Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

FDA Memo Does Not Simplify 1st Amendment Considerations

By **Diane Lifton, Hughes Hubbard & Reed LLP**

Law360, New York (January 30, 2017, 12:23 PM EST) --

Diane E. Lifton

On Jan. 18, 2017, just two days before a new administration was set to take over, the U.S. Food and Drug Administration issued a memorandum purporting to address First Amendment and other considerations as part of its reexamination of FDA rules and policies relating to company communications of truthful nonmisleading information regarding unapproved uses of approved/cleared drugs and medical devices.[1] Those hoping the FDA might acknowledge directly that the sharing of such information constitutes protected free speech under the First Amendment, or less drastically, at least might simplify the universe of FDA guidances and good practice documents addressing its positions on the issue, will be disappointed. The FDA memorandum does little more than set out information about its positions that was already available in the public domain — including the FDA's position that it is not constrained by the First Amendment to penalize only company communications promoting unapproved uses of approved/cleared drugs and medical devices that are false and misleading.

For purposes of its later constitutional analysis, the FDA first promotes the various ways in which its own pre-market review of safety and efficacy, as part of the drug/medical device approval/clearance process, advances public or individual health interests,[2] including by:

1. Motivating the development of robust scientific data on safety and efficacy;

2. Preventing harm to members of the public;

3. Protecting against fraud, misrepresentation and bias;

4. Preventing the diversion of resources toward ineffective treatments;

5. Ensuring access to accurate information on the safe and effective use of drugs/medical devices;

6. Protecting the integrity and reliability of promotional information regarding drug/medical device uses;

7. Protecting human subjects receiving experimental treatments;

8. Protecting innovation incentives by ensuring meaningful patent protection; and

9. Promoting the development of products for underserved patients.

By contrast, the FDA acknowledges just two ways in which "reliable scientific information" communicated by companies about unapproved uses of approved/cleared drugs and medical devices can advance public or individual health interests, including (1) supporting informed decision-making for patient treatment, particularly where approved/cleared therapies are unavailable or have failed; and (2) furthering scientific understanding and research "through hypothesis generation, and increasing scientific understanding in new and developing areas."[3]

The FDA devotes the second half of its memorandum to justifying its continued proscription — and punishment — of company communications of truthful nonmisleading scientific information about off-label uses of drugs and medical devices. The FDA claims it seeks to ensure "a policy approach that integrates the multiple public health interests to maximize public good and reflects appropriate consideration of the First Amendment."[4] Its legal analysis, however, continues to fall short. Notwithstanding recent precedent finding the FDA's criminal prosecution of pharmaceutical and medical device companies for truthful, nonmisleading off-label promotion under the Food, Drug and Cosmetic Act to be unlawful under the First Amendment,[5] the FDA relies on a Second Circuit statement that does not even rise to the level of dictum to argue that it remains entitled to "prove misbranding on a theory that promotional speech provides evidence that a drug is intended for a use that is not included in the drug's FDA-approved label."[6] Alternatively, the FDA argues that its restrictions on speech, applicable solely to pharmaceutical companies, nevertheless survive heightened scrutiny, even if content- and speaker-based, because the FDA's approach "furthers the substantial government interest in preventing harm to the public health" and is narrowly tailored to only companies which have "an economic motivation related to product distribution."[7] However, the Second Circuit rejected precisely this approach in Caronia.[8]

Last, to illustrate its position that no other viable limitations exist for narrowly tailoring its restrictions on truthful and nonmisleading off-label promotion, the FDA addresses and rejects various approaches — some mentioned in court opinions and others by commentators.[9] The list of alternatives rejected by the FDA includes the extreme examples of an outright ban of or placing caps or other limitations on off-label prescribing, but also includes educating prescribers "to differentiate false and misleading promotion from truthful and non-misleading information" and allowing truthful and nonmisleading promotion for unapproved uses if the company discloses the use is unapproved and provides appropriate warnings. Of note, the FDA expressly rejects as inadequate limiting the type of evidence it can use to show the intended use was off-label to speech that it can prove is false or misleading, arguing that "[s]uch an approach would undermine the current incentives to generate scientific evidence sufficient to establish safety and effectiveness for each intended use of a medical product."[10]

At the same time it issued its memorandum, the FDA issued two new guidances, one addressing communications with payors, and the second addressing communications that are consistent with FDA-approved product labeling.[11] These guidances join predecessor guidances and best practices that make up the FDA's continued patchwork approach to limiting the dissemination of scientific information on off-label uses.[12] The comment period with respect to the memorandum and the two new guidances runs through April 19, 2017.[13]

Diane E. Lifton, a partner in the Hughes Hubbard & Reed LLP litigation department, Co-Chairs the Firm's Product Liability Group.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

[1] U.S. Food & Drug Admin., Memorandum: Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products (Jan. 2017) [hereinafter the "FDA Mem."]. A link to the FDA Memorandum can be found here: https://www.regulations.gov/document?D=FDA-2016-N-1149-0040.

[2]. FDA Mem. at 3-16

[3]. Id. at 17-18.

[4]. Id. at 20.

[5]. United States v. Caronia, 703 F.3d 149, 168-69 (2d Cir. 2012); Amarin Pharma Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196, 224-28 (S.D.N.Y. 2015).

[6]. FDA Mem. at 22 (citing United States ex rel. Polansky v. Pfizer, Inc., 822 F. 3d 613, 615 n.2 (2d Cir. 2016) (citing Caronia, 703 F.3d at 162)). But see Caronia, 703 F.3d at 162 n.9 ("Although we assume, without deciding, that such of use of evidence of speech is permissible under [Wisconsin v.] Mitchell, 508 U.S. 476, 113 S.Ct. 2194, we observe that it still remains unclear how the government would identify criminal misbranding from communications between drug manufacturers and physicians authorized to prescribe drugs for off-label use.").

[7]. Id. at 24-25.

[8]. Caronia, 703 F.3d at 167 (holding that the FDCA's misbranding provisions failed even intermediate scrutiny, because they were "more extensive than necessary to achieve the government's substantial interests").

[9]. FDA Mem. at 26-34.

[10]. Id. at 33.

[11]. Links to "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities" and "Medical Product Communications That Are Consistent With the FDA-Required Labeling" can be found at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf and http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537130.pdf, respectively.

[12]. FDA Mem. at 20-21 (first citing U.S. Food & Drug Admin., Revised Draft Guidance for Industry, Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices (Feb. 2014), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf; U.S. Food & Drug Admin., Good Reprint Practices for Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, Guidance for Industry (Jan. 2009), available

at http://www.fda.gov/oc/op/goodreprint.html; then citing U.S. Food & Drug Admin., Draft Guidance for Industry, Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (Dec. 2011), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf).

[13]. Statement, Robert Califf, M.D., Commissioner, U.S. Food & Drug Admin., Statement from FDA Commissioner Robert Califf, M.D. announcing new draft guidances on medical product communications (Jan. 18, 2017), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm537371.htm.
