Up Front

FDA Can Relax. I Did Most of the Work for Them!

I should blame Bon Jovi for why this March 2010 isue of *Pharma Marketing News* is a bit tardy.

Last week, I took a night off to see the rocker in concert in Philadelphia. It lasted almost three hours and I got back home way past my bedtime. The next day was a waste of time. I just couldn't focus on my work.

Speaking of work, the best song at the concert was *Work for the Working Man*. The music and the multimedia show was awesome. Many of the graphics were reminescent of the WPA era of the thirties.

But I finally did get down to my work, which was to read practically all the comments submitting to the FDA regarding "Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools."

But there was a lot more work than I bargained for as I sifted through the platitudes to find the real nuggets, especially among the comments submitted by the regulated drug industry itself.

Once the nuggets were found, I had to organize them so that readers could compare suggestions from different companies regarding each major issue and/or question posed by the FDA.

In other words, I did the work of the FDA! So, bring up the stage lights and listen to my song:

> *Who's gonna work for the FDA (work)*
> *Work for the FDA (work)*
> *Get the hands in the docket, who's gonna work off the non-guidance curse (work)*
> *Brother Ive been damned (work), if I dont raise a hand (work)*
> *Work for the FDA, FDA, work for the FDA (work)*

So Jean-Ah and her staff can relax and just copy the articles in this issue when they summarize the comments, which I hope they do when they finally issue the expected guidance.

I also included the most updated charts showing the results of the *Pharma Marketing News* reader survey, which collected more than 700 comments from 274 people.

Not every question asked by the FDA was answered by the drug industry in its comments submitted to the public docket. The most detailed and extensive comments dealt with three main issues of paramont importance to the industry:

1. How to deal with space limitations and satisfy FDA regulations requiring fair balance.
2. Define the responsibility of drug marketers for content posted to social media sites, including social media sites that they own.
3. How to manage adverse event reporting requirements when monitoring and participating in social media sites.

I organized comment nuggets about these issues in three separate articles, each devoted to one of the above issues.

The first article examines who made comments compared to who made presentations at the public hearing held in November, 2009. In that article, I included practically ALL the comments submitted by individuals and consumer advocates.

After reading these articles, you should get a much better idea of what the drug industry might be able to do with social media if the FDA follows its recommendations.

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