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October 9, 2012

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Hamburg:

I write to you regarding the recent fungal meningitis outbreak thought to be related to epidural steroid injections.

As you know, this is not the first case of fungal infection as a result of contaminated methylprednisolone acetate produced by a compounding pharmacy, nor is this the first case of contamination and adverse events resulting from compounded sterile injectable products. In this more recent case, it is my understanding that an investigation into the source of the outbreak is still ongoing; however, the New England Compounding Center (NECC) in Framingham, Massachusetts, has voluntarily recalled preservative-free methylprednisolone acetate products produced and distributed from this facility. I am aware of the fact that U.S. Food and Drug Administration (FDA) have recommended that none of the facility's compounded products be used, and further, NECC has voluntarily shut down.

While these actions may help to prevent a larger outbreak from occurring, I am deeply concerned that this outbreak may be due to a contaminated pharmaceutical produced by a company that has not been properly regulated by federal or state authorities. Therefore, I respectfully request the answers to the following questions.

1. Although the investigation is still ongoing, FDA has discovered fungal contamination of sealed vials of methylprednisolone acetate collected at NECC. How many vials of this steroid has NECC produced? How many vials of this steroid produced by NECC have been distributed? How many facilities have received vials of this steroid produced by NECC? Where are these facilities located? When were the vials linked to the outbreak distributed? How many patients have received injections of this steroid produced by NECC thus far?

2. Who first discovered the contamination of vials of methylprednisolone acetate? When was the contamination first discovered? Where was the contamination first discovered? How was contamination discovered? When was the contamination first reported to FDA? How did this contamination occur?

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3. NECC has issued a voluntary recall of the methylprenisolone acetate products and has voluntarily shut down. When was the voluntary recall first initiated? How many lots have been recalled? How many doses were included in the recall? When did NECC shut down its facility?

4. Are any vials of methylprednisolone acetate from NECC still available on the market? If yes, how many vials remain on the market?

5. What alerts regarding methylprednisolone acetate has FDA issued to health professionals? What alerts regarding methylprenisolone acetate has FDA issued to consumers? How have these alerts been transmitted to these parties?

6. With what federal and state agencies has the FDA been working on this investigation?

7. It has been reported that Massachusetts's Board of Registration in Pharmacy has had at least four previous complaints about the sterility of NECC's products – in 2002, 2003, 2011, and one complaint is currently being investigated. Were these complaints shared with the FDA? If yes, when were these complaints shared?

8. What has been the inspection history of the NECC facility? When was the NECC facility in Framingham last inspected? What were the results of that inspection?

9. Does FDA have the authority to inspect compounding pharmacies? If yes, when was the last time FDA officials have inspected NECC's facility? What were the results of that inspection?

10. It has been reported that more than 17,000 vials compounded by NECC have been recalled thus far. What does FDA consider to be legitimate forms of pharmacy compounding? What volume does FDA consider to be legitimate uses of pharmacy compounding?

11. Do compounding pharmacies, like NECC, register with FDA? If yes, how many compounding pharmacies are currently in operation?

12. Do compounding pharmacies list their products with FDA? If yes, how many products produced by compounding pharmacies are currently on the market?

13. Does FDA approve drug products produced through compounding pharmacies? Are drug products made through pharmacy compounding required to meet the safety and efficacy standard set by FDA?

14. Does FDA have sufficient authority to oversee compounding pharmacies, such as NECC, now? If so, please explain why. If no, please explain why.

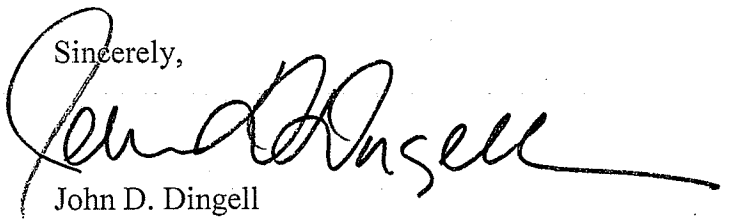
15. Does FDA need additional authority to oversee compounding pharmacies? If yes, please explain why and list the authorities needed. If no, please explain why.

While I recognize that compounding serves an important purpose and provides pharmaceuticals for individual patients with unique needs, I am concerned that NECC was operating at such a volume to be outside of what may be considered traditional pharmacy compounding. Further, I am concerned that a facility with a long history of sterility complaints was allowed to operate at such margins and endanger the lives of thousands of patients. I urge FDA to use its enforcement authority to the fullest extent possible to ensure that NECC cannot again distribute contaminated compounded drug products and to swiftly identify what other authorities are needed to ensure such an incident cannot occur again. I will be sending you further inquiry as to what FDA can do with existing regulatory authority and what additional statutory authority is needed by FDA.

Given the serious nature of this outbreak, I respectfully request that a response be sent to my office no later than October 22, 2012. Should you or your staff have any questions, please do not hesitate to contact me or Kimberlee Trzeciak of my staff at (202) 225-4071.

With every good wish,

Sincerely,



John D. Dingell
Member of Congress