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Bolder Cures Act Could Ease Limits On Drug Cost Claims

By **Jeff Overley**

Law360, New York (May 26, 2015, 3:16 PM ET) -- A brief section in the fast-evolving 21st Century Cures Act would modestly loosen U.S. Food and Drug Administration restrictions on drugmaker claims of cost-effectiveness but will only provide significant cover from enforcement actions if lawmakers get bolder with the legislative language, experts say.

The proposal, part of the Cures bill that won broad bipartisan support on Thursday, would tweak Section 114 of the Food and Drug Administration Modernization Act of 1997. That section spells out rules for communicating so-called health care economic information to formulary committees that decide which drugs will be covered by health insurers.

Health care economic information aims to show that taking one drug will produce a desirable outcome and be cheaper than doing nothing or using another drug, device or procedure. Under the current version of Section 114, economic information must “directly relate” to an approved drug indication in order to avoid being viewed as false or misleading, which can result in FDA warning letters or other discipline. Under the Cures proposal, such information would only have to “relate” to an approved drug indication.

That standard would be less restrictive and potentially allow for the use of studies, analyses and databases that cover a slightly broader range of patients than those covered by an approved drug indication.

Joshua P. Cohen, who researches formularies and comparative effectiveness at the Tufts Center for the Study of Drug Development, told Law360 that the change would offer “some degree of flexibility for drug firms.”

Stephen Paul Mahinka, a partner in the FDA group at Morgan Lewis & Bockius LLP, made a similar point, saying the proposed tweaks “would open up the possibility of providing this kind of data ... in a broader way than FDA has allowed.”

The communications are tricky because claiming that one product is better than another can be viewed as off-label promotion. That promotion is not necessarily improper, but it gets dicey.

"It’s really a question of what kind of health care economic information of the effectiveness of the products can be provided," Mahinka said. "That’s been very controversial because it dovetails with this question of whether you can give out information that is truthful and nonmisleading but is off-label."

The issue correlates closely to so-called comparative effectiveness research, or CER, that has rapidly gained importance in recent years. The stimulus bill and the Affordable Care Act both made investments in CER, and drugmakers hope that CER, along with economic information, can justify the sky-high price tags of specialty medications and help give them a leg up on the competition.

The issue is already front and center on the FDA's radar. Regulators previously announced plans to issue guidance on Section 114 this year, and they agreed last year to provide more guidance on permissible interactions with formulary committees.

The Cures provision could affect those efforts, but it's unlikely in its current form to significantly curtail the FDA's powers, experts said. That's partly because the revised Section 114 would allow use of a slightly wider universe of research while still letting the FDA determine whether it constitutes "competent and reliable scientific evidence."

"It is not entirely clear from the proposed changes which sources of data would be permissible and which not," Cohen said. "More work needs to be done to clarify what types of clinical claims are allowed to be disseminated as health care information and the standards that should apply to [nonclinical-trial] data sources."

The FDA hasn't provided many official insights into its views on Section 114. But informal statements, such as a 2012 presentation at a meeting of the National Pharmaceutical Council, seemed to interpret the section narrowly. That presentation, for example, said that comparative claims "must be supported by substantial evidence that directly compares the treatments in question."

With that history in mind, experts said that the current Cures language would not force the FDA to do anything it doesn't want to do.

"These changes are just not clear enough," Mahinka said. "The agency has for decades resisted health care economic outcome information that is not based on randomized clinical trials."

As a result, authors of the Cures bill will probably have to revisit their proposal if they expect it to significantly change the status quo.

"The draft changes represent a cautious first step," Cohen said. "But more clarity on allowable health care information and clinical claims is needed to exert more impactful change."

--Editing by John Quinn and Christine Chun.
