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Contact: Giselle Barry (Markey) 202-225-2836, 202-510-3240

New Markey Report Reveals Before Current Outbreak At Least 23 Deaths, 86 Serious Illnesses, Injuries Associated with Compounding Pharmacy Practices

*Lawmaker's review also shows industry resistance to FDA, limited state
role in safety oversight*

WASHINGTON, D.C. – With the meningitis outbreak death toll reaching 25 and 344 more sickened by injectable steroids manufactured at the New England Compounding Center (NECC), Congressman Edward J. Markey (D-Mass.) today released a new comprehensive report documenting more than a decade of violations and problems at compounding pharmacies throughout the nation. Rep. Markey's report, "[Compounding Pharmacies, Compounding Risk](#)" describes the nature of regulatory oversight and gaps in legal authority that, even before the current meningitis outbreak, led to at least 23 deaths and 86 serious illnesses or injuries in at least 34 states. Violations at compounding facilities included compounding pharmacies selling copies of commercially-available drugs, selling drugs made using ingredients that were not Food and Drug Administration (FDA)-approved or were recalled for safety or effectiveness reasons, cases where sterile facilities were visibly dirty and contamination of the drug product was known to have occurred, and either selling drug products without a valid prescription or manufacturing large quantities of drug products.

Drawn entirely from media reports, publicly-available FDA and state Boards of Pharmacy documents from all 50 states, Puerto Rico and DC, Rep. Markey's report shows how FDA's efforts to assure the safety of compounding pharmacies have been challenged at every juncture by some members of the compounding pharmacy sector. The report also reveals that the state Boards of Pharmacy do not typically and consistently oversee the safety of the drugs made by compounding pharmacies and do not always provide records of their enforcement activities in an easily searchable and publicly available format.

“The risks of allowing the safety of compounding pharmacies to go largely unregulated have been recognized for years, but a patchwork of state regulation, incomplete and often inaccessible information about serious health issues caused by compounding pharmacies and

industry efforts to thwart better government oversight have complicated efforts to understand the true scope of this problem,” said Rep. Markey, senior member of the Energy and Commerce Committee. **“The tragedy of NECC is clearly just the tip of an industry iceberg that has long needed reform and federal oversight. This tragedy demands the strongest response from Congress and federal and state authorities to ensure safeguards are in place to protect patients.”**

“This analysis provides very useful insight into our understanding of this issue,” said Rep. Henry A. Waxman, Ranking Member of the Energy and Commerce Committee. “The report makes clear that we need to ensure that FDA has the statutory authority to perform meaningful oversight of compounding pharmacies.”

A copy of Rep. Markey’s report, “*Compounding Pharmacies, Compounding Risk*” can be found [HERE](#). A timeline of Rep. Markey’s work on compounding pharmacies, including his plan to introduce legislation, can be found [HERE](#).

Other findings from Rep. Markey’s report include:

- Since June 2001, the FDA has attempted to rein in the activities of dozens of pharmacies through the issuance of warning letters, all of which are publicly available.
- FDA records document 23 deaths and at least 86 serious illnesses or injuries associated with these practices. These totals should be considered to be conservative, since in many cases the reviewed documents noted the existence of adverse events but did not specify the type or quantity; and in other cases, the warning letters may have been issued prior to a full realization of the health impact of the alleged violation.
- State enforcement records related to the safety of compounding pharmacy practices were not typically found in the enforcement records reviewed, because state regulators appear to focus on more traditional pharmacy licensing activities.
- In many cases, the information available on the state Board websites is limited. Most state Board websites do not allow for keyword searches, preventing members of the public from easily locating or downloading enforcement records. State enforcement action records related to pharmacies are often limited to alphabetical or temporal lists or summaries of violations that are not themselves searchable.

“For years, the compounding pharmacy sector has resisted federal oversight and assured everyone that state regulators were adequately overseeing their activities,” said Rep. Markey. **“This report demonstrates that this is simply not true.”**

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