FDA Allows Off-label Communications to Payors, Formulary Committees, and Similar Entities. What's Next?

Seth S. Ray

In June, FDA issued two final guidance documents on medical product communications for drug and device manufacturers. The first guidance concerns "Medical Product Communications That Are Consistent With the FDA-Required Labeling." As you will recall, the second guidance on "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities," allows manufacturers to provide certain types of information (not limited to health care economic information) about unapproved uses of approved or cleared drugs and devices.[1]

It is important to remember that these allowances for providing information about unapproved uses are limited to audiences that include only payors, formulary committees, or other similar entities. FDA has yet to provide updated guidance addressing manufacturer communications about unapproved products or unapproved uses to other important audiences, such as health care providers making individual prescribing decisions.

Nonetheless, there are several scenarios through which FDA could allow off-label information to be disseminated more freely to health care providers.

- As suggested by health policy researchers, FDA could authorize a third-party advisory body to determine whether specific clinical evidence or other information is truthful and not misleading.
- FDA could establish a new regulatory pathway (e.g., an advisory opinion process) that would allow companies to submit information that, unless the agency deems the information to be false or misleading in a timely manner, could be disseminated without legal risk. Of course, drug companies can currently submit draft promotional pieces to FDA's Office of Prescription Drug Promotion (OPDP) for review and comment under 21 C.F.R. Part 202.1(j)(4). However, it often takes a long time for companies to obtain comments from OPDP, and the agency has been reluctant to provide comments on promotional pieces that raise possible First Amendment issues.
- Congress could pass legislation that allows companies to communicate more freely, limit FDA's regulatory oversight, or both. This was debated in the House Energy and Commerce Committee as part of the 21st Century Cures legislation, but a provision on off-label communications contained in a draft of the bill was ultimately deleted.
- New lawsuits could be brought challenging FDA's actions or policies or through which the Second Circuit's ruling in U.S. v. Caronia could be embraced by other circuits or by the U.S. Supreme Court.[2]
- The most likely scenario is for FDA to issue new guidance. FDA could respond to requests from the industry-supported Medical Information Working Group seeking clarification from the agency on a narrower scope of what constitutes "labeling," "advertisements," and establishing a new "intended use," and what are the parameters of permissible "scientific exchange."

What is more likely, in our opinion, is that FDA would issue draft guidance addressing manufacturer communications about investigational products and unapproved uses to health care providers. FDA prepared comprehensive guidance along these lines during the Obama Administration; however, it

1 We have previously written Bulletins on these guidances. See https://www.agg.com/Talk-This-Way-Pt-2-07-11-2018/

2 703 F.3d 149 (2d Cir. 2012).

was rejected by the Office of General Counsel (OGC) at HHS due to legal and legislative risks and policy considerations. Nevertheless, it is believed that many of the concerns expressed by OGC could be remedied or minimized through revisions and reframing.

It is particularly important for FDA to issue additional guidance because the Department of Justice and states continue to pursue enforcement actions against drug and device companies, resorting to civil remedies (False Claims Act) and other avenues, and often supported by general allegations of false or misleading promotional claims or conduct. Although promotional activities (including corporate speaker programs) and anti-kickback practices remain the most common areas of government scrutiny, DOJ has also investigated manufacturer donations to patient assistance programs, reimbursement support, and related privacy issues. So far, in 2018, DOJ has announced civil False Claim Act settlements with three medical device companies of $3.1 million, $7.62 million, and $33.2 million, concerning corporate speaker programs, aggressive sales tactics, and manufacturing problems.[3]

This area of the law remains highly convoluted, and FDA has found it extremely challenging to reconcile competing public health interests and First Amendment considerations. Hopefully, FDA will issue additional guidance before Congress or the courts do it for them.

3 "3 New Settlements Highlight DOJ Scrutiny of Device Makers," Law 360, April 4, 2018.

Authors and Contributors

Seth S. Ray
Of Counsel, DC Office
202.677.4926
seth.ray@agg.com

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Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
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