Insight

#FDALimitsFreeSpeech

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Introduction

Like many areas of marketing, pharmaceutical and medical device manufacturers are frequently subject to limitations on the exercise of free speech. With the rapid development of technology and social media, pharmaceutical companies often find themselves in an unregulated 'gray area' where there are no explicit regulations on speech, yet the fear of penalties by the U.S. Food and Drug Administration (FDA) has chilled the desire to release promotional materials on these platforms without explicit government permission.

Proposed Guidance

Last week the FDA illuminated some of that technological gray area with the release of proposed guidance. The proposed guidance addresses use of social media communications with character limits, i.e. Twitter.

For other industries, the Federal Trade Commission (FTC) allows marketing that does not address limitations or risks, as long as they are only 'one-click' away. However, it is the FDA who regulates promotional labeling of pharmaceutical products, including ads published, broadcast, or otherwise distributed to consumers.[1] The FDA considers a promotion 'misbranded' if any representations about the product are made without disclosing potential risks to the consumer.[ii]

To avoid being 'misbranded,' any claims made on social media or other platforms must: be truthful and non-misleading; include the entire indicated use of the product; include all serious risks of use; include information reasonably necessary about customary use of product, with limitations and intended patient population; and include all required label information. The required label information must be prominent and readable; all 'serious' risks included on boxing label, anything known to be fatal or life-threatening, and any contraindications on the label must be included in the same Tweet. For medical devices, if a particular risk is associated with a specific identifiable population, it must be listed; if none of the above exists the Tweet must include the most significant warnings or precautions. Some additional rules apply for veterinary pharmaceuticals as well.

The FDA guidance recommends that producers should include both the brand and established (generic) name of the drug. They are also encouraged to include a link to a webpage with more complete risk information – though a link to risks is not itself sufficient as the FDA has already banned a 'one-click rule used by the FTC.

The FDA further recommends that at least one specific dosage form is included along with quantitative ingredient information.

The FDA provided an example of an acceptable Tweet for "NoFocus:"

> Sample Tweet: "NoFocus for mild to moderate memory loss; may cause seizures in patients with a seizure disorder www.nofocus.com/risk"

But the FDA explained the example they provided, though compliant with all requirements lacks much of the recommended information and is permissible largely because of the heavy emphasis on the risks rather than benefits of the drug.

Use of Social Media in Pharmaceutical Promotions

The FDA recommends that if a producer is unable to include all of the required and recommended information within the space limitations (140 characters), they should consider abandoning that particular promotional platform.

This guidance, however, does not impact the use of "reminder" promotions that simply draw attention to the brand/name of a drug or device because no risk information is required if no claims about the product are being made.

For example: NoFocus featured in #NIHstudy www.fakenihstudy.gov

Impact of the Proposed Guidance

The strict enforcement of requirements for each promotional Tweet that makes a claim about a product makes it virtually impossible for most manufacturers to use social media to promote their products. Pharmaceutical companies have effectively been banned from Twitter and other social media with character limitations.

Conclusion

This proposed guidance is incredibly limiting, and the continued use of the ban on the one-click rule presupposes an unrealistic lack of tech-savvy among Twitter users. The result is a restriction on free speech intended to protect consumers from a phantom danger.

The chilling effect these strict guidances will likely have on manufacturers as technology and social media continue to develop should be considered when producing guidance or other regulations addressing free speech. With each additional regulation limiting free speech in marketing, producers are under more pressure to refrain from any advertising at all for fear of harsh repercussions for inadvertently crossing an invisible line. When drug and device manufacturers are afraid to use the latest and most popular technologies to market their products, companies and patients both pay the price.

21 CFR 202.1(1)(1)