Testimony of Dr. JudyAnn Bigby, Secretary
Executive Office of Health and Human Services
Joint Hearing of the House Committees on Public Health,
Public Safety and Post-Audit Oversight
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Chairman Sanchez, Chairman Naughton, Chairman Linsky, and members of the Committee, good morning. Thank you for inviting me here today.

I am Dr. JudyAnn Bigby, Secretary of the Executive Office of Health and Human Services.

Our Interim Commissioner of the Department of Public Health, Dr. Lauren Smith, is unable to attend, as she is testifying before the United States Congress on the very matter that brings us here today -- the fungal meningitis outbreak that originated from the New England Compounding Center (NECC).

This is one of the greatest health care tragedies in my memory and it represents an incredible violation of trust for patients across the nation. It is a travesty that sick people in need of medical care instead received treatment that made them more ill. This has been devastating for families.

The victims and their families are in the forefront of our thoughts. I know you are questioning what happened, and I am too. These past few months have weighed heavily on me, both as the Secretary of HHS and as a doctor. I have committed my life to providing health care to others and protecting the most vulnerable members of society. It pains me to know that this tragedy impacted so many people who trusted the health care system and those responsible for overseeing it. And I take seriously the expectation that the agencies in Health and Human Services deliver high quality services and closely regulate these industries.

These events have uncovered unacceptable breaches on the part of individuals, gaps in regulatory processes and above all, a need for immediate and lasting solutions. I am committed to answering the questions: how could this have happened and how do we prevent it from ever happening again?

There are individuals at NECC that bear a tremendous amount of personal responsibility for these tragic outcomes. I also fully acknowledge that the Board of Pharmacy and its staff should have done better. We have removed employees who failed to act and displayed serious lapses in judgment, and we are working to address other shortcomings and implement improvements quickly.

We are here today to begin the process of renewing the public's trust, and yours.

For nearly two months, our Department, alongside the FDA, has conducted a joint investigation into New England Compounding Center, the source of this devastating fungal meningitis outbreak. When I learned that Barry Cadden also owned and operated Ameridose and Alaunus, I directed DPH to begin an investigation at those companies, which are now shut down.

NECC knowingly disregarded sterility tests, prepared medicine in unsanitary conditions and violated their pharmacy license, endangering thousands of lives as a result. NECC bears the primary responsibility for the harm they have caused with these actions.

NECC was first licensed by Massachusetts in 1998. Since then, NECC and its owner, Barry Cadden, have been the subject of numerous complaints, resulting in a series of investigations by the state and the FDA. These investigations led to a proposed reprimand and probation in 2004. Inexplicably, the Board and its staff moved to weaken this proposal in 2006, allowing NECC to continue to operate without disciplinary actions, pending an independent evaluation. Dr. Biondolillo will provide more details about the chronology of these events.

Multiple times between 2002 and 2012 Board staff failed to take decisive action on NECC complaints that came to their attention. This raises the question of whether they could have prevented all or some of these tragic events. Poor judgment, missed opportunities and a lack of appropriate action allowed NECC to continue on their troubling course.

We have removed those responsible from their jobs.

From the early days of this outbreak, we have acted swiftly and decisively. The Board of Registration in Pharmacy secured a surrender of NECC's license, shut down its operations and forced a recall of all NECC products.

The Board then moved to permanently revoke NECC's license, as well as the individual licenses of the three principal pharmacists who ran NECC, so they may never practice pharmacy in Massachusetts again.

While taking these forceful and necessary actions, DPH has reexamined the approach to regulating this industry. Massachusetts state regulations, while comparable to most states, needed to be strengthened.

On November 1st, the Board approved a series of emergency regulations that enhance monitoring to bring greater scrutiny to this industry. The new regulations stem from the lessons learned from this tragedy and require sterile compounding pharmacies in Massachusetts to report volume and distribution figures to the state, for the first time. This alerts us to any pharmacy that is acting like a manufacturer which requires an FDA license.

These regulations also require all licensed pharmacies to report to the state when they are the subject of investigations by or received a complaint from any other states or the federal government. This will allow the Board to know when other entities have identified issues with Massachusetts licensed pharmacies.

Since the outbreak, the Board of Pharmacy has begun unannounced inspections to review all sterile compounding pharmacies. Teams are in the process of conducting additional inspections as we speak. DPH also issued a letter to all hospitals, ambulatory surgery centers, clinics and long-term care facilities, reminding them that they must produce patient-specific prescriptions to sterile compounding pharmacies in order to receive products from them.

To further strengthen our oversight over sterile compounding pharmacies, we need to explore changes to state law. I look forward to working with you through our Special Commission to examine these issues, and we have named Christian Hartman, an expert in pharmacy practice and medication safety, as its chairman. The Commission will include legislators appointed by leadership of the General Court, and experts in pharmacy practice, regulatory affairs, and patient safety. We will look to best practices in other states and consider the interplay between state and federal authority. The first meeting of the Commission is scheduled for this month. This body will report its findings to the Governor by December 31.

I understand you are asking the question, “Who should ultimately be held accountable for these lapses?” As Secretary, I share responsibility for oversight of these core government functions and have acknowledged that some of these lapses were preventable and all were unacceptable.

I am committed to a high level of oversight for all of the Commonwealth’s health and human services agencies.

Looking to the future, I will be working actively with Interim Commissioner Smith to identify a departmental leader to address issues of quality assurance and safety across the department which is responsible for regulating critical areas ranging from health care to environmental safety. The Department will examine and standardize policies and procedures, strengthen cross-training of inspectors, surveyors, and other staff to enhance their ability to fulfill their roles, and work with state and federal regulators to ensure actions are well coordinated.

Additionally, working with the Commission, we will examine the structure of the health professions boards. Historically the boards have been predominantly made up of the people who represent the professions subject to the Board’s oversight. While it is important that professional expertise be represented, there needs to be a better balance of oversight to include members who are free of conflict. All representatives must embody the principles of quality, safety, and transparency.

The victims and their families remain in our thoughts and we must do everything we can to ensure that nothing like this happens again.

Thank you. I look forward to working with you to identify solutions and I commend you all for moving swiftly to examine these critical issues.

I also know that you have asked for materials related to the operational and procedural practices of EOHHS and DPH. We have provided materials that speak to that, and I'm happy to answer questions.