

Reprints draft guidance no gift to industry

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Sales reps could be effectively barred from circulating journal article reprints discussing off-label uses under FDA's draft guidance on "Good reprint practices," and the agency considers the policy to be effective already, even in its draft form.

DDMAC director Tom Abrams said in an email to *MM&M* the draft guidance "reflects the agency's current thinking." Reps "may disseminate peer-reviewed reprints but cannot promote their drug products for unapproved uses." Furthermore, "this material should be distributed separately from material that is promotional in nature, should not be the subject of detailing discussions, and should not be distributed in promotional exhibit halls or at promotional speakers' programs."

That's a lot of asterisks for a rep to wriggle around.

While initial press reports, parroting Rep. Henry Waxman's pre-emptive strike on the guidance, suggested that it represents a liberalization of agency policy on reprints, it actually limits distribution of journal articles sharply—more than companies felt comfortable doing in the absence of a stated safe harbor, experts in food and drug law say.

"This is a very limited proposal that virtually only allows [manufacturers] to do what the First Amendment demands they be able to do under the Washington Legal Foundation case," said Coalition for Healthcare Communications head John Kamp, referring to court decisions, from 1998-2000, in which WLF argued companies have a right to distribute articles on off-label uses.

Decisions in 1998 and 1999 favored the WLF's position, but in 2000, a federal appeals court, while sanctioning the reasoning of the earlier decisions, ruled them moot because the FDA said it did not prosecute companies for distributing such articles. The FDA later reaffirmed that policy but added that it would include distribution of journal articles on off-label uses as evidence of intent to promote products off-label in larger cases.

The draft guidance represents a step forward, said Kamp. “For the last 10 years, in the absence of FDA authority, the policy has been hijacked by HHS-OIG and investigators have been pretty much making it up as they go along,” said Kamp. “This limits the ability of HHS and state investigators under the False Claims Act to essentially make up new policy about what off-label means. This puts that authority in the hands of the FDA.”

“It's a safe harbor, but with a really big dragon at the mouth of it,” said Coleen Klasmeier, a partner at law firm Sidley Austin and a former special assistant to the chief counsel at FDA. “It's good in the sense that the FDA is saying, in a somewhat authoritative context, that there is a public health upside to the distribution of off-label information.”

Klasmeier said that's consistent with prior safe harbors affirming the rights of companies to engage in scientific exchange with respect to off-label uses, to respond to unsolicited requests for information on off-label uses from physicians and to sponsor medical education, even if content includes discussion of off-label uses. But Klasmeier worries that the draft guidance does not acknowledge those safe harbors. “One of my concerns is that prosecutors will read this and interpret it as the only way for manufacturers to do off-label information. It also doesn't do anything to recognize, apart from those safe harbors, the First Amendment right to engage in truthful and non-misleading speech, as the WLF case held.”

Perhaps most worryingly, Klasmeier said, wording in the draft guidance could be read to suggest that if a manufacturer following the policy engages, separately, in any violative promotion, “that safe harbor conduct suddenly becomes fair game.”