Pharma Marketing News

Reprint

New Social Media Regulatory Framework

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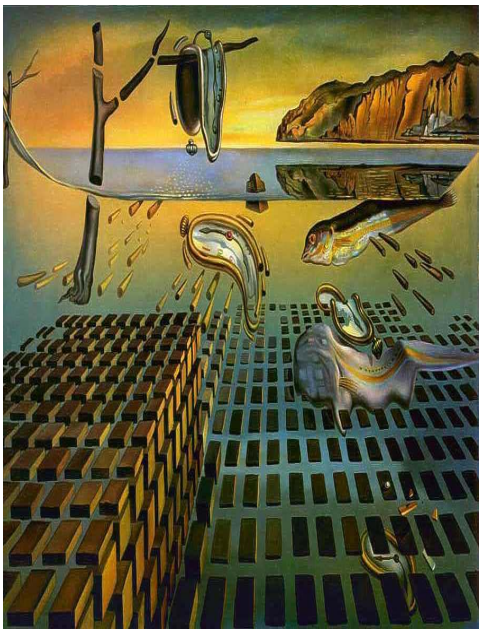

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Analysis

New Social Media Regulatory Framework

A Critical Analysis

By John Mack

At eyeforpharma's recent Annual eCommunication and Online Marketing conference, Fard Johnmar (Founder, Envision Solutions), Jim Nail (CMO, TNS Media Intelligence/Cymfony), and John C. Serio (partner, Seyfarth Shaw LLP) talked about regulatory issues relating to Web 2.0 and summarized a new social media monitoring and marketing framework for pharmaceutical companies. This article takes a critical look at the "Framework" and offers further insights into the regulatory issues it raises.

There's no dispute that the pharmaceutical industry has been slow to exploit alternative "social" media (aka, Web 2.0) for marketing purposes (see, for example, "Pharma Marketing Stuck in Web 1.5"). While some companies insist they have plans to significantly increase their investment in technology-enabled communication channels to reach their customers "on their terms"—see, for example, "Merck Rejiggers Its Marketing Mix"—so far, the needle has not moved much.

There are two reason often cited for pharma's miniscule online marketing/advertising budget:

1. Regulatory challenges and risks, and
2. Traditional media have proven ROI and continue to work well

You can't argue with reason #2 except to say that for some therapeutic categories—eg, weight loss and smoking cessation—and for some purposes—eg, improving adherence (see article in this issue)—traditional media may NOT be working well and non-traditional media may offer higher ROIs.

There is no doubt that use of social media by the drug industry for marketing purposes involves unique regulatory challenges, which have been discussed many times in this newsletter and on Pharma Marketing Blog. Not the least of the challenges is trying to understand where in the sand FDA's DDMAC draws the line or hides it head when it comes to Internet-specific guidances (see box, pg. 21).

But the regulatory challenges may be easier to overcome than the marketing challenges, according to Preeti Pinto, Head of Medical Education and Regulatory Compliance at Astrazeneca, who also presented at the eyeforpharma conference.

Pinto doesn't believe the industry needs new Internet guidelines from the FDA, which focuses on content not channel issues. "Looking at Web 2.0," said Pinto, "regulatory issues seem to me easy to overcome. Marketing issues are another matter." She cited loss of control of marketing messages as the major problem marketers face when plying their trade in the Web 2.0 space.

Still, without knowing where the regulatory boundaries and mine fields are and how to deal with them, pharma marketers are reluctant to tackle Web 2.0 marketing issues and take advantage of social media. That is precisely the reason Cymfony *et al* wrote their "Regulatory Framework" white paper ("Managing the Risks and Regulatory Issues Associated with Successful Pharmaceutical Social Media Monitoring and Marketing") in September, 2007. In the introduction, the authors stated:

"In the absence of FDA guidance on marketing in blogs, social networks and other social media forms, drug firms' marketing, compliance and legal staffs must work closely to design initiatives that are sensitive to FDA concerns. This paper provides a framework to clarify and mitigate the risks of a range of social media initiatives."

CAVEAT: "While this paper cannot substitute for FDA guidance, it can give marketing, legal and compliance professionals a common understanding of the regulatory environment, examples of how pharmaceutical companies are moving ahead with social media initiatives and a framework for discussing the elements of their own company's social media programs."

Fair Balance and the "One-Click Rule"

One of the key principles that marketers should factor into any DTC promotional activity, including promotions via social media, is Fair Balance: ensuring the public receives information about a drug's safety and efficacy profile.

"Although the FDA has not released firm guidance on pharmaceutical Internet communications," say the Framework authors, "we have many years of received precedent to guide us. Drug companies

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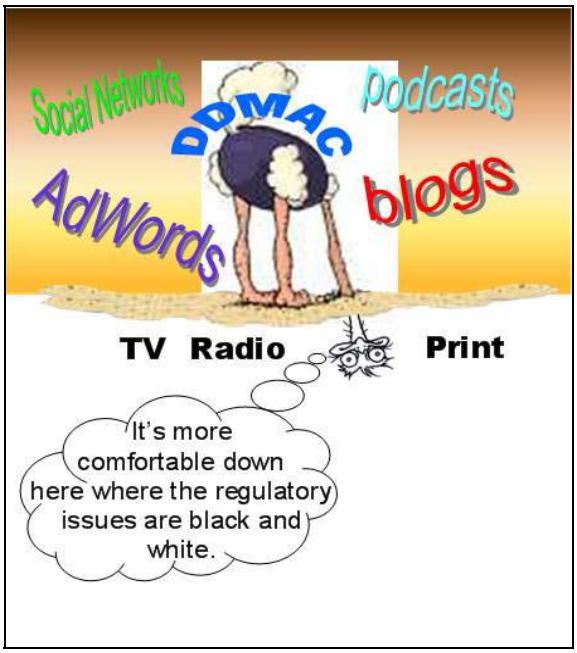
With Respect to Internet Guidelines, Where's DDMAC's Head At?



In the new world of Web 2.0, pharma marketers need to know where the lines are drawn by FDA's DDMAC, the Division of Drug Marketing, Advertising, and Communications, which is the FDA entity in charge of regulating all promotion and advertising of prescription drugs, including direct-to-patient (DTC) and advertising and physician promotion.

Unfortunately, the FDA has not been inclined to say much more than the Internet will be treated just like other media when it comes to applying regulatory guidelines. This despite the fact that the Internet has advanced well beyond electronic brochures and printed pages.

The saga of the FDA vs. the Internet goes back at least ten years—to October 16 & 17, 1996—when the FDA hosted its first ever (and maybe last ever) public hearing on the Internet. The purpose of this 2-day gathering was to help FDA evaluate how "the statutory provisions, regulations, and policies concerning advertising and labeling should be applied to product-related information on the Internet and whether any additional regulations, policies, or guidances are needed."

What's needed today is a re-examination of the question "Are any additional regulations, policies, or guidances needed?" in light of the NEW Web 2.0 capabilities available.

have developed a body of best practices that enable them to pursue their marketing goals via the Internet in keeping with the spirit of FDA regulations for print and broadcast ads."

One of the "best practices" mentioned in the Framework is following the "one-click" rule—i.e., prominently displaying a hyperlink to information about medication side effects on all product Web sites—to adhere to fair balance regulations.

In response, I posted the following comment to the Comfy Blog on Sep 6, 2007:

> If you search Google on "one-click rule FDA" you won't find any references to this rule that

Continues…

the FDA has made, but you will find my post "Girl from Google."

That's because, in that post, I discuss how the so-called "one-click rule" was used to justify Google Adwords (aka, "BAdwords") that violate FDA guidelines—these ads mention the brand name and indication, but do NOT include any fair balance as is required by FDA.

One person from a pharmaceutical company, perhaps playing the devil's advocate, contended that these "BAdword" ads may pass muster with the FDA because the package insert or brief summary is "one or two clicks away." His argument was that without specific guidance from the FDA, no one knows what is correct in this case.

The "one click away" defense does not apply here. FDA says it's OK on an Rx product Web site to merely provide a link to the package insert or brief summary. In that case there is no need to provide that information on the same page that mentions the drug name and its indication.

Thus, an AdWord could be said to comply with the "one click rule" only if within the AdWord text there was a direct link to the package insert (PI) or brief summary.

In "BAdwords," there is only a link to the product Web site, not the PI. Presumably, the user would have to find the link to the PI once on the product Web site.

So, if there actually is a "one-click rule," it is not correct to invoke it for every kind of ad on the Internet, and surely not in cases where you really need TWO clicks to get to the PI or fair balance!

It is a shame that the FDA does not have any guidance for the industry as far as Internet advertising is concerned. This means that marketers can use lack of guidance as a defense for sneaking in ads that push the envelope. What are the chances that the FDA would ever notice. These ads are fleeting, here today, gone tomorrow!

For Jim Nail's response to this comment—aka "rant," according to Serio—see the box on the right. Nail asks: "Are you saying that the act of buying the keyword and having their ad pop up is tantamount to including it as an indication in their ad?" No, only when the tradename and the indication are mentioned in the same Adword is it a problem.

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Jim Nail's Comments on "One Click Rule"

Agreed -- there is no "official" FDA one-click rule, nor do we say there is. But there is a "received precedent" that if you have one click from your brand site to the PI or labeling information, that is acceptable. Or call it "best practice". Or call it just "common practice". In our paper we say that if you have a branded blog, social network, discussion forum, etc. have a link to the PI prominently n the navigation or other links on the site.

You raise some interesting points about search. We focused solely on the social media realm, not the "traditional" interactive realm. We only touch on other Internet marketing to make the point that marketers don't have to wait for FDA guidance to take advantage of new marketing forms.

That said, I agree. In a strict interpretation, paid search ads are probably verboten: given the space restrictions, there's no way to get any sort of "fair balance" statement into an AdWord ad.

But I think it is more complicated than that. I just Googled High Blood Pressure. A Lipitor ad pops us but only says, "Visit Lipitor.com to learn ways to lower your cholesterol." Click through and the first thing on the page is "Diet and Exercise". The second heading on the page is "Cholesterol-Lowering Medication".

I guess this is an example of one of the tricks you mention: within the confines of the AdWord text, they never make a claim or even explicity state the indication.

Are you saying that the act of buying the keyword and having their ad pop up is tantamount to including it as an indication in their ad? It would be interesting to do some consumer perception research: I wouldn't be surprised if the consumer walks away with the link between Lipitor and lower blood pressure, in which case there could well be a cause for the FDA to issue a warning letter.

Nail suggested that it would be interesting to do some consumer perception research about Adwords. In my opinion, it would be interesting if the FDA commented on their interpretation. This is just one small example of where debate exists and FDA guidance is really necessary, despite what industry compliance executives and consultants say.

Aside from fair balance, the Framework authors point out two other major regulatory issues that are central to FDA regulation of the drug industry's monitoring of and participation in social media:

1. **Off-label promotion**: patients may ask questions or discuss uses of a drug that have not been tested and approved. Drug companies are prohibited from off-label promotion and so are understandably reluctant to be associated with these discussions.
2. **Adverse event reporting**: in discussing their experiences with drugs, patients may describe side effects they experience or state that they don't believe the drug worked for them. Due to the unique characteristics of social media, drug firms are unclear about whether or not social media carries the same obligation to report these events that FDA regulations specify for other marketing activities.

The Framework authors discuss approaches to creating an editorial policy to minimize these risks. They cite common examples of how Pharmaceutical companies have avoided off-label promotion and managed adverse reporting in Internet marketing campaigns.

Avoiding Off-label Promotion:

1) Carefully control medical content on corporate Web sites. Example: www.lexapro.com
2) Support "unbranded" educational Web sites developed by third party organizations. Content is neither reviewed, approved or censored by company representatives. Example: www.depressionisreal.org
3) Develop corporate disease awareness Web sites where content is vetted by internal legal/regulatory officials. Example: www.adhdbalance.net

Serio warned that a pharmaceutical company that hosted a social media forum that contains off-label posts by consumers can imply endorsement of the off-label use if not handled properly. In essence, the more editorial control the pharma company has over content, the more problems it will have with FDA.

The Framework authors suggest that drug firms avoid off-label promotion on social media sites by distributing unbranded corporate information via controlled social media channels like podcasts, "where content can receive thorough review to remove any un-permitted promotional content (e.g. off-label promotion) before it is distributed. In addition, many drug firm podcasts do not invite or include consumer commentary, which reduces the chances that it will contain off-label information."

A hands-off sponsorship of unbranded social media developed by third parties was also recommended.

Managing Adverse Event Reporting:

1) Managing adverse event reports from identifiable (nonanonymous) patients by following internal policies and procedures.
2) Avoiding review of online and offline material that may contain information about adverse events reported by identifiable patients.

Serio reminded the conference attendees that according to the FDA, manufacturers should have knowledge of the following four data elements before considering any clinical incident for submission to the FDA:

1. an identifiable patient;
2. an identifiable reporter;
3. a suspect drug or biological product; and
4. an adverse event or fatal outcome.

Reports without such information, says FDA guidance make interpretation of their significance difficult, at best, and impossible, in most instances.

How likely are all four of these requirements to be met on a social network site? "The fear of monitoring and reporting adverse events on these sites," said Serio, "is unfounded."

Red Means Stop, Green Means Go

The Framework white paper evaluates a number of common social media communications tactics and organizes them into three risk categories:

1. **Red**: These are social media activities that may place a pharmaceutical company at high risk of violating FDA regulations.
2. **Yellow**: Companies may be at moderate risk of being cited for non-compliance by implementing these tactics.

Continues…

3. **Green**: These activities carry low risk of violating FDA regulations, either because drug firms are already implementing them or they can be very tightly controlled.

The authors warn, however, that before launching a campaign, drug firms must determine whether their corporate culture is "social media friendly" (e.g., can executives engage in candid conversations with the public, are they willing to experience and constructively address negative online commentary?). Other factors to consider are how conservatively their internal compliance officials interpret FDA regulations and the company's tolerance for uncertainty. "Social media is constantly evolving and is not yet easily measured with traditional metrics," suggest the authors.

For each social media tactic, the authors assign a risk level associated with violating fair balance, off-label, and adverse event reporting FDA requirements and guidelines. It is not feasible to summarize all the recommendations the authors have for various social monitoring and marketing tactics. You can read the full white paper and review it for yourself. However, a few points should be emphasized.

First, when talking about monitoring social network sites (as opposed to marketing through these sites), the authors distinguish between activities undertaken by pharma companies themselves (internal resources) and activities performed by their agents and vendors (external resources). They emphasis that vendors should be educated about FDA regulations regarding adverse event reporting.

Agents Need Monitoring

What the Framework doesn't do, however, is take into consideration that drug companies also use external sources for marketing via the Internet. Experience shows that some of the Internet marketing advice pharmaceutical companies are getting from a few external sources may not be grounded on a full appreciation of FDA regulations (see, for example, "The Girl from Google"). Agencies also engage in questionable online practices without close supervision of their Pharma clients (see, for example, "Influencing the Dialogue: Marketers Suck at It!" and "Web 2.0 Pharma Marketing Tricks for Dummies").

What About Public Relations Risks?

The most important drawback of the Framework document is that the authors are looking at risks solely from a regulatory point of view. They do not address the public relations risks at all. Yet public backlash may be the bigger problem for pharma marketers. That problem is evident in the recent calls by politicians to limit DTC (direct to consumer) advertising in print and TV. As more and more consumers turn to the Internet and social media sites, more public light will be shone on what Pharma marketers are doing there even though it may all pass muster with the FDA. Shouldn't the industry, therefore, develop "best practices" for Internet-based DTC as it have dome for print and TV-based DTC?

FDA or PhRMA guidelines for pharmaceutical marketing on the Internet—similar to guidelines these organizations have issued for TV and print media—are the holy grail of the pharma eMarketing community. Without such guidelines, the Internet—version 1.0, 2.0, or whatever—will always remain a Wild, Wild, West where patients and consumers are the cattle and marketers are the rustlers!

Even with guidelines, there will always be "banditos"—those marketers that flout the "rules" or refuse to sign on and display their "badges."

Pharma Marketing News

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Experts Consulted

The following experts were consulted in the preparation of articles for this issue.

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- **Manuel Prado**, CEO, datumRx, 415-462-2845, manuel.prado@datumrx.com

Resources

The following resources were used in the preparation of articles for this issue.

- "**Managing the Risks and Regulatory Issues Associated with Successful Pharmaceutical Social Media Monitoring and Marketing**"; http://www.cymfony.com/pharma.asp
- World Health Organization (WHO) report: "**Adherence to Long-Term Therapies**"; http://www.emro.who.int/ncd/Publications/adherence_report.pdf
- "Guidance for Industry: **Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products -- Clarification of What to Report**"; http://www.fda.gov/medwatch/report/guide2.htm

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