



February 24, 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 Internet presents unique opportunities to advance public awareness of disease and the medical options available to patients. At the same time, the Internet poses challenges, not least the fast pace of change in communications channels, technical usability and peoples' preferred sources of information.

Novartis Pharmaceuticals Corporation welcomes the opportunity to respond to the questions raised by the Food and Drug Administration (FDA) around the use of Internet and social media applications in healthcare. The FDA's public hearing and its invitation for written comments by all stakeholders should help the Agency determine appropriate steps forward that best serve the needs of patients.

About Novartis

Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides healthcare solutions that address the evolving needs of patients and societies. Focusing on unmet medical needs inspires us to connect science with customer and patient insights to develop new products and drive industry standards. Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products.

Growing influence of the Internet

Based on research we glean from Pew Research, Nielsen Buzz Metrics and other experts, we consider the Internet to be an influential source of health information for patients, healthcare providers and caregivers. Broadband technology and the Internet have 'democratized' information by enabling anyone with a computer to develop and publish information. This information is much more easily found and shared thanks to advances in 'search' and the increasing use of social media.

Research shared at the FDA's public hearing suggests people are using the information they find on the Internet to inform healthcare choices and decisions. We believe it is therefore essential that industry and public-sector organizations be able to assist patients, caregivers and physicians in accessing accurate and high-quality information.

A commitment to education and outcomes

The Internet offers industry and the public sector a powerful platform to explain disease and available treatment options. In our view, the key question will remain how to differentiate between a commitment to educate from an intent to promote.

In addressing the FDA's questions Novartis wishes to show its support for the Agency's request for input and to communicate our commitment to the appropriate use of the Internet and social media.

Answers to FDA questions

1. For what online communications are manufacturers, packers, or distributors accountable?

Manufacturers should only be held accountable for those online communications which they directly own or control.

Many not-for-profit/patient advocacy groups provide online communications to the public as a public service. Many times, manufacturers provide funding to these not-for-profit/patient advocacy groups. Generally, the funding is made through an agreement that specifies that the manufacturer will not have any control over content nor is the funding for the purpose of promoting the company's products.

It is imperative that manufacturers be able to continue supporting not-for-profit/patient advocacy groups financially without the threat of being held accountable for something that, contractually, the manufacturer has disclaimed. The funding provided by manufacturers furthers patient education about disease awareness and furthers the efforts of these organizations to provide support for patients. The Agency should not equate "sponsoring" with control. Unless a manufacturer owns a site or otherwise knowingly exerts control over that site, the manufacturer should not be held accountable for that site's content.

Nevertheless, a manufacturer (as well as the site) should be transparent about any funding provided to the owner of the site. For example, the site may state "X Manufacturer has provided funding" for this site. In addition, the manufacturer should enter into an agreement with the owner of the site setting forth the terms under which the funding is provided. The agreement should specifically state that the manufacturer has no control over content and that the funding is not provided for the purpose of promoting any of the manufacturer's products.

Novartis agrees that if a manufacturer owns a site or otherwise controls the content of a site, then it should be held accountable for that content. Similarly, if a manufacturer engages a vendor to create a site for the benefit of manufacturer, then the manufacturer should be accountable for the content of that site.

But merely linking to a third-party site should not make the manufacturer responsible for that site. For example, certain of Novartis' product sites provide links for patients to other resources (e.g., American Heart Association, Susan G. Komen Foundation). Such linking is done with a disclaimer pop-up:

You are now leaving the [Brand.com] site and moving to an external website independently operated and not managed by the Novartis Pharmaceuticals Corporation. Novartis assumes no responsibility for the site. If you do not wish to leave this site, click Cancel. Or, click OK to continue.

By having such a disclaimer, the manufacturer is making clear that it does not own or otherwise exercise control over the content of the third-party site. Consequently, the manufacturer should not be accountable for that site.

2. 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)?

Please see our response to question 4

3. What parameters should apply to the posting of corrective information on Web sites controlled by third parties?

Given the enormity of the social media universe, manufacturers should not be obligated to monitor and correct information regarding their products on web sites controlled by third parties. However, given the increasing importance of such media to patients as a source of health information, neither should manufacturers be penalized for seeking to correct misinformation of which they come to learn. Any such corrections must comply, to the extent reasonably possible, given the medium, with applicable promotional and other regulations. Should the manufacturer's corrections be subject to further revisions or misstatements by third parties, FDA should not penalize the manufacturer for not engaging in a futile effort to further correct the corrections.

4. When is the use of links appropriate?

We believe that Questions 2 and 4 are connected. Given that information is being shared and discussed in shorter, more mobile information delivery tools, both the concept of fulfilling regulatory requirements and patient education are best served by the use of short, understandable links. We ask that the FDA consider the following suggestions as they may be opportunities to make patient safety, education, and prescription information easily accessible from these limited-space environments.

Information will be shared by non-industry entities through the Internet with or without the involvement of manufacturers. We support a view that manufacturers should be permitted to provide reliable information to the public about products and disease so long as the communication is done for educational purposes, as opposed to promotional purposes. If our communication is to be heard through the chatter and noise of the Internet then content will need to be compelling, portable and compatible with the Internet and Social Media.

More recent Social Media channels impose character and space limitations – for instance a message on Twitter – a 'Tweet' – is limited to 140 characters; and on Facebook people typically communicate through short, frequent messages.

To save on space, people use tools like tinyurl.com or bit.ly to shorten long, complicated website addresses, or URLs (Universal Resource Locators). For example, using the

URL-shortening tool bit.ly, the full URL for the website Medwatch (www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm) is shortened to: bit.ly/bW5WC. Thus, this shorter URL would take a user to the same Medwatch website as the standard longer address would. Fifty-nine characters become twelve.

Our first recommendation then is focused on how manufacturers can draw attention to product-safety information and ensure fair balance in short Internet communications. We believe a tool could be developed to shorten the URLs for product-safety information but still drive public awareness. A new short URL, essentially a bit.ly for the FDA, that points to drug information on an FDA controlled website could be set up. Our recommendation is that the URL include a mention of “safe” or “safety.” This website could then contain prescribing information and important safety information wholly controlled and approved by the FDA, removing the need for multiple, additional reviews by an FDA committee of language used on the Internet. One review, many uses.

With regard to fair balance, disclosure of indication and risk information, we see an opportunity to assist the public in search and clarity of message. People search for health information through Google, Bing and Social Media channels such as Twitter and Facebook. The FDA might consider establishing a set of search terms that are in the interest of public health and the FDA’s compliance agenda. These terms can be assigned a hashtag (“#”). Widely recognized by Social Media users, hashtags communicate and make it easier for people to find information.

As an example, a manufacturer putting out a disease or product awareness message could then include in the message tags such as #[disease state], #usonly and #blackbox to alert patients and physicians to important aspects of the communication. It also assures the FDA that appropriate patient education steps are being carried out.

Having these search terms added should not, however, be permitted to become an undue burden on the message itself. The benefit of a short message can become somewhat lost if it is buried in a stack of agency-required hash tags.

The FDA and manufacturers should be aware that a message that is created for the distribution of information may be redistributed by the public with or without some of the hashtags or shortened URLs initially created. Manufacturers should only be held responsible for messages that are created or repurposed by people in their employ or under their control, i.e. agencies, employees, or other agents of the company.

The proposals in this answer are designed to enable manufacturers to communicate compelling educational information that is portable through Social Media at the discretion of the public user. Further, these suggestions recommend that links are appropriate, and their use is compelling in disseminating fair balance and safety information through Social Media. We would recommend that these, and any, suggestions be tested with relevant audiences to understand what approach best communicates a balance of benefit and risk.

5. Questions specific to Internet adverse event reporting

a. Manufacturer’s obligation to monitor its own social media programs

We fully agree that manufacturers should have policies and procedures to monitor their own social media programs for potential adverse events. Qualifying reports must be collected and handled per 21 CFR 314.80, Postmarketing reporting of adverse drug experiences. FDA social media policy should reflect this obligation and also make clear that manufacturers do not have a regulatory obligation to monitor sites they do not control. Rather, manufacturers should only be required to conduct systematic adverse event monitoring of their own social media programs. See response to Question 1 re control.

b. Manufacturer's obligations concerning third-party tools that are permanently linked to its own social media programs

New Internet applications such as "Sidewiki" allow external parties to permanently attach tracking or comments pages to a manufacturer's social media programs without the manufacturer's consent. Comments may be posted by anyone and content is not controlled or funded by the manufacturer. We believe that manufacturers have no regulatory obligation to monitor such content under current statutes, although they may wish to do so for informational purposes. For regulatory purposes, these sites should be considered "third party".

FDA guidance should stipulate that a manufacturer has no obligation to monitor these sites.

c. Manufacturer's obligations when systematically monitoring external (third-party) social media programs

We believe that manufacturers have no regulatory obligation to monitor such content under current statutes, although they may elect to voluntarily monitor third-party sites to glean further insight on how their products are perceived and used in the marketplace.

We acknowledge that a manufacturer or contracted vendor acting on the manufacturer's behalf may opt to conduct extensive data mining of electronic media to gather such information. These programs can identify vast numbers of comments that do not contain an identifiable reporter, patient, drug or adverse event.

Manufacturers should ensure there are mechanisms in place for identifying reportable cases meeting the four criteria so that these cases can be routed to the company's pharmacovigilance department for evaluation.

d. Manufacturer's obligations when inadvertently identifying a potential adverse event on an external (third party) social media program

Adverse events may be posted by organizations or individuals on private homepages or websites, or in other third-party forums such as "chat rooms" or "bulletin boards" where people can post their own unfiltered comments or participate in discussions. In the event that a manufacturer does not actively monitor such postings, it is possible that the manufacturer's employees may inadvertently access sites that contain potential adverse event information. Employees have an obligation to forward these reports to the manufacturer's pharmacovigilance department for evaluation.

Manufacturers should ensure there are mechanisms in place for identifying reportable cases meeting the four criteria so that these cases can be routed to the company's pharmacovigilance department for evaluation.

e. Definition of an Identifiable Reporter

We believe the definition of "Identifiable Reporter" in the FDA's August 1997 Guidance: Clarification of What to Report, fails to cover social media reporters adequately.

It is normal in social media that individuals choose to remain anonymous or will use a screen name or pseudonym. In these instances it is rarely possible to correspond with an individual who has made reference to a potential adverse event. We believe the FDA's definition should be expanded to specifically include this category of reporter.

We propose the following inclusion to the FDA's planned guidance: An identifiable reporter must be privately contactable – for instance, it is possible to readily communicate directly

with the reporter without posting questions to a public forum/environment to obtain more information. An e-mail address without any further identifying information (such as a name, address or phone number) should not constitute an identifiable reporter and a lack of further information (such as age or gender or relationship to the reporter for an identifiable patient) does not constitute an identifiable patient.

f. Solicited vs. spontaneous designation for adverse events?

There is no regulatory guidance on whether adverse event reports (meeting the four criteria for reportability) received through social media are defined as solicited or spontaneous. Under 21 CFR 314.80, this has an important bearing on reportability.

In general, we believe that qualifying adverse event reports – meaning all 4 case criteria are met – made to a manufacturer’s social media program can be either spontaneous or solicited, depending on whether or not the program format actively encourages patients to describe their experiences with a drug. Manufacturers should have the flexibility to determine which category applies to individual social media programs.

We believe that qualifying adverse event reports detected through systematic monitoring of permanently attached third-party links and third-party social media sites are part of a systematic data collection scheme. As detailed in the August 1997 Guidance: Clarification of What to Report, these reports should be treated as solicited, and therefore are subject to manufacturer causality assessments and to the related FDA reporting paradigms described in 21 CFR 314.80.

We believe that qualifying adverse event reports inadvertently detected by company employees accessing third-party social media sites should be handled as spontaneous reports.

g. Manufacturer's obligations when detecting a potential adverse event with another manufacturer's product

Current FDA guidance on dealing with reports of “another applicants drug” were written in 1992. Instructions are vaguely worded and have led to a variety of practices within industry. The Agency’s social media guidance represents an excellent opportunity to correct this deficiency by clarifying responsibilities.

Adverse events with another manufacturer’s product should only be forwarded to that manufacturer by the receiving company if:

- The report meets the four minimum criteria for a reportable adverse event.
- The report was actively submitted to the manufacturer by e-mail or by posting on a manufacturer-owned social media application. (This rule could also be expanded to include telephone and postal contacts, thereby clarifying manufacturer obligations for these more traditional media as well).

For all other adverse events detected through passive monitoring of electronic media, FDA guidance should stipulate that it is not the responsibility of a manufacturer to collect and forward adverse event information detected with another manufacturer’s product.

We look forward to the Agency’s next steps with respect to Social Media, and appreciate the opportunity to provide these comments.

Respectfully submitted,

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