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November 1, 2012

The Honorable Edward J. Markey
United States House of Representatives
Rayburn House Office Building 2108
Washington, DC 20515

Dear Congressman Markey:

This letter is to express my strong support for your recently announced legislation the *Verifying Authority and Legality in Drug Compounding Act of 2012* (the Valid Act).

Your legislation and your leadership are critical to closing a regulatory gap created by the fact that over the years and for a variety of reasons, some pharmacies have transformed from neighborhood drug stores into large-scale manufacturers that sell products across state lines. As you know, normally interstate commerce is a matter of federal oversight, but for various reasons there has been little of that over the years. Thankfully, you are leading the charge to strengthen FDA's oversight to reflect this new reality, and your legislation represents an important step forward on this front.

I am pleased to report that we are taking actions to respond on the state level as well. Immediately following the meningitis outbreak at the end of September, our Department of Public Health took decisive steps to isolate and remove the contaminated substances. The Board of Pharmacy, under the direction of DPH, shut down operations at New England Compounding Center (NECC) and its sister operations, suspended the

pharmacist licenses of company leaders, and secured a nationwide recall of the products.

We worked with health care professionals and boards of public health to notify patients who received NECC products. We reminded the Commonwealth's 25 other compounding pharmacies that make sterile injectable medications that state rules require them to have a patient-specific prescription in hand for each treatment they produce, and to follow nationally-accepted pharmacy standards.

Last week the Board of Pharmacy voted to permanently revoke NECC's license to operate in Massachusetts, as well as the licenses of the company's three principal pharmacists.

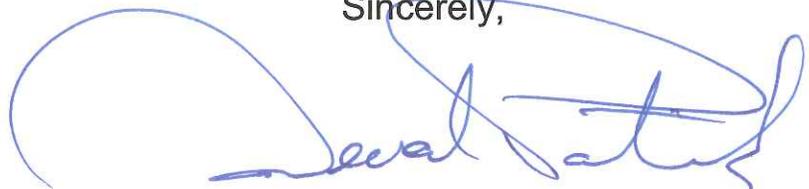
Today they approved emergency regulations to enhance oversight of compounding pharmacies. While the Commonwealth's rules overseeing compounding pharmacies are consistent, and in some cases more stringent, than those in place in other states, for the first time we will now be able track volume and distribution at compounding pharmacies to determine if they are operating more like a manufacturing facility subject to FDA licensing. The emergency regulations also require pharmacies to report to the state when they are the subject of an investigation by another state or federal authority, among other requirements, and create stiffer penalties if pharmacies fail to comply with rules and regulations.

Additionally, we are in the process of forming a special commission to examine best practices in other states and potential changes at the federal level, and to advise us on what changes we should make in state law through legislation to further assure the public's safety.

I know like me you believe no one should live in fear that medicine is unsafe. Your legislation will close the regulatory gaps thousands of compounding pharmacies nationwide fall through right now, and deliver much needed patient protections that states cannot provide on their own.

I commend you for your decisive actions and look forward to continuing to work with you to ensure patient safety.

Sincerely,

A handwritten signature in blue ink, appearing to read "Edward J. Markey", written over a large, loopy blue scribble that spans across the signature and extends to the left.