Bicameral, Bipartisan Talks Keep Drug Compounding In Focus During Recess

House and Senate staff have been working on a bipartisan, bicameral basis throughout August recess to come to an agreement on drug compounding legislation, and stakeholders said they are encouraged by the continued focus on the issue. The National Community Pharmacists Association the last week of recess also voiced support for a House draft proposal that the group says preserves some longstanding compounding practices that the Senate bill does not.

Stakeholders said the bicameral, bipartisan discussions appear to be productive, although no concrete proposals have emerged. Coming to an agreement seems doable, albeit tackling the issue is challenging, they said.

"I think they have been trying to work through various frameworks and draw lines, which of course on this issue are very hard to draw," said Allan Coukell, senior director of drugs and medical devices at the Pew Charitable Trusts. He said it does not appear as though staffers are "entrenched in positions that are far apart" but rather focused on finding a mutual path forward.

A Senate health committee spokesperson would only say that committee Chair Sen. Tom Harkin (D-I-A) believes congressional action is necessary. The office of Morgan Griffith (R-VA), who spearheaded a House proposal, did not return a request for comment.

Other sources pointed to a July House hearing as contributing to progress. There was a bipartisan discussion about which criteria could be employed to determine facilities that are compounding versus manufacturing under the guise of compounding. Heading into the August recess a House proposal was in draft form and some sections have yet to be fleshed out, including a possible volume restriction for compounders.

The recent discussions come after senators tried unsuccessfully to hotline the Pharmaceutical Quality, Security and Accountability Act, drawing discontent from groups like NCPA. The group said it instead supports the House legislative efforts, according to a letter sent Wednesday (Sept. 4) to top lawmakers on the House Energy and Commerce Committee.

"Our independent pharmacies provide a needed service in compounding medications and have a long history of protecting patient safety while preserving patient access to vital medications," according to the letter. "While NCPA cannot support S. 959 in its current form, NCPA supports the Griffith discussion draft in the House as a workable solution that appropriately addresses the issues that led to the NECC tragedy." NCPA took issue with the Senate bill's office use provision, requirements to notify FDA when compounding a drug in shortage and "overly broad" authority to create a "do not compound" list.

The letter comes as Congress will return to an agenda dominated by the budget, debt ceiling and Syria. Sources said they are encouraged by the fact that committee staff remain focused on the issue, although it is unclear how drug compounding will fit into the broader legislative discussions.

Further, a slew of FDA enforcement actions throughout the past month highlight continued issues with drug compounding. One firm refused to initiate a recall, prompting FDA to issue an alert to providers. A Texas compounding pharmacist's injections were
tied to bloodstream infections found in hospital patients. And FDA recently raised concerns with a laboratory's verification of compounded drugs, sending compounders searching for other means to check the sterility of their products and prompting several recalls.

"We think it provides further evidence we really have to address the regulatory gaps," one pharmacy source said. Further, heading into the August recess, the Government Accountability Office called for Congress to clarify FDA's authority, bolstering the argument, the source said.

"I think there has been a kind of continued drumbeat of reasons to be concerned about compounding in the current regulatory structure," Coukell said, referencing the recent regulatory action.

Sarah Sellers, who leads the Working Group On Pharmaceutical Safety, described FDA's enforcement efforts as extraordinary, given that there is no active surveillance and the firms are not required to register. "It's only a fairly small representation of what problems exist in the marketplace," she said. Sellers, a former FDA staffer, leads the working group with former HHS Secretary Tommy Thompson.

She said a lot of congressional energy is being put toward the issue. The House investigation into the outbreak has provided knowledge about the limitations of FDA's authority and the Senate has explored the interplay between FDA and state authority.

"I'm encouraged by the extent to which staff on both the Senate side and the House side in a bipartisan manner are really engaged in some very deep problem solving from many different angles," she said. -- Alaina Busch (abusch@iwpnews.com)