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**DeLauro, Lowey Introduce Legislation Strengthening Oversight of
Compounding Pharmacies**

Bill Would End Current State-by-State, Patchwork System

WASHINGTON, DC—Representatives Rosa DeLauro (D-CT) and Nita Lowey (D-NY) introduced legislation today to improve the failed regulatory framework currently governing compounding pharmacies and clarify the Food and Drug Administration (FDA)'s ability to oversee such pharmacies. A compounding pharmacy in Massachusetts was responsible for the meningitis outbreak that sickened over 500 people and caused at least 36 deaths.

“I wish this legislation were not necessary, but recent, tragic events have proven that it is,” **DeLauro** said. “The actions of the New England Compounding Center have made clear that strong Federal authority is necessary to ensure patients know they are receiving safe compounded drugs. It has also become clear that federal and state regulators must better communicate to identify trouble facilities and leverage their resources to protect patients.

“Yesterday’s announcement that multiple NECC products were contaminated simply underscore that this was not an isolated incident. We must end the current regulatory morass so that no more lives are placed at risk.”

Lowey said: “As recent events have made clear, it is critical to ensure compounding pharmacies are operating safely and the products consumers receive will improve - not jeopardize - their health. Federal oversight is critical to identify and correct potential problems and keep consumers safe.”

The Supporting Access to Formulated and Effective (S.A.F.E.) Compounded Drugs Act would:

- Require compounding pharmacies to register their facility with the FDA
- Ensure patients know they are receiving a compounded drug
- Require compounded drugs to be labeled appropriately
- Establish a FDA database of information on compounding pharmacies to inform oversight by the FDA and appropriate state regulators
- Ask the FDA to set minimum production standards
- Direct the FDA to offer training opportunities for state regulators
- Seek additional information on third party accreditation and the various models used by state regulators
- Improve communication between federal and state regulators to facilitate more comprehensive inspections

DeLauro, a senior member of the committee responsible for funding the FDA, announced she would introduce the legislation on October 9, the same day she wrote to Health and Human Services Secretary Sebelius on the issue. On October 19 she and Representative Sanford Bishop wrote to Sebelius and Veterans Affairs Secretary Shinseki to ensure the safety of pharmaceuticals given to participants in Medicare, Medicaid, and the Veterans Health Administration.

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DeLauro.House.Gov