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Article

# Industry and Consumer Advocates Square Off Regarding Social Media

## An Analysis of Who Submitted Comments to FDA

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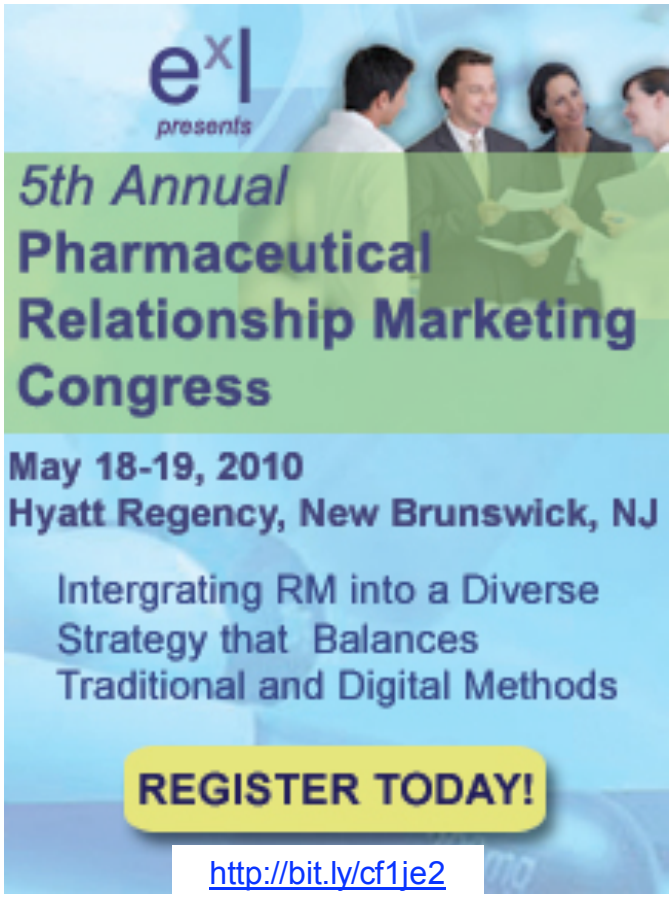


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## *What Sanofi-Aventis Learned from Its FaceBook Experience & What the Experts Recommend It Do Now*

**LIVE Podcast * Tuesday, April 6, 2010 * 2:00 PM**

A conversation with Dennis Urbaniak, VP U.S. Diabetes at sanofi-aventis, about the recent activity on S-A's VOICES corporate Facebook page. We'll discuss the lessons learned and hear advice from independent experts.

Some Questions/Topics to be Discussed

- Tell us more about VOICES, what its mission is, how it began, etc.
- How prepared was S-A for dealing with comments from the public such as those from Ms. Ledlie?
- What has S-A learned from this experience?
- What's next?

Visit http://bit.ly/bkPq6y for more information and to LISTEN live or hear the audio ARCHIVE afterward.

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## *Online Community Management*

### Moderation Best Practices & Other Tips for Pharma Social Media Managers

**LIVE Podcast * Thursday, April 15, 2010 * 2:00 PM**

A conversation with Jenna Woodul, EVP, Chief Community Officer, LiveWorld, Inc., about how pharma companies can manage their social media interactions using technology and "credentialed participants" for moderating and managing online discussions.

Some Questions/Topics to be Discussed

- What's wrong with how many pharma companies are currently managing their social media campaigns?
- What's your opinion of moderation? Should pharmacos moderate posts BEFORE they are published on their social media sites?

Visit http://bit.ly/aN9bGj for more information and to LISTEN live or hear the audio ARCHIVE afterward.

The deadline has come and gone for sub-mitting comments to docket FDA-2009-N-0441 regard-ing "Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools." You can find ALL of the comments at Regulations.gov and easily download them at fdaSM.com. If you don't feel like spending hours sifting through the comments for the golden nuggets, have no fear! You can find them here.

**Who Submitted Comments?**
Seventy (70) different entities submitted one or more comments to the docket. These submitters can be organized into the following eight general categories:

1. **HCP Org** - Health Professional (HP) or HP Assn
2. **Search Engine** - Google and Yahoo!
3. **Trade Media** - Blog, newsletter, publication focused on drug industry news
4. **Pharma Company** - Drug, device, or diagnostic company
5. **Consumer Advocate** - Individual or consumer advocacy group
6. **Industry Advocate** - Trade association or ad hoc group
7. **Health Website** - Patient, physician, or health activist focus
8. **Industry Service Provider** - Marketing, communications, ad or PR agency that provides services to drug industry

A pie chart is the best way to illustrate what percen-tage of the 70 different entities each category represents (see Figure 1, this page). Sixty-one percent (61%) of these entities are pharma companies (22%), industry service providers (22%), and industry advocates (17%). Only17% are consumer advocates.

**Presenters Vs. Commentators**
Pharma companies and consumers are better represented among commentators than among the entities that made presentations at the November 2009 public hearing. A bar chart is the best way to illustrate this (see Fig 2, pg 3). See "Industry Groups will Eat Consumer Advocates' Lunch at FDA Social Media Public Hearing" (http://bit.ly/2y2arq) for an analysis of entities that made presentations at the public hearing.

It's immediately obvious that there is a more even distribution among commentators than among presenters (see Figure 2, pg 3). Whereas only 7% of presenters at the public hearing were pharma

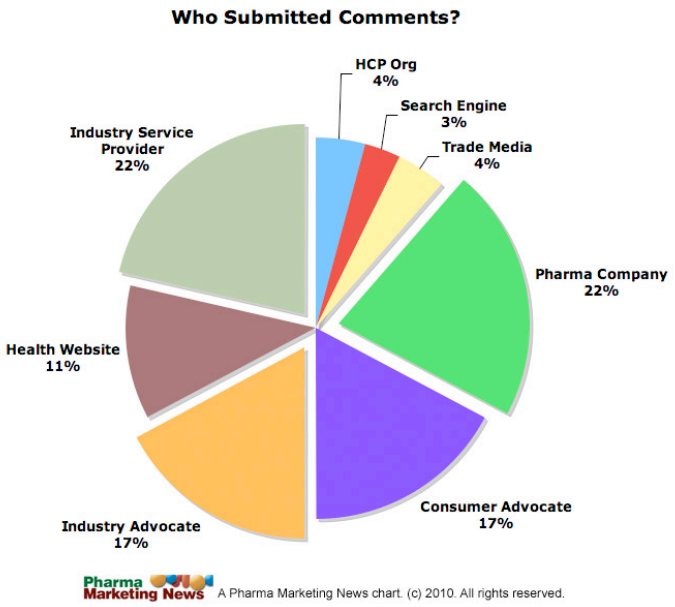


Figure 1. Groups that Submitted Comments to FDA

companies, 21% of commentators were pharma companies. Pharma obviously played it close to the vest and many companies decided not to be in the limelight at the public hearing but waited until the very last minute to submit comments to the docket.

Consumer Advocates also stepped up to provide comments, whereas very few made presentations at the public hearing. As suggested at the time, it cost money to attend these hearings and individuals simply cannot afford it.

**Comments from the Industry**
Although these numbers are interesting, it's more important to look at the comments themselves. This article covers some of the overarching concerns or novel ideas expressed by the drug industry in its comments to the FDA. A complete summary of the industry's comments regarding specific questions posed by the FDA is presented in other articles in this issue of *Pharma Marketing News*. Comments submitted by consumer advocates are summarized at the end of this article.

**Pfizer Asks for New FDA Regulations**
Pfizer—the world's #1 pharmaceutical company—stands alone in calling upon the FDA to develop new regulations for the Internet and social media rather than issuing guidance that puts an "interpretative gloss" on existing rules. Pfizer's comments are heavily laden with citations of court decisions and references to legal precedents, especially with regard to First Amendment concerns. Apparently, this is a warning shot across FDA's legal bow.

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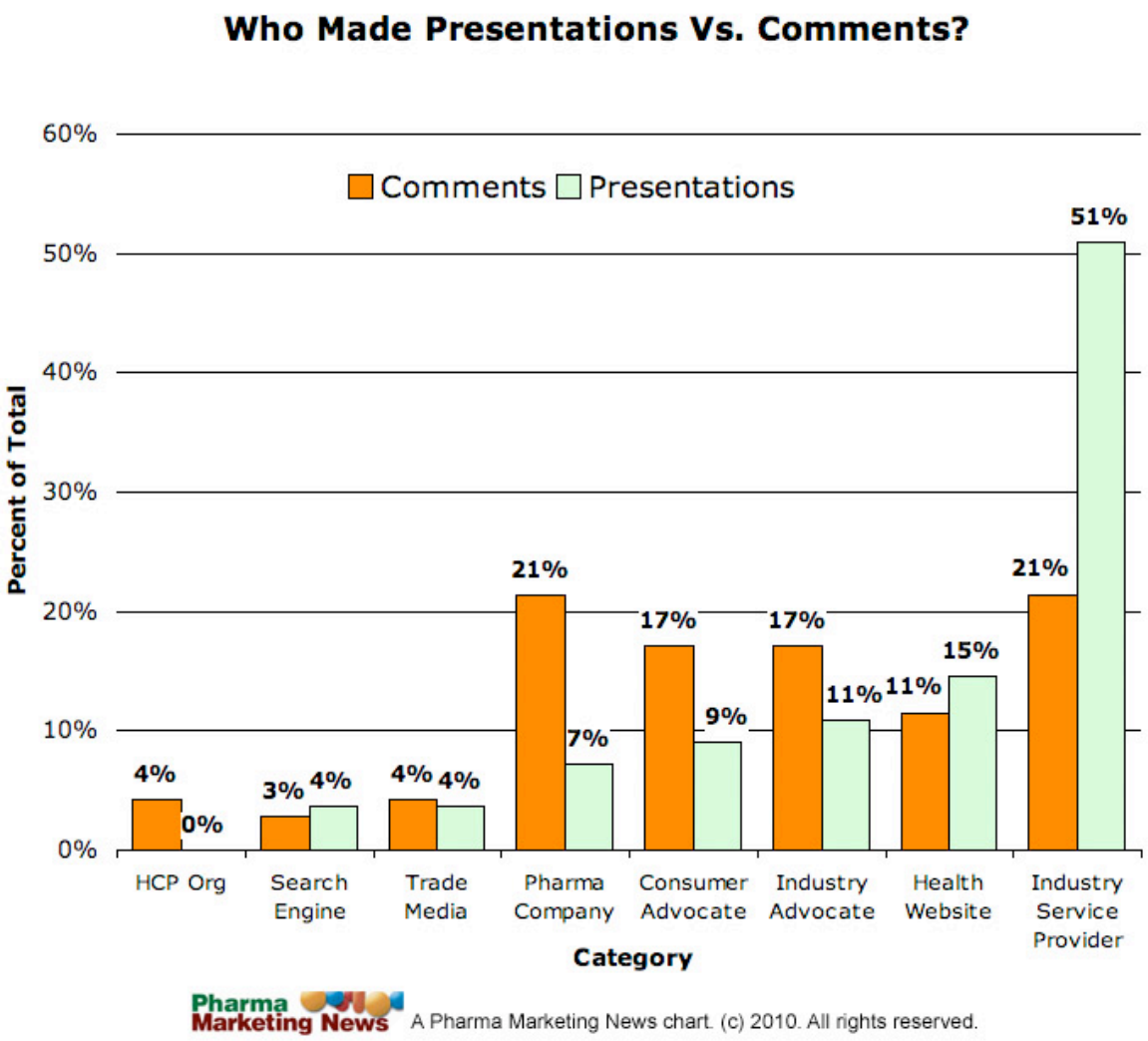


Figure 2. A Comparison of Groups Who Presented at the November 2009 Public Hearing to Groups that Submitted Comments to the Public Docket.

"FDA should not try to fit the square peg of Internet and social media communications into the round hole of the Agency's existing rules developed for conventional media," said Pfizer in its comments. Pfizer said that FDA should develop comprehensive new rules describing the actions manufacturers must take in order for their online communications to be "truthful and non-misleading in the specific context of the online environment. The Agency should ultimately establish these new rules not in guidance—which by definition cannot change existing rules but can merely provide an interpretive gloss on those rules—but rather in new regulations." Pfizer claimed the public health would be benefitted by the establishment of "binding, legally enforceable new rules that have been developed by FDA specifically for new media."

**First Amendment Concerns**

Pfizer contends that "for FDA to regulate in this sensitive area through guidance instead of rule-making inherently raises First Amendment concerns because of the nature of the process used to develop guidance, and the nature of the Agency pronouncements that result." Guidance, says Pfizer, is too vague and engenders "extensive litigation."

Citing litigation brought by the Washington Legal Foundation (WLF) against FDA's guidance process (versus notice-and-comment rulemaking), Pfizer said it "believes it would be imprudent for FDA to repeat this pattern of seeking to address an entirely new field of conduct, where First Amendment rights are clearly at stake, without the discipline that comes with a rulemaking proceeding." Pfizer noted that as

*Continues…*

a result of WLF litigation, the courts have become "more aggressive in policing FDA regulation of speech."

Pfizer predicted that vague guidance will inhibit companies from engaging in social media: "Many manufacturers simply will decide, as a risk management matter, that they will not engage, irrespective of any guidance from FDA, because the enforcement discretion reference means that the Agency regards that engagement as potentially violating a statutory or regulatory provision."

In other words, Pfizer believes guidance would stifle pharma's use of the Internet and social media rather than encourage it, which Pfizer implies should be the goal of FDA. "Such an approach [issuing guidance rather than new rules] would not be ideal, however, if FDA genuinely wants to encourage manufacturers to increase their level of engagement in online activities."

**AstraZeneca Proposes Social Media Principles**

"AstraZeneca understands the value of social media to engage key stakeholders in today's technology-driven world," said Bob Perkins, AZ's Vice President, Public Policy and Promotional Affairs. "While we have developed a corporate presence in the digital space, we believe it is increasingly important to participate in online channels to provide accurate and regulated information about our branded products in conversations with patients, caregivers, and health care providers."

AstraZeneca (AZ) listed five principles that it said "should be at the core of any company engagement in social media:

- **Truth and Accuracy**: Content must be created, developed, or made available that is truthful, balanced, accurate, and not misleading.
- **To Be Respectful**: 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 relationship.
- **Protect and Advance Patient Health**: Facilitate patient access to quality information for use with their physician to improve their health and protect patients through encouraging accurate and timely reporting on medicine safety.
- **Transparency**: Any product sponsor participation should be accomplished in a manner that, at all times, is entirely transparent to other participants as to the role of product sponsors as participants in online discussion.
- **Respect the Views of Others**: Acknowledge 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.

**Merck Encourages Ongoing Dialogue**

Merck encouraged FDA to maintain a dialogue with the industry through public workshops and an Advisory Committee.

"Merck strongly believes that policies and standards on the use of the Internet as a tool to promote FDA-regulated products are needed. However, we recognize and appreciate that FDA will be constantly challenged to provide guidance that addresses the rapidly evolving technologies and web-based forums, along with issues raised by this rapidly dynamic medium." Merck encouraged FDA to maintain a dialogue with industry, third-party providers, trade associations, and other groups to stay abreast of new technologies as well as the challenges and issues with Internet promotion. "This dialogue and continued learning could be accomplished in several ways, including public workshops," said Merck.

"Since the Internet and associated tools are ever changing," said Merck, "FDA should consider the establishment of an Advisory Committee comprised of key experts (including consumer advocates, representatives from the medical community, technical experts, and industry representatives) to review issues periodically that involve the communication of product information over the Internet and via social media tools. Such a committee could exist as a subcommittee to the FDA Science Board or the Risk Communication Advisory Committee."

**Most Consumer Advocates Are Anti-Pharma Marketing**

Perhaps some of the consumer advocates who submitted comments to the FDA may be included in the Advisory Committee recommended by Merck. The "Consumer Advocate" category of commentators is comprised of the following 12 organizations and individuals:

1. Anonymous, Individual
2. Bruce Overman Jr, Individual
3. Center for Digital Democracy, Consumer Advocacy Group
4. Consumers Union, Consumer Advocacy Group
5. Kathryn Rowerdink, Individual
6. Kathy Lambert, Individual

*Continues...*

7. Melvin Flowers, Individual
8. Michael E. Bailey, Individual
9. National Organization for Rare Disorders, Consumer Advocacy Group
10. Randall Pecsek, Individual
11. Michael E. Bailey, Individual
12. PEW Prescription Project, Consumer Advocacy Group

Ten (83%) of these consumer advocates expressed ANTI-pharma marketing sentiments such as the following:

"I think the implications of this can get out of hand. Social media and the internet allows for too much false, partially true, information which can harm the lay people who do not know the difference. It may lead to unapproved/remakes of devices that are not safe." -- *Anonymous*

"I and many, many others are very much against any further promotion or advertising of Food and Drug Administration-Regulated Medical Products, particularly prescription drugs. I am very much in favor of outlawing the existing practice of advertising prescription drugs. Billions of dollars are spent by pharmaceutical companies to advertise drugs, confusing and misleading the public, most of whom do not have the expertise needed to make proper judgments where these drugs are concerned. This massive amount of money should, instead, be used to reduce the cost of these drugs." -- *Bruce Overman Jr*

"By using an array of new digital marketing tools -- including behavioral targeting, social media, online video, and mobile -- pharmaceutical companies now have unprecedented abilities to take advantage of consumers." -- *Center for Digital Democracy*

"The experience with DTC ads from 1997 to the present should be a cautionary tale and compel the agency to carefully examine its options and the appropriate mechanisms to assure against widespread and unbalanced promotion of drug products via online media." - *Consumers Union*

"I do not want Rx drugs advertised or promoted on TV or through media to the public." -- Kathy Lambert

"This is surely helpful use the FDA regulatory authority. There need to be control on the Internet advertisements epically when it relates to medical devices and labeling." -- *Melvin Flowers*

"The manufacturers of medications and their representatives must be held accountable for each claim they put on any online media concerning their products because the public health and safety demands it. There maybe some online media that are not suited for drug advertising because of the space limitations involved. There may not be enough space for the important risk information that needs to come with the claims. It is too risky and dangerous to allow the drug company claims alone without the risk information. It is not enough to put in a link that you can click on to take you to another site to get the risk information because many people won't do that and will only read the claims of the drug company that it puts up on the social media. But they should always provide a link to the FDA website for people who want an unbiassed and fair assessment of the drug, and so people can report bad reactions to the drug. Thank you and best wishes, *Michael E. Bailey*."

"The last thing this country needs is MORE advertising by drug companies. Prescription drugs need to be administered by doctors acting in the best interest of their patients. Patients need to talk to their doctor about a medical "problem", and let the doctor determine the best treatment. Drug ads serve only to feed hypochondria in the public. Marketing of drugs and the costs of advertising serve only to drive up prescription drug costs in America. Our capitalist system is out of control, driving Americans to spent money frivolously. Let's not expand advertising opportunities, let rein them in and recind the rules which allow drug companies to advertise anywhere except medical journals intended for doctors. How many more erectile dysfunction ads do we need to be subjected to?" -- *Randall Pecsek*

"[W]e urge caution in promulgating rules that could effectively establish new and pervasive modes of industry marketing. It is important that current FDA guidance on the presentation of risk information not be compromised to the detriment of the public health in favor of accommodating evolving industry marketing practice. If a marketing tool, such as a space-limited microblog, or tweet, is unable to satisfy basic consumer protective measures such as the fair balance requirement, that tool should be considered inappropriate for the promotion of pharmaceutical products." -- *PEW Prescription Project*

"To reduce demand and help curb online diversion, we urge FDA to more stringently regulate pharmaceutical companies' advertising of controlled prescription drugs to physicians and consumers." -- The National Center on Addiction and Substance Abuse, Columbia University

**There were two "PRO" commentators:**

"Patients and patient organizations increasingly are using the social media as an important communications tool. We expect this trend to continue.

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continue. Patients and families affected by rare diseases have a great need for information since they typically have a greater-than-usual participation in their own, or their loved one?s, disease management and treatment. There is opportunity for the social media to perform a helpful role in facilitating the exchange of information for rare-disease patients and families. There also is significant potential for misuse of the social media or for the circulation of inaccurate or misleading information. It is NORD?s recommendation at this time that FDA continue its deliberation of how best to provide guidance regarding manufacturers? participation in the social media, since the use of social media for sharing of medical information is widespread and growing. We understand that FDA?s resources are limited. However, it is our sense at this time that clear guidance from FDA, similar to that which is currently being provided for traditional advertising modalities, would help to define appropriate ways for manufacturers to participate in this newest of the new media. If NORD, as the primary representative of the rare disease patient community, can assist FDA with defining what the guidelines should be, we would be happy to work with FDA on that process." -- *National Organization for Rare Disorders*

"I believe transparency is requested for all of the healthcare industry. Prior to twitter, facebook etc. the public was posting comments on drugs (pros and cons). I have googled drugs by their marketed and generic names to read about other peoples' experiences. I had some reactions to a steroid medication I was prescribed and wanted to find others who might have experienced the same. Doing a search and finding the right forum was extremely difficult and time consuming. A drug makers facebook page or a separate page for each drug was available, it would have made life much easier. A Facebook etc with non-censored updates, stories and comments etc. would have helped me and been faster. If the drug companies and insurance companies (although this is not the topic for the FDA)agree not to censor comments and stories, this is e a great avenue for information exchange. The pros and cons of a drug are more easily assessed through other peoples experiences and comments. Regulations and laws have forced the drug industry to use very complex wording in the packaging (in good faith of full disclosure) however this not helpful to the consumer but overwhelming. I would much rather go to a social media site and view what the possible tangible experiences are so that I may weigh my options and assess the risk. If the FDA chooses to regulate social media I do not see how this is a move toward transparency. The more the FDA represses communication avenues the less people feel informed. Regulating the censoring of comments etc. should be enforced but there are too many loopholes in trying to prevent the healthcare industry from engaging in new communication avenues. The FDA should encourage communication between patients and drug makers. Not only will this help the drug companies to assess needs and fill gaps but consumers are more likely to make their voices heard and feel empowered." -- *Kathryn Rowerdink*

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