

12/1/2010



ASTRAZENECA

WHITE PAPER: SOCIAL MEDIA IN THE
PHARMACEUTICAL INDUSTRY

Introduction

During this period of uncertainty in social media engagement for the pharmaceutical industry, AstraZeneca sought feedback on our submission to the Food and Drug Administration (FDA) Call for Comments—not from the FDA—but from a variety of active participants in social media. This white paper is a report of this feedback and provides unique insights into the beliefs of various stakeholders about how pharmaceutical manufacturers have engaged in social media and how they should engage, while also suggesting approaches for FDA regulation.

While this is not a traditional “white paper,” social media is not traditional media, and it seems only appropriate that this paper is in many ways simply the continuation of a broad conversation initially started in 2009 with the FDA’s Public Hearing on Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools.

Developing a White Paper on Social Media through Social Media

Through our response to the FDA Call for Comments submitted in February of 2010, AstraZeneca had the opportunity to provide its views on the future of pharmaceutical engagement in social media to help shape FDA’s anticipated guidance. Certainly, the forthcoming FDA guidance will have an impact on pharmaceutical engagement in social media. However, participants in social media—general thought leaders in the online, regulatory, health and industry sectors—will also have an important influence on pharmaceutical engagement as well as being influential in shaping participation of the pharmaceutical industry in social media.

While the pharmaceutical industry waits for clearer guidance from the FDA, AstraZeneca has continued to refine its views by seeking feedback directly from a cross-representation of online community participants on our submission to the FDA’s Call for Comments that contained both our principles and proposed regulatory framework. This feedback guided this white paper that addresses expectations for both the FDA and the pharmaceutical industry regarding the use of social media. This white paper also contains a constructive review of AstraZeneca’s social media principles and proposed regulatory framework.

What is Social Media?

Social media is the catch-all term for internet activities that engage or encourage engagement through online discussions or interactions. While static websites are often the first “online step” for many companies (e.g., homepages), the internet is becoming increasingly about active engagement and interactions—whether through blogs, microblogs (Twitter), listservs, chat rooms, forums, multimedia posting (YouTube), or social networking (Facebook).

Health information remains a hot topic on the internet. A June 2009 study by the Pew Internet & American Life Project found that 61 percent of American adults search online for health information and that 41 percent of these “e-patients” have read someone else’s commentary or experience about health or medical issues on an

online newsgroup, website or blog. These online health consumers gather, share and use a range of tools when evaluating treatment options. The value of these engagements is as varied as the sources of healthcare information – from restricted physician group sites to alternative healthcare marketers to litigators. In many ways, the internet remains a “wild west” of information and misinformation.

Pharmaceutical Manufacturers & Social Media – Varied, Though Generally Cautious, Approaches

While numerous industries have embraced these new communication channels – including a wide variety of healthcare-related companies – pharmaceutical manufacturers have remained cautious about their engagement in social media. The industry’s limited involvement can be attributed to two factors:

- 1) Established FDA regulations and guidelines and industry standards for pharmaceutical marketing fail to adequately address the realities, both in terms of opportunity and risk, presented by these new and fast evolving communication channels; and
- 2) Inconsistent enforcement of existing rules in the online environment has left many pharmaceutical manufacturers hesitant to fully engage in these important spaces.

Despite the lack of guidance and clarity, most major pharmaceutical manufacturers engage in social media for product promotion, disease/health awareness and corporate affairs purposes to varying extents.

FDA Call for Comments

In late 2009, the FDA announced its intention to issue guidance to companies on its approach to regulating the promotion of FDA-regulated medical products on the internet and through the use of social media tools. In preparation for this guidance, the FDA held a public hearing from November 12-13, 2009 and simultaneously put out a Call for Comments with a February 28, 2010 deadline. At the November hearing, a range of online participants testified including patient groups, consumer groups, trade association representatives and online content providers. As of the date of this white paper, the guidance is still forthcoming.

AstraZeneca’s Response to the FDA Call for Comments

In the fall of 2009, AstraZeneca formed an internal Social Media Team to consider the commercial, legal, policy, political, regulatory and safety implications of social media engagement. The team began with a careful assessment of where AstraZeneca currently was and where AstraZeneca wanted to go with its social media activities. The AstraZeneca Social Media Team then set out to develop principles that would be central to AstraZeneca’s response to the FDA Call for Comments. The principles were proposed as a high level roadmap to the FDA that would underpin the specific guidance to be developed by the FDA and would, together with an assessment of the regulatory environment and the risks and benefits of any individual situation, guide AstraZeneca’s engagement in social media – whether related to corporate affairs, disease awareness or product promotion.

The five principles proposed by AstraZeneca are as follows:

- To Ensure Truth and Accuracy. Guidance should direct product sponsors to ensure that any content created, developed, or made available by them in social media is truthful, balanced, accurate and not misleading.
- To Be Respectful. Guidance should encourage product sponsor participation that respects the interests of patients, caregivers and health care providers, particularly related to matters of privacy and the primacy of the patient/physician relationships.
- To Protect and Advance Patient Health. Guidance should facilitate patient access to quality information that they can use with their physician to improve their health and protect through encouraging accurate and timely reporting on medicine safety.
- To Be Transparent. Guidance should require that any product-sponsored participation be accomplished in a manner that, at all times, is entirely transparent to other participants about the product sponsor's role in the online discussion.
- To Respect the Views of Others. Guidance should respect that patients, caregivers, clinicians and others who participate in social media have their own opinions and that, when they differ from those of the product sponsor, it is not the role of a product sponsor to censor or limit these views but to add the product sponsor's own views to the discussion.

In addition to these principles, AstraZeneca also recommended that the FDA consider a regulatory framework that defines, distinguishes and distinctly regulates three types of communications on the internet and in social media. The framework would tie pharmaceutical manufacturer accountability for web content to its control over the content. The proposed framework is based on the following categories:

- Company-controlled, hosted online communications. Such communications would be defined as communications placed on websites and other online properties that are under the control of a product sponsor. Pharmaceutical manufacturers would have the most accountability for this type of activity.
- Company-controlled communications. Such communications would be defined as communications that a product sponsor places or provides for use by websites and other online properties that the sponsor does not control and where such communications are used in the form, manner and context for which the sponsor provides it. Pharmaceutical manufacturers would be held responsible for the content provided.
- Real-time, social media participation communications. Such communications would be defined to include company real-time, social media interactions on websites and online forums that are not company controlled. Such communications typically occur in chat areas, comment areas or as an

integral part of the website operation. This would have the least level of accountability for pharmaceutical manufacturers.

Stakeholder Feedback

Given the interactive nature of social media, developing a white paper built on discussion and feedback seemed most appropriate. AstraZeneca began the dialogue through two interactive sessions in fall 2010 – one in New York and one in Philadelphia.

“That’s the crux of why we’re here, because AstraZeneca really wants to learn from you and hear your views on how we can continue to advance the conversation, advance engagement, as well as hear your views on OUR views.” – AZ representative

AstraZeneca’s Social Media Roundtable & Digital Pharma East

On October 14, 2010, AstraZeneca held a roundtable focused on “Examining the Roles of the FDA and the Pharmaceutical Industry in Social Media” in New York. The meeting was facilitated by Google Health and participants included a number of influential health bloggers and online thought leaders. The meeting sought specific feedback on AstraZeneca’s principles and regulatory framework and included an open and frank discussion about the role of the FDA and the pharmaceutical industry in social media.

A few days after the roundtable, AstraZeneca raised these discussion points at a broader gathering of health bloggers and digital stakeholders at Digital Pharma East (DPE) in Philadelphia. Once again, participants shared their opinions about the FDA and pharmaceutical manufacturer engagement in social media.

The remainder of this white paper summarizes and addresses key discussion points that stemmed from both the Social Media Roundtable and DPE. The paper will conclude with AstraZeneca’s key messages and actions that will help define our path forward in the digital space.

Key Discussion Points

Early on in the group discussions at both meetings, two themes emerged and were revisited with some frequency:

- Social media is a fundamental part of advancing public health; and
- Pharmaceutical manufacturers have a responsibility to engage more fully in social media.

These two themes were evident in the discussions and are set out in more detail in the key points below that revolved around both the role of the FDA as social media regulator and the role of the pharmaceutical manufacturer as an information provider and information seeker in social media.

The Role of the FDA

Participants¹ at both the roundtable and DPE turned first to the role of the FDA, discussing its mission and goals, and identifying several considerations for the FDA in its development of social media guidance. Key discussion points and recommendations included the following:

- ***New Media.* The FDA should recognize that social media is a new communication channel that both distinguishes and can appear to intermix the dissemination of information and advertising in the digital space.**

Participants defined social media as a unique forum for online dialogue that ultimately requires a specifically tailored, yet sufficiently flexible regulatory approach. To appropriately regulate in this space, the participants noted that the FDA should acknowledge that existing rules may not always work for new or emerging technologies and communication channels. They also encouraged the FDA to be flexible in their approach – to allow for adjustments to address not just the demands of technology, but that also consider the evolving needs of other stakeholders, including patients and caregivers.

- ***FDA Mission.* The FDA’s mission includes protecting drug safety and promoting public health, two aims that pharmaceutical manufacturers are in a position to help with when it comes to social media.**

Participants were generally comfortable with the FDA’s role as a regulator in social media, but would encourage the agency to work more closely with those impacted by their regulatory efforts. Arguably, drug manufacturers are in the best position to provide accurate and thorough information about their medicines. Yet, there is a lot of “bad” information – including inaccurate or misleading information – that affects all web users that come from sources other than manufacturers. Participants felt strongly that it would behoove the FDA to work with the pharmaceutical industry to help balance the “bad” information. In other words, pharmaceutical manufacturers can be a valuable source of accurate information that can help clear up confusion and promote better public health.

“Because let’s face it, before there was online information, you went to a pharmacy, you picked [prescriptions] up, you may or may not have read your insert. You may or may not have understood what it said. So, I think they [FDA] are starting to look at that [social media] and say ‘Wow, patients are actually interacting with safety information in a much more effective way...’” – Roundtable participant

¹ “Participants” refers to attendees at both the Social Media Roundtable in New York City and Digital Pharma East in Philadelphia.

- ***Shades of Gray.* Regulating social media will mean the FDA will find itself addressing many “shades of gray.”**

Social media does not always lend itself to black and white decision making in determining what should be permissible and acceptable for online engagement. Participants agreed that the FDA should recognize that not everything in social media is easily categorized and allow for a “gray zone” in how pharmaceutical manufacturers engage in this space. In other words, the FDA should consider being flexible in its approach and application of regulations.

“[The FDA is] not quite sure where the gray zone is between what exists between regulated speech and unregulated speech.” – Roundtable participant

- ***Patient/Caregiver Voice.* Patients/caregivers have emerged as major players in social media both as providers and seekers of information.**

Participants recognized that the emergence of the patient/caregiver as a key player in social media is game-changing in how information is sought, provided and shared in the online environment. Given the perspective of the patient/caregiver as having both a desire and right to accurate information on pharmaceutical products, this should be a critical factor for the FDA to consider when regulating in this space. More than ever, patients are seeking more individual control over their health and desire more in-depth information about their health to enable them to make informed decisions.

“...the FDA’s new role should be to promote the conversation instead of strapping or blocking it.”
– Roundtable participant

“The FDA has to change the way they think of regulations. You now have millions of people that are really empowered and...[the FDA should not]...treat us as if we are people who don’t understand anything about science, about treatment.” – Roundtable participant

- ***Shared Dialogue.* The FDA should be encouraged to engage with the pharmaceutical industry to help them research and resolve issues raised in social media.**

Social media by its nature is interactive and participants considered that perhaps the FDA should embrace the interactive nature of social media in its own engagement with pharmaceutical manufacturers by acting as a sounding board for new ideas and the development of best practices. For example, participants discussed the benefits of the FDA’s encouraging “best practices” among pharmaceutical manufacturers by providing guidance not just when

companies overstep or make mistakes in their online engagements, but when companies are acting appropriately.

The Role of Pharmaceutical Manufacturers

In addition to sharing their perspectives on the FDA's role, participants also discussed their perspectives on the role of pharmaceutical manufacturers in social media. Key discussion points and recommendations included the following:

- ***Ongoing Dialogue.* Social media is a two-way opportunity for communication between pharmaceutical manufacturers and patients/caregivers.**

As discussed earlier, many pharmaceutical manufacturers have been reluctant to engage in social media in the absence of a focused FDA guidance. While participants had varying degrees of understanding as to why pharmaceutical manufacturers are at times reluctant to engage in social media, they agreed that social media could be viewed as an opportunity for the pharmaceutical industry to engage in a positive way with individuals who take their products. There was also a belief that the pharmaceutical manufacturers were likely in the best position to know the most about their own products and patients want them to share their knowledge.

Participants also noted that pharmaceutical manufacturers should be more transparent about their decisions to engage or not engage in social media. If the decision to not engage in social media is because of uncertainty related to regulatory action, patients/caregivers want to know that..

“... [pharmaceutical manufacturers should] collectively help consumers understand a little bit better why they are and aren't engaging in certain places.” – Roundtable participant

- ***Mutual Agreement/mutual Benefit.* Pharmaceutical manufacturer engagement in social media should be based on mutual agreement and mutual benefit with patients/caregivers.**

Social media may be an opportunity for pharmaceutical manufacturers, but it could be a lost opportunity if the pharmaceutical industry does not take the time to ask and understand what patients/caregivers want and expect from this type of engagement. Participants urged pharmaceutical manufacturers to consider implementing a process for seeking ongoing feedback from patients/caregivers as the industry continues to change and tweak its social media engagements. From this process – whether an informal survey or formal advisory panel – participants saw this as an important means of helping the pharmaceutical industry determine the best way to engage in this space in the best interests of patient health.

“The business [for pharmaceutical manufacturers] is providing value to patients and doing marketing that has more relevance and listening to what's going on and understanding what our patients' lives are really like, what unmet needs they have, what concerns they have that aren't being answered by the channels that we're pushing out in. That's the business.”
– Roundtable participant

- **Policies.** Pharmaceutical manufacturers should develop social media and ethics policies that best reflect their understanding of why they are engaging in social media.

Participants encouraged pharmaceutical manufacturers to assess their intent to become active using social media and whether it was for product promotion, enhancing corporate reputation or advancing public health. From there, companies can—and should—develop policies that are transparent, practical and in the best interests of patient health.

- **Adverse Events.** Pharmaceutical manufacturers should be explicit about their policies for monitoring and addressing adverse events.

Pharmaceutical manufacturers must report adverse events to the FDA when there is an identifiable patient, reporter and suspect drug. However, these current requirements cannot always be neatly applied in social media and pharmaceutical manufacturers are often uncertain as to requirements for handling safety data that appears in this media.

Participants called for pharmaceutical manufacturers to have explicit policies for monitoring and addressing adverse events that are transparent and clear. This was viewed as a necessity for the pharmaceutical industry given the opportunity social media presents for the early identification of adverse events.

“I speak with the regulatory lawyers from all of the major pharmaceutical companies. I can tell you I’ve never heard this statement—‘we don’t want to hear adverse events.’ There’s a thirst for more precision in the requirements.” - Roundtable participant

Participant Feedback

In addition to general discussion about the roles of the FDA and the pharmaceutical industry in social media, participants were asked for specific feedback on two aspects of AstraZeneca’s submission to the FDA Call for Comments: AstraZeneca’s principles and recommended regulatory framework.

- **Principles**

AstraZeneca’s five principles set forth above were viewed as a good starting point for appropriate pharmaceutical manufacturer engagement in social media. However, participants also considered the principles as more of a floor, rather than a ceiling, and encouraged AstraZeneca to be open to revisiting our principles as social media continues to evolve.

➤ **Regulatory Framework**

The FDA's Call for Comments specifically requested information related to the pharmaceutical industry's ability to meet current regulatory requirements given the unique challenges presented in social media engagement. AstraZeneca's suggested regulatory framework was intended to suggest a pharmaceutical manufacturer's level of accountability for web content based primarily on the manufacturer's level of control over the content and the site.

While participants tended to agree to the link between content control and accountability, they believed that AstraZeneca's suggested categories should be reframed and recommended an alternative regulatory framework to the one proposed in AstraZeneca's submitted comments to the FDA (see above). The categories are very similar, but more specific than the ones put forth by AstraZeneca. In particular, the participants' proposed categories are as follows:

- Company-controlled websites that offer the total brand experience;
- Moderated/curator-led sites;
- "Join/Integrate" options – such as Facebook;
- "Dialogue participation" – true social media communities; and
- Closed forums.

Participants reasoned that manufacturers should be responsible for any content located on company controlled sites and third-party sites on which they act as moderator or maintain a company page. In categories where manufacturers exert less or no control and/or influence, such as "true social media communities" or closed forums, then they should not be responsible for content.

AstraZeneca: Creating a Path Forward

AstraZeneca believes that we have an obligation to participate in social media in a responsible way to help educate patients, caregivers, health care providers and the general public. Our active participation can provide information to help ensure that patients get the appropriate medicine at the right time and that it is taken in the right way.

As we await FDA guidance and determine the appropriate path forward for AstraZeneca, outreach to other individuals who engage in this arena – patients, caregivers, health bloggers, media stakeholders – simply makes sense; it has helped inform and shape AstraZeneca’s perspective on key issues.

For AstraZeneca, this white paper is about determining how a pharmaceutical manufacturer can best begin and continue an ongoing dialogue in social media, while keeping the focus squarely on what is in the best interests of patient health. With that in mind, here are AstraZeneca’s key action steps that are a direct result of this engagement:

➤ **AstraZeneca’s Social Media Principles Will Stay in Place—For Now.**

Given the positive feedback from the roundtable and DPE participants, AstraZeneca does not currently intend to modify our five principles. While some participants recommended that the principles be tailored to specific social media platforms, AstraZeneca has decided to maintain the more generalized approach to allow for greater flexibility.

However, as suggested, AstraZeneca will establish a process for a regular review of the principles to allow for revisions based on, among other things, changes in technology and/or patient and other stakeholder expectations.

➤ **Proposed Regulatory Framework Will be Reviewed.**

AstraZeneca will consider revising its proposed regulatory framework to better align with how information is provided and presented online. This includes considering the alternative categories presented by participants at the roundtable.

➤ **Patient Advisory Panel is Under Consideration.**

When asked directly whether AstraZeneca currently engages patient groups as a means of seeking feedback on our social media engagements, we recognized immediately the opportunity for action. Certainly, the formation of a patient-focused advisory panel could be instrumental in identifying opportunities and challenges from the patient perspective.

AstraZeneca has already taken some preliminary steps to investigate how such a group would be established as well as setting forth expectations for all participants.

Conclusion

In developing this white paper, AstraZeneca has bolstered its belief that the pharmaceutical industry's continued engagement in social media when done appropriately is in the best interests of patient health. The determination of what is appropriate will be a continuous challenge for all participants in social media, even after the FDA guidance is released. We are hopeful that using guidelines such as AstraZeneca's Social Media Principles will be useful tools for AstraZeneca and for others who choose to engage in the discussion.

AstraZeneca would like to thank the following individuals for taking the time to provide their unique perspectives and thoughtful insights that are the foundation of this white paper:

- Alex Baldwin, Executive Vice President and General Counsel, HealthCentral (www.HealthCentral.com)
- Alicia Staley, Founder, The Staley Foundation
- Amy Cowan, Head of Industry, Health, Google
- Christopher M. Schroeder, Chief Executive Officer, HealthCentral (www.HealthCentral.com)
- Diedra Henderson, Director Communications & Public Affairs, PhRMA
- Earl Whipple, Senior Director, Corporate Communications, AstraZeneca
- Gilles Frydman, Founder, Association of Cancer Online Resources
- Jeanine Boyle, Senior Director, Federal Policy, AstraZeneca
- Jeffrey K. Francer, Assistant General Counsel, PhRMA
- Jonathan Richman, Director of Social Media, Bridge Worldwide
- Leigh Householder, Digital Strategist, Pink Tank and iQ inside GSW Worldwide
- Mark Bard, President, Manhattan Research
- Mary Ann Belliveau, Health Industry Director, Google
- Melissa Davies, Strategic Account Director, Healthcare at NM Incite, a Nielsen/McKinsey company
- Peter Pitts, President, Center for Medicine in the Public Interest
- Shannon Paul, Social Media Manager, Blue Cross Blue Shield of Michigan

We are hopeful AstraZeneca's approach to engagement and intention to continue to engage in social media will convey the importance of facilitating industry participation in social media in a meaningful way while best positioning pharmaceutical companies like ourselves as continued trusted sources of information on our products.