Testimony of Dr. Lauren Smith, Interim Commissioner
Massachusetts Department of Public Health

Senate Committee on Health, Education, Labor, and Pensions

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Good morning,

Chairman Harkin, Ranking Member Enzi, members of the Committee, thank you for having me here today. My name is Dr. Lauren Smith, I am the Interim Commissioner of the Massachusetts Department of Public Health and I welcome the opportunity to have this discussion.

I want to say from the outset that my thoughts are with the victims and families affected by this tragic outbreak. As a mother, a pediatrician, and a public health leader, I have devoted my life and career to protecting the health of others. Have no doubt that these events invoke in me the same outrage that you and the rest of the public feel. The natural first question we all ask is "How could this possibly have happened?" The necessary second question is "What can we do to ensure that this terrible situation does not happen again?"

For nearly two months, our Department has conducted a joint investigation of New England Compounding Center (NECC), alongside our federal partners at the Food and Drug Administration (FDA), to answer these questions.

NECC is a Framingham, Massachusetts-based pharmacy that compounds sterile medications. It was identified as the source of the devastating fungal meningitis outbreak that has sickened hundreds and led to dozens of deaths across the country. For many of you, and for those with cases among your constituents in particular, I know these losses hit close to home.

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

I was given the responsibility as interim commissioner less than three weeks ago, to lead my department during this crisis. And like you, I have spent the last several weeks trying to put together the pieces of this troubling puzzle.

Although the majority of these events happened in the previous administration and well before I came to the Department, I offer the following chronology based on a review of documents and reports from the time.

Let me begin by noting that by statute, the Massachusetts Board of Registration in Pharmacy, supported by the Department of Public Health's Division of Health Professions Licensure, has primary responsibility for oversight of the practice of pharmacy in the Commonwealth.

The Board of Pharmacy is an independent body, with 11 members appointed by the Governor. The Board has the responsibility and legal authority to license and regulate pharmacies and pharmacists. DPH staff investigators, lawyers, administrators, and an executive director support the Board's operations.

The Massachusetts Board of Registration in Pharmacy's interaction with NECC began on July 16, 1998, when it obtained its initial license. On February 2, 1999, the Board received the first complaint against NECC, which alleged that the pharmacy had provided a prescriber with pre-printed prescriptions that specifically listed NECC medications. State law prohibits pre-printed prescriptions. Prescriptions are required to be patient-specific, and based upon the patient's diagnosis, medical history, allergies, tolerance, and the specific constellation of symptoms that the patient is presenting. This complaint was resolved in October 1999 with an informal reprimand letter, a non-disciplinary action.

In April 2002, working with the FDA, the Board visited NECC and obtained records related to a recent MedWatch report concerning betamethasone, a compounded steroid suppository. The FDA investigator met with Barry Cadden, owner of NECC, and conducted an inspection on April 9, concerning procedures, sterility and record keeping.

In October 2002, the Board initiated a joint investigation with the FDA at NECC related to the April 2002 betamethasone complaints as well as MedWatch reports associated with the use of methylprednisolone acetate, the injectable steroid medication implicated in this current outbreak. The MedWatch reports pertained to two patients who received the steroid and experienced pain and headaches and were hospitalized with meningitis-like symptoms. Laboratory tests from these investigations identified subpotency of betamethasone and superpotency of methylprednisolone acetate. The FDA also noted contamination of one lot of methylprednisolone acetate with bacteria. These investigations continued into 2003.

Also in 2002, Board of Pharmacy member Karen Ryle convened a Task Force to study Board oversight of the compounding pharmacy industry. Barry Cadden served on this Task Force, which met for nearly two years. The Task Force

discussed proposals to change regulations around compounding, but records do not show whether formal recommendations were made, and the Board did not adopt new regulations.

In February 2004, the Board conducted a follow up inspection of NECC and noted that all deficiencies surrounding sterility, safety, quality and procedures from the 2002-2003 investigations had been resolved. Just weeks later, however, the Board received a complaint, from a pharmacist in Wisconsin, expressing concerns with the safety of a topical anesthetic product. The complaint alleged that NECC advised the pharmacy to unlawfully use a staff member's name rather than an individual patient's name in filling a prescription. The Board then in place resolved this complaint with a disciplinary warning letter on September 30, 2004.

Based on this series of investigations, in September 2004, the Board voted unanimously to sanction NECC with a reprimand, a three-year probation, and a requirement that Barry Cadden obtain additional training in sterile compounding. NECC objected to these sanctions, but the Board reaffirmed this approach through an additional unanimous vote on November 23, 2004.

More than a year later, on January 10, 2006, NECC entered into a non-disciplinary consent agreement with the Board that was significantly weaker than the earlier version. The signed consent agreement stipulated a one-year probation to be stayed with the condition that NECC hire an independent evaluator. The Board's staff identified Pharmaceutical Systems, Inc. (PSI) as the evaluator to conduct inspections of NECC's compounding practices.

Despite interviews with Board and staff members involved with these decisions and a thorough review of the limited records retained from this period, troubling questions remain about what influenced the more lenient consent agreement resolution, given NECC's track record. I will not be satisfied until we know the full story behind this decision.

What we know now is that from January to April 2006, the independent evaluator PSI conducted an assessment of NECC's compliance with United States Pharmacopeia Standards, and oversaw development of policies and procedures. PSI also issued recommendations for process improvement and provided training for NECC staff. An April 7, 2006 report from PSI described NECC's compliance with the evaluation.

Our investigation has revealed that in late April 2006, some Board of Pharmacy and Health Professions Licensure staff, including the Board's executive director and legal counsel, learned that PSI executives were convicted of federal crimes related to defrauding the FDA and selling unapproved sterilization equipment to hospitals. However, we have found no evidence to indicate that the Executive Director or staff attorney of the Board provided this crucial information to the

Board. Nor did they see fit to send inspectors back to NECC in 2006 to determine if they were fulfilling the requirements of the corrective action plan.

In May 2006, the Board voted to affirm that NECC was in compliance with the terms of the consent agreement, thus accepting PSI's findings in overseeing NECC's compliance.

Consistent with Board policy at the time, which was to inspect pharmacies only upon a change in licensure status or upon receipt of a complaint, the next time a Board investigator returned to the pharmacy was five years later on May 24, 2011 to inspect NECC following its renovation and expansion. This inspection included a full review of the facility space, operations, sterility protocols, and compliance with United States Pharmacopeia among other factors. The inspector found no evidence to suggest that NECC was violating patient-specific prescription requirements, and no deficiencies were cited.

In March 2012, the Board received a complaint pertaining to an insufficiently potent eye anesthetic distributed by NECC. This complaint focused on the potency of the medication but did not reference sterility concerns. This investigation continues.

In July 2012, some of the same staff members who failed to inform the Board of the issues surrounding PSI received a report from the Colorado Board of Pharmacy documenting violations of Colorado and Massachusetts pharmacy laws. The information provided to the Board executive director and legal counsel by Colorado showed that NECC had distributed bulk shipments of drugs to many hospitals in that state between 2010 and 2012 without patient–specific prescriptions, in violation of NECC's Colorado and Massachusetts licenses. The Colorado Board of Pharmacy issued a cease and desist order to stop NECC from engaging in the unlawful distribution of prescription drugs in the state in April 2011. Colorado informed the FDA of the adverse action, and provided them with the report, supporting evidence, and copy of the order. However, there is no record of Colorado providing similar notice to the Board or DPH.

Colorado contacted Board staff in July 2012 because NECC was violating the April 2011 cease and desist order by continuing to prepare and dispense bulk shipments without patient-specific prescriptions. However, after receiving the July report, both the executive director and legal counsel failed to order an investigation, inform the Board of the complaint, or take any other action on the Colorado complaint.

The first two lots of contaminated methylprednisolone acetate linked to the meningitis outbreak were prepared in May and June of 2012. The Colorado report was received two weeks prior to the production and shipping of the third lot of contaminated vials, which were prepared in August. Though issues of contamination with NECC products were not included in the Colorado report,

given NECC's history and the evidence from Colorado that the company was violating Massachusetts pharmacy regulations, prompt action was warranted.

The individuals responsible for this failure to act have been removed from their jobs. These steps are consistent with the swift and decisive actions of DPH since we became aware of the outbreak.

Late in the evening of September 24th, the Tennessee Department of Health notified our Department about a cluster of six exceedingly rare fungal meningitis cases. All six cases shared common risk factors, including an epidural injection of a steroid prepared by NECC. The Massachusetts DPH secured a list of medical facilities in 23 states that had received shipments of the steroids from three suspect lots identified by the Centers for Disease Control and Prevention. A day later, we secured a recall of those three lots, totaling 17,676 vials, and began our on-site investigation at NECC.

On October 1st, we were joined on-site at NECC by the FDA and commenced our joint investigation. Among a list of troubling findings, investigators observed visible black particulate matter in sealed vials that had been returned to NECC through the recall. Several batches of the drugs had been shipped by NECC prior to the completion of internal sterilization tests. Investigators also found evidence that NECC had been dispensing medication in bulk shipments rather than filling a patient-specific prescription for each dose dispensed.

We secured a surrender of NECC's license, shut down its operations and issued a total recall of NECC products.

Our aggressive investigation not only focused on NECC, but also companies with shared ownership. On October 10, we secured the voluntary suspension of operations of Ameridose, a Westborough, Massachusetts drug manufacturer also owned by Barry Cadden. This closure allowed for a full investigation by DPH and the FDA, and eventually led to a total recall of Ameridose products. Ameridose remains closed as the investigation continues.

The Board of Registration in Pharmacy 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. The Board also issued a cease and desist order to all pharmacy staff at NECC to bar them from any compounding activities.

While taking these forceful and necessary actions, we have also reexamined our own approach to regulating this industry.

It is clear that the compounding pharmacy industry has changed drastically from the days of neighborhood businesses that served a local clientele. We

recognized that our state regulations needed to be strengthened to address the realities of this industry, which has evolved over time, and again we took action.

On November 1, Massachusetts enacted a series of emergency regulations to bring greater scrutiny to the industry and ensure that we have the tools to prevent such a tragedy from happening again.

Our 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 will alert us to any pharmacy that is acting like a manufacturer by producing medication on an industrial scale, which requires an FDA license and the additional scrutiny and adherence to high manufacturing standards for safety and quality that FDA oversight requires. We are also requiring all licensed pharmacies to report to the state when they are the subject of investigations by any other states or the federal government. This will allow us to know when other entities have identified issues with pharmacies in Massachusetts, including other states that issue non-resident licenses to pharmacies in Massachusetts.

The Board of Pharmacy's prior approach to inspecting pharmacies when they first apply for a license, and then again only if they move or if there is a complaint, though not out of line with the approach used by most states, is no longer sufficient to keep pace with the changing nature of the industry. Since the outbreak we have begun unannounced inspections of the state's 25 sterile compounding pharmacies to review how they function when they are not aware that an inspection is scheduled. Teams are in the process of conducting additional inspections as we speak.

Massachusetts sterile compounding pharmacies have also been required to attest under penalty of perjury that they are meeting all state laws and regulations.

To further strengthen our oversight over sterile compounding pharmacies, we need to explore changes to state law. We created a Special Commission, and named Christian Hartman, an expert in pharmacy practice and patient safety, as its chairman. The Commission will include members of the Massachusetts' Legislature and experts in pharmacy practice, regulatory affairs, and patient safety. We will look at best practices in other states, explore new ideas, and consider the interplay between state and federal authority. The first meeting of the Commission is scheduled for this month and this body will report its findings to the Governor by December 31.

As we work to raise standards in Massachusetts, we urge Congress to act to strengthen federal oversight. It is clear that the patchwork of disparate state regulations is not enough to keep the public safe.

Congressman Markey's leadership in putting forward legislation is laudable and would help fill what he has aptly called a "regulatory black hole" that exists between state and federal oversight. Congressman Markey's report also shows that at least 34 states have had deaths or illnesses stemming from violations at compounding pharmacies nationwide before this current meningitis outbreak. We join Congressman Markey in supporting immediate federal action.

As a pediatrician who has looked into the faces of children and families at their most vulnerable moments, I understand the faith and trust that patients place in our health care system. I would never have contemplated that a medicine I might prescribe to my patients could actually be the source of such harm. We must use these terrible events as an impetus to work together, as public health officials and legislators, to reaffirm the trust that has been broken by the circumstances surrounding this outbreak.

I pledge to you that Massachusetts will continue to do whatever we can, make any changes, and identify any areas of new law to make sure something like this never happens again. We intend to identify responsibility but also focus on reforms that will be effective and lasting.

As the victims and their families remain always in our thoughts, we accept the challenge of reform that lies ahead.

Thank you. And I am happy to take your questions.