Drug/Device Makers Get Guidance on Product Communications

By Bronwyn Mixter and Dana Elfin

Drug and device manufacturers now have more guidance from the FDA on what they can say about their products. However, the latest efforts from the Food and Drug Administration were greeted with skepticism by health-care attorneys.

The agency Jan. 18 released two draft guidances on manufacturer communications about medical products. The first guidance provides recommendations to drug and device makers about how to communicate with payers, such as health insurers (Docket No. FDA-2016-D-1307). The second guidance explains how the FDA evaluates medical product communications, including promotional materials, that present information that isn’t in the FDA-approved labeling, but that refers to a product’s approved use (FDA-2016-D-2285).

The agency also released a memorandum laying out issues it’s sorting through as it attempts to overhaul its policies on what manufacturers can say about the off-label uses of their products.

The drug and device industries have been pushing the FDA to clarify its policy on medical product communications for a long time. Under long-standing policy at the FDA, 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 claim it infringes manufacturers’ free speech rights.

Chilly Reaction

Many FDA lawyers are skeptical about whether the newly released guidances and memorandum will actually clarify anything. “Make no mistake: FDA has not addressed its First Amendment problem” about what companies can say, Coleen Klasmeier, a lawyer with Sidley & Austin in Washington, told Bloomberg BNA Jan. 18. “This is a side-show.” Klasmeier is a former FDA official.

Comments on the draft guidance documents and the memorandum (FDA-2016-N-1149) are due April 19. Federal Register notices announcing the documents will be published in the Jan. 19 Federal Register.

Doubts on Clarification

Marc J. Scheineson, a former associate commissioner at the FDA, now with Alston & Bird in Washington, told Bloomberg BNA the new documents don’t shed much new light on off-label policy.

“Adding this memo to the open docket does little to make it any easier for the next Commissioner to clarify FDA’s implementation of the judicial mandate to allow the use of off-label information by manufacturers unless it is clearly false or misleading,” he told Bloomberg BNA Jan. 18.
And Klasmeier said the additional delays will only add to enforcement and regulatory problems.

“We have been waiting for years for clarification on specific FDA policies, and the delay in the comment period will exacerbate the problems with the existing regulatory and enforcement environment,” Klasmeier said. “The delay is frustrating because it is clear what the law is and clear what FDA must do to its policies as a result of constitutional limitations.”

But Adriane Fugh-Berman, associate professor in the Department of Pharmacology and Physiology and in the Department of Family Medicine at Georgetown University Medical Center, praised the memo. “This is a valiant defense of the FDA's mission. It's a spirited affirmation of public health principles,” she told Bloomberg BNA Jan. 18. “Allowing off-label promotion would gut the FDA's ability to protect the public. It would take us back to the 19th century, when hucksters sold potions with no evidence of efficacy,” she said.

Fugh-Berman has been a paid expert witness in litigation regarding pharmaceutical marketing practices and directs PharmedOut, a Georgetown University Medical Center project that advances evidence-based prescribing and educates healthcare professionals about pharmaceutical marketing practices.

Influencing New Administration?

Food and drug law experts said the memo is the FDA's attempt to defend its policies and influence policy in the new Trump administration.

“The First Amendment memo lays out the best case possible defending the current FDA policies on off-label,” John Kamp, consulting counsel to Wiley Rein LLP and executive director of the Coalition for Healthcare Communication, told Bloomberg BNA Jan. 18. “Indeed, it appears to be a statement that current policy is constitutional and FDA is prepared to continue to defend it in court.”

“So far, that hasn't worked,” Kamp said. “Meanwhile, we will have a new President and a new administration.”

“These documents are being released late in the Administration for a reason,” Klasmeier said. “This area is fraught for FDA, and the timing indicates that agency—and especially HHS—officials are hoping to affect the incoming Administration's approach.”

“This is definitely not the last chapter in this novel,” Kamp said.

Califf Comments

FDA Commissioner Robert Califf said in a statement on the new documents that “we recognize that there is a high level of interest regarding FDA's views on communications about medical products” and “we are committed to an ongoing dialogue with industry and other stakeholders, and when needed, providing guidance to clarify the agency's thinking on these issues.”

FDA's dialogue with industry on what companies can say about their products will continue into the new administration. Califf is still the FDA commissioner, but will step down on Jan. 20 at noon, “as per the traditional presidential transition process,” an FDA spokeswoman told Bloomberg BNA.

Stephen Ostroff, the FDA's deputy commissioner for foods and veterinary medicine, is expected to become the acting commissioner. Ostroff also was the acting commissioner before Califf was confirmed.

Scattershot Approach?

Deborah M. Shelton, a partner in the FDA Practice Group of McCarter & English in Washington, told Bloomberg BNA Jan. 18 “the good news is the FDA is at long last moving on issuing guidance that many have long advocated and pressed FDA for,” but it “certainly would have been helpful if the FDA had issued the draft guidelines earlier. Unfortunately, the current approach comes across as rather scattershot.”

In November 2016, the FDA held a public hearing to obtain input about its policies on manufacturer communications concerning communication about unapproved, or off-label uses, of their products (14 PLIR 1550, 11/18/16). The agency also opened a docket to obtain written comments after the hearing (Docket No. FDA-2016-N-1149).

Shelton said it would have been helpful to have had these guidance documents earlier so that they could have been included
in the hearing’s discussion and “to have earlier informed the substantial work that many have already invested in the post-meeting comments.”

Comments to the docket were initially due Jan. 9, and then in mid-December the FDA announced a 90-day extension until April 10. “And now, further creating confusion, they’ve added a 60-page white paper to that docket, and issued two additional guidance documents to separate dockets,” Shelton said.

In the draft guidance documents, the FDA “is trying to flesh out their interpretation of truthful and nonmisleading” and “now we’ll have to see as we go through these drafts, what we agree with and what we don’t,” Shelton said.

“And separate and apart from the draft guidances that FDA has now issued, a looming question that still remains, of course, is how is the FDA going to treat product communications about unapproved uses?” Shelton said. “You would hope the same overarching principles of truthful and nonmisleading will be the guides, but we’ll see.”

Communicating With Payers

A number of FDA’s statutory and regulatory provisions potentially affect manufacturer communications with payers, including section 114 of the FDA Modernization Act of 1997 (FDAMA) (Pub. L. No. 105-115) and section 3037 of the 21st Century Cures Act (Pub. L. No. 114-255), the agency said. Section 114 of FDAMA allows drug companies, under certain conditions, to provide off-label information to payers.

Section 3037 of the Cures Act essentially says that health care economic information provided to payers on prescription drugs for coverage or reimbursement purposes, isn’t considered to be false or misleading if the information refers to an approved indication.

The first draft guidance “provides FDA’s thinking on frequently asked questions regarding such communications in order to provide clarity for firms and payors,” the agency said.

Specifically, the guidance explains how medical product manufacturers should communicate health-care economic information (HCEI) about approved prescription drugs to payers, formulary committees, or other similar entities, the agency said. It also answers common questions about manufacturer communications on investigational drugs and devices to payers before the FDA has approved or cleared these products.

Payers “seek a range of information on effectiveness, safety, and cost-effectiveness of approved prescription drugs, including information from firms, to help support their drug selection, formulary management, and/or coverage and reimbursement decisions on a population basis,” the FDA said. “Often, this information differs from and can be provided in addition to the information FDA reviews in order to make approval decisions.”

The FDA said in some situations, payers need to plan for and make coverage and reimbursement decisions before the FDA approves or clears a medical product.

The agency said all communications to payers should be “truthful and non-misleading.”

Communications on Approved Uses

Medical product manufacturers “have expressed interest in communicating, including in promotional materials, data and information that are not contained in their products’ FDA-required labeling, but concern the approved/cleared uses of the products,” the FDA said.

The FDA said a manufacturer’s communication of information that isn’t in the product's labeling, but that is determined to be consistent with the labeling, isn’t alone considered evidence of a new intended use. But even if a communication is consistent with the labeling, the suggestions made about the product would misbrand the product and could subject a company to enforcement action if the suggestions are false or misleading, the agency said.

Therefore, the second draft guidance describes the “FDA’s thinking on the types of information that are consistent with the FDA-required labeling and provides general recommendations for how this information can be conveyed in a truthful and non-misleading way,” the agency said.

Industry Comments
Khatereh Calleja, senior vice president of technology and regulatory affairs at the Advanced Medical Technology Association (AdvaMed) said in a Jan. 18 statement to Bloomberg BNA: “while we are still reviewing the draft guidances, AdvaMed has long supported FDA's thoughtful review and clarification of its policies to facilitate understanding of agency thinking and ensure appropriate scientific discourse of fundamental importance to the public health.”

“As the agency has acknowledged, the public health can be served with truthful and non-misleading scientific and medical information on medical products,” Calleja said. “We believe that timely and robust scientific discourse on device innovation is critical to the public health and in the best interests of patients, health care professionals, and the overall health care system in the U.S.”

A spokesman for the Biotechnology Innovation Organization (BIO) told Bloomberg BNA in an e-mail that BIO is “currently reviewing both documents and look[s] forward to providing our comprehensive feedback to the FDA in due course.”

The Pharmaceutical Research and Manufacturers of America (PhRMA) didn't return a request for comment.

To contact the reporters on this story: Dana Elfin in Washington at delfin@bna.com; Bronwyn Mixter in Washington at bmixter@bna.com

To contact the editor responsible for this story: Brian Broderick at bbroderick@bna.com

For More Information

The guidance on communications with payers is at http://src.bna.com/luG.
The guidance on communication about approved uses is at http://src.bna.com/luK.
The FDA's memorandum is at http://src.bna.com/lv5.