



ePharma Insights and Prescriptions
A Conversation with Mark Senak
Part 3

What emerging digital modality or medium do you think pharmaceutical marketers should pay closest attention to now and why? There's obviously a lot of chatter about, well, Twitter. You mentioned YouTube in our last conversation. There are other emerging technologies, obviously. What do you think people should be paying really close attention to?

Mark: Well, two things. One is about the presence and that is that Twitter has become the plumbing in terms of the way we communicate. What I mean by that is you wouldn't buy a house without it. I think Twitter has actually become such an integral part of the way news is spread at this point that not only is it important to have a Twitter feed, but it may be essential to have multiple Twitter feeds that are targeted to very specific audiences who want very specific messages. And so that you also have a capacity for hearing what's going on. I mention that just because so many reporters are now on Twitter. For example, I follow a number of them. One I really like is Jake Tapper, who reports on the White House. Of course, if you watch his reports, they are one thing. But, if you follow his Twitter feed you get insights like what the President is doing at that very moment. I was even watching his Twitter feed one day on my HootSuite and I see him say: "Oh, I just met Bo the dog. He's great." Well, that's not something you are ever going to see on his evening report. But, it's a kind of constant reporting in the moment that's happening. It's important to be on Twitter because it has become endemic to the way we are talking today and to the way news is spread. It provides a very new, very granular insight into things that you didn't get before. For the future, everything began -- when the Internet was invented, one of the great catalysts for the Internet was the introduction of the ability to search because without that, you are just in a big warehouse full of things and you couldn't really find them. Search helped you find so many of the things you want. I think, and I could be

wrong about this, but I think that in the future search will continue to evolve. You get the semantic web and when you search in the future, you'll get a lot more context to your search than you ever did before. I actually read about this recently where one organization just organized a tremendous amount of video in terms of global development and when you search for video on their site, you get all the videos that you want. You can go very granular, but you get all the videos. You went under a certain subject matter and you can keep paring down that subject matter. But, as you do, off to the side what you're also getting is: "If you want to donate to organizations about this topic" or "If you want to be volunteering in this area." You get all this very rich context for your search that is categorized and classified and adds a lot more quality to your experience as the user in terms of finding things that you want to do. So, it not only can lead me to the information I'm looking for, it can lead me to new resources where I might take action. I think that that is very important to think about in terms of the future in medical products so that if I'm looking up a diabetes treatment, I get not only information about treatments and maybe prevention, but also support groups in one box and places to volunteer in another. Places that are doing research, clinical trials, all that appears and is organized in my search so that I don't have to go and hunt and peck to find it. I think that companies that can make that happen and help support that kind of vision are partnering with the patient at a new level that says something about the corporate image and not about the product.

To your point you've made a couple of times in our previous discussions was that there is that activation element there.

Mark: Right.

And it's really bringing it to a whole new level. It's pretty incredible stuff to think about. We discussed at the conclusion of our last interview, we left off on the regulatory landscape. And we opened this one up with the emerging digital modality of choice, which would be Twitter. Your November 23rd blog focused on Twitter and the regulation of social media, in general. Can you tell us a little bit more about that entry? In particular, what struck me about it as obviously a fan and a reader is why you concluded with the question: "To tweet or not to tweet?" Isn't this rhetorical based on what you just said? If not, why?

Mark: It was probably me just being glib about ‘to tweet or not to tweet’. I have been known to be that way. I think that for -- you have a lot of different regulatory cultures and risk mindsets in pharmaceuticals and medical product manufacturers. You have a whole range out there. So, you have some companies that have developed Twitter feeds that are specific to certain geographies that are linguistically appropriate and really going out there and pushing the envelope. You have others that don’t even have an RSS feed set up to distribute their press releases. So, you have a whole spectrum out there of mindsets and experience with what’s going on. So, I think for many the question is still: “To do it or not to do it.” What’s happened is we are in this ridiculous situation where we are waiting for the regulatory authority to define the environment with regulation that will help make those decisions. That’s not going to happen. First of all, the process that the FDA uses for this is ridiculously slow. When you consider the fact that they only first uttered something about the need to regulate social media back in March of ’09 (they felt that it’s not the medium it’s the message) was enough regulation in this area and then really ignoring all the nuance that the Internet and social media brings in terms of questions about how to operate within this medium. So, that was in ’09. We are now in the end of 10 and going into 11. We are going into our third year, really, and we still don’t have -- all we’ve had is process so far. We have no product in terms of regulatory definition. Well, you know what? Twitter is only three years old. The wheels are moving so slowly in terms of defining the regulatory parameters and the medium is not waiting. The medium is exploding. So, you are at a choice where you are going to have tough questions about: “Gee, if I re-tweet something that someone else re-tweets, can I do that?” or “If someone re-tweets what I tweet, will I get into trouble?” or “If someone changes my content and posts it, what does that mean?” Well, those are questions that you have and they are legitimate questions. But, you know what? You’re not going to get answers to them right away. And even when there are answers, there’s still going to be more questions. So, you have to do a risk/benefit analysis for yourself. On the risk side is you may proceed in some areas where there’s going to be a regulatory slap on the wrist as a result; a notice of violation letter because the FDA wants to help define the environment through taking regulatory action through a letter that it can do much more quickly than it can develop a guidance. But, you know, you have to decide you want to take that risk in

order to achieve the benefit you're going to have, which is that presence you're going to have, which we've discussed. And if you don't, well, you know, you're going to the backseat and that's okay. Just know that that's where you're going to be.

Right. And when the time comes, if ever, that guidance is out there and you want to move ahead, well, you're going to be pretty far behind.

Mark: You could be behind. And also, to be fair to the FDA, there's a lot of big questions. They can't deal with this from a platform-specific point of view because these platforms could very well change very quickly.

So, guidelines for Twitter exactly?

Mark: Exactly. Facebook has half a billion people on it now, but tomorrow, there could be the next best thing. So, you can't be platform specific. It has to be based in principles. You do have to get everybody's input. But, the whole process started way too late and the guidance process is probably not an appropriate means for doing this. There needs to be some quicker mechanism. One that I've talked about as a possibility before is even an advisory committee sort of mechanism where issues are brought before an advisory committee and defined much more quickly and in short order than going through a multi-year guidance development process when you have such a fast-moving set of media like social media and the Internet.

You've pretty much addressed this question, but I want to throw it out there again. You've noted that the FDA is having a really tough time keeping up with communication's technology. Much tougher so than, perhaps, marketers who are also struggling. You've mentioned an advisory board as a possibility. What else could pharma marketers do to help the FDA establish some sort of sensible, responsible policy that protects the public without inhibiting our ability to engage that same public?

Mark: That's the big question. I think that there are a number of things that the industry can do, but it has to really recognize that it's very limited to what it can do vis-à-vis getting FDA to move more quickly. Even Dr. Sharfstein, who is Deputy Commissioner at FDA, has stated before: "I wish I could make things move faster." It is a big, behemoth of an organization

and big behemoths don't turn on a dime. So, I think it's going to be very hard to get it to move more quickly at this point. But, I think that for itself, the industry can explore the issues, raise the questions and continually provide input. Not waiting for a public meeting to provide input, like what was held at the end of 2009 by the FDA. What happened there is that very few pharma companies actually participated in the meeting itself and then with the docket that was opened, it was not until the last few days of the docket being opened that very many companies started putting in comments. This should be an ongoing process. It's not an event. We've got to treat it as such and create some sort of infrastructure, even if it's just within the company for considering new developments, digesting them and raising important questions.

This is for my own edification. We had a blog for the ePharma Summit post recently that featured an item that was based on Katherine Hobson's Wall Street Journal Blog basically entitled: "Who's Responsible for Tweets About a Drug?" Our headline asked: "Would the FDA Care if Kanye West said 'Lipitor' was his Drug?" What's your response to that question and why?

Mark: It's always hard to tell some of the time what the FDA cares about and what they don't and I can't pretend to second guess them. I don't see a problem with a celebrity stating that they use a particular drug. But, it opens up a lot of questions when you use celebrities. It's not even just the FDA. It's the FTC, as well. If the person is being paid to do this, it makes a difference. It is a complicated set of circumstances. So, when you are going to engage in social media, you really do have to sit down and scenario-play these things out and talk about what the FDA would think; WWFDAT? Ask the hard question and just assume this is wrong and build around why it's wrong and why it would be right. You have to really question: "Are we covered under risk information?" "Are we covered under Fair Balance?" "Could this be interpreted as being inappropriate in some way?" I was at the FDLI Conference this year here in DC where the FDA presented a fake ad that they made up on the screen. I think it was for an anti-allergy medicine and it was for seasonal allergies. There was a dog in the picture and a baby and the whole family was outside playing together, essentially. It was like: "Okay. What's wrong with this ad?" Well, some of the people said: "There's a dog in the ad and this is for seasonal allergies. It's implying

that pet allergies are included in the indication when they are not” and “Oh, look. There’s a child in the ad and this drug is only for people over the age of 12.” That’s the kind of exercise it takes when you’re considering any kind of communication. I have to pull this apart and look at it and ask every single question I can about it.

I love the point about just assume you’re wrong. And the other thing is probably realize that there is no grandfather clause here.

Mark: If you grew up with me, you’d know about starting with the proposition that you’re wrong.

Well, along these lines, you made a really great point about this being a process, not an event. And by that I mean pharmaceuticals, marketers and the industry trying to work with the FDA to hash these things out. Obviously, we’re not going to see any kind of significant guidance by the end of the year as some people might have hoped. But is the pharmaceutical lobby, based on that process vs. event point, is the lobby in Washington focusing on the right points? Are they missing anything? How successful would you rate their efforts thus far, just from your perspective, if you will.

Mark: I don’t know that I’m even qualified on that comment on their lobbying agenda. What I will say is that the industry itself, as a whole is, of course, going through a rough time in terms of how people perceive it. I’m always struck by that because my background growing up and working in HIV in the 1980’s when there were no HIV treatments. People were dying right and left and the only thing that made a difference with truly staggering mortality and suffering was the development of a drug. So, to me, still, people who develop treatments for life-threatening illnesses are heroes. And yet there’s a disconnect between that ultimate end result and perception of the people who bring that end result. And there are a lot of reasons for that and a lot them are very legitimate reasons. But, I don’t think the industry has done a great job in demonstrating a lot of the other things that it brings to the table. For example, the tremendous amount of philanthropy that goes on collectively. If you added it all together, it is quite huge in terms of the impact it has in developing nations. But, I don’t think most people are aware of that. So, I think it’s a story that’s not been spelled out well.

I've seen data visualizations that make it -- it is a staggering amount, as you've pointed out. But, it can be presented in a way that even when people are paying attention, it doesn't look like enough. Not to take us off track, but I think it's interesting that the image problem that this industry suffers from (and I'm keeping in mind no offence to you because you are a public affairs expert working in the pharmaceutical space), I don't understand why. I understand why the industry, like any industry, has its issues. But, to compare pharmaceuticals, to rank them below or on par with the tobacco industry, is astonishing to me. I'm wondering, who's not doing their job here?

Mark: That's another \$60,000 question.

Right. I'll leave you with one last question and we'll get away from that. Given the pace of change, we've talked about the FDA. We've talked about the technologies. Do you think this space can even be regulated effectively? Or should we look at it -- you mentioned event process. Is there a different way to look at this? An alternative, perhaps, to regulation? Or are we just buckled in and we have to stay for the ride and see what happens?

Mark: I think it's definitely a challenge and there might be a lot of circumstances in which regulation isn't necessary. But, I think there is some need to be watchful over communications. It is, particularly in pharmaceuticals, a highly-regulated industry. I don't think that we need to regulate every potential circumstance and talk about every possible scenario. But, I think that principles can be laid out that address some of the nuances that the Internet and social media bring in terms of questions. Such as, what if somebody picks up your content online and changes it and posts it? Are you responsible? So, the idea of talking about those kinds of principles as opposed to the platforms, as we discussed earlier, is very important. Will there still be questions? There will *always* be questions. There are still questions about DTC in broadcast and print. There are still questions about any kind of communication. You can't regulate every single circumstance. There will always be questions. But, you can certainly construct guideposts that help people make decisions.

Well, Mark, you have given us a wealth of insight here and you've been extremely generous with your time. On that note, I think we'll conclude

part three of our three-part interview with Mark Senak on a variety of areas related to e-pharmaceutical marketing practice. Mark, I want to thank you so much for your time.

If you would like to learn more, Mark will be co-conducting a workshop on: *“FDA/DDMAC Enforcement Trends”* at the ePharma Summit on Monday, February 7th. I also very strongly recommend visiting Mark’s blog at www.eyeonfda.com

Thanks to our listeners. For anyone who would like more information about the ePharma Summit taking place February 7th through 9th in New York City, please visit us online at www.iirusa.com/epharmasummit It’s going to be our tenth anniversary and this should be one of the most original and exhilarating e-marketing events in the life science’s industry. I’m really looking forward to it and I hope to see you with us in New York February 7th through the 9th.