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PROMOTION OF FOOD & DRUG ADMINISTRATION-REGULATED
MEDICAL PRODUCTS USING THE INTERNET
AND SOCIAL MEDIATOOLS

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The role of marketing communications is to advance the bottom line and the public good – and not necessarily in that order. Giving back is an integral part of the New Normal. And there has never been a better tool to accomplish this mission than social media.

But healthcare marketing – and particularly of the regulated variety -- is between a rock and a hard place. On the one hand, marketers understand the importance and opportunity in social media. It's where the people are. It's where the action is. But then there are all those pesky regulatory concerns.

As Walter O'Malley – the man who moved the Brooklyn Dodgers to Los Angeles once commented, "The future is just one damn thing after another."

While everyone else is using social media as a healthcare communications blitzkrieg, or "lightening war," regulated industry is digging in for a sitzkrieg, a "sitting war."

This is not good news for pharma, physicians, or patients (also known as "consumers"). Social media is the newest arrow in the communications quiver, but it's a discipline both misunderstood and frightening to those operating in the heavily regulated world of healthcare.

The Internet can be extremely useful in informing patient discussions with doctors. It can be a helpful tool to empower an individual in their medical decisions. But it is important to remember that not everything online is true. The Internet has made it easier than ever before for charlatans and quacks to spread fear and misinformation. Mark Twain wrote, "Beware of health books. You might die of a misprint." Having a website does not replace having insight.

Regulated companies mustn't feel safe behind a social media Maginot Line. Social media is a social movement and using the excuse that healthcare firms can't engage because "we're different," misses the point. Compliance issues are very important, but it's precisely because of the "special difference" -- the responsibility of advancing the public health -- that these companies must engage actively and creatively in social media.

As the great social media philosopher, Buffalo Springfield, opined, "*There's something happening here. And what it is ain't exactly clear*."

There are a number of key issues relative to the use of social media by regulated healthcare entities. Let me address five:

1. **User-Generated Content**

If a consumer with no financial relationship or corporate interest posts a comment on a social media site that's supported by a regulated entity – say a pharmaceutical company – is the regulated entity responsible for the content of the comment?

User-generated content is *de facto* "interested" (otherwise there would be no content generation) – but does that mean that, *de jure*, it should be considered as regulated speech?

As they say, where you stand often depends on where you sit. And if you sit in Europe, consider a new European Court of Justice ruling that says information about medicines produced by independent third parties outside *any* commercial or industrial activity may constitute advertising, even though they have no connection with the product's manufacturer or marketer. According to the court, "… even though the third party in question is acting on his own initiative and completely independently of the manufacturer and the seller of such a medicinal product."

That's carte blanche for an almost complete gag order on anyone who wants to discuss anything to do with medicines.

Under such a regulatory environment – would letters to the editor become liable for an FDA warning letter? What about radio call-in comments? What about freedom of speech?

2. Blogs

What about blogs and other social media sites that accept pharmaceutical advertising? Why are social media sites that accept advertising any different from publication such as *the New York Times*, or *the Washington Post*, or *the New England Journal of Medicine*? When is "interest" not "conflict of interest?"

A related issue is that of "user" versus "property owner." Specifically, websites owned and maintained by a regulated entity, but whose online content is created exclusively by users without any financial "interest" behind their participation. For example, a social media site for people with diabetes that's created and maintained by a company that markets a diabetes medicine. What are the responsibilities of the "property owner" and what do they need to prove vis-à-vis "disinterest?"

Relative to "intended to promote" -- How can this be differentiated from "intended to share and educate?" And whose job is it to define such differentiation?

As Don Draper said, "I'm enjoying the story so far, but I have a feeling it's not going to end well."

3. Substantive Influence

Which leads us to the issue of "substantive influence." What rules should apply when a healthcare company wants to pitch a story to a blog or some other social media site with an audience that's relevant to its marketing strategy?

As the agency asked in its Federal Register notice, "Are there different considerations that should be weighed depending on the specific social media platform that is used or based on the intended audience? If so, what are these considerations?"

One thing that healthcare companies' worry about is that social media commentators will not factually report the news. A legitimate concern, but is this any different then accurately pitching a story to a reporter at the New York Times and having her miss or misrepresent a clinical data point?

Whether it's the New York Times or a blog or a social media site for caregivers, information "in" is vetted and controlled. Information "out" is not. Errors and hyperbole are, for better or worse, freedoms of the press.

4. Corrective Information

The FDA's Federal Register notice comments that:

"… companies have stated that they have not corrected what they believe is misinformation in the belief that they could be viewed by such an action as being responsible for all the information on the target Web site rather than just the information that they post or submit."

This is an issue that really strikes at the heart of the matter – the unintended consequences of having responsible and regulated companies shy away from social media even to correct erroneous information.

According to the Pew Internet and American Life Project, 113 million Americans search online for answers to their health questions. Three quarters of these individuals rarely, if ever, check the sources of the material they find

Without the participation of regulated healthcare players, the social media field is left to snake-oil salesmen, Internet drug dealers, unscrupulous trial lawyers and others who operate without almost any constraints whatsoever. Nature abhors a vacuum. It is irresponsible not to correct healthcare information errors. And yet that is precisely the advice being regularly given by regulatory consultants. It is a sad state of affairs indeed that ambiguity on behalf of the FDA has led us to this dangerous state of affairs.

5. Adverse Event Reporting

The real bête noire of social media – adverse event generation.

Should companies 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.

As F. Scott Fitzgerald wrote, "At 18 our convictions are hills from which we look; at 45 they are caves in which we hide."

Social media is still too young an adventure for us to seek shelter in the caves of caution, complacency and compliance.

Social media is communications at the speed of life. As Marshall McLuhan wrote, "At electric speed, all forms are pushed to the limits of their potential." That's a terrific challenge, to be pushed to the limits of our potential. But are we willing to be roused and animated by the new frontier that is social media and the nascent healthcare experience? Are we up to the challenge?

Yes we are.

Yes we can.