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Re: Draft Guidance for Industry on Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical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

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of America (PhRMA) is pleased to submit these comments in response to the Food and Drug Administration's (FDA) Draft Guidance for Industry on Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (Draft Guidance).[1] PhRMA is a voluntary, non-profit association that represents the country's leading pharmaceutical research and biotechnology companies.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 on Internet/social media platforms with character space limitations, is truthful and not misleading.[2]

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[1] 79 Fed. Reg. 34759 (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 PhRMA additionally submitted comments on April 11, 2014 concerning the "Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics" (January 2014 Draft Guidance) released under Docket No. FDA-2013-N-1430.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 is also submitting comments in response to

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The extensive and growing use of online media and new technology for healthcare communication by both FDA and the Department of Health and Human Services demonstrates the promise and value of such media to benefit patients.[3]

PhRMA and its member companies would like to highlight that FDA's Draft Guidance is inconsistent with the agency's *own* responsible communications about medicines using Internet and social media platforms with character space limitations. FDA's recommendations would significantly burden companies' communications using character-limited platforms, which would be expected to decrease transparency and the beneficial flow of information about their medicines to healthcare professionals and patients. Specifically, FDA now uses character-limited platforms to announce information about drugs and does it in a responsible, truthful way, including providing safety overviews after Twitter links. Yet FDA proposes to restrict manufacturers from using the same social media tools that FDA uses. FDA's own actions – including the use of links to present risk information and general descriptions of the benefits of drugs – provide reasonable standards for appropriate use of these media. Significantly, the limitations FDA recommends cannot withstand basic First Amendment scrutiny, because there are less restrictive means of ensuring that information presented on these platforms is truthful and non-misleading. Moreover, it cannot be truthful and non-misleading for FDA to use character-space-limited platforms in one way, but misleading for biopharmaceutical companies to do the same.

In addition, PhRMA provides other suggested revisions for the Final Guidance in these comments, including addressing technical issues related to Internet/social media platforms with character space limitations such as clearly defining what does and does not constitute an Internet/social media platform with character space limitations.

Introduction: The Importance of the Internet and Social Media in a Patient-Centric Approach to Healthcare

Now more than ever, patients are turning to the Internet to gather health information. Internet users are using social networks, blogs, and other social media to access information and to share their experiences with other users. According to a survey published in 2013 by the Pew Research Center, 58% of American adults (72% of Internet users) now look online for health information.[4] One out of every four Internet users surveyed by Pew said they

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Docket No. FDA-2014-D-0447 concerning the "Draft Guidance for Industry/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices."

[3] *See, e.g.*, @US_FDA, "FDA approves Orbactiv (oritavancin) to treat skin infections: http://go.usa.gov/NvhB," (Aug. 8, 2014), available at https://twitter.com/US_FDA/status/497740502650085376.

[4] Susannah Fox & Maeve Duggan, Pew Internet and American Life Project, Health Online 2013 6 (2013) (Pew Health Online Survey).

specifically go online to find information about drug safety.[5] And a separate study by PricewaterhouseCoopers found that one-third of American adult consumers are using social media in particular to get health information or participate in health-related activities.[6] These resources not only benefit patients, but also provide a place where professionals can exchange information on medical research and topics of common interest.[7]

Importantly, research shows that the Internet is supplementing rather than replacing the advice of health professionals. Seventy percent of adults still consult a health professional when they have a health issue.[8] Forty-eight percent of adults who seek online health information said their purpose in doing so is to inform themselves ahead of a doctor's visit.[9] Seventy-seven percent of people who used the Internet to research illness symptoms said they discussed the information they found with their doctor.[10] And 45% of patients who look to social media for health information said the information they find would affect their decision to seek a second opinion from another doctor.[11]

Access to truthful, reliable information on the Internet will improve public health. Given the extraordinary volume of dangerous, inaccurate, and unverified information about medicines on the Internet, it is imperative that FDA facilitate the availability of truthful, scientifically accurate and FDA-regulated information online, including on Internet/social media platforms with character limits. In a survey by Wolters Kluwer Health, 53% of doctors listed misinformed patients as the most common barrier to healthy doctor-patient communication.[12] Increased access to reliable online health information is helping to address this challenge. In fact, nine out of ten doctors said that greater patient access to online health information has improved the quality of care at their practice.[13] Patients have also had positive experiences seeking health information online – nearly one-third of adults say they or someone they know

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[5] Susannah Fox, Pew Internet and American Life Project, The Social Life of Health Information, 2011 9 (2011) (Pew Social Life Survey).

[6] PricewaterhouseCoopers, Health Research Institute, Social Media "Likes" Healthcare: From Marketing to Social Business 3 (2012).

[7] *See, e.g.*, American Medical Association Facebook Profile, https://www.facebook.com/AmericanMedicalAssociation; Reach-MD Facebook Profile, https://www.facebook.com/reachmd.

[8] Pew Health Online Survey at 9.

[9] Wolters Kluwer Health, Wolters Kluwer Health Q1 Poll: Self Diagnosis 4 (2012), *available at* http://www.wolterskluwerhealth.com/News/Documents/White%20Papers/Self-Diagnois%20Poll.pdf.

[10] *Id.*

[11] PricewaterhouseCoopers at 15.

[12] Wolters Kluwer Health, 2011 Point-of-Care Survey 4 (2011), *available at* http://www.wolterskluwerhealth.com/News/Documents/White%20Papers/Wolters%20Kluwer%20Health%20Survey%20Executive%20Summary-Media.pdf.

[13] Wolters Kluwer Health Q1 Poll: Self Diagnosis 3.

has been helped by health information they found on the Internet.[14] This includes 44% of caregivers and 40% of people who have experienced a recent personal health change like losing weight, becoming pregnant, or quitting smoking.[15]

The Department of Health and Human Services' Healthy People 2020 initiative recognizes the power of the Internet/social media to provide patients with health information, noting that "[e]ffective use of communication and technology by health care and public health professionals can bring about an age of patient- and public-centered health information and services."[16] One of the goals of Healthy People 2020 is to increase Internet access, because "[d]isparities in access to health information, services, and technology can result in lower usage rates of preventive services, less knowledge of chronic disease management, higher rates of hospitalization, and poorer reported health status."[17]

Comments

The Draft Guidance states that "[f]or 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…"[18] PhRMA respectfully disagrees. Such platforms can accommodate truthful and non-misleading information about benefits and risks by using general information about benefits and the existence of risks, accompanied by links to pages that contain additional information. Indeed, FDA uses social media in just this way.

The Final Guidance should take a patient-centric approach that permits manufacturers to utilize Twitter, sponsored links and other character-limited platforms in order to convey important public health information.

FDA now uses character-limited platforms to announce information about medicines and does so in a responsible, truthful way. Yet FDA's own use of social media is decidedly not the way the agency claims that companies should use these platforms. FDA's own use of Twitter – including the use of links to present risk information and the use of general descriptions of the benefits of drugs – should set the standards for appropriate use of these media.[19] FDA has long recognized under its regulations that risk and benefit information do not

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[14] Pew Social Life Survey at 12.

[15] *Id.*

[16] HHS, HealthyPeople.gov, Health Communication and Health Information Technology, http://healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=18.

[17] *Id.*

[18] Draft Guidance 5.

[19] Although not all use of social media by sponsors constitutes advertising or labeling, to the extent it is either, it is generally advertising rather than labeling. Although "labeling" is a broad concept that includes some written, printed or graphic material that does not physically accompany the product, *Kordel v. United States*, 335 U.S. 345 (1948),
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need to appear together in all portions of a communication. FDA's Draft Guidance fails to take such an approach to Internet/social media platforms with character space limitations including through the use of hyperlinked pages.[20]

I. The Final Guidance Should Be Consistent with FDA's Own Use of Internet/Social Media Platforms with Character Space Limitations

FDA's recommendations would render character limited platforms unusable for firms with products with complex indications or extensive serious risks. FDA even states that such firms "should reconsider using that platform for the intended promotional message."[21] Because these restrictions apply only to companies sharing information about their medicines, the restrictions constitute significant content- and speaker-based burdens on speech subject to heightened scrutiny.[22]

"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." *U.S. v. 24 Bottles "Sterling Vinegar & Honey,"* 338 F.2d 157, 158-59 (2d Cir. 1964). 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. *Id*.; *see also Sorrell v. IMS Health*, 131 S. Ct. 2653, 2663-64 (2011); *Founding Church of Scientology of Washington, D.C. v. U.S.*, 409 F.2d 1146, 1157 (D.C. Cir. 1969); *U.S. 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). Although FDA has found web sites to be labeling if they are linked on product labels, it is clear that much of the information on the Internet does not constitute labeling as it is not part of an integrated commercial transaction. *See* FDA Response Letter to Citizen Petition to Daniel J. Popeo and Paul D. Kamenar (Nov. 1, 2001); FDA Warning Letter to Mr. Michael Larsen, CocoKefir LLC (Nov. 22, 2011).

[20] Specifically, the recommendation in the Draft Guidance that "[b]enefit information should be accompanied by risk information *within each individual* character-space-limited communication" is inconsistent with FDA's regulations concerning advertising (emphasis added). Draft Guidance 9. Unlike FDA's suggestion in the Draft Guidance, the requirement of 21 C.F.R. § 202.1(e)(1) that a "true statement of information relating to side effects, contraindications, and effectiveness applies to the entire advertisement" does not mean that advertisements "must contain risk information in each part." Rather, the regulation stipulates that "untrue or misleading information in any part of the advertisement will not be corrected by the inclusion in another distinct part of the advertisement of a brief statement containing true information…." 21 C.F.R. § 202.1(e)(1). Thus, as evident in direct-to-consumer print advertising, a statement alerting consumer's that a drug has risks and that the "brief statement" can be found elsewhere (*i.e*., an opposing page, another part of the spread) is sufficient. Similarly, the Final Guidance should permit the use of hyperlinks on character-space-limited platforms to connect consumers to a "brief statement" and additional risk information. Moreover, with respect to the particular risk that should be communicated, the Draft Guidance suggests that "the most significant warnings or precautions about the product should be communicated" in the context of any benefit information. This requirement is not only inconsistent with long-standing FDA requirements and industry practices to include risk information that is relevant to the claimed benefit, but also results in a presentation of information to the public that omits other relevant information (*e.g*., the most common risks associated with a product).

[21] Draft Guidance 5.

[22] *See Sorrell*, 131 S. Ct. at 2663-64. Although FDA has latitude to require risk information in advertising, restrictions are subject to heightened scrutiny if they are "unduly burdensome" (in this case, because they effectively

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FDA's restrictions cannot be justified as necessary to ensure that statements on character-limited platforms are truthful and not misleading, because there are less restrictive means of conveying benefit and risk information that FDA has already determined to be adequate. More specifically, biopharmaceutical companies should be permitted to use character-limited platforms in the same way that FDA itself uses these platforms to discuss prescription medicines. FDA uses character-limited platforms and has set the standard for how one can communicate in a truthful, non-misleading and complete manner about medicines. This includes conveying general rather than detailed descriptions of benefit information, and including risk information via hyperlinks to pages that include both benefit and risk information.

Put another way, FDA's tweets announcing approved medicines convey appropriate and truthful information, but they do so in a way that does not comply with the very restrictions it seeks to impose on biopharmaceutical companies. FDA's tweets contain *only* benefit information about new medicines (and general information, at that), accompanied by a link to a FDA news release outlining some risks and additional benefits – even for products with black box warnings and contraindications. FDA also fails to list any risks at all (or even a general disclosure that there *are* risks) directly within each individual communication.

For example, after FDA issued the Draft Guidance, the "FDA Drug Information" Twitter feed published a tweet concerning Afrezza, a recently approved drug with a black box warning and multiple contraindications.[23]

prohibit use of character-limited platforms for a range of drugs) and thereby "chill protected commercial speech." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985).

[23] *See* https://twitter.com/FDA_Drug_Info/status/482616336930332672 ("#FDA approves #Afrezza to treat diabetes: http://go.usa.gov/97wG").

The drug is indicated to "improve glycemic control in adult patients with diabetes mellitus." FDA tweeted more generally that the drug is intended "to treat diabetes," without reference to the adult patient population, notwithstanding the Draft Guidance's recommendation that the description of the indication include "limitations to the indication or the relevant patient population."[24] The tweet itself did not directly provide any information about the existence of risks, the specific risk concepts in the black box warning, nor the drug's multiple contraindications. Instead, FDA's tweet sensibly contained that information in a link accessible from the tweet. Moreover, the linked information did not contain *only* risk information as recommended in the Draft Guidance, but instead contained a fair presentation of both risks and benefits.

FDA's tweet was re-tweeted at least 62 times, including by physicians, a pharmacist, a drug reference Android application, and an academic. Needless to say, FDA did not (and could not) punish the re-tweeters for merely repeating what FDA said about Afrezza. And yet the Draft Guidance suggests that companies that research, develop, and deliver innovative medicines – and these companies alone – could be punished for doing just that (or for sending their own tweets with identical information), because FDA's own tweet failed to conform to its own recommendations in the Draft Guidance.

FDA's tweet about Afrezza is not an aberration. In 2014, FDA has responsibly used Twitter in a similar manner to announce the approval of other drugs, including Zydelig[25], Zontivity[26], Entyvio[27], and Zykadia[28]. We note that in the past few weeks, FDA appears to have stopped using the name of newly approved medicines in its tweets, perhaps in an attempt to comply with its own Draft Guidance. Such new practices serve to decrease the usefulness and transparency of the tweets to patients and healthcare professionals; moreover, such new use does not correct FDA's appropriate use of Twitter for many years, when the agency responsibly used the name of drugs and a portion of the approved indication.

This is not to suggest that FDA should change its practices to match those set forth in the Draft Guidance; to the contrary, we believe that FDA is communicating about drugs in a responsible, truthful and complete manner – *and in a manner that clearly benefits patients and healthcare professionals*. As a matter of First Amendment law and logic, it cannot be

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[24] Draft Guidance 6.

[25] *See* https://twitter.com/FDA_Drug_Info/status/492001274284765185 ("FDA approves Zydelig for three types of blood cancers. http://go.usa.gov/5US5 ").

[26] *See* https://twitter.com/FDA_Drug_Info/status/464814199299117057 ("#FDA approves #Zontivity to reduce the risk of heart attacks & stroke in high-risk patients http://1.usa.gov/RvN4SJ"").

[27] *See* https://twitter.com/FDA_Drug_Info/status/469500960197595137 ("#FDA approves #Entyvio to treat #UlcerativeColitis and #Crohns disease. http://go.usa.gov/89J9").

[28] *See* https://twitter.com/FDA_Drug_Info/status/461523633975095296 ("#FDA approves #Zykadia for late-stage lung cancer. http://1.usa.gov/1khoKuv").

truthful for FDA to use Twitter in this way but misleading for product sponsors to do the same.[29] The Draft Guidance contains no justification – much less a compelling one – for such divergent treatment.

To facilitate beneficial communication using platforms such as Twitter and sponsored links, FDA's Final Guidance should allow manufacturers to present "introductions" to health information, including brief but accurate indication descriptions, just as FDA now does in its own Twitter postings (as discussed above). These introductions are appropriate methods of conveying information within the space constraints of some new media. Such an introduction could also contain an affirmative statement about the risks of a medicine, even if initially abbreviated or introduced by a statement such as "Click here for risk information" or on character-limited platforms, "risks here" and continued in a pop-up or link.

FDA should recognize, as the FTC has, that space limitations in certain advertising formats warrant allowing certain long warnings to be accessed using a prominently labeled hyperlink. FTC guidance on online advertising acknowledges the utility of hyperlinked disclosures, stating that "[h]yperlinked disclosures may be particularly useful if the disclosure is lengthy."[30] For space constrained advertisements, the guidance notes that "some disclosures may be too detailed to be disclosed effectively within the ad itself. These disclosures may sometimes be communicated effectively to consumers if they are made clearly and conspicuously on the website to which the ad links."[31] Character-limited platforms emphasize brevity, but are largely designed to encourage the consumer to "click through" to a separate site where further product information and disclosures can be provided. With 74% of online adults active on social media sites,[32] consumers on the Internet are increasingly accustomed to click-throughs and other communication mechanisms that are unique to new media, such as pop-ups, rollover text and hyperlinks.

While companies should be permitted to provide information in the same manner that the government does, in the Final Guidance, FDA should indicate that the link label itself – perhaps with a universal graphic symbol as discussed below – could provide appropriate balance to a truthful abbreviated indication statement. For example a company should be permitted to

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[29] *See Sorrell*, 131 S. Ct. at 2663-64. The requirement that certain risks must be disclosed on space-limited-platforms burdens specific content concerning drugs with complex indications or extensive serious risks on such platforms and creates speaker-based burdens for pharmaceutical manufacturers. Content- and speaker-based burdens are subject to heightened scrutiny. *Id.*; *see also United States v. Playboy Entertainment Group, Inc.*, 529 U.S. 803, 812 (2000) ("Government's content-based burdens must satisfy the same rigorous scrutiny as its content-based bans").

[30] FTC, Dot Com Disclosures, How to Make Effective Disclosures in Digital Advertising 10 (2013), *available at* http://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-staff-revises-online-advertising-disclosure-guidelines/130312dotcomdisclosures.pdf.

[31] *Id.* at 15.

[32] Pew Internet Project, Social Networking Fact Sheet, http://www.pewinternet.org/fact-sheets/social-networking-fact-sheet/.

provide balancing information in a link label itself, if the label: (i) is prominently marked (ii) clearly signals that use of the drug entails risk, and (iii) directs the user directly to a page containing a comprehensive statement of the indication and risk information. FDA's adoption of such a standard would be consistent with the FTC's standards.

As suggested in PhRMA's February 26, 2010 comments, the Final Guidance should permit the use of FDA's own logo or a new universal graphic symbol to indicate direct links to FDA-regulated information in space-constrained media. Such postings could include a standard universal signal of risk information that would be approved by FDA (*e.g.*, "All drugs have risks. Click here for more information from the manufacturer," or for more limited platforms, "Risks here:" or "Click for Risks:"). The prominent graphic and link would take users directly to pages displaying the FDA-approved Prescribing Information (PI), Medication Guides and/or FDA-reviewed important safety information. The use of FDA's own logo, or some other FDA-approved symbol, would increase the prominence of the link and also help patients and healthcare professionals identify the official manufacturer sites containing FDA-regulated benefit and risk information. While use of such a universal graphic symbol would require the cooperation of many parties, including Internet companies, PhRMA hopes that this proposal is one way to improve communication of the risks and benefits of medical products in new online media.

Finally, FDA proposes that companies provide a direct hyperlink to a destination that is devoted exclusively to the communication of risk information. The Draft Guidance goes on to state that an example that "…the Agency would not consider to provide direct and exclusive access to risk information would include a hyperlink only to a product's home page that also includes benefit information and other claims or graphics."[33]

We recommend that the Agency reconsider the omission of benefit information and graphics, both of which FDA utilizes on its linked pages via Twitter. In particular, creative elements, including format options that otherwise exist in educational materials, could enhance the understanding of risk information. The use of graphics is acceptable when communicating fair balance and is mentioned in FDA's 2009 "Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion."[34] PhRMA proposes that the Final Guidance permit firms to link to pages that include benefit information and graphics, so that firms have the flexibility to format the risk information in a way that is easily read and comprehended by consumers and so consumers can have full benefits and balanced information at their disposal.

[33] Draft Guidance 10.

[34] FDA, "Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion" 8 (May 2009).

II. The Final Guidance Should Clarify Existing Technical Concerns Relating to Internet/Social Media Platforms with Character Space Limitations

Finally, PhRMA respectfully submits the following technical comments on the Draft Guidance.

First, the Draft Guidance states that it does not "address promotion via product websites, webpages on social media networking platforms (*e.g.*, individual product pages on websites such as Facebook, Twitter, YouTube), and online web banners, as the Agency believes that these specific types of Internet/social media platforms do not impose the same character space constraints as online microblog messaging and online paid research."[35] Furthermore, the Draft Guidance simply states that examples on Internet/social media platforms with character space limitations include online microblog messaging and online paid searches but that the recommendations "may also apply to advertising and promotional labeling on other types of…platforms with character space limitations."[36] The Draft Guidance also does not comment or clarify requirements in the context of the use of multimedia within social media (*e.g.*, photographs, videos, graphics, etc.).

The Final Guidance should more clearly address what does and does not constitute an Internet/social media platform with character space limitations, especially with regards to online web banners. The Draft Guidance only cites two examples and permits FDA to have broad discretion in determining what other platforms may join those two examples in the future. Instead, the Final Guidance should provide a definition and/or characteristics of such platforms, so manufacturers clearly understand the landscape as new platforms emerge or evolve. Furthermore, the Draft Guidance fails to take into consideration instances where permitted Internet/social media platforms, like Facebook, truncate public posts in a character-limited manner – or where Internet/social media platforms permit inclusion of multimedia, beyond textual representations – and how firms should treat such situations.

Second, FDA should also consider more expansive use of abbreviations than presented in the Draft Guidance. The examples provided by FDA in lines 474-544 of the Draft Guidance could only be used by a small number of products. FDA should allow industry standard abbreviations for disease states – for example, "UTI" for urinary tract infection or "tdap" for tetanus, diphtheria and acelluar pertussis, as long as the complete name is provided via the risk information link.

Third, the Draft Guidance stipulates that a mechanism, such as a hyperlink, should be provided within each character-space-limited communication to allow direct access to a more complete discussion of risk information about the product. In Example 2B of the Draft Guidance, this mechanism is provided via Google's "Sitelink extensions." However, Google

[35] Draft Guidance 2.

[36] *Id.*

spokesman Aaron Stein recently confirmed that "Sitelinks" do not always show and that only certain portions of desired "Sitelinks" may be displayed at any given time.[37] This is confirmed in the company's publicly available advertising policies.[38]

In any Final Guidance, therefore, FDA should take into consideration that certain platforms, like Google "Sitelink extensions" and perhaps other future Internet/social media platforms, do not permit conformance to the recommendations the Agency makes in terms of allowing the balance of benefit and risk information. FDA should also consider the technical feasibility of its recommendations in the context of the ranking systems and algorithms used by sites such as Google and other search engines, which in effect determine the appearance – and order of appearance – of information on such platforms. Furthermore, the Agency should acknowledge that there are certain platforms where manufacturers may not have control of the formatting. For example, some platform owners, such as Google, change the format of postings without providing manufacturers with any advance notice of these changes. In the Final Guidance, FDA should not hold manufacturers responsible when these types of changes are made to their submitted advertisements.

[37] Jeff Overley, "Google Ad Policies Cloud FDA's Drug Promo Guidance" (July 16, 2014), http://www.law360.com/lifesciences/articles/556983?nl_pk=29a3411f-8057-4891-9bc7-23a861224693&utm_source=newsletter&utm_medium=email&utm_campaign=lifesciences.

[38] Google Policy, "Show additional sitelinks below you ad text", https://support.google.com/adwords/answer/2375416?hl=en ("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. We consider several factors when determining what types of sitelinks we'll display with your ad, and whether we'll display sitelinks at all.")

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 its 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