

Up Front

Adverse Event Reporting: A Missed Opportunity

When asked what the # 1 concern pharmaceutical marketers have regarding using social media, the adverse event reporting boogey man is cited most often. Many marketers hope the FDA will issue guidance to help them neutralize the boogey man, but that is not likely to happen any time soon. In fact, I've heard that DDMAC won't be issuing those guidelines (see, for example, <http://bit.ly/gMDxmC>), but has handed the job over to another division of the agency. In my mind that does not bode well—at least DDMAC is the devil we know!



"Writing for the unanimous court," NPR reports, "Justice Sonia Sotomayor said that medical researchers and the FDA often reach initial conclusions based on evidence that is not statistically significant."

"The decision will make compliance with the securities laws more difficult" for corporations, said James Martin, who filed a brief in the case on behalf of lawyers who represent corporations.

The decision will also make it more difficult for pharma marketers to deal with the adverse event boogey man when engaging consumers in the social media

While the FDA Fiddles, the Supreme Court Decides

Meanwhile, a recent Supreme Court ruling may have greater repercussions for adverse event reporting by the drug industry than any guidelines the FDA may issue.

In the case *MATRIXx INITIATIVES, INC., ET AL. v. SIRACUSANO ET AL.*, the court ruled that investors can sue pharmaceutical companies for failing to disclose reports of adverse events even if the evidence is not "statistically significant" ("Supreme Court Allows Investors to Sue Pharma-cos Over AE Reporting Lapses"; <http://bit.ly/g4u7zn>).

In a brief to the court, PhRMA (the US pharmaceutical trade association) said "A collection of adverse event reports that is not statistically significant does not permit a reasonable inference that a particular medicine actually caused the reported adverse event" (the brief is attached to the post cited above).

But what is "statistically significant?" According to PhRMA, "The statistical significance standard requires disclosure only once a correlation between an adverse event and the subject product can be reasonably inferred to be causal. It is only at that point that a manufacturer or regulatory body might react to adverse events, that a medicine's sales would be threatened, and that a rational investor might consider this information in making investment decisions."

realm, even if new FDA guidance seems to make it easier. Let me explain.

We have been told by our pharma marketing colleagues that the fear of lawsuits initiated by patients has prevented them from discussing adverse events in open online forums. But perhaps the lawsuits pharma fears the most are NOT from disgruntled PATIENTS, but from disgruntled INVESTORS!

When the adverse event reporting issue comes up during industry conferences such as the recent iPharmaConnect conference hosted by CBI, there are always pharma rank-and-file employees in the audience who wish their companies would embrace adverse event communication with consumers/patients as a way of supporting the users of their products. During my panel discussion—"Utilization of Social Media: How Far Is Too Far" (see <http://bit.ly/gAWIQw>)—"one pharma employee in the audience had this to say:

"I think as an industry that we should really turn this [social media] adverse reporting [issue] on its head and look on it as an INCREDIBLE opportunity to really engage with the ultimate end user who is really the most important person and use it as an opportunity to find out WAY more than we ever do about how [our products] really affect their lives. ...I think this [pharma aversion to dealing

Continues...

head-on with AER in social media] is EXACTLY why people don't like the pharma industry—because we're always doing things that are SO secret. 'Oh, we can't talk about that.' It's ridiculous! We save people's lives and we should be ENCOURAGING [patients] to tell us what's going on and how these medicines are affecting their lives. I just think it's a missed opportunity."

Her statements were followed by immediate, spontaneous applause!

Could it be that the fear of disgruntled investors runs deeper than the fear of disgruntled patients in pharma companies? That fear runs all the way up

to the top of the organization; ie, to the CEO, who is rewarded based upon stock price performance, not how well the company services patients. Long gone are the days when a pharma CEO can truthfully say:

"We try to remember that medicine is for the patient. We try never to forget that medicine is for the people. It is not for the profits. The profits follow, and if we have remembered that, they will never fail to appear. The better we have remembered that, the larger they have been." -- George Merck - Founder of Merck & Co Inc.

John Mack, Editor



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Physicians Favor Brands with Compelling Adherence Platform

Highlights of Physician Survey



A conversation with **Katrina S. Firlik, M.D.**, Chief Medical Officer, and **John Ruvane**, Vice President, Sales and Business Development, HealthPrize, highlighting results of an independent physician survey that suggests HealthPrize's patient adherence program can sway physician prescribing preferences.

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