FDA, Off-Label Uses and the Internet – Something New for 2012 (Well sort of)

Friday, December 30, 2011

It is the end of the year – a time to look back and reflect and a time to look forward and ponder. We've already looked back and posted about the best and worst prescription pharmaceutical and medical device cases of the year. So, on this the last posting-day of 2011, we'd thought we'd look at something aimed toward the future – FDA's Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices. As this is just a draft guidance right now, we don't really know what the future holds, but we thought this looked a bit like an FDA New Year's Resolution – FDA resolves to admit the internet exists and to figure out what to do about it. We just aren't sure they are going about it the right way. Sort of like resolving to lose weight, but going about it by cutting back to only 2 doughnuts per day – it's really not going to get the job done.

Off-label promotion – just the words leave our clients shivering. Pharmaceutical and medical device manufacturers walk a fine line between providing current, relevant, and accurate medical information to their clients (health care professionals) and being accused of violating FDA regulations against off-label promotion. Even the FDA admits that:

> "FDA has long taken the position that firms can respond to unsolicited requests for information about FDA-regulated medical products by providing truthful, balanced, non-misleading, and non-promotional scientific or medical information that is responsive to the specific request, even if responding to the request requires a firm to provide information on unapproved or uncleared indications or conditions of use."

Draft Guidance at 6. How to accomplish that scientific communication without running afoul of FDA regulations is the tricky part. And, the FDA is now admitting, technology has made it a bit trickier.

The FDA hasn't said much about internet promotion in any context, so this guidance is interesting just for admitting the internet exists. Even more interesting is the recognition that there is a lot of information floating around on the internet and not all of it is good. For instance, a consumer recently prescribed a drug for an off-label indication can post a question on Yahoo! Answers and it can be answered by anyone – no medical degree, no

pharmaceutical experience, no scientific background required. So, we were encouraged by the FDA's admission that maybe the drug and device manufacturers might offer better answers than Aunt Millie or anonymousknowitall@server.com:

"Furthermore, as these firms are regulated by FDA and have robust and current information about their products, FDA recognizes that it can be in the best interest of public health for a firm to respond to unsolicited requests for information about off-label uses of the firm's products that are addressed to a public forum, as other participants in the forum who offer responses may not provide or have access to the most accurate and up-to-date information about the firm's products."

Draft Guidance at 3.

But, the FDA is still trying to hide the off-label ball; trying to force anything substantive to be non-public. Drug and device manufacturers have long been aware of the FDA's rules regarding how it should respond to non-public requests (phone calls, direct emails, one-on-one communications) for off-label information about their products and those rules really haven't changed – the response has be specifically tailored, truthful, non-misleading, accurate, balanced, and scientific. But what about those internet questions – those posted on product websites, chat rooms, discussion boards, etc. When Aunt Millie responds to those public questions, her response – no matter how inaccurate – is out there for the whole world to see. So, shouldn't the specifically tailored, truthful, non-misleading, accurate, balanced, and scientific response by the manufacturer get equal all-access status. Not according to the FDA:

"[B]ecause product information posted on websites and other public electronic forums is likely to be available to a broad audience and for an indefinite period of time, FDA is concerned that firms may post detailed public online responses to questions about off-label uses of their products in such a way that they are communicating unapproved or uncleared use information about FDA-regulated medical products to individuals who have not requested such information. In this circumstance, communications to persons who have not requested information may promote a product for a use or condition for which FDA has not approved or cleared. FDA is also concerned about the enduring nature of detailed public online responses to off-label questions because specific drug or device information may become outdated (e.g., new risk information may become available)."

Draft Guidance at 10. So, anonymousknowitall's response can linger forever to be discovered years later by someone searching at random for information about a product, but a drug manufacturer's informed medical response has to be hidden under a rock. Essentially, the manufacturer can respond to a public request for off-label information only by providing contact information where the requester can make a non-public request. Draft Guidance at 11.

"Therefore, any substantive communication about off-label uses for the product, in response to the original unsolicited off-label question, should occur solely between the firm and the individual who made the request. Regardless of the fact that the original, unsolicited off-label question may have been available to a very broad audience, the firm should not make its detailed response with off-label information publicly available within the same forum."

Id.

This is simply weird. The FDA admits that the information itself, properly vetted and hemmed in by mandatory disclosures and fair balance (not the Fox News kind, either) requirements is not misleading if done privately. How could it possibly be misleading when it's public? Especially when the alternative is so easy. If the FDA is worried about the information somehow going stale, the posting companies could be made to keep track of where they post and update the information accordingly. That's not hard. We do it all the time on our own scorecards.

The public/private distinction is just silly – the FDA is making a mockery of free speech yet again for its bureaucratic reasons. Equally silly is the FDA's solicited/unsolicited distinction. The same information that the FDA admits is truthful and beneficial in one context becomes illegal in another, for reasons having nothing to do with the content of the speech and everything to do with the FDA's seeming death wish to continue banning truthful off-label promotion. Well we have seen the future and it is Sorrell – we fervently hope.

Still, we guess it is better than nothing. Some people will get beneficial information for some of their medical problems. We can only hope that when someone requesting information about a drug gets a response from anonymousknowitall claiming to "know it all" and a response from the drug's manufacturer saying "please call us," they do the latter.

But doesn't the FDA know that it's impossible to censor the Internet? We trust it will find out the hard way like every other would-be Savanorola or Breen Master of the Web before them. Before the Civil War, the Post Office censored the mail to remove abolitionist literature. May the FDA's attempt meet with the same historical fate.

In hopes of hastening that eventuality we'd like to point out – to any of you entrepreneurs out there – that the FDA's Draft Guidance creates the possibility for a wonderful online business opportunity. The partial censorship that the FDA is proposing practically cries out for some industrious on-line aggregator to defeat it, and make a buck doing it. Here's how:

(1) There are lots of authoritative sources listing accepted off-label uses. There's a list in the Physicians Desk Reference. There are the three compendia that Medicare uses in determining whether to reimburse off label uses. See 42U.S.C. §1396r-8(g)(1)(B)(i) (listing the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the DRUGDEX Information System).

(2) Some enterprising soul – unaffiliated with any FDA regulated entity, of course – could send non-public emails, compliant with the Draft Guidance, to companies requesting information about all the off-label uses contained in these lists. We'd recommend a separate email for each off-label use. There's no business reason for the recipient companies not to respond with compliant replies, since sales are sales.

(3) Collect all of the non-public responses and create a website – like "offlabeluse.com" or something similar; then post all the responses for the cyber world to see. Google's spidering capabilities take care of the rest. The world gets useful information, the aggregator's website charges for it in one way or another, money is made, and censorship is defeated. Win-win.

And, if you run with this idea and it makes you rich, don't forget your friends at the Drug and Device Law Blog (a modest finder's fee would not be looked upon negatively!)

Happy New Year!