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October 10, 2012

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

I write again regarding the recent deadly outbreak of fungal meningitis linked to spinal injections of a pain-relieving steroid, and specifically with regard to the possibility that Federal regulators may have been 'misled' by the company responsible for making the drug in question.

This outbreak, the source of which has been traced to contamination of an injectable steroid produced by New England Compounding Center, a company located in my Congressional District in Framingham, MA, has raised questions related to the adequacy of oversight of compounding pharmacies. While State regulators have primary oversight over the regulation of compounding pharmacies, GAO said in 2003¹ that State pharmacy board officials they interviewed "indicated that resource limitations affected their ability to conduct routine inspections."

Moreover, it is unclear whether New England Compounding Center was operating as a pharmacy in the first place. According to an October 10, 2012 statement made by Massachusetts Governor Deval Patrick, "What they were supposed to be doing is filling specific prescriptions for specific patients as I think any of us would understand a pharmacy to do. What they were doing instead was making big batches and selling out of state as a manufacturer would and that is certainly outside their state licensing authority." The Governor went on to say that "It does seem like the agencies both at the state and federal level may have been misled by some of the information we were given." The Governor's statement is supported by the Centers for Disease Control and Prevention, which has said that this compounding pharmacy shipped the drug to 75 hospitals and clinics in 23 states, and that about 13,000 people have been injected with the product.

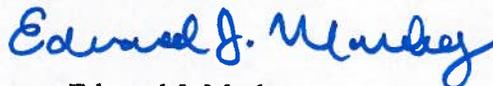
To better understand FDA's role in oversight and enforcement related to the New England Compounding Center case, I ask for your prompt response to the following questions:

¹ <http://www.gao.gov/assets/120/110456.pdf>

1. How and when did FDA become aware of the extent and scope of New England Compounding Center's activities? Please provide documentation supporting your response, including any correspondence or other materials prepared or obtained by FDA personnel related to the FDA becoming aware or suspicious of the extent of New England Compounding Center's scope of operations.
2. FDA's guidance² related to compounding pharmacies states that FDA would consider taking enforcement action against compounding pharmacies that engage in nine different specified activities, including "Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions," "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 "failing to operate in conformance with applicable state law regulating the practice of pharmacy." Did New England Compounding Center ever assert to FDA that it was not engaging in any of the nine different activities that FDA flagged as having the potential to lead to FDA enforcement actions? If so, please provide all documents or other records associated with any such assertion.
3. Does FDA believe that it was misled by New England Compounding Center, and if so, please provide all documents or other records associated with such a belief?
4. What sanctions, fines, civil or criminal penalties or actions could the FDA impose against the New England Compounding Center, both for any actions taken in contravention of law or regulation, or for any effort to mislead Federal authorities?

Thank you for your assistance and cooperation in this matter. I request that you provide a full and complete response within 15 working days or no later than close of business on October 29, 2012. Should you have any questions about this request, please have your staff contact Dr. Michal Freedhoff or Dr. Avenel Joseph of my staff at (202) 225-2836.

Sincerely,



Edward J. Markey

² <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM118050.pdf>