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September 16, 2014

Via Electronic Submission

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

Re: Draft Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (Docket No. FDA-2014-D-0397)

The Medical Information Working Group (MIWG) submits these comments in response to FDA's June 18, 2014 notice (79 Fed. Reg. 34759) inviting comments on the Agency's Draft Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (Draft Guidance).

The MIWG is a coalition of medical product manufacturers formed to consider issues relating to the federal government's regulation of truthful, non-misleading, scientifically substantiated manufacturer communications about approved drugs and approved/cleared medical devices. The members of the MIWG are: Allergan, Inc.; Amgen Inc.; Bayer Healthcare Pharmaceuticals Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Eli Lilly and Company; Genentech, Inc.; GlaxoSmithKline LLC; Johnson & Johnson; Novartis Pharmaceuticals Corporation; Novo Nordisk, Inc.; Pfizer, Inc.; Purdue Pharma L.P.; and Sanofi US.

The MIWG appreciates FDA's efforts to provide guidance with respect to use of the Internet and social media platforms with space limitations. Instead of enabling the appropriate use of these channels of communication, however, the Draft Guidance effectively precludes such use. The draft guidance recommends disclosures that, given the complexity and sheer length of the corresponding information in approved labeling, simply cannot be made in space-limited platforms in the manner described in the draft for the vast majority of products. Because of the burden the Draft Guidance would impose on speech based on its specific content and the identity of the speaker, the draft cannot be squared with foundational First Amendment principles, as articulated in Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011).

Part I of these comments examines the ways in which the Draft Guidance limits manufacturer speech. Part II addresses the constitutional issues raised by the Draft Guidance.

I. The Draft Guidance is Tantamount to a Ban on the Use of Space-Limited Platforms for Product Communications

The Draft Guidance sets forth recommendations for firms seeking to use important Internet and social media platforms that place limits on the number of characters that can be used in messages or advertisements. As the draft notes, websites such as Twitter limit

message length to 140 characters, and sponsored links through Google and other search engines have character space limitations as well.[1] To facilitate use of these communication formats, the draft attempts to apply FDA's customary approach to manufacturer communications to these platforms—without accounting for their inherent limitations.

- The Draft Guidance indicates that a microblog entry (e.g., via Twitter) should include the proprietary name of the drug, the drug's established name, an accurate description of benefit information that includes all material facts (e.g., limitations to an indication or the relevant population), a description of the most serious product risks, and a link to a webpage devoted exclusively to risk information about the drug—all in 140 or fewer characters.[2] The draft would make the use of Twitter and comparable platforms impossible in all but the rarest cases.

- The Draft Guidance also effectively prohibits manufacturers' use of paid search on Google (e.g., sponsored links). The draft indicates that, if a manufacturer describes the use of its product through Google's online paid search, then risk and other information should be conveyed via supplemental links called Sitelinks.[3] Google's policies, however, state that there is no guarantee that Sitelinks will always display.[4] Thus, under FDA's proposed approach, manufacturers can use Google's sponsored links only at risk, and the draft operates as a ban with respect to this channel as well.

Indeed, the draft makes clear that FDA expects manufacturers to avoid using space-limited platforms to provide product information in many, if not most, cases. The draft (at page 5) observes:

> For some products, particularly those with complex indications or extensive serious risks, character space limitations imposed by platform providers may not enable meaningful presentations of both benefit and risk . . . . If an accurate and balanced presentation of both risks and benefits of a specific product is not possible within the constraints of the platform, then the firm should reconsider using that platform for the intended promotional message . . . .

The draft similarly instructs manufacturers to "determine whether a character-space-limited platform is a viable promotional tool for a particular product,"[5] and cautions manufacturers to "consider whether, once benefit information is conveyed in an accurate and non-misleading manner, enough capacity will remain in the character-space-limited communication to adequately convey required risk information . . . [and] certain other required information, as applicable."[6] Thus, the Draft Guidance, by its own account, prohibits manufacturers from

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[1] Draft Guidance at 1.
[2] Id. at 1, 4, 6, 9-10, 13.
[3] Id. at 7, 11 n.18.
[4] Google, Show additional sitelinks below your ad text, http://tinyurl.com/l2zlfon.
[5] Draft Guidance at 6.
[6] Id. at 7; see also id. at 4, 8 (acknowledging the difficulty or impossibility of following the draft's recommendations in some instances).

making "accurate and non-misleading" benefit claims by imposing balancing and other disclosure requirements that space-limited platforms will not accommodate.[7]

The draft provides two examples using fictional products. The first example is a hypothetical Tweet about a product called NoFocus. The drug has a simple indication, "no boxed or other warnings and no known fatal or life-threatening risks," and a single risk deemed to be the "most significant."[8] The Tweet reads as follows:

> NoFocus (rememberine HCl) for mild to moderate memory loss- May cause seizures in patients with a seizure disorder www.nofocus.com/risk[9]

Even this example, which describes a drug with a very simple indication and a single significant risk, uses 134 of the allotted 140 characters.

Any additional complexity regarding a product or its use—even a longer established name—could easily require more than the additional six characters remaining in the model Tweet. And generally, FDA-approved labeling from which mandated disclosures are drawn includes far more complicated use, benefit, and risk information than the fictional drug—particularly for recently approved products. Indications are often lengthier; limitations of use more commonly appear in approved labeling; and multiple significant or serious risks are not uncommon. Applying the draft guidance to real-world examples would frequently require hundreds of characters more than Twitter permits.[10] Thus, as many have observed, the Draft Guidance's recommendations are tantamount to a ban on the use of space-limited communications.[11]

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[7] The Draft Guidance suggests that manufacturers who cannot present required risk, benefit, and other information should consider "reminder" advertising and labeling instead. Id. at 4-5. Merely mentioning a product's name without describing its potential benefits, however, significantly diminishes the incentive for readers to click on links to learn more. See Google, A Proposal for Sponsored Links, at 10 (Nov. 2009), available at http://tinyurl.com/kc88ac4 (citing Google internal data indicating that pharmaceutical advertisements that do not describe a product by name and its potential benefits are "[l]ess [t]ransparent and [r]elevant," resulting in fewer clicks on the links provided). Further, FDA regulations do not permit the use of reminder advertising and labeling for all products (e.g., products with certain boxed warnings).

[8] Draft Guidance at 7, 11, 14.

[9] Id. at 14.

[10] See Dale Cooke, Regulatory Alert: FDA Releases Guidances on Presenting Risk and Correcting Misinformation Online, cohealthcom.org (June 17, 2014), http://tinyurl.com/owkea5y (observing that "one product chosen at random has a 692-character boxed warning, not including additional contraindications and other life-threatening risks").

[11] See, e.g., Jeff Overley, FDA's Biggest New Policies Of 2014: Midyear Report, Law360 (July 28, 2014), http://tinyurl.com/lq2ld2l; Elizabeth Harrington, FDA's Proposed Twitter Rules Could Limit Free Speech, The Washington Free Beacon (July 2, 2014), http://tinyurl.com/oxgwfkv ("[T]he guidance would make it 'virtually impossible for most manufacturers to use social media to promote their products.'" (quoting Brittany La Couture, health policy analyst, American Action Forum)); Elizabeth Nolan Brown, The FDA Is Now Regulating Tweets, Reason.com (June 19, 2014), http://tinyurl.com/pzdxxxz ("[T]weeting about pharmaceuticals will be effectively banned if new Food and Drug Administration (FDA) guidelines are adopted.").

The second example involves the use of Google's Sitelinks to advertise a fictional drug called Headhurtz. The guidance presents the risk and benefit information for Headhurtz as follows:

> Headhurtz (ouchafol) [20/25]
> www.headhurtz.com [17/35]
> For severe headache from traumatic brain injury [47/70]
> Boxed Warning [13/25] — Warning [7/25]
> Potential for brain swelling [28/35] — Potentially fatal drug reaction [31/35]
> Warning [7/25] — Risk information [16/25]
> Life-threatening drop in heart rate [35/35] — Important safety information [28/35][12]

The draft explains that Google "allows up to six additional links (Sitelinks) to be shown in addition to the destination URL (www.headhurtz.com in this example)," and that each portion of the sponsored link has defined character space limitations.[13] The example achieves the recommended disclosures of risk information using four Sitelinks, three "to convey the most serious risks" and one to "provide[ ] direct access to a more complete discussion of risk information."[14]

Under Google's policies, however, Sitelinks are not always guaranteed to appear, meaning that risk information may or may not display alongside product benefit claims. Google warns: "Keep in mind that your ads won't always show sitelinks. Also, when your ads show sitelinks, the format that appears could vary. For instance, anywhere from two to six sitelinks may appear on desktop ads."[15] This significant technical limitation is not addressed by the Draft Guidance.

II. The Draft Guidance Raises Significant Constitutional Issues by Effectively Preventing Manufacturers from Communicating about Their Products Using Space-Limited Platforms

Because the Draft Guidance effectively prohibits manufacturers from communicating about the use of their products using space-limited digital channels, it creates serious constitutional concerns. The MIWG believes the Draft Guidance, as currently written, describes a restrictive approach to manufacturer communication that does not meet the rigorous requirements for limiting speech and thus violates the First Amendment. Moreover, the draft lacks the specificity required by the Due Process Clause of the Fifth Amendment as construed in recent judicial decisions.

In Sorrell v. IMS Health Inc., the Supreme Court held that "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment."[16] There, the Court struck down a Vermont law limiting pharmaceutical

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[12] Draft Guidance at 15. "[I]nformation in brackets denotes character spaces used/available character spaces per line of the sponsored link promotion." Id. at 8.
[13] Id. at 11 n.18.
[14] Id. at 12.
[15] Google, Show additional sitelinks below your ad text, http://tinyurl.com/l2zlfon.
[16] 131 S. Ct. 2653, 2659 (2011).

manufacturers' speech.[17] The law at issue restricted pharmacies' ability to sell or disclose information about physicians' prescribing practices, and it prevented pharmaceutical manufacturers from using prescriber information for marketing purposes without doctors' consent.[18] The Court observed that the Vermont statute imposed both content- and speaker-based restrictions, making it "presumptively invalid" and subject to heightened scrutiny.[19] To withstand heightened scrutiny, a restriction on truthful, non-misleading manufacturer speech must, at a minimum, "directly advance[ ] a substantial government interest" and be narrowly drawn to achieve that interest.[20] The Court left open the possibility that an even greater showing would be required to support restrictions on manufacturer speech.[21] Ultimately, the Court rejected each of the government's justifications for the Vermont law's restrictions on speech and held that the law violated the First Amendment.[22]

The Draft Guidance's recommendations impose both content- and speaker-based restrictions, making them "presumptively invalid" under Sorrell.[23] The guidance sets out recommendations that are impossible to follow with respect to certain content (i.e., truthful statements about the use of the vast majority of medical products). And the draft's restrictions only apply to specific speakers (i.e., "manufacturers, packers, and distributors . . . of prescription human and animal drugs . . . and medical devices for human use").[24] Consequently, to meet constitutional demands, the draft's restrictive approach to manufacturer communications must satisfy heightened scrutiny—a standard the draft could not possibly meet.

The recent Third Circuit decision in Dwyer v. Cappell further highlights the constitutional infirmities in the Draft Guidance.[25] In Dwyer, the appeals court invalidated a ban on attorney "advertising with quotations from judicial opinions unless the opinions appear[ed] in full."[26] The court observed that the ban did not allow online advertisers to satisfy the full disclosure requirement by accompanying the quoted excerpt with a hyperlink to the full opinion. The Third Circuit ruled that the "onerous" and "cumbersome" disclosure obligations violated the First Amendment "where the required disclosure is so lengthy that it 'effectively rules out' advertising by the desired means."[27] The implications of Dwyer for the Draft Guidance are clear: just as the attorney advertising ban in that case violated the First Amendment on the ground that it imposed unduly extensive disclosure requirements on the advertiser's preferred method of communicating the availability of legal services, so, too, does FDA's approach to manufacturers' use of space-limited digital communications offend the First Amendment by—as

[17] Id. at 2667-72.
[18] Id. at 2660.
[19] Id. at 2662-64, 2667.
[20] Id. at 2667-68; see also Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 565 (1980) ("[T]he First Amendment mandates that speech restrictions be narrowly drawn." (citation and internal quotation marks omitted)).
[21] Sorrell, 131 S. Ct. at 2667.
[22] Id. at 2667-72.
[23] Id. at 2667 (quoting R.A.V. v. St. Paul, 505 U.S. 377, 382 (1992)).
[24] Draft Guidance at 1.
[25] No. 13-3235, 2014 WL 3893001, at *1, *7-8 (3d Cir. Aug. 11, 2014).
[26] Id. The Dwyer court did not have to determine whether the ban was subject to review under Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985), or the more stringent Central Hudson standard, supra n.20, finding the ban invalid even under the more lenient test. 2014 WL 3893001, at *1, *7.
[27] Id. at *7-8 (quoting Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, 512 U.S. 136, 146 (1994)).

the Draft Guidance concedes—making it a practical impossibility for manufacturers to use Twitter and similar media to communicate the availability of their products.

The Agency's own use of Twitter vividly illustrates the constitutional deficiencies in the draft. Until very recently, FDA routinely issued Tweets regarding drug approvals that used the following format:

> FDA approves [proprietary name of a drug] to treat [disease]: [link to a webpage listing more complete information about the drug and the risks and benefits of its use][28]

The Agency's Tweets did not include the established name of the drug, limitations on the drug's use, or any risk information. Instead, FDA's communications provided the brand name of a product, a short description of the product's indication, and a link to additional product information.

FDA frequently communicates about drug approvals through Twitter, and its Tweets have often listed the proprietary name of a product, a brief statement describing the product's intended use, and a link to more complete information. For example, on July 3, 2014, FDA issued the following Tweet:

> #FDA approves #Beleodaq to treat rare, aggressive form of non-Hodgkin #lymphoma. go.usa.gov/XY54[29]

The link go.usa.gov/XY54 leads to an FDA news release that provides additional information about the product (including its established name), its use in the treatment of peripheral T-cell lymphoma, and important risk information.[30]

It seems unlikely that FDA would consider its own Tweets to be misleading. Instead, the Agency's drug approval communications reinforce the idea that the public health benefits from information about the availability of potentially helpful treatments. But while a message from FDA would be considered by the Agency to be non-misleading and beneficial to the public health, the same message could be considered misleading under the Draft Guidance if it were issued by a manufacturer. Such speaker-based restrictions are particularly problematic on Twitter, where users often re-post others' Tweets (i.e., "Retweet") to share others' messages with their own followers. As it is currently written, however, the Draft Guidance could be interpreted to prohibit manufacturers from Retweeting messages that the Agency itself originally posted. The Supreme Court has observed that speech restrictions "that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment."[31] Thus, the limitations imposed by the Draft Guidance—which not only restrict the dissemination of information that is beneficial to the public

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[28] See FDA Drug Information on Twitter, https://twitter.com/FDA_Drug_Info. FDA issued a Tweet following this format on August 1, 2014, but its most recent announcements of drug approvals have omitted drugs' proprietary names. See, e.g., id. ("#FDA approves new type of sleep drug: go.usa.gov/Exxm").

[29] Id.

[30] See FDA, FDA approves Beleodaq to treat rare, aggressive form of non-Hodgkin lymphoma, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm403929.htm.

[31] Greater New Orleans Broadcasting Ass'n, Inc. v. United States, 527 U.S. 173, 193-94 (1999).

health, but also arbitrarily distinguish content based on a speaker's identity—are untenable under the law.

The Draft Guidance not only functions as a prohibition on the use of the digital channels it covers by manufacturers of regulated medical products to communicate about their products, but also includes language that is insufficiently precise to satisfy a different, but related, set of constitutional requirements—those imposed on FDA by the Due Process Clause of the Fifth Amendment. For example, the draft (p. 9) fails clearly to explain how to identify "the most significant warnings or precautions about the product." In FCC v. Fox Television Stations,[32] the Supreme Court emphasized that, for agencies to meet their obligations under the Fifth Amendment, they must establish clear standards that give "fair notice of what is prohibited," particularly when imposing limits that chill protected speech.[33] The Draft Guidance's description of the "most significant warnings or precautions" does not provide a clear guidepost for industry in determining what risks should be described.

FDA should, at a minimum, permit manufacturers to use space-limited communication channels in the same way the Agency previously used these platforms. Rather than effectively banning manufacturer communication when space constraints prevent the presentation of extensive information as described in the draft, FDA should allow manufacturers to use the functional attributes of digital media and provide access to extensive product information through concise statements linking to webpages that satisfy FDA's requirements. This mirrors FDA's own prior use of Twitter and would avoid lengthy disclosure obligations that prevent manufacturers from using space-limited platforms like Twitter. Applying this approach to online paid search would also eliminate the guidance's reliance on Sitelinks that may not consistently appear.

We appreciate the opportunity to comment.

[32] 132 S. Ct. 2307 (2012).
[33] Id. at 2317-18 (quoting United States v. Williams, 553 U.S. 285, 304 (2008)).

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