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SOCIAL MEDIA AND THE US FDA

The impact of new guidance for pharma

Despite years of consideration - and occasional public process - the social media guidance published by the US Food and Drug Administration (FDA) in June of this year reflects the sclerotic strictures of statutory language rather than the open marketplace of ideas in today's online environment.

Recent US legislation finally gave the agency a deadline for action, but did not change the ground rules. In the end, the guidance (the public comment period ended in mid-September and the final version of the guidance may be some time in coming) offered some 'safe harbours' for drug and device manufacturers and their social media teams, but they are so narrow that they are virtually unusable. Greater opportunity for involvement in social media by pharma brands is afforded by another guidance document published the same day, focused on the correction of misinformation that is posted by independent third parties.

The key issue holding up final action on short-form internet marketing was fair balance – the need to communicate risks as well as benefits in as short a message as a tweet (140 characters). Per the FDA guidance, benefit information should be accurate and complete, as should risk information. The most serious risks should be identified in the body of the tweet, Google Ad, or the like, with a link to more complete risk information. Benefits and risks should be equally prominent.

The FDA guidance detailed sample tweets and short-form Google ads, and gave annotated examples of satisfactory character-limited ads, including, for example:

NoFocus (rememberine HCl) for mild to moderate memory loss-May cause seizures in 502 patients with a seizure disorder www.nofocus.com/risk

FDA headquarters

This tweet includes brand and established names, just a dash to separate benefits from risks, and a link to the safety information page of the product website.

This sample text complies with the FDA requirements but, in the end, it does not resemble a tweet – there is no call to action, no engagement, nothing social about it. In addition, it would be easy to imagine a circumstance where the required elements of the message would far exceed 140 characters. In the end, short-form branded social marketing seems unlikely to gain any traction given the fair balance requirement and the FDA's unwillingness even at this late date to entertain the desired but elusive 'one-click rule' (ie, a rule recognising that with risk and benefit information one click away, it does not even have to be summarised in the tweet).

CASE STUDIES

Even before finalising the guidance, the FDA began enforcing its terms. The guidance is non-binding sub-regulatory guidance - nothing more - although these guidance documents are the object of much examination by FDA watchers. Two cases are worth detailing:

In one case, the FDA sanctioned a company for its branded use of Google AdWords that did not comply with relevant requirements. The drug in question was being promoted as a cure for a condition,

"The guidance makes the use of Twitter and platforms like Google AdWords extremely unattractive"

The FDA's own tweets do not need to include limitations on indications, risks and benefits in the way required of a drug manufacturer

when in fact it has been approved only as a treatment for symptoms; the ad omitted risk information; the established name for the drug was not used; and the ad was not submitted to the FDA.

In the other case, the FDA sanctioned a company for website, Twitter and Facebook claims about products sold over the counter that have never been subject to FDA review; and for liking Facebook posts endorsing one or more of its products. The FDA views these products as 'misbranded' 'new drugs' since the seller is making claims as to efficacy in treating certain conditions even though they had never been approved by the FDA.

The social media aspects of this case serve mostly to emphasise the fact that the FDA is monitoring social media activity of drug and device manufacturers and distributors; the crux of the issue is that the OTC products are being marketed with claims that bring them under FDA jurisdiction.

While the FDA apparently has not had the opportunity to do so since the guidance was released, it could sanction a drug manufacturer for liking a Facebook post regarding an FDA-approved drug if the initial post was not wholly compliant with the guidance.

LACK OF CONSIDERATION

In the end, the guidance makes the use of Twitter and platforms like Google AdWords extremely unattractive, because the vast majority of the 'real estate' must be given over to brand and generic names, indications for use, benefits, risks and a link to fuller information about risks. As far as the truly social short-form online tools go, the truth is that the FDA addressed itself to short-form communication without considering the way in which it is used most effectively - not as a canvas for ads, but as a forum for conversation.

The ultimate indignity inflicted on drug and device manufacturers is that the FDA has become a user of social media in its own right, and even tweets announcements of its approvals of new drugs (see example at top of the page).

None of the factors laid out in excruciating detail in the guidance to industry seems to have been followed in this tweet from the FDA. We learn what the drug is for, but limitations on indications, risks and benefits are not laid out in the way required of a drug manufacturer. Had the manufacturer of this drug tweeted this very same tweet – or retweeted it – the FDA could have issued a warning letter.

Two new pieces of FDA guidance...

Internet/social media platforms with character space limitations

- Guidance for pharma's use of Twitter, Facebook, YouTube and paid search results links
- Companies should include a link to a 'more complete discussion' of any risks associated with their products.

Correcting independent third-party misinformation

- Guidance on how pharma can respond to misinformation on an online forum or social media
- This applies to both positive and negative misinformation.

WHERE DO WE GO FROM HERE?

Unbranded Tweetchats

While branded use of social media by pharma companies is unlikely to increase as a result of the guidance, drug and device companies should continue to use – and increase the use of - unbranded tweetchats, Facebook pages, and the like. They were permissible before the draft guidance was issued, and they still are.

Correction of misinformation

The correction of misinformation guidance released by the FDA on the same day as the short-form marketing guidance creates an alternative set of regulatory hurdles – lower ones – for corrections posted by a drug or device manufacturer, compared to those applicable to proactive marketing messages that must meet higher standards and may be subject to pre-review.

The misinformation guidance does not require a drug or device manufacturer to address all misinformation online about its products. Corrections must be focused responses to what others put out online, and should link to fuller information where appropriate, but corrections should not include or link to promotional material. This guidance allows some conversations to begin – stilted though they may be. The short-form marketing guidance does no such thing.

THE BOTTOM LINE

Unbranded social media efforts are still a valuable arrow in the quiver, and the misinformation guidance delineates an area of opportunity for drug and device manufacturers. In the context of corrections, brands can engage in the kinds of conversations that are natural online, offering information about their products as necessary to respond to misinformation.

It remains to be seen whether and when the regulatory structures in this domain will catch up with the realities of the 21st century marketplace of ideas - and products.

THE AUTHOR

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