

SOCIAL MEDIA FOR PHARMA BRAND MANAGERS



► The emergence of social media has posed some difficult problems for marketers, in some ways more complex than the emergence of Internet marketing channels in the 1990s.

Drugmakers, for their part, must address even more difficult challenges than other industries. Pharma managers face painful consequences if their social media promotions don't meet FDA requirements—and ignoring adverse reaction reports on forums like Facebook or Twitter could lead to big problems as well.

Fortunately, the next several months should do much to clear up confusion and help pharmas move ahead with their social media plans.

By the end of this year, drugmakers should be in a better position to move ahead with social media, as the FDA is due to issue guidelines for the industry during 2010. While the issues will remain complex, such guidance should reduce the risk of mounting social media campaigns.

With that safety net in place, brand managers can tap into the experiences of colleagues who have already taken the plunge. After all, while the industry may not have a best-practices manual to work from yet, early adopters in the pharma world have begun to figure out which social techniques (such as educational forums, support groups and branded social media applications) can produce results.

In the following pages, we've set out a guide to help prepare you for the next wave in pharma social media use—including a look at the important legal, regulatory and strategic problems you'll encounter. Since issues are still in flux, we haven't got hard-and-fast answers to offer, but we hope to give you plenty of food for thought.

Thank you in advance for reading this eBook. We hope it helps you move forward in your social media efforts! ●

– Editors of FiercePharma

▼ THANK YOU TO OUR SPONSOR:



3
Meeting
Consumers
Where they Live

5
Pharma Social
Media Marketing
Blunders

7
Sermo: Engaging
Physicians
On-Demand Through
Social Media
Sponsored Content

8
What Works:
Pharma's Social
Media Success
Stories

9
The Future of
Pharma Advertising:
DTC Goes Social

12
FDA Social
Media Proposals
Put Pharmas
on Notice

14
Adverse Reaction
Reporting
Challenging in
Social Media

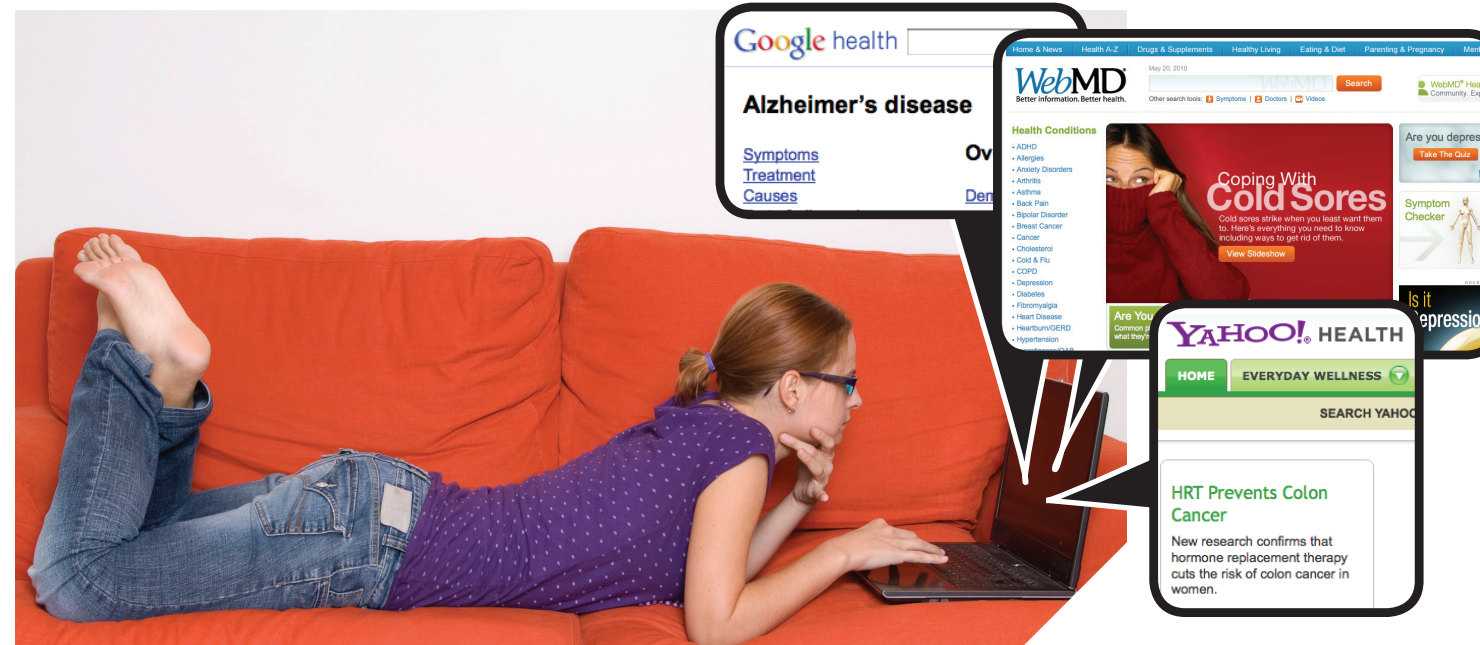
Meeting Consumers Where they Live

BY ANNE ZIEGER

► Pharma brand managers spend a lot of time wondering how to reach consumers through social media. This is a risky proposition, given that the FDA is still weighing what kind of social media marketing it will permit. As a result, some pharma marketers have stayed away from social media entirely, and others have cut off many community-building features, including consumer comment functions.

But pharma marketers don't need to sit on their hands when it comes to social media, or mount crippled campaigns. One way to keep making progress, researchers say, is to spend time digging into where consumers are already getting their drug-related information online, both inside and outside of social media channels. Studies increasingly suggest that if pharmas meet consumers where they live, social media-wise, their campaigns will be far more effective.

"Pharma marketers shouldn't be seduced by the bright, shiny object of 'running a social media campaign' when there's so much that they can do with social media behind the scenes," argues Aaron Gerrick, senior director of the Strategic & Analytic Consulting Group with marketing services firm Epsilon. "With the right tools and



expertise, the social web becomes a rich source of consumer insight."

To date, critics argue, drugmakers have been far more prone to transfer their existing sales pitch to, say, Facebook or YouTube rather than

One way to keep making progress, researchers say, is to spend time digging into where consumers are already getting their drug-related information online, both inside and outside of social media channels.

find out how to find and connect with their audience. But if they find out which sources consumers trust, and what types of drug information they share, this gives pharma marketers a significant leg up.

One data point worth considering is that consumers find high-profile medical Web properties like

WebMD, YahooHealth and Google Health to be credible, according to research by marketing services firm Epsilon. What's more, visitors spend an average of 91 percent more time on health content sites than they do on branded pharma sites, according to a recent study by digital marketing research firm comScore. The most popular social media sites used for finding health information are Facebook and Wikipedia, comScore researchers found.

While websites are still pivotal channels, social media channels are becoming an important part of the mix, with 53 percent of Internet users reporting that they've used social media tools to discuss health topics. Thirty-one percent of those respondents are looking for prescribed or available medication, comScore found.

Not surprisingly, Epsilon's research found that pharma campaigns that reach out through these sites' social media tools can be

very effective. Forty percent of respondents that use web tools engage with social media tools on health sites, the firm's researchers found; in fact, almost 20 percent of respondents do so every week. Getting involved in these discussions is more effective than offering solely branded drug content.

Another key issue is understanding what consumers are looking for when they stumble across pharmaceutical advertising on the web. Epsilon found that about 50 percent of consumers are looking for disease-related information, and about 30 percent are looking to check out what symptoms mean. Meanwhile, just over 10 percent of consumers reported that they were scouting for drug information. Still, 46.7 percent of comScore respondents reported that social media sites help them make better medical decisions, a stat that pharma brand marketers can leverage.

"It's clear that the main interest

of consumers is the foundational information—they want to understand their condition, learn about the symptoms and treatment options and understand key terms," the Epsilon report found. Addressing those content interests should be front and center for pharma marketers, researchers concluded.

Then there's the question of who's actually using social media channels and visiting health sites. According to comScore, 78 percent of people with an identified condition visit health sites and use

the site's tools. But 56 percent of caregivers also visit such sites. Pharma marketers should also consider how consumers at different stages of treatment and awareness differ. For example, sophisticated patients may go directly to branded drug sites, while newly diagnosed patients or caregivers may visit social sites or channels to communicate and share experiences.

Perhaps most importantly, it's important to consider what behavior consumers engage in when they

continued on page 5

MEASURING SOCIAL MEDIA ROI

It can be slippery to measure ROI when you're working in a new medium. (Remember when it seemed almost impossible to measure returns for Internet campaigns?) But according to researcher Kevin Kruse (@kevinkruse), there's a well-defined set of steps that provides reasonable ROI numbers for your social media campaign. These include:

- Bear in mind that while social media use may be free, creating campaigns isn't. To estimate social media expenses, pharmas should look at factors such as staff time to be invested, agency fees, video production and editing for YouTube campaigns, and the budget for making the video's sponsored content.
- Create a list of click-throughs that foster the goals of your marketing effort. For example, pharma marketers might track click-throughs from social media content to their branded sites, disease-related sites they've sponsored, free trials, doctor discussion guides or ordering brochures.
- Establish which benefits you'd like to realize as a result of your campaign. For drugmakers, Kruse suggests new patient prescription starts and increased refills of existing scripts.
- Leverage your social media presence by driving patients into customer relationship management programs, and measure the results. For example, Kruse notes, if patients in CRM programs stay on a drug four months longer than those who aren't in the program, that could be a \$4,000 gain in revenue. In that case, pharmas could assign a \$4,000 value to patients who sign up after clicking on a social media link.

continued from page 4

hold health-related conversations on social media sites. According to comScore, 51 percent of respondents said that information found on social media sites had prompted them to speak with their doctor about a particular drug, and 62 percent planned to speak with their doctor about a disease or condition.



Ultimately, even with extensive consumer data in hand, social media marketing is still in transition, and drugmakers will need to experiment and learn, observers argue. The key is to simply jump in and get engaged in the social media conversation, suggests pharmaceutical industry blogger Steve Woodruff. "Measure what and when you can," Woodruff says. "But don't sit at the starting line when being involved in social networking can bring about so much potential good over time." ●

Pharma Social Media Marketing Blunders

BY ANNE ZIEGER

► While pharma social media marketing is just beginning to hit its stride, the issues it raises have been percolating beneath the surface for quite some time. Below, take a look at some examples of how unskilled use of social media tools can come back to bite brand managers.

J&J STUNNED BY MOTRIN MOMS BACKLASH

Back in September 2009, Johnson & Johnson's McNeil Consumer Healthcare brand began running television ads promoting OTC pain reliever Motrin. The ad suggested that mothers who "wear" babies in slings develop backaches and, moreover, that mothers wear baby slings to be fashionable and trendy.

The response was immediate and angry. Not long after the ads aired, offended mothers began



Twitter and used it to post comments critical of the ad.

From that point, J&J's problem escalated into a crisis. Influential "mommy bloggers" posted items critical of the ad, other moms posted videos critical of the spot on YouTube, and more than 1,300

Twitter and used it to post comments critical of the ad. From that point, J&J's problem escalated into a crisis. Influential "mommy bloggers" posted items critical of the ad, other moms posted videos critical of the spot on YouTube, and more than 1,300

While the statement was a good idea, most critics suggested that J&J did too little, too late. For one thing, in simply apologizing and moving on, the pharma blew an important opportunity to engage in a conversation with its customers, according to *Advertising Age's* Tom Martin. Perhaps more importantly, if J&J had tested the social media waters and taken the pulse of real moms, it might never have had this problem in the first place.

YAZ BRAND GETS TRASHED BY YOUTUBE VIDEOS

In theory, the brand managers behind Bayer contraceptive YAZ were working from the right playbook. With pharma marketers being encouraged to push their content onto social media sites, a YouTube channel could be a great idea.

Unfortunately, being one of the first pharmas to create a YouTube channel didn't work out the way that the company had hoped. Instead, Bayer lost control of its message, which is just about any marketer's nightmare.

As *Pharma Marketing Blog* editor John Mack notes, the YAZ Birth Control Channel looks fine when viewed in its original form. But if users click on "view comments, related videos and more," the trouble begins. They're presented with the "generic" YouTube format, which includes a sliding right-hand panel of video links presented by

the site. Those links are chosen to be relevant to the video users are watching at that moment.

Bayer lost control of its message, which is just about any marketer's nightmare.

In this case, the videos were largely placed by law firms suing Bayer, alongside of parodies of YAZ television commercials, Mack notes. Bayer turned off comments when it realized its image was being compromised, but it still can't prevent viewers from seeing these inappropriate videos.

Mack concludes, "My advice to pharma marketers: Unless you intend to promote a real discussion or upload a series of videos that will enhance the value of your YouTube channel, stay away from YouTube!" ●

If Johnson & Johnson had tested the social media waters and taken the pulse of real moms, it might never have had this problem in the first place.

venting their feelings on Twitter. The topic became so popular that it acquired its own hashtag, #Motrin-Moms. Meanwhile, an aggrieved critic seized the @motrin identity on

members of Facebook joined a group boycotting Motrin.

Eventually, a senior member of McNeil's executive team posted an apology for the ad. "We cer-



Sermo: Engaging Physicians On-Demand Through Social Media

BY GREG SHENK

THE SERMO COMMUNITY:

As the largest online community for physicians, Sermo has become a valuable resource for MDs to share advice and educate each other. To date, more than 115,000 physicians have joined Sermo to discuss a wide range of issues ranging from clinical cases to advice about drugs and practice management. Sermo is only for physicians and every member must be verified and credentialed before they can join.

Unlike a standard discussion board, Sermo conversations happen in the form of a post and are not edited or moderated. Each post includes an insight or question, a poll, and a comment section. This allows physicians to gather both qualitative and quantitative feedback from colleagues both within and outside their specialty. This model has driven nearly 50,000 posts, 1 million comments and 3.5 million votes. It also allows for “crowdsourcing” about the most talked about drugs, disease states, and therapies – even new innovations.

THE BUSINESS MODEL: HOW DOES IT WORK?

Sermo’s social media platform allows Life Sciences Companies (pharma, med device, biotech) to interact directly with its physician community. Because there’s already an active group of MDs

collaborating online, Sermo can provide fast, candid exchanges not possible through other channels. Engagements that used to take months can now happen in as little as a few days.

Sermo’s business model is often described as a “two-sided” marketplace. On one side, physicians benefit by teaching and learning from each other in a private, peer-to-peer setting. On the other side, Life Sciences Companies benefit by engaging physicians in the Sermo community for market research, awareness, and promotion.

ENGAGING PHYSICIANS: PROVEN SOCIAL MEDIA INTERACTIONS

MARKET RESEARCH

Because physicians on Sermo are already collaborating online, Sermo can provide fast, quality, and cost-effective interactions with any group of physicians. You can target physicians by demographic criteria or match them against a target list. Perhaps the biggest differentiator for Sermo is that its physicians are already sharing honest and candid feedback with each other– and they bring that same thoughtfulness to their interactions with clients.

Sermo’s market research includes both quantitative and qualitative services. Clients

SPONSORED CONTENT

can survey physicians, conduct online focus groups, spark discussions, and monitor organic physician dialog across the entire community.

AWARENESS & PROMOTION

Sermo does not offer traditional advertising. Instead, it allows for educational exchanges with practicing MDs about topics of interest such as clinical trial data, new studies, products, or events.

In order to achieve the best possible outcome, Sermo works with every client to pinpoint key messages and create a productive dialog. This can be done in the form of a Sermo Survey or Sermo Panel, which allow clients to inform their message(s) before launching a campaign.

After determining the right message set, Sermo works with its clients to create awareness about the topic through variety of promotional channels, including email, special highlight areas within its community, sponsorships, and pages dedicated to a therapeutic area, topic, or drug (sponsorships/ pages coming soon!)

To learn more about engaging physicians on Sermo visit www.sermo.com/client.



What Works: Pharma’s Social Media Success Stories

BY ANNE ZIEGER

▶ Given the regulatory issues pharma companies face when experimenting with social media, it’s hardly surprising that many brand managers decide to take a pass. But that doesn’t mean pharma has stayed away from it entirely.

The following case studies were selected by Jay Krall of Cision, a public relations shop based in Chicago. Some are fairly dated, but as Krall notes, the pickings are slim, since many drugmakers put a freeze on social media marketing once the FDA began to focus on the issue.

Having said that, there are still some good ideas being tested. Here are Krall’s top choices for pharma social media campaigns:

- McNeil Pediatrics chose Facebook for its [ADHD Moms](#) site, which fosters both medical and social discussion among participants. The page offers educational information, advice, guided community discussion, a non-employee “Mom-bassador” tasked with writing up her experiences as a caregiver, and podcasts. When checked in mid-2010 the page had more than 11,000 fans. The site, which seems to be active, states in a few locations that it’s sponsored

by McNeil. However, it doesn’t pitch any form of medications.

- Johnson & Johnson Acuvue’s [Acuminder](#) application on Facebook offers the ability to remind consumers of any “little details” that their life involves—including, of course, reminders of when to change contact lenses, buy new ones or schedule an eye exam. With 567 fans, it’s only a minor success from a Facebook standpoint—some retailers have hundreds of thousands—and seems to have gone non-functional in the roughly 15 months since it was created. Still, for a while it did a good job of tying together real conversations with promotions, Krall reports.

- GlaxoSmithKline’s [MyAlli](#) offers a community function it calls “allicircles.” While the approach harkens back to computing days of old—it’s a modern version of a basic threaded discussion—it still gets the job done, fostering supportive conversations and information sharing among users in a way which also promotes trust in the product. Not surprisingly, the site also offers links to its page on Facebook, its Twitter account and YouTube, but these seem to be there to

enhance, not substitute for, real conversation-building.

- AstraZeneca maintains a [YouTube channel](#) offering updates on charitable activities such as its support for Boston’s Hope Lodge Center. It also presents a large number of videos featuring AZ’s CEO David Brennan. As with many other pharmaceutical companies, AZ has turned off the comment function that accompanies the videos. Much of the material seems to involve official statements more typically aimed at members of the media or at Wall Street.

Many pharma marketing experts predict that as DTC ads migrate online, and the FDA offers more guidance for drugmakers on social media marketing, pharmaceutical companies will launch far more robust social media offerings. But until then, success stories may be hard to come by.●



The Future of Pharma Advertising: DTC Goes Social

Q&A WITH DJ EDGERTON, CO-FOUNDER OF PHARMA DIGITAL MARKETING AGENCY, PIXELS & PILLS



► **FiercePharma:** Why are pharmas using social media at all, given the regulatory risks involved?

DJE: Obviously, the regulations in place never have considered social media as a type of communication that would ever exist.

I think the knee-jerk reaction is that if pharma companies and brands don't participate, others will participate on their behalf. The conversation is happening regardless. Consumers in general are partici-

pating in a conversation whether it's specific to a disease state or treatment in general. I think it's the responsibility of the pharmas to participate in the conversation.

Also, when pharma companies are looking to put their finger on the pulse of what's going on out there, there's no better format than social media to reach people suffering from diseases or health conditions. You can't go the bus stop and talk to another mom whose child suffers from MS. Those people don't exist in the localized circle of influence, so it's very hard to share some of the challenges involved. Social media allows for some very strong bonds to occur, and often they go offline as bonds mature.

Another reason why pharma companies are going this way is because they see the potential in what we call "enlightened moderation." You can empower patients, caregivers and physicians with the platforms that they need to have real, meaningful dialogue and sharing.

FiercePharma: What social media techniques have you seen that have proven to be successful for pharma brand managers?

DJE: Sites that I think have provided value include (Facebook-based) [ADHD Moms](#), which was launched with the intent to provide real information to moms whose children have the disorder. This has

created a community of parents who really do share information.

The trend is that patients are going to the Internet for third-party endorsements in circles of influ-

"When pharma companies are looking to put their finger on the pulse of what's going on out there, there's no better format than social media to reach people suffering from diseases or health conditions."

ence that they trust. If you can create a community of like-minded individuals facing the same health-care challenges, you are inherently going to create a bond among

them that will have a trickle-down effect to that pharmaceutical company and brand associated with that support mechanism. You don't necessarily have to pitch a

particular drug; all you have to do is empower people to talk amongst themselves as a service to them because you really care.

The pharmaceutical companies that people believe actually care are the ones that will be successful. And social

media's not the be all and end all, but it is a wonderfully effective tool to give people the impression that you actually care. Consumers can

continued on page 11

More Views on Pharma Social Media Use

► Should [pharmas] actively avoid participation—even to the degree of monitoring—lest they uncover an adverse experience? Shouldn't companies embrace social media so that adverse experiences can be found with greater alacrity? Shouldn't companies be rewarded for such behavior? If regulated industry wants the FDA to be both regulator and colleague, then it's not a leap of faith to imagine that the FDA would like industry to be proactive in its search for new ways to surface adverse events.

I know of one large pharmaceutical company whose policy is not to monitor social media sites because they don't want to unearth adverse events. Is this responsible? Is it even supportable? If this company received a call from a reporter and was asked if they purposely avoid social media so as not to find adverse experiences, would the truth set them free? Legally they may be in compliance, but it wouldn't look good on Page One or sound very good in front of a congressional subcommittee. "In compliance" and "in the best interest of the public health" must not be mutually exclusive propositions.

— Peter J. Pitts, President, Center for Medicine in the Public Interest

► To date, Lilly has avoided significant interaction with healthcare professionals and patients about our products in social media forums—largely because of a lack of clarity in understanding FDA's expectations as to how we could participate and comply with FDA requirements.

We did recently launch a blog on Medscape, written by our U.S. medical team, to share information with physicians. Participants are allowed to post comments, either about our blog post or about each other's comments. That's the essence of social media, after all—the ability to share information, experiences and opinions with others in the community. We are pre-screening all comments, however, and declining to post any that mention a product.

— Eli Lilly and Company

► Many non profit "disease advocacy" groups which are primarily or substantially funded by industry have expanded the scope and range of material and interactive media tools they have on the Web. This is of great concern to us. We have reached the conclusion that FDA should consider regulating portions of the content of the Web sites of groups that get a substantial portion or majority of their funding from drug or device companies.

— Steven Findlay, Senior Health Policy Analyst, Consumers Union

continued from page 10

see right through the sales pitch, but they'll embrace the community aspect if you support it in an honest and effective way.

FiercePharma: What pharma social media strategies have been less successful?

DJE: One of the things to keep in mind is that the most effective component of social media on, say, Facebook is the Wall post. It's an immediate opportunity to have conversations on particular subject matters.

The problem is that under FDA guidelines the need to report adverse events creates such a level of risk that most pharmaceutical companies shut off that functionality.

"Before moving in any direction at all, you need to have in your corporate DNA the willingness to change the way you talk to your consumers. Because the way people are communicating with each other is changing..."

But in my opinion, that robs the audience of the entire reason that they want to participate in the community. It's kind of like throwing a party and putting duct tape on everyone's mouth. No one's going to go to that party.

The reality is, nobody wants to "friend" Lipitor, but people will join a community that provides information and support so that people with high cholesterol and who have

family with high cholesterol will socialize.

Besides, technology is now available—through semantic filtration as well as building applications within Facebook—to allow for the dialogue to happen but also weed out and flag conversations that might be risky.

One of the things pharmaceutical companies forget is that if you provide real value exchange, consumers will agree to terms and conditions that are often far more restrictive than what the common consumer would agree to. If you back up those terms and conditions with technology that monitors posts, you can provide an environment which allows people to have healthy and compliant communication without creating an enormous amount of risk.

And the upside potential is huge. With just some intelligent tweaks to the consumer model, you can leverage social media so that you create a groundswell

of patient support and insight that goes a long way in developing a relationship. The consumer is going to know who was there when they needed them.

On the other hand, not having guidelines is a big mistake. Before moving in any direction at all, you need to have in your corporate DNA the willingness to change the way you talk to your consumers. Because the way people are



communicating with each other is changing, and if you don't adopt your guidelines correctly and empower your employees to do the right thing, you run the risk of some unfortunate situations.

FiercePharma: Finally, how is traditional DTC advertising going to be affected by social media? Will it change?

DJE: DTC advertising is going to change with regulation to the point where it's almost undoable. Nobody's going to pay for three minutes to offer the necessary fair balance that will be required. And who wants to pay for five ads in a magazine when one is brand-related and the rest is only information that goes behind it?

One of the big things that's going to happen in the next 12 to 24 months, if not sooner, is that digital will be driving DTC. As [a speaker at a conference] said, the only place that real DTC belongs is on the Internet. Instead of it just being branded messaging to inform people about a brand and what disease it treats, it's going to be more along the lines of informing and educating people to a whole suite of other things related to that drug.

My suggestion would be the most successful strategies for DTC will be the ones that are driven by digital, not where digital is an adjunct. Because the place where patients will be truly educated is not going to be a TV commercial or a print ad, it's going to be the web. ●

FDA Social Media Proposals Put Pharmas on Notice

BY ANNE ZIEGER



► Last November, the FDA let the public—and more notably, drug-makers—know that it planned to issue regulations on how pharma could use social media. While the new regs should hit the street by the end of this year, that's still a long time for pharma marketers who are struggling to make their campaigns meet existing offline guidelines.

The agency is starting pretty much from ground zero in its efforts. Officials concede that there's no regulation specifically addressing Internet promotion separately from other types of promotion. What's more, no regulation prohibits the use of certain types of media to promote drugs and medical devices.

The question for the FDA is

whether existing rules can be stretched to cover regulation of social media, and if not, what regulations would best extend existing drug and device standards to these new tools.

Perhaps the most basic issue the FDA faces is determining which online communications from manufacturers, packers or distributors should be regulated in the first place.

For one thing, the agency is trying to figure out how much control such entities should exert

No regulation prohibits the use of certain types of media to promote drugs and medical devices.

over their own content. Officials are also trying to sort out whether drug- and devicemakers should screen and respond to comments by the public, and if so, under what circumstances. Not only that, the agency is mulling how much companies involved with the manufacturers of pharma products should control content, and even disclose their involvement.

Where do drugmakers stand on this issue? According to Johnson & Johnson, pharma should be held responsible for content they post on their own site or third-party sites, according to J&J presenters Elizabeth Forminard and Philomena

continued on page 13

continued from page 12

McArthur, who spoke at the November hearing. A drug-maker should also disclose any material connection between itself and a content provider, they said.

On the other hand, comments by the public are another matter entirely. "Generally, user-generated content should not be considered promotional labeling or advertising," the J&J reps argued.

Another concern for the FDA is how to make sure pharmas provide fair, balanced and accurate information in new media channels (such as Twitter) that don't allow for deeper messages. While websites may offer plenty of space to present complete drug information, a Facebook fan page may not.

Yet another question the agency is examining is the use of links in pharma social media marketing. While drugmakers are not allowed to promote drugs for unapproved purposes, the Internet and social

label uses of those drugs.

Some observers consider the FDA's battery of questions to be thorough, but some critics still think the agency hasn't covered all of its bases. "There's more

there will be serious consequences if FDA allows them to use the full array of social media."

What's more, the FDA has bypassed an issue Chester sees as critical. "Drugmakers never talk about the social media monitoring they may be deploying," he notes. "I think pharmas thought they could pull the wool over the Commission's eyes."

Chester, who expects to meet with top FDA officials soon, will urge them to focus more on consumer data collection through social media. "The agency didn't get into privacy concerns this time," Chester said. "I think it failed to do due diligence." ●

While drugmakers are not allowed to promote drugs for unapproved purposes, the Internet and social media seem to be providing them with a loophole.

media seem to be providing them with a loophole. At present, some pharmas provide links from branded sites to other information sites that may contain information on off-

than meets the eye here," said Jeff Chester, executive director of the Center for Digital Democracy. "Pharmas have presented social media as mom and apple pie, but



Adverse Reaction Reporting Challenging in Social Media

BY ANNE ZIEGER

► For years, pharmas have been struggling to use promotional advertising on the web effectively, as the medium is far more elastic than traditional product packaging or even television advertising. While most have managed to adapt, a few have received FDA warnings over content that the agency perceived as lacking risk-benefit balance.

The game has gotten more complex with the emergence of social media. Not only do pharmas have to meet FDA promotional guidelines, they also have to figure out how to deal with adverse event reports. What's more, the problem is likely to grow more complex as social media networks emerge, merge and add new features.

At the moment, drugmakers still aren't sure how to cope with adverse events reported on the web, much less on Facebook, within tweets, in articles targeted by social bookmarking sites, or content on blogs.

The FDA's [current position](#) is that pharmaceutical companies should simply follow existing guidelines for other media when they go online. However, that leaves questions unanswered, said Areta L. Kupchyk, a DC-based partner in the life science health industry group of law firm ReedSmith.

"Let's say there's a website talking about the use of a specific

product, and party X says that someone was killed by that product," Kupchyk said. "The question is whether pharmas should monitor [all comments to screen for this type]. And if they're not monitoring comments, do they need to respond to them at all? Do they need to have a disclaimer on a page offering consumers a phone number to call if they've experienced adverse events?"

Then there's the question of

While most [pharmas] have managed to adapt, a few have received FDA warnings over content that the agency perceived as lacking risk-benefit balance.

whether pharmas have an affirmative obligation to mine the web and social media for adverse reaction reports. The FDA is mulling over this issue, but hasn't reached a conclusion. Not surprisingly, drugmakers addressing a recent FDA meeting on social media promotion emphatically denied that they should be required to do such research.

With the stakes so high, should pharmas avoid social media until the FDA offers ironclad guidance on the adverse event issue? Not necessarily, as long as they do it carefully, argues Kalah Auchincloss, an associate with the D.C. office of law firm Foley Hoag LLP.

"I'd advise any company to turn off the comment feature of interactive websites, but I don't think pharmas should be afraid to use social media, if they use it in a way that complies with the law," she said. "Just be smart about it. Use your intuition, and if something feels like it's wrong, check it out." ●

