Social Commentary

At last the FDA has offered some semblance of guidance for digital promotional activities in the medical space. Was it worth the wait? And will it change anything? **Peter Pitts** picks it apart

In January the FDA rolled out its latest social media operetta, the draft guidance entitled, "Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics"—or, as fans of Gilbert & Sullivan might prefer to call it, "Patience."

The most interesting parts of the draft guidance focus on user-generated content (UGC). The fact that the FDA recognizes the primacy of UGC is, in itself, a significant step in the right direction.

FDA recommends that a firm be transparent in disclosing its involvement on a site by clearly identifying the UGC and communications of its employees or third parties acting on behalf of the firm.

But the real nugget is between lines 188-193:

However, a firm generally is not responsible for UGC that is truly independent of the firm (i.e., is not produced by, or on behalf of, or prompted by the firm in any particular). FDA will not ordinarily view UGC on firm-owned or firm-controlled venues such as blogs, message boards, and chat rooms as promotional content on behalf of the firm as long as the user has no affiliation with the firm and the firm had no influence on the UGC.

Social media keeps rolling along—and industry keeps falling further behind

In its September 21, 2009, *Federal Register* notice (the one that announced the now-famous November 12, 2009, Part 15 hearing), the FDA asked about the issue of property owner vs. property user as well as user-generated content more broadly: "When should third-party discussions be treated as being performed by, or on behalf of, the companies that market the product, as opposed to being performed independent of the influence of the companies marketing the products?"

As I testified at the hearing, "Would letters to the editor be liable for an FDA warning letter? What

about radio call-in comments? What about freedom of speech? 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."

Four-plus years later, the property owner vs. property question is asked and answered. So far, so good, on the UGC front. Better late than never.

Now the question is, does regulated industry really want uncontrolled, unfiltered, and unpredictable UGC on their sites? Because, let's be honest, it ain't all gonna be pretty. Is pharma ready to mix it up in real time with real people?

On a more discouraging and frustrating note, there's a peculiar little codicil in the draft guidance that appears on lines 246-249, to wit:

Once every month, a firm should submit an updated listing of all non-restricted sites for which it is responsible or in which it remains an active participant and that include interactive or real-time communications. Firms need not submit screenshots or other visual representations of the actual interactive or real-time communications with the monthly updates.

Hugely cumbersome? To be sure. But what's really troubling is the good folks at OPDP think such a "running list" is even plausible. Do they really think that regulated healthcare companies are centralized to such a degree that any one person or department knows the full extent of social media participation? And even if this was the case, is this information really any business of the FDA? Are companies currently required to submit their media plans along with creative for agency review – *on a running basis,* no less?

"Is pharma ready to mix it up in real time with real people?"

—Peter Pitts, president, Center for Medicine in the Public Interest

And just who will review these lists? What are the qualifications of such reviewers? Since OPDP isn't hiring, where in the review queue will these lists reside? Will they be made public? This is mission creep extraordinaire. Danger, Will Robinson. Danger.

Like Old Man River, social media *keeps on rolling along* with or without FDA guidance (draft, bottled or otherwise). List-making isn't going to limit it. And no amount of hoping/wishing/praying is going to make it static. Social media just *keeps on rolling along*. And regulated industry just keeps falling further and further behind the curve.

How can the FDA help to facilitate, encourage, and expedite more activity on the part of regulated industry? After all, as Janet Woodcock has said, "Social media is where the people are." The answer isn't "more process."

Will any of this "free" Pharma to pursue more aggressive social media strategies? Stay tuned. Compliant social media is in the eyes of the engager – and it's about the content, not the platform. Bottom line? It's time for another Part 15 hearing. ■

Peter J. Pitts, a former FDA associate commissioner, is president of the Center for Medicine in the Public Interest.

You can download the draft guidance at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatory Information/Guidances/UCM381352.pdf

The cost of non-compliance—and how to stop the bleeding

The misalignment between commercial and regulatory functions is costing pharma a fortune—"$2 million in waste for every 10 brands," says Ilyssa Levins, president of the Center for Communication Compliance, which has done robust research on this issue. CCC data reveals that some companies abort up to 23% of initiated promotional efforts, while across the board 25% of regulatory's time is lost each month to rewrites.

Levins suggests three steps to align objectives and reduce the waste:

1 **Change the mindset.** Effective collaboration requires cultural change, leadership development and the breaking down of silos. An important first step is to "bust" any myths and misperceptions that commercial may hold about MLR, such as: "They say no before they even listen to the idea"; "We are at a disadvantage when competitors promote in ways that we're not allowed"; "They don't understand how difficult it will be to achieve my forecast this year"; and "They don't offer alternatives, we have the same conversation over and over."

2 **Align regulatory knowledge.** According to CCC research, marketing and agency executives (even those who hold senior positions) are often lacking in knowledge of basic regulations, including those that address risk communication, disease state websites and the use of spokespeople. According to King & Spaulding, 83% of OPDP-cited allegations in 2013 included the omission or minimization of risk information.

3 **Remove non-negotiable materials.** Non-compliant elements should be filtered out during the concept execution stage to minimize the number of rewrites as well as accelerate the review process. To accomplish this, Levins recommends that brand teams adopt an "ROI mentality" to evaluate proposed campaigns—e.g., will the cost of compliance-readiness outweigh the sales impact?—and articulate the value of early concept reviews. In addition, she suggests developing mock digital assets in order to demonstrate more clearly their proposed functionality.