

ONE HUNDRED TWELFTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

October 9, 2012

The Honorable Fred Upton  
Chairman  
Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Joseph Pitts  
Chairman  
Subcommittee on Health  
Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, D.C. 20515

The Honorable Cliff Stearns  
Chairman  
Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Upton, Chairman Pitts, and Chairman Stearns:

We are writing to request that the Committee begin an investigation and hold hearings on the ongoing meningitis outbreak caused by a contaminated injectable steroid. The steroid was manufactured by a pharmacy compounding facility, New England Compounding Center (NECC), and provided to patients at pain clinics throughout the country. This incident raises serious concerns about the scope of the practice of pharmacy compounding in the United States and the current patchwork of federal and state laws and systems that oversee this practice.

To date, there have been seven deaths among 91 people who appear to have contracted fungal meningitis from spinal injections of the steroid, preservative-free methylprednisolone

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acetate, made by NECC in Framingham, Massachusetts.<sup>1</sup> NECC shipped 17,676 vials of this dangerous drug apparently contaminated with a common fungus to 75 pain clinics in 23 states, potentially exposing thousands of patients.<sup>2</sup>

Compounding pharmacies can serve an important public health function by mixing or altering medications designed to fulfill special needs of individual patients – such as when compounders create new dosage forms for children or others who cannot tolerate the FDA-approved dosage forms. In other cases, however, compounders may simply provide a less expensive version of an FDA-approved product without having to adhere to the rigorous manufacturing standards required of FDA-approved versions.

In 1997, Congress included several provisions regulating the practice of pharmacy compounding as part of the Food and Drug Administration Modernization Act (FDAMA).<sup>3</sup> For instance, that law exempted compounded drugs from the other requirements of the Federal Food, Drug, and Cosmetic Act so long as the pharmacy was licensed in a state and made the drug pursuant to a valid prescription for an individual patient.<sup>4</sup> Court rulings subsequent to the enactment of FDAMA have raised questions about FDA's authority to regulate compounding pharmacies.<sup>5</sup> But it is clear Congress intended pharmacy compounding to be confined to these limited instances and did not intend for a compounding pharmacy to be permitted to operate as a small drug manufacturer.<sup>6</sup>

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<sup>1</sup> CDC, Multistate Meningitis Outbreak Investigation, October 7, 2012 (online at: <http://www.cdc.gov/hai/outbreaks/meningitis.html>).

<sup>2</sup> The New York Times, "Scant Oversight of Drug Maker in Fatal Outbreak" (Oct. 7, 2012) (online at: <http://www.nytimes.com/2012/10/07/us/scant-drug-maker-oversight-in-meningitis-outbreak.html?hp>).

<sup>3</sup> Section 127, Public Law 105-115.

<sup>4</sup> See Federal Food, Drug, and Cosmetic Act, Section 503A.

<sup>5</sup> In *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002), the Supreme Court held that FDAMA's advertising restrictions on compounding pharmacies were unconstitutional, but did not rule on the severability of those provisions. Two circuit courts have since issued conflicting decisions on whether those provisions are severable. See *Medical Center Pharmacy v. Mukasey*, No. 06-51583 and *Western States Med. ctr. v. Shalala*, 238 F.3d 1090 (9th Cir. 2001). A more detailed description of the legal status of Section 503A can be found online at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm134919.htm>.

<sup>6</sup> See, e.g., S. 830, H.R. Conf. Rep. No. 105-399 at 94 (Explaining that the compounding provisions in FDAMA were designed to "ensure continued availability of compounded drug products as a component of individualized drug therapy, while limiting the scope of

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Yet it appears that this is exactly NECC did: it appears it was able to essentially operate as a manufacturer, producing large quantities of the drug, shipping it to hundreds of pain clinics in dozens of states, and even flying in sales representatives to potential customers, all with no oversight from FDA.

FDA is not the sole regulatory body charged with overseeing this situation. The practice of pharmacy is chiefly regulated by the states, and NECC is licensed in all 50 states. Although the Massachusetts Board of Registration of Pharmacy has legal authority over the company – and in 2006 signed a consent agreement with the company that required an inspection by outside auditors – it is not clear the extent to which the state conducted ongoing oversight and inspections to maintain safety or whether the state was even aware of NECC’s interstate sales practices.

Careful oversight is crucial because of the possibility that pain clinics and doctors are using compounded drugs instead of safer FDA-approved versions because the compounded versions are more profitable under Medicare – a concern Rep. Waxman first raised almost a decade ago – and under private insurance plans.<sup>7</sup> According to the *New York Times*, NECC was selling the compounded version of the drug for a price that was as much as 45% lower than the price of the FDA-approved drug from the manufacturer. Despite these wholesale price differences, the *Times* reported that Medicare and many private insurers’ reimbursement rates for the drug were the same, regardless of the source, meaning there may have been a significant profit motive for doctors and clinics to use the compounded product.<sup>8</sup>

There are other important policy issues raised in this case. Did real or apparent shortages of the FDA-approved version of the drug encourage use of the compounded product, and if so, what can be done to address this problem? FDA has not approved the drug for epidural use. How strong is the scientific basis for using the drug in this way? Were there legitimate medical reasons for using the compounded product? Did the lack of clear federal or state authority result in delays in identifying the initial source of the outbreak? Were patients and doctors aware that they were using or being prescribed compounded products?

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compounding so as to prevent manufacturing under the guise of compounding.") (online at: <http://www.gpo.gov/fdsys/pkg/CRPT-105hrpt399/pdf/CRPT-105hrpt399.pdf>).

<sup>7</sup> Letter from Ranking Member Henry A. Waxman to the Honorable Tommy Thompson (Sep. 28, 2004).

<sup>8</sup> The New York Times, “Scant Oversight of Drug Maker in Fatal Outbreak” (Oct. 7, 2012) (online at: <http://www.nytimes.com/2012/10/07/us/scant-drug-maker-oversight-in-meningitis-outbreak.html?hp>).

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A committee investigation and hearing should address these important issues. Among the key questions we should investigate are the following:

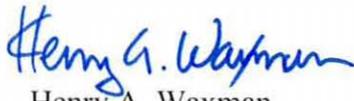
- Did FDA know that NECC was manufacturing and shipping the over 17,000 vials of steroid to 23 states in this case? If so, did FDA have clear authority to act in this case, and did the agency take appropriate action before and after the outbreak?
- What impact have the court rulings subsequent to FDAMA had on FDA's pharmacy compounding authority under section 503A of the Federal Food, Drug, and Cosmetic Act? Is legislation necessary to provide FDA with additional authority to prevent future outbreaks?
- What state laws governed NECC's activities? Did the Massachusetts Board of Registration of Pharmacy know NECC was manufacturing and shipping the steroid in such large quantities? If so, did the Board take any actions to prevent NECC from doing so? If not, why not? Are there state laws – in Massachusetts or in other states where NECC was licensed – that prohibit this practice?
- What practices did NECC use to ensure safety of their sterile injectable and other drug products, and was NECC aware of potential safety concerns regarding its products?
- What practices did NECC engage in to sell their products to pain clinics and other health practices for this unapproved use?
- Why are pain clinics around the country ordering compounded steroids instead of the FDA-approved version? What role, if any, do Medicare and private insurers' reimbursement practices play in such decisions by health providers? How many other types of medical practices purchase compounded medications and why do they do so?
- Was NECC serving a legitimate medical need in this case? Was the company helping to alleviate drug shortages, and if so, what caused these shortages?

We request that you join us in promptly sending letters of inquiry to the FDA, NECC, the Massachusetts Board of Pharmacy, and pain clinics that played a role in this outbreak. We also request that you immediately schedule hearings to further explore this public health threat.

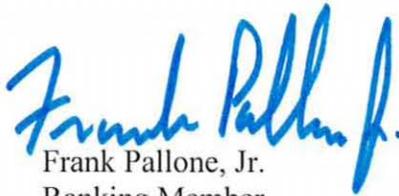
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We look forward to working with you in a timely way on this critical public health issue.

Sincerely,



Henry A. Waxman  
Ranking Member



Frank Pallone, Jr.  
Ranking Member  
Subcommittee on Health



Diana DeGette  
Ranking Member  
Subcommittee on Oversight  
and Investigations