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Social commentary

Will FDA regulatory policies evolve with the world-wide web, or will the web need to conform to the agency's regulations initially developed for print media? What would an Internet guidance say, if one were developed by the FDA? How should the industry proceed with social media campaigns until a formal guidance is issued?

These are a few of the questions the Center for Communication Compliance (CCC) posed to five regulatory, compliance and industry experts immediately following the FDA's social media public hearing held on 12-13 November. All stakeholders are looking for guidance on how to promote human and animal drugs and biologics, and medical devices using the Internet and social media. Industry, consultants, promotional agencies, patients, healthcare practitioners – everyone has a stake in the outcome.



It's more important than ever to know the fundamentals of regulatory compliance for these valuable tools, specifically the current laws and policies, as well as the issues yet to be resolved. Fortunately, there are practical and timely ways to remain up to date and objectively confirm that you understand the evolving terrain.

Wayne Pines, president of regulatory services and Healthcare at APCO Worldwide and chair of the CCC advisory board

There is certainly a future for marketing prescription products on the Internet. I don't think there's any question about that. I did not hear any discouraging remarks from anybody at the FDA, either on the podium or behind the scenes that would indicate that they're thinking about squelching the Internet as a vehicle for providing information on the web about prescription drugs and devices. The FDA didn't have people on the podium who are looking at the Internet as a threat. I think they are looking at it as an opportunity, and now it's their job to define what that opportunity is.

The key challenge that the FDA is going to have – and the testimony that they heard hopefully will help them – is how to make adequate provision for risk information. How many clicks away does the risk information need to be? The FDA heard from a number of individuals at the hearing who said that one click away is too many. I don't think that that will emerge as the ultimate FDA policy, but nevertheless the FDA did hear that message.

Secondly, when you have risk information, how detailed does it need to be in the initial disclosure? How much information is adequate? If you look at some of the direct-to-consumer advertising in the print area, you will see that, in some cases, there is more risk information than there is benefit

information. So the question is whether the FDA is going to impose the same standard on Internet advertising and Internet disclosure as it does in the print area.

I think we're going to see an FDA policy emerge that deals with both formal paid advertising as well as social media such as blogs and other information that is more out of the companies' control than paid advertising.

One thing is very clear in my mind, and that is that, when the FDA does come out with its proposed social marketing policy, the level of enforcement scrutiny will become much more intense, because the FDA will want to make sure that companies understand what the new policy is and are abiding by it. It will examine the sites that are up at the time or that emerge after the policy comes out to ensure that the policy is actually being followed.

Michael Misocky, president, Misocky Consulting Group

The FDA feels it's about the message and not the medium, but I think the medium does provide some context, so it's a fascinating juxtaposition of two essential terms and two core issues coming from this meeting. The bottom line is: does the pharmaceutical company content comply with the regulations? Is it false, misleading or lacking in fair balance? Those are the considerations the FDA really can't change. So, it's about the interpretation given the context. Does the context somehow make the information less false, less misleading or less lacking in fair balance? That will be a fascinating question as the FDA moves forward in developing guidance, but I think the core regulatory principles will remain.

Arnie Friede, principal, Arnold I. Friede & Associates

This hearing was pretty much a one-way conversation in two respects. First, it was one-way in that industry, which pretty much predominated the speakers – both the pharma industry and to a larger extent the agencies that support that industry – were talking to the FDA, but the FDA wasn't saying very much.

Second, with perhaps one or two exceptions, there was a notable absence of folks speaking on the other side of the issues, so if you spent the two days in the hearing room, you could walk away with the impression that there was a groundswell of absolute enthusiasm and support with nary a contradictory view about the legitimacy, appropriateness, merit, utility and public health value of the pharma industry engaging in a social media dialogue. At least from my vantage point, there is another side to that coin that, for any number of reasons, wasn't represented at the hearing. There was not a really fair presentation of thought about why it might be inappropriate for pharma to participate in the debate, why pharma might not have in the past demonstrated its trustworthiness in communicating with consumers, and why the government ought to be the one providing more health information to the public and not the pharma industry and its agencies.

So, I think that, as we used to say in law school, you have to take what was said at the hearing 'cum grano salis', or with a grain of salt. While there's an enormous amount of enthusiasm in the so-called blogosphere, I think we have to take that as just one aspect of the debate and not as telling the entire story.

I don't mean to rain on any parades, but one could come away from these two days of hearings with the thought that the FDA may have been overwhelmed by the sheer magnitude of the marketing activity that surrounds the pharma industry. I would speculate that none of the FDA participants had any appreciable sense of the sheer commercial context in which social media is

transpiring and the economic importance of that medium to so many companies. And that's a double-edged sword: it might show that we know how to do it responsibly, but by the same token, it might reinforce the notion that many people already have that this is all about commercialism and has little to do with the public health.

Ann Moravick, president, Rx4Good and co-chair, WOMMA Healthcare Committee

One takeaway from the hearing is that companies, the FDA and everyone communicating to patients in a social media setting need to be more aware of how patients receive information and what is useful to them in order for us to be more effective in enhancing the public health. The MedWatch program was criticized throughout the hearing for not being a useful resource for patients. Some said it was too complicated; others said there really wasn't an incentive for patients to be responding and reporting information on adverse events. So, figuring out how to communicate to patients in a way that meets their needs will be really important. Someone mentioned proximity and prominence of information, and I thought that was a really good way of describing how companies need to look at fair balance, in that there should always be an equality of prominence and proximity.

The information presented at the hearing really suggested that patients do not go to drug sites for information about disease, that they find those sites less credible and somewhat suspect. Even sites that offer information about disease that are sponsored by industry aren't as credible from a consumer standpoint. Consumers looking for disease information will go first and foremost to disease-related sites like WebMD or some of the sites that are sponsored by health organizations. So, I think the takeaway here is that patients really know more or less where they're going to get that credible information.

So this poses an interesting question: if there is this underlying belief that industry information isn't as credible and is in some way suspect, then how does industry use its presence on the web to increase its value to the public health, or is this even possible? One of the challenges ahead will be to sort out how industry can participate online in a way that builds and engenders greater trust with the consumer.

Christina Markus, partner, King & Spalding LLP

FDA regulatory requirements are not the only factors at play when addressing use of the Internet and other social media tools. There are other government agencies including, but not limited to, the Drug Enforcement Administration (DEA), the Centers for Medicare and Medicaid Services (CMS), and State Boards of Pharmacy that have legal requirements affecting electronic prescribing communications.

There are anti-kickback laws that punish certain actions (including furnishing various items or services of value) that are intended to induce prescribing and product selection decisions, and laws that punish the submission of 'false claims' to government payors. Other legal considerations are products liability law – for example, what responsibility does a firm sponsoring a drug product bear to monitor and qualify inaccurate information about its product that may have been disseminated? – and intellectual property laws, concerning the use and protection of trademarks and other business assets.

That's why, with or without new FDA guidance, the broader legal landscape requires careful attention as the industry moves forward.

The Author

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