



UNITED STATES SENATE
WASHINGTON, D.C. 20510

October 11, 2012

The Honorable Eric H. Holder, Jr.
The Attorney General
Washington, D.C. 20530

Dear Mr. Attorney General:

I know that you are as deeply troubled as I am by the tragic deaths and sicknesses caused by the apparent wrongdoing of the New England Compounding Center (NECC). I am concerned by the increasing amount of information available publicly and privately that indicates willful violations of law as well as basic standards of care by the NECC.

In light of recent reports that the NECC may have flagrantly and blatantly violated both state and federal law, directly contributing to contamination of steroid products distributed nationally across state boundaries, I request that the Department of Justice begin a criminal investigation of the company, its officers and employees, and others who should be held accountable. Relevant to considering possible criminal enforcement are the horrific consequences of this tragedy – at least 169 victims, including 14 deaths, as well as thousands still at risk during the incubation period for fungal meningitis. The NECC's apparent history of problems is also pertinent. In 2006, the FDA issued a warning to the pharmacy to change its practices, which seems to have been disregarded. In Massachusetts, each compounded medication requires an individual prescription. However, this requirement was allegedly ignored by the NECC.

Previously, I have called for new legislative authority, giving the FDA enhanced inspection and enforcement power that would help prevent such tragedies in the future. In some respects, compounding pharmacies like the NECC, which often make drugs in large quantities without specific individual prescriptions, engage in manufacturing that is effectively lacking in oversight. They operate in a regulatory black hole – a legal netherworld – without the regulation generally applied to pharmaceutical drug makers assuring that products are safe and effective.

Regardless of any possible ambiguity regarding regulatory authority, this company seems to have committed misconduct, potentially involving misrepresentation, fraud, and other criminality. One claim is that the NECC knowingly misled governmental authorities, as well as health care providers. Such misstatements may constitute mail or wire fraud under state and federal law, and other possible legal violations.

I ask that the Department of Justice take the lead in coordinating investigations and prosecutions that may include state as well as federal authorities. Obviously, I have reached no conclusion as to criminal liability, but there seem to be sufficient, credible factual allegations and harm to warrant this request. I appreciate your interest and concern.

Sincerely,

A handwritten signature in blue ink that reads "Richard Blumenthal".

Richard Blumenthal
United States Senate

