Protect the Public and Preserve Pharmacy Compounding

S. 959 -- legislation introduced in the United States Senate -- creates more ambiguity and greater potential for confusion about which regulatory agency should oversee pharmacy compounding.

As written, S. 959 is too far-reaching in its scope and micromanagement of practitioner decisions. S. 959 must be amended to eliminate unnecessary FDA oversight of traditional compounding and assure the ability of physicians to make informed decisions about appropriate medication therapy.

IACP believes that S. 959 rewards the FDA with new sweeping powers without holding the agency accountable for its past inaction and failure to protect the public.

S. 959 Confuses Pharmacy Practice with Manufacturing

- Defines an individual compounded medication as a “new drug.”
- The definition of a “compounding manufacturer” refers to “prescriptions.” Pharmacies dispense prescriptions, manufacturers sell drugs.

S. 959 Interferes with State Regulation of Pharmacy Practice

- Ignores “office-use” by requiring an “identified individual patient prescription.”
- Repeats the problem of disregarding state law in the bill’s convoluted description of “anticipatory compounding.”
- S. 959’s provisions on “traditional compounders” contradict existing and evolving state laws pertaining to “office-use” and “anticipatory compounding.”

S. 959 Unduly Restricts Access to Ingredients and Prescriber & Pharmacist Decision Making

- S. 959 permits the FDA to create a “do not compound” list based on ambiguous definitions about “complex” or “difficult” to compound issues, rather than true patient safety issues.
- S. 959 places the FDA in the role of determining whether a compounding pharmacist’s preparation and dispensing of a variation of a marketed drug is “clinically significant.”

S. 959 Does Little to Prevent the FDA’s Lack of Accountability Which Contributed to the NECC Tragedy in 2012

- S. 959 provides for no Congressional oversight of the FDA’s actions pertaining to problems associated with compounded medications despite the agency’s clear failure to act in a timely manner... a failure that could have led to prompt action against the New England Compounding Center (NECC).
- S. 959 puts the FDA in charge of determining if a pharmacy is acting within the scope of its permit instead of the State Board of Pharmacy.