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Digital Health Coalition

For Digital Pharma Marketers, Proposed FDA Guidance Brings Us One Step Closer to A Clearer World…Or Does It?

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Over this past weekend, the FDA released draft guidance for interactive promotional media, calling for comments. The Digital Health Coalition congratulates the FDA on this draft guidance. Although we believe the current draft guidance has a number of deficiencies, this kind of document and clarification is exactly what the Coalition – and many industry stakeholders – have been asking for from the FDA for years.

One thing can be said about the recent guidance issued by the FDA specific to interactive promotional media and UGC (user generated content): If you were scared to participate in digital (and social) last week then you are most likely still scared this week. And, upon a little self-reflection, it probably has less to do with the FDA's guidance than other barriers for participating. However, for the companies already participating in social media the guidance provides additional insight into the current thinking (stress *current*) of the FDA and provides additional common-sense guardrails to guide program development and their digital strategy overall.

We will not discuss the historical background with regard to a lack of guidance from the FDA specific to digital over the past several years and the ramifications the lack of guidance has had on innovation. It is a widely held belief that everyone in the industry has been operating in a highly uncertain – and many feel risky – environment where there has been no clarity and where boundaries have not been known when it comes to interactive promotion and social media, fields that move far faster than the regulatory environment that governs it.

Understandably, companies are always assessing risks and are always making decisions, independently, on what constitutes a higher or lower risk, what mitigations may or may not be appropriate, and what they may be able to live with in the overall framework of what they do. Companies interpret control and influence differently.

Will some companies disagree with the FDA's proposed definition of control? Of course!! In our experience with the Digital Health Coalition, as far back in 2011, we know some companies believe in the absolute definition of "control" and they - and their legal - believe they should only be held responsible if they have had absolute control over the content (e.g., a kill switch to the server or one step to stop).

If they are mere observers or incidental participants, they believe this does not confer them the ownership of control and therefore should not be responsible for comments made by others. Other companies have adopted a more conservative stance where they believe that any such comments, whether or not in full control, could bring upon them elements of liability. And this liability is not only FDA regulatory liability, but even potentially more significant, product or failure to warn liability.

In the subsequent pages we will provide initial comments on the draft Guidance in a number of areas; however, the most important subject matter in our view is "control" or "influence". These are quite subjective terms that are at the cornerstone of whether or not a company is in compliance with these regulations. If a company has control or influences a comment or action, then it is responsible for it. But what is "control" or "influence"?

The Digital Health Coalition, in 2012, issued our opinion on this subject:

Regulated healthcare companies are not responsible for user-generated content online that they do not control. Regulated healthcare companies are deemed to "control" health and medical content if

(i) it owns such health and medical content and has <u>material</u> editorial authority or

(ii) it paid for the creation of such content and has material editorial authority over such content.

Perhaps the greatest debate within the halls (and corporate meeting rooms) of pharmaceutical marketers and their agencies in the weeks and months to come will be over the meaning of the word: *influence ...* and to a lesser extent its accompanying phrase*: limited in scope.*

NEW FDA GUIDANCE:

A firm is responsible for product promotional communications on sites that are owned, controlled, created, influenced, or operated by, or on behalf of, the firm.

In summary, regardless of financial support, if a firm has any control of, or influence on, the third-party site, even if limited in scope, it is responsible for submission to FDA to meet the postmarketing submission requirements.

The DHC leadership has had the opportunity to discuss these matters with the FDA's OPDP and brief them on the Social Guiding Principles project back in 2012 and also explain the thinking that went into the principles (based on conversations with various stakeholders and DHC members).

http://digitalhealthcoalition.org/publications/social-guiding-principles/

Although "owned, controlled ... operated by, or on behalf of, the firm" can lead reasonable consumers to the same conclusion, it is clear that informed people can and will disagree about the definition of influence. By its nature, it is gray. What one person deems influence may be radically different than what another person deems influence. The future of digital health and innovation will certainly require additional clarity on this front.

Yes, we all know it when we see a situation free from any influence at all. However, as we move down the curve of “limited scope” with regard to influence the debate quickly spins out of control. An ambiguous phrase sitting on top of an unclear term leaves plenty of room for interpretation -- and thus consequences -- if a firm’s social media program is deemed to aggressive. We need more concrete examples when limited scope has been reached – as well as examples of that limited scope on leading platforms such as Facebook, Twitter, and YouTube looks like. The FDA can’t provide guidance for every site and platform, but if we agree on standards and examples for the largest sites and platforms that framework and thinking will apply to sites and platforms going forward.

Again, we also need debate at the industry level about the definition of “limited scope” with regard to influence on a third party site or platform. As mentioned in the opening, those firms already participating in social media in the absence of guidelines will most likely implement additional internal parameters defining limitations of scope. Though, those firms that have been held back due to legal or regulatory concerns will find little solace in the ambiguity.

Given these are draft guidance there is a real opportunity to help the FDA eliminate ambiguity now and to provide our understanding so that tighter parameters around exactly what are the limitations to the scope of influence that might be established. As an industry and as consumers seeking involvement in social media on healthcare issues, the fruits of the debate should be captured and presented back to the FDA.

Although we do not live in a world of black and white we need additional and more concrete examples of what “limited scope” with regard to influence means in the real world. These are topics the DHC plans to take up with the membership in the coming months and years.

NEW FDA GUIDANCE:

A firm is responsible for the content generated by an employee or agent who is acting on behalf of the firm to promote the firm's product.

That having been said...

FDA will not ordinarily view UGC on firm-owned or firm-controlled venues such as blogs, message boards, and chat rooms as promotional content on behalf of the firm as long as the user has no affiliation with the firm and the firm had no influence on the UGC.

Although not a green light for most brands and marketers to proceed full speed ahead with social media and UGC, the current thinking and guidance provides much needed assurance that the FDA will not pursue third party UGC and comments on sites when control and influence are not present – even if those sites are owned or controlled by the brand or company. Of course we also have the caveat "*will not ordinarily*" as well as the disclaimer the "...*the user has no affiliation with the firm and the firm had no influence*".

This is also a great opportunity to revisit one of the fundamental beliefs in the DHC Social Guiding Principles (referenced above). The DHC's sixth principle is...

Regulated healthcare companies should endeavor to make reasonable efforts to correct misinformation that is factually incorrect.

Despite the fact companies are not held liable for comments and content from consumers with no affiliation with the firm and the firm had no influence on the UGC, we believe responsible firms with a long term view of digital and social media will endeavor to correct misinformation in venues where they are active and engaged as brands and corporate citizens.

We were also surprised the guidance did not address response time in the draft guidance and we hope that the industry continues to work towards best practices in this area. Once again, the DHC's principles considered these scenarios and accounted for them:

Regulated healthcare companies should endeavor to respond to questions on sites they control within a reasonable period of time, and to implement reasonable measures to enable timely responses to crisis and emergency situations (DHC's fifth principle).

Finally, one critical point of any guidance is applicability in the real world. It will be important for the Coalition, for the FDA and for other stakeholders to take as many practical and real examples of current social media tools and environments and run simulations on what this Guidance could mean in each case. To complicate this endeavor, there are innovations and new platforms coming out all the time and one could never be exhaustive about it without being dated months later, but such a detailed and joint exercise with industry and agency experts would be highly informative and would reveal the practical realities of this evolving guidance. The DHC would be pleased to work with the FDA and other partners in building such a "lab" to help ensure the guidance progresses in a manner and at a rate to be informative and protective for all parties involved.

Overall, we are pleased to see the FDA issue this draft guidance and spark public and industry debate about the structure and how the guidance applies in the real world. We are also pleased that the latest draft guidance supports many of the "Social Guiding Principles" the DHC issued to the membership in February 2012.

Best Regards,
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