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Save the Compounding Legislation: *Prevent Another New England Compounding Center Tragedy*

Special interests that stand to benefit from keeping the status quo are pulling out all the stops to block compounding legislation designed to prevent another tragedy like the NECC, which killed 61 people and injured 749 with tainted sterile products.

The Senate bill (S.959) would create a new category, called “compounding manufacturer,” that would be overseen by the FDA. According to the legislation, “compounding manufacturers” compound preparations without or in advance of a prescription and offers to sell the drug in interstate commerce.

Traditional compounding by pharmacies (including hospitals) for individual patients by pharmacies would not fall under this new category and would continue to be regulated by state boards of pharmacy. Additionally, pharmacies in hospitals would also continue to be under the oversight of accrediting bodies with strict standards, such as The Joint Commission, to meet conditions of participation by the Centers for Medicare & Medicaid Services.

Special interests are working to defeat the bill by frightening patients with untruths, stretches in logic, and scare tactics. These include:

- Marshaling [anti-abortion lobby](#) to oppose the bill.
 - FACT: S. 959 has no provisions that would increase abortions.
- Claiming the bill would restrict patient access to appropriately compounded medications
 - FACT: Patients will still be able to receive compounded medications. The legislation protects patients by ensuring the compounded preparations they receive are prepared in accordance with appropriate safety standards.
 - FACT: This bill targets large scale businesses that are preparing compounded sterile products without a patient specific prescription and selling across state lines, acting more like a manufacturer than a pharmacy. The bill closes regulatory gaps that allowed companies like NECC to evade FDA authority.

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- Calling for hospital pharmacies to be considered “compounding manufacturers,” even though these pharmacies are already following strict standards in order to be accredited and participate in Medicare and Medicaid
 - o Pharmacies outside of hospitals are not accredited in this strict manner
- Making wild claims of restricted patient access to garner grass roots opposition
 - o http://www.aapsonline.org/index.php/site/article/coalition_letter_against_s.959?newsletter=off
 - o <http://www.protectmycompounds.com/>
 - o http://www.wellnesshealth.com/news.asp?record_no=25539
 - o http://www.collegepharmacy.com/index.php?/site/detail/senate_bill_959_call_to_action_alert

The bottom line:

Pharmacies that act like manufacturers need to be treated like manufacturers in order to protect patients from tragedies like the one that occurred with NECC.

- Operations like NECC were behaving like a manufacturer but without appropriate oversight and not following safe practices.
 - o Because these businesses do not fit within the existing regulatory structure, this new category of “compounding manufacturer” is essential to prevent a repeat of NECC.

For more information, contact:

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