

Off-Label Drug Bills Back on Track But Democrats Could Run at Least One Off the Rails

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The off-label debate is back on track again. Congress is considering two bills that failed in 2016 but have been reworked in 2017. The Medical Product Communications Act of 2017 would allow drug manufacturers to provide more information about off-label uses of approved drugs to physicians and other providers,¹ while the Pharmaceutical Information Exchange Act would allow those companies to provide information to formulary committees on investigational drugs.² In the latter case, the idea is to provide health care economic information (HCEI) to insurers and their P&T committees in advance of a drug's approval, so that insurers won't find themselves unprepared when the Food and Drug Administration (FDA) approves expensive new drugs that blow up insurance company pharmacy budgets. Broader HCEI would ostensibly make insurers better prepared to consider value-based formulary contracts.

When Congress passed the 21st Century Cures Act last fall, it included one provision that required the FDA to open the spigot a little in regard to HCEI.³ The agency produced draft guidance on that provision earlier this year.⁴ But some groups, such as the Academy of Managed Care Pharmacy (AMCP), criticized the draft guidance for limiting the provision of HCEI only to new drugs, not new indications of approved drugs, and for not having the force of law, which only Congress can bestow.

However, despite changes to the two bills to make them more amenable to health insurers and public interest groups, both of which are skeptical, hearings in a House subcommittee in July demonstrated that congressional efforts

to allow drug and device companies to supply a broader range of information on approved drugs and HCEI on investigational drugs still may be far from the Capitol Hill finish line.

For P&T committees, the HCEI bill may be the more important of the two and also the more likely of the two to move further through Congress, albeit with further clarifications. The Pharmaceutical Information Exchange Act would clarify how drug and medical device companies can share HCEI or scientific information with a payor, formulary or technology review committee, or other similar entity with knowledge and expertise in the area of health care economic analysis.² That information must be based on competent and reliable scientific evidence on an investigational drug or device not yet approved by the FDA. Studies meant to support an application for approval of a new use for a drug must already have been conducted, although the language leaves plenty of room for interpretation. It says the studies must be those the "sponsor anticipates could be sufficient to support the approval, clearance, or licensing of such use..."

How does one prove someone's anticipation was wrong? The manufacturer must "intend" to submit a supplemental application, and the information relayed to a P&T committee must include a conspicuous and prominent statement describing any material differences between the information provided and the FDA-approved product labeling in the case where the HCEI is about a new use of an approved drug. This bill has broad support, including that of the AMCP, Pharmaceutical Research and Manufacturers of America, and some insurers, such as Humana and the Blue Cross and Blue Shield Association.

While some insurers fully support the bill, the America's Health Insurance Plans (AHIP) group, which represents health insurers, wrote in a "Statement for the Record" submitted to the House Energy and Commerce Committee Subcommittee on Health: "AHIP supports the goals

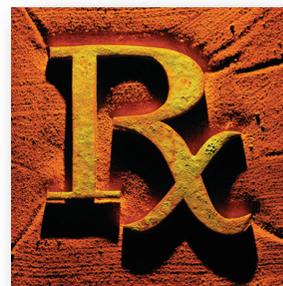
of this draft legislation." The organization appears to want further enhancements to the bill, however, including making clear that "competent and reliable scientific evidence" is defined in the context of the FDA definition, meaning "developed using generally accepted scientific standards, appropriate for the information being conveyed, that yield accurate and reliable results."⁵ Cathryn Donaldson, Director of Communications and Public Affairs for AHIP, says, "It would be accurate to interpret our letter to the House Energy and Commerce Committee on July 12 as support for the Pharmaceutical Information Exchange Act."

The AHIP definitely opposes the Medical Product Communications Act: "It would not provide or ensure that patients and care providers have access to better research and evidence. Rather, it would allow drug manufacturers to communicate information about prescription drugs that has not been approved by the FDA," the AHIP said in a statement.⁵ The bill would clarify and broaden the types of information drug and device companies could provide to physicians and health insurers beyond what is on the drug's labeling.

The bill would create a safe harbor for companies that pass along information not included in the drug's labeling if that information met five standards: 1) it is not advertising; 2) it is supported by competent and reliable scientific evidence; 3) appropriate context is provided, including the limitations of the data; and conspicuous and prominent statements are included to indicate that 4) the information is not in the labeling, and 5) no use has been demonstrated to be safe and effective.

But Michael Carome, MD, Director of Public Citizen's Health Research Group, says that Congress needs to understand that the primary reason drug and device company representatives distribute scientific and medical information regarding unapproved uses is to promote those uses to physicians and other health care providers in the hope of increasing the

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prescribing of the companies' products. By their very nature, these communications are promotional. He also notes evidence from articles published in peer-reviewed journals may appear to be competent and reliable, but still may be seriously flawed.

Congress is more likely to swallow the Pharmaceutical Information Exchange Act, considered more unobjectionable by Democrats, if some changes are made. But given that Representative Gene Green (D-Texas), the top Democrat on the House Health subcommittee, says the Medical Product Communications Act would "undermine public health... discourage pharmaceutical research... and prevent the FDA from ensuring consumers don't get snake oil," that bill will have a much harder time getting to the White House.

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