Frequently Asked Questions About Compounding

What is pharmacy compounding?

Pharmacy compounding is the customized preparation of a medicine that is not otherwise commercially available. These medications are prescribed by a physician, veterinarian, or other prescribing practitioner, and compounded by a state-licensed pharmacist. A growing number of people and animals have unique health needs that off-the-shelf, one-size-fits-all prescription medicines cannot meet. For them, customized medications are the only way to better health.

Who are compounding pharmacists?

Pharmacy compounding is a centuries-old, well-regulated and common practice. Pharmacy is one of the most respected and trusted professions in the United States. In a recent survey, pharmacists ranked second (only behind nurses) as the most trusted professionals in our society. Compounding has evolved into a specialty practice within the pharmacy community today. New applications to meet today's patient needs require additional education, equipment and processes that not all pharmacies possess.

Are compounded medications safe? How does one know that the compounded medication they are taking is safe and effective?

Compounded medications are similar to the so-called "off-label" use of FDA-approved drugs. When the FDA approves a specific drug as safe and effective, this determination applies only to the specific disease or condition for which the drug was tested. But physicians and veterinarians often prescribe medications for treatments for which they have not been specifically approved. Medical professionals do this because, in their judgment, the treatment is in the best interest of the individual patient. Similarly, medical professionals often prescribe compounded medications because they believe it is the best medical option for their patients. It is estimated that one fifth of all prescriptions written for FDA-approved drugs are for uses for which they were not specifically approved.

There are thousands of FDA-approved drugs on the market for just about any ailment. Why do we still need compounded medications?

Some valuable medications are available only by compounding. Restricting a doctor's access to compounded medications would be a serious mistake. Moreover, because of the economics of pharmaceutical manufacturing, FDA-approved drugs that serve a limited population are often discontinued by manufacturers. In most of these cases, the only option left for doctors and their patients is to have a compounding pharmacist make the discontinued drug from scratch using pharmaceutical grade ingredients.

What suppliers sell ingredients to compounding pharmacies? How are these suppliers regulated?

Just like big pharmaceutical manufacturing companies, compounding pharmacies get their ingredients for medications from suppliers that are registered and inspected by the FDA. Foreign suppliers are FDA-registered facilities.

How are compounding pharmacies and pharmacists regulated? Should there be increased federal oversight?

All pharmacies and pharmacists are licensed and strictly regulated at the state level. Compounding is a core component of pharmacy and has always been regulated by state boards, which are constantly updating their standards and regulations. In addition, standards set by the United States Pharmacopeia (USP) are integrated into the practice of pharmacy compounding. The Pharmacy Compounding Accreditation Board (PCAB) has developed national standards to accredit pharmacies that perform a significant amount of compounding.

Does the FDA have the expertise and federal power to regulate compounding pharmacies? Why shouldn't compounded medications, especially the most commonly used combinations, have to go through the FDA's established drug approval process?

The medical profession, including the practice of pharmacy, has always been regulated by the states. State boards of pharmacy are in the best position to inspect pharmacy operations, develop appropriate regulations and respond to problems or violations. The FDA does have an important role to play in making sure that ingredients used in compounding are safe and are manufactured by FDA-registered and inspected facilities, but there is no such thing as an "FDA-approved" pharmacy.

The FDA's drug approval process takes years and can cost hundreds of millions of dollars. Requiring this for individually personalized medications that fulfill an individual doctor's prescription is both impractical and contrary to the best interests of patients requiring immediate treatment.

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