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Drugmakers Find Much To Love In Final FDA Reform Bill

By **Rachel Slajda**

Law360, New York (June 19, 2012, 9:24 PM ET) -- The U.S. House of Representatives is expected to vote Wednesday on a final version of the Food and Drug Administration user fee bill, which has been stripped of controversy but will still largely benefit the industry, with provisions extending exclusivity for certain drugs and directing the FDA to accept foreign clinical data and issue a comprehensive social media policy.

Three weeks of negotiations to reconcile the House and Senate versions of the bill stripped the legislation of controversy, including an industry-backed proposal to create a nationwide system to trace drugs throughout the supply chain. The final language was released late Monday and is expected to pass easily through both houses before July 4.

Lawmakers also dropped a provision favored by the generics industry that would prohibit brand-name manufacturers from using certain FDA-imposed restrictions to block generics companies from getting samples of the reference drug, which they need for bioequivalence testing.

But overall, the bill, which authorizes the FDA to collect billions in user fees over the next five years and makes a slew of reforms at the agency, is a positive for the drug and device industries.

Generic-drug makers and pharmacies breathed a sigh of relief at the removal of a provision that would have made the popular painkiller hydrocodone much harder to get. That provision, passed with the Senate version, would have reclassified hydrocodone as a Schedule II controlled substance. The final bill only directs the FDA to have a public meeting on hydrocodone's classification, which the FDA has already announced plans to do.

One provision directs the FDA to accept data from clinical trials performed in other well-regulated countries when reviewing drugs and devices, or to explain to sponsors why the data is inadequate. Although the agency can already accept foreign data, this would make it the default, and could save sponsors money and time on clinical trials.

Another provision requires the FDA to issue guidance within two years describing its policy on the promotion of drugs and devices over the Internet, including via social media. Stephen Mahinka, chair of the life sciences and health care group at Morgan Lewis & Bockius LLP, said such guidance would satisfy a longtime industry desire to have more certainty about what they can and cannot say over social media.

One surprise, Mahinka said, is a provision directing the FDA to have a patient representative "in appropriate agency meetings with medical product sponsors and investigators." The bill is low on specifics, and Mahinka said it could likely be a positive thing for sponsors, especially if the patient reps are likely to push for the approval of a drug when the FDA is on the fence. Patients are often said to be more tolerant of risks than the FDA.

But it could also be bad for the industry. In other sectors, such as public utility commissions, consumer advocates are generally opposed to industry interests. Patient reps could argue that expensive drugs should not be approved, or should undergo comparative effectiveness testing, Mahinka said.

"People put these things in there, they think it's like motherhood and apple pie: Why not? But these things have consequences," he said.

The bill also extends incentives for pediatric drugs, allows drug companies to make minor changes to their risk evaluation and mitigation strategies without FDA approval, directs the FDA to use the fast-track review process on more drugs and allows the agency to change the risk class for a device without going through the rulemaking process.

Certain provisions will create more work for the industry. Drugmakers will have to report potential shortages to the FDA six months in advance, a big expanse of reporting requirements. The bill also gives the agency much more authority to scrutinize the supply chain. Drug importers and the makers of inactive ingredients must register with the FDA, and the agency will have the power to destroy potentially adulterated drugs at the border.

The bill seeks to speed up final regulations on a unique device identifier, which was called for in the last round of user fee agreements five years ago. A unique serial number or other ID would help the agency track adverse events and issue recalls, supporters say. But the proposed regulations have been held up at the White House, without explanation, for months.

The bill would require the FDA to issue its proposed rules by the end of this year, and would have six months after the comment period to issue a final rule.

--Editing by Sarah Golin and Andrew Park.