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FDA Testimony – Social Media

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We appreciate the FDA's effort to embrace and understand how social media and the online world are changing and what it means for regulation of the healthcare industry's communications. We have worked extensively in the healthcare and technology industry, among others, and have developed a clear point of view on how future social media guidelines can improve patient safety, increase education of consumers and physicians and enable appropriate engagement of industry in online conversations.

The main goal of our testimony is to focus on why it is important to open up conversation online so that the experts (industry) for a drug, device or diagnostic can share their knowledge and also learn directly from patients and healthcare providers. We will also illustrate how important it is to deal with the spam, splogs and mis-information that will continue to unduly influence people online due to lack of content sharing and corrective information from industry.

Before we start, we would like to place the change we are undergoing in context. As we all know, DNA was discovered in 1953, but 57 years later, personalized medicine is just starting to be realized treatment by treatment. Monoclonal antibodies were invented in 1975, were not humanized until 1988 and are now a mainstream treatment 35 years later. The worldwide web was described in 1989, e-commerce began in 1995, Facebook in 2004 and Twitter in 2006. Said another way, we are at the beginning of change online. We're not late in creating guidelines.

This is why it is important for the guidelines to be open enough to allow for the rapid pace of change we expect to occur in the future.

Let us now begin with our nine recommendations for consideration during the guideline creation process by FDA.

#1 – Standardize the Baseline for Online Policies of Industry – the FDA should recommend, as part of its guidelines, that any company or organization that participates in social media have its own policy that is publicly displayed on their online properties. The FDA should request a minimum standard be met that includes the following components:

1. **Transparency** – There is a great need for transparency in social media. In other words, companies that choose to engage in social media communities must identify themselves accurately and without misrepresentation, every time. Similarly, company employees who engage in social media communities that are related to the employees' line of work must identify themselves as a company employee, regardless of when, where, or why they are participating in the topically relevant community.
2. **Accuracy** – if a mistake is found on a company site or in an exchange by a company representative in an online site independent of the company, the company agrees to correct immediately any content it is has previously generated.
3. **Employees Who Break the Rules** – Any employee or other company representative, who does not comply with this policy, will be subject to discipline, up to and including dismissal from the company.

In addition, privacy rights would be outlined. For further review of best practices in the industry, we recommend a closer look at the already vetted ethics and disclosure policies of both [WOMMA](#) and the [Social Media Business Council](#), respectively. There is no need to reinvent the wheel.

Overall, we believe that a review of the current standards from key organizations representing companies and agencies, in addition to the core principles above, can lead to excellent guidance for a required policy of industry and should be a requirement in the guidelines.

#2 – Hold Industry Accountable, in Aggregate, for Conversational Content -- it is possible today to monitor all conversations about a topic or brand in all publicly available sites online. Companies, such as Radian6 or Visible Technologies, are able to scrape what is shared and provide these updates and insights direct to one's desktop. Even regular Google web searches have expanded significantly to be able to segment results as blogs, Twitter, and forum conversations.

Due to the advance of technology, we believe the FDA can ask industry to monitor the conversations related to its brand and ensure that any content that is produced by the company is accurate and any conversations they enter are accurate, in terms of what the company states publicly. The company would also be in the position of correcting mis-information proactively online. The FDA can easily track this progress via the embrace of this technology.

If the FDA requested that companies accept responsibility for monitoring their content and output directly, this would lead to two important actions:

Companies can join the conversation – if a company can join a conversation and be held accountable for the overall discussion and not each individual comment one at a time, a productive exchange can occur. However, if each comment must be scrutinized and approved in advance by either by the company or FDA, this will lead to zero conversation and create an educational gap in the market, potentially leading to mis-information and increased safety risk.

FDA's mission is advanced – The FDA's mission clearly states that the FDA is responsible for protecting the public health and is also, **“responsible for advancing public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.”** We believe this will occur if the experts for a drug, device or diagnostic, as well as healthcare providers, are free to engage in dialogue to share their expertise.

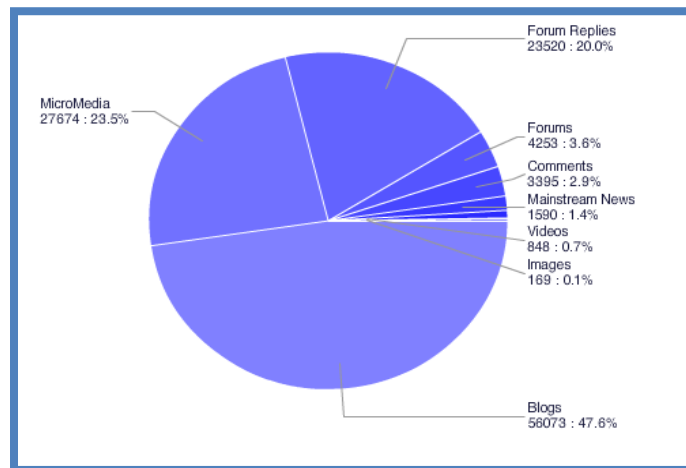
There is one analogy worth sharing here. For many years, the FDA has not required that it know the contents of each conversation that a company has via phone with patients and providers. Rather, the FDA looks, in aggregate, at how a company is approaching the market. Online, although it is a public place, is no different in this request for conversations. And, we live in a world where the direct phone call is decreasingly important as a way to learn or inquire for more information. In modern times, community forums and search engines are the new direct call/the new 800#.

Overall, we recommend that FDA adopt a standard requesting that companies monitor their own brands online and remain accountable for the content they generate and/or share via conversations. The FDA, in turn, can monitor the industry via the same technology. It is an environment of total transparency, one that is good for patients, providers, industry and FDA.

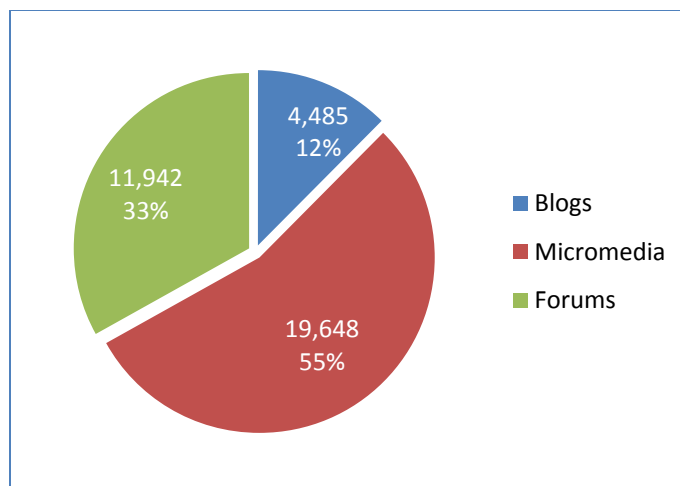
#3 – Be Clear on Responsibility for Conversations – we believe it is important for companies to be accountable for the content they create and share. Nothing new here. However, it is not fair or reasonable to hold companies accountable for the conversation trail that may occur after they comment. Similar to a phone call, a company is not held accountable for word of mouth in the patient's

neighborhood after a call. A company cannot account for what may be said after they engage and leave a comment on a forum or blog. However, if we hold to #2, it is possible to request that companies correct any incorrect information that may occur in a trail of conversation, since both the company and FDA are monitoring the overall conversation.

To support this point, it is highly relevant to point out where learning often occurs for patients. Community forums, which are driven by conversations, are a key area of learning, yet today, companies do not participate at all in forums due to lack of guidelines. We recently did research to evaluate 117,522 posts for 22 pharma brands and found that forum replies and micro media (Twitter) accounted for 44% of mentions of these brands. Here is a summary of our data pulled in early February, 2010 for 22 top Pharma brands.



That is only part of the story, however. Due to the high volume of spam for pharmaceutical drugs that lives in blogs, we analyzed even deeper with an advanced spam prevention approach. After doing so we learned that the true percent of pharma brand mentions in micro media and user forums is actually **88%**.



Of these conversations, we learned there is an average of 5.53 replies to every forum post. This is where the vast majority of conversations are taking place that have a meaningful impact on consumers.

#4 – Understand how Learning is Changing – guidelines must reflect how people are choosing to learn online. The two best examples are video and mobile.

Today, industry is reticent to share videos via YouTube and other video channels and, as a result, we have a growing education gap. In fact, less than 1% of the brand mentions for the data we referenced previously was in video. Here is why video is so important.

Overall, YouTube is now the 2nd largest search engine in the world. In the United States as well as around world, we are experiencing relatively strong growth in broadband and fiber access, making it easier to view video. We know via neurological studies that visual information can improve understanding of spoken words and that our brain uses images to clarify ideas, interacts with images to create engagement, and augments memory with persistent and evolving views. The result is that video is becoming the top choice for learning, but healthcare is falling behind.

Our recommendation is to work with industry to develop an effective approach for a YouTube video channel that shares all relevant safety/risk/benefit information and also enables the viewer to learn in a style that they will want to repeat over time. We believe industry will provide FDA with examples of what is possible and encourage FDA to consider developing a standard approach.

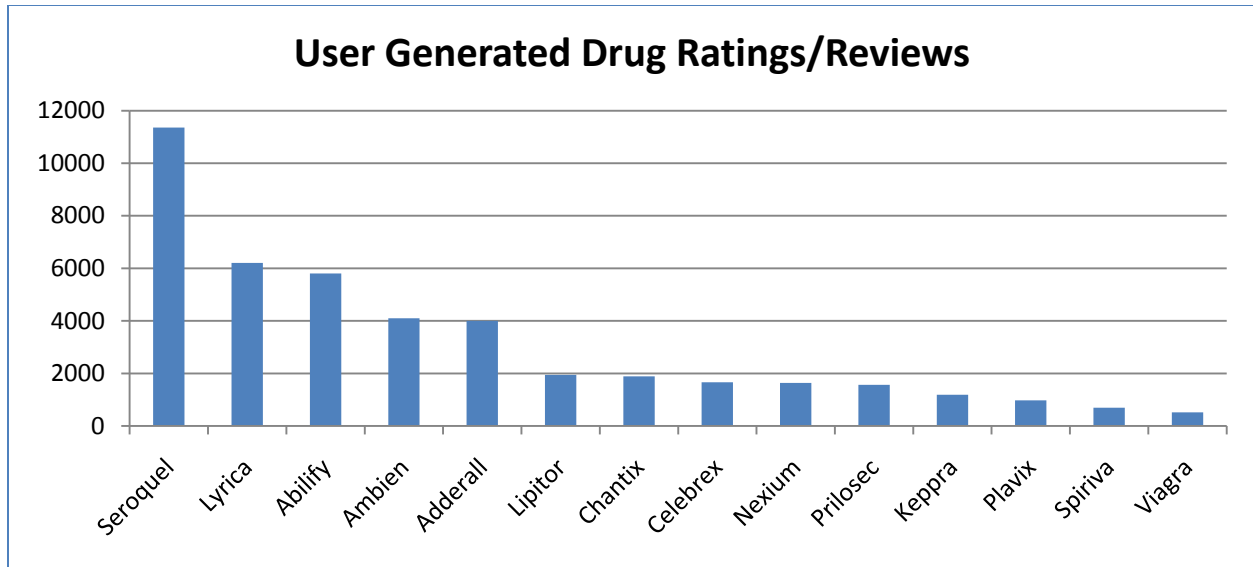
Mobile is another important area. Imagine that only the top one-third of a search page or a website is relevant to a cell-phone user and you can see why it is important to enable clear content to emerge. The majority of the world is learning via cell phone today, in addition to laptop. Physicians prefer smart phones. Applications are being designed in the tens of thousands for healthcare. Mobile is rapidly becoming its own platform for communications.

It is important to assume that how an ad or an initial exchange looks on a cell phone will never be enough for someone to fully understand what is being shared.

Our recommendation is that we don't create guidelines for the laptop screen that don't apply to the mobile screen. The best way to avoid this is to focus on the "experience" of the person searching for information and understand what they will receive, rather than spend all of our energy on what the initial ad or site looks like. Mobile users know they will need to click to get to the real experience, often on the 2nd screen.

#5 – Ability to Answer Questions Proactively – we did an analysis on January 10, 2010 of user generated ratings and reviews of pharma drug brands on five health websites: WebMD, Drugs.com, AskAPatient, DrugRatingz and DailyStrength.

It is instructive to point out that consumers are already answering any and all questions about prescription drugs today, with or without substantial knowledge and, in many cases, without any formal training. Here is a chart showing an example of reviews, ranging from a few dozen to more than 10,000 total consumer-generated drug reviews across five of the top sites for ratings and reviews.



Next, we went to Yahoo! Answers, a popular place to find answers to your question. In fact, we found that people are highly active in answering questions about Abilify (6,450); Seroquel (11,600); Lyrica (5,040); Chantix (5,390); Ambien (13,600); Keppra (1,100); Advair (3,270); and Topamax (4,900). However, these numbers pale in comparison to the number of questions being answered about Depression (624,000), Fibromyalgia (17,200), Smoking Cessation (76,600), Insomnia (124,000), Epilepsy (26,800), Asthma (70,900), and Seizures (47,400).

We drew no conclusion on the relevance of the answers, but anecdotal evidence is plentiful that answers are often factually inaccurate or at least incomplete. Overall, we recommend that FDA consider joining these conversations and also enable companies to enter the conversation to add their value to the discussion.

#6 -- Team up to Defeat Spam -- Pharmaceutical drugs are the most spammed topic on the internet and blogs are the primary spam engine. Unfortunately, today, our research shows that more than 90% of all blog posts that mention drugs are spam. We appreciate that actual percentages can change week to week, month to month, but the underlying problem remains the same. Spammers attack areas where consumers are easily beguiled and they have identified pharmaceutical drugs as a priority target.

Industry must be able to do its part to eliminate spam and its unhealthy influence.

The easiest way to do this is to enable conversations to occur on community user forums, since they are the leader in legitimate conversation due to multiple registration and spam prevention protocols, as well as user moderation. If companies can participate in the conversation at the right forums, the community's interest will shift to these sites and decrease the impact of spam far more than any technology achievement.

This requires FDA to enable conversations to occur as noted in #1.

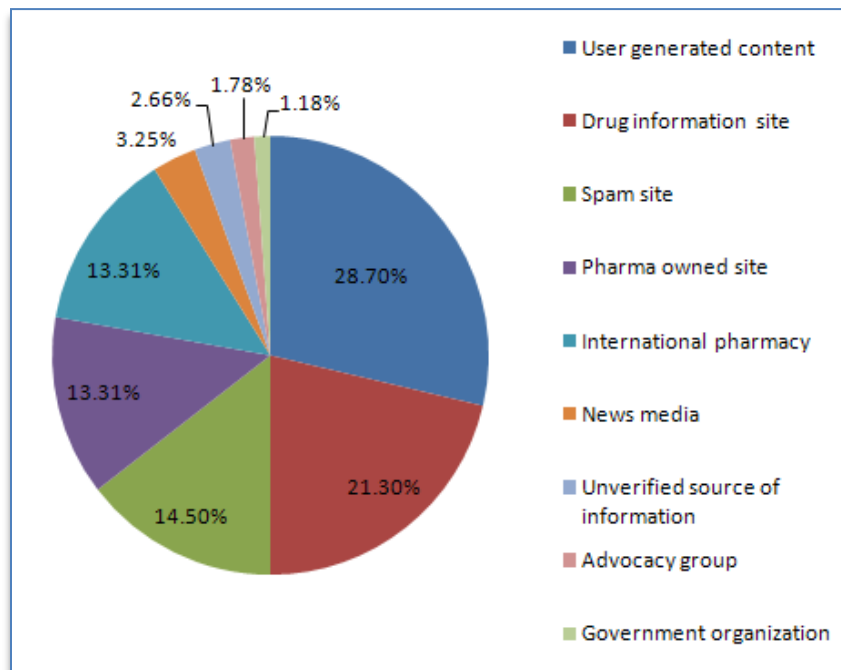
#7 – Improving the Patient Experience – it easy to get lost in the regulation of companies and forget that patients and consumers of all types could care less about companies. They are personally motivated to learn more about their health and are most often starting their journey to learn via search engines. From

there, they will go to whatever content is available. In our analysis noted in #5, what we found is instructive.

In the past two years, Google has made sweeping changes to the way that it finds and displays search results. Forum conversations, blog posts, online videos or images, and Tweets are now displayed at the very top of search results in Google. For many consumers, these are shaping their first impressions of a drug or disease area. Today, when a consumer searches Google for the name of a drug, our research has found there are an average of 17.933 results on the first page, including search results, sponsored results, and images or videos that Google displays to the user. On average, 4 of these results are held responsible by the FDA in some manner: Pharma-owned websites; News media; and Government agencies. However, an average of 13.933 of these results are unregulated: User generated content; Spammers; Drug information websites; and online pharmacies.

The natural search position that we analyzed is influenced by the number of conversations and amount of relevant content of each participant.

The conclusion is simple. A lack of conversational capability by industry and a slower rate of content production is leading to poor representation in search. This is not the optimal position for experts to be in when the sharing of their insights could be helpful in the decision-making process related to one's health, whether it is disease or brand related.



#8 – Fight Splogs Together – Splogs are blogs made to look like a news site or online resource that mask an ulterior motive. The average internet user may be misled by spam blogs. They exist due to an imbalance in the supply/demand of content. Since there is a higher demand for pharma information online than there is supply, splogs currently fill this gap.

We recommend allowing for more content from industry, which will displace splogs and increase relevance of content.

#9 – Understanding Benefit/Risk Online – we believe that the benefit/risk ratio will improve online via more industry participation. Here is why.

To better understand benefit/risk mentions in online conversations, we analyzed over 100,000 conversations that mentioned at least one of 22 pharmaceutical drug brands earlier this year. Benefits were classified as mentions of a product's indication to treat a disease, comments on effectiveness, or product endorsements. Risks were classified as mentions of a product's safety warning, or words of caution related to using a product. A key clarification is that many social media conversations include mentions of both benefits and risks, and so are counted in both. Here is what we found.

Using mainstream news articles as a benchmark, we found a ratio of 60.3 / 39.7 benefit to risk mentions. This is the ratio that underscores how print and broadcast journalists report on pharmaceutical drugs. By contrast, across all social media sites, we found a ratio of 66.5 / 33.5 benefit to risk mentions for the same drugs during the same time period. We also found that benefit/risk conversations are impacted by the type of social media site where the conversation is taking place. Twitter was 73.9 / 26.1; user forums were 67.2 / 32.8 and blogs were 66/34.

In user forums, people are twice as likely to mention a Risk when replying to someone else's post. This is how the community offers people advice. Users without credentials in medical fields repeatedly post information assessing side effects – some that are not included on official drug websites – and drug interactions. Comments and claims online are generally unsubstantiated and provide no sourcing references. Much of this unaccredited information is available in, and is being ingested from, wide ranging, topically disparate forums and blogs

Our conclusion is that the naturally occurring benefit/risk equation is reasonably strong, considering it is currently being done in a self-policing manner. This does not mean, however, that the information is all correct.

Our recommendation is to enable industry to participate actively in these discussions with a goal of improving the benefit/risk ratio of conversations, which can be measured online by brand, disease area or any other parameter. FDA could even go so far as to suggest a benchmark that reflects, on average, what you believe is an appropriate benefit/risk ratio online.

Overall, we believe that online will continue to undergo rapid change, which will require guidelines that provide a degree of clarity related to standards and engagement, but are also open enough for change to occur with time. We only have to look at the future of mobile to realize that what we propose today for the laptop will be greatly different in terms of our experience in a matter of years.

We wish you success and much patience as you develop the guidelines.

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