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# The FDA and the Regulation of Social Media

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Social media is everywhere. There is Twitter, LinkedIn, YouTube, blogs, and countless other tools and sites. Facebook now has over 900 million members. But social media is more than just social—it is also big business. People use it to research and discuss the products that they are using or considering. So, more and more, companies are creating a presence on social media to provide customers with information and join their discussions.

But this participation raises concerns, particularly regulatory concerns. What companies say or invite others to say on social media will be monitored. For companies in heavily regulated industries, the concerns are greater, particularly for those in the pharmaceutical, biologic, and medical device industries where the principal regulator, the Food and Drug Administration, has provided only limited guidance on the use of social media.

The FDA certainly recognizes the need for guidance. It describes social media guidance as among its "highest priorities," even listing topics in development:

> *[R]esponding to unsolicited requests; fulfilling regulatory requirements when using tools associated with space limitations; fulfilling post-marketing submission requirements; on-line communications for which manufacturers, packers, or distributors are accountable; use of links on the Internet; and correcting misinformation.*

The problem is, while the FDA has held a public hearing on social media and is conducting surveys on its impact,

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the regulator has issued only one draft guidance—"Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices" (aka, draft off-label guidance). And that guidance only partly addresses social media.

But there is some potential good news: Guidance may be coming, if not for a couple of years. Congress is currently considering the Food and Drug Administration Safety and Innovation Act [PDF], which would require, within two years of its enactment, the FDA to issue guidance "regarding the promotion, using the Internet (including social media), of medical products."

In the meantime, though, we are left with glimpses of the FDA's thinking so far. Here is what we have seen.

## Off-Label Communications

The FDA's draft off-label guidance focuses on whether a company solicited a third party's request for off-label information and, if not, how the company may respond. It discusses the parameters of a proper response, most of which are not new, and it discusses a new distinction between public and private responses (that is a topic for another article).

For our purposes, though, what is most interesting are the FDA's examples of what it believes might constitute solicitation by a company through social media:

- Tweeting study results and suggesting that an off-label use is safe and effective.
- Establishing standard response websites that in part include off-label information.
- Encouraging third-party bloggers to post about off-label use.
- Creating a username, e-mail address, or URL that suggests off-label use.
- Requesting users to post videos about their product experience on a site such as YouTube, resulting in videos on off-label use.

Not surprisingly, these examples signal that the FDA will hold companies responsible for their direct actions, such as in the examples of a company's own tweets or sites with off-label information. They also signal that the FDA may hold companies responsible for third-party postings (the blogger example) if the company explicitly encouraged that third party to post improper information. And the FDA will monitor implied, as well as direct, company representations, such as those made via usernames, e-mail

addresses, and URLs.

What is surprising, though, is the FDA's indication that it may hold companies responsible for the content of third-party postings even if the company did not request that content. In its example of a company inviting users to post videos of their product experience, the company did not request off-label videos. Yet the FDA considered users posting such videos to have been solicited by the company. This leaves things murky at best. Accordingly, companies hosting social media sites should consider limiting the subject matter of user posts, disclosing those limits, and screening for improper user posts.

## Disclosures, Given Space Limitations

Internet advertisements often have space limitations. Twitter, sponsored links (on search engines like Google), and share widgets (on sites like Facebook) generally do not have enough space for the type of risk disclosures that the FDA requires. In a recent untitled letter [PDF], the FDA found the following sponsored link (names redacted) misleading because it suggested efficacy without disclosing risk information:

*[Drug] Lowers Risks of Future Heart Attack or Stroke from [disease]*

*See how [Drug] may help patients with recent heart attack, recent stroke, or established [disease] at Diseasefacts.com*

The FDA also found [PDF] the following sponsored link misleading, even though it makes no explicit claim about the drug:

*[Drug]® Official Site*

*www.DRUG.com[Disease]Can Be Tough.* Learn About a [Disease] Medicine

This example illustrates that, even if the sponsored link or widget does not explicitly state that the product treats the disease, the FDA may find an implied connection and require risk disclosures in the link text.

The FDA has issued over a dozen such untitled letters on sponsored links or share widgets. It wants more disclosure. The safest approach, for now, would be to avoid such advertisements altogether until the FDA offers better guidance.

## One Click Away

In the examples above, the links brought users to another web page with risk disclosures, presumably to balance the product claims (express or implied) made by the text of the sponsored links. The FDA found [PDF] placing such disclosures "one click away" from the product claims to be deficient:

[F]or promotional materials to be truthful and non-misleading, they must contain risk information in each part as necessary to qualify any claims made about the drug.

Now, the FDA might determine that placing risk disclosures "one click away" is sufficient if the text of the sponsored link, unlike in the examples above, discusses only the disease, does not name the product, and makes no implied or express representations about the product (i.e., makes no product claims), and the product is instead first named, along with risk disclosures, on the other side of the link. But until the FDA issues further guidance, this is uncertain.

The FDA might eventually adopt an approach similar to that in its broadcast advertising guidance, which allows companies to make just a "major statement" of a product's risks and adverse events, if it accompanies that statement with an "adequate provision" of access to a more complete discussion of risks—possibly via a link to another web page. But even this approach may be unworkable, since the text of a "major statement" may be too lengthy (think of side-effects voice-overs from commercials) for the space limitations of Internet links and widgets.

## Employee-Created Content

The FDA issued an untitled letter [PDF] to a company whose sales representative allegedly created and uploaded to YouTube a video that promoted a product but contained no risk disclosures. This underscores the importance of updating Internet and social media-use policies and educating employees about them.

## Third-Party-Created Content

Companies have begun implementing precautions on social media sites. Some companies shut down Facebook pages after Facebook restricted companies' ability to prohibit posts on the service's walls. Other companies screen for and remove improper Facebook comments. Companies adopting these measures should consider disclosing that they do such pre-screening and removal, and disclosing topics, such as unapproved uses, that are prohibited. Keep in mind, though, that these precautions bring with them responsibilities and the costs to implement them with properly trained personnel.

*John Sullivan, a litigation partner at Dechert, represents global companies in the life sciences, chemical, and other industries in class action and complex litigation with claims ranging from negligence, failure-to-warn, securities fraud, consumer fraud, and design defect, to conspiracy, contract, quasi-contract, warranty, and fiduciary duty. He has defended clients in numerous mass torts, where he focused on the scientific, expert, and FDA regulatory areas, and has served on several trial teams. Mr. Sullivan is a graduate of Rutgers University School of Law and a co-author of the award-winning Drug and Device Law blog. Michael Planell, a Dechert associate, defends clients in mass tort, product liability, class action, consumer fraud, and complex commercial litigation matters. He is a graduate of Fordham University School of Law. Darren Goldman, also a Dechert associate, focuses his practice on product liability and mass tort matters. He is a graduate of Boston University School of Law.*