United States Senate

Bipartisan HELP Senators Unveil Major Effort to Clarify Oversight for Pharmaceutical Compounding; Ensure Consumer Safety

"This legislation is a significant step forward in protecting the public from unsafe compounded products. By clarifying FDA authority over high-risk compounding practices, this bill will enhance protections for patients taking compounded drugs and help prevent crises like last year's tragic meningitis outbreak." – ***Chairman Tom Harkin (D-IA)***

"Last year's meningitis outbreak was a nightmare for Tennesseans, and this legislation will help ensure that it never happens again. Our goal with this bill is to put an end to FDA inaction and make it clear who is on the flagpole—who is in charge and accountable for oversight of these pharmacies and manufacturers."- ***Ranking Member Lamar Alexander (R-Tenn.)***

Following the recent illnesses and deaths from contaminated compounded drug products, a bipartisan group of HELP Committee Senators led by Chairman Tom Harkin (D-Iowa), Ranking Member Lamar Alexander (R-Tenn.), Sen. Pat Roberts (R-Kan.), and Sen. Al Franken (D-Minn.) have released draft legislation. Their proposal would help improve the safety of compounded human and animal drugs by making clear the oversight responsibilities of state and federal authorities.

Among the highlights of their draft legislation:

- The draft establishes a clear boundary between traditional compounders and compounding manufacturers, which make sterile products without or in advance of a prescription and sell those products across state lines. It clarifies a national, uniform set of rules for compounding manufacturers while preserving the states' primary role in traditional pharmacy regulation. The draft creates a similar structure for oversight of compounded animal drugs, and clarifies the law on compounding from bulk chemicals for animals.

- The draft clarifies that compounded drugs are new drugs subject to the Federal Food, Drug, and Cosmetic Act (FFDCA), and specifies which provisions of the law will apply to traditional compounders, and which will apply to compounding manufacturers. A compounding manufacturer is an entity that compounds a sterile drug prior to or without receiving a prescription and introduces such drug into interstate commerce, with the exception that interstate shipment within a hospital system will not cause a hospital pharmacy to be considered a compounding manufacturer. Any entity that pools sterile products, or that repackages sterile, single-use, preservative-free vials is also a compounding manufacturer. In order to maintain clear accountability, compounding manufacturers cannot be licensed as pharmacies.

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- The draft defines the Food and Drug Administration's (FDA's) role in oversight of compounding manufacturers. It calls on compounding manufacturers to register with the FDA and tell the agency what products they have made, make products under a pharmacist's oversight and in compliance with Good Manufacturing Practices, investigate and report adverse events, and label products to indicate that they are compounded and to specify other identifying information. A compounding manufacturer will pay an annual establishment fee to defray the cost of compounding oversight (e.g. inspections), and will cover the agency's costs for any needed reinspections.

- The draft legislation preserves the states' primary role in oversight of traditional pharmacy, while ensuring the compounded products meet certain minimum standards. It prohibits compounding of certain drug products, including those identified by regulation as being demonstrably difficult to compound (such as complex dosage forms and biologics), marketed FDA-approved drugs that are not in shortage, variations of marketed FDA-approved drugs unless they fulfill a specific patient need, or products subject to certain risk evaluation and management strategies unless the compounder utilizes comparable safety controls. Wholesale distribution of compounded products is also not permitted.

- The draft enhances current bulk chemical requirements for the ingredients used in all compounded products. It affirms, with minor modifications, the existing restrictions on bulk compounding of human drugs. The same restrictions apply to compounding animal products from bulk chemicals for minor species, such as exotic animals. The FDA must affirmatively list bulk chemicals for compounding products for food-producing animals and major species (horses, dogs, cats).

- Finally, the draft encourages communication among states and increases communication between states and the FDA. If the FDA receives a complaint from a state regulatory agency about a traditional pharmacy in another state, the FDA must promptly relay that information to the relevant state pharmacy board.

With the release of this draft, Senators Harkin, Alexander, Roberts, and Franken and other members of the HELP Committee are requesting that stakeholders provide feedback on the policy merits, potential unintended consequences, and opportunities to improve the legislative language.