# NEWS

July 12, 2017

## Off-Label Rx Promotion Bills Would Affect Safety: House Democrats



*By Bronwyn Mixter*

Draft bills that would loosen restrictions on drug and device promotions could undermine safety, Democratic lawmakers said July 12.

The lawmakers, Reps. Frank Pallone Jr. (D-N.J.) and Gene Green (D-Texas), said they are concerned that two draft bills considered by the House Energy and Commerce Health Subcommittee July 12 would undermine the current protections against marketing unsafe and ineffective medical products. Pallone is the ranking member of the full House Energy and Commerce Committee and Green is the ranking member of the Health Subcommittee.

Meanwhile, Rep. Michael C. Burgess (R-Texas), chairman of the subcommittee, said the current legal framework "for the regulation of manufacturer communication prevents health-care professionals from receiving the most current scientific information available about the benefits and risks of FDA-approved medicines" and "a lack of relevant information can lead to physicians making patient care decisions with incomplete information."



Under long-standing policy at the Food and Drug Administration, companies can be subject to criminal prosecution and civil liability if they promote their products for uses the FDA hasn't specifically approved. Industry has criticized the policy as unduly restrictive and claims it infringes manufacturers' free speech rights. But consumer groups don't want looser restrictions on off-label communications because, they say, it could cause safety issues.

### Draft Bills

The first bill considered by the subcommittee would clarify what information manufacturers can communicate prior to the FDA's approval of a product. The second bill would enable drug and device manufacturers to proactively discuss certain information outside the scope of FDA-approved labeling.

Reps. Morgan Griffith (R-Va.) and Brett Guthrie (R-Ky.) offered these draft bills as amendments during the Energy and Commerce Committee's June 7 markup of legislation ( H.R. 2430) to reauthorize the FDA's user fee programs. But Griffith and Guthrie withdrew the amendments due to their controversial nature.

Burgess said the bills offer "a targeted approach to addressing the problems presented by our outdated regulatory framework for medical product communication."

"We owe it to the patient and medical communities to ensure that there is free and full dissemination of truthful and nonmisleading scientific and medical information to health-care professionals," Burgess said.

Rep. Greg Walden (R-Ore.), chairman of the Energy and Commerce Committee, also expressed support for congressional action to clarify off-label communications. He said the uncertainty in the statute and implementing regulations for off-label communications "does nothing to protect patients."

"It is our job to clarify this statute and get it right," Walden said.

Katherine Khachatourian, who testified on behalf of the Academy of Managed Care Pharmacy at the hearing, said existing laws and regulations keep manufacturers from sharing "information proactively on emerging therapies with population health decision makers, who have indicated that waiting until FDA approval is often too late for the critical planning, budgeting, and forecasting associated with health benefit design." Khachatourian also is the vice president of pharmacy services, strategy, and delegation oversight at QualChoice Health Plan Services Inc.

Khachatourian said allowing manufacturers to give payers and health-care decision makers information about emerging treatments would improve patient access to new drugs.

**FDA Approval Standards**

But Pallone and Green said the bills could reduce the incentive for manufacturers to go through the FDA's approval process.

Green said the bills "would undermine public health and discourage pharmaceutical research" and undermine the FDA's ability to ensure medical products are safe and effective.

"There is an incentive currently for companies to seek FDA approval but allowing manufacturers to communicate about unapproved uses would lessen that incentive," Green said.

Aaron S. Kesselheim, associate professor of medicine at Harvard Medical School and Brigham and Women's Hospital, said at the hearing, "expanding off-label

promotion would reduce manufacturers' incentives to conduct well-controlled trials of potential off-label uses in the first place, incentivizing manufacturers to seek approval of drugs and devices for the narrowest indication possible and then conduct studies of variable quality showing the utility of these products for unapproved indications that would not meet the current FDA standards for scientific rigor."

Pallone said he is willing to discuss giving manufacturers more clarity on communications, but "broadening communication in the ways proposed under these discussion drafts would undermine FDA's regulatory review process and the safety and effectiveness approval standard."

**Consumer Group's Concerns**

Michael Carome, director of Public Citizen's Health Research Group, July 11 urged the subcommittee in written comments to reject the two draft bills.

"These bills would threaten patient health and safety by undermining the current regulatory regimes for ensuring that drugs and medical devices are safe and effective for each intended use," Carome said.

Carome said that while prescribing medical products for unapproved uses is common, the scientific evidence to support such uses often is lacking. He said a recent study conducted in Canada found that the vast majority of off-label uses—81 percent—lacked strong scientific evidence of effectiveness. Patients who received a prescription for an off-label use lacking strong evidence of effectiveness were 54 percent more likely to experience an adverse reaction that resulted in stopping use of the medication than were those who were prescribed a medication for an approved use, Carome said."Objective evaluation by the FDA is crucial to ensuring that medicines and medical devices are safe and effective," Carome said.

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**For More Information**