Bridge Worldwide White Paper Series

The Myth of Adverse Event Reporting

I've written a fair amount about the use of social media on my blog, Dose of Digital. And, like many other people working to try to enhance healthcare marketing by including channels such as social media, I've heard all the same excuses. Despite this, many healthcare companies (or many other industries for that matter) aren't ready to incorporate social media into the mix. The specific reasons are different for each industry, but they share some commonalities. Here are the big reasons:

1. Afraid to give up control of the brand
2. It doesn't work/impossible to measure
3. No one in my target audience uses social media
4. Worried about bad reviews

For pharma, these same reasons persist, but they have a little different spin:

1. Same as above
2. I can't track it like physician-level prescription data
3. Older people use my products and they don't use social media
4. Adverse Event reporting

So, let's take a look at each of these one at a time. We'll save the most complex, Adverse Event Reporting, for last.

1. Afraid to give up control of the brand

Surprise, you already lost control of your brand. Conversations are going on without you already. Don't believe me? Pull up any discussion board on WebMD. It's going on without you. Search for your company's products and see what people are saying. They're saying it's great, it's horrible, it gives me gas, it makes my teeth whiter, and it made Aunt Sally turn blue. They're also giving and receiving medical advice that only a physician should give. So, if you think that allowing people to comment or post information about your product might take control from you, you're right. However, do you want it happening on WebMD where you have no control and can't really respond effectively or do you want it happening on your site where you can?

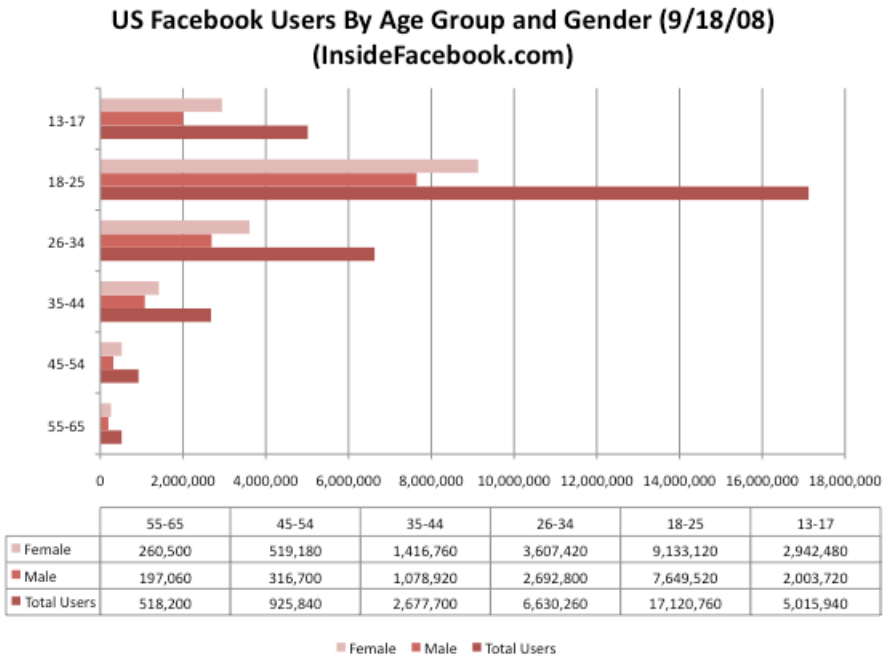
2. It doesn't work/impossible to measure (for pharma: I can't track it like physician-level prescription data)

First, social media is no harder to track or correlate with sales than any other online program done in healthcare (or offline for that matter). It is far more difficult in pharma to track the effects of a

specific promotion on sales compared to other industries. In consumer packaged goods (CPG), for example, you can do panel match studies where you know who is doing what, what messages they are exposed to, and if it had a specific lift in sales. Our company does this all the time. In pharma, you don't have this level data and you never will. HIPPA prevents it. So, get used to that. You can't determine if someone who saw your commercial actually went and got a prescription and filled it. You can ask them, but that's not reliable. The fact is that you may need to use other measures to determine if the program is effective. You do many programs where the efficacy is measured in clicks or visitors (rightly or wrongly) and you can do the same in social media. In addition, in social media, you can actually track real-time brand sentiment. Instead of being a tactic to completely change opinions, you can actually use it as the proverbial "canary in a coal mine" to see if your other activities and messages are having an impact on opinion. For example, if you put out a new TV ad, you can rest assured that someone is commenting on it right now online. What does that conversation look like?

3. No one in my target audience uses social media (for pharma: Older people use my products and they don't use social media)

This simply isn't the case anymore. You should know this by now. No? Well, here's the info one more time. Consider just one social networking site for a minute. Facebook. Its share of college age users continues to decline every month. In addition, in the US, there are over 4 million users over the age of 35.



	55-65	45-54	35-44	26-34	18-25	13-17
Female	260,500	519,180	1,416,760	3,607,420	9,133,120	2,942,480
Male	197,060	316,700	1,078,920	2,692,800	7,649,520	2,003,720
Total Users	518,200	925,840	2,677,700	6,630,260	17,120,760	5,015,940

Isn't 4 million a lot? Sure, it's not number of people watching American Idol each week, but it's not a small number. That's just Facebook. Rest assured that the number of "older" people using social media will only increase in the future.

4. Worried about bad reviews (for pharma: Adverse Event reporting)

This is the main reason for this paper, but since you came all this way, I figured I'd give you a few other things first. Let's address bad reviews first. Product reviews are the norm now in ecommerce, but they weren't always. One of the big reasons is that companies were afraid of negative reviews. It turns out, of course, that simply having reviews can increase traffic, conversion rate, and average order value. In addition, negative reviews aren't an issue so long as there aren't only negative reviews. Consider yourself for a minute. You're checking out a product online and all the reviews are glowing. What do you think about that? You'd probably feel like the results might not be all that authentic. Instead, when there are negative reviews, it actually can lend credibility to the product (and site) because people know the reviews are actually genuine. Negative reviews don't turn people off. They read them and consider whether the negative would actually bother them. For example, someone ranks a product 1-star and says "this didn't work on my Mac." Well, if you have a PC, you aren't worried. Simple example, but you see how it works.

Adverse Events are nothing more than negative reviews. If you want people to genuinely talk about your brand, they are going to say negative things. But how often do posts include adverse events? Nielsen decided to take a look at this rather than simply assume it was "a lot," which of course is a difficult number to manage. Nielsen looked at Yahoo Health boards and took 500 postings. Of these, only 1 contained enough information to qualify as an adverse event that needed to be reported. That's 0.2%. Why so low? Turns out that someone simply saying that your drug caused them to have a headache isn't enough to qualify as an adverse event. Nielsen summed up the pieces of information required to report an adverse event and there are four pieces: "(i) an identifiable patient; (ii) an identifiable reporter; (iii) a specific drug or biologic involved in the event; and (iv) an adverse event or fatal outcome." The study showed that one or two of these pieces were often available, but not all four. In addition, they found that it would be impossible to get all four even with some effort. The FDA is clear on what to do with incomplete reports: "[Without all this information] a report on the incident *should not be submitted* to the FDA because reports without such information make interpretation of their significance difficult, at best, and impossible, in most instances."

This is because people often don't register or leave their personal information in a post, so there is no way for a company to follow up and fill in the blanks. Naturally, if there is something significant, every effort should be made, but on the often anonymous Internet, this is usually difficult. Suppose for a moment there were several adverse events that need to be reported. How often do they need to be reported? The FDA is pretty clear on this. For new drugs, reports need to be filed quarterly for three years. After that, it's annually. "Serious and unexpected" have to be reported wihtin 15 days. However, there's a pretty high threshold for an adverse event to be considered "serious and unexpected." Every company already has these reporting channels in place, so it is simply a matter of including adverse events received from social media into the workstream.

Yes, it's a balance. The fact is adverse events should not be the reason why healthcare shies away from social media. These risks can easily be mitigated and, if done right, can actually be used in a positive way. So, don't use adverse events as an excuse anymore. You've got the data.

1 in 500 posts include a reportable event. You report quarterly at most (which you're doing anyway). How much ongoing effort do your other marketing programs require? Probably quite a bit more than this. Next time you hear this excuse, you've got the data to dispel the myth of adverse event reporting.

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