
# Social Media

# Challenge and Opportunity for Pharmaceutical Manufacturers

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# The Social Media Challenge and Opportunity for Pharmaceutical Manufacturers

*The prevailing dynamic of social media growth represents an unprecedented challenge for both Pharmaceutical Manufacturers and the FDA.*

**Opportunity for Pharmaceutical Manufacturers**

Pharmaceutical manufacturers have communicated directly to both professionals and consumers for years in a one-way communication methodology acceptable to FDA guidelines on the dissemination of medical information. The advent of social media has changed the paradigm whereby the balance of power has shifted from the communicator to the audience in what is now a two-way exchange featuring discussions of testimonials, disease states, product usage, and product performance.

Surveys by the Pew Internet & American Life Project, a nonprofit and nonpartisan research organization, reported last year that 61% of American adults look online for health information. Pew reported further two thirds of those users (representing 40% of the entire group) who looked online for health information did so by reading somebody else's commentary.[1]

Social media presents a new opportunity for pharmaceutical marketers. Aside from product recognition and disease state awareness, social media can provide real time market research regarding attributes such as product adoption, patient acceptability, side effects and tolerability, as well as physician attitudes in real time. This type of data typically is gleaned from expensive third party retrospective market research and analyses that often include second and third hand testimonials from prescribers and consumers that may or may not be the targeted or desired audience. In the current age of "viral marketing" it appears the value of social media cannot or should not be ignored.

**Regulatory Constraints**

Pharmaceutical manufacturers have been somewhat reluctant thus far to utilize social media to its fullest capacity due to the risks associated for potential regulatory issues. The FDA has yet to issue explicit direction on pharmaceutical manufacturer responsibilities related to social media. After holding a hearing in November of 2009 on the topic, where 69 speakers and 77 presentations were heard, the FDA has reported that they are on track to issue such guidance. Tom Abrams of DDMAC hinted in October of this year that the agency would be issuing guidance in a series of releases to reflect the ever advancing nature of technology, the first of which will hopefully be published by year end. In the meantime, the FDA has demonstrated reliance on basic principles of pharmaceutical advertising and promotion pertaining to social media. Dr. Jean-Ah Kang, Special Assistant to the Director of DDMAC has declared, "It's not the medium, it's the message".[2] DDMAC has issued 14 Warning letters referencing social media, including the July 29th letter to Novartis on Tasigna and the utilization of a Facebook widget to link the Tasigna site user to a Facebook discussion board.[3]

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[1] Pew Internet & American Life Project, "61% of American Adults look online for health information", Press Release June 11, 2009; www.pewinternet.org

[2] Podcast Interview with Mark S. Senak, March 17, 2009; www.eyeonfda.com

[3] www.fda.gov

**First Amendment**

It has been argued that the First Amendment preserves the right to freely discuss topics via social media similar with other forms of media. However, it is clearly documented that the government can intervene where there is a "substantial" interest, for example the protection of public health. In other words, when there is evidence that harm to the consumer could occur, commercial speech can be subject to regulation. As social media continues to assimilate as a standard form of communication and research, it could be possible for an online discussion of an off-label use of a pharmaceutical product, or the discussion of that product without full disclosure, could potentially cause harm to a consumer. The mission of DDMAC remains "to protect the public health by assuring prescription drug information is truthful, balanced and accurately communicated".[4] First Amendment challenges to the FDA in the past have been largely unsuccessful, most recently evidenced by Allergan's settlement with the Department of Justice. After filing a first amendment lawsuit arguing for their right to promote Botox for off label uses, Allergan negotiated a settlement of a $600 million fine, and an agreement to drop the First Amendment case.[5]

**Third Party Social Media**

Pharmaceutical product websites are customarily static in that they restrict two way discussions. However, product sites also routinely include links to various patient advocacy websites which do allow, and often encourage, discussions of patient testimonials on how best to treat and live with disease. For example, several patient advocacy websites contain blogs and message boards discussing individual product usage, which rarely if ever include fair balance statements or assurance of discussions only within the FDA approved indications. Further, pharmaceutical manufacturers often support the advocacy groups hosting these sites with annual financial donations. Thus, it may possibly be construed that the manufacturer might be inadvertently supporting these conversations, which of course are not regulated with product full disclosure or discussions only within FDA approved indications.

The advocacy groups rely heavily upon the pharmaceutical companies for funding. A New York Times piece in October 2009 titled "Drug Makers Are Advocacy Group's Biggest Donors", reported that the industry funded $23 million dollars over the years 2006-2008 to one advocacy group alone, the National Alliance on Mental Illness.[6] Reviews of several patient advocacy websites demonstrate a host of pharmaceutical companies contributing to the advocacy efforts, and reviews of product websites often contain links to advocacy sites.

Another area that may cause an indirect linkage to pharmaceutical manufacturers is banner advertising on large social media sites such as Facebook or Twitter.

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[4] www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm

[5] DOJ Press Release, September 1, 2010; www.mmm-online.com/allergan-drops-fda-lawsuit-as-part-of-off-label-settlement/article/178168/

[6] "Drug Makers Are Advocacy Group's Biggest Donors", New York Times October 22, 2009

**DDMAC Guidance – A Prediction**

Considering the history of FDA guidance and strict regulatory interpretations, it may be prudent for pharmaceutical manufacturers to prepare for restrictive measures related to social media responsibilities.

Two-way communication exchanges via message boards and blogs of pharmaceutical product usage are not being monitored or regulated on a routine basis. As adoption to social media continues to escalate in popularity and develops into a cultural norm, it may be only a matter of time before FDA construes the unauthorized comments posted on some websites to be harmful to the consumer. Consumer harm could surface in a myriad of ways including the off label usage of a product, an undesirable side effect that was not disclosed to the consumer, or an unreported adverse event.

The FDA has rigid policies that must be adhered to regarding adverse event reporting. Social media again presents yet another challenge on the complete and accurate reporting of adverse events that may appear in social media.

FDA has always placed the onus of responsibility onto the pharmaceutical manufacturers for assuring prescription drug information to be truthful, balanced and accurately communicated. It would be a paradigm shift for FDA to stray from this precedent. Thus, it is possible that the agency mandate some form of manufacturer responsibility for discussions occurring on websites with direct or indirect linkage.

**Industry Reaction to Guidance**

Should DDMAC mandate manufacturer responsibility for content of discussions on financially supported advocacy websites, the industry would be faced with some tough decisions. One option could be to cease financial ties with advocacy groups. Based upon the financial support that the advocacy groups rely upon to meet their mission of improving patient's lives and the advancement of disease treatment, there would likely be a consumer, and consequently legislative uproar. Advocacy groups will most likely argue that their not for profit status does not provide the resources to police social media content regarding individual product usage, and further they do not possess the expertise in regulatory and compliance matters to accomplish such a task. Thus, once again the onus of responsibility falls to the pharmaceutical manufacturers. Manufacturers have the most up to date and comprehensive information about their products and the disease states they address.

The future policy may include manufacturer responsibility for social media content whereby the content is directly or indirectly sponsored by a manufacturer. A very conceivable notion is for the manufacturer to be responsible for a "reasonable effort" to ensure that discussions of their products include truthful, balanced, and accurately communicated information.

**Social Media Monitoring**

It is clearly impossible to "police" every website and every discussion occurring via social media. However, is can be argued that it is the social responsibility of the pharmaceutical manufacturer to provide "reasonable steps"[7] "to assure prescription drug information is truthful, balanced and accurately

[7] Federal Sentencing Guidelines Manual 8b2.1

communicated".[8] This presents yet another challenge to Pharmaceutical Compliance Departments, already facing lean times within the industry. It is reported that industry headcount has declined by over 45,000 people through the third quarter of 2010 alone.[9] Monitoring of social media web sites and discussions with direct or indirect linkage represents another strain on available resources. However, technology exists to search select websites with key word searches of risk assessed topics that may uncover discussions of their products, and the opportunity to post a corrective statement of the product's indications and fair balance where appropriate.

**Summary**

FDA regulations require promotional messages to be truthful, non-misleading, and fairly balanced between the benefits and risks associated with a particular product. Patient testimonials via social media can give rise to compliance-related misconduct. Monitoring of social media sites and posting corrective statements where appropriate can provide valuable information to marketers, as well as provide the FDA with assurance of fair, balanced and truthful communication regarding individual prescription products. Pharmaceutical manufacturers have the opportunity to lead the process for DDMAC, fulfill their social responsibility, and glean valuable and timely information.

***About ICC***

*Independent Commercial Compliance™ (ICC) is a full service health care compliance agency with expertise in all compliance related matters to the pharmaceutical industry.*

*For further information, you can visit their website at www.independent-commercial-compliance.com, or contact them directly at sreardo23@independent-commercial-compliance.com.*

[8] www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm

[9] Source: Challenger, Gray & Christmas