Public Citizen Calls on the FDA to Reinspect Compounding Pharmacies That Previously Received Warnings

Many Compounding Pharmacies May Still Pose Public Threat

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WASHINGTON, D.C. – The U.S. Food and Drug Administration (FDA) should promptly reinspect drug compounding pharmacies that have received warning letters from the agency regarding their manufacturing practices, Public Citizen said today in a letter addressed to FDA Commissioner Margaret Hamburg.

Publicly available data reviewed by Public Citizen show that between 2003 and 2012, the FDA sent at least 18 warning letters to 16 pharmacy compounding companies operating in 15 states. The pharmacies listed were headquartered or had facilities inspected by the FDA in one or more of the following states: Alabama, Arkansas, Connecticut, Florida, Illinois, Kentucky, Maryland, Mississippi, Missouri, New Jersey, New York, Ohio, Pennsylvania, Texas and Utah. Addresses and links to FDA warning letters are included in a table enclosed with Public Citizen's letter.

In five of the warning letters, the FDA identified patient injuries or deaths allegedly associated with products produced by the company. In other warning letters, the agency identified manufacturing conditions that posed threats to patients' safety. For each pharmacy listed in these letters, the FDA identified activities that allegedly crossed outside the bounds of traditional compounding and into drug manufacturing, and violated the Food, Drug, and Cosmetics Act. These alleged violations included:

- Producing drugs on a large scale or without an individualized patient-specific prescription;

- Producing copies of commercially available drugs; and

- Making drugs from active ingredients that were not FDA-approved.

The letters identified patient injuries and deaths from infections linked to dextrose injections (sugar water injected through an intravenous line) that had been contaminated with bacteria or other micro-organisms, and from eye infections linked to potentially contaminated Avastin, used to treat macular degeneration. In addition to infections, the letters referenced improperly prepared or labeled drugs. The agency noted at least 70 complaints of adverse events possibly related to incorrect amounts of preservatives added to an injectable steroid, as well as the death of a 25-year-old woman from an anesthetic skin cream after a compounding pharmacy's printed instructions failed to include appropriate warnings to avoid a toxic overdose.

The FDA letters also mentioned other safety threats that had been identified by FDA inspectors, including inadequate sterility practices, poorly cleaned equipment and inappropriately trained staff

using poor techniques, such as touching non-sterile items, including trash cans, in between handling sterile drugs. One inspection even revealed that vials of one injectable drug contained a solvent used in wood stains and industrial cleaners.

In recent weeks, Public Citizen has been critical of the FDA's response to the deadly meningitis outbreak that started in September and was traced to contaminated injectable steroid drugs made by the New England Compounding Center in Framingham, Mass. The FDA has claimed that the agency lacks authority to properly regulate compounding pharmacies and requires legislative action to do so – a direct contradiction of the content of the agency's warning letters.

"The FDA's warning letters show that the agency doesn't need any additional actions by Congress to enforce the Food, Drug, and Cosmetics Act against pharmacies that engage in illegal drug manufacturing," said Dr. Michael Carome, deputy director of Public Citizen's Health Research Group. "By not fully investigating what could potentially be deadly violations of the law, the FDA is disregarding its primary purpose, which is to protect the lives of citizens."

The FDA did not announce any further action after issuing its warning letters, so Public Citizen could not determine whether the agency later verified whether the companies corrected alleged violations. Public Citizen has submitted a Freedom of Information Act request to the FDA asking for records regarding any additional FDA inspections carried out at these firms after the warning letters were issued.

In addition to reinspecting the 16 compounding pharmacy companies that received FDA warning letters, Public Citizen urges the agency to immediately assess the FDA's previous enforcement efforts against compounding pharmacies, and to initiate a systematic program to determine whether other compounding pharmacies are engaged in illegal practices.

In the Freedom of Information Act request, Public Citizen also asks that the agency produce all 483 reports from inspections carried out since April 2003 at facilities managed by compounding pharmacies, including those that may not have received warning letters.

To read the letter, visit http://www.citizen.org/hrg2085.

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Public Citizen is a national, nonprofit consumer advocacy organization that has worked to protect health, safety and democracy since 1971.