and endorsements be clearly identified and substantiated, and relationships with influencers that include any exchange of value, monetary or otherwise, be clearly disclosed.



medical devices. Regulatory agencies may hold drug and device firms accountable for statements made by social media influencers that they engage to promote their products. How, then, can these companies take advantage of the many benefits of social media influencers, and particularly micro-influencers, without running afoul of the myriad advertising and promotional regulations and requirements for their products? What follows is a list of best practices for those medical device and pharmaceutical companies interested in the space.

Medical device and pharmaceutical companies, however,

bear the additional burden of compliance with the detailed and often complex FDA regulations covering labeling and advertising requirements for drugs and

Understand FDA's requirements for advertising and promotion of prescription drugs and medical devices

The Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the sale of a drug or medical device without first receiving the required approval from FDA, as well the promotion of

that all prescription drug or device labeling (including promotional material), must be truthful and not misleading. This means the labeling must (among other things): reveal material facts regarding the product's use; not omit or minimize risk information or overstate the efficacy of the product; not make a misleading representation with respect to another drug or device.

an approved drug or device for unapproved or "off-label" uses. Additionally, the FDCA requires

- Although the specific rules that apply to drugs and medical devices differ, in general, the following rules of the road apply: Promote only products that have been approved
- Do not promote products for uses that are not approved or cleared by FDA. Make only claims that are supported by adequate substantiating data and that are consistent with the product's clearance or approval. For additional information about what FDA considers to be

or cleared by FDA.

- "consistent" with a product's clearance or approval, refer to Medical Product Communications That
- most recent draft guidance from FDA on social media use

These rules apply regardless of what medium of advertisement is used, and while FDA acknowledges that character space limitations in social media can pose

a challenge in providing the required information, it provides a hard bottom line: if such information cannot be

communicated in the relevant medium, a business should not use that medium to

advertise the product in question.



Get familiar with the

As noted above, promotional material for prescription drugs and medical devices must present a fair balance between information relating to risk and information relating to benefit. This means that risk information must appropriately qualify the representations made about the product and must be presented with a prominence and readability reasonably comparable to claims about the product's benefits. The risk information may be concisely presented, but only if it is supplemented by a prominent reference to the presence and location elsewhere in the advertisement of a more complete discussion. In addition, in determining whether a drug or device is misbranded because its labeling or advertising is misleading, FDA will consider whether the labeling or advertising fails to reveal material facts with respect to possible consequences of the use of the product as represented in the labeling or advertising.

In June of 2014, FDA published a Draft Guidance entitled, Internet/Social Media Platforms with Character Space Limitations–Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices. Although FDA guidance documents are

not legally binding, and this particular guidance remains in draft form, it does describe the agency's current thinking on the subject. The document provides helpful guidance for advertising and promoting prescription drugs and medical devices using limitedcharacter internet platforms (think Twitter tweets or Sponsored Links in Google or

Yahoo) in compliance with the FDCA—it does not apply to webpages and social media platforms generally.1 1 The draft guidance specifically does not apply to individual product websites, webpages on social media platforms (such as individual product pages on Facebook, Twitter, and YouTube), nor does it apply to online web banners (i.e., banner ads), as these platforms do not impose the same character space constraints as online microblog messaging and online paid searches. FDA offers the following recommendations for developing appropriate promotional content for prescription drugs and medical devices using limited space social media communications:

information associated with the targeted use or device advertisements must include both the population. proprietary (trade or brand) name and established name (for drugs, often referred to as the generic 4. Risk information should be presented within each name) within the character-space-limited character-space-limited communication, and at communication. The generic name of the product

a minimum, should reveal the most serious risks associated with the product, such as the black box warning (for drugs), contraindications, or key risk

1. Benefit information should be accurate and non-

(e.g., each individual message or tweet).

space-limited communication.

2. Benefit information should be accompanied by

misleading and reveal material facts within each

individual character-space-limited communication

risk information within each individual character-

3. Risk information should be presented within each character-space-limited communication, and at

a minimum, should reveal the most serious risks associated with the product, such as the black box

warning (for drugs), contraindications, or key risk

The FTC's Guidelines require clear and conspicuous disclosure of any relationship between the influencer and business which consumers could reasonably perceive as affecting the influencer's opinion. Such a "material connection" (i.e., a connection that might affect the weight or credibility that consumers give the endorsement)

may include payment for the endorsement,

influencer, compensation for the social media

free products or services given to the

influencer's travel or accommodations, discounts for the influencer on products or services, donations from the company to charity for positive review from the

influencer, etc.

including the following:

constitute a sufficient disclosure.

may vary" are not sufficient disclaimers.

Best practices would include the following provisions:

5. Requirements for compliance with FTC

6. Requirements for pre-approval by the company

Restrictions on content of the sponsored posts, such as not mentioning competitors, not using

disclosure requirements

offensive language etc.

review of sponsored content

reasonably be used to help address character space constraints. Click here for additional and to see the full document:

information associated with the targeted use or

within each individual character-space-limited

communication, taking into consideration any

formatting capabilities available on the specific

with other applicable legal requirements for

prescription drug and medical device advertising. For example, prescription drug and restricted-

should be listed directly to the right of, or directly

To help meet these requirements, FDA advises that common abbreviations (including scientific

and medical abbreviations), punctuations marks, and other symbols may, in many cases,

5. The prominence of risk information should

be comparable to the benefit information

Internet/social media platform.

below, the brand name.

6. The communication should also comply

population.

Get familiar with the latest FTC disclosure requirements



to follow and in terms easily understandable to Disclosures should tell the full story of the influencer's connection to the brand. Simply posting consumers. Disclosures should use the same kind #thanks[INSERT COMPANY] is not enough, as the of language for the endorsement and should appear close to the claims to which they relate. nature of the relationship between the influencer and the company may still be ambiguous to the public. Disclosures should appear prominently, i.e. Disclosures should be in an easily readable font. at the top of the post or caption. This means that disclosures should be in a color or Disclosures should not be hidden or buried shade that stands out against the background of in footnotes, in blocks of text that people are the post or content. not likely to read, or in the middle of a string For video ads, the disclosure should be on the screen of hashtags or in hyperlinks. On Instagram, long enough to be noticed, read, and understood disclosures should not appear after the and for audio disclosures, the disclosure should "More" link in the caption. be read at a cadence that is easy for consumers

In addition, while many social media networks have "in partnership features" or options that allow users to create "sponsored posts," this feature is not always sufficient to satisfy the FTC's disclosure

requirements above. The FDA has advised that simply starting a post or caption with #ad can

Another cornerstone of the FTC Guidelines is to require truth in advertising. Thus, under the guidelines, a social media influencer cannot endorse a product or service that he/she has no

experience with, that he or she did not like, nor make claims about a product that would require proof that is not available. The old stand-ins like "Results are not typical" and "individual results

For more specific information, see the FTC Guides:

grounds for termination of the contract, including

11. Specification of the length of the engagement

repeated violations of 1-6

Outlining the terms of the

your company's expectations for the social media influencer's engagement, identify potential

engagement up-front help establish

or campaign

While the Guidelines do not require the disclosure to be in any specific language, they do set forth a number of rules intended to help influencers ensure compliance,



Given the high stakes involved in the advertising and promotion of healthcare products, companies should clarify the terms of their engagement with social media influencers up-front and in writing.

1. Requirements for use of the sponsored products 8. Payment terms: consider making payment or services contingent upon certain milestones or activities achieved or performed by the influencer, instead 2. Requirements for content of the sponsored posts of providing for a lump-sum up-front payment Requirements for timing of the sponsored content 9. Penalties for non-compliance with 1-6: consider Requirements for compliance with applicable providing for withholding of pay or return FDA requirements for prescription drug and of payment medical device labeling and advertising, including 10. Conditions for termination of the engagement: prohibition of off-label promotion consider which actions by the influencer may be

points of disagreement or discussion, and highlight for your social media influencer the importance of compliance with government regulations.

Educate your influencer and

hold periodic trainings

department of your company is likely to be familiar with these requirements and can assist your marketing department to prepare these trainings. Social media influencer trainings should also provide guidance on how the influencer can address the following common topics: positive and negative health stories, financial information, requests for more information, adverse events and product complaints, response to suicide and suicidal posts, treatment questions and comments, alternative treatments, mentions of branded products, derogators, offensive language, or threats. Monitor the influencer's sponsored posts for compliance with disclosure requirements

character space limitations.

Ensuring that your social media influencer

and requirements that come with their job,

understand your products, as well the restrictions

including those unique to the healthcare space, is critical. Your company should consider holding periodic trainings to educate your social media influencer on the kind of health claims he/she can and cannot make and updated on both FDA and FTC disclosure requirements. The regulatory

Even if your company is pre-approving sponsored post content, it should still implement a system for regular monitoring to ensure compliance with FDA and FTC requirements, as well as your company's guidelines and brand ethos. In addition, content that may be compliant on one platform could become non-compliant if edited and shared on another, particularly if the forum has Having a monitoring and education system in place for your company's social media influencers can also help mitigate your liability should the influencer post non-compliance content. Remember, the company can be held responsible by FDA or FTC for the content of statements made by influencers engaged to promote its drug or medical device products. In August 2015, FDA issued a Warning Letter to Duchesnay, Inc. for a Social Media Post by Kim Kardashian that misbranded the prescription drug DICLEGIS, which is approved for treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. The post was found to be false or misleading because it presented efficacy claims for DICLEGIS, but failed to present any risk

> Select Your social media influencer with an eye toward long-time partnership and vet them thoroughly

Consumers tend to trust real people—celebrities, doctors, dieticians, fitness experts, and other

and take your time in selecting the right person who will be able to help grow your brand

in reaching the right demographic than the top A-list celebrity of the week.

patients—over companies. As trust and authenticity are key, investigate each candidate thoroughly

organically. Consider the market or demographic you are trying to reach. In the healthcare space in particular, a patient who has suffered or may suffer from the same ailment may be more useful

An example of such successful partnerships:

AmCal Pharmacy's partnership with supercar driver, Jack Perkins. Mr. Perkins teamed up with Amcal Pharmacy to educate his followers on diabetes by discussing his personal journey and how AmCal Pharmacy helps him manage

Regardless of whether subject to FDA regulation, disease-awareness ads must still comply with the FTC's disclosure requirements for social

sponsored posts for compliance

Select your social media influencer

with disclosure requirements

with an eye toward long-time

partnership and vet them

thoroughly

media influencers.

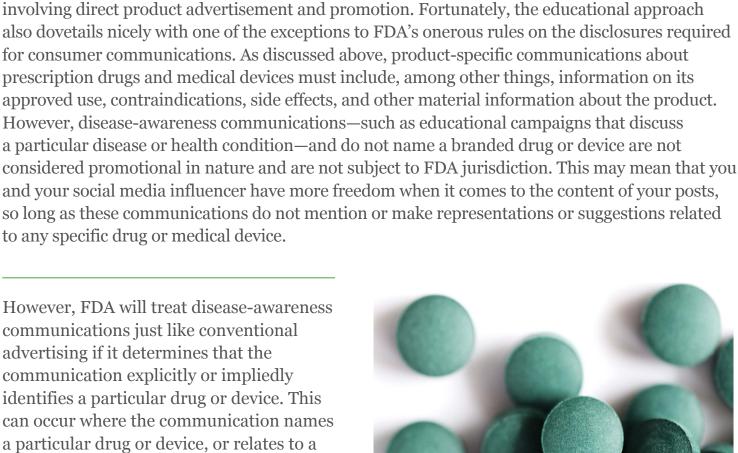
his disease.

information and omitted material facts about use of the drug.

Thus, the FTC ultimately closed its investigation against Microsoft.

In the same year, the FTC settled charges against an online entertainment network called Machinima, Inc. for allegedly engaging in deceptive advertising by paying influencers to post YouTube videos endorsing Microsoft's Xbox One system and

games. The influencers did not disclose that they were being paid for their opinions on the system. While the FTC decided that Microsoft was responsible for the influencers' failure to disclose their material connection to the company, the FTC considered the fact that these violations appeared to be isolated incidents that occurred in spite of, and not in the absence of, policies and procedures designed to prevent such lapses. Microsoft also quickly required Machinima to remedy the situation after they learned that Machinima was paying influencers without making the necessary disclosures.



diagnostic or therapeutic class of drugs that

Get familiar with the most

Get familiar with the latest

FTC disclosure requirements

for influencers and marketers

on social media use

3

Denver

Dusseldorf

Frankfurt

Hamburg

Hong Kong

Houston

Ho Chi Minh City

Hanoi

Dubai

Milan

Minneapolis

Monterrey

Moscow

Munich

Paris

Perth

**New York** 

Northern Virginia

recent draft guidance from FDA

includes only one product.

Consider educational campaigns

instead of direct promotion

for social media influencer content

Social media influencer campaigns that promote products through education and personal stories tend to receive higher levels of consumer engagement than social media influencer campaigns

Let's recap Educate your influencer Understand FDA's requirements for advertising and promotion and hold periodic trainings of prescription drugs and medical devices Monitor the influencer's 6



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Have a written contract with Consider educational campaigns instead of direct promotion for your social media influencer social media influencer content For more information on working with influencers, contact: Julia Matheson Partner, IPMT Senior Associate, IPMT Washington, D.C. julia.matheson@hoganlovells.com katherine.bastian@hoganlovells.com T: 1 202.637.6441

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