

STATEMENT OF INTERIM COMMISSIONER DR. LAUREN SMITH ON NECC INVESTIGATION

BOSTON -- Tuesday, November 6, 2012 – The following is a statement from Massachusetts Department of Public Health (DPH) Interim Commissioner Dr. Lauren Smith:

Today I am announcing a development in our ongoing investigation into NECC and administrative changes at the Massachusetts Board of Pharmacy. These personnel actions stem from troubling information that has come to light during our ongoing review of the Board's oversight of NECC.

We have discovered a Colorado Board of Pharmacy complaint against NECC, which was forwarded to James D. Coffey, Director of the Massachusetts Board of Pharmacy, on July 26, 2012.

The information shared by Colorado showed that NECC had distributed manufactured 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 contacted the FDA with this information and the FDA confirmed to them that NECC was not a licensed manufacturer.

As seen in the attached documents, this information was provided in detail by Colorado to Mr. Coffey in July, which he then forwarded to Board attorney Susan Manning and Board inspectors. The director of the Board is responsible for ordering investigations. Mr. Coffey failed to order an investigation or take any other action on the Colorado complaint.

It is incomprehensible that staff did not act on the Colorado complaint given NECC's past, and their responsibility to investigate complaints. Following the outbreak, staff also failed to disclose the existence of Colorado's complaint to leadership at DPH.

As a result of these findings, we have terminated James Coffey and placed Susan Manning, a member of a bargaining unit, on administrative leave pending the final conclusions of our investigation. We have identified highly qualified individuals to fill these positions and the important work of the agency will continue with even greater resolve at this critical juncture.

There is no evidence at this time that staff informed Board of Pharmacy members about the Colorado issues. We continue to interview all Board members as part of

our investigation into their handling of this situation and will not hesitate to make further changes and personnel actions if we deem them to be necessary.

Since starting as interim commissioner, I have promised and delivered swift and decisive actions.

I find the actions of NECC reprehensible. We have the right to expect that all companies producing medication for use in delivering health care to comply with laws designed to protect patient safety. But I also expect the staff charged with overseeing these companies to perform their duties with the highest standards of quality and supervision. I believe that failed to happen here.

This investigation and the Department's thorough response will not stop until we have a complete understanding of what happened, assign accountability where it is warranted and can be certain the failures that led to this tragedy never happen again.

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FOR IMMEDIATE RELEASE:

November 7, 2012

FURTHER INFORMATION:

Anne Roach (617) 624-5006

**STATEMENT OF INTERIM COMMISSIONER DR. LAUREN SMITH ON NECC
INVESTIGATION**

BOSTON -- Wednesday, November 07, 2012 -- The following is a statement from Massachusetts Department of Public Health (DPH) Interim Commissioner Dr. Lauren Smith:

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We have discovered a Colorado Board of Pharmacy complaint against NECC, which was forwarded to James D. Coffey, Director of the Massachusetts Board of Pharmacy, on July 26, 2012.

The information shared by Colorado showed that NECC had distributed manufactured 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 contacted the FDA who confirmed that NECC was not a licensed manufacturer.

As seen in the attached documents, this information was provided in detail by Colorado to Mr. Coffey in July, which he then forwarded to Board attorney Susan Manning and Board inspectors. The director of the Board is responsible for ordering investigations. Mr. Coffey failed to order an investigation or take any other action on the Colorado complaint.

It is incomprehensible that Mr. Coffey and Ms. Manning did not act on the Colorado complaint given NECC's past, and their responsibility to investigate complaints. Following the outbreak, staff also failed to disclose the existence of Colorado's complaint to leadership at DPH.

As a result of these findings, we have terminated James Coffey and placed Susan Manning, a member of a bargaining unit, on administrative leave pending the final conclusions of our investigation. We have identified highly qualified individuals to fill these positions and the important work of the agency will continue with even greater resolve at this critical juncture.

There is no evidence at this time that staff informed Board members about the Colorado issues.

I find the actions of NECC reprehensible. We have the right to expect that all companies producing medication for use in delivering health care to comply with laws designed to protect patient safety. But I also expect the staff charged with oversight to perform their duties to the highest standards. That failed to happen here.

Since starting as interim commissioner, I have promised and delivered swift and decisive actions. This investigation and the Department's thorough response will not stop until we have a complete understanding of what happened, assign accountability where it is warranted and can be certain the failures that led to this tragedy never happen again.

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