OLR RESEARCH REPORT

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COMPOUNDING PHARMACIES

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You asked for information on compounding pharmacies.

SUMMARY

Compounding pharmacies are pharmacies that combine, mix, or alter ingredients to create a medication, generally for an individual patient. Compounding is a common aspect of pharmacy practice. It is a way to prepare medicine that is not commercially available and allows pharmacists to provide an alternative delivery method, add flavors, or substitute inactive ingredients to which a patient may be allergic.

Pharmacies, including compounding ones, are regulated by individual states. Connecticut currently has 25 compounding pharmacies, which the Department of Consumer Protection (DCP) regulates through the Commission of Pharmacy. Connecticut regulations require compounding pharmacies to meet U.S. Pharmacopeia standards, which require secure storage, recordkeeping, certain labels, and other safety protocols. The commission enforces these provisions through site visits and investigations. If a compounding pharmacy fails to meet requirements, the commission can suspend or revoke a license and assess a civil penalty up to $1,000. (For more information on how other states regulate compounding pharmacies, visit: http://www.ncsl.org/issues-research/health/regulating-compounding-pharmacies.aspx.)

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The federal Food and Drug Administration (FDA) regulates commercial pharmaceutical manufacturing and does not subject compounded drugs to the new drug approval process. The FDA has produced a compliance guide to help determine when a compounding pharmacy is acting like a drug manufacturer. However, there is no bright line standard for when a compounding pharmacy becomes a drug manufacturer and thus subject to FDA regulation.

COMPOUNDING PHARMACIES

Compounding drugs in pharmacies is a common practice that has been around for decades. It allows pharmacists to produce a product, under a doctor's order, when a commercially available drug cannot meet a certain need. An example of when compounding is needed is when a young child needs a small liquid dose of a drug that is only made in adult-dosage tablets.

The original intent of compounding was for pharmacies to be able to individually prepare a drug for a particular patient. Compounding pharmacies generally cannot produce compounded drugs before receiving a prescription or provide them for general distribution. But compounding pharmacies have grown in recent years and the line between traditional compounding and drug manufacturing has been blurred.

Connecticut Regulations

DCP, through the Commission on Pharmacy, regulates 25 compounding pharmacies within the state. These pharmacies must meet specific compounding requirements in addition to requirements that all pharmacies must meet, such as licensing, drug storage, and recordkeeping.

By regulation, compounding pharmacies must adhere to current U.S. Pharmacopeia standards for sterile and non-sterile drug compounding (Conn. Agencies Regs. § 20-576-64, *et seq.*). The standards require compounding pharmacies to adhere to certain procedures for, among other things, sterilization, training, environmental control, clean room specifications, and verification methods. (For more information on U.S. Pharmacopeia standards, visit http://www.pharmacopeia.cn/v29240/usp29nf24s0_c797_viewall.html for sterile compounding and http://www.pharmacopeia.cn/v29240/usp29nf24s0_c795.html for non-sterile compounding.)

In addition, the regulations allow a compounding pharmacy to provide only a two-week drug supply to certain authorized personnel (i.e., doctor or dentist). They also require compounding pharmacies to prepare and maintain a policy and procedure manual that includes procedures for compounding, dispensing, delivery, administering, storing, and use of the drugs.

The commission enforces these provisions through announced and unannounced site visits, as well as complaint based investigations.

If a compounding pharmacy fails to meet these requirements, the commission may suspend or revoke its pharmacy license or refuse to renew it, or assess a civil penalty of up to $1,000 (CGS § 20-579(a)).

FDA Authority

The FDA has clear authority to regulate drug manufacturers, but it is unclear when a compounding pharmacy becomes one. The FDA does not subject compounded drugs to its standard new drug approval process under the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.).

In 1997, a law that would have clarified the FDA's authority over compounding pharmacies was largely invalidated by a 2002 Supreme Court decision. Section 127 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) distinguished compounding from manufacturing practices, but included three major exemptions to help protect smaller compounding pharmacies. Also included in the section was a provision that prohibited pharmacies from advertising and promoting their compounded drugs.

This advertisement provision was struck down in a U.S. Ninth Circuit Court decision on the grounds that it violated pharmacies' Constitutional right to free speech (Western States Medical Center v. Shalala, 238 F.3rd 1090 (9th Cir. 2001)). The Supreme Court upheld the Ninth Circuit's decision that found the provision to be unconstitutional and did not rule on whether the unconstitutional provision could be severed from the rest of the section. Accordingly, Section 127 of the law is now invalid in its entirety (Thompson v. W. States Med. Ctr., 535 U.S. 357, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002)).

Subsequently, the FDA issued a Compliance Policy Guide to compounding pharmacies (http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM118050.pdf). The guide states that the FDA will generally defer to the states for enforcement. But when a pharmacy's activities raise concerns that are normally associated with a drug manufacturer, the FDA will take enforcement action. However, the guidance does not (1) establish legally enforceable rights or responsibilities nor (2) bind the public or the FDA.

The agency lists nine specific circumstances for when it will take enforcement action against a compounding pharmacy. These include when a compounding pharmacy is:

1. failing to operate in conformance with applicable state law regulating the practice of pharmacy;

2. compounding drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions;

3. compounding drugs that were withdrawn or removed from the market for safety reasons;

4. compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application in accordance with 21 U.S.C. § 355(i) and 21 CFR 312;

5. receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility;

6. receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements;

7. using commercial scale manufacturing or testing equipment for compounding drug products;

8. compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale; and

9. compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.

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