

REMARKS

OF

ARNOLD I. FRIEDE

**PUBLIC HEARING ON PROMOTION OF FDA-REGULATED MEDICAL PRODUCTS
USING THE INTERNET AND SOCIAL MEDIA**

**DAY 1
NOVEMBER 12, 2009**

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Good morning. I am a practicing food and drug lawyer with a longstanding interest in, and direct involvement with, FDA's regulation of medical product advertising and promotion. This engagement goes back almost 35 years to the late 1970's when I was an Associate Chief Counsel in the agency's Office of Chief Counsel. In that role, I was responsible, among other things, for pursuing fraudulent claims about the bogus cancer cure, "Laetrile". That effort culminated in the U.S. Supreme Court's decision in *United States v. Rutherford*, upholding FDA's statutory authority to require proof of safety and effectiveness as a condition to market entry. I have written and spoken extensively on various facets of FDA regulation of advertising and promotion, including a recent article I co-authored for the Food and Drug Law Institute Update Magazine titled, "Yes We Can: Time for an FDA Internet Drug Advertising Policy". (Copy attached).

There are three primary interpretive impediments to the evolution of a more hospitable -- and more rational -- FDA policy on use of Social Media and the Internet more generally. These have to do with FDA's interpretation of (1) where and how risk information must be disclosed in advertising and promotion, (2) whether and when statements should be attributed to a medical product "sponsor" for purposes of the prohibition on "off-label" promotion, and (3) mandatory reporting requirements whenever a sponsor becomes "aware of" information suggesting that an adverse event may have been caused (or "contributed to") by one of the sponsor's products. This morning, I'd like to suggest a framework for thinking about the risk disclosure and off-label promotion issues. Tomorrow, I will have some thoughts on adverse event reporting.

1. Risk Disclosure.

In its 14 Notices of Violation (NOVs) issued earlier this year on sponsored website links, FDA effectively took the position that instantaneous and contemporaneous disclosure of all risk information is required whenever a product name and any mention of any product attribute appear together in a sponsored medium. Given the limitations of many new media, this is not always possible. Nor is it necessarily even desirable. However, there is an alternative construct that is consistent with current law and FDA's approach in other analogous circumstances. That alternative construct focuses on *context* in determining the adequacy of risk disclosure. So, for example, in the case of internet search engines, a link conspicuously identified as "Risk Information" that calls attention to the availability of a landing page with the mandatory disclosures may well be adequate, in context, to amount to the required disclosure. This notion that context is relevant in determining where and how risk information may appropriately be disclosed is consistent with the approach taken by the Federal Trade Commission Staff in its so-called "Dot.com Disclosure Guides". It is also consistent, as outlined in our FDLI Update paper, with the approach FDA has taken to "bookending" of help seeking and reminder advertisements,

where FDA has said that it will look to overall context, including perceptual similarity, in deciding if the two in proximity to each other should be considered a single “advertisement” subject to risk disclosure requirements. And it is fundamentally consistent with the statutory definition of “labeling”, which looks at overall “context” in determining when an item “accompanies” a product so that it is deemed, by law, to be “labeling”.

Moreover, there is an existing regulatory architecture that already acknowledges that, in specific media, all of the mandatory disclosures need not be instantaneously available. We need only look to the “adequate provision” requirements that apply to direct-to-consumer (DTC) television advertising. There, FDA acknowledges that contemporaneously available complete risk information, even if not physically or technologically connected in any way to the advertising in question, can nevertheless satisfy statutory risk disclosure requirements. An analogous “adequate provision” rule seems perfectly do-able and reasonable in the Internet and Social Media context. What the specific contours and requirements for such a rule might be can be worked out by the agency in an appropriate guidance or rulemaking with input from stakeholders. At the same time, the principle that context is relevant in determining the adequacy of risk disclosure is already enshrined in FDA policy and can --and should-- be adapted to Social Media and the Internet more generally. Doing so would not necessarily amount to the disguised adoption of the never-codified “one click” that FDA has implicitly repudiated in its NOV’s on sponsored links. On the contrary, the principles on “adequate provision” for Social Media and the Internet more generally would be developed in a deliberate and thoughtful way considering the multiplicity of informational attributes and technical factors applicable to an array of new media. The specific final contours of such “adequate provision” criteria need not be articulated today. At the same time, the agency should acknowledge the need for adoption of such “adequate provision” principles and should commit to their development.

2. “Off-Label” Promotion.

There is a substantial, and eminently reasonable concern, particularly in light of all of the current FDA, DOJ, and OIG prosecutorial activity around “off-label” promotion, that any “off-label” mention by anyone on an Internet web site or Social Media site operated or sponsored by a pharmaceutical or medical device manufacturer will automatically be imputed to the manufacturer for purposes of “off-label” promotion liability. Imputing such “off-label” mentions to a manufacturer creates some serious problems, particularly, for example, in the context of technology such as Sidewiki, where information can be posted to, and effectively become part of, a web site without any involvement whatsoever by the manufacturer and can thereafter be viewed by anyone with the appropriate Internet tools.

The proposition that a manufacturer may have imputed liability for all “off-label” mentions that appear anywhere on a Social Media or other Internet site maintained or sponsored by the manufacturer works a serious distortion in the information marketplace. On the one hand, anyone and everyone can participate freely in all manner of conversation in the unaffiliated blogosphere. On the other hand, as soon as an individual posts an off-label comment to a site maintained or sponsored by a medical product manufacturer, there is a serious possibility in the current climate that the manufacturer may be charged with off-label “promotion”. That cannot possibly be a correct statement of current law where the manufacturer has done nothing more than provide a facility whereby someone posts an unsolicited off-label comment but otherwise lacks the ability to direct or control the content of the posting, except perhaps to delete it or disclaim it. By analogy, a publisher does not automatically have imputed liability, say, for false advertising by third parties who use its facilities to disseminate information.

In a variety of circumstances, FDA has acknowledged that a manufacturer is not automatically liable for third party behavior that it does not dictate or have the ability to control. For example, in the context of pharmacy benefit management companies (PBMs) that are subsidiaries of regulated entities, FDA in the mid-1990’s endeavored to develop criteria, akin to those that distinguish between “independent contractors” and “agents”, for determining when information disseminated by a PBM subsidiary would be imputed to an FDA-regulated parent pharmaceutical company. Likewise in the context of its Guidance on Continuing Medical Education (CME), FDA has implicitly acknowledged that agency law principles of “direction and control” are relevant in determining if “off-label” CME will be imputed to a manufacturer who provides funding for a CME program. This same principle of “direction and control” was likewise recently applied by the Federal Trade Commission, albeit again somewhat implicitly, in announcing its final revised Guides on Endorsements and Testimonials. In that case, endorsements by third party bloggers will be imputed to a product “sponsor” only if there are indicia of direction and control by the sponsor over the content of the communication. Otherwise, the product sponsor will not be liable for the endorsement.

Given the profound potential liability associated with “off-label” promotion, it seems only fair and appropriate for FDA, in consultation with the Department of Justice and the Office of Inspector General of the Department of Health and Human Services, to articulate clear standards, based on agency law principles involving the ability to “direct and control” the content of a communication, for when a company that maintains or sponsors a Social Media or other Internet web site is legally responsible for “off-label” communications posted there. It may well be, by analogy to principles that apply in the First Amendment context that favor “disclaimers” over outright speech suppression, that conspicuously posted “disclaimers” may well be adequate to correct any possible misimpression that a communication is necessarily attributable to a regulated manufacturer. Or perhaps the manufacturer who maintains or sponsors a Social Media or other Internet site has an affirmative obligation to monitor and take “corrective” action of some kind in response to an “off-label” posting that the company did not direct or control. Whatever the standards or criteria should be for whether and when “off-label” statements will be imputed to a product manufacturer who maintains or sponsors a Social Media or other Internet web site, these standards should be articulated by the FDA and other interested

regulatory and enforcement agencies with clarity and precision in a Guidance or rulemaking. In the 21st Century, it seems utterly unrealistic to maintain an *in terrorem* regime that most rational-thinking people currently believe imposes automatic liability on a manufacturer for off-label postings that it neither directs or controls.

Thank you.

REMARKS

OF

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**PUBLIC HEARING ON PROMOTION OF FDA-REGULATED MEDICAL PRODUCTS
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**DAY 2
NOVEMBER 13, 2009**

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Good morning. I am a practicing food and drug lawyer with a longstanding interest in, and direct involvement with, FDA's regulation of medical product advertising and promotion. This engagement goes back almost 35 years to the late 1970's when I was an Associate Chief Counsel in the agency's Office of Chief Counsel. In that role, I was responsible, among other things, for pursuing fraudulent claims about the bogus cancer cure, "Laetrile". That effort culminated in the U.S. Supreme Court's decision in *United States v. Rutherford*, upholding FDA's statutory authority to require proof of safety and effectiveness as a condition to market entry. I have written and spoken extensively on various facets of FDA regulation of advertising and promotion, including a recent article I co-authored for the Food and Drug Law Institute Update Magazine titled, "Yes We Can: Time for an FDA Internet Drug Advertising Policy". (A copy of that article is attached to my prepared remarks from yesterday.)

There are three primary interpretive impediments to the evolution of a more hospitable -- and more rational -- FDA policy on use of Social Media and the Internet more generally. These have to do with FDA's interpretation of (1) where and how risk information must be disclosed in advertising and promotion, (2) whether and when statements should be attributed to a medical product "sponsor" for purposes of the prohibition on "off-label" promotion, and (3) mandatory reporting requirements whenever a sponsor becomes "aware of" information suggesting that an adverse event (AE) may have been caused (or "contributed to") by one of the sponsor's products. Yesterday, I discussed a framework for thinking about the provision of risk information and off-label promotion. Today, I will briefly address AE reporting in the context of Social Media and the Internet more generally.

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I submit that the AE Reporting Issue, in the context of Social Media and the Internet more generally, is based on an underlying premise whose validity and applicability in the 21st Century is open to serious question. Here is what I mean. The concern about AE reporting stems from FDA rules that mandate reporting whenever a sponsor becomes "aware of" information of sufficient specificity showing that the sponsor's product may have caused, or contributed to, an AE. This has been interpreted by many to mean, for example, that if I am a pharma company employee and am on the Acela train from New York to this Public Hearing in Washington, DC, and I overhear a conversation with enough detail to make me "aware of" a reportable AE, I have an obligation to submit this information to the company's Safety Reporting Group and the company, in turn, has a legal and regulatory duty to investigate it and, assuming it meets reportability thresholds, to report it to FDA. But why worry about the obligation to report every last AE a sponsor becomes "aware of"? Some of this information is likely duplicative of what has already been reported. And some is undoubtedly cumulative in the sense

that the incidence and severity of the AE is already fully and completely addressed in the product's labeling and the additional information does not add meaningfully to what we know about the product's risks and how to manage them.

Notionally, companies probably spend 99% of the time in safety monitoring in finding and reporting the very last AE, which may be a seriously disproportionate effort given the likely marginal value in the overall safety picture from such incremental reporting. In fact, FDA recently entered into an agreement with a Contract Research Organization (CRO) to evaluate the agency's spontaneous drug adverse event reporting system. Required as part of the 2007 user fee reauthorization, the \$2.7 million study will specifically examine the "value of the spontaneous adverse event reports to support safety-related regulatory actions and report its findings to the FDA and the public." According to the CRO, the evaluation will develop "conclusions and recommendations for maximizing the system's ability to support safety-related regulatory actions for drugs and therapeutic biologics throughout a product's life cycle." "This complex and unprecedented evaluation of the FDA spontaneous adverse event surveillance system will involve the development and implementation of innovative methodologies. The FDA will use these findings to develop an implementation strategy for ensuring optimal use of the system as part of its pharmacovigilance efforts to protect public health."

In other words, the utility of the current AE reporting system has not been empirically validated as a meaningful basis for regulatory decision making. Why, then, should AE reporting be a serious impediment to a company's use of Social Media and the Internet more generally? After all, the Food and Drug Administration Amendments Act of 2007 provides new tools for affirmatively managing risk via the new Risk Evaluation and Mitigation Strategies provisions, and new authority to mandate on-going post-market study to further evaluate risk. The statute likewise calls on FDA to develop and implement an active surveillance system. All of this does not necessarily mean we should discard spontaneous AE reporting but it does suggest that FDA reconsider the "aware of" reporting standard. Put differently, a re-evaluation of when spontaneous AEs ought to be reported to FDA as part of a comprehensive architecture for a safety surveillance system may well address many of the concerns on the subject that serve as a serious impediment to the deployment of innovative Social Media and Internet tools of substantial importance and value to the public health. So while "special" rules for AE reports posted to Social Media sites and the Internet more generally deserve careful consideration, the ultimate "answer" to the problem may well involve a more fundamental reevaluation of whether, when, and how spontaneous AE reporting should be part of the drug safety regime going forward.

Thank you.