



Via Electronic Submission

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

Re: Promotion of Food and Drug Administration-Regulated Medical Products
Using the Internet and Social Media Tools; Docket No. FDA-2009-N- February 28, 2010
0441; 74 Fed. Reg. 48,083 (Sept. 21, 2009)

Dear Sir or Madam:

Bayer HealthCare LLC ("Bayer") is pleased to submit these comments in response to the Food and Drug Administration's ("FDA's") Federal Register notice issued in September 2009 seeking comments on the promotion of FDA-regulated medical products using the Internet and social media tools.¹ Bayer is the U.S.-based division of Bayer AG, one of the world's leading, innovative companies in the healthcare and medical products industry. Bayer combines the global activities of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. In the U.S., Bayer HealthCare Pharmaceuticals comprises several business units, namely Women's Healthcare, Diagnostic Imaging, General Medicine, Hematology/Neurology and Oncology. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

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I. Introduction

The Internet has become an important medium for pharmaceutical companies to disseminate information about their products to healthcare professionals and the public. The introduction and evolution of various social media tools (e.g., Facebook, YouTube, Twitter) have also raised new challenges for both the FDA and the pharmaceutical industry. Bayer strives to comply with FDA regulations and guidance on proper advertising and promotion and understand that the FDA recognizes the unique nature of the Internet and social media, and how new guidance from the Agency is needed in this area.

This is a challenging issue for all of us, as the Internet, unlike normal print or televised media advertising, has unique limitations and restrictions (e.g., space). Patient safety is a key priority for Bayer and we appreciate the efforts of the FDA in addressing this herculean task. Indeed, Bayer commends FDA for holding a public hearing on November 12 and 13, 2009, to examine its

¹ 74 Fed. Reg. 48,083 (Sept. 21, 2009).

regulatory policies governing the promotion of FDA-regulated products, including prescription pharmaceuticals, using the Internet and social media tools. Increasingly, both physicians and their patients are turning to the Internet and social media sites, such as Sermo and WebMD, for authoritative information about medical conditions and treatment options. The Internet thus holds great promise as a source of useful healthcare information that, even more than direct-to-consumer advertising, may help educate both physicians and their patients about available treatment options, encourage a more informed dialogue between patients and physicians, prompt patients to discuss illnesses with their physicians for the first time, and promote improved compliance with physician-prescribed treatments.

FDA currently regulates Internet promotion using its long-standing regulations governing advertising and promotional labeling. These regulations are comprehensive and rigorous and have been effective at ensuring that the vast majority of promotional material disseminated by pharmaceutical companies presents truthful, accurate, well-balanced and useful healthcare information to physicians and patients.

The regulations also are flexible and have been applied in a number of different contexts and media, including print, telephone, radio and television. In the past few years, however, there has been growing uncertainty within the regulated industry as to how FDA intends to apply its existing regulations to Internet communications, such as banner ads, blog postings, and microblogs.² Questions also have arisen as to whether FDA's existing regulations adequately accommodate the unique technological characteristics of the Internet and social media tools, including tools with strict space limitations. These issues have dissuaded many companies from making full use of the tools available on the Internet to communicate useful benefit and risk information about their medical products to physicians and patients. Bayer does not believe this is in the public interest.

Accordingly, Bayer supports some meaningful revisions and updates to FDA's regulatory policies to take into account this new era of information which can be publicly available on the Internet. These revisions, however, should be carefully targeted and should take into account three overarching principles. First, any FDA approach should seek to maximize the dissemination of accurate healthcare information to patients and their caregivers, including FDA-regulated information about prescription drugs. Second, FDA's regulatory approach should recognize, accommodate and seek to leverage the unique technological characteristics of the Internet and social media tools to communicate benefit and risk information about FDA-regulated products. Finally, FDA must ensure that both its existing regulatory policies, and any revised policies, are consistent with

² Indeed, at this time it is unclear whether FDA intends to regulate Internet promotion as "labeling," "advertising," or both. FDA's recent untitled letters regarding sponsored links highlight this uncertainty, as FDA cited both the labeling and advertising regulations as authority for its letters. *See, e.g.*, Letter from Shefali Doshi, M.D., DDMAC, to Robert Clark, Pfizer (March 26, 2009).

the First Amendment and do not impose unnecessary restrictions on truthful and accurate information provided via the Internet and social media tools.

Bayer believes that the Internet and social media tools are revolutionizing the way patients and physicians learn about medical conditions and treatment options. FDA's regulatory policies should embrace these new technologies in a manner that encourages the communication of truthful and accurate healthcare information via the Internet.

II. The Value of Online Communications

Patients these days are taking a more active role in managing their healthcare. Increasingly patients are turning to the Internet as an important source of healthcare information. For example, FDA patient surveys on direct-to-consumer ("DTC") advertising conducted in 1999 and 2002 showed that the number of people using the Internet to find information about a health-related subject after viewing a DTC advertisement increased from 18% in 1999 to 38% in 2002.³ In a more recent survey conducted by the Pew Internet & American Life Project, which is an initiative of the Pew Research Center, researchers found that approximately 80% of Internet users – 61% of all adults – look online for health-related information.⁴ Likewise, a recent survey conducted by Manhattan research indicates that of the approximately 168 million adults who use the Internet every year, more than 145 million "used the Internet to research health and medical information in 2008," and over 60 million use social media tools like blogs, message boards, chat rooms and online patient support groups.⁵

As FDA itself has acknowledged, research indicates that greater patient involvement in healthcare may lead to better health outcomes.⁶ By prompting more productive doctor/patient dialogue and furthering consumers' interest in their own healthcare, Internet communications and promotion enable patients to more effectively partner with their healthcare providers to determine appropriate treatments. The Pew Research Center for the People and the Press, an independent organization noted for its unbiased public opinion research, conducted a survey which indicated that 42% of all adults have been helped, or know somebody who has been helped, from health information found on the

³ K. Aikin *et. al.*, *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results*, Final Report, at 2 (Nov. 19, 2004) ("*FDA Survey*"), available at www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm109875.pdf.

⁴ Susannah Fox & Sydney Jones, Pew Internet and American Life Project, *The Social Life of Health Information*, at 6 (June 2009) ("*Pew Survey*").

⁵ Manhattan Research, Cybercitizen Health™ v8.0, *The State of eHealth: Trends of Today's eHealth Consumer*, at 2-3 (2008), available at www.ahdionline.org/ca/ahdi-wa/news/articles/The_State_of_eHealth.pdf.

⁶ *FDA Survey*, at 88.

Internet.⁷ Moreover, the Pew researchers concluded that the Internet “supplements, but does not replace, traditional sources of health information. The vast majority of people with a health question or concern say they consult a health professional.”⁸ In short, the survey found that “technology is not an end, but a means to accelerate the pace of discovery, widen social networks, and *sharpen the questions someone might ask when they do get to talk to a health professional.*”⁹

The Internet and social media sites also are changing the way physicians search for, find, and communicate about new information regarding FDA-regulated products such as prescription drugs. Physicians historically have used traditional sources of information, such as continuing medical education (“CME”) conferences, journal articles and pharmaceutical representatives, to stay abreast of the latest medical developments. According to the testimony of Wayne Gattinella, President and CEO of WebMD Health Corporation, virtually all physicians are now online and use the Internet for medical information in a way that has replaced or supplemented these traditional sources.¹⁰ Indeed, social networking sites dedicated to physicians, such as Sermo, now serve more than a hundred thousand physician members in each of the 50 states. These physician communities, according to Sermo, “welcome[] information that is timely and relevant, whether this is branded product information or unbranded disease state information.”¹¹

In sum, the Internet and social media tools play an essential role in meeting the needs of increasingly sophisticated, information-seeking health care consumer and physician communities. Pharmaceutical companies are perhaps the most valuable source of accurate, up-to-date information about the safety and effectiveness of the drugs they discover, develop, manufacture and/or market, and the information they disseminate is strictly regulated by FDA. FDA’s policies should recognize this and permit pharmaceutical companies to provide useful healthcare information about the products they manufacture using the full spectrum of social media and other tools available via the Internet.

III. Bayer Healthcare Responses to FDA’s Questions

The following provides Bayer’s responses to specific questions raised by FDA in its September 21, 2009 Federal Register notice. Bayer’s responses are presented in the order in which the issues were listed in the Federal Register notice, respectively.

⁷ *Pew Survey*, at 4.

⁸ *Pew Survey*, at 6-7.

⁹ *Pew Survey*, at 7 (emphasis added).

¹⁰ Testimony of Wayne Gattinella, President & CEO, WebMD Health Corp., FDA-2009-N-0441, at 1 (Nov. 12, 2009).

¹¹ Testimony of Daniel Palestrant, M.D., Chief Executive Officer, Sermo, FDA-2009-N-0441 (Nov. 13, 2009).

A. Accountability for Online Communications of Third Parties

In Bayer's view, companies should be held responsible for online communications only if they control or have exercised substantive influence over such communications. Moreover, in the interest of transparency, there should be a prominent disclosure regarding the company's identity and/or involvement whenever a company controls or exercises substantive influence over a communication or communications during an online discussion. If a company simply monitors a site independently, however, no such disclosure should be required. Finally, if an unrelated third party appropriates, embeds, or otherwise uses content originally disseminated by a pharmaceutical manufacturer, responsibility for the new or modified communication should rest exclusively with the third party, not the manufacturer.

Control and Substantive Influence. Pharmaceutical companies should be held responsible only for online communications that they control or over which they exercise substantive influence. The Internet offers numerous possibilities for third parties to post information about a company's products, including wikis, blogs, blog comments, "tweets," and online discussions. While much of this information is accurate and useful, some may be inaccurate, fail to contain adequate safety warnings, or discuss off-label uses of a marketed drug. If such communications are not made by or on behalf of a pharmaceutical company, there is no basis for FDA to hold the company responsible for a third party's communications.

In similar circumstances involving continuing medical education ("CME"), FDA has examined whether activities and communications are performed by or on behalf of a company, and thus are subject to regulation, or are essentially independent of the substantive influence of a company, and thus are exempt from FDA regulation.¹² Among other things, the Agency looks to whether the speaker has maintained "full control" over the content of the communication. The Agency also considers the following to be relevant factors: (1) whether meaningful disclosures have been made regarding any support from a company; (2) the focus of the program or communication; (3) the relationship between the speaker and the company; and (4) whether the speaker also is involved in marketing activities for the company. Bayer believes that many of the factors listed in the *CME Guidance* are relevant in the context of online discussions. FDA should develop similar factors for use in the context of Internet communication that would permit companies to provide support for independent websites, such as Sermo, WebMD and others, through advertising, grants or otherwise, without becoming responsible for the information posted on such sites by independent third parties.

Prominent Disclosures. If a website or third party accepts support from a pharmaceutical company, that support should be prominently disclosed on the website or in conjunction with any statements regarding the company's products. Likewise, if a company representative participates in an online discussion

¹² *Guidance for Industry: Industry-supported Scientific and Educational Activities*, 62 Fed. Reg. 64093 (Dec. 3, 1997) (referred to herein as the "*CME Guidance*").

regarding the company's products or a related health condition, the representative should prominently disclose his or her affiliation. This disclosure is necessary to permit other users to accurately assess the source of the information. If a company simply independently monitors a particular website or online discussion without participating, however, no disclosure should be required.

Third Party Use of Company Content. Finally, if an unrelated third party uses content originally posted online by a pharmaceutical manufacturer, responsibility for the new communication should rest exclusively with the third party, not the manufacturer. In some cases, third parties may appropriate or embed content, such as videos, that originally were posted online by a pharmaceutical manufacturer. In doing so, the third party may strip out important information, such as safety disclosures, that were included in the original posting in order to meet applicable regulatory requirements. Third parties also may post their own commentary about or in close proximity to the embedded content. In such situations, FDA should not seek to hold the pharmaceutical manufacturer responsible for any regulatory deficiencies associated with the modified communication.

This situation is no different than that presented by press releases and video news releases ("VNRs"). In such cases, manufacturers are responsible for the information they provide to the news media, not for any subsequent use of such material in news reports or articles. Indeed, news organizations invariably redact the comprehensive safety and other information provided by the manufacturer in order to meet time and/or space requirements applicable to the medium. News organizations also may include their commentary or additional information in news stories using manufacturer content from a press release or VNR. If manufacturers were held responsible for this subsequent use – which is recognized as completely independent of the manufacturer – an important source of new medical information would dry up, and the public health would suffer. Consequently, FDA should treat online use of manufacturer content by unrelated third parties the same way it treats third party use of press releases and VNRs.

B. Fulfilling Regulatory Requirements

The modes of communication available on the Internet are diverse, varied and constantly evolving. While FDA's current regulatory policies easily can be applied to some types of Internet promotion, i.e., those that mirror conventional advertising, such as online videos, it is not clear that FDA's regulations are flexible enough to accommodate other modes of communication, particularly those that incorporate space limitations, such as microblogs and sponsored links. Bayer believes that FDA should, at a minimum, apply its existing regulations flexibly to accommodate truthful and accurate Internet communications by regulated companies. We further recommend that the FDA issue new guidance documents and/or regulations that are tailored to the unique technological characteristics of the Internet and social media tools.

The Internet offers a vast array of methods for communicating healthcare information to physicians and patients. Some of these methods mirror or

incorporate traditional forms of product promotion, such as promotional labeling and advertising. For example, pharmaceutical companies can post full versions of DTC television advertisements on their own websites or on third-party websites, such as YouTube. These online videos can and should be reviewed and regulated in the same manner as broadcast television advertisements, including requirements for the “major statement” regarding contraindications and side effects and “adequate provision” of the approved labeling.

Other types of Internet promotion, however, differ markedly from traditional forms of promotional labeling and advertising. These include, among other things, blogging, microblogging (e.g., Twitter), social networking (e.g., Sermo, PatientsLikeMe), mobile applications (e.g., ePocrates), sponsored links (e.g., Google, Yahoo), banner advertisements, and widgets.

These forms of communication significantly differ from traditional advertising and promotion in several ways. First, many of these methods are symmetrical and interactive. Unlike traditional newspaper or television advertisements, which are one-sided communications, these new methods permit, and even foster, interaction and dialogue. Second, on sites where interaction is permitted, such as social networking sites or blogs with open comments, this dialogue often occurs in real-time. Third, patients and physicians typically are not passive recipients of online communications about healthcare issues but rather are active seekers of such information. For example, a sponsored link for a prescription drug will not appear randomly and unsolicited on a user’s computer screen (like an advertisement on a television screen) but rather must be triggered by a relevant search by the seeker of information regarding a disease or health-related condition. Finally, many types of Internet promotion are subject to strict space limitations that preclude companies from providing a full “brief summary” or “major statement.” These space limitations, however, are balanced by the ability to provide “links” to a virtually unlimited amount of safety and effectiveness information.

Because of these important differences, FDA should regulate Internet communications differently than traditional forms of promotion. This is not only appropriate, but necessary, since many of the technological features that define the Internet experience, such as strict space limitations, are static and cannot be changed by the pharmaceutical industry just to accommodate the regulatory requirements currently imposed on industry. Rather, the pharmaceutical industry will have to adapt its regulatory processes to these existing (and future) technologies. In order to permit companies to make use of these Internet technologies to provide appropriate and responsive information to physicians and the public, the FDA will need to apply its existing regulations flexibly. Additionally, in many instances, we submit that the FDA may even need to formally revise its existing regulatory policies by issuing new guidance documents and/or revised and/or new regulations.

1. Limited Space Formats

Bayer believes it is possible to provide truthful, accurate and balanced information about a pharmaceutical product, including a product with a boxed

warning, even when space is severely limited. In particular, FDA should recognize that Internet users rely upon space-limited formats primarily as launching pads to obtain more in-depth information about a drug product or disease. Thus, while a drug's name and use constitutes relevant and material information for such Internet users, safety information does not and should not be routinely required by FDA in space-limited formats. Rather, FDA should allow manufacturers to make comprehensive benefit and risk information available via a conspicuous link.

FDA regulations require promotional materials, other than reminder pieces, to disclose risk and other information about the promoted drug.¹³ FDA takes the position that such materials are misleading if they fail to reveal facts that are material in light of the representations made in the promotional materials or with respect to the consequences that may result from use of the drug as recommended or suggested by the promotional materials.¹⁴ Thus, if a promotional piece makes any representation or suggestion about the indications or efficacy of a drug, it also must include balancing risk information. FDA regulations and policies generally require this balancing information to include, at a minimum, a drug's most serious risks as well as common non-serious side effects most likely to affect a patient's quality of life or compliance with drug therapy.¹⁵

Unfortunately, this type of detailed risk information cannot be presented in space-limited formats such as sponsored links, Twitter feeds, and banner advertisements. In an attempt to comply with FDA's regulations, therefore, many companies have sought to strip out any information about an advertised drug's approved indication or efficacy, thereby creating reminder advertisements that do not require safety disclosures. For drugs with boxed warnings, which cannot use reminder advertisements, companies have deleted any mention of the drug's name in Internet advertisements and, when linking to a drug-specific website, have created feeder links that do not incorporate the drug's name but nevertheless lead to the official drug website.

This situation is problematic from a public health point of view because it makes information *less transparent* to physicians and consumers and results in reduced click-through rates ("CTRs") to FDA-regulated drug information, including the approved package insert and/or patient package insert. Indeed, when links are stripped of a product name (i.e. for drugs with boxed warnings) or indication (e.g., to avoid the need to disclose risk information), then the link is no longer visually or graphically relevant to the user. For example, if the user is conducting an Internet search on a particular disease state, the user will identify

¹³21 C.F.R. §§201.100(d), 202.1(e).

¹⁴ *Id.* §202.1(e)(5)(iii); *see also* 21 U.S.C. §321(n).

¹⁵ *See Draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion*, at 12 (May 2009) (hereinafter referred to as *Draft Risk Presentation Guidance*); *see also, Draft Guidance on Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements*, at 3-6 (Jan. 2004) (hereinafter referred to as *Draft Brief Summary Guidance*).

the most relevant search results by scanning the brief descriptions appended to each link. If the description or link does not include information that highlights the link's relevance to the user's search, such as product name or indication, the user will be less likely to click on the link.

This, in fact, is what happened following FDA's issuance of several untitled letters in March 2009 to pharmaceutical manufacturers regarding their sponsored links. According to internal data provided by Google during the public hearing, CTRs for sponsored links dropped precipitously and are still below the rates for 2008.¹⁶ Bayer believes that this situation is detrimental from a public health perspective because Internet users are less likely to be able to identify company-sanctioned information, including the FDA-approved package insert or patient package insert, and are more likely to obtain medical information from sites that are not subject to FDA oversight. Many of these sites may, in fact, contain inaccurate, misleading or even harmful information.

FDA should address this situation by explicitly permitting companies to use product names and indication or effectiveness information in Internet formats with space limitations provided the company provides a *conspicuous link* directly to complete benefit and risk information. Moreover, as discussed further below, this rule should be applied equally to drugs whose labeling contains a boxed warning.

Conspicuous Link. FDA should explicitly state that it will consider risk information presented in a space limited format to meet relevant legal and regulatory requirements if such risk information is provided via a conspicuous link to complete product information. In other words, FDA should explicitly adopt the "one-click rule." Under this rule, the requirement to provide comprehensive product information, including safety information, in promotional material is considered to be satisfied if such information is directly accessible from a link in the original promotional piece, i.e., no more than one click away. To comply with this rule, any such link should be prominent and conspicuous.

FDA regulations support this position. For example, FDA's advertising regulations provide that balancing risk information "may be concise" if it is supplemented by a "prominent reference" to the presence and location elsewhere in the advertisement of a more complete discussion of the risk information.¹⁷ The link to complete benefit and risk information could serve as this "prominent reference," and the linked information could satisfy the requirement for a complete discussion of risk information.

¹⁶ Presentation of Mary Ann Belliveau and Amy Cowan, Google, FDA-2009-N-0441, at 10 (Nov. 12, 2009).

¹⁷ 21 C.F.R. §202.1(e)(3)(i); *see also id.* 202.1(e)(7)(xii) (contemplates that risk information may be provided in a "distinct part" of an advertisement).

Because the original promotional piece (e.g., Twitter feed, sponsored link) and the linked landing page would be designed to function as a unit, they should be treated as individual parts of a *single promotional piece*, not as separate promotional pieces themselves. In similar circumstances involving help-seeking advertisements, FDA has taken the position that two separate communications could be treated as a single advertisement for purposes of FDA's promotional requirements if the communications are (1) perceptually similar in the use of graphic, visual, thematic, or other presentation elements, and (2) presented in close physical or temporal proximity.¹⁸ The same considerations support treating limited-space Internet communications and prominently-linked safety information as a single promotional piece that, together, satisfies FDA requirements regarding the presentation of risk information.

Moreover, Bayer believes that FDA has the flexibility to decide that, in the context of Internet communications using tools with significant space limitations, risk information is not "material" and thus is not required in the body of the promotional message. As discussed above, promotional material is considered to be misleading if it fails to reveal "material facts" about a drug.¹⁹ In assessing materiality, FDA looks to "the degree to which information is objectively important, relevant, or substantial to the target audience."²⁰ In the case of Internet communications using tools with significant space limitations, such as sponsored links and microblogs, comprehensive risk information is not objectively important, relevant or substantial to the relevant target audience, i.e., Internet users.

Indeed, Internet users typically rely upon limited space formats, such as sponsored links and microblogs, merely as guideposts that provide direction (in the form of links) where to find more complete information about a drug or health-related condition; Internet users do not rely upon such tools as standalone sources for comprehensive benefit and risk information. Thus, while it is important to include comprehensive benefit and risk information on a landing page that is "one click away," it would be counter-productive, and inconsistent with the "guidepost" function of such promotions, to require more comprehensive information.

It also may be inconsistent with good risk communication practices. Indeed, FDA has recognized that in many cases, *more* risk information may actually detract from a user's comprehension of drug risks. As the Agency has stated, "FDA believes that exhaustive lists of minor risks distract from and make

¹⁸ *Draft Guidance for Industry: "Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms*, at. 5-7 (Jan. 2004) (hereinafter *Draft Help-Seeking Communications Guidance*).

¹⁹ 21 C.F.R. §202.1(e)(5)(iii); *see also* 21 U.S.C. §321(n).

²⁰ *Draft Risk Presentation Guidance*, at 11.

it difficult to comprehend and retain information on the more important risks.”²¹ In this case, Internet users want information presented in a concise and meaningful way, particularly in limited space formats, and they likely will skip over or ignore postings that incorporate comprehensive safety disclosures. In similar circumstances, the Federal Trade Commission (“FTC”) has allowed the use of disclosures that are made via conspicuous links.²²

Boxed Warning Drugs. Finally, FDA should apply this approach to drugs with boxed warnings. The same considerations that support this approach for prescription drugs generally likewise support applying it to drugs with boxed warnings. Indeed, it may be even more important for Internet users to have accurate guideposts as to where to find company-sponsored information, including the FDA-approved patient or physician labeling, for drugs with boxed warnings than for other types of drugs. While FDA may require the promotional communication to prominently mention the existence of a boxed warning, the Agency should not prohibit drugs with boxed warnings from providing useful “guidepost” information to motivated and sophisticated Internet users via sponsored links, banners ads, Twitter feeds and similar limited space communication methods.

2. Concerns About Proposals for a Universal Safety Symbol

Numerous commenters at the public hearing suggested the creation and use of a universal safety symbol that could be used on limited space formats to direct users to FDA-regulated safety information. Bayer is concerned that these proposals, if adopted, would serve merely as a temporary solution that could not be sustained long-term and that could not be universally adopted throughout “the web.” In particular, a universal safety symbol is not feasible because:

- It would need to be implemented separately for each search engine, an outcome that cannot simply be assumed;
- It will not be supported when a search engine feeds into other content networks and other websites;
- Graphics cannot be mandated on many sites, and even if a symbol were converted to text, there may be space limitation issues on many sites;

²¹ *Draft Brief Summary Guidance*, at 2. This “less is more approach” also is reflected in FDA’s regulations governing prescription drug labeling, which now incorporate a requirement for a “Highlights” section at the beginning of the approved package insert to improve comprehension. See 21 C.F.R. §201.57(a).

²² See *Dot Com Disclosures: Information About Online Advertising*, at 11 (2000), available at <http://www.ftc.gov/bcp/edu/pubs/business/e-commerce/bus41.pdf>. The FTC states that in determining whether a disclosure in a banner ad should be placed in the ad itself or on the Web site to which the banner ad links, it will consider: (1) how important the information is to prevent deception; (2) how much information needs to be disclosed, (3) the burden of disclosing the information in the banner ad itself, (4) how much information the consumer may absorb from the ad, and (5) how effective the disclosure would be if made on the linked Web site. *Id.*

- It will be administratively burdensome for both FDA and industry, particularly if linked information must be pre-approved by FDA as a condition of using the universal symbol; and
- It will require the industry to continually seek exceptions and chase the formats of potentially a large number of sites/technologies that will change faster than FDA's guidance and policies on a universal safety symbol.

Instead of a universal safety symbol, Bayer suggests that FDA adopt the proposal discussed in section B.1 above. In addition, as discussed further in section D, FDA should treat a URL that incorporates a drug trade name as a destination and not as a reminder advertisement. These proposals are flexible and should permit the effective linking of safety information in a manner that can be adopted across different platforms, search engines and websites.

3. Submitting 2253's for Real-Time Internet Communications

As mentioned above, a unique feature of many Internet communications is that they are symmetrical and occur in real-time. For example, a health-related blog may permit readers to post in real-time comments that respond to a blog entry or to other comments. Similarly, social networking sites like Sermo may encourage users to participate in online discussions about healthcare topics that are unmoderated or only lightly moderated. In its Federal Register notice, FDA asks whether a company that participates in such a dialogue should be required to submit FDA Form 2253 reflecting its participation.

Bayer recommends that FDA explicitly state that the submission of FDA Form 2253 is not required when a company participates in a real-time dialogue about one or more of its products on a social networking site, blog or similar Internet site. If FDA determines that it must revise its existing regulations to accomplish this goal, it should do so.²³

In Bayer's view, such online discussions are analogous to verbal discussions between a company and a physician or patient, which are not subject to the requirement to submit FDA Form 2253. Although an online discussion may be accessible to many more people than a verbal discussion, and for a longer period of time, this simply means that an online discussion will be easier for FDA to review and regulate than a verbal discussion, *even in the absence of a 2253 Form*. Indeed, it is well-known that such sites are self-policing, and if a company were to post inaccurate, misleading, off-label or other objectionable material during an online discussion, it would be exceedingly easy for a participant, including a competitor, to forward a link to the offending material to FDA for review.

Bayer also believes that the administrative burden of submitting a separate 2253 for each individual entry or discussion would be substantial and

²³ See 21 C.F.R. §314.81(b)(3)(i).

overly burdensome, both for the industry and for FDA, and would not be offset by any corresponding benefit. Bayer is not suggesting that other regulatory requirements should not apply to online discussions. On the contrary, just as verbal discussions must comply with applicable regulatory requirements, such as the prohibition against off-label promotion, so must online discussions. Bayer simply believes that there is little regulatory value in requiring the routine submission of 2253's for online discussions and that any such requirement could create strong disincentives for companies to participate in such discussions, which would be detrimental to the public health. Indeed, as demonstrated during the public hearing, both patient and physician groups value and encourage company participation in online discussions.²⁴

C. Posting Corrective Information

Bayer agrees with the multiple commenters at the public hearing who expressed the view that pharmaceutical companies (1) should be permitted to correct inaccurate information about a drug product posted on a blog or social media website but (2) should not be obligated to respond to such information, even if they become aware of it. If companies decide to participate in such online discussions, their communications must comply with the standard requirements applicable to promotional messages, including the presentation of balanced risk information. Companies, however, should not be held responsible for the information posted on such forums by unrelated third parties.

Participation Permitted. Interactive internet tools, such as blogs with open comments and social media sites, are becoming an increasingly important source for healthcare information,²⁵ and many pharmaceutical companies are interested in joining the dialogue. Testimony at the public hearing indicates that both physicians and consumers value and welcome the input of pharmaceutical companies provided such input is transparent. Because of a lack of clarity regarding FDA's policies governing the Internet, however, many companies have been dissuaded from participating in online discussions regarding their drug products. In particular, there is a concern that by participating in an online discussion, a company may be held responsible for any statements made during the discussion, even by unrelated third parties. Indeed, even when companies become aware that inaccurate information is being disseminated about one of their products on a blog or social media site, they often refrain from correcting such information because of these regulatory concerns and uncertainty. Bayer does not believe that the current regulatory approach, which creates disincentives for companies to participate in health-related dialogues, is consistent with good public health policies.

Accordingly, Bayer requests FDA to explicitly state in a guidance document or regulation that companies may participate in online discussions – including to correct inaccurate information about one of their drugs – without

²⁴ See *supra*, note 11.

²⁵ *Pew Survey*, at 3.

becoming responsible for content posted by unrelated third parties. Any company response, of course, must satisfy all other applicable requirements, including requirements that the posted information be accurate, non-misleading, fairly-balanced and consistent with the approved labeling. Bayer wishes to emphasize that it is not seeking a blanket exemption from applicable regulatory requirements for online discussions; only a clear statement by FDA that companies will be held responsible solely for their own statements, not the statements of third parties.²⁶

In meeting these regulatory requirements, companies should be permitted to make appropriate use of links, as discussed in sections III.B, above, and III.D, below, to provide complete benefit and risk information without detracting from the flow of the online discussion. In other words, company posts during online discussions should not be required to include comprehensive, boiler-plate safety disclosures, which are unnecessary in this context and could be extremely distracting to all participants in the discussion. Rather, FDA should permit companies to provide a concise statement of risk information that is commensurate with the posted efficacy information, paired with a conspicuous link or web address (if a link is not supported) to more comprehensive benefit and risk information. Since complete benefit and risk information could be found by following the relevant link or web address, such information would be easily accessible to all online participants, thereby satisfying applicable regulatory requirements.

Company postings during online discussions also should be completely transparent to all participants. Company representatives should not disguise their identity or affiliation by using an alias or failing to identify their employer. This is essential so that participants can properly assess the value and trustworthiness of the disseminated information. Accordingly, FDA should require companies and company representatives to disclose their identities when participating in online discussions. Further, FDA should take the position that the failure to do so could result in the disseminated information being deemed “misleading.”

In many online discussions, participants may raise issues regarding the off-label use of a drug product. Bayer believes that companies should be able to respond to these off-label discussions by (1) clearly identifying the information as “off-label” information; and (2) providing a link or web address (if a link is not supported) to the FDA-approved package insert or patient labeling. This type of limited response fosters the public health by providing easy access to information about the approved uses of a drug product, including approved dosing schedules and instructions. Accordingly, FDA should clarify that by making this type of limited response to off-label information posted by a third party during an online discussion, a company itself will not become responsible for the off-label information.

²⁶ In this regard, even if a company responds to one comment, it should not be required to respond to other or subsequent comments. Indeed, a company should be permitted to explicitly disclaim responsibility for responding to other or future comments, even if such comments likewise contain inaccurate information.

Participation Not Required. Finally, FDA should explicitly state that companies are under no obligation to monitor Internet postings or discussions regarding their drug products or to respond to inaccurate information about their drug products, even if they become aware of such information. Although several commenters at the public hearing supported this type of requirement, Bayer is not aware of any provision in the Federal Food, Drug, and Cosmetic Act or other relevant law that would provide the statutory authority for such a broad, burdensome and amorphous requirement. Moreover, the “forced speech” aspect of any such requirement would raise significant First Amendment issues.²⁷ Companies are not required to monitor or correct third party discussions or statements that take place outside the Internet, and there is no good reason for applying a different standard to discussions and statements that occur within the Internet. FDA thus should explicitly disclaim any intent to apply a different standard to Internet communications.

D. Use of Links

One of the defining features of the Internet – and one of its greatest strengths – is the ability to create links to a virtually unlimited amount of data and information. FDA regulatory policies should recognize and leverage this unique and useful technological feature. In particular, FDA should: (1) treat URLs as destinations rather than reminder advertisements, even if the URL incorporates a drug trade name; (2) adopt the “one-click rule” with respect to safety information (as discussed in section III.B.1 above); and (3) adopt the “two-click rule” for links between a company-sponsored website, such as a product site, and an independent third-party website.

URL as Destination. For clarity’s sake, pharmaceutical companies often use a drug product’s trade name in or as the URL for the official, product-specific website. For example, the URL for the official website dedicated to Bayer’s cancer drug Nexavar is www.nexavar.com, and the URL for the U.S. version of this site is www.nexavar-us.com. The use of a drug’s trade name in a URL makes linking to the official website intuitive and transparent. Internet users know exactly where the link will lead.

If FDA were to treat URLs incorporating drug names as advertisements, it would be difficult or impossible for companies to provide transparent links to websites for drugs with boxed warnings. This is because naked links, i.e., those without any appended safety or effectiveness information, would be viewed as reminder labeling or reminder advertising, and FDA regulations currently

²⁷See, e.g., *United States v. United Foods, Inc.*, 553 U.S. 405 (2001) (striking down statutory scheme compelling fresh mushroom handlers to pay assessments for generalized advertising); *Riley v. Nat’l Fed’n. of the Blind of N.C., Inc.*, 487 U.S. 781 (1988) (striking down North Carolina statute requiring professional fundraiser to disclose the average percentage of his gross receipts that are turned over to charities prior to making any appeal for funds).

prohibit the use of reminder pieces for drugs with boxed warnings.²⁸ The marketing industry has frowned on the concept of redirecting in general, since it is misleading from a consumer standpoint. However, because of uncertainty regarding FDA's regulations, the pharmaceutical industry has been forced to resort to this method, in some cases, for drugs with boxed warnings.

FDA's policies should encourage transparency, not redirection. Accordingly, FDA should explicitly state in a guidance document or regulations that URLs that incorporate a drug name will be considered *destinations*, not advertisements. Merely including a product name in a URL, therefore, should not invoke the need to provide safety and/or effectiveness information for products with boxed warnings.

One-Click Rule. FDA also should adopt the "one-click rule" with respect to safety information in Internet promotional pieces. Under this rule, the regulatory requirements for posting comprehensive safety information should be considered met as long as it is directly accessible via a prominent and conspicuous link, i.e., one click away. The one-click rule should not obviate the need to provide balancing safety information in the body of the Internet advertisement where space limitations are not an issue,²⁹ but this balancing safety information should only be required to be commensurate in depth and detail with the effectiveness information presented in the advertisement. For example, if the Internet advertisement presents concise information about efficacy, a similarly concise statement about risks should suffice to meet fair balance requirements, provided that more complete safety information, such as a patient package insert, is one click away. For a more complete discussion of the "one-click rule," please reference the discussion in section III.B.1. above.

Two-Click Rule. Finally, FDA should explicitly adopt a "two-click rule" with respect to links from a company's website to a third party website. Under this rule, a manufacturer would not be held responsible for information provided on the third-party website, including off-label information or discussions, provided there is a clear delineation between the manufacturer's website and the third-party website and any off-label statements or discussions are at least two clicks away from the manufacturer's site.

The clear delineation can be accomplished in a number of different ways. For example, the manufacturer could require the link to open in a new window, making it impossible for the user to navigate back and forth between the manufacturer's site and the third-party site. In addition, the manufacturer could

²⁸ 21 C.F.R. §§201.100(f), 202.1(e)(2)(i).

²⁹ As discussed in Section III.B.1 above, where space limitations do apply, FDA should permit companies to include use information as a "guidepost" without the need for safety disclosures (other than a conspicuous link). In such cases, safety information, even concise safety information, is not material for Internet users.

incorporate a pop-up screen notifying the user that he or she is leaving the manufacturer's website and entering a third-party website over which the manufacturer has no control. If the pop-up screen requires the user to click on a statement agreeing to leave the manufacturer's site, this should be considered as the second "click," thereby satisfying the two click rule.

E. Adverse Event Reporting

Bayer fully supports and adopts the comments submitted by the Pharmaceutical Research and Manufacturers of America with respect to adverse event reporting.

IV. First Amendment Protection Applies to Online Communications

FDA's regulation of online communications via the Internet and social media tools must be consistent with the free speech protections of the First Amendment to the United States Constitution.

When the FDA restricts the speech of pharmaceutical manufacturers and other regulated entities, the restrictions are subject to scrutiny under the First Amendment to the United States Constitution. Recent decisions of the Supreme Court and other federal courts confirm that such restrictions cannot be justified as merely incidental to FDA's regulation of conduct or as automatically authorized by FDA's public health mandate. Speech that is false, misleading or proposes an otherwise unlawful transaction is not protected under the First Amendment. However, in order to justify limitations on truthful, non-misleading speech about lawful products and activities – such as online communications of approved drug products – the Agency must show that the ends served and the means employed are legitimate and appropriately circumscribed.

Online communication via the Internet and social media platforms – like other forms of advertising and promotion via other media – is, at a minimum, commercial speech that is protected by the First Amendment.³⁰ Any restriction on such communication therefore must satisfy the well-known *Central Hudson* test in order to pass constitutional muster. *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). The First Amendment protects commercial speech because the speech "assists consumers and furthers the societal interest in the fullest possible dissemination of information."

³⁰ Some online communications by pharmaceutical companies may be regarded as "core" speech and thus be subject to greater protections than commercial speech. For example, the posting of clinical trial information on the government database ClinicalTrials.gov may be viewed as a purely scientific communication, rather than a commercial transaction, meriting heightened First Amendment protection.

Under *Central Hudson*, the initial inquiry is whether the speech at issue proposes a lawful transaction and is not misleading. *Central Hudson*, 447 U.S. at 563. Regulations that effectively ban truthful, non-misleading commercial speech about a lawful product “hinder consumer choice [and] impede debate over central issues of public policy and, therefore, “rarely survive constitutional scrutiny.” *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503-04 (1996).

It is clearly established that “FDA may not restrict speech based [simply] on its perception that the speech could, may, or might mislead.” *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999). Rather, FDA must put forth concrete proof that the restricted speech is actually or inherently misleading. *Ibanez v. Florida Dept. of Business and Prof. Regulation*, 512 U.S. 136, 146 (1994) (government’s burden is not satisfied by “rote invocation of the words ‘potentially misleading’”); *see also Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993) (the government’s “burden is not satisfied by mere speculation or conjecture”).

If speech concerns a lawful activity, and the Agency cannot make a record establishing that the speech is in fact misleading, then the Agency must satisfy the three remaining prongs of the *Central Hudson* inquiry in order to justify a restriction on the speech. Specifically, the restriction must: (1) promote a substantial government interest; (2) directly advance that interest; and (3) be no more extensive than necessary to achieve the asserted government interest. *Central Hudson*, 447 U.S. at 566. Because the government generally has a substantial interest in protecting the health and safety of its citizens, the constitutionality of FDA-imposed limitations on non-misleading speech typically turns, first, on whether the action directly advances the asserted government interest, and, second, on whether the government’s legitimate interests could be served in a less restrictive way.

To demonstrate that a limitation on speech directly advances a government interest, the government “bears the burden of showing not merely that its [action] will advance its interest, but also that it will do so to a material degree.” *44 Liquormart*, 517 U.S. at 505 (internal quotation and citation omitted). The government must prove that “the harms it recites are real and that its restriction will in fact alleviate them to a material degree.” *Edenfield*, 507 U.S. at 770-71.

To satisfy the final element of *Central Hudson*, the agency action that abridges speech must not be more extensive than necessary to serve the government’s legitimate interests. *Thompson v. Western States Medical Center*, 535 U.S. 357, 371 (2002). A restriction is not appropriately tailored if “there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech.” *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417, n. 13. “[I]f the government can achieve its interests in a manner that does not restrict speech or that restricts less speech, the Government must do so.” *Western States*, 535 U.S. at 371.

In this case, First Amendment principles support allowing companies to promote their products via limited space formats, such as sponsored links and microblogs. As discussed above, if such communications include a conspicuous link to more comprehensive product information, it is unlikely they would be regarded as misleading, particularly given the “guidepost” purpose of such ads and their intended audience. Indeed, there is evidence that restrictive FDA policies actually are detrimental to public health by reducing “click-through rates” to FDA-approved labeling and FDA-regulated benefit and risk information.³¹ Moreover, if FDA were to require companies to include comprehensive safety information in such space-constrained contexts, it would amount to an outright ban. Bayer believes that any such ban would raise significant First Amendment issues.

FDA has a constitutional obligation to ensure that it acts in accordance with the First Amendment, and therefore its approach toward regulating new modes of communication, such as the Internet and social media, must be carefully scrutinized under the First Amendment.

V. Conclusion

We thank you for your consideration of these comments. If you have any questions, please do not hesitate to contact the undersigned directly.

Sincerely,



Christopher L. Cannon
Senior Counsel
Law and Patents

³¹ See *supra*, note 16.