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April 14, 2014

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

Re: Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics
79 Fed. Reg. 2449 (January 14, 2014)

Dear Sir/Madam:

The Washington Legal Foundation (WLF) submits these comments in response to the Food and Drug Administration's draft Guidance for Industry (the "Draft Guidance") on requirements for submitting "interactive promotional media" to FDA, for the purpose of allowing FDA to determine whether the submitted materials comply with regulatory requirements. The Draft Guidance defines "interactive promotional media" (referred to here on occasion as "IPM") to include "modern tools and technologies that often allow for real-time communications and interactions (e.g., blogs, microblogs, social networking sites, online communities, and live podcasts) that firms use to promote their drugs."

WLF applauds FDA for recognize the need to provide guidance in this area. On topics such as this, the existence of a relatively clear set of rules is often far more important to the regulated industry (which wants to know what it can safely do without incurring the wrath of government regulators) than whether the rules make sense. Specifically, WLF applauds FDA for

attempting to provide some guidance regarding when a product manufacturer should be deemed responsible for the written material in question.

WLF nonetheless has serious concerns with the Draft Guidance and urges FDA to withdraw Section IV (entitled, "Factors Considered in Determining Postmarket Submission Requirements for Interactive Promotional Media") in its entirety. The Draft Guidance's basic premise is that everything a manufacturer posts on-line: (1) qualifies as "promotional" material; (2) falls within FDA's statutory purview; and (3) is not protected from FDA regulation by the First Amendment. While the Draft Guidance is willing to concede that there are instances in which a manufacturer is not responsible for what *others* say about its product, it takes as a given that everything the manufacturer itself says is subject to strict FDA regulation. That premise is demonstrably incorrect. Accordingly, agency policy in this area ought to begin with guidance regarding where FDA draws the line between speech that it is and is not permitted to regulate. The Draft Guidance brushes aside such concerns and makes clear that FDA intends to regulate *everything* that a manufacturer says regarding its products on social media sites.

By addressing basic regulatory questions in reverse order, the Draft Guidance is worse than no guidance document at all. It chills manufacturer speech by requiring all such speech to be submitted for agency review yet failing to provide manufacturers with any assurance that at least some of the submitted material is not subject to FDA regulation. Recent Warning Letters issued by FDA's Office of Prescription Drug Promotion (OPDP) provide ample evidence that at least some FDA officials intend to regulate manufacturer speech on social media sites without

regard to statutory and constitutional constraints—thereby ensuring that the chill on speech will be substantial.

In particular, the Draft Guidance does not appear to take into account that FDA is engaged in the regulation of speech and, as such, is subject to significant First Amendment constraints. Indeed, the term "First Amendment" never appears in the Draft Guidance. FDA's position that it is largely exempt from the First Amendment has been repeatedly rejected by the Courts. The Draft Guidance ought to reflect a recognition by FDA that it is subject to the same constitutional constraints as all other federal agencies. Those constraints largely prohibit FDA from regulating any manufacturer speech that does not explicitly or implicitly propose a commercial transaction, because regulation of such "noncommercial" speech is subject to an exacting level of First Amendment review that FDA cannot hope to meet. WLF recognizes that some manufacturer speech that appears on social media sites can legitimately be deemed "commercial" in nature (and thus is entitled to a somewhat lesser degree of First Amendment protection). We also recognize that at least some such speech may qualify as "labeling" and thus falls within FDA's regulatory authority under the Food, Drug, and Cosmetic Act (FDCA). But unless FDA makes some effort to explain the circumstances under which it will determine that manufacturer speech on social media sites constitutes both "commercial" speech and "labeling," it has not begun to provide any sort of meaningful guidance.

Moreover, any FDA effort to regulate speech must be based on its authority to prevent manufacturers from conveying information to doctors and consumers that is at least potentially

misleading. Accordingly, it is incumbent on FDA to provide manufacturers with guidance regarding the circumstances under which it will deem speech appearing on social media to be misleading. Unfortunately, Warning Letters issued by OPDP all too often simply include an *ipsi dixit* that the speech is false or misleading without explaining the basis for the conclusion or providing evidence that readers are likely to be misled by the speech. Any document issued by FDA ought to provide guidance regarding when it will deem speech to be misleading so that manufacturers can adjust their speech accordingly, or else prepare First Amendment defenses to potential FDA enforcement action. Such guidance should also explain why FDA believes that its concerns regarding potentially misleading speech cannot be addressed in a manner more narrowly tailored than the one FDA proposes.

It is no answer to WLF's concerns to state that FDA guidance regarding social media speech has to begin somewhere, and that FDA is acting reasonably by focusing on requirements for postmarketing submissions. FDA regulations require postmarketing submission of "advertisements and promotional labeling." *See* 21 C.F.R. § 314.81(b)(3)(i) (human drugs); 21 C.F.R. § 601.12(f)(4) (biologics); 21 C.F.R. § 514.80(b)(5)(ii) (animal drugs). A manufacturer's *noncommercial* speech on the Internet cannot readily be deemed either an "advertisement" or "promotional labeling" and thus cannot be made subject to FDA's submission requirements. Accordingly, by failing to announce standards by which it will determine whether speech fits into one of those two categories, FDA has failed to provide manufacturers with even minimal guidance regarding what material must be submitted—unless one adopts the position that

constitutional and statutory constraints are irrelevant and that FDA is free to classify all manufacturer speech regarding its products as either advertising or promotional labeling.

I. *Interests of WLF*

The Washington Legal Foundation is a public interest law firm and policy center with members and supporters in all 50 States. WLF regularly appears before federal and State courts and administrative agencies to promote economic liberty, free enterprise, and a limited and accountable government. 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 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 authority to suppress manufacturer dissemination of certain journal articles/medical texts 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 "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.,* FDA Docket No. 2008-D-0053 (April 21, 2008) (response to FDA Draft Guidance for Industry 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 conform to constitutional constraints on its activities); FDA Docket No. 2011-D-0868 (March 29, 2012) (response to FDA Draft Guidance on unsolicited requests for off-label information); FDA Docket No. 02N-0209 (October 28, 2002) (response to FDA's request for public comments on First Amendment issues).

II. *FDA's Statutory Authority*

Congress adopted the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. §§ 301 *et seq.*, 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 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 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 (21 U.S.C. § 352(n)) and a small subset of medical devices referred to as "restricted" devices, *i.e.*, 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 some substantial relationship between a product and the written matter alleged to constitute "labeling" for that product.[1]

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). 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 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 regulations provide that written materials supplied by the manufacturer and containing "drug information" and intended for use by "medical practitioners, pharmacists, or

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[1] The Draft Guidance cites *Kordel* for the proposition that for purposes of determining whether 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 at 3. But nothing in *Kordel* suggests that written material becomes "labeling" simply because it mentions a drug by name. Rather, the Supreme Court made clear that the word "accompanying" requires some degree of physical proximity between the drug and the written materials describing it.

nurses" in dispensing the drug are deemed to be labeling. 21 C.F.R. § 202.1(*l*)(2).

III. *FDA Regulation of Social Media*

Commentators have been urging FDA for at least two decades to provide guidance regarding manufacturer speech on the Internet. For example, WLF filed a Citizen Petition in April 2001, urging FDA to conclude that material on the Internet should generally *not* be considered "labeling." FDA Docket No. 01P-0187/CP 1. FDA denied the Petition by letter dated November 1, 2001. But in the course of doing so, FDA acknowledged that at least some manufacturer speech on the Internet should not be deemed "labeling." Rather, it suggested that the material should be deemed labeling only to the extent that it is directly tied to "distribution and sale" of an FDA-approved product:

> FDA believes that, in certain circumstances, information about FDA-regulated products that is disseminated over the Internet by, or on behalf of, a regulated company can meet the definition of labeling in section 201(m) of the FDCA. For example, if a company were to promote a registered product on its website and allow consumers to purchase the product directly from the website, the website is likely to be "labeling." The website, in that case, would be written, printed, or graphic matter that supplements or explains the product and is designed for use in the distribution and sale of the product.

November 1, 2001 Letter from Margaret M. Dotzel, Associate Commissioner for Policy, at 2.

The Draft Guidance takes a far broader view of "labeling." It essentially declares that *everything* a manufacturer writes about its product is "labeling" and thus subject to FDA regulation. Draft Guidance at 2-3. Moreover, the Draft Guidance makes no mention of the First Amendment and thus contains no discussion of constitutional limits on the agency's authority to regulate any and all materials that it deems to be "labeling" within the definition of the FDCA.

Instead, the principal focus of the Draft Guidance is to set forth factors to be used in determining whether speech by others should be attributed to the manufacturer. *Id.* at 3-5.

IV. *First Amendment Precedent*

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). FDA seeks to control manufacturer speech in the context of "interactive promotional media" (IPM); the burden rests on FDA at all times to demonstrate an interest sufficient to justify its speech restrictions.

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." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748, 762 (1976). Indeed, the Supreme Court has "characteriz[ed] the proposal of a commercial transaction as '*the test* for identifying commercial speech.'" *City of Cincinnati v. Discovery Network, Inc.,* 507 U.S. 410, 416 (1993) (emphasis in original) (quoting *Bd. of Trustees of State University of New York v. Fox*, 492 U.S. 469, 473-74 (1989)). Fully protected speech is not transformed into commercial speech merely because the speaker is drawing a salary (or otherwise making a profit) while speaking. *Id.* at 482 ("Some of our most valued forms of fully protected speech are uttered for a profit. *See, e.g., New York Times Co. v. Sullivan*, 376 U.S. 254 (1964); *Buckley v. Valeo*, 424 U.S. 1 (1976) (per curiam).").

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).[2] For the *Central Hudson* test to be satisfied, the

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[2] 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 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.

Court must be persuaded that the cost of the regulation has been "carefully calculated." *Discovery Network,* 507 U.S. at 416 n.12. As with fully protected speech, the burden of justifying its restrictions rests squarely with the government. *Bolger*, 463 U.S. at 71 n.20 ("party seeking to uphold a restriction on commercial speech carries the burden of justifying it"); *Thompson v. Western States Medical Center,* 535 U.S. 357, 373 (2002).[3]

The government undoubtedly has a 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 the are "unduly burdensome" and thereby "chill protected commercial speech." *Id.* at 651.

V. *The Draft Guidance Inadequately Addresses The Nature of IPM*

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

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[3] 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)).

statutory definition of "labeling" and attempts to regulate it as such. Some manufacturer speech will meet that definition, but other speech will not. FDA regulations require manufacturers to submit "advertisements and promotional labeling" to the agency. 21 C.F.R. § 314.81(b)(3)(i) (human drugs); 21 C.F.R. § 601.12(f)(4) (biologics); 21 C.F.R. § 514.80(b)(5)(ii) (animal drugs). In the absence of an explanation of when manufacturer speech is deemed to constitute advertising or labeling, the Draft Guidance fails to provide meaningful guidance to the regulated community.

As noted above, 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 materials that manufacturers normally place on-line do not easily fit that description. For example, a typical manufacturer page on Facebook will include information about the manufacturer's products, but it only infrequently will frame that information as an offer to sell. Moreover, a Facebook page 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 consumers. Rather, the only readers on a manufacturer's Facebook page 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 what sorts of speech are reportable to FDA as advertising within the meaning of 21 C.F.R. § 314.81(b)(3)(i).

Nor is it at all clear that manufacturer speech on social media sites qualifies as "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). If FDA believes that all manufacturer speech appearing on social media sites can be said to "accompany" the product in question, it has never explained the basis for that belief. 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). There is 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 experiences with the drug. Even assuming that *some* such speech qualifies as "labeling,"[4] an FDA guidance document is unhelpful unless it explains precisely when speech so qualifies so that manufacturers can know when they are obligated to report the speech to FDA.

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[4] As noted above, FDA asserted, in response to WLF's 2001 Citizen Petition, that manufacturer speech on the Internet could qualify as "labeling" to the extent that "a company were to promote a regulated product on its website and allow consumers to purchase the product directly from the website."

VI. *Failure to Consider First Amendment Constraints*

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 on numerous occasions held 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 (2002); *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 afforded to noncommercial speech, FDA could not plausibly argue that its regulation of such speech could pass constitutional muster. Accordingly, any speech regulation by FDA must be limited to commercial speech. 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 thing, much of the speech does not involve any sort of effort by manufacturers to reach out to potential customers; rather, the information they post on-line is only seen by those who affirmatively seek to find it. For another thing, 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 listeners 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. *Fox*, 492 U.S. at 482 ("Some of our most valued forms of fully protected speech are uttered for a profit."). Thus, 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 newspapers 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 reasonable 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 rights. Nothing in the Draft Guidance exhibits a recognition of that responsibility.

Under the *Central Hudson* test applicable to judicial review of commercial speech restrictions, 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. Otherwise, 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. 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 on-line regarding its products should be deemed commercial speech and, for precisely that reason, is reportable to the agency as either advertising or labeling. In the absence of such a belief, FDA could not conclude that all such speech is reportable under 21 C.F.R. § 314.81(b)(3)(1), which

provides that only "advertising and promotional labeling" is reportable to FDA.

The Draft Guidance's likely chilling effect on speech rights is underscored by a Warning Letter recently issued by OPDP 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.[5] 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 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 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 talk to talk to their doctor about Tirosint, without suggesting that Tirosint was effective or what the doctor might say about the drug. Nor

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[5]Warning Letter dated February 24, 2014 to IBSA from Kendra Y. Jones, Regulatory Review Officer, FDA's Office of Prescription Drug Promotion (available at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/warningletersandnoticeofviolationlettersstoppharmaceuticalcompanies/ucm388800.pdf).

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 here) it is the consumer that sought out the manufacturer's speech by going to its Facebook page.[6] Moreover, even if one conceded that the Facebook 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 to the alleged potential for confusion.

In sum, the net effect of the Draft Guidance, when considered in conjunction with the IBSA Warning Letter, is to send a strong message to manufacturers: we will closely examine everything you say in social media contexts, and we will use the information you provide us to find fault with speech of which we disapprove for any reason. That message is likely to have a

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[6] WLF has not seen the Facebook page in question, which apparently was taken off-line soon after IBSA's receipt of the Warning Letter. But based on its past dealings with OPDP, WLF strongly suspects that OPDP's letter likely omitted highly salient facts, such as that a reader interested in learning risks associated with Tirosint could have, with just one click, gone to a IBSA web page that displayed all such risks.

strong chilling effect on truthful, noncommercial speech by manufacturers.

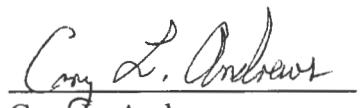
Manufacturers who desire to speak on social media platforms may well be unable to placate FDA's concerns by adding burdensome risk warnings to everything they say about a product. For example, Twitter is a highly popular social media platform, and part of its appeal is the brevity demanded of all messages posted there. No message can be more than 140 characters in length. Twitter creates an opportunity for consumers to seek out drug manufacturers and to sign up to receive short, easily digestible messages regarding health issues. Yet if FDA is free to demand detailed risk disclosures in connection with every statement uttered by a manufacturer, Twitter becomes unusable. Other social media platforms, including Instagram and Facebook, share with Twitter limitations on the lengths of posts; those limitations would render their use by manufacturers problematic if FDA were to continue to demand the same burdensome risk disclosures demanded in the IBSA Warning Letter.

VII. *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 limitations.

Sincerely,

Richard A. Samp
Chief Counsel



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