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950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

Jeffrey K. Francer
Vice President and Senior Counsel

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

Re: Draft Guidance for Industry on Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (Docket No. FDA-2014-D-0447)

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments in response to the Food and Drug Administration's (FDA) Draft Guidance for Industry on Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (Draft Guidance).[1] PhRMA is a voluntary, non-profit association that represents the country's leading pharmaceutical research and biotechnology companies. PhRMA members are dedicated to developing medicines that allow patients to live longer, healthier, and more productive lives. In 2013 alone, PhRMA members invested an estimated $51.1 billion in the research and development of new medicines.

PhRMA and its members understand the importance of conveying reliable and timely information about medicines to healthcare professionals and patients, and we are committed to helping ensure that all communication about medicines, including information available on the Internet/social media, is truthful, accurate, and not misleading.[2] In particular,

[1] 79 Fed. Reg. 34760 (June 18, 2014).

[2] To help accomplish these goals, PhRMA has created its "Code on Interaction with Healthcare Professionals" and "Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines." *See* http://www.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf; http://www.phrma.org/sites/default/files/pdf/phrmaguidingprinciplesdec08final.pdf. PhRMA was also an active participant in FDA's two-day public meeting on this topic in November 2009 and provided input in response to Docket No. FDA-2009-N-0441 following the meeting. PhRMA additionally submitted comments on April 11, 2014 concerning the "Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics" (January 2014 Draft Guidance) released under Docket No. FDA-2013-N-1430.

PhRMA recognizes that the correction of third-party information concerning members' products on the Internet/social media may benefit the greater public health.[3]

Executive Summary

PhRMA welcomes FDA's Draft Guidance as an important step toward helping to ensure the availability of timely, accurate and accessible information about medicines. Though many challenges remain before this goal is fully attained, PhRMA appreciates FDA's initial efforts to address questions relating to the correction of third-party information about medicines in its Draft Guidance.

The public health will be best served by clear policies for the correction of third-party information about medicines that both encourage open and frank dialogue about truthful, scientifically accurate information and do not unduly chill healthcare communication. PhRMA member companies have the most complete and timely information about the medicines they research, develop and manufacture. Given the extraordinary growth of the Internet as a source of health information—and the enormous amount of inaccurate and non-regulated information about medical products online—FDA should avoid chilling manufacturers' responsible communication of medical information about their products and the correction of third-party misinformation concerning these products. Moreover, any guidance document or other policy statement issued by FDA should be consistent with the principles and limitations of the Federal Food, Drug and Cosmetic Act (FDCA) and the First Amendment.

PhRMA would like to raise two fundamental concerns with the Draft Guidance. First, the Draft Guidance—similar to the January 2014 Draft Guidance—assumes that a biopharmaceutical manufacturer can be held accountable for content written by third-parties on third-party web sites if the company merely "influences" the third party. This premise is overbroad and is inconsistent with the FDCA. Moreover, by limiting the scope of the guidance in such a way, FDA's draft guidance, perversely, is likely to result in *more* inaccurate information about medicines online that will go uncorrected. Second, the Draft Guidance appears to recognize that some statements on social media correcting misinformation are neither "labeling" nor "advertising," but fails to give guidance as to what kinds of statements would be regulated as such. The Draft Guidance should expressly recognize that many statements on the web are not labeling, that non-promotional statements are not advertising, and that many statements correcting misinformation will be neither. FDA should provide adequate guidance so that sponsors can be aware of the potential consequences of their actions in correcting misinformation.

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[3] *See* FDA's Social Media Draft Guidance Webinar Q&A's 2 (July 10, 2014), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM404784.pdf ("While the correction of misinformation is a voluntary activity, it may benefit the public health for companies to correct misinformation about their products (including, for example, situations in which a company is aware of misinformation that may be dangerous or harmful to the public health)"); Draft Guidance 3.

In addition to identifying and discussing these two fundamental issues, PhRMA provides additional suggested revisions for the Final Guidance in these comments. In the Final Guidance: (1) FDA should confirm its commitment to protecting online scientific exchange using the Internet/social media; (2) FDA should discuss how companies may correct third-party misinformation concerning uses of medicines by healthcare professionals outside of FDA-approved labeling; and (3) FDA should permit companies to provide a link to any web site that otherwise complies with any applicable FDA regulations when correcting misinformation.

I. The Final Guidance Should Recognize That Manufacturers Are Responsible Only For Third-Party Statements They Cause or Control

PhRMA appreciates FDA's willingness to provide a safe harbor in which companies may correct misinformation posted online about the medicines that they research, develop, and deliver to patients and healthcare professionals. Yet the scope of the guidance and the proposed safe harbor is limited inappropriately. Namely, FDA states at lines 95-98 of the Draft Guidance that it "does not apply when a firm is responsible for the product communication that contains misinformation. A firm is responsible for communications that are owned, controlled, created, or *influenced*, or affirmatively adopted or endorsed, by, or on behalf of, the firm" (emphasis added).

A biopharmaceutical manufacturer can only be accountable for a web site or for other content that it causes or controls, which should be defined as content that is controlled entirely by the manufacturer or its agents. This understanding of accountability is supported by the FDCA and its implementing regulations and should be reflected in FDA's Final Guidance. Accordingly, the scope of the Draft Guidance is inappropriately limited and would, perversely, be expected to result in more inaccurate information about medicines online that goes uncorrected. PhRMA recommends that FDA will provide an adequate safe harbor for companies to correct misinformation about medicines online by expanding the scope of the Draft Guidance through elimination of the "influenced" prong of FDA's definition of applicable communication. As discussed below, the term "influenced," when used to limit the proposed safe harbor for the correction of misinformation, is both vague and overbroad.

A. **The Draft Guidance's "Influence"** Test Is Overbroad and Not Supported by the FDCA

The Draft Guidance suggests that mere "influence" is sufficient to hold a manufacturer accountable for third-party statements or user generated content (UGC), and that the Draft Guidance would not be applicable to such statements and content. These views are not supported by the FDCA.[4] For the reasons discussed below and as stated in our comments regarding the January 2014 Draft Guidance, FDA should eliminate the "influence" test for determining whether companies should be accountable for third-party communications online.

[4] 21 U.S.C. § 301 *et seq.*

Although Section 301 of the FDCA enumerates prohibited acts, both the commission and "causing" of which are prohibited, it does not purport to reach the "influence" of actions that could otherwise be considered prohibited.[5] The nebulous term "influence" inappropriately sweeps in third-party statements not caused or controlled by the manufacturer. "Influence," which is commonly defined as "[a] power indirectly or *intangibly affecting* a person or event,"[6] provides an insufficient basis for attributing third-party statements to a manufacturer. By excluding communication of those who are "influenced" by biopharmaceutical companies from the proposed safe harbor, FDA would inappropriately limit the ability of companies to correct misinformation about the medicines that such companies research and develop. Such a limitation can be expected to result in inaccurate information about medicines online that will go uncorrected – to the detriment of public health.

The interactive and interconnected nature of social media separates it from traditional media and also amplifies the overbreadth of the standard set forth in both the Draft Guidance and the January 2014 Draft Guidance. For example, if a firm invites all comments about its prescription medicine on a firm owned bulletin board, will it be deemed to have influenced all of the subsequent posts and therefore be prohibited from correcting misinformation generated by independent third parties? If a firm acknowledges users' posts or thanks users for their comments on a firm-owned site, will a firm be deemed to have influenced potential user generated comments in response? Indeed, given the ambiguous nature of the term "influence," what is the likelihood that a firm could make a statement or actively participate on social media in communication about one of its medicines *without* being perceived to somehow indirectly or intangibly affecting someone's response?

The Draft Guidance's examples applying the "influence" test confirm its overbreadth. The Draft Guidance states that "if a firm writes, collaborates on, or exerts control" on product-specific content provided by a third party, then the firm is responsible for the content and the Draft Guidance does not apply. Neither the statutory language of the FDCA nor ensuing regulations provide a basis to find a manufacturer liable if a third party not under the manufacturer's control misbrands a drug. As written, the Draft Guidance will severely chill a manufacturer's First Amendment right of association; if a manufacturer "collaborates" with a third-party on any aspect of a third-party site, the manufacturer will become potentially responsible for all speech by that third party. Manufacturers could then be subject to

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[5] FDA's interpretation of "causation" in this context must be appropriately tailored to comply with the First Amendment, otherwise it would be subject to the same concerns as FDA's overbroad "influence" test discussed below. The internet and social media are an "unlimited, low-cost capacity for communication of all kinds," *see Reno v. ACLU*, 521 U.S. 844, 870 (1997), and the content-based regulation of speech on social media announced in the Draft Guidance, potentially enforced with the threat and stigma of criminal convictions, mandates higher scrutiny, *id.* at 871-72. Moreover, there is no justifiable government interest in chilling the speech of a manufacturer providing a forum to discuss health information, while similarly situated entities that do not manufacture pharmaceuticals may enjoy such rights without such burdens. *See Sorrell v. IMS Health*, 131 S. Ct. 2653, 2663-64 (2011) (striking down content and speaker based restrictions focused solely on pharmaceutical marketers disseminating information for pharmaceutical marketing purposes).

[6] Webster's II New College Dictionary 582 (3d ed. 2005) (emphasis added).

burdensome regulatory requirements and the threat of criminal penalties for speech that they do not even control.[7] FDA should therefore remove the "influence" test from the Draft Guidance.

B. The "Influence" Test Is Not Supported by the Communications Decency Act, Which Expressly Prohibits Holding Web Site Hosts Responsible for Third-Party Speech

As mentioned in our comments submitted concerning FDA's January 2014 Draft Guidance, Congress has spoken to similar issues in the Communications Decency Act, 47 U.S.C. § 230 (CDA), which further demonstrates that the "influence" test is overbroad. As FDA acknowledged in its January 2014 Draft Guidance, the CDA provides that "[n]o provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider."[8] The definition of "interactive computer service" is broad.[9] The effect of this provision is to protect Internet service providers, such as entities hosting an interactive web site, blog, or chat room from liability based on the speech of third-party content providers using such forums. Courts have consistently held that providing a neutral forum does not make an Internet service provider a content provider (content providers are not immune from liability based on their speech in such forums).[10] The CDA has been credited with helping make possible widely used forums such as Yelp, Wikipedia, YouTube, Facebook, and Twitter.[11]

A firm might choose to edit or review content for the sole purpose of monitoring[12] objectionably dangerous content about its products—an act specifically protected by the CDA in

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[7] *Cf. Elfbrandt v. Russell,* 348 U.S. 11, 17 (1966) (holding that the First Amendment forbids penalizing an individual for association with an organization that commits unlawful acts, without evidence that the individual shares the unlawful purpose or participates in unlawful activity).

[8] 47 U.S.C. § 230(c)(1) (1994).

[9] "The term 'interactive computer service' means any information service, system, or access software provider that provides or enables computer access by multiple users to a computer server, including specifically a service or system that provides access to the Internet and such systems operated or services offered by libraries or educational institutions." *Id.* at § 230(f).

[10] *Chicago Lawyers' Comm. for Civil Rights Under Law, Inc. v. Craigslist, Inc*., 519 F.3d 666 (7th Cir. 2008) (finding that as the host of a neutral forum, Craigslist was not responsible for discriminatory advertisements—it had no duty to police users' postings and was not responsible for the content of the statements posted).

[11] Electronic Frontier Foundation, "CDA Section 230: The Most Important Law Protecting Internet Speech," available at https://www.eff.org/issues/cda230.

[12] Example 4 of the Draft Guidance states, "A firm hosts a discussion forum about its drug's or device's FDA-approved use on its corporate website and does not participate in the discussion, but it does *monitor* the forum for profanity and obscenity. The forum includes an overarching clear and conspicuous statement that the firm did not create the content of the forum. The firm is not responsible for the information that is posted by independent third parties and can, if it so chooses, correct misinformation according to this guidance" (emphasis added). We recommend inserting "and moderate" after "monitor," as the expectation would be to remove or respond to posts that contain profanity or obscenity. We believe that within the bounds of a clearly defined monitoring and
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many circumstances, but inconsistent with FDA's proposed "influence" test.[13] Such actions would be entirely reasonable, and indeed, may help increase public safety by ensuring that potentially dangerous misinformation about the firm's products is not spread to patients. Removing such content for public safety purposes (*i.e.*, exercising "editorial" privilege) should also not convert the remainder of the independently generated content to regulated advertising or promotion.

C. The Final Guidance Should Clearly Define When Manufacturers Are Responsible for Communications by Third Parties

Manufacturers should be held responsible only for promotional communications that are controlled or caused by the firm, which should be defined as content that is controlled entirely by the manufacturer or its agents and that the manufacturer or its agents are authorized to edit or delete in the manufacturer's sole discretion.[14] For reasons already discussed, FDA cannot hold firms accountable for independent third-party statements or UGC under the FDCA; therefore, FDA should clarify when content is viewed as controlled or caused by the manufacturer in the Final Guidance. A useful way to do this would be for FDA to provide examples of situations when the manufacturer is and is not responsible for the third-party speech or UGC.

For example, if an independent third-party posts a statement about an unapproved use of an approved drug for diabetes on the firm's site, the firm should not be held responsible for the content of the statement, if the firm merely made a neutral call for comments about diabetes.[15] Similarly, if a firm creates a discussion board inviting comments on patient experiences with diabetes, it should not be deemed to have prompted the content of the posts made by independent, third-party users. Furthermore, if a firm has terms of use for its site that

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moderation plan, the firm should not be viewed as influencing UGC content that is independent of the firm, when removing or responding to posts that violate the rules of engagement.

[13] 47 U.S.C. § 230(c)(2); *Zeran v. America Online, Inc.*, 129 F.3d 327 (4th Cir. 1997), *cert. denied*, 524 U.S. 937 (1998).

[14] As discussed later in this section, a manufacturer should not be held responsible for content generated by independent third-parties that the firm is authorized to edit or delete in its sole discretion if this authority derives from the firm's terms of use for its site that consist of neutral rules governing the site and makes edits based on those terms of use.

[15] In the Draft Guidance, FDA states that a firm generally is "not responsible for third-party UGC about their products when the UGC is truly independent of the firm (e.g., is not produced by, or on behalf of, or *prompted by the firm* in any particular) (emphasis added)." The phrase "prompted by the firm" is too ambiguous and does not provide firms with sufficient guidance on what type of UGC content they will be held responsible for on interactive social media. And to suggest that the mere creation of a forum with a general invitation to comment on a drug or a disease would lead to a sponsor's responsibility for everything stated in the forum as "prompted by" the sponsor would raise significant constitutional concerns. It is beyond dispute that health web sites that do not hold drug applications can create a forum for the discussion of diseases or drugs. To create liability for drug sponsors for engaging in the same activity based on the content of third-party posts and the identity of the person setting up the forum would constitute a speaker-based and content-based restriction. *See Sorrell*, 131 S. Ct. at 2663-64.

consist of neutral rules governing the site (*e.g.*, no profanity) and makes edits and deletions based on the neutral terms of use, the firm should not be considered to control the content generated by independent third-parties.

As an additional example, and as addressed in our comments concerning the January 2014 Draft Guidance, while a firm should be responsible for comments by an employee, agent, advisor, or paid speaker acting on behalf of the firm, the Final Guidance should clarify that such agents may be speaking on their own behalf, in which case their content should be treated as independent of a manufacturer. For example, some paid speakers may be experts in therapeutic areas, and although a firm might engage a speaker to speak on the firm's behalf on occasion, the individual may make statements in social media without the firm's knowledge or control. Similarly, a firm might engage with a third party, such as a consumer health advocate, to develop content for the firm-owned site. The health advocate may make statements in social media about her specific area of interest without the firm's knowledge or control. Likewise, a firm may maintain policies, training and education for employees about appropriate use of interactive social media. Nevertheless, that employee may act outside the scope of his employment and independently post information about a personal experience with a medicine or some other event without the firm's knowledge or control. Therefore, we suggest that FDA provide examples in the Final Guidance that illustrate when an employee, agent, or paid speaker is not acting on behalf of or prompted by the firm. The firm should be responsible only for statements that it actually causes or controls. As previously discussed, it would be inappropriate to hold a firm responsible for independently generated statements—even from individuals with whom the firm has a financial or other relationship—if the firm did not cause or control the content.

II. The Final Guidance Should Clearly Define When Statements Correcting Misinformation on Social Media Constitute Labeling or Advertising

For enforcement purposes, once FDA determines that content is caused or controlled by a manufacturer, the Agency must then determine whether the material may be regulated as labeling or advertising under applicable law. Not all manufacturer communications, however, meet the definition of labeling or advertising. Indeed, the Draft Guidance appears to recognize that some statements, including the correction of misinformation, about drugs on company blogs, microblogs, social networking sites, online communities, and similar forms of social media are not labeling or advertising under the FDCA.[16] For example, a press release describing clinical trial results for a scientific audience should not be considered promotional and therefore advertising or labeling. Similarly, a manufacturer statement correcting information on

[16] *See* Draft Guidance 3 ("If a firm voluntarily corrects misinformation in a truthful and non-misleading manner and as described in this draft guidance, FDA does not intend to object if the corrective information voluntarily provided by the firm does not satisfy otherwise applicable regulatory requirements regarding labeling or advertising, *if any*" (emphasis added)). *See also* FDA Citizen Petition Response Letter to Daniel J. Popeo and Paul D. Kamenar 2 (Nov. 1, 2001) ("Accordingly, 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" (emphasis added)).

a site that is not itself labeling because it bears no connection to the product (such as through a web link on the product's label) is not labeling merely because it is the manufacturer making the correction. Especially in the context of speech protected under the First Amendment, FDA should more clearly define when statements about a product in social media will be viewed as labeling or advertising.

The FDCA defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[17] Courts have held that material does not need to be physically attached to be considered as "accompanying" the article.[18] But labeling "does not include every writing which bears some relation to the product. . . . and, if the statutory purpose is to be served, it must be drawn in terms of the function served by the writing."[19] It has thus long been established that materials constitute "labeling" under the FDCA only where they are designed for use in the distribution and sale of the product, and related in such a way to the product to be considered part of an integrated distribution program.[20] Many truthful, non-misleading statements that correct product misinformation will likely fall outside the definition of "labeling."

Likewise, "advertising," which is not defined by the FDCA, cannot reasonably be understood to encompass all statements correcting third-party misinformation simply because those corrective statements reference a drug or are made on a forum controlled by the manufacturer. The common meaning of the term envisions promotion for commercial sale, a motivation held only by the drug's manufacturer or its agents.[21] FDA regulations accordingly specify that manufacturers must submit "specimens of mailing pieces and any other labeling or advertising *devised for promotion of the drug product* at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product."[22] As the Draft Guidance highlights in its examples, it is likely that many statements

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[17] FDCA § 201(m) (defining labeling).

[18] *See, e.g.*, *Kordel v. United States*, 335 U.S. 345 (1948).

[19] *U.S. v. 24 Bottles "Sterling Vinegar & Honey*," 338 F.2d 157, 158-59 (2d Cir. 1964).

[20] *Id.*; *see also Kordel*, 335 U.S. at 351; *Founding Church of Scientology of Washington, D.C. v. United States*, 409 F.2d 1146, 1157 (D.C. Cir. 1969); *United States v. Harkonen*, 08-cv-00164 MHP, 2009 WL 1578712, at *12 (N.D. Cal. June 4, 2009) (holding there was no "integration" between the shipment of a drug product and the distribution of t-shirts allegedly containing promotional labeling). In *Kordel*, for example, the manufacturer was the source of the literature that the Supreme Court found constituted "labeling" and the manufacturer's actions were a part of "an integrated distribution program." *Kordel*, 335 U.S. at 351. The mere act of previewing or reviewing content or directing placement of promotional content does not suggest that otherwise independently generated content is "designed for use in the distribution and sale of the [product]" nor that the reviewed or previewed content is part of "an integrated distribution program." *See, e.g.*, *Founding Church of Scientology of Washington, D.C.*, 409 F.2d at 1157.

[21] Black's Law Dictionary 59 (8th ed. 2004) (defining advertising as "[t]he action of drawing the public's attention to something to promote its sale").

[22] 21 C.F.R. § 314.81(b)(3)(i) (emphasis added). Under 21 C.F.R. § 514.80(b)(5)(ii), a manufacturer of prescription and over-the-counter new animal drugs must submit one set of specimens of mailing pieces and other labeling at the

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correcting misinformation regarding products are not promotional at all. For example, statements concerning the scope of the approved indication (Example 5), statements concerning whether a drug has certain food restrictions (Example 6), or statements about a drug's particular dosage form could be made in a manner that is neutral in tone and not promotional, and therefore in a way that does not render the statements arguably "advertising."

FDA recognizes that a sponsor is not required to correct misinformation. However, without signposts for when advertising and labeling rules will apply to those corrections, sponsors will be left with an insufficient basis to guide their conduct. FDA has declined to clearly answer when corrective online statements constitute advertising or labeling. Without such clarity, the Draft Guidance is unconstitutionally vague because it fails to give "fair notice of conduct that is forbidden or required."[23] For example, if a firm promotes a regulated product on its website and allows consumers to purchase the product directly from the website or if the website is listed on a product label, the website could potentially be defined as "labeling."[24] But many manufacturer statements correcting misinformation could occur on sites that are not linked on product labels, and that are not portals for purchase of the product. Furthermore, product-specific *promotion* presented on a non-company website that is very similar to messages FDA has traditionally regulated as advertisement in print media (*e.g.*, advertisements in magazines, newspapers, periodicals) could be viewed as advertising.[25] But neutral statements correcting misinformation and not further encouraging use of the product are not likely to fit under any reasonable definition of "advertising." FDA should therefore provide clear guidance as to when corrective information will be considered advertising or labeling.

III. The Final Guidance Should Confirm that FDA Maintains Its Commitment to Protecting Online Scientific Exchange Using Social Media

The Final Guidance should confirm that it does not intend to signal a departure from FDA's longstanding practice to respect the free exchange of scientific ideas. Previous FDA guidance and related court decisions have long established the "jurisdictional line" between "[a]ctivities (programs and materials) performed by, or on behalf of, the companies that market the product" and "activities, supported by companies, that are otherwise independent from the promotional influence of the supporting company."[26] Such communication of scientific

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time of initial dissemination. For prescription new animal drugs, the applicant must also submit one set of specimens of any advertisement at the time of initial publication or broadcast.

[23] *FCC v. Fox Television Stations,* 132 S. Ct. 2307, 2317 (2012).

[24] *See* FDA Citizen Petition Response Letter to Daniel J. Popeo and Paul D. Kamenar at 2; *see also* FDA Warning Letter to Mr. Michael Larsen, CocoKefir LLC (Nov. 22, 2011).

[25] *Id.*; *See also* Black's Law Dictionary 59 (8th ed. 2004) (defining advertising as "[t]he action of drawing the public's attention to something to promote its sale").

[26] *See, e.g.*, 21 C.F.R. § 312.7(a); FDA's "Guidance for Industry: Industry–Supported Scientific and Educational Activities," 62 Fed. Reg. 64,093, 64,096–99 (Dec. 1997).

information, including the correction of misinformation, should be permitted if they are made on social media platforms, just as they are when made using traditional media.

IV. The Final Guidance Should Discuss the Practice of Correcting Misinformation Concerning Uses of Medicines Outside of the FDA-Approved Labeling

The Draft Guidance provides that statements correcting misinformation must be "consistent with FDA-required labeling for the product." But some of the examples of correcting misinformation could relate to alternative, or "off-label," uses of medicines—including medically accepted uses that appear in compendia and practice guidelines and are regularly reimbursed. For example, the Draft Guidance discusses "incorrect statements about a product's safety or efficacy" (Example 1); "inaccurate information about a firm's product" (Example 3); "misinformation…about the…indication" (Example 5); statements "inconsistent with information from the required labeling" (Example 6); "exaggerated efficacy claims" (Example 9); and comments "downplay[ing] a labeled contraindication" (Example 15).

Information about such alternative uses of approved medicines could, in some circumstances, be worthy of correction. Firms should be allowed to address and correct misinformation concerning such uses of medicines, and the Final Guidance should provide examples of how to appropriately correct such statements. For example, FDA should set forth reasonable recommendations for correcting misinformation regarding alternative uses under which the correction will not be viewed inappropriately by FDA as creating a new intended use for the product.[27] FDA should permit a firm to state that the misinformation pertains to an unapproved use of the medicine and allow companies to provide correcting information about medically accepted alternative uses of medicines. The firm should also be permitted to include a mechanism for providing readily accessible current FDA-required labeling, as explained below.

V. The Final Guidance Should Clarify Whether There Are Time Constraints on When a Firm Can Correct Misinformation

In the Draft Guidance, FDA provides a list of criteria that must be satisfied for the correction of misinformation to be deemed "appropriate corrective information." Neither this list nor any of the examples provided in the Draft Guidance clarify whether firms should correct misinformation only within a certain amount of time of it being posted on the Internet/social media platform or if a firm can correct the misinformation at any time. Because firms become aware a of misinformation at different times, FDA should make it clear in the Final Guidance

[27] This could be similar to FDA's approach in its "Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices," which discusses the circumstances under which responses to unsolicited requests do not constitute "evidence of a new intended use." 76 Fed. Reg. 828303 (Dec. 30, 2011).

that there is not a set time frame within which a firm may voluntarily elect to correct misinformation.

VI. The Final Guidance Should Permit a Firm to Provide a Link to Any FDA-Compliant Website in Correcting Misinformation

The Draft Guidance states that in correcting misinformation a firm's response should include "FDA-required labeling" or be provided "in a readily accessible format." The Draft Guidance advises that this information "should not be provided by including a link to a promotional website even if the information is available on the promotional website."

The Final Guidance should permit a firm to provide the FDA-approved labeling in a link to any site that complies with any applicable FDA regulations that would otherwise apply to that site, provided that the FDA-approved labeling appears conspicuously at that site (including as a link). So, for example, if the correction links to a site that would otherwise constitute advertising or labeling (for example, because the site is promotional or is to a link that is displayed on a product's label), then FDA should permit the use of this link as long as the site complies with applicable advertising or labeling regulations. From a public health perspective, the key question should be whether the information is truthful (*i.e.,* accurate) and non-misleading (providing sufficient context given the audience) – *not* whether the site is considered "promotional" or not.

VII. The Final Guidance Should Provide Clear Examples that Demonstrate How Misinformation May be Corrected on the Most Commonly Used Healthcare Information Web Sites

The Final Guidance should provide clear examples about how misinformation can be corrected on the most frequently visited healthcare information websites. For example Wikipedia is a top source of healthcare information;[28] yet FDA does not provide clear direction on how firms may correct misinformation on this type of website in the Draft Guidance. Specifically, it is unclear whether a firm may replace inaccurate information with the correct information or if a firm should only *respond* to misinformation. In the Draft Guidance, FDA states that for a communication to be considered "appropriate corrective information," a firm should either post the corrective information "in conjunction with the misinformation in the same area or forum (if posted directly to the forum by the firm), or should reference the misinformation and be intended to be posted in conjunction with the misinformation (if provided to the forum operator or author)." The Final Guidance does not, however, directly state how a firm should correct misinformation on sites that allow the firm to modify the misinformation.

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[28] Julie Beck, *Doctors #1 Source for Healthcare Information: Wikipedia*, THE ATLANTIC (March 5, 2014); Cathy Kelly, *Wikipedia Drug Searches Rise Sharply Following FDA Study Warnings – NEJM Study*, THE PINK SHEET (June 26, 2014).

Therefore, in the Final Guidance, FDA should clarify whether a firm may directly edit/change the misinformation on this type of website.[29]

Furthermore, the Draft Guidance does not explain how firms may correct misinformation on platforms with space and character limitations that prevent them from satisfying the list of criteria recommended for "appropriate corrective information." Because misinformation is likely to be generated on micro-blogging platforms with character and space limitations (*e.g.*, Twitter), FDA should address how firms can correct misinformation on these types of platforms in the Final Guidance. Firms should be permitted to correct misinformation on platforms with space constraints by making a sequential series of entries that in total convey the necessary truthful and non-misleading corrective information.

VIII. The Final Guidance Should Clarify What Constitutes Internet/Social Media Platforms

In the Draft Guidance FDA states that the guidance "is intended to describe FDA's current thinking about how manufacturers, packers, and distributors (firms) of prescription human and animal drugs (drugs) and medical devices for humans (devices) should respond, if they choose to respond, to misinformation related to a firm's own FDA-approved or –cleared products when that information is created or disseminated by independent third parties on the Internet or through social media or other technological venues (Internet/social media), regardless of whether that misinformation appears on a firm's own forum or an independent third-party forum or website." FDA does not provide any further clarification regarding what constitutes the Internet, social media, or "other technological venues." For example, it is unclear whether the guidance document applies to a drug reference source that may be hosted on the Internet for limited subscribers to use. In the Final Guidance, FDA should therefore define the scope of Internet/social media resources covered by the guidance document.

[29] Further clarification could be provided by expanding on Example 11 in the Draft Guidance to state whether a firm can alter the existing inaccurate information. In Example 11 FDA currently states: "A firm finds a webpage about its product that was written by an independent third party on an Internet-based, interactive, collaboratively edited encyclopedia. The firm may choose to contact the author of the webpage and provide corrective information to the author."

Conclusion

PhRMA applauds FDA for its significant efforts in providing its latest thinking in the Draft Guidance, which takes an important step toward addressing how best to regulate information about prescription drugs on the Internet/social media. Given the importance of social media as a tool of modern communications, including healthcare communications by patients and healthcare professionals, PhRMA intends to continue to serve as a constructive partner on these issues and would be happy to meet with the agency to discuss the agency's regulation of online communications. Please do not hesitate to contact us if you have any questions about our comments.

Sincerely,

Jeffrey K. Francer
Vice President and Senior Counsel