Docket No. FDA-2014-N-0447

COMMENTS

of

THE WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH & HUMAN SERVICES

Concerning

DRAFT GUIDANCE FOR INDUSTRY ON INTERNET/SOCIAL MEDIA PLATFORMS WITH SPACE CHARACTER LIMITATIONS: PRESENTING RISK AND BENEFIT INFORMATION FOR PRESCRIPTION DRUGS AND MEDICAL DEVICES

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 79 *FED. REG.* 34759 (June 18, 2014)

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Submitted Electronically (www.regulations.gov)
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Re: Draft Guidance for Industry on Internet/Social Media Platforms With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices
Docket No. FDA-2014-N-0168, 79 Fed. Reg. 34759 (June 18, 2014)

Dear Sir/Madam:

The Washington Legal Foundation (WLF) is pleased to submit these comments in response to the Food and Drug Administration's (FDA) proposed draft guidance for industry regarding how manufacturers may present risk and benefit information for prescription drugs and medical devices on Internet/social media platforms with character space limitations (the "Draft Guidance"). WLF has grave concerns regarding several provisions of the Draft Guidance. Although FDA does not say so explicitly, the gist of the Draft Guidance is that manufacturers should rarely, if ever, attempt to use Internet/social media platforms with character space limitations because those limitations do not provide manufacturers with sufficient space to include all the risk and benefit information that FDA asserts is a necessary part of any such communications. That *de facto* prohibition on use of such Internet/social media platforms is inconsistent with FDA's statutory mandate and raises serious First Amendment concerns regarding the rights of manufacturers to speak truthfully on important health care issues. For the reasons set forth herein, WLF urges FDA to withdraw the Draft Guidance in its entirety and to

replace it with one that respects statutory and constitutional constraints on FDA's authority.

The Draft Guidance is particularly objectionable because it neither references the First Amendment nor exhibits any awareness of the significant constraints that the U.S. Constitution imposes on FDA's regulation of manufacturer speech. Any meaningful FDA guidance regarding speech restrictions must include a discussion regarding FDA's understanding of the dividing line between constitutionally protected speech and speech that FDA is authorized restrict; otherwise, manufacturers wishing to assert their First Amendment rights are left to guess regarding when FDA will resist the assertion of those rights. Moreover, the Draft Guidance's discussion of requirements imposed by the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, and applicable FDA regulations, badly misstates those requirements. Accordingly, these WLF comments discuss applicable constitutional, statutory, and regulatory requirements at length in order to clarify why FDA's proposed speech restrictions are so objectionable.

I. *Interests of WLF*

The Washington Legal Foundation is a public interest law firm and policy center with supporters in all 50 States. WLF regularly appears before federal and state courts and administrative agencies to promote economic liberty, free enterprise, a limited and accountable government, and the rule of law. In particular, WLF has devoted substantial resources over the years to promoting the free speech rights of the business community, appearing before numerous federal courts in cases raising commercial free speech and other First Amendment issues. *See, e.g., Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011); *Nike v. Kasky*, 539 U.S. 654 (2003). WLF has successfully challenged the constitutionality of FDA restrictions on speech by

pharmaceutical manufacturers. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). As a result of that litigation, FDA is subject to a permanent injunction limiting FDA's authority to suppress dissemination of certain journal articles/medical texts by manufacturers discussing off-label uses of their FDA-approved products. More recently, WLF lawyers played a key role in overturning—on First Amendment grounds—the criminal conviction of a pharmaceutical representative for conspiring to violate the FDCA; the representative's alleged "crime" consisted of speaking truthfully about off-label uses of a drug manufactured by his company. *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012).

WLF also regularly participates in FDA administrative proceedings in support of expanded First Amendment rights. *See, e.g.*, Docket No. FDA-2008-D-0053 (May 15, 2014) (response to revised FDA Draft Guidance on distributing scientific and medical publications on off-label uses); FDA Docket No. FDA-2013-N-1430 (April 14, 2014) (response to FDA Draft Guidance on postmarket submissions to FDA of interactive promotional media); FDA Docket No. FDA-2011-D-0868 (March 29, 2012) (response to FDA Draft Guidance on unsolicited requests for off-label information); FDA Docket No. FDA-2008-D-0053 (April 21, 2008) (response to FDA Draft Guidance on good reprint practices); FDA Citizen Petition No. 2006P-0319/CPI (August 11, 2006) (documenting repeated First Amendment violations by FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) and calling on DDMAC to comply with constitutional constraints on its activities); FDA Docket No. FDA-02N-0209 (October 28, 2002) (response to FDA's request for public comments on First

Amendment issues).

II. *The First Amendment Protects Manufacturer Speech*

The federal courts have long recognized that the First Amendment, subject only to narrow and well-understood exceptions, does not countenance governmental control over the content of messages conveyed by private individuals. *See, e.g., Texas v. Johnson*, 491 U.S. 397, 414 (1989). "As a general matter, 'state action to punish the publication of truthful information seldom can satisfy constitutional standards.'" *Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001) (quoting *Smith v. Daily Mail Publishing Co.*, 443 U.S. 97, 102 (1979)). While the courts have very occasionally upheld content-based speech restrictions, they have always imposed on the government a heavy burden of demonstrating the necessity of such restrictions. *See, e.g., R.A.V. v. St. Paul*, 505 U.S. 377, 382 (1992) ("Content-based regulations are presumptively invalid," and the government bears the burden to rebut that presumption.); *Burson v. Freeman*, 504 U.S. 191, 198 (1992).

As the Draft Guidance makes clear, FDA seeks to compel a drug or device manufacturer to include detailed risk and benefit information in connection with virtually any information it disseminates regarding one of its drugs or medical devices. Under the First Amendment, the burden rests on FDA at all times to demonstrate an interest sufficient to justify such regulation of commercial speech.

The Supreme Court has lessened somewhat the burden of proof imposed on government speech regulators when the speech in question is deemed "commercial speech," albeit such speech is still entitled to a substantial degree of constitutional protection. *See, e.g., Central*

Hudson Gas & Electric Corp. v. Public Service Comm'n, 447 U.S. 557, 562-63 (1980). In general, "commercial speech" is defined as "speech which does no more than propose a commercial transaction," a definition that encompasses virtually all "advertising" as that term is commonly understood. *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976).

Although the government has greater leeway to regulate commercial speech, putative regulators of such speech still face a significant burden. At a minimum, the Supreme Court requires that the government prove that the restriction "directly advances" a "substantial government interest" and is "narrowly tailored" to achieve a reasonable "fit" between FDA's stated goals and the agency's means of achieving them. *Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980).[1] For the *Central Hudson* test to be satisfied, the Court must be persuaded that the cost of the regulation has been "carefully calculated." *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 416 n.12 (1993). As with fully protected speech, the burden of justifying restrictions rests squarely with the government. *Bolger v. Young Drug Prods. Corp.*, 463 U.S. 60, 71 n.20 (1985) ("party seeking to uphold a restriction on commercial speech carries the burden of justifying it"); *Thompson v. Western States Medical*

[1] Under the four-part *Central Hudson* test, courts consider as a threshold matter whether the commercial speech concerns unlawful activity or is inherently misleading. If so, then the speech is not protected by the First Amendment. If the speech concerns lawful activity and is not inherently misleading, then the challenged speech regulation violates the First Amendment unless government regulators can establish that: (1) they have identified a substantial government interest; (2) the regulation "directly advances" the asserted interest; and (3) the regulation "is no more extensive than is necessary to serve that interest." *Central Hudson*, 447 U.S. at 566.

Center, 535 U.S. 357, 373 (2002).[2]

The government undoubtedly has an interest in regulating commercial speech to reduce the possibility that consumers might be misled by the speech. In such circumstances, the "narrowly tailored" government response is to direct the speaker to include disclaimers designed to minimize the possibility that consumers will be misled, rather than banning the speech altogether. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985). The government's authority to impose disclaimer requirements is subject to strict limitations, however; disclaimer requirements are constitutionally impermissible if they are "unduly burdensome" and thereby "chill protected commercial speech." *Id*. at 651.

III. *FDA's Statutory Authority Is Circumscribed by the FDCA's Limits on: (1) the Definition of "Labeling"; and (2) FDA's Authority to Regulate Advertising*

Congress adopted the FDCA in 1938 to regulate the sale of drugs and medical devices to the public. Section 505(a) of the FDCA, 21 U.S.C. § 355(a), provides that no "new drugs" may be introduced into interstate commerce unless they are approved by FDA. Once FDA has approved a drug or device for introduction into interstate commerce, it has only limited statutory authority to control the dissemination of information regarding the product. For example, FDA is authorized by statute to restrict what manufacturers have to say about their drugs and medical

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[2] The evidentiary burden is not light; for example, the government's burden of showing that a commercial speech regulation advances a substantial government interest "in a direct and material way . . . 'is not satisfied by mere speculation or conjecture; rather, a government body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will alleviate them to a material degree.'" *Rubin v. Coors Brewing Co.,* 514 U.S. 476, 487 (1995) (quoting *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993)).

devices to the extent that such materials constitute "labeling" of those products within the meaning of § 201(m) of the FDCA, 21 U.S.C. § 321(m). FDA's statutory authority also extends to "advertisements" of prescription drugs (but not over-the-counter drugs), 21 U.S.C. § 352(n), and of a small subset of medical devices referred to as "restricted" devices (*e.g.*, hearing aids). 21 U.S.C. § 352(q). The FDCA grants FDA no authority to control what those other than manufacturers and distributors say about the proper uses of FDA-approved drugs and medical devices.

The FDCA defines "labeling" as "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). While *Kordel v. United States*, 335 U.S. 345 (1948), held that the word "accompanying" as used in § 321(m) is to be defined broadly, *Kordel* still required that there be a spatial relationship between a product and the written material alleged to constitute "labeling" for that product.[3] A drug or device is "misbranded" if, *inter alia*, "its labeling is false or

[3] The Draft Guidance cites *Kordel* for the proposition that for purposes of determining whether the material meets the definition of "labeling," "[n]o physical attachment between the materials and the article is necessary; rather, it is the textual relationship between the items that is significant." Draft Guidance ("DG") at 2. If (as appears likely) FDA intends the phrase "textual relationship" to encompass *all* written material that mentions the product by name, FDA has clearly misread *Kordel*. Nothing in *Kordel* suggests that written material becomes "labeling" simply because it mentions a medical product by name. Rather, the Supreme Court made clear that the word "accompanying" requires some degree of physical proximity between the product and the written materials describing it. In *Kordel*, the written materials in question were not shipped together with the product; instead, brochures and dietary supplements were shipped separately to the same health-food store with the understanding that the brochures would be displayed on store shelves alongside the dietary supplement. The Court concluded that that the brochures sufficiently "accompan[ied]" the dietary supplements to qualify as "labeling," notwithstanding the fact that they were shipped separately and were never physically attached to

misleading in any particular." 21 U.S.C. § 352(a).

The FDCA regulates advertising of prescription drugs by declaring a drug "misbranded" unless its advertising meets requirements set forth in 21 U.S.C. § 352(n); in particular, all advertisements must include a "brief summary" describing the drug's "side effects, contraindications, and effectiveness." FDA regulations implementing that statutory authority are set forth at 21 C.F.R. § 202.1. The regulations cite "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisement broadcast through media such as radio, television, and telephone communications systems" as examples of advertisements subject to regulations under § 352(n). 21 C.F.R. § 202.1(*l*)(1). *Not* included within the regulatory definition of "advertising" are written materials supplied by the manufacturer and containing "drug information" and intended for use by "medical practitioners, pharmacists, or nurses" in dispensing the drug; rather, FDA regulations assert that such material is to be regulated as "labeling." 21 C.F.R. § 202.1(*l*)(2).

IV. *FDA's Proposed Guidance Adopts an Extremely Broad Understanding of "Labeling," Under Which Virtually Everything a Manufacturer Says About Its Products Constitutes "Labeling"*

The Draft Guidance begins with a recitation of FDA's alleged statutory authority, a recitation that makes clear FDA's belief that virtually anything expressed by a manufacturer regarding one of its drugs or devices is "labeling" and thus subject to FDA regulation under 21

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the products. *Id*. at 349 (stating that to allow manufacturers to avoid labeling restrictions by shipping product and literature to the same location in separate packages would "create an obviously wide loophole" in the FDCA's misbranding provisions).

U.S.C. § 352(a). As explained more fully in Section V below, FDA's overly broad definition of labeling is inconsistent with the definition set forth in 21 U.S.C. § 321(m).

Citing *Kordel*, the Draft Guidance asserts that § 321(m) defines labeling "broadly, to include all materials that supplement or explain an article." DG at 2. Materials constitute "labeling" so long as a "textual relationship" exists between the written materials and the drug or device. *Ibid.* The Draft Guidance then divides labeling into two categories: (1) "FDA-required labeling," which (a) is subject to FDA review and approval, (b) must directly accompany an FDA-approved product, and (c) provides detailed safety and effectiveness information; and (2) "promotional labeling," a term not defined by the FDCA or FDA regulations but which the Draft Guidance defines broadly as "any labeling, other than FDA-required labeling, that is devised for promotion of the product." *Id.* at 3. In employing its extremely broad definition of "labeling," the Draft Guidance suggests that *all* advertising is also labeling and that "promotional labeling" is largely synonymous with advertising.

In light of the Draft Guidance's broad definition of "labeling," it is unsurprising that the Draft Guidance simply assumes without discussion that virtually any material posted by a manufacturer on Internet/social media platforms constitutes "labeling" and "advertising" and thus must comply with FDA's restrictions on dissemination of "labeling" and "advertising." *See, e.g., id.* at 3 ("Any promotional labeling that makes claims about a firm's prescription drug or prescription device must include certain information, such as the indicated use of the product *and* the risks associated with use of the product."); *id.* at 4 ("Any advertising that makes representations about the use of a firm's prescription drug must include certain risk

information.") (citing 21 U.S.C. § 352(n) and 21 C.F.R. § 202.1).[4]

In light of those extensive disclosure requirements, the Draft Guidance "acknowledges that Internet/social media platforms associated with character space limitations may pose challenges for firms in providing a balanced presentation of both risks and benefits of medical products." DG at 4. FDA's acknowledgment of "challenges" is an understatement. For example, Twitter, a widely used social media platform, imposes a 140-character limit on all messages ("tweets"). FDA's response to the near-impossibility of including all the FDA-mandated risk and benefit information within every 140-character message: "If the firm concludes that adequate benefit and risk information, as well as other required information, cannot all be communicated *within the same tweet*, then the firm should reconsider using Twitter for the intended promotional message." *Id.* at 7 (emphasis added). The Draft Guidance then proceeds at length to explain the types of risk and benefit information it would require to be included within any "promotional" message posted on Twitter. In particular, it makes clear that it would not suffice for a manufacturer to include a link to a site listing detailed risk and benefit information; rather, the Twitter message "should, at a minimum, include the most serious risks associated with the product," without regard to the seriousness of those risks. *Id.* at 9.

[4] Indeed, the Draft Guidance lists as its paradigmatic example of "promotional labeling" and "advertising" the following phrase posted on the website Twitter regarding a hypothetical drug named NoFocus: "NoFocus for mild to moderate memory loss." DG at 7. In other words, a manufacturer that does no more than write the name of its drug and one of the drug's FDA-approved uses has engaged in promotional labeling and advertising.

V. *FDA's Overly Broad Definitions of "Labeling" and "Advertising" Are Inconsistent with Its Statutory Mandate; It Lacks Statutory Authority to Regulate Many of the Manufacturer Statements That the Draft Guidance Seeks to Regulate*

The Draft Guidance fails to take into account the highly varied types of speech engaged in by manufacturers on social media sites. Instead, it simply assumes that all such speech meets the statutory definition of "labeling" and attempts to regulate it as such. Some manufacturer speech will meet that definition (or the agency's definition of "advertising"), but other speech will not. FDA should withdraw the Draft Guidance and replace it with a document that draws a line that accurately explains the statutory limits on FDA authority to limit manufacturer speech.

Advertising—which is made subject to FDA regulation by 21 U.S.C. § 352(n)—is generally understood to consist of a sales pitch from a seller to potential buyers. FDA regulations cite "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communications systems" as examples of advertisements subject to regulation under § 352(n). *See* 21 C.F.R. § 202.1(*l*)(1). The types of material that manufacturers normally place online do not easily fit that description. For example, a typical manufacturer online posting will include information about the manufacturer's products, but it only infrequently will frame that information as an offer to sell. Moreover, a typical online posting is fundamentally different from a typical advertisement appearing in a newspaper or broadcast on television, in that it does not entail a manufacturer seeking out potential customers. Rather, the only readers on a site maintained by a manufacturer are individuals who have reached out to the manufacturer by

clicking on that page. If FDA believes that some of the written material appearing on social media sites constitutes advertising, it is incumbent on FDA to explain why and to let manufacturers know the dividing line between social media posts that are deemed to propose a commercial transaction and those that do not. Moreover, as FDA concedes, its statutory authority over advertising is limited; it is not authorized to regulate advertising for over-the-counter drugs, and its authority to regulate device advertising is limited to the small percentage of devices that qualify as "restricted" devices.

Nor is there reason to conclude that manufacturer speech on social media sites meets the statutory definition of "labeling." Labeling is defined as "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). FDA apparently contends that all manufacturer speech appearing on social media sites can be said to "accompany" the product in question, but it has never explained the basis for that contention, which is inconsistent with ordinary understandings of the word "accompany." Labeling "functions as the primary mechanism through which FDA and drug manufacturers communicate essential, science-based prescribing information to health care professionals." *Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc.*, 499 F.3d 239, 244 (3d Cir. 2007). FDA's own regulations confirm that "labeling," when not directly attached to the product in question, consists of material directed to health care professionals.[5] There is

[5] For example, in an effort to provide some distinction between "advertising" and "labeling," FDA regulations state:

Brochures, booklets, mailing pieces, detail pieces, file cards, bulletins, calendars, price

little evidence to suggest that manufacturer speech on the Internet is intended to convey prescribing information (or any other sort of information) to "health care professionals." Instead, such speech often takes other forms, such as inviting those who visit the site to share their experience with the drug or to provide truthful information to consumers interested in learning more about a drug. Even assuming that *some* portion of such speech might qualify as "labeling," an FDA guidance document is unhelpful unless it explains precisely when speech so qualifies so that manufacturers can know when that speech is subject to FDA regulation.

In an apparent effort to expand the scope of "labeling," FDA has invented the term "promotional labeling," and defined it to include "any labeling, other than FDA-required labeling, that is devised for promotion of the product." DG at 3. The term "promotional labeling" appears in neither the FDCA nor FDA regulations; FDA apparently began using it in informal guidances within the past decade only, in an apparent effort to expand its regulatory reach. By defining "promotional labeling" in a manner that is largely synonymous with "advertising," FDA apparently has hoped to fill perceived gaps in its statutory authority dictated

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> lists, catalogues, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug or references published (for example, the "Physicians Desk Reference") *for use by medical practitioners, pharmacists, or nurses*, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor *are hereby determined to be labeling* as defined in section 201(m) of the act.

21 C.F.R. § 202.1(*l*)(2) (emphasis added).

by the agency's limited jurisdiction over advertising. But use of the term "promotional labeling" cannot logically be used to expand FDA's statutory authority; if material does not meet the statutory definition of "labeling" (because it does not "accompany" the product to which it refers), calling the material "promotional labeling" does not lead to a different result. While the Supreme Court's *Kordel* decision held that the word "accompanying" as used in § 321(m) is to be defined broadly, *Kordel* still required that there be a spatial relationship between a product and the written material alleged to constitute "labeling" for the product. The mere fact that an online posting mentions a drug or device and its indicated use is not enough to create a spatial relationship between the posting and the product, of the sort contemplated by the Supreme Court. If the allegedly "promotional" posting can plausibly be understood to constitute an offer to sell the product, then it may qualify as an "advertisement" for purposes of § 352(n), but such an offer does not meet the definition of "labeling."

VI. *FDA's Statutory Authority Over Manufacturer Postings on Internet/Social Media Platforms with Space Character Limitations Is Limited to Postings That Qualify as Advertising Because They Either Explicitly or Implicitly Propose a Commercial Transaction*

As explained above, manufacturer postings on Internet/social media platforms will virtually never qualify as "labeling" because they cannot be said to "accompany" any FDA-approved product (regardless how broadly one seeks to define that word) and they are not directed to medical professionals. Such postings may constitute advertising (and thereby may be subject to FDA regulation) if they explain to readers how they can go about purchasing the medical product described in the posting or otherwise implicitly encourage purchase of the

product. But when the platforms at issue include strict space character limitations, it is unlikely that any such encouragement could be readily conveyed.

The Draft Guidance sets forth, as an example of "advertising" and "promotional labeling" subject to FDA regulation, a message on Twitter stating, "NoFocus for mild to moderate memory loss." Such a message, considered in isolation, cannot plausibly be deemed an offer to sell the hypothetical drug NoFocus, particularly in the absence of information indicating who manufactures the drug or how a reader could go about purchasing it. FDA insists that manufacturers should not be permitted to post such messages online even if totally truthful (*i.e.*., even if NoFocus has been approved by FDA to treat "mild to moderate memory loss"), unless accompanied by detailed risk and effectiveness information—data that could not easily be fitted within the 140-character space limitation imposed by Twitter. Thus, FDA is effectively banning inclusion of most such messages on Twitter. As the following section of these comments demonstrates, any such prohibition would raise serious constitutional issues. In order to avoid such constitutional concerns, FDA should accord the FDCA its most natural reading and re-write the Draft Guidance to make clear that most manufacturer messages posted on Internet/social media platforms with space character limitations are not subject to FDA regulation as either "labeling" or "advertising."

VII. The Draft Guidance's Failure to Consider First Amendment Constraints on FDA's Authority to Regulate Speech Is Inexcusable in Light of Recent Case Law Directly Limiting That Authority

Over the past several decades, federal courts have repeatedly held that FDA's restrictions on manufacturer speech are subject to significant First Amendment constraints and have held on

numerous occasions that FDA speech restrictions were constitutionally impermissible. *See, e.g.*, *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (202); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). In light of that history, WLF finds it very disappointing that FDA could issue a draft guidance document that directly addresses speech restrictions without once discussing its views regarding how its regulatory scheme has been shaped to avoid running afoul of the First Amendment.

An initial issue that FDA must address is whether the speech it seeks to regulate constitutes "commercial" or "noncommercial" speech, as defined in First Amendment case law. Given the extremely high level of constitutional protection accorded to noncommercial speech, FDA could not plausibly argue that its regulation of such speech on Internet/social media platforms could pass constitutional muster. Accordingly, any speech regulation by FDA must be limited to commercial speech. Yet, there is considerable evidence that significant portions of manufacturer speech on social media sites is noncommercial in nature and thus not subject to FDA restrictions.

FDA officials must come to grips with Supreme Court case law defining commercial speech as speech that "does no more than propose a commercial transaction." *Bolger v. Youngs Products Corp.*, 463 U.S. 60, 66 (1983). While some manufacturer speech on social media sites likely meets that definition, other speech does not. For one, much of the speech does not involve any sort of effort by manufacturers to reach out to potential customers; rather, the information

they post online is only seen by those who affirmatively seek to find it. For another, much of the speech makes no reference (even indirectly) to product sales, so there is little basis for concluding that such speech explicitly or implicitly proposes that readers should purchase the manufacturer's product.

It may well be true, of course, that manufacturers engage in such speech with the ultimate aim of maximizing profits. They may believe that the goodwill generated by their speech on social media sites will ultimately (if indirectly) translate into future sales. But the existence of a profit-making motivation has never been deemed sufficient to transform noncommercial speech into commercial speech. *Bd. of Trustees of State University of New York v. Fox*, 492 U.S. 469, 482 (1989) ("Some of our most valued forms of fully protected speech are uttered for a profit."). In the most famous libel case ever to come before the Supreme Court, the Court granted full First Amendment protection to a newspaper's speech, even though it was uttered in the context of a paid advertisement soliciting funds for a civil rights organization, and even though the defendant sold copies of its newspaper for a profit. *New York Times Co. v. Sullivan*, 376 U.S. 254 (1964). Thus, if it is to avoid major First Amendment pitfalls, a meaningful FDA guidance document must differentiate between commercial and noncommercial manufacturer speech and not attempt to regulate speech falling into the latter category.

Moreover, even the online manufacturer speech that FDA reasonably determines to be commercial in nature is still entitled to considerable constitutional protection, and it is incumbent on FDA to tailor its regulatory scheme to ensure that it is respecting First Amendment boundaries. Nothing in the Draft Guidance exhibits a recognition of this responsibility.

As noted above, the *Central Hudson* test provides that government regulation of truthful speech concerning a lawful activity violates the First Amendment unless government regulators can establish that: (1) they have identified a substantial government interest; (2) the regulation "directly advances" the asserted interest; and (3) the regulation "is no more extensive than is necessary to serve that interest." *Central Hudson*, 447 U.S. at 566. In the absence of any mention of First Amendment principles in the Draft Guidance, there is little cause for confidence that FDA is taking them into account in its regulation of speech on social media.

Of course, FDA may respond that it does, in fact, take First Amendment considerations into account and that a First Amendment discussion would be out of place in a document that does no more than discuss reporting requirements. But any such response overlooks language in the Draft Guidance indicating FDA's belief that everything a manufacturer publishes online is "promotional" (*i.e.* "commercial") in nature and, for precisely that reason, is subject to FDA regulation as either advertising or labeling or both.

The Draft Guidance's likely chilling effect on speech rights is underscored by a Warning Letter recently issued by the Office of Prescription Drug Promotion in connection with a manufacturer's speech on Facebook. The February 24, 2014 letter faulted Institut Biochimique SA ("IBSA") for making "false or misleading" statements regarding one of its products, Tirosint.[6] The letter faulted IBSA for the following language posted on its Facebook page:

If you have just been diagnosed with hypothyroidism or are having difficulty controlling

[6] Warning Letter dated February 24, 2014 from Kendra Y. Jones, Regulatory Review Officer, FDA's Office of Prescription Drug Promotion.

> your levothyrozine blood levels, talk to your doctor about prescription Tirosint, a unique liquid gel cap form of levothyroxine.

Letter at 2. FDA said that the statement was "misleading" because "it makes representations about the efficacy of Tirosint, but fails to communicate any of the risks associated with its use." *Id.* According to FDA, by omitting "the most serious and frequently occurring risks associated with Tirosint," the statement "misleadingly suggests that Tirosint is safer than has been demonstrated." *Id.*

The IBSA Warning Letter constitutes a severe restriction on online speech rights that cannot pass muster under *Central Hudson*. The letter's assertion that IBSA made "representations about the efficacy of Tirosint" is blatantly false. The Facebook page did nothing more than suggest that readers suffering from certain conditions should speak to their doctors about Tirosint, without suggesting that Tirosint was effective or what the doctor might say about the drug. Nor did the Facebook page "suggest that Tirosint is safer than has been demonstrated." Indeed, the page made no suggestion whatsoever about product safety. An *ipse dixit* statement by FDA that manufacturer speech includes misleading suggestions regarding safety and efficacy does not make it so. Nor is there a realistic danger that patients would inaccurately conclude that a drug poses no dangers simply because the drug's name is mentioned without a simultaneous recitation of the drug's risks. Even if one concedes that FDA might be within its rights to insist that risks be disclosed in connection with any mention of a drug in an advertisement in which the manufacturer reaches out to consumers and proposes a commercial transaction, there can be little justification for such a requirement where (as with IBSA and all

online postings) it is the consumer who seeks the manufacturer's speech by going to an online site. Even if one conceded that IBSA's statement constituted commercial speech, FDA could not possibly demonstrate that its speech restriction did anything to eliminate potential consumer confusion, or that the remedy it mandated constituted a narrowly tailored response.

Although the IBSA Warning Letter was ill-considered, the Draft Guidance is even more constitutionally problematic. At least manufacturers such as IBSA are not faced with space limitations when posting material on Facebook. Accordingly, the Warning Letter provided IBSA with a method of complying with FDA's demands while still posting truthful information on Facebook: it could keep posting so long as it included all safety and effectiveness information demanded by FDA. Those posting on Twitter and other social media platforms with space character limitations do not have a similar option; in most instances they will be unable to include all FDA-mandated information and still stay within Twitter's 140-character limit. FDA's only response: that's too bad, but you'll just have to find some other platform on which to exercise your First Amendment rights. As the Supreme Court has repeatedly made clear, the First Amendment does not permit the imposition of severe disclaimer requirements that effectively prevent companies from speaking at all within a chosen medium. *Zauderer*, 471 U.S. at 651 (disclaimer requirements are constitutionally impermissible if they are "unduly burdensome" and "chill protected commercial speech."). Such speech restrictions are impermissible even though the speaker can use other media to exercise his speech rights. *See, e.g., Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 565 (2001) (striking down ban on outdoor tobacco advertising, even though manufacturers and retailers had other means of advertising

their products).

Many manufacturer postings on social media platforms are of great benefit to public health. For example, if a manufacturer wishes to truthfully convey to consumers new safety or effectiveness information about its product, it might post the following message on Twitter: "For new safety info on use of NoFocus for mild to moderate memory loss, see this New England Journal of Medicine article," and then include a link to the cited, peer-reviewed article. Such postings, if truthful, are in the public interest, do not propose a commercial transaction, and could not possibly mislead any consumers. Accordingly, any FDA effort to restrict such postings violates the First Amendment and negatively impacts public health.

V. *Conclusion*

WLF respectfully requests that FDA revise the Draft Guidance in the manner described herein, in order to bring it into compliance with First Amendment and statutory limitations.

Sincerely,

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