

United States Senate

Bipartisan HELP Senators Introduce Major Effort to Clarify Oversight of Compounding Pharmacies; Help Ensure Consumer Safety

“We cannot wait for the next public health crisis—as we saw with the New England Compounding Company disaster that led to more than 50 deaths and caused serious illness in 700 more—to act to improve the safety of compounded drugs. The Pharmaceutical Compounding Quality and Accountability Act will help protect the public from unsafe compounded products and clarify FDA authority over high-risk compounding practices.” – Chairman Tom Harkin (D-IA)

“My primary goal with this legislation is to erase the confusion over who regulates pharmacies and manufacturing facilities, and make it clear exactly who oversees each business. Putting one agency on the flagpole for each of these businesses will mean greater safety for American families, so they don’t have to question whether the drugs they take are safe.” – 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.) released draft legislation to help improve the safety of compounded human and animal drugs. Over the past several weeks stakeholders have provided feedback on the draft legislation. The legislation introduced today includes changes to address that stakeholder feedback while still making clear the oversight responsibilities of state and federal authorities.

Among the highlights of their legislation:

- The legislation establishes a clear boundary between traditional compounders and compounding manufacturers. It preserves the states’ primary role in traditional pharmacy regulation. Compounding manufacturers are defined as those that make sterile products without or in advance of a prescription and sell those products across state lines. The legislation clarifies a national, uniform set of rules for compounding manufacturers, while preserving the states’ primary role in traditional pharmacy regulation. The legislation creates a similar structure for oversight of compounded animal drugs, and clarifies the law on compounding from bulk chemicals for animals.
- The legislation clarifies current law that compounded drugs are new drugs subject to the Federal Food, Drug, and Cosmetic Act (FFDCA), and specifies which exemptions from the law will apply to traditional pharmacy 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 pharmacies within health systems will not be considered a compounding manufacturer and will remain regulated as traditional pharmacies. Any entity other than a hospital or health system that pools sterile products, or that repackages sterile, preservative-free vials is also a compounding manufacturer. The legislation clarifies pooling, repackaging and other relevant terms. In order to maintain clear accountability, compounding manufacturers may not be licensed as pharmacies.

United States Senate

Bipartisan HELP Senators Introduce Major Effort to Clarify Oversight of Compounding Pharmacies; Help Ensure Consumer Safety – Page 2

- The legislation 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 to tell the agency what products they have made to facilitate a risk based inspection schedule, 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 be responsible for a reinspection fee to help cover the agency’s costs for any needed reinspections. Small businesses, as defined by annual sales, pay reduced fees.
- The legislation preserves the states’ primary role in oversight of traditional pharmacy, while ensuring the compounded products meet certain minimum standards. It recognizes certain drugs as being demonstrably difficult to compound (such as complex dosage forms and biologics) and allows the Secretary through the flexibility of a notice and comment regulatory rulemaking to prohibit compounding of these drugs. The legislation prohibits compounding of 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 it is to fulfill a specific patient need and the compounder utilizes comparable safety controls. Wholesale distribution of compounded products is also not permitted. The legislation clarifies that marketing of compounded drugs must not be false or misleading.
- The legislation 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. For horses, dogs, cats, and other major species, pharmacies may continue compounding unless and until FDA makes a ruling on that bulk chemical.

Finally, the legislation encourages communication between states and the FDA, while encouraging efforts to increase communication between states. The FDA must establish a point of contact for states to identify potential compounding manufacturers. When FDA identifies a compounding manufacturer through this process, the agency is then required to notify the state in which the compounding manufacturer is located, and the state that first raised the concern, if different, within 15 days.