Unintended Consequences of S.959

Overview

PCCA believes that FDA oversight of the pharmacy profession will result from the passing of Senate S.959 with the unintended consequence of restricting access to compounded medications for hundreds of thousands, if not, millions of patients each year.

While the goal of the bill was to originally provide oversight of those compounding sterile products, dispensed interstate for non-patient specific situations, S.959 allows sweeping intrusions into compounding while it excludes key areas of compounding, specifically hospitals, and does not help prevent another NECC-like tragedy.

We believe that bill S.959 includes too many unintended consequences that have been outlined below and we therefore oppose it.

Unintended Consequences of Senate Bill S.959

- Creation of the compounding manufacturer category
  
  o PCCA believes that this will lead to confusion about how a pharmacy is regulated, that the FDA will penalize pharmacies that occasionally ship sterile products without a patient specific prescription out of state and potentially set up a market that would ultimately limit patient access to certain compounded medications.

- Classifying all compounds as “new drugs”
  
  o PCCA believes that this will impair a patient’s ability to seek reimbursement for compounded medications from insurance companies and will increase FDA enforcement actions against compounding pharmacies that do not file a New Drug Application for every compound they make.

- Proposing a list of “demonstrably difficult” to compound dosage forms
  
  o PCCA opposes any restrictions of compounded drug based on an arbitrary finding by the FDA as to what is (and is not) demonstrably difficult. Codifying a set of dosage forms as difficult to compound today does not address the rapid innovation that occurs in our industry. Also, the FDA could use this avenue to outlaw the compounding of certain classes of medications they deem as ineffective, with little or no scientific evidence to prove their claim.
- Positive list of Active Pharmaceutical Ingredients (APIs)
  - PCCA opposes the promulgation of a positive list of APIs that the FDA approves as safe for compounding. Allowing the Agency, who is notoriously slow to change, will limit patient’s access to compounded medications that are currently available.

- Expanding the scope of the negative list of APIs, to include “not effective”
  - PCCA opposed this as compounds are, by definition, not required to prove effectiveness to the FDA. Allowing the FDA to list compounded APIs as not effective will give the Agency great power to outlaw any medication whenever they feel like it. This provision will decrease patient access to compounded medications.

- Death of compounding for office use
  - S.959 allow for cumbersome and almost impossible provisions that a small community pharmacy will chose not to overcome when asked to compounded something for office use for a prescriber. Limiting treatment options, many of which are either unsafe for the patient to use without medical supervision or is only needed for specific situations in the course of a prescribers course of practice, will ultimately cause harm to patients.

- Issues with anticipatory compounding
  - Definition of an arbitrary number, which could be interpreted widely by the FDA, puts a pharmacy practice in danger of being inspected and/or fined by the FDA. Anticipatory compounding should only be based on the historical trends seen in the particular pharmacy practice’s setting.

- “Essential copies”
  - As is, the FDA’s idea of “essential copy” would severely limit treatment options for patients with allergies to fillers or preservatives found in commercially made medications. Also, the prescriber would have to prove to the FDA that a change in the commercially available medication is medically necessary for the patient, placing the FDA squarely in the realm of the prescriber’s rights to practice medicine.

- Compounding for drug shortages/notification to FDA
  - Requiring pharmacies to notify the FDA before compounding a commercially available medication that cannot be supplied by the drug manufacturer impairs the ability of the compounding pharmacist to fill a critical void in patient care, thus decreasing the patient’s access to these (quite often, life-saving) medications and limiting the prescribers choices in their particular practice of medicine.