



Litigation/Product Liability Practice

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FDA Issues Final Guidance Regarding Distribution of Off-Label Medical Articles

On January 12, 2009, the FDA published a Final Guidance for Industry for the distribution of medical journal articles regarding unapproved uses (“off-label reprints”) of FDA approved drugs and medical devices (“Final Guidance”).¹ Despite concerns from some that the guidance could lead to promotion of off-label uses of FDA-approved drugs and devices, the Final Guidance provides some clarity in an area left unsettled since September 2006, when a prior federal law expired.² The Food, Drug and Cosmetic Act and the FDA’s implementing regulations prohibit manufacturers of drugs or medical devices from promoting their products for uses that have not been approved through the FDA’s regulatory process. The FDA’s new guidance effectively creates a “safe harbor” for the lawful use of off-label reprints that is much less complicated and burdensome than the previously applicable statutory safe harbor requirements, which expired in 2006. The FDA’s decision to allow the use of reprints in this fashion acknowledges their value to public health. Pharmaceutical and medical device companies should update their corporate compliance measures to reflect this new guidance.

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Recommendations on Content and Use of Medical Reprints

As a statement of the FDA’s current enforcement policy, the Final Guidance provides the industry with some latitude regarding the use of medical journal articles regarding off-label topics, provided the article and its means of distribution meet certain criteria. The Final Guidance identifies principles that should be followed regarding types of scientific or medical articles and the manner in which they are distributed to health care providers. Some of the recommendations for medical reprints include that they: 1) should be peer-reviewed; 2) should be accompanied by the approved labeling for the drug or device; 3) should identify any person known to have provided funding for the study; 4) should not be written, edited or published for, or at the request of, a drug or device manufacturer; and 5) should not be distributed with information that is promotional in nature. The Final Guidance recommends a prominent statement on the reprint indicating, among other things, that the uses described in the reprint have not been FDA approved.

www.winston.com Recognized Public Health Importance

The Final Guidance acknowledges that public health may be advanced when health care providers receive truthful and non-misleading medical and scientific information on unapproved

1. See FDA Final Guidance for Industry, “Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices U.S.,” available at <http://www.fda.gov/oc/op/goodreprint.html>.

2. For additional analysis regarding this topic published by Winston & Strawn’s attorneys, see “The FDA’s Medical Reprint Policy - A Cautious Compromise, August 2008,” available at <http://www.winston.com/siteFiles/publications/FDA'sMedicalReprintPolicy.pdf>.

uses of approved or cleared drugs and devices. While the Final Guidance stops short of acknowledging a First Amendment right to distribute truthful medical reprints on off-label topics, it does acknowledge that off-label uses or treatments may be important and may constitute a medically recognized standard of care.

Other Observations Related to Enforcement Issues

The Final Guidance indicates that if a manufacturer follows the guidance, the FDA does not intend to consider the distribution of such medical articles as evidence of intent to promote off label. Apart from providing insight into the FDA's current enforcement policy, the Final Guidance does not create any enforceable rights, and does not bind the agency or the public.

Footnote 9 of the Final Guidance settles any lingering doubts about whether the FDA expects manufacturers, as a condition to disseminating off-label reprints, to comply with the procedures set forth in the law that expired in September 2006. That law set out steps that included: 1) submitting an application to the FDA for a new drug use; 2) providing the FDA with the reprints and supporting clinical trial data 60

days in advance of dissemination; and 3) satisfying several other detailed provisions. The Final Guidance states explicitly that these "other elements . . . are no longer applicable" to the FDA's enforcement policy and the "safe harbor" created by the guidance.

The guidance indicates that reprints should not be "the subject of discussion" during sales visits and recommends that sales representatives refer questions from physicians regarding the reprints to their company's medical or scientific department.

Recommendations for Pharmaceutical and Device Compliance Programs

Pharmaceutical and medical device companies should update their compliance programs to ensure that company sales representatives and medical science liaisons adhere to the principles of "good reprint practices" outlined in the Final Guidance. Specifically, each company should incorporate the Final Guidance, as appropriate, into the company's written standards of conduct, its education and training programs for employees who deal with medical and scientific reprints, and its compliance monitoring functions.

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