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Client Alert

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Federal Legislation Introduced to Regulate Pharmacy Compounding In Response to Deadly Meningitis Outbreak

In recent weeks there have been daily reports on people dying of meningitis caused by a tainted drug from a compounding pharmacy in Massachusetts. The New England Compounding Center (NECC) has been found to be the source of contaminated injectable steroids that have to date led to 28 deaths and 377 illnesses in 19 states. This deadly loss has led many people to ask: "What is pharmacy compounding, and how is it regulated?"

Traditional pharmacy compounding involves a practice in which state licensed pharmacists, in accordance with a prescription issued by a patient's physician, combine, mix, or alter drug ingredients to create a unique medication to meet the specific medical needs of that individual patient. The Food and Drug Administraion (FDA) recognizes that the practice of pharmacy is regulated at the state level, typically involving a permitting process administered by each state's Board of Pharmacy. Compounded drugs are not approved by the FDA, and they are not reviewed by the FDA for safety and effectiveness. Although FDA may take enforcement action when it believes a compounding pharmacy is behaving like a drug manufacturer or is producing standardized versions of FDA-approved drugs, FDA has not historically viewed compounded drugs as unapproved new drugs and hence, illegal. Nor does FDA routinely inspect compounding pharmacies. Rather, FDA has acknowledged a public need that traditional compounding pharmacies meet. For example, FDA recognizes the legitimate need for a specially-compounded drug for a patient who is allergic to an ingredient in the commercially available drug or when a diluted dosage is required for a child. Thus, with regard to traditional pharmacy compounding, FDA has largely left regulation to state board of pharmacies.[1]

The public outcry over the NECC tragedy, however, has renewed questions about the need for more federal and state oversight of pharmacy compounding. Indeed, evidence suggests that NECC engaged in activities more closely resembling those of a drug manufacturer than a traditional compounding pharmacy, and FDA is reportedly conducting a criminal investigation of NECC and its officers. Undoubtedly, more investigation of NECC and of pharmacy compounding, in general, will continue, and indeed, steps to tighten federal regulation in this area are already being considered.

1 FDA has published Guidance for FDA Staff and Industry, Compliance Policy Guides Manual, Section 460.200 Pharmacy Compounding, which outlines nine key factors that the agency considers in deciding whether to institute enforcement action against a compounding pharmacy.

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On November 2, 2011, Congressman Edward J. Markey (D-Mass.) introduced legislation that will strengthen federal regulation of compounding pharmacies. The NECC is located in Rep. Markey's Congressional District.

The proposed legislation, **The Verifying Authority and Legality in Drug (VALID) Compounding Act**, will amend the Federal Food, Drug, and Cosmetic Act (FDCA) and give the FDA clear, new authority to oversee certain compounding pharmacy practices throughout the country. This bill builds on the structure of a 1997 amendment to the FDCA that established a regulatory system for pharmacy compounding. That law was struck down as unconstitutional by the U. S. Court of Appeals for the Ninth Circuit in 2001 because of certain provisions dealing with promotion and advertising of compounded drugs (this new legislation does not contain such a provision).

The proposed VALID Compounding Act has eight main features:

1. **Provide that the new drug approval requirements of the FDCA do not apply to a drug product in these circumstances.**

   - The drug is compounded for an identified individual patient based on the receipt of 1) a valid prescription; or 2) a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient;
   - The drug is compounded by a licensed pharmacist in a state-licensed pharmacy or a federal facility, or a licensed physician pursuant to such prescription order or notation;
   - The drug is compounded exclusively from: 1) ingredients that comply with an applicable UPS or National Formulary monograph; or 2) if such monograph does not exist, ingredients that are contained in an FDA-approved drug;
   - Any bulk substance used to compound the drug is: 1) manufactured by an establishment that is registered with FDA; and 2) is accompanied by valid certificates of analysis;
   - The pharmacist complies with the standards of any applicable USP chapters on pharmacy compounding;
   - The drug product, including the dosage form and any ingredient thereof, is not included in a list of drug products that should not be compounded (**see below**);
   - The drug product is not a copy of a commercially available drug.

2. **Specify drugs that should not be compounded.**

   The VALID Compounding Act provides that the Secretary of HHS shall develop a list of drug products that should not be compounded, including on the list at a minimum, those drugs whose compounding is reasonably likely to cause an adverse effect on safety or effectiveness of such drug product and those drugs that have been withdrawn or removed from the market because they have been found to be unsafe or not effective.

3. Preserve state regulatory authority for traditional small compounding pharmacy activities.

The VALID Compounding Act provides for an exemption from certain FDA regulations if compounding pharmacies meet specific conditions, including:

- The drug must be compounded by a licensed pharmacist or physician for an identified patient with a valid prescription;
- The drug must be compounded using safe and approved ingredients, and using good manufacturing practices; and
- The drug cannot be a copy of a commercially-available drug.

4. Ensure that compounding pharmacies that are operating as drug manufacturers are regulated by the FDA as drug manufacturers.

The legislation requires compounding pharmacies whose activities are classified by FDA as being more akin to drug manufacturing (for example, because of the volumes of products they make or the extent to which the pharmacy sells the drugs across state lines) to register with the FDA as manufacturers rather than pharmacies, and be subject to the same FDA inspection authority as drug manufacturers are.

5. Allow some compounding pharmacies to request waivers to enable them to compound drugs before the receipt of a valid prescription.

The VALID Compounding Act requires the FDA to define requirements (i.e., safety, testing, inspection, reporting or other requirements) for types of compounding pharmacies that are not classified as drug manufacturers, but that wish to compound drugs before receiving a valid prescription for an identified patient. These types of compounding pharmacies could include hospital pharmacies, community pharmacies that wish to make small batches of compounded drugs for their regular customers, or compounding pharmacies that have small sterile compounding facilities. The FDA also can delegate the authority for granting each type of waiver to state regulatory authorities if the state authority has the resources to implement the waiver program and oversee the facilities.

6. Allow the FDA to waive the requirement to compound drugs solely for individual patients with valid prescriptions in the event of a drug shortage or to protect public health.

Waivers are for a period of one year, and extendable only if the drug shortage or need to protect public health remains in effect.

7. Allow the FDA to waive the requirement to compound drugs only if the compounded drugs are not copies of commercially-available drugs if doing so is necessary to protect public health or well-being.

Waivers are for a period of one year, and extendable only if the need to protect public health or well-being remains in effect.

8. Increase transparency regarding compounded drugs.

The VALID Compounding Act requires that:

- FDA create and maintain a "Do Not Compound" list of drugs that are not safe or effective when compounded and make the list available to the public and state regulators (see # 2 above).
- The FDA is given clear authority to inspect any compounding pharmacy that receives any waiver under the Act.
- Compounding pharmacies and physicians that become aware of adverse reactions to compounded drugs or of potential safety problems with drugs they have already distributed must report to the FDA.
- Compounded drugs must be labeled to ensure that recipients are aware that FDA has not tested the drug for safety or effectiveness and to provide a means to report serious adverse drug reactions. The labeling must include this statement: "This drug has not been tested for safety and effectiveness and is not approved by the FDA. Serious adverse reactions to this drug should be reported to the pharmacy where it was received and the FDA at _____." (FDA is required to supply a telephone number and a web site).

A copy of the proposed legislation can be found by clicking here. [2]

2 http://markey.house.gov/sites/markey.house.gov/files/documents/VALID%20Act%20legislation.pdf