

## **FDA Knew of Poor Drug Production Practices at Specialty Compounding Months Before Recent Patient Infections and Product Recall**

*Public Citizen Calls on HHS to Investigate and Take More Aggressive Action; 50 Compounding Pharmacies Found to Have Significant Problems, But Most Are Still Operating*

August 14, 2013

Contact: Ben Somberg (202) 588-7742; Angela Bradbery (202) 588-7741

WASHINGTON, D.C. – The U.S. Food and Drug Administration (FDA) may have been able to prevent recent bacterial infections linked to a Texas compounding pharmacy, Specialty Compounding, by taking swift action against the company when the agency found significant problems in a March 2013 inspection, Public Citizen said today. In a [letter](http://qz.salsalabs.com/dia/track.jsp?v=2&c=wuvMIT9N2Y2%2F4FeOs16uFONk9fOGGKas) (<http://qz.salsalabs.com/dia/track.jsp?v=2&c=wuvMIT9N2Y2%2F4FeOs16uFONk9fOGGKas>), Public Citizen called on Health and Human Services (HHS) Secretary Kathleen Sebelius to order the FDA to stop the pharmacy from producing sterile products until it complies with all applicable federal laws and regulations, to order an Inspector General investigation of why the FDA did not act earlier and to review other cases of pharmacies that were found during inspections to have serious problems.

Since the fall of 2012, the FDA has identified significant objectionable conditions at [50 compounding pharmacy facilities](http://qz.salsalabs.com/dia/track.jsp?v=2&c=8B1FjFxbErOfDwdN9YBRnuNk9fOGGKas) (<http://qz.salsalabs.com/dia/track.jsp?v=2&c=8B1FjFxbErOfDwdN9YBRnuNk9fOGGKas>), but only 16 of those have initiated a product recall or have been the subject of an FDA [enforcement action beyond issuance of an inspection report](http://qz.salsalabs.com/dia/track.jsp?v=2&c=MCIEeFyinO6RGD%2F4r0NCpuNk9fOGGKas) (<http://qz.salsalabs.com/dia/track.jsp?v=2&c=MCIEeFyinO6RGD%2F4r0NCpuNk9fOGGKas>).

Specialty Compounding, located in Cedar Park, Texas, just north of Austin, issued a voluntary recall on Friday of all lots of unexpired sterile medications after reports that 15 patients in two Texas hospitals were infected with the same type of bacteria, potentially associated with intravenous infusions of calcium gluconate produced by the pharmacy. Calcium gluconate is routinely used in hospitalized patients to treat low blood calcium levels.

“The FDA knew there was a serious problem here but didn’t use its existing legal authority to take prompt, aggressive enforcement action against the company. That exposed patients to unnecessary risk and might have contributed to 15 people being infected,” said Dr. Michael Carome, director of Public Citizen’s Health Research Group. “What’s the purpose of inspecting a facility if you’re not going to take appropriate action when you find conditions that pose a safety threat to patients?”

Following a 2012 infection outbreak involving drugs manufactured at the New England Compounding Center, which has been linked to 63 deaths, the FDA has inspected dozens of compounding pharmacies. The agency inspected Specialty Compounding in March, and on March 22 posted an inspection report documenting numerous examples of poor sterile drug production practices at the facility, including a lack of adequate procedures to prevent microbiological contamination of drug products purporting to be sterile.

The FDA issues inspection report forms only after identifying “significant objectionable conditions” during a visit. But Specialty Compounding, like many other compounding pharmacies cited after such inspections this year, did not respond with a voluntary recall, and the FDA did not issue a public safety notice or otherwise place public pressure on the company to initiate a recall or halt production.

Public Citizen’s letter calls on Sebelius to:

- Require the FDA to seek an injunction against Specialty Compounding to prevent the company from producing any more sterile products until it complies with all applicable federal laws and regulations;
- Request that the Inspector General conduct an investigation to determine why the FDA did not announce a recall, issue a public safety alert or seek an injunction after the March inspection; and
- Require the FDA to review its inspections of compounding pharmacies since the fall of 2012 and initiate further action against all pharmacies with sterility concerns similar to those observed at Specialty Compounding.

The letter is available at <http://www.citizen.org/hrg2148>.

###