Tom Abrams of DDMAC hinted in October of this year that the agency would be issuing social media guidance to pharmaceutical manufacturers in a series of releases to reflect the ever advancing nature of technology, the first of which may be published by year end. A recent New England Journal of Medicine article suggests the issue to be volatile.

In a perspective piece, two physician researchers from Harvard Medical School and Brigham and Women's Hospital talk about the issues raised by using social media as a pharmaceutical marketing tool. The most impactful point made to pharmaceutical manufacturers in the article is that "physicians and consumers should hold the FDA and pharmaceutical manufacturers responsible for maintaining credible information in social media regarding the benefits and risks of therapies…Given the potentially important health implications of drug promotion in these media, regulators and manufacturers will have to share the responsibility for oversight." The article can be viewed at http://www.nejm.org/doi/pdf/10.1056/NEJMp1004986.

The authors opine, "Companies may intend to draw a line dividing their own media (such as a company Web site or a company-initiated chat area) from other online discussions of their products. But even if such a distinction were feasible, it would still be possible for manufacturers to support third-party bloggers, posters, and Twitter users who make flattering claims and discredit negative claims about their products in online discussions." Many patient advocacy groups host websites providing blogs and message boards to discuss various topics related to disease states. 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 could be "harmful to the consumer", thus enabling FDA to intervene.

One could argue that manufacturers are in a better position to monitor online discussions about their products: most U.S. companies that depend on copyright and trademark recognition currently engage in brand-protection activities through aggressive surveillance and litigation. Advocacy groups could argue their not for profit status does not provide the resources to police social media content regarding individual product usage; further they do not possess the expertise in regulatory and compliance matters to accomplish such a task, whereas manufacturers have the most up to date and comprehensive information about their products and the disease states they address.

FDA has 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 indirect linkage to the 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.