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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

Re: **Docket No. FDA-2008-D-0253**
Draft Guidance for Industry, Presenting Risk Information In Prescription Drug and Medical Device Promotion.

Dear Sir or Madam:

The Competitive Enterprise Institute (CEI) appreciates the opportunity to submit these comments on the U.S. Food and Drug Administration's (FDA's) Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion (May 2009). *See* 74 Fed. Reg. 25245 (May 27, 2009) (Draft Guidance). CEI is a non-profit, non-partisan public interest research and advocacy group that studies the intersection of regulation, risk, and markets. Our comments focus on FDA's regulation of advertising and promotion of prescription drugs in new media such as the Internet, but they are equally applicable conceptually to FDA's regulation of medical device advertising and promotion in these media.

1. Background.

As the Draft Guidance explains, FDA, in accordance with its interpretation of the Federal Food, Drug, and Cosmetic Act (the Act) mandates significant risk disclosure in all advertising and promotional communications for prescription drugs. The agency applies the same regulatory approach regardless of the medium. In principle, CEI disagrees that the current regime for risk disclosure in prescription drug advertising and promotion, no matter what the medium, optimally serves the interests of public health. On the contrary, in our view, encyclopedic disclosure of risk that is incapable of both meaningful comprehension by individuals of ordinary education and intelligence and meaningful cognitive integration in behavioral terms violates the "less is

more" tenet that FDA has repeatedly acknowledged to be appropriate[1] and that the agency's own research has repeatedly, albeit perhaps only implicitly, validated.[2] Moreover, and at least as applied to direct-to-consumer (DTC) advertising, such encyclopedic risk disclosure is not required by the Act, and is inconsistent with it.[3] It also necessarily elevates risks over benefits in the minds of consumers, which in many instances itself works a substantial disservice to the public health. Inasmuch as the "how to" aspects of the Draft Guidance are largely based on this flawed premise, CEI questions the document's overall utility. Nor is it apparent why FDA believes it ought to propose such a "how to" bible without first addressing, let alone resolving (or indeed even discussing meaningfully in the Draft Guidance), the significant issues raised in earlier agency proceedings about the nature and scope of mandatory risk disclosures in FDA-regulated prescription drug advertising and promotion.[4]

At the same time, however, and taking the encyclopedic disclosure premise as a given for analytic purposes, there remain serious concerns about how that premise should be accommodated in the context of FDA's regulation of new media such as the Internet. Tellingly, FDA's admonition in the Draft Guidance that the agency applies the same principles about risk disclosure in prescription drug advertising "… to all promotional pieces, regardless of the medium used …"[5] is a blunt reminder that, despite repeatedly being asked to do so,[6] FDA has not adopted a discrete policy governing Internet communications. In this respect, FDA's failure to appreciate the importance of the medium in determining the overall message in a promotional communication is both disappointing and squarely at odds with the "tech savvy" approach the Obama Administration has shown towards new media.[7] As we explain below, this is not only inconsistent with current law and FDA's policy in analogous contexts, but it fundamentally—and

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[1] *See, e.g.*, Statement of then-FDA Commissioner Mark McCllelan, Transcript of FDA News Teleconference Announcing DTC Draft Guidances at 2 (Feb. 4, 2004), *cited in and attached to "Comments of Pfizer Inc., In the Matter of : Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements,"* FDA Docket No. 2004D-0042 (May 7, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/may04/051004/04D-0042-emc00001-01.pdf ("Less is more for consumers because they can actually get more out of this information.")

[2] *See, e.g.*, *DDMAC Research Team Report*, Presentation by DDMAC's Aimee C. Donohue, Ph.D., at DTC National Congress, Washington, DC (April 17, 2009) at Slide 27, *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM148275.pdf (showing time spent by consumers in reading brief summary in DTC print advertising, including median time spent of 13.87 seconds, which means that half of consumers spend less time than that in reading, let alone comprehending, the brief summary in DTC print advertising).

[3] *See generally* Coalition for Healthcare Communication, *Citizen Petition Requesting Promulgation of Amended Regulation for Prescription Drug Advertising to Establish Separate Criteria for Practitioner-Directed and Consumer-Directed Advertising and To Establish a Standing Advisory Committee on Health Care Communication* (May 31, 2006), *available at* http://www.cohealthcom.org/content/FinalCHCCitizenPetition.pdf.

[4] *See, e.g., Comments of Pfizer, Inc., cited in* fn. 1 above.

[5] At 4 (lines 103-104).

[6] *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 (Nov. 1, 2001), *available at* 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 web site).

[7] *See generally* Arnold I. Friede and Robert B. Nicholas, *Yes We Can: Time for an FDA Internet Drug Advertising Policy*, FOOD AND DRUG LAW INSTITUTE UPDATE (July-August 2009) at 22-27 [hereinafter *Yes We Can*] (Copy attached and incorporated by reference herein).

ironically—misses the very import of the "net impression" test that the agency now explicitly adopts in the Draft Guidance for interpreting the meaning of advertising.[8]

Nor is the Draft Guidance the only recent example of FDA's failure to appreciate the Internet as a discrete medium of communication and to evaluate the meaning of advertising in that medium with sensitivity to its specific dynamics. For example, on April 2, 2009, the Division of Drug Marketing, Advertising, and Communications in FDA's Center for Drug Evaluation and Research (DDMAC) simultaneously issued 14 Notices of Violation (NOVs) to pharmaceutical companies in connection with sponsored links that are listed in response to key word queries on Internet search engines such as Google™.[9]

In the NOV's, DDMAC alleges that the failure to include all of the mandatory risk information on the face of the sponsored link categorically amounts to a violation of the Act. DDMAC makes this allegation despite the fact that (a) due to the constraints of the medium, the sponsored link is incapable of accommodating all of the required information on its face, and (b) the required information is accessible "one click" away on the landing page of the very URL to which the sponsored link directs the searcher. After all, finding responsive landing page URLs is precisely what an Internet key word search is all about. FDA's categorical rejection of context in evaluating compliance in such cases is at odds with the substantially more nuanced approach used by the Federal Trade Commission (FTC) in determining the adequacy of disclosures in Internet communications, including the adequacy of hyperlinked disclosures.[10] It is also directly at odds, as we explain below, with the "net impression" standard adopted by FDA in the very Draft Guidance at issue here.

2. The "Net Impression" Standard Requires Consideration of the Promotional Communication as a Whole in the Specific Context of the Medium Used to Disseminate the Message.

In determining what message is communicated in an advertisement, FDA, in the Draft Guidance, now explicitly adopts the Federal Trade Commission's long standing "net impression" standard determined from the perspective of the "reasonable consumer": "[W]e examine the practice from the perspective of a *consumer acting reasonably* in the circumstances."[11] As the FTC said in its underlying Policy Statement on Deception, which FDA has now adopted as its own, "[I]n advertising[,] the Commission will examine 'the entire mosaic, rather than each tile

[8] At 4, lines 111-112. ("FDA looks not just at specific risk-related statements, but at the ***net impression***—i.e., the message communicated by all the elements in the piece as a whole." (bold and italics in original)).

[9] *See 2009 Warning Letters and Untitled Letters to Pharmaceutical Companies* (May 2009), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm055773.htm.

[10] *See FTC Staff Working Paper on DotCom Disclosures* (May 3, 2000) at 12, *available at* http://ftc.gov/bcp/edu/pubs/business/ecommerce/bus41.pdf ("Under some conditions … a disclosure accessible by a hyperlink may be sufficiently proximate to the relevant claim. Hyperlinked disclosures may be particularly useful if the disclosure is lengthy …").

[11] Draft Guidance at 5 (emphasis supplied; quoting FTC Policy Statement on Deception (Oct. 14, 1983), appended to *FTC v. Cliffdale Associates, Inc., et al.*, 103 F.T.C. 110, 170 (1984)).

separately.'"[12] The principle that the agency should evaluate an advertisement based on the "entire mosaic" rather than "each tile" individually should be applied not only in determining what an advertisement means. It should also be applied in determining what elements of an advertising execution constitute the advertisement as a whole. The principle is likewise equally applicable in determining what constitutes "another distinct part" of an FDA-regulated prescription drug advertisement for purposes of evaluating when information in that "distinct part" may be disregarded by FDA in assessing compliance with risk disclosure requirements.[13] Put differently, context should guide application of the "net impression" test.

Nor should contextual interpretation be unilaterally applied, as FDA appears to do, only in determining non-compliance. On the contrary, context should be a bilateral consideration relevant in determining both compliance and non-compliance. Indeed, FDA itself has applied contextual analysis in determining regulatory policy in a variety of analogous circumstances. For example, FDA has said that "help seeking" and "reminder" advertisements, neither of which is independently subject to risk disclosure requirements, can be aggregated and considered as a single entity if perceptually similar and in close temporal or physical proximity.[14] In context, then, the components, according to the agency, can be aggregated and evaluated as a product promotional advertisement that requires risk disclosure.

Likewise, FDA has repeatedly endorsed, and endorses again in the Draft Guidance,[15] an interpretation of "labeling" based on the U.S. Supreme Court's decision in *Kordel v. United States*[16] that broadly defines when information "accompanies" a regulated article and when it should thus be evaluated along with the actual product "label" in determining whether statutory and regulatory requirements have been met. "[T]he labeling definition includes materials that supplement or explain an article, 'in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant.'"[17] Moreover, in its "major statement" guidance on risk disclosures in broadcast television advertising,[18] for example, FDA acknowledges that comprehensive risk information published contemporaneously elsewhere and utterly

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[12] FTC Policy Statement on Deception at §3 and fn. 31 (quoting *FTC v. Sterling Drug*, 317 F.2d 669, 664 (2nd Cir. 1963)).

[13] *See* 21 CFR §202.1(e)(3)(i) ("Untrue or misleading information in any part of the advertisement will not be corrected by the inclusion in *another distinct part* of the advertisement of a brief statement containing true information relating to side effects, contraindications, and effectiveness of the drug." (Emphasis supplied)).

[14] *See Draft Guidance for Industry, "Help Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms* (Jan. 2004) at 5-6 (perceptual similarity and close physical or temporal proximity increase likelihood that "… messages contained in the two pieces will be remembered in memory as one." *Id.* at 6 (lines 220-221)). *See also, e.g., Yes We Can* at 25; *FDA Warning Letter on Strattera®* (Sept. 25, 2008), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm049750.htm (even though promotional representations and disease awareness claims were not even proximate to each other, they were nevertheless aggregated by FDA and on this basis determined to amount to an implied "outcomes" claim).

[15] At 22.

[16] 331 U.S. 345 (1948).

[17] *Id.* at 350 (quoted in Draft Guidance at 22 (lines 749-752)).

[18] *See* FDA, *Guidance for Industry, Consumer Directed Broadcast Advertisements* (August 1999), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125064.pdf.

unconnected to the advertising execution in question can nevertheless be aggregated with the specific visual and audio information in the commercial itself for purposes of determining the overall adequacy of the risk disclosure that appears within the four corners of the advertisement. As explained by the agency, "A sponsor wishing to use consumer-directed broadcast advertisements may meet the adequate provision requirement through an approach that will allow most of a potentially diverse audience to have *reasonably convenient access* to the advertised product's approved labeling."[19]

As each of these examples illustrate, FDA has routinely evaluated related communications to determine whether they are part of the same integrated whole. This is entirely a contextual exercise that dovetails with the "net impression" standard adopted by FDA in the present Draft Guidance. There is no logical or legal reason why the same principle is inapplicable to regulation of new media, such as the Internet, as discussed further below.

3. The Internet Is a Distinct Medium for Determining "Net Impression". Communications in that Medium Should Be Evaluated in their Specific Contexts and a Correspondingly Distinct Regulatory Construct Should be Adopted by FDA.

It requires little citation of authority to prove what everyone knows and what FDA should "administratively notice"—the Internet is a medium in its own right that is substantially distinguishable from traditional print or broadcast communications. The medium has its own ever increasing diversity of tools, including e-mail, search engines, banner advertising, and an array of social media,[20] such as blogs, micro-blogs (e.g. Twitter™), social networks (e.g. Facebook), and an untold (and ever increasing) array of others.[21] Both everyday experience and empirical evidence establish that "the Internet is the place where many Americans look first to manage their health."[22] In fact, "more patients look[] for information online before even talking with their physicians."[23]

Given the indisputable reality of these new media, and how they are being used by consumers, FDA's failure in the Draft Guidance even to acknowledge the possibility that Internet communications should be evaluated for "net impression" in their specific context is perplexing at best and, frankly, somewhat shocking. Indeed, there is a direct analogy between FDA's ultimate acknowledgment of the need for a distinct construct for regulation of risk disclosures in broadcast television advertising for prescription drugs and the need for a comparable acknowledgment by the agency about the need for such a distinct construct for Internet communications. What such a distinct construct might look like is beyond the scope of these comments. CEI urges FDA to initiate a guidance development or rulemaking process to solicit comments from all interested stakeholders about an appropriate framework for regulation of communications using new media. Admittedly, development of a suitable policy governing

[19] *Id.* at 2 (emphasis supplied).
[20] *See* Wikipedia, *Social Media*, *available at* http://en.wikipedia.org/wiki/Social_media.
[21] *See*, *e.g.*, Mashable, The Social Media Guide, *Could Google Wave Redefine E-Mail and Web Communication?* (May 28, 2009), *available* at http://mashable.com/2009/05/28/google-wave-guide/.
[22] *Yes We Can* at 22 and fn. 3.
[23] *Id.* at fn. 3.

Internet communications would represent a significant regulatory and resource challenge for the agency. At the same time, however, it is absolutely essential to bring FDA's 1960s approach to prescription drug advertising and promotion into the 21st Century.

One immediate example that illustrates quite clearly why FDA should modernize its framework for regulating Internet communications has to do with the implications from DDMAC's NOVs on sponsored links. Every "consumer acting reasonably" knows how to run a key word query on a search engine like Google™, and every such consumer who is interested in the resulting information knows what to do with the ensuing "hits" (consisting of both "natural search results" and "sponsored links"). If interested, one clicks on the link and reaches the "landing page" where additional and contextually related information can be found. To suggest, as the NOVs implicitly do, that the landing page is entirely separate and "distinct"[24] from the face of the sponsored link and can be utterly ignored in determining the adequacy of the overall risk disclosure is to elevate form over substance and to disregard every reasonable consumer's everyday search experience.

Moreover, by effectively deterring use of sponsored links that direct Internet searchers to prescription drug product websites that are themselves highly regulated by FDA, the agency is necessarily elevating in prominence search results that quite often take consumers seeking relevant health information to sites that contain utterly unsubstantiated claims by fly-by-night operators for products that are largely beyond meaningful enforcement reach by FDA.[25] And the underlying logic in the NOVs about the need for instantaneous and contemporaneous disclosure of risk information on the face of the sponsored link, without reference to the link to the landing page, if applied to traditional media such as print and broadcast communications, would create absurd results by requiring everything to be communicated all at once. This is not do-able, and the Draft Guidance recognizes this by explaining at great length how manufacturers may integrate various elements of a more conventional advertising execution in order to develop a compliant piece. Exactly the same rationale could and should be applied to new media advertising, including but not limited to sponsored links.

* * *

Other aspects of the Draft Guidance also merit reconsideration by FDA. Notable among these is the agency's effort to erode the "net impression" standard, as determined from the vantage point of the reasonable consumer by aggrandizing to itself the right in all circumstances to determine what that individual thinks.[26] There are serious legal and constitutional problems with that approach, and we urge FDA to reconsider it.[27]

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[24] *See* fn. 13 above.

[25] *See Yes We Can* at 26.

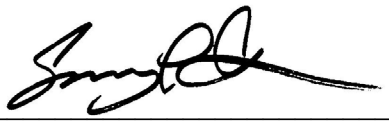
[26] "Trained professionals at FDA with expertise in areas including communication, drug information, medicine and law . . . evaluate claims in promotional pieces from the perspective of a reasonable consumer." Draft Guidance at 5 (lines 152-154).

[27] *See* Arnold I. Friede, et al., *Outcome of Food Misbranding Case Impacts FDA-Regulated Industries*, Washington Legal Foundation Legal Opinion Letter (May 8, 2009), *available at* http://www.wlf.org/publishing/publication_detail.asp?id=2068 (discussing Seventh Circuit's decision in *U.S. v. Farinella*, ___ F.3d ___, Nos. 08-1839, 08-1860 (March 12, 2009)).

We appreciate this opportunity to present our views. Again, we urge FDA to use this occasion to chart a new, more technologically sophisticated course on regulation of communications in new media. If done wisely, that would be of great value to the public health.

Respectfully submitted,

COMPETITIVE ENTERPRISE INSTITUTE

By: 

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ATTACHMENT

Yes We Can:

Time for an FDA Internet Drug Advertising Policy

by Arnold I. Friede and Robert B. Nicholas

By any measure, the Obama Administration is the most "tech savvy" in American history and recognizes clearly how we obtain information and communicate among ourselves in the 21st century. It was early to harness the power of the Internet and other new media both in getting itself elected and in governing the nation.[1] This Administration understands like none before that, as the visionary communications theorist H. Marshall McLuhan put it in his seminal work decades ago, *Understanding Media: The Extensions of Man,*[2] "the medium *is* the message." Ironic then, given its place at the center of public health protection, that the Food and Drug Administration (FDA) has barely acknowledged that the Internet is the place where many Americans look first for information to help manage their health.[3]

A case in point is FDA's recently issued *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion.*[4] Except for a footnote that appears to acknowledge that there is an Internet,[5] the *Draft Risk Disclosure Guidance* does not address the unique features of such common communications techniques as sponsored links, banner advertisements, e-mail to physicians and patients, social media such as blogs or Twitter, or any other form of Internet communication more generally.[6] Indeed, FDA expressly says in the *Draft Risk Disclosure Guidance* that the agency applies the same principles about risk disclosure by manufacturers in prescription drug advertising " … to all promotional pieces, regardless of the medium used … "[7]

Another telling example of FDA's approach to regulation of the Internet as simply a different form of

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print communication is the agency's recent enforcement actions that have significant and adverse implications for use of key word search engines, such as Google, which is perhaps the most powerful tool on the Internet for quickly locating and accessing relevant information on health and well-being. On April 2, 2009, the Division of Drug Marketing, Advertising, and Communications (DDMAC) in FDA's Center for Drug Evaluation and Research (CDER) sent a broadside to the pharmaceutical industry, and by implication, the internet advertising community, when it simultaneously issued 14 Notices of Violation (NOVs).[8]

The NOVs categorically reject the use by manufacturers of hyperlinks to web sites that are identified in the URL in the sponsored link by specific brand name; 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 be considered in the disclosure analysis even if fully and completely available "one click" away via the hyperlink.

Inasmuch as sponsored links resulting from key word searches are generally limited to a total of 70 individual characters for the text of the advertisement,[9] this approach effectively precludes the use of sponsored links that disclose the product name and provide a modicum of benefit information to alert searchers to what they will encounter when they click on the hyperlink.

Instead, manufacturers who wish to alert searchers to what information is available through a sponsored link must now use what may amount to "bait and switch" tactics by omitting from the URL the name of the very product whose FDA-regulated web site the searcher will be redirected to when activating the hyperlink. This anachronistic approach threatens not only the ongoing utility of sponsored links but also suggests either a hostility to, or perhaps a fundamental lack of appreciation for, the importance of an array of other Internet communications tools that can be used to provide valuable health information to consumers in connection with FDA-regulated products. It misses by a millennium the import of McLuhan's message by overlooking entirely the ability of the Internet to be the messenger, empowering those who wish to convey information and those who wish to obtain information, and, even more importantly, to link the two together, worldwide, in a virtual dialogue.

It is too early to tell whether the recent NOVs represent merely a public relations splash by the Administration intended to let the public know that this is a "new FDA" or whether, instead, these actions represent confirmation that, going forward, this FDA, like its predecessors, will continue to avoid addressing the distinctions among print, broadcast, the Internet and other types of new media communications.

While the recipients of the NOVs have responded by largely acceding to FDA's demands, the broader issue on the use of the Internet by manufacturers to communicate valuable product-related health information is far from settled. Fortunately, the regulated industry, including pharmaceutical and medical device manufacturers—and the Internet advertising community—has the opportunity to inform FDA's deliberations on application to new media of the *Draft Risk Disclosure Guidance* by responding during the 90-day comment period. After all, and while resisting for many years, FDA ultimately did adopt a policy that acknowledges to some limited extent the distinct features of television advertising as a discrete medium of communication.[10] Therefore, there is at least some reason to hope that with the opportunity for a sustained dialogue, the agency might likewise be persuaded to adopt discrete policies for regulation of the Internet and other new media.

Basis for FDA's Current Promotional Rules

FDA's current regulation of advertising and promotion for prescription drugs derives largely from its immediate post-1962 regulation of doctor-directed print communications.[11] While FDA has acknowledged the existence and value of direct-to-consumer (DTC) advertising, and while, as just noted, the agency in 1999 adopted a policy that recognizes to a limited extent the difference between advertising on television and in print, the paradigm of encyclopedic and contemporaneous risk disclosure that emerged in the context of physician-directed communication remains largely intact as applied to all communications regardless of the medium or the target audience.

Indeed, FDA's *Draft Risk Disclosure Guidance* loudly proclaims this congruence. The agency regulates all forms of product promotion for prescription drugs through its authority over drug "labeling"[12] and its post-1962 authority over drug "advertising."[13] This basic authority and paradigmatic approach remains largely unaffected

even by the recent Food and Drug Administration Act Amendments of 2007 (FDAAA) that added a number of specific provisions on DTC advertising.[14] The agency's regulations continue to make the longstanding distinction between, on the one hand, promotional communications that are subject to an array of mandatory disclosures from "reminder advertisements" that are not, without acknowledging any differences that might be occasioned by the use of different media.

The NOVs

Each of the NOVs makes accusations that information in a sponsored link that includes a website address consisting of the trade name for a specific product, and that appears on the results page of an internet search engine when a key word search is conducted, is not a reminder advertisement but instead is "labeling" and "advertising" that is categorically misleading and hence "misbrands" the drug within the meaning of the Act.

Even though each of the search results included a hyperlink to risk information that is accessible "one click" away, DDMAC nevertheless concluded that this is inadequate to communicate any risk information whatsoever because of the absence of the contemporaneous mandatory disclosures on the face of the sponsored link itself. Limitations in the number of letter characters available in this medium, however, make it impossible to provide encyclopedic risk information on the face of a sponsored link, yet it is readily accessible by clicking on the hyperlink. As such, if these enforcement actions continue to represent FDA policy going forward, then, as a practical matter, the NOVs effectively erode the value of sponsored links resulting from key word searches that identify a specific product by name in the URL or elsewhere on the face of the sponsored link.[15]

Discussion

Hopefully, DDMAC's preemptive war on sponsored links, and its unequivocal rejection of the "one click" rule that industry had long assumed was applicable in this context,[16] does not reflect the Obama Administration's long-term intention to continue to apply to manufacturer Internet communications the same regulatory regime that FDA applies to traditional print labeling and advertising.

FDA's approach on hyperlinked disclosures is likewise inconsistent with prior FDA policies that accept the limitations of particular media and with the Federal Trade Commission's (FTC's) approach.

By citing *both* its drug labeling and drug advertising authorities in the NOVs, FDA has implicitly again rejected the argument that Internet communications should not be regulated as "labeling" and appears to reaffirm implicitly its longstanding unwillingness to adopt a discrete regulatory policy on Internet communications that acknowledges the information value of new media and their technological differences from traditional communications channels.[17]

Surely the Administration's recognition of the significance of the Internet, and its own use of this medium as a health information source, requires that FDA adopt a more considered approach for these new media than the approach represented by DDMAC's enforcement tsunami of NOVs on sponsored links. Development through a public process that engages all stakeholders in deciding on a more thoughtful and effective information dissemination policy on new media is a laudable longer-term FDA objective that might be pursued through the opportunity to comment on the *Draft Risk Disclosure Guidance*. At a minimum, this comment opportunity provides a chance to present FDA with an alternative paradigm for regulation in this arena.

At the same time, there is ample room even under current law for FDA to apply a more nuanced approach to regulation of sponsored links, and to new media more generally, than the agency itself acknowledges in the NOVs. For example, in concluding that the face of the sponsored link represents an independently discrete portion of the advertisement that requires that all mandatory disclosures be immediately and contemporaneously

viewable when the link appears on the search results page,[18] DDMAC appears unwilling to recognize that hyperlinks are a technologically integral part of the Internet medium that virtually every Internet user is familiar with.

Indeed, the very purpose of a key word search is to list those hyperlinks that the searcher should "click" to find the relevant information being sought. After all, this is precisely why the searcher has initiated the key word search in the first place. To assert that the landing page of the linked information, through which the risk information is accessible, is irrelevant in determining the adequacy of the disclosure is to disregard the realities of the medium and to elevate form over substance.

FDA's approach on hyperlinked disclosures is likewise inconsistent with prior FDA policies that accept the limitations of particular media and with the Federal Trade Commission's (FTC's) approach. For example, in its "major statement" guidance for risk disclosures in television advertising,[19] FDA acknowledges the inability of TV to carry contemporaneous and instantaneous disclosure of all risk information and the agency provides a mechanism, through its so-called "adequate provision" principles, for full risk disclosure that is concurrently available in publications that, in fact, do not accompany the commercial.

The FTC, the agency with the most experience in regulating all types of advertising to ensure that it is truthful and not misleading, has taken a much more nuanced and "tech savvy" approach to hyperlinked disclosures. The FTC does not categorically reject hyperlinked disclosures in determining if an advertisement is or is not misleading.[20] Instead, the FTC examines the conspicuousness of the hyperlink, whether it signals the availability of risk information, and other contextual factors in determining the adequacy of the disclosure.[21] In this respect, the FTC acknowledges that there are differences occasioned by differing media and that regulatory policy should be flexible enough to accommodate these. The FTC apparently does recognize that anyone who has an interest in the affirmative information presented in the search results and who wants more information knows to click once using the mouse to gain access to additional, contextually relevant information.

Arguably, FDA's categorical rejection of the landing page as an integral component of the sponsored link stands in stark contrast to one of the cardinal principles of advertising interpretation that FDA itself has routinely adopted in a variety of related circumstances. For example, in its *Draft Guidance for Industry, Help Seeking and Other 'Disease Awareness Communications by or on Behalf of Drug and Device Firms,*[22] where it addresses "bookending" of "reminder" and "help seeking" advertisements, and even in quite recent Warning Letters on disease awareness and promotional advertising in the same piece,[23] FDA has taken the position that seemingly separate statements should nevertheless be aggregated and considered together in determining whether the ensuing "advertisement" does or does not comply with the risk disclosure requirements applicable to promotional labeling and advertising.

For example, and while neither help-seeking nor reminder advertisements are independently subject to risk information disclosure requirements, their appearance in close proximity, according to FDA, could make them jointly a product promotional advertisement that must disclose risk information:

> "Psychology and marketing research suggest that the greater the perceptual similarity between disease awareness communications and reminder or product claim promotions (i.e., similarities in terms of their themes, such as story lines, or other presentation elements, such as colors, logos, tag lines, graphics, etc.) 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."[24]

It is not apparent why this same logic is inapplicable to hyperlinked risk disclosures in sponsored links where, after all, the information is accessible "one click" away. In other words, the "one click" rule is just a different way of saying what everyone understands about the contextual relationship between in the information on the face of the sponsored link and the information available through the accompanying hyperlink.

FDA's authority over drug "labeling," which the agency cites in the NOVs, is predicated on a broad definition of what "accompanies" a regulated article. The agency cites this broad definition, and the U.S. Supreme Court's interpretation of that definition in *Kordel vs. United States*,[25] in the *Draft Risk Disclosure Guidance.*

While that draft guidance rejects McLuhan's theory because it explicitly applies the same rules to all promotional communications regardless of the medium, it nevertheless strongly endorses the *Kordel* approach on when one piece of information "accompanies" another and is hence subject to regulation by FDA as "labeling." Whatever one thinks about the correctness of such a broad interpretation of "labeling," it seems apparent that FDA is being inconsistent when it categorically rejects information that is "one click" away in determining if the risk information effectively "accompanies" the affirmative representations on the face of the sponsored link. If that principle that A accompanies B even if the two are not physically attached, then that same principle ought similarly to apply by analogy in determining what is and is not a discrete component of an advertisement in the first instance.

Arguably, FDA's categorical rejection of the landing page as an integral component of the sponsored link stands in stark contrast to other cardinal principles of advertising interpretation that FDA has now officially adopted. For example, in the *Draft Risk Disclosure Guidance*, FDA has expressly adopted both the FTC's "reasonable man" and "net impression" tests for interpreting how doctors and consumers, as the case may be, understand both affirmative benefit representations and risk disclosures.

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 should he wish to have more information. That is what the medium is all about and that is why the searcher uses it. Just like the newspaper reader knows to go beyond the front page to get to the rest of the story, and just like the television viewer knows to watch later parts of a commercial where risk information generally appears, so too does the web searcher know what a hyperlink is and how to use it.

To reject the ready accessibility of hyperlinked information in deciding if the disclosures are or are not adequate is to dismiss the "net impression" of the communication, which FDA acknowledges is the standard for how it interprets advertising and promotional materials. Indeed, a compelling argument can be made that "the reasonable man" who clicks through to the risk information via a hyperlink is much more likely to spend time reading and absorbing the complex risk disclosures than are consumers who are confronted with all of that detailed information on the face of the sponsored link, assuming it was even technically possible to provide all of this informaton within the constraints of that medium.

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.[26] 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 another yet another opportunity for the patient to be counseled by the pharmacist dispensing the drug. In this context, then, and however imperfect, the Internet is the first step in the chain of information provision to the patient—not the only step—and certainly not the last. FDA's approach of requiring that all risk information be instantaneously and comprehensively disclosed on the face of the sponsored link ignores this continuum of information provision.

Ironically but importantly, because FDA only regulates manufacturer communication, no matter what the medium, should manufacturers discontinue or curtail use of sponsored links because of DDMAC's approach, then the results from sponsored links by purveyors of all manner of products not subject to FDA's prescription drug regulations would ascend correspondingly. Indeed, a strong case can be made that if sponsored links go away, then the information seeker will be relegated to wading through a list of websites, most of which are not even regulated by FDA, and that will contain all manner of information whose validity is largely unknown.

To the extent that clicking on a sponsored link takes an information seeker to a landing page that consists of a product website, this is a medium that is highly regulated by FDA. So FDA's position on sponsored links could have the perverse effect of making regulated information less available to information seekers, while making unregulated and often entirely unvalidated information more available as a consequence.

Conclusion

The Obama Administration proclaims that it has charted a new course for FDA, one intended to restore the credibility of the agency. The new leaders of FDA and their allies in the Congress have an ambitious agenda. Having gotten everyone's attention with the NOVs, perhaps this tech savvy Administration can now seize

the opportunity to start a dialogue with stakeholders on the reality of the "medium of the Internet" as an integral part of its "message" and develop a viable advertising and promotion policy for the Internet and other new media.

1 *See e.g.* "Government Launches Public 'Brainstorming' on Transparency Ideas," Dickinson's FDA Webview (May 22, 2009) (discussing Obama Administration's solicitation of on-line feedback for ideas to improve transparency in government), *available at* http://opengov.ideascale.com/.

2 Mentor Press, NY (1964). The phrase has been explained as meaning that the form of a medium embeds itself in the message, creating a symbiotic relationship by which the medium influences how the message is perceived. *See* Wikipedia, *The medium is the message*, *available at* http://en.wikipedia.org/wiki/The_medium_is_the_message#cite_note-0.

3 *See e.g., 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*, Arch. Intern. Med., 165(22): 2618-2624 (2005), *available at* http://www.ncbi.nlm.nih.gov/pubmed/16344419 (concluding that data portray a tectonic shift in the ways in which patients consume health and medical information, with more patients looking for information online before even talking with their physicians).

4 *Draft Risk Disclosure Guidance,* (May 2009), *available at* http://www.fda.gov/cder/guidance/7427dft.pdf .

5 *Id.* at fn. 9 (identifying product web sites as among the communication vehicles subject to regulation by FDA as advertising and promotion).

6 *See e.g., Could Google Wave Redefine E-Mail and Web Communication?,* Mashable, The Social Media Guide (May 28, 2009), *available at* http://mashable.com/2009/05/28/google-wave/ (describing new internet tool that offers a hybrid of, among others, e-mail, chat, so-called IMing, and project management).

7 *Draft Risk Disclosure Guidance* at 4 (lines 103 to 104).

8 *See, Warning Letters and Untitled Letters to Pharmaceutical Companies 2009*, *available at* http://www.fda.gov/cder/warn/warn2009.htm.

9 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?, available at* http://adwords.google.com/support/bin/answer.py?hl=en&answer=6095.

10 *See, Guidance for Industry, Consumer-Directed Broadcast Advertisements,* (Aug. 1999), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070065.pdf. *See also* 21 CFR §202.1(e)(1).

11 *See generally, Coalition for Healthcare Communication Citizen Petition Requesting Promulgation of Amended Regulation for Prescription Drug Advertising to Establish Separate Criteria for Practitioner-Directed and Consumer-Directed Advertising and to Establish a Standing Advisory Committee on Health Care Communications,* (May 31, 2006), *available at* http://www.cohealthcom.org/content/FinalCHCCitizenPetition.pdf.

12 Section 502(a) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §352(a).

13 Section 502(n) of the FDCA, 21 U.S.C. §352(n).

14 *See e.g.* §§104 and 906 of Pub. L. 110-185.

15 In other words according to DDMAC, identification of a specific product name in the URL in the sponsored link triggers an array of disclosure requirements that can only be met by including all the information on the face of the sponsored link. That is impossible due to the constraints of the medium.

16 *See, 14 Warning Letters in a Day! What's That About*, Eye on FDA (Apr. 6, 2009) (one click rule based on "strong perception among marketers" of FDA's policy), *available at* http://www.eyeonfda.com/eye_on_fda/2009/04/14-warning-letters-in-a-day.html.

17 *See e.g.* Letter, dated Nov. 1, 2001, from Margaret M. Dotzel, FDA Associate Commissioner for Policy, Docket No. 01P-0187 (denying Citizen Petition seeking FDA determination that internet communications should be regulated as "advertising" not "labeling"), *available at* http://www.cfsan.fda.gov/~dms/labwww.html.

18 *See* 21 CFR §202.1(e)(3)(i).

19 *See* fn. 10 above.

20 *See, FTC Staff Working Paper on DotCom Disclosures,* (May 3, 2000), *available at* http://www.ftc.gov/bcp/edu/pubs/business/ecommerce/bus41.pdf.

21 *Id.* at 11-13.

22 *Draft Disease Awareness Guidance, available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070068.pdf.

23 *See e.g.*, DDMAC Warning Letter re Strattera®, (Sept. 26, 2008), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation /Enforcement ActivitiesbyFDA /WarningLettersandNoticeofViolationLetterstoPharmaceutical Companies /ucm054007.pdf

24 *See, Draft Disease Awareness Guidance* at 9 (lines 216 to 221 (citation omitted)).

25 335 U.S. 345 (1948).

26 *See* fn. 11 above.

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