



## Off-Label Communications Bill Allowing Discussion Of Unapproved Drugs Advances

18 Jan 2018  
ANALYSIS



Cathy Kelly [Catherine.Kelly@informa.com](mailto:Catherine.Kelly@informa.com)

### Executive Summary

Safe harbor for off label discussions between manufacturers and payers clears US House Energy & Commerce Health Subcommittee. Bill covers unapproved drugs as well as off label uses for approved agents.

Legislation allowing for communication between manufacturers and payers of clinical and economic information for unapproved drugs cleared the House Energy & Commerce Health Subcommittee Jan. 18, marking the first time a bill clearing the way for pre-approval information exchange has made it that far.

HR 2026, sponsored by Rep. Guthrie, R-Ky., now advances to the full Energy & Commerce Committee for consideration. It was passed by the subcommittee along

party lines, with no support from Democrats. A Senate version of the bill has not yet been introduced.

When the 21st Century Cures Act was enacted a year ago, it provided some additional leeway for information exchange between manufacturers and payers for approved drugs but did not address pre-approval communications. Guthrie's bill builds on those changes and applies to both unapproved drugs and off label uses of approved drugs.

The legislation codifies and expands upon FDA draft guidance, issued in January 2016, that allows manufacturers to share healthcare economic information with payers, formulary committees and similar entities. (Also see "[Industry Communications With Payors: US FDA Okays Info On Investigational Drugs](#)" - Pink Sheet, 19 Jan, 2017.) It has been strongly supported by the Academy of Managed Care Pharmacy. (Also see "['Safe Harbor' For Preapproval Information Exchange To Get Legislative Push](#)" - Pink Sheet, 18 Jan, 2017.)

In a statement on the bill, AMCP said that "a legislative safe harbor for [proactive information exchange] will confirm that the proactive dissemination of certain information does not violate the prohibitions against pre-approval promotions and does not run afoul of the labeling, misbranding, and intended use provisions of the federal Food, Drug and Cosmetic Act and its implementing regulations."

Guthrie explained during the markup that the bill is intended to provide payers with advance information about upcoming drugs so they can plan ahead during the rate setting process and so that coverage could be available as soon as drugs are approved.

He pointed to the public's experience with [Gilead Sciences Inc.](#)'s hepatitis C drug *Sovaldi* (sofosbuvir), in which patients experienced delays in obtaining coverage, as evidence that the legislation is needed.

"It seems like everybody in this room would want the day that a blockbuster drug like [Sovaldi] is approved ... it would also be covered by insurance so people have access to the drug," Guthrie said. "I guarantee if you wait until the day its approved before you even start the process with payers, then you're not going to have it [covered] anywhere close to the day it's approved."

The legislation creates a safe harbor allowing manufacturers to proactively exchange scientific or health care economic information with a "payor, formulary or technology review committee, or other similar entity" involved in coverage and reimbursement or "other population-based health care management." The bill was amended prior to the markup to cover both drugs and medical devices.

The information exchanged must be "truthful, non-misleading and based on competent and reliable scientific evidence," according to the bill.

And the exchange of information would only be permitted if:

1. "The study or studies the sponsor could objectively anticipate to be sufficient to support the approval...of such use must have been conducted,"
2. The "information must be derived from such study or studies," and
3. "The sponsor must intend that a submission will be made to the Secretary for approval."

The information would also need to include a "conspicuous and prominent statement" describing any material differences between the information provided and the labeling of the drug.

## **Bill Revisions May Address 'Promotional' Statements, FDA Access To Data**

Guthrie said he would be willing to discuss adding a statement to the bill that the information exchanged must not be "promotional" in nature.

Manufacturers "are not [permitted] to promote" under the bill, Guthrie said in an exchange with Rep. Ben Ray Lujan, D-N.M. The legislation "says they can only talk about health care economic information or scientific information, but I'd be willing to work with you before it comes before the full committee if we need to further clarify. ... I don't want them to be promoting or promoting to the general public."

In response to a concern raised by Rep. Anna Eshoo, D-Calif., Guthrie also said he would be open to discussing adding a statement about manufacturers providing FDA with the information they exchange with payers, if the agency requests it.

"Ms. Eshoo, you brought up a point about the access to the data being discussed between manufacturers and payers, should the [HHS] secretary have access to that information. I think it's something we need to work on," he said.

Changes to the bill regarding promotional claims and FDA access to the information were part of an extensive amendment to the bill offered by Lujan. The amendment would also have returned the scope of the bill to drugs alone, removed the safe harbor for unapproved drugs, required manufacturers to have actually filed for approval before exchanging information, rather than just intending to file, make clear that FDA can still take enforcement action if violations of the law take place and would "incorporate the technical assistance FDA provided to this committee."

Lujan's amendment was rejected by Republicans on the committee and did not pass. Nor did an amendment offered by Rep. Kurt Schrader, D-Ore., that would have narrowed the scope of the bill to approved drugs.