Robin Robinson

The HIGHS and LOWS of Social Media

As an industry used to functioning within stringent guidelines, pharma companies are finding the lack of regulations around social media disconcerting.

Pharma has made great strides in its digital marketing efforts, but many companies are still hesitant to walk the social media path. The lack of regulatory guidance is a major deterrent, according to a recent Cutting Edge Information report. Although the FDA provided some guidance in terms of social media in December 2011, the context is too vague for comfort for the risk-averse, heavily regulated industry. The industry is struggling to make its way through uncharted territory, and with good reason, our experts say.

In its recent survey, Cutting Edge Information found that the marketing mix has been shifting more and more toward digital over the past few years.

According to Ryan Maguire, research analyst, Cutting Edge Information, the results were a surprise; in 2011 54% of the marketing mix had shifted to digital compared with 34% in 2009.

"The industry is obviously not discounting digital media, but we believe there is still some uncertainty among companies on how to use it," he says. "The industry's communications are so highly regulated, and adopting new technologies can be scary."

The myriad of regulations that apply to print media are essentially the same for digital marketing materials, says Jim Andrew, life sciences and healthcare industry expert, at PA Consulting Group.

"It is in the sphere of social media that the rules get very ambiguous," he says. "Maintaining compliance in developing digital marketing programs is a fairly straightforward process, however, the industry may feel it is still a bit of the Wild West on the social media side. There is a lot of exciting marketing being done by the industry in the digital space, but not so much in social media. There are patient communities, Facebook pages, and forums that exist for patients to have discussions, but they aren't operated by pharma companies."

Mr. Andrew believes that the only risk-free way for pharma to use social media is as a push medium. The industry may never be able to take part in two-way conversations with its consumers, as it represents too much compliance risk, he says.

According to Mr. Maguire, however, the benefits of having a presence on social media far outweigh the disadvantages. As far as running afoul of the FDA, he notes that the FDA issued only two warning letters in 2012, and those were for violations pertaining to language being used on a website in which the FDA said the content understated the safety risks.

"These types of violations can happen to any company," he says. "In my opinion, the risk isn't big enough to validate pharma's hesitancy to take advantage of the opportunity to inform patients via a medium they want to be engaged with," he says.

The new digital consumer is very interested in two-way communication, he says, and pharma should use this fact to its advantage by becoming an educational resource that can be found on social media.

"Consumers don't respond well to push marketing these days," Mr. Maguire says. "They want to be a part of the conversation and they want to be heard, they want to know their opinion matters and they count."

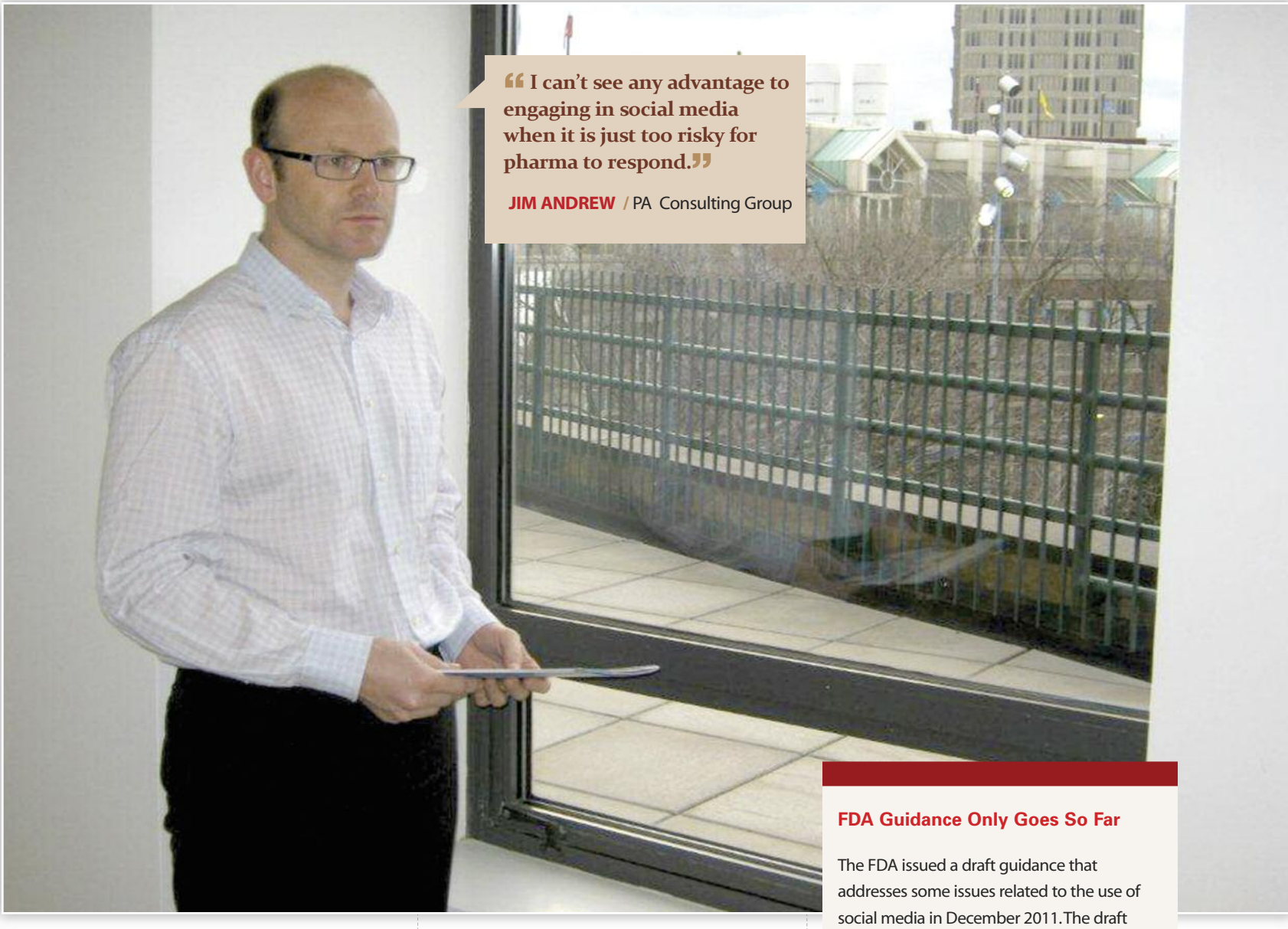
Engaging with patients on social media shows that a company cares about its patients and, according to Mr. Maguire, mitigates the "big-bad-profit-driven-corporate" reputation the industry has gained over the past few years.

There are some early adopters in the industry that have created tools and information

FAST FACT

THERE ARE MORE THAN 500 MILLION ACTIVE USERS ON FACEBOOK AND AN ESTIMATED 184 MILLION BLOGGERS WORLDWIDE TODAY.

Source: PA Consulting Group



> "I can't see any advantage to engaging in social media when it is just too risky for pharma to respond."
>
> **JIM ANDREW** / PA Consulting Group

that help patients have better outcomes, and they have gained a tremendous advantage in terms of public relations, Mr. Maguire says.

"Consumers view these companies as part of the solution," he says.

Tracy Acker, Pharm.D., president of the The Acker Group and a CCC Advisory Board member, agrees that the Internet and social media don't have to be completely off-limits for medical product promotion.

"There are things that companies can do as long as they are executed properly; for example, companies can use the product name, provided there is no suggestion about the product, otherwise known as reminder promotion," she says. "In this instance, of course, the company should comply with all the standard requirements pertinent to reminder promotion. Reminder promotion could be used in banner ads, Twitter feeds, chat rooms as well as in most promotion vehicles in printed, graphic, or Web-based media."

Should They or Shouldn't They?: An Open Dialogue is the Answer

A two-way conversation by definition has to work both ways. Some say pharma companies should start responding to emails and tweets to help dispel myths and defend their data and medicines. Other experts advise that companies should hold tight until there are clear guidelines from regulators.

"Pharma companies should be able to have their say, and I think patients would be happy to receive an email from a pharma company if it helped resolve an issue they were having with a product," Mr. Maguire says.

Mr. Andrew from PA Consulting Group is much more cautious in his advice.

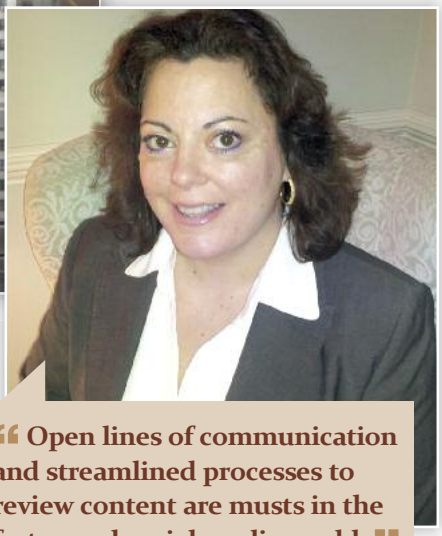
"I would advise pharma companies do ab-

FDA Guidance Only Goes So Far

The FDA issued a draft guidance that addresses some issues related to the use of social media in December 2011. The draft guidance, Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices, outlines the FDA's current views on how manufacturers and distributors (firms) of prescription human and animal drug products and medical devices can respond to unsolicited requests for information about unapproved or uncleared indications or conditions of use (off-label information) related to their FDA-approved or cleared products, including those that firms may encounter through emerging electronic media.

For more information visit, fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf.

> "Lack of specific guidance from the FDA is not the only challenge for social media marketers."
>
> **ILYSSA LEVINS**
> Center for Communication Compliance



> "Open lines of communication and streamlined processes to review content are musts in the fast-paced social media world."
>
> **PHILOMENA MCARTHUR**
> J&J International

solutely nothing until it is clear what the FDA requires," he says. "I can't see any advantage to engaging in social media when it is just too risky for pharma to respond. I think the industry should definitely take a wait-and-see approach to social media."

There is risk in doing nothing, however, says Dale Cooke, VP and group director, regulatory review, at Digitas Health. If a company waits too long to engage with consumers on social media, the competition will have already provided them with the information they were looking for.

"Waiting for further guidance from the FDA before adopting these channels will simply allow other entities to fill people's informational needs," Mr. Cooke says. "We know enough to use social media compliantly, but doing so requires a genuine commitment to learning about social media throughout the entire organization."

That learning should start with creating a designated team or leader who understands the nuances of social media. Many of the industry's C-suite executives are not social media savvy, therefore someone with expertise in the area must be given a seat at the proverbial table. For example, many leaders in the C-suite still print out emails and do not use digital media in their daily business operations, Mr. Andrew says. Having a social media advocate who can integrate and motivate the use of social media within the corporation and in communications to the public is a crucial role in this new world.

"One of the challenges today is that most pharmaceutical companies don't have leaders in the space to espouse the use of social media," Mr. Andrew says. "Social media needs to be integrated into regular operations. The industry needs to establish role model leaders in the digital space who have the skills and capabilities to build digital into the company's daily routine."

The Cutting Edge report shows that this is slowly beginning to happen. According to Mr. Maguire, one of the revelations to come out of Cutting Edge's recent social media study is that the industry is beginning to create digital marketing groups.

"This is a new digital age and it requires a group of like-minded people with an expertise in digital marketing to move acceptance higher up the corporate structure," Mr. Maguire says. "Companies with this internal expertise are able to form a comprehensive digital strategy that could filter down and be applied to different brands, and having a cohesive strategy gives companies an upper hand."

A leader in this space is Boehringer Ingelheim, Mr. Maguire says.

The company is using a full suite of social media channels — Facebook, Twitter, YouTube, and Pinterest — and each channel has been developed according to its unique characteristics all the while creating a uniform brand theme for its products.

"I wasn't sure how the industry was going to be able to use Pinterest, but Boehringer Ingelheim's page has eye-catching graphics, big diagrams on how cancer works, and how targeted medicines work; it's very interesting," Mr. Maguire says. "The company isn't using social media as a data dump; it is posting meaningful information and using the channels appropriately. The company also is keeping its message uniform from top down."

Philomena McArthur, senior director, regulatory advertising and promotion, pharmaceutical group healthcare compliance, at Johnson & Johnson International, believes that the industry can use social media effectively, especially if all organizations within the company are aligned.

"Open lines of communication and streamlined processes to review content are musts in the fast-paced social media world," she says. "When regulatory, communication, legal, marketing, and compliance colleagues partner early and work together, they can develop compelling, effective, and compliant digital and social media campaigns. To achieve this end result, it is important to align around goals and objectives, understand the underlying digital fundamentals, use nondigital analogies for reference, streamline pathways for applying the agreed-to principles, and engage in ongoing communication and monitoring to ensure goals are met compliantly."

Principles for Compliance

A company is clearly accountable and responsible for the content on its product website, sponsored link, YouTube channel, or Facebook page it develops, says Ilyssa Levins,

Lack of Guidance Top of Mind Concern

The Pharmaceutical Digital Marketing and Social Media study conducted by Cutting Edge Information asked pharmaceutical companies to rank challenges to their digital marketing efforts and FDA-related issues ranked very high. Pharmaceutical companies rated FDA-based concerns at an average of 7.4 and lack of FDA regulations as a 6.8 out of a possible 10. Overall, lack of regulatory guidance represented the top three concerns expressed by surveyed companies.

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>
> **DALE COOKE** / Digitas Health

president and founder, Center for Communication Compliance (CCC). But how much responsibility depends on close the company is to the content.

"When dealing with the FDA on regulatory considerations for social media, I like to refer to two principles stressed by Michael Misocky, a former FDA official and CCC advisory board member," she says. "First is the issue of accountability and responsibility. That is, the nexus or degree of the relationship between the content provider and the company. How closely is the manufacturer tied to the content in terms of either supplying the content, or providing monetary funding for that content? Did the company develop, host, influence, or pay for the content? Did it somehow have an influence on the direction in which the content goes out on the Internet?"

As the continuum of separation between company and content provider widens, the FDA will be ascertaining the nature of the relationship and the control or influence on the content being disseminated.

"Once the company has moved to independent third-party sites and discussion threads about the company products, there's less responsibility, and of course, a lower amount of accountability," Ms. Levins says.

She says the second principle is to stay within the established regulatory framework.

"Companies need to constantly evaluate if the content complies within the regulations and question whether the information is false, misleading, or lacking in fair balance within the context in which it is being used," Ms. Levins advises.

The risk of safety monitoring and the responsibility for content on other sites are the two areas that frighten the industry the most, according to some experts.

"When it comes to safety monitoring or pharmacovigilance, the responsibility for a random comment could stretch as long as 40 years," Mr. Anderson says. "According to the FDA, a company is responsible for information throughout the life of a product, even when it becomes a generic. A company certainly doesn't want to worry about an accidental posting forever."

Beyond the Fines

There are other scenarios in which improperly using digital marketing can harm a company, including, issues of fraud, product liability, and intellectual property.

According to Ms. Levins, if a social media campaign leads to a warning letter for off-label promotion, the Office of Inspector General (OIG) could be tipped off to investigate whether there was an act of fraud. For the last decade or so, the government has said if a company encourages the off-label use of a product, and if that product is then reimbursed by the government, this constitutes fraud because the physician was induced to prescribe off-label.

"The government spends a lot of money purchasing drugs under Medicare, Medicaid, and the Veteran's Administration, so it has an interest in making sure that drugs are used safely and effectively, and that they are promoted properly," Ms. Levins says.

There is also the issue of product liability claims, she says.

> "The industry is not discounting social media, but it is not sure how to use the channel yet."
>
> **RYAN MAGUIRE**
> Cutting Edge Information

"More information about a product increases the risk of legal action regarding safety," Ms. Levins says. "For example, if a pharmaceutical company has a blog or chat room where patients and/or doctors correspond with the company, this direct communication may include comments outside the approved label, making it easier for a claimant lawyer to prove its case and secure damages. Social media use also increases user-generated content that can infringe the intellectual property rights of others."

The fear of adverse-event reporting is still influencing many companies, Mr. Maguire agrees.

"Some of the companies surveyed for the Cutting Edge study still limit employees activities on social media and don't even monitor conversations on social media because they do not want to be liable for an adverse event report," he says. "I don't think forwarding a handful of new adverse events a year from listening to social media chatter is going to hurt business. It takes hundreds or thousands of adverse events to make changes to product labels or initiate a black box warning. But some companies don't want to even listen to discussions on social media."

Times are changing and according to the Cutting Edge survey, more companies are listening in on conversations and are training their front line employees on proper procedures for reporting adverse events.

Time will tell, and sooner rather than later, if high-compliance barriers and fears around regulatory repercussions will keep social media use low or if companies will develop the right level of procedures and fail-safes to engage patients in a two-way conversation. PV

FAST FACT

79% OF SURVEYED COMPANIES' MARKETING STRATEGIES ARE AFFECTED IN SOME WAY DUE TO THE LACK OF SOCIAL MEDIA GUIDANCE.

Source: Cutting Edge Information