



Thinking Deeper about Sidewiki and the FDA Why the obvious advice might just be wrong

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Five years from now, people may look back the Fall of 2009 as the season that finally changed the world of healthcare social media. That's because of two recent events that may disrupt the social media landscape for pharma, perhaps permanently.

The first was Google's introduction of Sidewiki as part of its latest toolbar download. For the three or four people who may have missed the volley of alarmed emails that followed the announcement, Sidewiki allows *anyone* using the Google toolbar to comment on *any* website, without asking *any* permission. The comments appear on the side of the web page in question (thus the name). They can be seen by anyone else who has installed the Google toolbar, and they can't be removed by the site owner. Call it "Social Media, Like it or Not."

The second event is the FDA's public hearings on November 12 & 13 on "the continually evolving nature of the internet, including Web 2.0 and social-media tools, as well as their expansion to applications such as mobile technology". A pretty big digital grab-bag there, but from the nature of FDA's specific questions, it seems clear that the agency is most interested in the implications of social media (note: the author has been invited to present his point-of-view at the hearings.)

The FDA's decision to seek guidance is newsworthy for several reasons. First, because the FDA has never, ever done so before when it comes to the internet, opting instead to answer questions as they came up from pharma companies, or to merely have people *guess* what the agency's position might be. Second, it indicates that the FDA is taking Web 2.0 much more seriously than it had before, perhaps – just perhaps – realizing that it represents a major advance in patient communications about medicines and other healthcare topics.

This is potentially very good news. For without clear guidelines, pharma has been wrapped in a social media straitjacket. The industry's efforts so far have been extremely constricted because they are not sure whether they will be held accountable for rogue comments, including possible adverse events or off-label claims.

Taken together, the invention of Sidewiki and the attention of the FDA may fundamentally alter how drug manufacturers participate in social media conversations. Sidewiki may force companies to finally participate; the FDA may enable it. But what should you do about it?

1. Why do we care about Social Media?

Before deconstructing the implications these developments may have on pharma's use of social media, a word on why any of us should care.

Social media represents a rich opportunity for patients, physicians, caregivers, and manufacturers to connect with each other and to participate in an open dialogue about their health conditions and their treatments. Social media may give us more transparency, more dialog, and, ultimately better health outcomes. Because allowing people who have questions to connect to people who have knowledge (including people who work for manufacturers) will lead to a better informed population, which is likely to translate into better preventative care, improved compliance and even reduced cost of care.

Strange as it may seem to have to say this, transparency of knowledge and open communications is a *good thing* for patients. And it's a good thing for the industry, too. Because it will help pharma companies claim their legitimate place in the social media conversation – as builders of opportunities for constructive conversations, and as suppliers of credible information about their therapies. It may even begin the long, hard journey towards improving the negative public image of the industry.

2. Current State: Social Paralysis

Sidewiki may serve as a technological trigger, and the FDA hearings may (eventually) lead to useful guidance, but something had better change the current woeful state of pharma social media. Virtually all the current exhibits (including McNeil's "ADHD Moms" on Facebook, Novartis' CML Earth, and Merck's "Take a Step Against Cervical Cancer," also on Facebook) represent 'safe' social media, which means pretty much useless social media. No ability to make a comment, to share a thought, to connect with a fellow sufferer. It's social media with the social part turned off.

This is both regrettable, and understandable. Medical, regulatory and legal managers have been concerned that the FDA may hold pharma companies responsible for social media conversations about their companies' brands. We think it's unreasonable for the FDA to make companies liable for the speech of individuals they don't control. But since FDA has never stated their position on social media, nearly every company has assumed the worst case, and thus adopted a highly cautious stance on their social media initiatives.

For the industry to use social media productively, a fundamental change in the regulatory climate needs to occur. That straitjacket needs to be unzipped.

3. Enter a Disruptive Technology: Sidewiki

While we hope that the upcoming FDA hearings may eventually lead to clearer guidance, realistically (actually, optimistically), it will likely take months for any kind of official ruling to be issued. But technology moves faster than your typical government agency. So you can't very well wait for FDA guidance to decide what to do about Sidewiki.

The way we see it, there are several viable options for companies reacting to Sidewiki's disruptive challenge. These options range from highly open, to extremely controlled. The best option for you will be based on your brand's position, your company's tolerance for risk, and, frankly, how much your leaders truly believe in open communications versus paying lip service to the idea.

Option A: Embrace Transparency.

Embracing Transparency means allowing Sidewiki to do its thing without any attempt to control it, or – better yet – installing social networking functionality of your own design into all your brand websites.

I can hear the med/reg/legal folks shrieking as I type. And yes, at first this it might seem, um, counterintuitive — how could a marketer of a prescription product with important safety information and formidable marketing restrictions allow *just anyone* to say *whatever* on their website? *Like, for sure.*

Isn't that like inviting the graffiti artists over to your freshly-painted house?

Well, yes, and no.

You do run the risk of negative comments, but you also demonstrate, very powerfully, your commitment to open dialogue. And as has been the case in other social media environments, over time, you will likely find that the nasty or sophomoric remarks will be greatly outnumbered by the more thoughtful, mature comments. In other words, you will see the "Wisdom of Crowds" at work, with legitimate ideas driving out the nasty or knuckle-headed ones. That's the way it works in truly open social communities — the group polices itself.

And there is another, ironic advantage to this approach. You might actually be *protecting* yourself from liability. Because if you make efforts to control the dialogue (for example, by being the first poster and attempting to take up Page 1 space with risk and benefit information), it may be interpreted that you are actually attempting to control the dialogue, and so you therefore have some responsibility for it (more on this below).

An obvious complication for the transparent approach to social media is the risk of Adverse Event reporting. What if someone complains about a side effect right on the product site? This is arguably the most serious concern for pharma companies, and it shouldn't be minimized. If you see an AE, you must take it seriously and report it if it meets the requirements of a true AE. For most companies, the reporting obligation may be reason enough to completely abandon the transparency option. "You want to make it *easier* for people to report AEs? Are you *nuts*?"

But before jumping to the admittedly reasonable conclusion that I am nuts, ask yourself these questions:

- If there's a true Adverse Event occurring, shouldn't you want to encourage patients to responsibly report it? Isn't that consistent with your values and your commitment to patients?
- If you took a step farther and actually gave them a private, patient-friendly tool for reporting the AE, wouldn't they be more likely to use this than to tell the whole world about something so personal in a public forum such as Sidewiki?
- And even if the AE was posted publicly, how would the rest of your patients view your thoughtful and responsible response? Would that raise or lower their opinion of your product and your company?

These are not easy questions to answer, but they may help frame the argument in a new way, leaving you open to a new way of thinking, which this new medium might well require.

Option B: Cautious Control

While we believe the transparency approach has real merit, we are realistic enough to know that many companies will be fearful of ceding control to the unknown and the unexpected. If this is your stance, you can do several things (although nothing is 100% risk-free.) First, you should immediately verify your site with Google Webmaster Tools. That way you can claim control over the initial postings on the site. Then, using Sidewiki, you can be the first to comment on all your company's websites. This 'comment' can be lengthy enough to take up the entire first page, thus possibly pushing any potential negative comments below the fold and preventing them from being viewed alongside your site's content.

While it may minimize some risk for your company, this approach has its downsides. Since Google displays comments based on their rank and relevance, not simply their order of submission, there is no guarantee that your cautiously-worded comment will actually remain in the primary position on the home page. And ironically, by being the first poster, you may be opening yourself up to some responsibility for the *entire* Sidewiki. You certainly can't very well claim you know nothing about it if you've been the first to comment. At the very least, the onus will be on you to actively monitor and engage in the conversation and to respond to potential risks reported there.

There's also another risk to this approach. Your 'stereotypical pharma' response may be perceived by patients and the online community to be 'more of the same,' tight-lipped, reactionary, and un-patient-friendly behavior that has undermined the industry's reputation.

Option C: Sidewiki-Silencer

The most extreme option for pharma companies is a technological response to a technological threat: dropping code on your website that will prevent the Sidewiki from functioning on your sites. (Disclosure: Heartbeat has developed and implemented such code for some of its clients.) This means that no one will be able to view or post any comments to your site, and there will be no risks of negative opinions or AE reports at all.

While this approach will certainly reduce your AE reporting risks, there is another, perhaps greater risk—that your company's lack of openness to social media will portray your brand and your company as anything but open, and that consumers may view this response as meaning you have something to hide.

That said, Sidewiki-Silencer may represent a viable short-term approach—buying time until you can develop a truly thoughtful social media strategy. But it really is only a stop-gap measure. In the technological arms race, it's only a matter of time before some clever Google engineer outsmarts your Sidewiki killer. And then you're right back where you are now.

Much better that you begin to develop a social media position that allows for true dialogue, one that you can frame and manage effectively. And with the help of some reasonable guidance from the FDA, you might just find you really can handle the truth.