The Special Risks of Pharmacy Compounding

Pharmacy compounding is a practice in which a licensed pharmacist combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient.

It's also a practice that is under scrutiny by the Food and Drug Administration (FDA) because of instances in which medications, primarily injectable medications that are intended to be sterile, have endangered public health.

Pharmacy compounding can serve an important public health need if a patient cannot be treated with an FDA-approved medication. For example, pharmacy compounding may occur if a patient needs a medication to be made without a certain dye because of an allergy. Or an elderly patient or a child may need a medicine in a liquid or suppository form that is not otherwise available.

"In its traditional form, pharmacy compounding is a vital service that helps many people, including those who are allergic to inactive ingredients in FDA-approved medicines, and others who need medications that are not available commercially," says Kathleen Anderson, Pharm.D., acting director of the Office of Unapproved Drugs and Labeling Compliance in FDA's Center for Drug Evaluation and Research (CDER).

"But consumers need to be aware that compounded medications are not FDA-approved," Anderson says. "This means that FDA has not verified their quality, safety and effectiveness."

Ilisa Bernstein, Pharm.D., acting director of CDER's Office of Compliance, says that poor compounding practices can result in contamination or in medications that don't possess the strength, quality and purity required. "And because patients who use these compounded medications may have serious underlying health conditions," she says, "these flawed methods pose special risks."

A Troubling Trend

The emergence of firms with pharmacy licenses making and distributing drugs in a way that's outside the bounds of traditional pharmacy compounding is of great concern to FDA.

"Some aspects of these firms' operations appear more consistent with those of drug manufacturers than with those of traditional pharmacies," says Bernstein. "Some firms make large amounts of drugs that appear to be copies of FDA-approved, commercially available drugs when it does not appear that there is a medical need for an individual patient to receive a compounded version of the drug."

Some of the adverse event reports received by the FDA associated with compounded medications have had devastating repercussions.

- The fall 2012 outbreak of fungal meningitis has been linked to an injectable steroid medication that the Centers for Disease Control and Prevention says has infected hundreds of people across the country, with serious injuries and deaths reported. These infections have all been linked to a firm in Framingham, Mass.
- In August 2011, FDA alerted health care professionals that repackaged injections of Avastin (bevacizumab) caused serious eye infections in the Miami area. A pharmacy had repackaged the Avastin from single-use vials into multiple single-use syringes, distributing them to multiple eye clinics, and infecting at least 12 patients. Some patients lost the remaining vision in the eye being treated.
- From November 2011 to April 2012, 33 eye-surgery patients in seven states suffered a rare fungal

eye infection tied to injectable drug products made by a compounding pharmacy in Ocala, Fla. Most of those patients suffered partial to severe vision loss.

What You Can Do

It may sometimes be difficult to recognize if you are taking a drug made by a pharmacy compounder. Be sure to ask your doctor and pharmacist whether the prescribed drug is compounded, why it is being compounded, where it is being compounded, and what are the possible side effects and safety concerns.

Bernstein offers these tips:

- Ask your doctor if an FDA-approved drug is available and appropriate for your treatment.
- Check with the pharmacist to see if he or she is familiar with compounding the product in your prescription, and whether he or she has the training, equipment, and processes in place to compound that product.
- Get information from your doctor or pharmacist about proper use and storage of the compounded product.
- If you receive a compounded drug, ask the pharmacist if your doctor asked for it to be compounded.
- If you experience any problems or adverse events, contact your doctor or pharmacist immediately.
- Report any adverse events experienced while using the product to FDA's MedWatch program

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