

**Promotion of FDA-Regulated Medical Products
Using the Internet and Social Media Tools
Public Hearing
November 12-13, 2009
Eli Lilly and Company Comments**

Good morning. My name is Michele Sharp. I am a Senior Director of U.S. Regulatory Affairs at Eli Lilly and Company. I am speaking on behalf of Lilly and thank you for the opportunity to participate in this meeting.

Over the next two days, you will be hearing from more than 60 speakers on various aspects of Internet promotion, especially focusing on social media tools.

While Lilly has robust experience with Internet promotion, most of the other speakers have, frankly, a longer history and more direct experience around social media.

So why are we here?

First, because there are still important unanswered questions around Internet promotion, and we believe FDA action on those issues would benefit the public health. And second, because we believe it's important for you to hear from companies like us about what has kept us from more active engagement in social media.

The Internet is an increasingly important tool for consumers and healthcare professionals looking for answers to healthcare questions, including pharmaceutical product information.

The FDA, in its strategic plan for risk communication, recognized the need to better understand how the Internet can be used to communicate accurate and timely information to consumers and healthcare professionals.¹ That's consistent with the FDA's stated responsibility for "advancing the public health by ... helping the public get the accurate, science-based information they need to use medicines and foods to improve their health."

Pharmaceutical manufacturers are well positioned to provide accurate, scientific product information and related resources online, but we are looking to FDA's leadership – through Guidance or executive channels – for the most appropriate means to provide critical disease state and product information via the web. Through such action, we may both achieve our common goals.

At Lilly, we believe we can and should play a significant role in providing patients not only pharmaceutical solutions, but information and support to help them make healthcare decisions that will have a positive impact on their lives.

To be successful with this vision, we must be visible and relevant in the places where patients, physicians, caregivers and payers are looking — where they are searching for, obtaining and sharing information on diseases and treatment options. These days, that includes the Internet and social media.

¹ FDA's Strategic Plan for Risk Communication. Fall 2009.

Through the Internet, patients now have new avenues and incentives to search out information on diseases, on diagnoses, and on treatments. Every day, patients are taking more and more ownership of their healthcare decisions and the healthcare decisions of their loved ones. Therefore, they are actively seeking information and educating themselves in an effort to make better choices. Where historically people turned to immediate family, close friends and neighbors for advice, they now are adding Internet-based social networks.

Social media allow individuals to find and support each other on a mass scale that's not limited by time or geography. Patients support each other by sharing their experiences and opinions – resulting in the generation of new information.

In the past, social interactions were limited by geography and time – with individuals gaining 'trust' of others and the healthcare advice or information they receive through personal relationships. That's still true, but relationships are now more distant and numerous, which adds a level of volume, complexity, and immediacy of information that provides both significant benefits and risks.

The benefits include the readily available and rapidly growing quantity of information available about any particular disease area and its potential treatment options. The risks include the varying levels of substantiation and accuracy the information may have. Many consumers will be forced to "sort" out the relevancy and accuracy of this information themselves – preferably in partnership with their healthcare provider.

In considering what actions should be taken to help consumers and their healthcare providers in making thoughtful decisions, FDA should also take into account the unintended consequences of either, 1) providing no further guidance to the pharmaceutical industry, the uncertainty of which keeps industry on the sidelines, or 2) imposing too many, or overly confining, restrictions on industry, which could silence an important voice in the chorus.

Currently, numerous unregulated sources are significantly contributing to the body of healthcare information on the web with what is often inaccurate, incomplete or imbalanced information, as well as supplying misbranded and potentially counterfeit medicines to U.S. consumers. With support from FDA via appropriate regulatory mechanisms, the pharmaceutical industry could more effectively balance and otherwise address these concerns with regulated content and help patients achieve better outcomes.

Frankly, to date, Lilly has avoided significant interaction with healthcare professionals and patients about our products in social media forums – largely because of a lack of clarity in understanding FDA's expectations as to how we could participate and comply with FDA requirements.

We did recently launch a blog on Medscape, written by our U.S. medical team, to share information with physicians. Participants are allowed to post comments, either about our blog post or about each other's comments. That's the essence of social media, after all – the ability to share information, experiences and opinions with others in the community. We are pre-screening all comments, however, and declining to post any that mention a product, for two main reasons.

First, it's unclear what our "fair balance" obligation would be if we allowed such posts, and how to meet that obligation within the limited constraints of a blog or other social media vehicle. The warning letters sent earlier this year around paid search ads have only heightened this uncertainty. Second, we are

concerned that if we allow product discussions, they could easily stray into off-label subjects, potentially resulting in accusations of off-label promotion.

Google's Sidewiki is another recent example. As you may know, Sidewiki essentially creates an independent Web site – over which we have zero control – allowing people to comment on the Web site to which the Sidewiki is attached, including our product Web sites. Comments on some sites have included seemingly fabricated adverse events, inaccuracies and other items of concern. Site owners can claim “first comment” position, but we have avoided this in part because it's unclear whether this would make us responsible for all the comments – including off-label comments – posted on that Sidewiki page, even though we can't control them.

Within Lilly, we have identified and debated many of the same questions posed in the Federal Register notice for this hearing. We do not purport to have definitive answers to the questions or solutions to all the issues. However, we would appreciate the opportunity to engage in further discussion with the Agency and other stakeholders.

We would recommend that FDA lead a series of public workshops, perhaps similar to the recently conducted workshop on Improving Communication with Patients. The public workshops could collectively generate ideas, leverage the knowledge, expertise and experiences of the participants and work toward viable solutions, so that FDA can provide the detail and clarity to the pharmaceutical industry and others through Guidance or executive channels. This approach allows for accurate, balanced and timely information to be in the most relevant places for patients and healthcare professionals.

We also recommend that the FDA create ongoing working groups, with representatives from a wide range of stakeholders, to help the agency address emerging technologies and issues on an ongoing basis in this rapidly changing space.

In closing, the flow of information to patients and healthcare providers has opened, and cannot be closed again. All stakeholders in this arena would benefit from FDA's leadership here. Thank you again for the opportunity to participate in this important discussion.