directions for use” labeling, manufacturing, and new drug approval requirements. *See* former 21 U.S.C. § 353a (a). Pub. L. No. 105-115, 111 Stat. 2296, former section 503A.

<sup>7</sup>H.R. Conf. Rep. No. 105-399, at 94 (1997).

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type of drug.”<sup>8</sup> This prohibition was challenged in court by a number of compounding pharmacies and eventually resulted in a 2002 Supreme Court decision holding that it was unconstitutional. As a result, the entire drug compounding section was declared invalid.<sup>9</sup> However, the Court did not address the extent of FDA’s authority to regulate drug compounding.

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### Current FDA Enforcement Focuses on Drug Compounding Outside of the Traditional Practice of Pharmacy

FDA issued a compliance policy guide in May 2002, following the Supreme Court decision, to offer guidance about when it would consider exercising its enforcement authority regarding pharmacy compounding.<sup>10</sup> In the guide, FDA stated that the traditional practice of drug compounding by pharmacies is not the subject of the guidance. The guide further stated that FDA will generally defer to state authorities in dealing with “less significant” violations of FDCA, and expects to work cooperatively with the states in coordinating investigations, referrals, and follow-up actions. However, when the scope and nature of a pharmacy’s activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of FDCA, the guide stated that FDA has determined that it should seriously consider enforcement action and listed factors, such as compounding drug products that are commercially available or using “commercial scale manufacturing or testing equipment,” that will be considered in deciding whether to take action.<sup>11</sup>

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<sup>8</sup>See former 21 U.S.C. § 353a (c).

<sup>9</sup>Both the district and appellate courts held that the prohibition was unconstitutional. However, the district court held that the prohibition was “severable” and that the rest of the pharmacy compounding section remained good law. While the appellate court agreed with the district court on the constitutional question, it disagreed on the severability issue and invalidated the entire section. The Supreme Court agreed with both courts on the constitutional issue, but because the severability decision was not challenged, the Court did not rule on it, and left it in place. See *Thompson v. Western States Medical Center*, 69 F. Supp. 2d 1288 (D. Nev. 1999), aff’d in part and rev’d in part, 238 F. 3d 1090 (9th Cir. 2001), aff’d, 535 U.S. 357.

<sup>10</sup>This guide was similar to an earlier compliance policy guide published by FDA in 1992. After the drug compounding section of FDAMA was declared invalid, FDA determined that it needed to issue new guidance to the compounding industry on what factors the agency would consider in exercising its enforcement discretion regarding drug compounding.

<sup>11</sup>“Compliance Policy Guide: Compliance Policy Guidance for FDA Staff and Industry”, Chapter 4, Sub Chapter 460, May 2002.

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Some representatives of pharmacist associations and others have expressed concern that FDA's compliance policy guide has created confusion regarding when FDA enforcement authority will be used. For example, some pharmacy associations assert that FDA's guidance lacks a clear description of the circumstances under which the agency will take action against pharmacies. In particular, they pointed to terms in the guide, such as "very limited quantities" and "commercial scale manufacturing or testing equipment" that are not clearly defined, and noted that FDA reserved the right to consider other factors in addition to those in the guide without giving further clarification. FDA officials told us that the guide allows the agency to have the flexibility to respond to a wide variety of situations where the public health and safety are issues, and that they plan to revisit the guide after reviewing the comments the agency received, but did not have a time frame for issuing revised guidance.

In several reported court cases involving FDA's regulation of drug compounders, the courts have generally sided with FDA. Two cases we identified involved drug compounders engaged in practices that were determined to be more analogous to drug manufacturing. In a district court case decided this year, the court upheld FDA's authority to inspect a pharmacy specializing in compounding, noting that it believed that FDA's revised compliance policy guide was a reasonable interpretation of the statutory scheme established by FDCA.<sup>12</sup>

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## Concluding Observations

While drug compounding is important and useful for patient care, problems that have occurred raise legitimate concerns about the quality and safety of compounded drugs and the oversight of pharmacies that compound them. However, the extent of problems related to compounding is unknown. FDA maintains that drug compounding activities are generally subject to FDA oversight under its authority to oversee the safety and quality of new drugs, but the agency generally relies on states to provide the necessary oversight. At the state level, our review provides some indication that at least some states are taking steps to strengthen state oversight, and national pharmacy organizations are developing standards that might help strengthen oversight if the states adopted and enforced them. However, the effectiveness of these measures is unknown, and

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<sup>12</sup>*In the Matter of Establishment Inspection of Wedgewood Village Pharmacy, Inc.*, 270 F. Supp. 525, 549 (D. N.J. 2003).

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factors such as the availability of resources may also affect the extent of state oversight.

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Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or other Members of the Committee may have at this time.

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## Contact and Acknowledgments

For further information, please contact Janet Heinrich at (202) 512-7119. Individuals making key contributions to this testimony included Matt Byer, Lisa A. Lusk, and Kim Yamane.

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