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Ripe for Revision: Reassessing the Constitutionality of Food and Drug Administration Restrictions on Protected Speech

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Ripe for Revision: Reassessing the Constitutionality of Food and Drug Administration Restrictions on Protected Speech

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I. INTRODUCTION

In April 2002, the U.S. Supreme Court struck down section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) on the grounds that the provision violated the First Amendment to the U.S. Constitution by prohibiting pharmacists from advertising their ability to compound specific drugs or categories of drugs.[1] The Food and Drug Administration (FDA) responded by launching a sweeping reassessment of its regulations, guidances, policies, and practices to determine whether any should be revised in light of the Court's ruling, and solicited comments from the public on a broad range of First Amendment issues to aid in its reevaluation.[2]

FDA received more than 700 comments in response, illustrating that there are a multitude of FDA policies that implicate significant First Amendment issues.[3] This article spotlights two of FDA's regulatory provisions that are ripe for revision. The first is the requirement that an applicant submitting a new drug application (NDA) subject to FDA's accelerated approval regulations[4] must submit copies of all promotional materi-

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[1] Thompson v. Western States Med. Ctr., 535 U.S. 357 (2002).

[2] Request for Comments on First Amendment Issues, 67 Fed. Reg. 34,942 (May 16, 2002). In addition, recent statements by FDA demonstrate that the agency recognizes its obligation to ensure that policies and procedures are consistent with the First Amendment. *See, e.g.*, Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (July 10, 2003) (noting that the objective of the interim procedures set forth in the guidance is "to ensure that [FDA's] premarket review is consistent with the spirit of the Nutrition Labeling and Education Act and the First Amendment").

[3] For example, health claim petitions raise substantial First Amendment issues. *See* 67 Fed. Reg. 71,461, 71,466-67 (Dec. 2, 2002). So do FDA's restrictions on stating that a device has been cleared by a 510(k) premarket notification (21 C.F.R. § 807.97), and FDA's detailed drug advertising regulation (21 C.F.R. pt. 202). The list of affected policies is quite extensive.

[4] 21 C.F.R. pt. 314, subpt. H ("subpart H" or "accelerated approval regulations"). FDA promulgated companion regulations that provide for the accelerated approval of biological products for serious or life-threatening diseases. *Id*. pt. 601, subpt. E. The biologics regulations parallel the accelerated approval regulations for new drugs and, therefore, also require that all promotional materials be submitted to FDA for review before they are disseminated or published. *Id*. § 601.45. The agency also promulgated regulations last year regarding the quantum and quality of evidence needed to demonstrate effectiveness of new drugs and biologics when human efficacy studies are not ethical or feasible. *See* 67 Fed. Reg. 37,988 (May 31, 2002) (final rule) (codified at pt. 314, subpt. I (21 C.F.R. §§ 314.600–314.650), and pt. 601, subpt. H (21 C.F.R. §§ 501.90–601.95)). All promotional materials associated with drugs or biologics approved under these regulations also must be submitted to FDA for review before they are disseminated or published. *See* 21 C.F.R. §§ 314.640, 601.94. While this article specifically addresses subpart H of FDA's NDA regulations, the arguments contained herein apply with equal force to subpart E of the agency's biologics licensing regulations, and to the new subparts I and H.

als for the agency's review before the materials are disseminated; the second is FDA's policies regarding the dissemination of information related to the use of approved products for unapproved uses ("off-label uses").

First Amendment jurisprudence suggests that, if challenged, FDA's promotional materials predissemination submission requirement for drugs subject to the accelerated approval regulations would fail to pass constitutional muster because it is an impermissible prior restraint on speech. The requirement also would be likely to give way under constitutional scrutiny because it is an impermissible government restriction imposed on protected commercial speech.[5] Governmental restrictions on commercial speech are unconstitutional unless they pass a four-part test. FDA's mandate of prior review of promotional materials fails the final part of that test—that the restrictions be "[no] more extensive than necessary to serve the [government's] interest."[6] The agency can ensure the safe use of products subject to the accelerated approval regulations through a number of measures already at its disposal that do not restrict speech, which renders FDA's pre-approval of subpart H promotional materials unconstitutional.

Similarly, FDA's policies that restrict the dissemination of truthful scientific information that may discuss off-label uses of approved products are vulnerable to attack on constitutional grounds. Under the Supreme Court's commercial speech jurisprudence, such scientific information, which may take the form of scientific journal articles, abstracts, posters, etc., is constitutionally protected provided it is truthful and not misleading. Rather than respect this broad constitutional protection, FDA historically placed restrictions on the dissemination of off-label information. More recently, FDA has accorded greater latitude to companies when distributing peer-reviewed scientific materials that discuss off-label uses. Sponsors enjoy a constitutionally-protected right to disseminate truthful, nonmisleading scientific information about regulated products, however, whether the information has been peer-reviewed or not.

II. SUBMISSION OF PROMOTIONAL MATERIALS PURSUANT TO FDA'S ACCELERATED APPROVAL REGULATIONS

Subpart H of FDA's NDA regulations establishes accelerated approval procedures for drugs that are intended to treat "serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments."[7] Applicants seeking approval under subpart H must abide by restrictions as a condition of accelerated approval that are not imposed on other NDA applicants. Among them is the requirement that the applicant submit all "promotional materials"[8] associated with the drug to FDA for review *before* the materials are disseminated. Specifically:

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[5] The core definition of "commercial speech" is that which simply proposes a commercial transaction. Commercial speech therefore includes advertising and other forms of promotional speech. *See* Bolger v. Young's Drug Prods. Corp., 463 U.S. 60 (1983).

[6] Central Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 599 (1980).

[7] 21 C.F.R. § 314.500. FDA can approve new drugs for serious or life-threatening illnesses via the accelerated approval regulations under two sets of circumstances. First, "FDA may grant marketing approval . . . on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely . . . to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity." *Id.* § 314.510 (the surrogate endpoint provision). Additionally, the agency may grant accelerated approval status to new drugs for serious or life-threatening illnesses that can be shown to be effective but that "can be safely used only if distribution or use is restricted." *Id.* § 314.520 ("the restricted distribution and use provision"). Under Subpart H, a new drug whose accelerated approval is predicated on surrogate endpoints can also be subject to the regulation's distribution and use restrictions.

[8] FDA has ascribed a broad interpretation to the term "promotional materials":

[T]he term *promotional materials* includes promotional labeling and advertisements.

continued

> [U]nless otherwise informed by the agency, applicants must submit to the agency for consideration during the pre-approval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the agency, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.[9]

Other applicants seeking drug product approval, by contrast, must submit promotional materials at the time the materials are first disseminated or published.[10] Subpart H's pre-approval submission requirement is not consistent with the First Amendment.

A. *Prior Restraint*

Any governmental restriction that seeks to prevent speech from occurring, rather than punishing it after the fact, is a prior restraint. Prior restraints are not unconstitutional *per se*,[11] but "[a]ny system of prior restraint . . . 'comes to [the] [c]ourt bearing a heavy presumption against its constitutional validity.'"[12] The presumption is born of "a theory deeply etched in our law: a free society prefers to punish the few who abuse rights of speech *after* they break the law than to throttle them and all others beforehand."[13] The doctrine of prior restraint protects commercial speech as well as other forms of speech, and has been applied by the courts to assess the constitutional validity of restrictions on commercial speech that FDA has sought to impose on industry.[14] The courts view prior restraints with a higher degree of suspicion than other constraints on speech because they are more likely to chill the exercise of First Amendment rights for all those subject to the restraints than would subsequent punishment.[15]

> Examples of labeling include, but are not limited to, brochures, booklets, detailing pieces, bulletins, calendars, motion pictures, and slides. (21 C.F.R. § 202.1(l)(2)). Advertisements include, but are not limited to, materials published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems (*Id.* § 201.1(l)(1)).

FDA Draft Guidance: Accelerated Approval Products—Submission of Promotional Materials 1 (Mar. 1999) [hereinafter Promotional Materials Guidance].

[9] 21 C.F.R. § 314.550.

[10] *Id.* § 314.81(b)(3)(i).

[11] *See* Bantam Books, Inc. v. Sullivan, 372 U.S. 58, 70 n.10 (1963) (citing Times Film Corp. v. Chicago, 365 U.S. 43 (1961)).

[12] Southeastern Promotions, Ltd. v. Conrad, 420 U.S. 546, 558 (1975) (quoting Bantam Books, 372 U.S. at 70) (citations omitted).

[13] *Id.* at 559.

[14] *See* Nutritional Health Alliance v. Shalala, 144 F.3d 220, 227 (2d Cir. 1998) (finding that "the prior restraint doctrine does play a role in evaluating the regulation of commercial speech" and rejecting FDA's argument that prior agency approval of health claims appearing on dietary supplement labels as mandated by the Nutritional Labeling and Education Act was not unconstitutional because the prior restraint doctrine does not apply to commercial speech) (citing New York Magazine v. The Metro. Transp. Auth., 136 F.3d 123, 131 (2d Cir. 1998) (citations omitted) ("Although the Supreme Court has indicated that commercial speech may qualify as one of the exceptions to the ban on prior restraints, (*see Central Hudson*, 447 U.S. at 571 n.13,) we see no reason why the requirement of procedural safeguards [in prior restraint cases] should be relaxed whether speech is commercial or not. We consider prior restraints to be particularly abhorrent . . . in part because they vest in governmental agencies the power to determine important constitutional questions properly vested in the judiciary.")). For its part, the Supreme Court has alluded to the possibility that prior restraint might not apply to commercial speech, but has never addressed the issue directly. *See* Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 772 (1976); *Central Hudson*, 447 U.S. at 571 n.13.

[15] *See* Southeastern Promotions, Ltd., 420 U.S. 546 (1975).

The subpart H regulation's prior submission requirement is a prior restraint on speech, and therefore is unconstitutional. Applicants must submit all promotional materials to the agency *before* they are disseminated, and in the case of promotional materials related to the drug product's launch, i.e., those intended for dissemination within 120 days after the product's approval, applicants must submit the materials for FDA's scrutiny *even before FDA has decided whether to approve the product*.

Perhaps in an effort to fend off constitutional challenges, FDA has stated that it "does not intend specifically to approve promotional materials."[16] The subpart H regulations do not specifically refer to agency "pre-approval" of promotional materials, but rather state that the materials must be submitted for FDA's "consideration."[17] It is clear from the agency's policy pronouncements and actions, however, that pre-approval of promotional materials is contemplated. FDA's draft Promotional Materials Guidance of March 1999, for example, states that for promotional materials related to a drug product's launch, "[t]he Agency expects that materials will *not* be disseminated or published until the Agency's objections are resolved."[18] Similarly, for promotional materials intended for dissemination after the product's launch, FDA states, "[i]f the Agency notifies the sponsor of significant objections to the proposed materials, the Agency expects that these materials will not be disseminated or published until the Agency's concerns have been resolved."[19]

Calling this review of materials a "consideration" rather than "approval" does not save this restriction from being unconstitutional. A company *must* submit materials to the government before they can be disseminated. An applicant with an NDA pending under subpart H has no choice but to revise its promotional materials to address FDA's objections for fear that the agency might not otherwise approve its drug product. A sponsor can try to persuade FDA to change its mind, but the reality—or at least the perception that controls sponsor behavior—is that a sponsor that does not resolve FDA's concerns regarding the claims is unlikely to obtain FDA approval. Regardless of FDA's nomenclature, the regulation requires prior approval.

An applicant who has secured an approval also is without meaningful options in the event of FDA objections, because failing to comply might lead FDA to withdraw the drug from the market on an expedited basis.[20] Moreover, waiting at least thirty days for FDA's "consideration," as is required under the accelerated approval regulations for promotional materials not related to a product's launch, is inconsistent with the First Amendment. The First Amendment does not permit the government to compel companies to refrain from exercising their constitutional right to free speech for any period of time. The inevitable chilling effect that FDA's *de facto* promotional materials pre-approval regime has on applicants' speech is precisely the danger that the courts have sought to eliminate with their prohibitions on prior restraint.

For these reasons, FDA would be hard-pressed to defend successfully its subpart H regulations against constitutional attack by arguing that the regulations' pre-dissemination submission requirement is not an impermissible prior restraint. This constitutional infirmity can be cured only by revising the agency's subpart H regulations to direct applicants seeking accelerated approval to submit all promotional materials at the time they are first disseminated or published, as is the case with drugs approved pursuant to the agency's conventional approval procedures.[21]

[16] 57 Fed. Reg. 13,234, 13,237 (Apr. 15, 1992) (proposed rule); *see also* 57 Fed. Reg. 58,942, 58,949 (Dec. 11, 1992) (final rule).

[17] 21 C.F.R. § 314.550.

[18] Promotional Materials Guidance, *supra* note 8, at 2 (emphasis in original).

[19] *Id.* at 4.

[20] 21 C.F.R. § 314.530(a)(5).

[21] *Id.* § 314.81(b)(3)(i). There also is the risk that FDA will apply different standards when conducting prior review. The agency may decide to object to a particular claim that, if encountered by FDA as part of its postmarket surveillance, would not elicit any objections.

B. *Commercial Speech*

The accelerated drug approval regulations' provision that mandates prior review of promotional materials also must give way because it is a constitutionally-impermissible regulation of protected commercial speech, and because FDA has at its disposal many other means to meet its objectives without restricting speech. The promotional materials that FDA seeks to regulate under subpart H—labeling and advertising—fall within the ambit of commercial speech.[22] The government may not regulate commercial speech unless its restrictive provisions meet a four-part test set forth by the Supreme Court in *Central Hudson Gas & Electric Co. v. Public Service Commission*.[23] Commercial speech may be prohibited or restricted under the *Central Hudson* test if it is inherently false or misleading, or if it espouses an unlawful activity. The government may prohibit or restrict commercial speech that is neither false or misleading nor concerned with unlawful activity only if "the asserted governmental interest is substantial," the regulation "directly advances the governmental interest asserted," and it is "[no] more extensive than is necessary to serve that interest."[24]

The Supreme Court applied and reaffirmed its *Central Hudson* analysis in a recent case involving an FDA restriction on commercial speech. In *Thompson v. Western States Medical Center*, the Court held that a provision in section 503A of the FDCA prohibiting a compounding pharmacy, pharmacist, or physician from advertising that it can compound a particular drug or category of drugs is a constitutionally-impermissible restriction of protected commercial speech.[25] The Court found that the government's restriction failed the *Central Hudson* test's fourth prong—the "Government . . . failed to demonstrate that the speech restrictions are 'not more extensive than is necessary to serve [its] interests'" in regulating the speech.[26] The Court noted that FDA could avail itself of several "non-speech-related means" to achieve its goal.[27]

As with the restriction struck down in *Western States*, the agency's regulation of commercial speech through its accelerated drug approval process also is unconstitutional because it is more extensive than necessary to serve the government's interests. FDA has at its disposal a number of "non-speech-related means" to ensure the safe use of products subject to approval under subpart H. These alternatives include, but are not limited to, restricting distribution to specially trained physicians; requiring that specific medical procedures be performed in conjunction with use of the product; requiring specific postmarketing studies and postmarketing safety reports; requiring special packaging (e.g., child-resistant containers); requiring a postapproval Risk Management Program; issuing Warning Letters; initiating expedited withdrawal of product approval; and taking various enforcement actions such as seizure, injunction, or prosecution. In addition, subpart H's mandated prior review of promotional materials fails the third part of the *Central Hudson* test—it does not directly advance the interests that FDA has asserted.

1. *Direct Advancement of Governmental Interests*

The government may not satisfy the *Central Hudson* test's third prong with mere speculation. Instead it must offer evidence that its asserted harms are real and that its

[22] *See Bolger*, 463 U.S. 60 (1983).
[23] *Central Hudson*, 447 U.S. 557.
[24] *Id*. at 566.
[25] *Western States Med. Ctr*., 535 U.S. at 376-77.
[26] *Id*. at 372 (quoting *Central Hudson*, 447 U.S. at 566).
[27] *Id*.

restrictions on speech will ameliorate materially the asserted harms.[28] The government's regulatory scheme also will fail the third prong of the *Central Hudson* test if it is irrational.[29] FDA's restrictions on speech as set forth in subpart H of its NDA regulations fail to meet these requirements.

The interests that the agency has asserted in mandating prior review of promotional materials for drugs subject to accelerated approval are nebulous at best, and FDA's assertion that restricting speech through this means will protect the public is conjectural. The agency appears indirectly to assert the safety, health, and welfare of patients who might use drugs approved under subpart H as its substantial interest. The harm that it seeks to guard against, however, is entirely unsubstantiated. FDA has sought to justify the restriction on the grounds that:

> Because drugs approved under the restricted use provision may be highly toxic or otherwise potentially harmful, [it] is concerned that certain promotional claims could cause inappropriate and, therefore, unsafe use. Similarly, the risk/benefit balance for drugs approved based on evidence of the drug's effect on a surrogate endpoint could readily be adversely affected by promotion that does not appropriately reflect the proper use of the product.[30]

This rationale fails to support FDA's restrictions on speech as required by the third prong of the *Central Hudson* test. The agency has not proffered any evidence, for example, demonstrating that drugs approved under the restricted distribution and use provision of its accelerated approval regime are more highly toxic or more potentially harmful than products approved through its conventional approval procedures. The conjecture that drugs approved under this system "may be highly toxic" does not justify imposing this scheme on all drugs receiving accelerated approval. Increased toxicity or risk is not a criterion for securing accelerated approval, that is, accelerated approval is not granted because of a drug's greater toxicity. Harmfulness is not a *sine qua non* for accelerated drug approval on drugs, and drugs approved under conventional NDAs can be highly toxic. Nor has FDA offered evidence demonstrating that, or explained how or why, promotional materials issued by drug manufacturers without prior agency review will affect adversely the "risk/benefit" balance of drugs subject to accelerated approval. The government cannot meet its burden simply by making unsubstantiated assertions. The agency has failed to meet its evidentiary burden of showing that its asserted harms are real, and that its restrictions on speech will alleviate its asserted harms. Accordingly, subpart H's prior approval requirement fails the *Central Hudson* test because it does not directly advance the government's interests.

Subpart H's restriction on commercial speech also fails the *Central Hudson* test's third prong because it is irrational when compared to FDA's regulation of promotional materials for drugs that are approved via other mechanisms that the agency has created to expedite the approval process. The agency has created other, alternative regulatory avenues to hasten market approval for certain products, such as subpart E of FDA's investigational new drug regulations[31] and mechanisms to designate certain NDAs,

[28] Edenfield v. Fane, 507 U.S. 761, 770-71 (1993).

> It is well established that 'the party seeking to uphold a restriction on commercial speech carries the burden of justifying it.' This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree. (citations omitted).

[29] *See* Rubin v. Coors Brewing Co., 514 U.S. 476, 488 (1995).

[30] 57 Fed. Reg. at 13,237; *see also id*. at 58,945.

[31] 21 C.F.R. pt. 321, subpt. E (Drugs Intended to Treat Life-Threatening and Severely-Debilitating Illnesses).

biological license applications, and premarket approval applications and 510(k) premarket notification submissions for medical devices for priority review.[32] None of these provisions, however, require applicants to submit promotional materials for review before they are disseminated or published. The restrictions on speech contained in subpart H cannot "directly advance[] the governmental interest asserted" in the face of discordant provisions because the agency's singling out of subpart H drugs is irrational.[33]

2. *No More Extensive Than Necessary*

Subpart H's restriction on speech also fails constitutional scrutiny because it cannot meet the final requirement of the *Central Hudson* test. The accelerated approval regulations' predissemination submission requirement is more extensive than necessary to serve FDA's interests.

As the Supreme Court reiterated in *Western States*, "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, [it] must do so."[34] A number of other provisions contained in FDA's subpart H regulations, and elsewhere in the FDCA and its implementing regulations, empower the agency to directly achieve its interests without impermissibly impinging upon protected speech. For example, applicants whose drugs are approved under subpart H as a condition of approval typically must conduct postmarketing studies to verify the drugs' clinical benefit and safety.[35] FDA reserves the right to approve drugs under subpart H on the condition that their distribution be restricted to "facilities or physicians with special training or experience" or be "conditioned on the performance of specified medical procedures."[36] The agency also can withdraw subpart H drugs from the market on an expedited basis.[37] And, FDA can bring to bear its full range of enforcement sanctions, such as seizures, injunctions, and prosecutions in case of violative promotional procedures. In short, subpart H's promotional materials pre-approval requirement is more restrictive than needed to address the agency's asserted risks, and therefore is a constitutionally-impermissible restriction on commercial speech. FDA has failed to explain why, with all these other tools at its disposal, it also needs prior review and approval of communications.

Accordingly, FDA should abolish its accelerated drug approval regulations' promotional materials pre-approval requirement. The agency can cure subpart H's constitutional infirmities by treating promotional materials for drugs subject to accelerated approval the same way that it treats other drugs, i.e., requiring that subpart H applicants submit all promotional materials at the time they are first disseminated or published.[38] FDA states in its draft Promotional Materials Guidance that when reviewing promotional materials submitted for review pursuant to subpart H, "[its] goal is to provide comments in a timely manner, usually within 15 working days of the day the materials are

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[32] *See* Center for Drug Evaluation and Research, FDA, MAP 6020.3, Priority Review Policy (Apr. 22, 1996); Center for Biologics Evaluation and Research, FDA, SOPP 8405, Complete Review and Issuance of Action Letters (May 1, 1998); Center for Devices and Radiological Health, FDA, PMA/510(k) Expedited Review—Guidance for Industry and CDRH Staff (Mar. 20, 1998).

[33] *Coors Brewing Co*., 514 U.S. at 486, 488-89 (quoting *Central Hudson*, 477 U.S. at 566) (holding that federal regulations prohibiting the disclosure of alcohol content on beer labels fail to directly advance the government's interests because the government's regulatory regime was irrational in that it also allowed for alcohol content disclosure in beer advertising in some states, and allowed for, and in some cases required, the disclosure of alcohol content on labels of wines and spirits).

[34] *Western States Med. Ctr.,* 535 U.S. at 371.

[35] 21 C.F.R. § 314.510.

[36] *Id*. § 314.520.

[37] *Id*. § 314.530.

[38] *Id*. § 314.81(b)(3)(i).

received."[39] Thus, the agency has acknowledged that it can review subpart H promotional materials expeditiously. The agency could address its heightened concerns regarding promotion of subpart H drugs by requiring that these submissions be identified as subpart H promotional materials, subjecting the submissions to priority reviews, and communicating any concerns that it might have to applicants on an expedited basis. Accelerated review postdissemination is constitutionally permissible; mandating prior submission is not.

III. THE CONSTITUTION LIMITS GOVERNMENTAL RESTRICTIONS ON THE EXCHANGE OF SCIENTIFIC INFORMATION ON OFF-LABEL USES

As noted above, the First Amendment protects truthful, nonmisleading commercial speech from "unwarranted governmental regulation."[40] FDA's policies need to be revised so as not to infringe on a sponsor's constitutional right to disseminate important scientific information about regulated products, including information on off-label uses.

A. *Constitutional Protection of Speech: Is Scientific Information Describing Off-Label Use Pure Speech or Commercial Speech?*

When disseminated by a manufacturer, scientific information (e.g., journal articles, abstracts, posters, or other materials or educational activities that discuss off-label uses of its products), *at a minimum*, fits the category of constitutionally-protected commercial speech. Courts will strike down laws that restrict truthful, nonmisleading commercial speech unless the government can show that the restriction on speech meets the requirements of the *Central Hudson* test.[41]

This is not an easy test for the government to meet—the *Central Hudson* test is characterized as "intermediate scrutiny." Courts will apply an even higher level of scrutiny to governmental restrictions on pure speech, particularly where the restrictions are content-based. There is little doubt that FDA's restrictions on the dissemination of off-label use information are content-based. The restrictions are derived entirely from the message conveyed, i.e., the information on a product use not described in the FDA-approved labeling. Furthermore, they are based on who disseminates the materials. The same materials would not be objectionable to FDA if sent by one physician to a colleague, or if a physician saw the abstract at a conference or read the article in a medical magazine.

A plausible argument can be made, therefore, that materials such as scientific journal articles, abstracts, and posters, as well as other scientifically-recognized materials prepared by third parties and distributed by sponsors to facilitate the scientific exchange of information about their products, are not commercial speech and are entitled to an even higher level of constitutional protection. Courts apply a more stringent test to governmental restrictions on pure speech. Courts will subject content-based restrictions on pure speech to strict scrutiny—a standard more exacting and more difficult for the government to meet than the *Central Hudson* test. When strict scrutiny is applied, the government must show a compelling interest in restricting the speech and that the restriction is necessary and narrowly tailored to achieve that end.[42]

The fact that materials are disseminated—or the exchange of scientific information is facilitated—by the product manufacturer should not automatically lower the status of

[39] Promotional Materials Guidance, *supra* note 8, at 2.
[40] *Central Hudson*, 447 U.S. at 561.
[41] *Id.* at 566.
[42] *See, e.g.*, Boos v. Barry, 485 U.S. 312, 321 (1988).

the information from pure speech to commercial speech and subject it to a lesser degree of scrutiny by the court. For example, a scientific journal article—standing alone—is not commercial speech. It is not clear then why the same material should be deemed commercial speech solely because the manufacturer or its representative has disseminated the material. Nor is it clear why a poster on display at a scientific meeting is pure speech while the identical poster handed out by a company representative at a booth at the same conference receives a lower level of protection. While the manufacturer's motivation for disseminating the material may be, at least in part, commercial, that is not usually the case for the author. The speech is no less valuable because a company representative hands it out, and the motivation of the intended recipient is not commercial at all.

The exact boundaries of what constitutes commercial speech or what line must be crossed to change pure speech to commercial speech are not entirely clear. The principal case in which the Supreme Court addressed the outer limits of the definition of commercial speech is *Bolger v. Young's Drug Products Corporation*.[43] In *Bolger*, the Supreme Court wrestled directly with the question of whether the speech at issue was in fact commercial speech.[44]

The *Bolger* Court identified three factors that led it to determine that the speech at issue was commercial speech. The speech in *Bolger* consisted of pamphlets and brochures that described the benefits of use and the availability of condoms. The condom manufacturer disseminated the material to the public through the U.S. mail. Noting that some of the material did not meet the core definition of commercial speech (i.e., speech that merely proposes a commercial transaction) because it was of educational value, the Court set forth the following factors, which, taken *together*, led it to deem the condom information to be commercial speech: 1) the manufacturer had conceded that the pamphlets were advertisements; 2) the pamphlets referred to a specific product; and 3) the manufacturer had an economic motive for distributing the material.[45]

A strong argument can be made that scientific information disseminated by the product manufacturer, which refers to off-label use, is not commercial speech under the *Bolger* factors.[46] First, scientific materials, such as scientific journal articles, medical texts, and abstracts and posters from scientific meetings, are not advertisements. Second, such materials may not necessarily mention a "product" name. The chemical name for the drug may be used, multiple products may be mentioned, or the piece may discuss physiological mechanisms of action. In any event, this factor can hardly be controlling. Third, while the manufacturer's motivation to distribute the material may be at least in

[43] 463 U.S. 60 (1983).

[44] In other commercial speech cases it was clear that the speech at issue was commercial. That is, the speech came very close to or met the core definition of commercial speech, speech that does no more than propose a commercial transaction. *See, e.g.*, *Western States Med. Ctr.*, 535 U.S. at 357 (holding that restrictions on compounding pharmacists' advertising unconstitutional); 44 Liquormart v. Rhode Island, 517 U.S. 484 (1996) (holding ban on advertising prices of liquor unconstitutional); Florida Bar v. Went For It, 515 U.S. 618 (1995) (holding thirty-day wait before lawyers may contact victims/survivors and potential clients constitutional); Rubin v. Coors, 514 U.S. 476 (1995) (holding ban on displaying the alcohol content of beer on labels unconstitutional); Federal Communication Comm'n v. Edge, 509 U.S. 418 (1993) (holding ban on lottery advertisements by radio stations licensed in a state where lotteries are illegal constitutional); *Central Hudson*, 447 U.S. 557 (holding ban on promotional advertising by a utility unconstitutional); and Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (holding ban on pharmacists' advertising the price of prescription drugs unconstitutional).

[45] *Bolger*, 463 U.S. at 66-67.

[46] The *Washington Legal Foundation* court, however, held otherwise. *See* Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51, 64 (D.D.C. 1998) (finding that the dissemination of peer-reviewed journal articles and medical texts as well as manufacturer-sponsored educational seminars should be classified as commercial speech under the *Bolger* factors).

part economic, physicians and other healthcare workers who may invoke their constitutional right to *receive* such information have no economic motivation at all. Moreover, the individuals who generated the materials generally will have done the research and drafted the documents without the objective of benefiting the manufacturer. Indeed, the research and writing typically are done to acquire, and then disseminate, knowledge.

The *Bolger* Court stressed that it was all three factors taken together that led it to conclude that the speech was commercial in nature. Thus, under the same analysis, there is a strong argument to be made that a manufacturer disseminating medical information on its products engages in pure speech, entitled to the highest constitutional protection.[47]

The stage was set for the Supreme Court to expound this term on the outer limits of commercial speech as well as expand First Amendment jurisprudence. On April 23, 2003, the Court heard oral arguments in *Nike, Inc. v. Kasky*.[48] At issue in *Nike* was whether a corporation's letters to newspapers and other published materials are "commercial speech," where the content involves important social issues, but where the speech is disseminated for the purpose of protecting or restoring the company's reputation as a good corporate citizen, and where the motivation appears to be, at least in part, to affect the public's purchasing decisions. Nike argued to the Court that the speech at issue did not meet two out of the three *Bolger* factors: It was not an advertisement and it did not refer to a particular product.[49]

Unfortunately, the Court, in a one-line *per curiam* decision, dismissed Nike's writ of certiorari as improvidently granted.[50] In a concurring opinion, however, Justice Stevens, joined by Justices Ginsburg and Souter, acknowledged that the speech at issue "represent[ed] a blending of commercial speech, noncommercial speech and debate on an issue of public importance."[51] In a dissent to *Nike*'s dismissal, Justice Breyer, joined by Justice O'Connor, also emphasized that the communications at issue were not purely commercial in nature; rather, according to the dissent, they would be "better characterized as involving a mixture of commercial and noncommercial (public issue-oriented) elements."[52]

The dissent went further in forecasting what the Court might have done had it reached the merits. Justice Breyer noted that the form (not traditional advertisements) and content (matters of significant public interest) distinguish the speech from "more purely 'commercial speech' described in prior cases."[53] Indeed, based on the format, content, and regulatory context of the speech at issue, Justice Breyer concluded that had the Court reached the merits in *Nike*, it would have held that heightened scrutiny applied.[54]

Justice Breyer distinguished Nike's speech from pure commercial speech, such as product advertisements. He pointed out that the materials at issue convey information to "individuals who have 'a general curiosity about, or genuine interest in,' the public controversy surrounding Nike."[55] Additionally, the content concerned a "matter that is of significant public interest and active controversy" and described "factual matters related to that subject in detail."[56] Justice Breyer emphasized that Nike's communications sought to inform the public about important public issues.[57]

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[47] *See* Anne Marie Murphy, *"It's Time to Make a Good Agency Better": The Food and Drug Administration Modernization Act of 1997 and the First Amendment*, 53 FOOD & DRUG L.J. 603, 618-23 (1998).

[48] Nike, Inc. v. Kasky, 123 S. Ct. 2554 (2003).

[49] *Nike*, Brief for the Petitioners at 25.

[50] *Nike*, 123 S. Ct. at 2554.

[51] *Id*. at 2558 (Stevens, J., concurring).

[52] *Id*. at 2565 (Breyer, J., dissenting).

[53] *Id*. at 2566 (Breyer, J., dissenting).

[54] *Id*. (Breyer, J., dissenting).

[55] *Id*. (Breyer, J., dissenting) (citing Bigelow v. Virginia, 421 U.S. 809, 822 (1975)).

[56] *Id*. (Breyer, J., dissenting).

[57] *Id*. (Breyer, J., dissenting).

Similarly, material on off-label use disseminated by a product manufacturer is designed to provide information to physicians about a drug product. Like the journalists who rely on information to keep the public informed of public issues, physicians rely on information about drug products to inform patients of their treatment options and to decide how to best treat patients. Moreover, like the communications at issue in *Nike*, scientific information disseminated by manufacturers differs from commercial speech in both its format and content: It is not an advertisement and it concerns factual information that is important to the public. Material from a manufacturer about a drug product contains noncommercial scientific information. Under the First Amendment, restrictions on the dissemination of such material should be held to heightened scrutiny.[58]

B. *FDA Policy on the Exchange of Scientific Information on Off-Label Use and the Washington Legal Foundation Litigation*

While FDA does not attempt to limit the off-label *use* of approved products by physicians, it prohibits manufacturers from *promoting* such uses. FDA does not have jurisdiction over the practice of medicine and it will not interfere with a physician's decision to prescribe a product "off-label."[59] Paradoxically, the very fact that physicians choose to prescribe products for off-label use makes dissemination of scientifically sound information on off-label use all that more important to the public health. Physicians and other healthcare workers have a keen interest in receiving such information. Manufacturers, as experts on their own products, have the right and the obligation to facilitate the exchange of scientific information—both positive and negative—about their products, including information about off-label use.

Despite professing its value,[60] historically, FDA's policies have limited this scientific exchange. In the past, for example, FDA essentially banned manufacturers' unsolicited distribution of peer-reviewed scientific journal articles and medical texts that discuss off-label uses.[61] After filing a citizen petition to compel FDA to change its policies, the Washington Legal Foundation (WLF) sued FDA and successfully argued before the district court that that policy was unconstitutional. The court found that FDA's policy failed to pass constitutional muster under *Central Hudson* because, although FDA demonstrated it had a substantial interest in regulating the speech, the restriction burdened more speech than was necessary. The court issued an injunction that barred FDA from enforcing the policy.[62]

Shortly thereafter, the Food and Drug Administration Modernization Act of 1997 (FDAMA)[63] went into effect. Provisions of FDAMA allowed manufacturers to distribute off-label reprints, subject to onerous conditions. FDA asked the court to clarify how the injunction applied to these FDAMA provisions. The court held that the FDAMA provisions were unconstitutional as well.[64]

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[58] *See id.* (Breyer, J., dissenting).

[59] Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 350 (2001) (noting that off-label use of medical devices is accepted by FDA and that that acceptance is consistent with FDA's mission to regulate products without interfering with the practice of medicine).

[60] *See* CDER, FDA, POSITION ON THE CONCEPT OF SOLICITED AND UNSOLICITED REQUESTS (Apr. 22, 1982) (noting the importance of the "full exchange of valid and legitimate information" on regulated products); 21 C.F.R. § 312.7(a) (noting that FDA's restriction of promotional claims for investigational drugs is "not intended to restrict the full exchange of scientific information concerning the drug").

[61] FDA, Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed. Reg. 52,800, 52,801 (Oct. 8, 1996).

[62] Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998).

[63] Pub. L. No. 105-115, 111 Stat. 2296 (19197).

[64] Washington Legal Found. v. Henney, 56 F. Supp. 2d 81 (D.D.C. 1999).

On appeal, FDA clarified its position by indicating that the agency would use distribution of off-label reprints as evidence of a firm's intended use for a product, but that the distribution of off-label reprints could not be the sole basis for the violation.[65] In response, WLF said at oral argument that it no longer objected on constitutional grounds. Because of this apparent agreement between the parties, the court vacated the injunction. Nonetheless, the underlying constitutional protections and the court's logic survive.

After the injunction was vacated, FDA stated in a *Federal Register* notice its policy on the distribution of off-label information. FDA said it may proceed with an enforcement action against off-label promotion based in part on written materials disseminated by sponsors. FDA affirmatively recognized that in any such enforcement action a manufacturer could raise a First Amendment defense.[66] This policy is so suspect that it affirmatively invites a constitutional challenge upon the agency's first attempt at enforcement. As Judge Lamberth noted in the most recent substantive *WLF* opinion:

> [T]he issue remains 100% unresolved, and the country's drug manufacturers are still without clear guidance as to their permissible conduct. To say that FDA's March 16, 2000 Notice finally clarifies the situation is a farce; the Notice specifically invites a constitutional challenge to each and every one of its enforcement actions.[67]

FDA's policy should be revised. The agency should not attempt to restrict the dissemination of truthful, nonmisleading scientific information, including materials that discuss off-label uses of regulated products. Since the *WLF* cases ended, FDA apparently has not brought an enforcement action based on the distribution of reprints. As Judge Lamberth noted, however, should FDA decide to bring an action, it would invite a constitutional challenge. In the meantime, FDA's position remains ambiguous. This ambiguity, in turn, deters companies from distributing scientifically valid materials to physicians. Rather than engaging in more protracted and probably fruitless litigation, FDA should develop policies that recognize the constitutionally protected status of these materials.

C. *The Constitution Protects a Wide Variety of Means to Facilitate the Exchange of Scientific Information on Off-Label Use*

Physicians and other healthcare providers require scientifically sound information—both positive and negative—on FDA-regulated products, including information about off-label uses. The product manufacturer, as the entity most familiar with the universe of information about its product, may be in the best position to ensure and facilitate the full exchange of this information. Even if the manufacturer's motivation is, in part, economic, that motivation in no way minimizes the value of the information exchanged. This value is not derived from—or diminished by—the participation of the manufacturer.

In addition to the dissemination of off-label reprints—the primary focus of the *WLF* litigation—manufacturers use a variety of other means and venues to facilitate the exchange of valid scientific information on their products, including sponsoring continuing medical education programs and grand rounds, educating clinicians, having

[65] Washington Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000).

[66] 65 Fed. Reg. 14,286 (Mar. 16, 2000). Subsequently, the WLF filed a motion to confirm and enforce the earlier injunction. The court denied that motion, finding that the injunction had been wholly vacated. *See* Washington Legal Found. v. Henney, 128 F. Supp. 2d 11 (D.D.C. 2000).

[67] *See Washington Legal Found. v. Henney*, 128 F. Supp. 2d at 15.

face-to-face meetings with physicians, responding to unsolicited requests for product information, sponsoring clinical studies, developing speakers bureaus, and disseminating adverse event information. Whether they focus on off-label uses or uses described in the product's FDA-approved labeling, these activities—provided they convey truthful, nonmisleading, scientifically valid information—deserve protection under the First Amendment. Sponsors should not be discouraged from disseminating such information for fear of violating a vague FDA policy that is ill-defined and inconsistent.

For example, FDA should provide expressly for the dissemination of truthful, nonmisleading scientific information even though it has not been peer-reviewed or otherwise published. FDA currently distinguishes between scientific information that is peer-reviewed and that which is not. The FDA policies that were struck down in the *WLF* litigation provided only for the dissemination of unabridged reprints or copies of peer-reviewed articles, or of reference medical texts.[68] Although the WLF challenged only textbook and peer-reviewed journal articles, the First Amendment also protects other forms of medical communications.

A distinction that uses publication in a peer-reviewed journal as a touchstone lacks merit. FDA appears to say that peer review automatically imbues scientific information with an inherent or elevated level of validity, and that materials that are not peer-reviewed are presumptively false or misleading. It is not up to FDA, however, to be the arbiter of the truth of medical information. Indeed, when FDA argued so in *WLF*, the court rejected the assertion, stating that the agency had "exaggerate[d] its overall place in the universe."[69]

Moreover, the distinction between peer-reviewed and nonpeer-reviewed scientific information does not pass constitutional muster. First, a blanket prohibition on the dissemination of nonpeer-reviewed materials may violate the doctrine of prior restraints by blocking the distribution of an entire class of manufacturer communications. Even if the doctrine of prior restraints did not apply, FDA restrictions on the dissemination of nonpeer-reviewed information would have to meet the requirements of the *Central Hudson* test: FDA would be required to show either that the specific materials were false or misleading or that the agency had a substantial interest in regulating the dissemination, that its restrictions directly advanced that interest, and that the restrictions were no more extensive than necessary.[70]

Abstracts, for example, are neither presumptively inaccurate nor misleading. While abstracts will not contain all the details of a full paper, readers recognize this limitation. A physician reading an abstract presented at a scientific conference, for example, will not be misled into believing that it is a comprehensive report of the study. Although the information in certain abstracts may not be robust enough to warrant distribution,[71] other abstracts may describe large-scale, well-controlled clinical trials or convey other

[68] *See* former FDC Act § 552; 21 U.S.C. § 360aaa.

[69] *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d at 67. The *WLF* litigation challenged a policy that addressed peer-reviewed articles. Since the court was not asked to address other materials, FDA cannot rely on this case to argue that restrictions on other scientific articles are valid. Although the constitutionality of prohibiting off-label abstracts and other scientific materials was not directly presented to the court by WLF, its finding that constitutional protections are afforded to peer-reviewed journal articles extends equally to other types of scientific documents that healthcare professionals use in evaluating products.

[70] *Central Hudson*, 447 U.S. at 566. Thus, under the approach we advocate, FDA can take enforcement action against a company that does distribute false or misleading materials.

[71] Companies that are considering dissemination of these materials would be well advised to consider not only the regulatory implications, but potential product liability consequences as well. Companies should be certain that the materials are balanced and do not provide a distorted perception of a product's performance.

meaningful information. Abstracts also may represent the vehicles by which new research findings are first introduced. FDA cannot bar the distribution of all abstracts, posters, or similar peer-to-peer communications that mention off-label use simply because some such documents may be deficient.

Because the agency can take other less restrictive measures, it would be hard-pressed to devise a regulatory regime categorically restricting the dissemination of nonpeer-reviewed scientific information that would satisfy the fourth prong of the *Central Hudson* test. FDA has a constitutional duty to take measures that restrict conduct instead of speech, or, at the very least, restrict as little speech as is necessary. As the Supreme Court said in *Western States*, "[i]f the First Amendment means anything, it means that regulating speech must be a last—not first—resort."[72]

FDA should revise and clarify its policies to expressly provide for the dissemination by manufacturers of all truthful and nonmisleading scientific information, including facilitating educational activities that promote the exchange of scientific information about regulated products. Permissible dissemination should expressly include valid scientific information describing off-label use, and should not be limited to information that has been peer-reviewed and published. Nothing in First Amendment jurisprudence supports the use of peer review as the gatekeeping test that a scientific report distributed by a manufacturer must pass to achieve constitutional protection.

In addition, to the extent that FDA's policy is based, at least in part, on the notion that the disseminated material will lead recipients to make poor choices, it fails to pass constitutional muster. Manufacturers of regulated products often have the best access to the latest scientific information related to their products. Such scientific information may discuss new uses and may be presented in a wide variety of formats, including but not limited to, scientific journal articles, abstracts, and posters—some of which may be peer-reviewed, some of which may not—as well as continuing medical education programs and a variety of other activities. Dissemination of independent scientific information by manufacturers should not be restricted by arbitrary categories. Provided that the scientific information is truthful and not misleading, barring its dissemination is impermissible, particularly where the reason for barring its dissemination is that the public may make poor choices or decisions based on the information.

Supreme Court jurisprudence is replete with examples that strike down such paternalistic restrictions on speech. In *Western States*, for example, the court disagreed with the government's argument that FDA restrictions on the advertising of compounded drugs were justified because consumers may convince their doctor to prescribe unneeded drugs.[73] The court posited an alternative: "That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to *open the channels of communication* rather than to close them."[74] Indeed, the Court has recognized that government restrictions of truthful, nonmisleading commercial speech "usually rest solely on the offensive assumption that the public will respond 'irrationally' to the truth."[75]

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[72] *Western States Med. Ctr.,* 535 U.S. at 373.

[73] *Id.*

[74] *Id.* at 375 (quoting *Va. Bd. of Pharmacy*, 425 U.S. at 770) (emphasis added).

[75] *44 Liquormart*, 517 U.S. at 503 (citing Linmark Assoc., Inc. v. Willingboro, 431 U.S. 85, 96 (1977); *see also* Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999) ("[The government's] . . . argument runs along the following lines: that health claims lacking 'significant scientific agreement' are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of sale*. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous.").

In *WLF*, Judge Lamberth made a similar observation:

> To endeavor to support a restriction upon speech by alleging that the recipient needs to be shielded from that speech for his or her own protection, which is the gravamen of FDA's claim [with regard to dissemination of off-label use information], is practically an engraved invitation to have the restriction struck.[76]

FDA's restrictions on manufacturers' dissemination of nonpeer-reviewed information to the medical community are particularly suspect. That is, the manufacturers' intended audience—physicians and others in the scientific and medical community—are highly educated, learned intermediaries whose education, training, and experience leave them well-suited to judge *for themselves* the value and validity of the disseminated scientific materials.[77] Physicians routinely receive, analyze, and make therapeutic decisions based on this type of information. Physicians, who are free to prescribe products off-label, attend continuing medical education programs where off-label uses are discussed, request off-label information from manufacturers, receive off-label reprints from manufacturers, visit poster sessions at medical seminars reporting on off-label uses, view the proceedings of meetings containing reports of off-label uses, obtain abstracts discussing off-label uses in symposium proceedings, attend scientific meeting discussions, to conduct internet searches for off-label information, and subscribe to journals replete with articles describing off-label uses. It is reasonable to expect physicians to evaluate and weigh truthful, nonmisleading reprints, posters, abstracts, and other materials, even when those materials are distributed by manufacturers.

IV. CONCLUSION

It is time for FDA to state clearly that the dissemination of all truthful, nonmisleading scientific materials discussing off-label uses, including those that have not been peer-reviewed, is permissible and indeed encouraged. Such a message is wholly consistent with FDA's mission to promote and protect the public health. Similarly, to comply with the First Amendment, FDA should eliminate the prior review requirements in subpart H of its regulations.

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[76] *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d at 70.

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> In this instance, the government's notion that the scientific research product which the manufacturers seek to distribute needs to be withheld for the 'good of the recipient' is even more unsupportable than usual. First, it must be noted that the manufacturers are not seeking to distribute this information to the general consumer public, who likely lack the knowledge or sophistication necessary to make informed choices on the efficacy of prescription drugs. (citations omitted) Rather, they seek to disseminate this information exclusively to physicians. A physician's livelihood depends upon the ability to make accurate, life-and-death decisions based upon the scientific evidence before them. They are certainly capable of critically evaluating journal articles or textbook reprints that are mailed to them, or the findings presented at [continuing medical education] seminars. (footnote omitted) Furthermore, FDA does not question a physician's evaluative skills when an article about an off-label use appears among a group of articles in the New England Journal of Medicine, or when one physician refers a peer physician to a published article he recently perused, or even when a physician requests a reprint from a manufacturer. Why the ability of a doctor to critically evaluate scientific findings depends upon how the article got into the physician's hands . . . is unclear to this court.

See id.