InsideHealthPolicy.com's
FDA Week
an exclusive weekly report on Food and Drug Administration policy, regulation and enforcement
from **Vol. 19, No. 31 — August 2, 2013**

Addressing Senator's Concerns...

Updated Compounding Bill Exempts Infusion Pharmacies

A Senate manager's amendment released last week exempts infusion pharmacies from falling under compounding manufacturer requirements, addressing concerns brought by home infusion providers and Sen. Johnny Isakson (R-GA) when the bill passed out of committee earlier this year. The bill otherwise drew opposition from several pharmacy stakeholders, who said many of their concerns still had not been addressed with the updates, as lawmakers attempted to hotline the bill this week.

When the Senate Health, Education, Labor and Pensions Committee passed the Pharmaceutical Quality, Security and Accountability Act, Isakson raised concerns with pooling and repackaging provisions. He said the definitions could increase the cost of ophthalmology treatments and negatively affect home infusion providers.

Washington insiders had been monitoring how the bill affects the use of drugs Avastin and Lucentis — both of which are manufactured by Genentech and used to treat macular degeneration. However, Avastin is not approved for the purpose and is repackaged for this use at a cheaper price, although Isakson never directly referenced these drugs. The updated bill allows continued repackaging of ophthalmic treatments, sources said. As of press time, Genentech did not respond to a request for comment.

"Senator Isakson's concerns on home infusion and ophthalmology have been addressed in the manager's amendment," a spokeswoman for the lawmaker said. "He is appreciative of the Committee's work to resolve these issues."

Despite the fact that home infusion providers use patient-specific formulations, initial versions of the bill's pooling and repackaging definitions appeared to bring them under the definition of compounding manufacturers.

The bill establishes a three-part test to determine which facilities would fall under federal oversight — those compounding sterile formulations that are not patient specific and shipped interstate. Ken Van Pool, vice president of legislative affairs at the National Home Infusion Association, said home infusion providers are not exempted from the three-part test, which is not expected to affect them, but rather the pooling and repacking definitions.

"We can live by the three part test," Van Pool said. "The problem is the pooling and repacking (definitions)."

Still, the exemption goes beyond home infusion and exempts other infusion providers that could have been affected, such as hospice and other long-term care facilities that use infusion for pain management and to administer parenteral nutrition. He said the committee put parameters around the exemption to keep it from becoming a loophole and defined infusion pharmacies as a state-licensed pharmacy or federal facility, being accredited by national bodies approved by the secretary, and providing infusion therapy pursuant to an individual patient prescription received prior to compounding and pooling. Four main accrediting bodies already exist, Van Pool said.

"By including this provision, the committee has recognized the value of home infusion as part of the healthcare industry," he said, referencing the overall changes. "It's very clear that they understand that there is value to receiving this care in the home."

NHIA also recently sought to head off potential problems with a House drug compounding draft that includes a yet-to-be-defined section on volume restrictions to help differentiate between manufacturers and compounders. During a recent hearing, House lawmakers discussed volume and other potential criteria to define manufacturers, although NHIA warned in a July 18 letter that volume restrictions could have unintended consequences.

"It is NHIA's position that if there were any volume restrictions in the bill they should be isolated to non-patient specific compounding," according to the letter. "Home infusion providers compound a great majority of the drugs for our patients in a patient specific manner and any volume limitation that is based either on percentage of business or number of drugs compounded that included patient specific medications could result in all home infusion providers being classified as manufacturers." — *Alaina Busch*