

ONE HUNDRED TWELFTH CONGRESS
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House of Representatives
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Opening Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
Hearing on “The Fungal Meningitis Outbreak: Could It Have Been Prevented?”
Subcommittee on Oversight and Investigations
November 14, 2012

Thank you, Mr. Chairman for holding this important hearing and for working with the Democrats in making this a bipartisan hearing.

We are convening this hearing amidst an ongoing public health tragedy. The New England Compounding Center shipped across state lines over 17,000 vials of a steroid—an untold number of which were contaminated with a dangerous fungus. These injections have so far killed 32 people and sickened 438 people with meningitis.

This is a tragedy that has brought unspeakable devastation to so many families. That’s why I’m very grateful, Mrs. Lovelace, for you being here today. It takes a lot of courage to come forward to speak about this, but it’s important that you do so.

The facts we have learned to date reveal are very troubling.

First of all, let’s not lose sight of the wrongdoer as we go around blaming the regulators. The regulators deserve blame, but the primary blame, in my mind, is the company.

We had to subpoena the former President of NECC, Barry Cadden, to be here to testify about how this company handled the matter. And what we learned was that even ten years ago, people who were regulating the company found that there were sloppy practices that could lead to a public health problem. In fact, the FDA, ten years ago, knew that there could be a possible meningitis outbreak. And it wasn’t corrected by the company. And the company went about its ways, I suppose always telling people that they were going to behave better.

That doesn’t mean that we don’t insist our regulators watch out for the public interest. And I’m pleased both sides of the aisle are talking about the need for regulation, and what we need to do is straighten out who has responsibility to be sure it’s clear.

The Massachusetts Board of Registration in Pharmacy and other state regulators and healthcare providers identified the problem at the company. The Massachusetts Board inspected the facility after the outbreak. They found a horrifying list of problems, and it's shameful that those who ran this facility allowed this to happen.

The Massachusetts Board had primary jurisdiction. No one questions that. The State had primary jurisdiction to regulate the company. They were informed numerous times of problems. They even did their own investigation identifying serious issues. But the Board never took actions tough enough to stop the New England Compounding Center from putting consumers at risk.

Finally, we have FDA. FDA was informed of problems, they conducted investigations, and they raised concerns about the NECC. But the most aggressive action the agency took was a warning letter sent in 2006. That letter and previous attempts by FDA to inspect and review NECC actions were met with stubborn refusals and challenges to FDA's authorities.

And the FDA is questioning their authority. Congress acted specifically in 1997 to limit the authority of the FDA. Then there was a Supreme Court case that left the FDA in doubt to exactly the authority it had left.

This is a tragedy that demands action from this Congress. Mr. Markey has a bill that is a good start.

I think we want to work during this lame duck session to pass bipartisan legislation that preserves compounding pharmacies' abilities to operate safely in appropriate situations, yet gives FDA the clear and effective authority to prevent compounders from becoming dangerous drug manufacturers, like NECC.