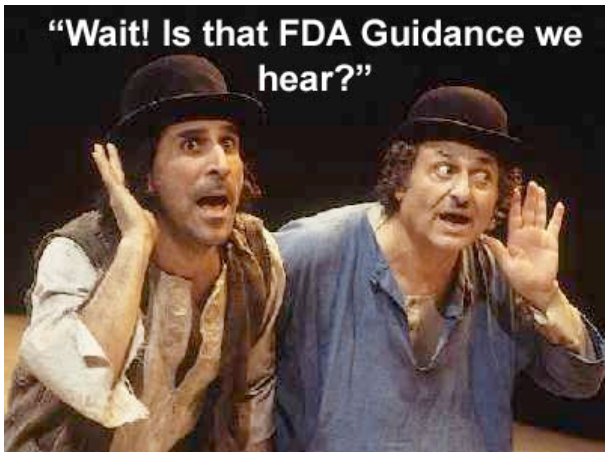
Up Front

Waiting for Goduidance

In ACT I of Samuel Beckett's play *Waiting for Godot* (rhymes with go) the character Estragon looks about and says to Vladimir, the other main character in the play:

> "Charming spot." (He turns, advances to front, halts facing auditorium.) "Inspiring prospects." (He turns to Vladimir.) "Let's go."
>
> Vladimir says: "We can't."
>
> Estragon: "Why not?"
>
> Vladimir: "We're waiting for Godot."



I was reminded of this play while listening to a panel discussion recently at the 9th Annual ePharma Summit in Philadelphia. At least one panel member—Dennis Urbaniak, VP, Customer Channels and Innovation, sanofi-aventis—advised attendees not to wait for the FDA to publish its much anticipated guidelines regarding regulation of pharmaceutical marketing on the Internet and social media sites.

"If you are expecting clarity in any kind of guidance," said Urbaniak, "I would encourage you to go back and read current guidance about any other advertising channel that exists today. My fear is that there is a bunch of people out there hoping to get the answer and once it comes it's still going to be vague because it has to be—you have to take your own risk position. And it's going to take another year for you to figure out what to do. So I'd like to shift the dialogue away from 'Is it coming?' and 'When is it coming?' because it implies that the answer IS coming."

But like Godot, the "answer" will never come. That is, not an answer to how much risk you should take in interpreting FDA regulations with or without guidance.

Urbaniak suggested that the dialogue be shifted to "How can we take what we know today and responsibly put forward guideposts now?"

BTW, the FDA has posted its intention to release its draft guidance on "Promotion of Prescription Drug Products Using Social Media Tools" before the end of 2010 (see http://bit.ly/agvOoT).

This guidance, in fact, may look much like the draft guidance submitted to the FDA in October, 2009, by the Social Media Working Group (see "Pharma's Social Media Working Group: Who It Consists of, How It Formed, and Its Role in Driving FDA Guidance"; PMN Reprint #92-03; http://bit.ly/9sbfYp).

Personally, I do not think that FDA guidance is particularly vague. Guidelines for broadcast DTC, for example, clearly state what has to be included in TV drug ads; namely, information where consumers can get more complete information. The guidance specified using a 1-800 number or referring to a publication where the complete prescribing information can be found. That's pretty clear to me.

But I think the main point Urbaniak was trying to make was that no matter what the FDA guidance may specify, each company will have to interpret it according to its own tolerance for risk. Some pharmaceutical marketers like to take risks and push the envelope. They are willing to get FDA warning letters and push back when necessary. Others are more risk-adverse and do not want to receive any letters from the FDA.

Also, no matter how many guidance documents FDA may come up with, not all the issues raised at the November 2009 public hearings will be addressed.

The FDA, for example, may not issue any guidance regarding search engine ads, general websites, or display/banner ads.

Continues…

Which still leaves us waiting for Goduidance!

At the end of Beckett's play, Vladimir says:

> "We'll hang ourselves tomorrow. Unless Godot comes."
>
> Estragon says: "And if he comes?"
>
> Vladimir: "We'll be saved."

Save yourself! Understand your risk tolerance and put up your social media marketing guideposts. If you need help, take my **Social Media Pharma Marketing Readiness Self-Assessment** (http://bit.ly/ahmFll). Good luck!

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John Mack, Editor

Pharma's Social Media Working Group
Who It Consists of, How It Formed, and What Its Objectives Are

A conversation with **Cynthia Phillips**, Sr Dir Labeling and Promotional Compliance at Millennium Pharmaceuticals and **Mark Gaydos**, Senior Director, U.S. Regulatory Affairs Marketed Products at sanofi-aventis, about their views on how pharmaceutical companies should handle posts made on social media sites owned or sponsored by them.

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