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Markey Announces Legislation to Strengthen Compounding Pharmacy Regulations

VALID Compounding Act will give FDA authority it needs to ensure the safety of the compounding pharmacy sector nationwide

WASHINGTON, D.C. – Today, Congressman Edward J. Markey (D-Mass.) announced legislation he plans to introduce tomorrow that will strengthen federal regulations for compounding pharmacies. The New England Compounding Center (NECC), a compounding pharmacy located in Rep. Markey’s Congressional District, has been found to be the source of contaminated injectable steroids that have led to 28 deaths and 377 illnesses in 19 states. The Verifying Authority and Legality in Drug (VALID) Compounding Act will give the Food and Drug Administration (FDA) clear, new authority to oversee compounding pharmacy practices throughout the country.

“Compounding pharmacies have been governed by fragmented regulations for too long, leading to the worst public health disaster in recent memory,” said Rep. Markey, senior member of the Energy and Commerce Committee. **“The VALID Compounding Act ends this regulatory black hole by giving the FDA new, clear authority to protect patients and oversee these companies. I look forward to working with my colleagues in Congress on a bipartisan basis to move this legislation forward.”**

A copy of the VALID Compounding Act can be found [HERE](#) (<http://markey.house.gov/document/2012/valid-act-legislation#overlay-context=document/2012/valid-act-one-pager>). A one-page description of the legislation can be found [HERE](#) (<http://markey.house.gov/document/2012/valid-act-one-pager>).

The VALID Compounding Act will:

- Preserve state regulatory authority for traditional small compounding pharmacy activities;
- Ensure that compounding pharmacies that are operating as drug manufacturers are regulated by the FDA as drug manufacturers;
- Allow compounding pharmacies with a legitimate reason to compound drugs before the receipt of a valid prescription to request a waiver to enable them to do so;

- Allow the FDA to waive the requirement to compound drugs solely for individual patients with valid prescriptions in the event of a drug shortage or to protect public health;
- Allow the FDA to waive the requirement to compound drugs only if they are not copies of commercially-available drugs if doing so is necessary to protect public health or well-being; and
- Increases transparency to the public by mandating that compounded drugs be labeled to ensure that recipients know that the drugs have not been tested for safety or effectiveness, publishing a “Do Not Compound” list of unsafe or ineffective drugs, and reporting of bad reactions to compounded drugs or any drug that poses a safety risk.

“This bill will save lives by ensuring that compounding pharmacies play by the rules that are essential to protect patients,” said Diana Zuckerman, PhD, president of the Cancer Prevention and Treatment Fund. **“This month’s tragic meningitis outbreak from contaminated steroid injections was absolutely preventable. We call on Congress to work in a bipartisan manner to pass Congressman Markey’s legislation, which is necessary to protect our families from these predictable, preventable tragedies.”**

The legislation has been endorsed by Cancer Prevention and Treatment Fund, Jacobs Institute for Women’s Health, National Consumers League, National Research Center for Women & Families, Our Bodies Ourselves, and Union of Concerned Scientists. A copy of the endorsement letter can be found [HERE](http://markey.house.gov/document/2012/valid-act-endorsement-letter) (<http://markey.house.gov/document/2012/valid-act-endorsement-letter>).

Earlier this week, Rep. Markey released the report **“[Compounding Pharmacies, Compounding Risk](http://markey.house.gov/press-release/new-markey-report-reveals-current-outbreak-least-23-deaths-86-serious-illnesses)”** (<http://markey.house.gov/press-release/new-markey-report-reveals-current-outbreak-least-23-deaths-86-serious-illnesses>), which revealed that even before the current outbreak, problems at compounding pharmacies led to at least 23 deaths and 86 illnesses in 34 states, and that state regulatory bodies typically focus on more non-safety related traditional pharmacy licensing activities. A timeline of Rep. Markey’s work on compounding pharmacies can be found [HERE](http://markey.house.gov/content/timeline-rep-markeys-work-compounding-pharmacies). (<http://markey.house.gov/content/timeline-rep-markeys-work-compounding-pharmacies>)

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