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February 26, 2010

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Request for Comments Regarding Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools [Docket No. FDA-2009-N-0441]**

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the use of the Internet and social media tools to promote and communicate information regarding FDA-regulated medical products and we appreciate the Agency's recent attention to this important issue. BIO encourages FDA to initiate rulemaking to address the need for clarity around issues of drug advertising, promotion and communications on the Internet and in social media. The Agency could then supplement these regulations with additional guidance as warranted by technological and other developments.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology technologies, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

As stated by the Director of FDA's Division of Drug Marketing Advertising and Communications (DDMAC) on the first day of FDA's November 2009 hearings on these

issues, FDA wants "consumers and healthcare professionals to have accurate, balanced and timely information about medical products."[1] BIO and its members are pleased that FDA is devoting attention to the issue of medical product communications on the Internet and in social media, and we agree wholeheartedly with this objective. We believe that FDA's policies should enable the simultaneous achievement of three important goals: regulatory compliance, reaping the benefits of the technological features of new media, and meeting the informational needs of users. The abundant interest of stakeholders in this issue is evidenced by the hundreds of people that sought to attend FDA's November public meeting. Several BIO members testified at the hearing, and we agree with their statements regarding the importance of this information. Many consumers and health care professionals rely upon the Internet and social media to obtain health and medical information, and the convenience of and access to this information advances health education and encourages the safe use of products. BIO and its members strongly believe that if there is vigorous discussion of biopharmaceutical products and treatments in these media, the manufacturers must be a part of the dialogue to ensure that accurate, credible information about FDA-approved products is available to those searching for it.

Internet and social media users have a distinct profile. Unlike audiences for print or broadcast advertising, they are typically active participants, proactively seeking information. Surveys of Internet users consistently reveal that seeking online health information is a highly engaging process involving multiple steps and sources. For example, a 2006 survey by the Pew Internet & American Life Project found that 66% of those seeking health information online begin their health inquiry with a search engine.[2] This tool, by definition, provides information seekers with a range of options for further study. The survey further found that 72% of these health information seekers visited two or more sites during their last health information session, and one third of these health seekers subsequently talked to a doctor or other healthcare professional about the information they found online. [3]

Given that many BIO members are devoted to the development of drugs for rare diseases, it is also important to highlight the particular significance of the Internet and social media as essential communication tools for the rare disease community. Social media facilitates communication between patients and/or caregivers; provides community education and support; and can reinforce the commitment of manufacturers to the rare disease population. Using the Internet allows patients and/or caregivers the opportunity to connect with others who understand the challenges of living with a rare disease.

Further, recent study results indicate that a large majority of physicians are actively using the Internet to seek out medical information.[4] The survey, commissioned by Google, was

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[1] Abrams, Tom, Director of Division of Drug Marketing Advertising and Communications (DDMAC), FDA, (November 12th, 2009).
[2] Pew Internet and American Life Project, "Online Health Search 2006" (October 29, 2006).
[3] *Id.*
[4] American Medical News, "86% of Physicians Use Internet to Access Health Information" (Jan. 4, 2010). http://www.ama-assn.org/amednews/2010/01/04/bisc0104.htm

conducted in May/June 2009 and results were released in November. 86% of surveyed physicians said they use the Internet to search for health, medical, or prescription drug information; most searched online more than once per day; and the majority start their search for information using a search engine such as Google. It has also been reported that physicians using social media are active practitioners who are looking for a way to connect with peers to exchange ideas that impact their practice of medicine. According to Sermo, one of the largest physician social networks, their member profile closely resembles that of the US physician population with representation in 68 specialty areas throughout the 50 states. Sermo data indicates that physicians use Sermo to ask questions of their peers, build consensus around medical trends, and exchange medical insights about patients, drugs and devices. [5]

The increased access to and interest in health and medical treatment information is a positive development. However, BIO is concerned that FDA's issuance of 14 Untitled Letters to biopharmaceutical manufacturers in March 2009, citing sponsored links on Internet search engines, has led to considerable confusion in this area and reduced the helpfulness of sponsored links for patients and healthcare providers. These letters reportedly resulted in a considerable decline in biopharmaceutical company sponsored link advertising and Internet user exposure to this information.[6] Further, it was indicated in testimony at FDA's November hearing that the types of advertisements that have replaced those sponsored links are less informative. BIO also notes, anecdotally, that use of Internet search engines to seek disease-specific information appears to lead to many links for products that are less highly regulated than FDA-approved drugs and biologics, such as herbal remedies. BIO is concerned that such restrictions on promotion of FDA-approved products could result in an imbalance of information on the Internet, leaving users that are actively seeking information with comparatively less exposure to information that has the credibility and reliability of FDA-approved labeling.

1. FDA's Approach to the Regulatory Framework for Internet and Social Media

BIO understands that FDA may be planning to address Internet and social media promotion through guidance as opposed to issuing regulations. We believe the Agency should initiate rulemaking to address the need for clarity around issues of drug advertising, promotion and communications on the Internet and in social media. The Agency could then supplement these regulations with additional guidance as warranted by technological and other developments. BIO believes that rulemaking is warranted in light of the advances in technology and changes in the access, frequency and methods by which consumers and healthcare providers obtain information from the Internet and via social media regarding their health and available treatments. Further, the body of available data on physician and consumer perceptions of medical product communications has been expanded recently, as FDA, expert bodies, industry, and other entities have focused on risk communications. We

[5] Sermo User Demographic Data, data on file (February 2010).
[6] Comscore Press Release (October 1, 2009) www.comscore.com

encourage FDA to rely upon such data, as it can help to inform new regulatory approaches to providing product information in an effective manner. Finally, there have been significant developments in the law relating to commercial speech and exchange of scientific/medical information by manufacturers that should be carefully considered as the Agency addresses medical product promotion and communications in the Internet and social media context. As detailed below, we believe the First Amendment requires FDA to take special care in developing binding legal requirements that affect protected speech.

However, BIO understands that the nature of regulations may not enable FDA to inform manufacturers with sufficient specificity as to how the regulatory framework will apply to various technologies. To this end, BIO believes that -–in addition to rulemaking--FDA should also issue guidance for industry on the use of the Internet and social media to promote and communicate about regulated medical products. BIO members are concerned about the current lack of clarity in this area, and while regulations are warranted, guidance would also be useful, either on an interim basis while regulations are in development, or to clarify how the regulations will apply to specific technologies.

a) FDA Should Establish Binding, Enforceable Requirements Through Rulemaking

FDA cannot, through guidance, "create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress."[7] Fundamental principles of administrative law, as reflected in the Federal Food Drug, and Cosmetic Act (FFDCA) and FDA's regulations state that binding legal norms may be established by FDA only through the promulgation of regulations after notifying interested parties and providing a meaningful opportunity for comment.[8] Absent notice and comment rulemaking, FDA is limited to "advis[ing] the public of the agency's construction of the statute and rules which it administers." [9]

The rulemaking process "improves the quality of agency rulemaking by exposing regulations to diverse public comment."[10] We believe that new regulations in this area, issued pursuant to appropriate notice and comment under the Administrative Procedure Act, would provide the regulated industry with the clarity and certainty it needs to engage fully in promotional and other communications employing the Internet and social media tools, and to adequately communicate important information to consumers and health care providers. Further, only binding regulatory provisions can provide the basis for swift, effective enforcement action in cases where manufacturer communications may be violative.

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[7] *L.A. Closeout, Inc. v. Dep't of Homeland Sec.,* 513 F.3d 940, 942 (9th Cir. 2008).
[8] Section 701(h) of the FFDCA, 21 U.S.C. 371(h); 21 C.F.R. 10.115.
[9] *Id.*
[10] *Id.*

b) Guidance Alone Is Inadequate to Ensure Clarity

Although issuing guidance might present advantages—whether because it is thought to take less time to develop guidance relative to regulations, or because guidance is believed to be easier to adapt to changing technologies—in fact, providing solely "enforcement discretion" guidance without an underlying rulemaking creates compliance issues for regulated manufacturers. Guidance is by definition non-binding on regulated entities and therefore often fails to provide an adequate basis for a manufacturer to engage in FDA's recommended conduct with assurance that it will not later be pursued through enforcement action.[11]

It is the experience of BIO's members that guidance on this topic —particularly guidance that is written in terms of "enforcement discretion"—is simply not adequate to provide pathways for regulated entities to engage in conduct that, while perhaps satisfying FDA, may be questioned in court by the many non-FDA parties, both public and private, who now seek to enforce the FFDCA directly or indirectly. We therefore urge FDA to initiate notice-and-comment rulemaking to establish clear regulatory provisions governing the use of the Internet and social media to promote FDA-regulated products.

c) For First Amendment Reasons, Rules Are Far More Appropriate Than Guidance

The First Amendment requires FDA to take special care in developing binding legal requirements that affect protected speech by manufacturers. The First Amendment protects truthful, non-misleading speech, including both scientific exchange and commercial, promotional activities. [12] Even when the First Amendment allows restriction of the content of certain commercial speech, the Government must have, at a minimum, a substantial governmental interest, and the restrictions must directly advance that interest without being "more extensive than is necessary to serve that interest." [13] Accordingly, FDA cannot purely justify greater speech regulation by declaring that medical products present serious public health considerations or by invoking the possibility that manufacturers might engage in false or misleading speech to justify an unduly restrictive regime. FDA's approach to manufacturer communications through the Internet and in

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[11] This is exacerbated by the peculiarities of the enforcement scheme under the FFDCA. FDA does not have independent litigating authority, but rather is represented in formal enforcement actions in court by attorneys from the Department of Justice (DOJ). Enforcement decisions therefore are not solely FDA's province, and do not necessarily reflect FDA's own enforcement policy priorities. Moreover, individual United States Attorneys' offices are empowered to initiate investigations and enforcement actions under the FFDCA, and often do so with little coordination with FDA itself. For these reasons, the actual enforcement of FDA's own primary enabling statute often can and does conflict with guidance developed by FDA intended to encourage manufacturers to disseminate information to practitioners. BIO and its members are aware of countless other investigations in which DOJ scrutinized conduct that appeared consistent with FDA guidance and other non-binding statements.

[12] Thompson v. Western States Medical Center, 535 U.S. 357 (2002).

[13] Central Hudson Gas & Electric Corporation v. Public Service Commission of New York, 447 U.S. 557, 566 (1980).

social media must be carefully crafted to advance an important policy goal, and any limits on speech must serve that objective.

The best way for FDA to assure that its regulatory approach to the promotion of medical products on the Internet and in social media satisfies these high First Amendment standards is to engage in rulemaking based on an administrative record developed through public notice-and-comment. From time to time in the past, FDA has attempted to address broad new categories of speech, in large part through guidance, but the speech implications of those efforts have resulted in protracted litigation.[14] The discipline and rigor of the process that is used to promulgate regulations distinguishes rulemaking from guidance development, and the degree of public participation and attention can help to assure that the resulting regulatory provisions adequately reflect the full range of relevant considerations. FDA is much more likely to craft a regulatory regime for promotion of medical products on the Internet and in social media that passes constitutional muster if it proceeds through notice-and-comment rulemaking than if it attempts to address such communications through guidance.

2. Specific FDA Questions

a) For what online communications are manufacturers, packers, or distributors accountable?

Manufacturers should be accountable for Internet content that is their own or directly under their control. Each manufacturer should also be accountable for content on any website that is fully within its control. Company control of an entire website can only reasonably be asserted when the company has full control of content creation, authority to add and remove all content, and funds the entirety of the website. This would extend to any agent acting on behalf of the company as well. For example, a company does not have control of the presentation of content through functions, such as Sidewikis, that appear in conjunction with a site based upon the actions of the user, when it only funds part or all of the website through a grant that does not include editorial control, or when it allows third-parties to post content on a portion of a company website (e.g., a patient or physician chat room or social networking function). The company should not be held responsible for third party content that has been posted on its site if the content was not requested or solicited by the company.

A company does, have control over content its employees post as part of their employment, regardless of where the content is posted, and those employees should be required to disclose their company affiliation and ensure that any posted content is truthful, accurate and presents risks and benefits in a balanced manner. The same accountability should apply to content posted by consultants or others whose actions a manufacturer has the

[14] See, *e.g.,* the Washington Legal Foundation (WLF) line of cases, including *WLF v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998).

ability to control, if they post content pursuant to a request by the company. Company employees may also post content related to the subject of their employment outside of working hours and from personal computers and e-mail addresses. While companies may wish to adopt policies to prohibit the posting of non-compliant content, in these circumstances, companies cannot be held responsible for such content, as they would neither have control or full knowledge of the postings. Similarly, a company should not be held responsible for such postings by consultants or other affiliated persons, if they have not been directed to do so by the company.

With regard to third party postings on a website that is otherwise company controlled, a company should have a responsibility to monitor those postings and take appropriate corrective measures in a timely manner. To that end, what is appropriate may depend upon the nature of the website. For example, if a company has created a disease state website, posted disease state content, and allowed for third-party comments to be posted with a request that such comments not discuss pharmaceutical products, the company should monitor the site, and there should be a reasonable period of time allowed for the company to identify and take down postings that violate its policy. A company does not, however, have a responsibility to monitor the entire Internet, nor to take corrective measures for inaccurate statements made by third parties on sites it does not otherwise control.

It follows that third-party content should not be deemed promotional labeling or advertising where it is not caused or controlled by the manufacturer. Accordingly, the degree of company accountability must be differentiated based upon company control and ability to cause content to be posted.

b) <u>How can manufacturers, packers, or distributors fulfill regulatory requirements (e.g., fair balance, disclosure of indication and risk information, postmarketing submission requirements) in their Internet and social media promotion, particularly when using tools that are associated with space limitations and tools that allow for real-time communications (e.g., microblogs, mobile technology)?</u>

i. Use of FDA's Existing Policies as a Model

The basic FDA regulatory requirements--assuring that drug labeling and advertising is not false or misleading; inclusion of product indication; inclusion of risk information; and achieving a fair balance between effectiveness information and risk information—can be met in various ways. FDA has a history of enabling manufacturers to employ new vehicles for the communication of drug information, through policies that take into consideration the specific vehicles for that communication, and allow alternative approaches to meeting

the regulatory requirements. From print advertising directed to physicians,[15] to print advertising directed to consumers, [16] to direct-to-consumer (DTC) broadcast advertising, [17] policies that allow the message to fit the medium and the audience have enabled progressive presentation of information. Although this piecemeal adoption of policies has not been ideal when compared to a rulemaking to provide a flexible yet definitive framework for such communications, it has provided the outline of a framework that would be useful going forward.

FDA has recognized the need to accommodate different audiences, as well as audiences with varying access to technology, and interpreted the regulatory requirements flexibly to meet each situation. Physicians have long had access to the full package insert (PI), so a brief summary of the risk information has been viewed as adequate for advertising to medical professionals. For DTC print advertising, FDA has recognized that consumer-friendly language summarizing the contraindications, warnings, precautions and side effects is appropriate, and for consumer-directed broadcast advertising, a "major statement" of the product's major risks, combined with "adequate provision" of the approved labeling, through mail, telephone, magazines, brochures, medical professionals, and/or the Internet meets the needs of the audience, including "many persons with limited access to technologically sophisticated outlets, (e.g, the Internet.)"[18] FDA's policy enabling DTC drug ads to fulfill regulatory requirements by means of a major statement of a product's risks and adequate provision of the approved product labeling is a good start toward a model for a practicable, feasible approach that allows the message to fit the medium and the needs of the audience. FDA should similarly adapt its existing policies and guidance to create a practical, feasible paradigm enabling manufacturers to promote and otherwise communicate about their products on the Internet and in social media. The time is ripe for FDA to continue that progression so that drug advertising, promotion and other manufacturer communications can meet the technological needs of new media, the informational needs of users of those media, and fulfill regulatory requirements.

FDA should employ the "reasonable consumer" standard in evaluating promotional materials, *i.e.* the "perspective of a consumer acting reasonably in the circumstances" in order to "examine reasonableness from the perspective of that group." [19] This would be consistent with the Agency's position in its recent Draft Risk Information Guidance that it would evaluate the presentation of risk information from the perspective of the reasonable consumer. In so doing, FDA pointed to a number of factors it would consider, including quantity of information, the target audience, format and layout. These factors are all relevant in evaluating promotional materials on the Internet and in social media. As FDA's

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[15] Section 502(n) of the FFDCA provides that a "brief summary" of side effects, contraindications and effectiveness to be included in prescription drug advertisements. This provision is further defined in FDA's regulations at 21 C.F.R Section 202.1(e).

[16] FDA, Draft Guidance for Industry, "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements" (January 2004).

[17] FDA, Guidance for Industry: "Consumer-Directed Broadcast Advertisements" (August 1999).

[18] *Id.*

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

Draft Risk Information Guidance recognizes in regard to the quantity of information presented, a shorter promotional piece presents less effectiveness information and accordingly requires less risk information. It is also significant that a target audience that has access to and uses the Internet and sophisticated technologies differs from other audiences in that the user is proactively seeking health information, whereas other audiences may only be passively receiving health information.

Internet/social media communication vehicles can also provide user control, so a user may lengthen the duration of exposure to drug-specific information, and in doing so, can enhance readability and pacing. Internet users also have the availability of other tools and resources at their direct disposal to learn more about information they are exposed to in a company sponsored ad or website. Although ideally these factors should be further examined and developed in a rulemaking process, drug promotion on the Internet and in other social media can be evaluated using the same factors as FDA uses to evaluate other drug promotion vehicles—and some of the qualities of the Internet can make information more accessible and understandable to consumers in ways that other media cannot. The reasonable consumer standard—from the perspective of a reasonable consumer that is a user of these technologies—should again serve as a guide**.**

FDA has relied upon "a vast scientific body of knowledge regarding human cognition" in identifying and assessing which factors to consider in evaluating promotional pieces for the purpose of regulatory decision-making.[20] Similarly, FDA should rely upon knowledge and data to evaluate consumer cognition and comprehension of drug information on the Internet and in social media. In developing science-based rules and guidance, FDA should consult, as necessary, with industry and outside experts, and consider consumer focus group data that evaluates consumer use and understanding of information presented via these media. It may also be useful to consult with technology companies regarding technological feasibility in the presentation of information, as well as the new types of communications vehicles that may be on the horizon. It is important that FDA policies—whether in regulations or guidance--provide the flexibility to meet the needs of users of today's technologies as well as the flexibility to allow extension to new media as technology advances.

ii. Reasonableness of a "One-Click" Policy

We noted earlier in these comments the impact of FDA's issuance of the 14 Untitled letters in March 2009, which many have interpreted as rejecting a "one-click" policy, *i.e*. enabling a user to access more expansive product safety information by clicking a single hyperlink. BIO believes that a "one-click" policy would be reasonable, and urges FDA to consider this for use in the context of sponsored links, as well as other vehicles. This would be consistent with current regulatory requirements, as FDA's regulations specifically provide that information relating to side effects and contraindications may be included on a

[20] *Id.*

separate page.[21] A "one-click" policy would be consistent with this regulation. Further, the Federal Trade Commission (FTC) recognizes that a "click-through" to disclosure information is appropriate for advertising disclosures when a hyperlink is obvious, labeled appropriately, and easy for consumers to use.[22] The FTC Guidelines specifically state that "hyperlinked disclosures may be particularly useful if the disclosure is lengthy…"[23] We suggest that FDA consider the FTC Guidelines as an example in establishing a policy that will meet both user and technological needs. In situations where there are space limitations, such as in sponsored web links and other online vehicles such as microblogs and mobile technology, manufacturers can adequately fulfill the regulatory requirements of including the product indication and the risks associated with the use of the product, enabling the user to quickly and easily access the full information with just one click. Internet users understand that web links are space limited and may not provide relevant information in full. They are adept at clicking on a link to obtain additional information of products of interest. The fact that additional, more complete information is available one click away is something that is commonplace in this venue. Providing a hyperlink to a product website that appropriately discloses the indication statement and risk information, as well as a link to the full prescribing information, is an appropriate means to provide the required balanced information in space-constrained examples.

BIO believes that one-click to important drug information is a reasonable approach that would accommodate the habits and needs of Internet users. BIO strongly urges FDA to reconsider its position on this policy. We suggest that FDA base any decision regarding this paradigm on research regarding consumer cognition and understanding, and expert evaluation of that research. If the science indicates that users would not be adequately informed using this approach, BIO encourages FDA to adopt an alternative approach that would similarly enable the use of advertising and other communications in situations where there is limited space.

iii. Proposed Alternative to "One-Click" Policy

As discussed above, the environment and use of sponsored links to promote biopharmaceuticals has changed in the last year, following FDA's March 2009 issuance of the Untitled Letters to manufacturers. BIO believes that sponsored links can provide important information to consumers who often are searching for such information. We propose that an approach similar to that proposed by Google in its November 2009 testimony could serve to fulfill FDA's regulatory requirements and meet both the technological and user needs.

The concerns FDA raised in the March letters related to sponsored links that, generally speaking, named a drug product, the product use, and provided a one-click link to further information about the drug product, but did not include the established name and risk

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[21] 21 CFR 202.1 (e)(7)(xi)
[22] FTC, "Dot.com Disclosures, Information About Online Advertising" (May 2000).
[23] *Id*

information in the language on the landing page of the sponsored link. If warranted based upon research on consumer cognition, BIO believes that a reasonable alternative to having the product risk information one click away would be to briefly flag the risk information in the sponsored link language. For example, a sponsored link advertisement could state the product name; include a reasonably inclusive indication statement; and then a directive for the user to see full product use and product risk information.

For example:

> Drug X Brand name
> For treatment of condition XYZ
> See full product information and warnings. www.DrugX.com

The link could then provide direct access to consumer-oriented labeling. Another option would be to include a link from each section of the advertisement, so the indications for use section would link straight to complete use information and the warnings section could link straight to complete risk/warning information. BIO believes that this approach would be user friendly and uncomplicated. Fair balance would be met within the language of the sponsored link as well as in the more complete labeling language that would be one click away from the landing page. This approach could potentially work for other media with a limited amount of space, or a limited number of characters, such as twitter, and would be consistent with FDA's recognition of the appropriateness of tying the amount of language about a product's efficacy to the amount of risk information.

For advertising in a medium that has more space available, manufacturers could include a comparatively lengthier, more detailed statement of efficacy**,** balanced by a more detailed risk statement.

For example:

> Drug X for treatment of condition Y
> Helps relieve the symptoms A and Z
> Warning: Do not take if you are or may be pregnant. See full product information and warnings. www.drugx.com

Using this approach, the risk information provided on the landing page could be contextually tied to the efficacy claim—*i.e.* a specific claim would be balanced by the risk information pertinent to that claim.

c) What parameters should apply to the posting of corrective information on Web sites controlled by 3rd parties?

As discussed above, a manufacturer should only be responsible for correcting Internet content on a website that is within its control and should not be responsible for monitoring or correcting content on other websites. Further, correcting third party content where the

company does not otherwise have control of a website should be acceptable without triggering responsibility for monitoring subsequent or surrounding content-- precisely because of that lack of control. Moreover, corrective information posted on a third-party website should also not be considered promotional advertising or labeling, but should be subject to a requirement that the information not (i) be false or misleading, or (ii) cause the content on the third-party website to be false, misleading or lack fair balance.

d) When is the use of links appropriate?

Given the advances in and widespread use of technology by health care providers and patients, manufacturers of biopharmaceutical products have responded by sponsoring product and disease-state-specific websites providing easy access to important information about biopharmaceutical products and the diseases they are designed to treat. BIO member company websites frequently include hyperlinks to external websites as resources that may be of interest to users. By choosing to include hyperlinks to external websites, manufacturers do not alter the independent nature of such websites. Unlike the content of manufacturer's own websites, manufacturers do not control the content of the external websites. Accordingly, FDA's labeling regulations should not apply to such content.

Provided that a manufacturer does not use links to such sites for the purpose of circumventing otherwise applicable regulations, biopharmaceutical companies should be able to link to them without triggering FDA regulations or responsibility on the part of the company to monitor independent websites. As a precaution to minimize these risks, the following factors can be considered:

- Notifying the user that he or she is leaving the company site before enabling the user to link into the external website;
- Disclosing to the user that the site is independent of the company (if accurate); and
- Notifying the user that the third party site may contain information or claims that have not been evaluated or approved by the FDA and that the user should consult www.FDA.gov or product prescribing information for approved use and dosage information.

e) Questions specific to Internet Adverse Event Reporting

BIO believes that the existing regulations for adverse event reporting[24] are adequate as they apply to Internet and social media applications. Manufacturers are required to report adverse events that come to the manufacturer's attention through normal business processes if the adverse event information meets the four basic elements for submission of an individual case safety report. As specified in FDA's Draft Guidance on Postmarket Safety

[24] 21 CFR sections 310.305, 314.80, 314.98, 514.80., 600.80, and part 803

Reporting [25] manufacturers should, at a minimum, have knowledge of: an identifiable patient, an identifiable reporter, a suspect drug or biologic, and an adverse experience or fatal outcome suspected to be due to the suspect drug or biologic.[26] These factors apply regardless of the medium by which the information is found. The Draft Guidance on Postmarket Safety Reporting specifically states that manufacturers should review any Internet sites they sponsor for adverse experience information, but are not responsible for reviewing Internet sites that they do not sponsor. It further states that if a manufacturer becomes aware of an adverse experience on an Internet site that it does not sponsor, the adverse experience information should be reviewed to determine if it should be reported to FDA. BIO agrees that while sponsors should monitor their own websites for potential adverse events, they cannot monitor those that are out of their control, and should not be responsible for scouring or policing the Internet in search of reportable adverse events. It would be useful for FDA to clarify and confirm this understanding.

Consistent with these policies, BIO notes that challenges occur in the context of Internet and social media when the identity of a patient is undetermined. In these situations, information would not be reportable without an "identifiable patient". Further, information obtained by a manufacturer regarding a potentially reportable event should be considered non-validated until the event can be confirmed through contact with the reporter. The definition of "identifiable reporter" should be "an individual that is privately contactable", *e.g.* provides an associated email address.

To address some of these challenges, BIO believes that it may be useful for manufacturer-sponsored websites to prominently present information for users regarding how to report an adverse event, either by use of the Internet or by referring the user to a toll free number, and providing clear instructions so that adverse events can be properly reported.

Conclusion

BIO appreciates your consideration of these comments regarding *Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools* and looks forward to FDA's efforts on these issues. If you have any questions, please feel free to contact me at 202-962-6673.

Sincerely,

Sandra J.P. Dennis
Deputy General Counsel for Healthcare
Biotechnology Industry Organization (BIO)

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[25] FDA, Draft Guidance for Industry: "Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines" (March 2001) ("Draft Guidance on Postmarket Safety Reporting")
[26] *Id.*