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FDA and Internet Advertising

The Medium is the Message

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In September 2009, the U.S. Food and Drug Administration (FDA) announced that it would begin using the social media site Twitter to convey news and other information about drug safety and regulation. "Messages on Twitter provide consumers, healthcare professionals, the pharmaceutical industry, and others with timely information on new drug approvals, safety alerts, compliance actions, and consumer information,"[1] notes an agency website. It is helpful that the agency regulating an estimated 25 percent of the U.S. economy has come to recognize that "the Internet is the place where many Americans look first to manage their health."[2] However, the medical products industry has been feeling its own way around the Internet and other new media, including Twitter, for several years without substantive guidance from the FDA on manufacturers' legal obligations as to how they may present information to consumers.

That may change soon. In November 2009, the agency will hold a public hearing on the promotion of drugs and medical devices on the Internet and other new media tools, as a first step in the development of a formal policy on the matter.[3] This is a welcome development, one that could eventually increase consumers' ability to access useful information relevant to their health and well-being. However, if the FDA's evolving policy fails to take adequate account of the Internet's unique ability to present information in novel formats, it could have significant and adverse implications for consumers, Web service providers, and the medical products industry.

Advertisements and Comprehensive Risk Disclosure. The FDA, in accordance with its interpretation of the Federal Food, Drug, and Cosmetic Act, mandates significant risk disclosure in all advertising and promotional communications for prescription drugs and medical devices. Any advertisement or other promotional material that mentions the name of a prescription drug

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or medical device and a positive attribute, such as the medical condition the product is intended to treat, must also include comprehensive information describing the product's known side effects, contraindications, and effectiveness in treating the condition.[4]

Given the ease with which consumers can access information on the Internet with a click of the mouse, one might reasonably assume that it is legally permissible to include brief benefit claims on a web page, banner ad, or sponsored link, and notify viewers that additional information, including a full risk disclosure, is available one click away on a hyperlinked page.[5] For several years, the drug industry, Internet search engines, and ad makers all assumed this to be the case. After all, the very purpose of promotional tools such as sponsored links and banner advertisements is to help users navigate to a website page containing substantive content.

Manufacturers and advertisers adopted this "one click" rule as a different way of acknowledging what everyone understands about the contextual relationship between the information on the face of the sponsored link and that available on the linked page: The ad is not the end, but merely the starting point for an Internet user's search for information. The FDA, however, recently made clear that it did not recognize the "one click" rule, and informed several drug makers that their use of sponsored links did not satisfy its advertising regulations.[6]

In other industries, the absence of an applicable statutory or regulatory policy generally means that businesses and individuals have the flexibility to innovate. But, when it comes to the FDA's regulation of drug and device promotion, the absence of clear guidance effectively works as a prohibition on the kinds of innovation that would deliver complete risk and benefit information in ways that take advantage of the Internet's unique capabilities. It is no surprise then that drug and device manufacturers are still uncertain how to proceed with many new media tools, such as banner ads, sponsored links, email messages to physicians and patients, social media like blogs, Facebook, micro-blogs such as Twitter, or any other form of Internet communication.

The FDA's Not So Benign Neglect. As early as 1996, the FDA held a two-day public meeting to discuss issues related to the advertising and promotion of medical products on the Internet.[7] Since that time, the medical products industry has repeatedly urged FDA to offer more guidance.[8] However, the agency has never developed a formal policy to inform manufacturers of their legal obligations when using the Internet or other new media to convey information to physicians and patients. Indeed, in May 2009, FDA issued a draft guidance document on drug and device promotion generally. Except for a footnote listing product websites among the communication vehicles subject to regulation as advertising and promotion, that document barely acknowledges the Internet's existence.[9] The draft guidance expressly notes that the FDA applies the same principles about risk disclosure by manufacturers in prescription drug advertising "to all promotional pieces, regardless of the medium used."[10] By that wording, the agency seems determined to regulate the Internet as just another form of print communication.

The FDA's failure to distinguish between static print ads and the dynamic formats available through new media suggests that the agency may not fully understand communications theorist H. Marshall McLuhan's great insight that, "The medium *is* the message."[11] The medium's unique features influence how an audience perceives the message, and thus become an integral part of the message itself. Many new media tools have unique formats that defy the strict

application of rules designed to apply to newspaper and magazine ads, but have additional functionality that permit advertisers to present useful information in innovative ways.

One jarring example is the agency's recent enforcement actions against the use of sponsored links on Internet search engines like Google and Yahoo. On April 2, 2009, FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) issued 14 Notices of Violation to drug manufacturers for their use of sponsored links that include the name of a drug and a brief affirmative statement about the product or the disease it treats on Internet search engines, while directing users to a separate website that contains complete benefit and risk information.[12] If there is any affirmative statement about the product or the disease it treats on the face of the sponsored link, then, according to DDMAC, all of the mandatory risk information otherwise required by FDA's advertising and promotion regulations must likewise appear on the face of the sponsored link and will not satisfy the risk disclosure requirement even if fully and completely available "one click" away via the hyperlink. This applies even if the only mention of the product name appears in the hyperlinked URL itself, and not in the paid text.

DDMAC concluded that the face of the sponsored link represents an independent and discrete portion of the advertisement, and therefore must include—immediately and contemporaneously viewable—all of the product's risk disclosure information alongside the link on the search results page.[13] Sponsored links resulting from key word searches are generally limited to a total of 70 individual characters for the text of the advertisement,[14] so this approach effectively precludes the use of sponsored links that disclose the product name and provide any modicum of benefit information to alert searchers to what they will encounter when they click on the hyperlink.

The agency appears unwilling to recognize that hyperlinks as an integral part of the Internet with which virtually every Internet user is familiar. Indeed, the very purpose of a key word search is to generate sponsored links to those sites where the searcher may find the relevant information he or she needs. This is precisely why a searcher initiates a key word search in the first place. To assert that the sponsored link's landing page—on which the risk information is accessible—is irrelevant in determining the adequacy of the risk disclosure is to disregard the realities of the medium and to elevate form over substance.

TV Ads and the Flexibility Precedent. It is too early to tell whether these recent enforcement actions represent merely public relations stunts intended to announce a new "get tough" approach toward the pharmaceutical industry by the new administration, or whether they signal that FDA, after all these years, still fails to recognize the distinctions among print, broadcast, and online media. Fortunately, the November 2009 public hearing on Internet drug and device promotion offers the agency a prime opportunity to begin devising a policy that accounts for differences among the various types of media.

That would not be unprecedented. After it resisted doing so for many years, the FDA eventually adopted a policy that acknowledges, to a limited extent, the distinct features of television advertising. In its "major statement" guidance for risk disclosures in television advertising, FDA acknowledged the inability of TV to carry contemporaneous and instantaneous disclosure of all risk information.[15] Because TV ads are limited to just 30 or 60 seconds, the agency permits drug manufacturers to include just a brief description of the product's "most important risk

information," while providing the full risk disclosure through alternative means, such as a toll-free telephone number, in print advertisements that appear concurrently in publications reaching the same audience likely to see the TV ad, or *on the Internet*.

It is ironic that FDA's drug and device promotion policy allows for viewers of a television ad to be directed to a product's full risk disclosure on a website not directly connected with the TV commercial, but requires sponsored links to contain the risk disclosure on the face of an ad that directly links to the same website. Still, there is some reason to hope that FDA, upon further consideration, might be persuaded to adopt more rational policies for regulation of advertising on the Internet and other new media.

Arguably, FDA's categorical rejection of the landing page as an integral component of the sponsored link violates one of its own principles of advertising interpretation. In other contexts, the agency has taken the position that seemingly separate statements should nevertheless be aggregated and considered together in determining whether the ensuing "advertisement" complies with the risk disclosure requirements applicable to promotional labeling and advertising.[16] For example, so-called "reminder advertisements" merely mention the product's name but say nothing about the illness the product is intended to treat. "Disease awareness advertisements" inform viewers that a treatment for a particular medical condition is available, and direct viewers to "consult a doctor," but do not mention the product's name. By themselves, neither is generally subject to the risk information disclosure requirement. However, if a reminder ad appears in close proximity to a disease awareness ad—by, for example, appearing in the same magazine—the FDA could consider them jointly a promotional advertisement that must disclose risk information. As the agency noted in its May 2009 draft guidance:

> Psychology and marketing research suggest that the greater the perceptual similarity between disease awareness communications and reminder or product claim promotions … and the closer they are presented physically or in time to one another, the more likely it is that the separate messages contained in the two pieces will be remembered together in memory as one entity.[17]

It is not apparent why this same logic is inapplicable to hyperlinked risk disclosures in sponsored links where the information is accessible only one click away. If the principle that A accompanies B even if the two are not physically attached, then that same principle ought to apply in determining what constitutes a discrete component of an advertisement in the first place.

The FTC's "Net Impression" Approach. The FDA's approach to hyperlinked disclosures is particularly frustrating in light of the Federal Trade Commission's (FTC) more nuanced approach for advertising in other industries. The FTC does not categorically reject hyperlinked disclosures in determining whether an advertisement is misleading or not.[18] Instead, when considering the adequacy of a required information disclosure, it examines the conspicuousness of the hyperlink, whether it signals the availability of risk information, and other contextual factors.[19] Rather than ticking off arbitrary boxes, the FTC looks at an entire presentation and considers the "net impression" that a "reasonable man" would form when viewing the information aggregated on linked web pages. In this respect, the FTC acknowledges the

important differences that exist between differing media and the need for regulatory policy to be flexible enough to accommodate those differences.

The FTC seems to recognize that anyone with an interest in the affirmative information presented in the search results and who wants to learn more knows to click on the available link to gain access to that information. Curiously, in its May 2009 draft guidance document, the FDA explained that it too was adopting both the FTC's "reasonable man" and "net impression" tests for interpreting how consumers understand affirmative benefit representations and risk disclosures.[20] But, in its enforcement actions against drug manufacturers using sponsored links, the FDA nevertheless came to the exact opposite conclusion.

It would be hard to argue that the hypothetical "reasonable man" who conducts a key word search using an Internet search engine does not know to click on the hyperlinked information for more information. That is what the medium is all about and why the searcher uses it, just like a newspaper reader knows to go beyond the front page to get to the rest of the story. Moreover, the "reasonable man" who clicks through to the risk information via a hyperlink is much more likely to take the time to read and absorb the complex risk disclosures than are consumers confronted with all of that detailed information on the face of the sponsored link—even if it were technically possible to provide all of that information within the constraints of that medium.

Could FDA's Approach Increase Risk? Ironically, FDA's position on sponsored links could have the unintended effect of making regulated information less available to consumers while making less reliable and unsubstantiated information more available. A crackdown on sponsored links and other Internet advertising by the regulated industry could elevate the prominence of search results that link to websites containing utterly unsubstantiated claims by fly-by-night operators for products that are largely beyond the agency's enforcement reach. Indeed, if sponsored links for highly regulated drugs and devices become more rare, then an information seeker will be relegated to wading through a list of websites that contain all manner of information of dubious validity.

Also missing from FDA's analysis is any recognition that the risk disclosure regulations in question apply to *prescription* drugs, which, by definition, entail a learned intermediary relationship between the doctor and the patient. In this context, and in order to manage treatment, the doctor must first make a diagnosis, decide which, if any, drug to prescribe, and then write the prescription. Filling the prescription provides yet another opportunity for the patient to be counseled by the pharmacist dispensing the drug. In this context, the Internet is only the first step in the chain of information provision to the patient. FDA's insistence that all risk information be instantaneously and comprehensively disclosed on the face of an Internet ad ignores this continuum of available information.

Conclusion. Given the indisputable ubiquity of the Internet, and how it is being used by consumers, FDA's failure in its May 2009 draft guidance to even consider evaluating the Internet's communications capabilities for "net impression" in their specific context is perplexing at best and, frankly, somewhat shocking. There is a direct analogy between FDA's acknowledgment of the need for a distinct framework for the regulation of risk disclosures in TV advertising and the need for a comparable acknowledgment regarding Internet advertising.

There is ample room, even under current law, for FDA to apply a more nuanced and flexible approach to the regulation of drug and device promotion on the Internet and other new media. The November 2009 public hearings present a valuable opportunity for the agency to take a bold first step in developing a constructive policy for Internet advertising. Bringing FDA's 1960s approach to prescription drug advertising and promotion into the 21st century is long overdue.

Notes

[1] Food and Drug Administration, "Drug Information on Twitter," http://www.fda.gov/Drugs/ucm181556.htm.
[2] *See*, *e.g.*, B.W. Hesse, D.E. Nelson, G.L. Kreps, R.T. Croyle, N.K. Arora, B.K. Rimer, and K. Viswanath, "Trust and Sources of Health Information: The Impact of the Internet and its Implications for Health Care Providers: Findings From the First Health Information National Trends Survey," *Archives of Internal Medicine*, vol. 165, no. 22 (2005), pp. 2618-2624, http://www.ncbi.nlm.nih.gov/pubmed/16344419.
[3] FDA, "Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing," *Federal Register*, vol. 74, no. 181 (September 21, 2009), pp. 48083-48088.
[4] *See* Section 502(a) and 502(n) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §352(a) and (n), and 21 CFR §202.1.
[5] *See*, Anon. "14 Warning Letters in a Day! What's That About," *Eye on FDA* (April 6, 2009), http://www.eyeonfda.com/eye_on_fda/2009/04/14-warning-letters-in-a-day.html.
[6] Id.
[7] FDA, "Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing."
[8] See, e.g., Letter from Margaret M. Dotzel, FDA Associate Commissioner for Policy to Daniel J. Popeo, et al., FDA Docket No. 01P-0187/CP 1 (November 1, 2001), http://www.fda.gov/ohrms/dockets/dailys/01/Nov01/110901/01p-0187_pdn0001.pdf (denying Citizen Petition filed by Washington Legal Foundation seeking adoption of FDA regulatory policy on information presented or available on a company's Internet website).
[9] FDA, *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion*, (May 2009), footnote 9, *http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm155480.pdf*. See
[10] Id., p. 4.
[11] Marshall McLuhan, *Understanding Media: The Extensions of Man* (New York: Mentor Press, 1964).
[12] *See*, FDA, "2009 Warning Letters and Untitled Letters to Pharmaceutical Companies," http://www.fda.gov/cder/warn/warn2009.htm.
[13] *See*, 21 CFR §202.1(e)(3)(i).
[14] Sponsored links are generally limited in the number of permitted characters. For example, Google AdWords limits the total number of characters, including spaces, to 25 for the title, 70 for the ad text, and 35 for a display URL (Univeral Record Locator). *See*, "Google AdWords Help—How much text can I have in my ads?" http://adwords.google.com/support/bin/answer.py?hl=en&answer=6095.
[15] *See*, *Guidance for Industry, Consumer-Directed Broadcast Advertisements*, (August 1999), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070065.pdf. *See also* 21 CFR §202.1(e)(1).
[16] *See*, FDA, *Draft Guidance for Industry "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms*, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070068.pdf; and FDA, DDMAC Warning Letter regarding Strattera®, (September 26, 2008), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm054007.pdf.
[17] *See*, FDA, *Draft Guidance for Industry "Help-Seeking" and Other Disease Awareness Communications*, p. 6.
[18] *See*, FTC, *DotCom Disclosures: Information About Online Advertising*, FTC Staff Working Paper (May 2000), http://www.ftc.gov/bcp/edu/pubs/business/ecommerce/bus41.pdf.
[19] *Id*. at pp. 11-13.
[20] FDA, *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion*, pp. 4-5.