FDA Should Follow FTC For Influencer Health Post Rules

By **Reena Jain and Carly Kessler** (August 11, 2020)

Reena Jain

Carly Kessler

Social media influencers have become the latest source of health information. This is especially true right now, in the middle of the ongoing and rapidly evolving COVID-19 pandemic.

Influencers are being tapped to spread the word about public health campaigns, wellness goods and services, prescription drugs, and medical devices. Because these promotions and unsolicited advertisements are rampant, they deserve the close attention of not only consumers, but of our government.

Influencers have advertised a variety of health information, including flu shots at Walgreens, ovulation tracking devices and Otezla. But not all of the information they disseminate is accurate. And recently, certain celebrities, from Woody Harrelson to Chris Brown, have been spreading misinformation about COVID-19.[1]

Indeed, a Reuters Institute study, which examined 225 social media posts published between January and March and concerning COVID-19, revealed that 38% of the posts were completely fabricated, while about 59% of them consisted of reconfigured information — i.e., a twisting of the truth.[2]

That being said, influencers can also be the source of accurate information. On March 19, for example, the surgeon general called upon Kylie Jenner, Kevin Durant and others to help young people understand the severity of COVID-19.[3]

The influence that influencers have is a double-edged sword. Their ability to disseminate accurate messages should not be overlooked, but influencers must recognize that their messages can have serious impacts.

Influencer marketing is a growing and complicated business, which can have far-reaching effects on our everyday health and well-being. Today, more than ever, consumers must conduct their own due diligence on health-related social media posts and influencers must be careful about the information they share.

In this article, we explain how the U.S. Food and Drug Administration and the Federal Trade Commission regulate social media with respect to health care; present case studies demonstrating the drawbacks and sometimes dangers of influencer advertising; and propose additional measures that the FDA should implement to protect the public.

Current FDA and FTC Guidelines

The FDA and FTC have both considered the implications that social media influencers have on health care, and while their regulatory authority overlaps greatly, their roles also differ.

The FDA has primary responsibility with respect to the regulation of the truth and falsity of prescription drug and restricted device advertising, as well as responsibility for regulating the labeling of foods, drugs, devices, and cosmetics.

The FTC, on the other hand, has primary responsibility for regulating the truth or falsity of all advertising other than labeling of foods, drugs (with the exception of prescription drugs), devices and cosmetics. The FTC's responsibility includes regulating the truth or falsity of over-the-counter drugs (i.e., nonprescription drugs).[4]

When it comes to social media influencers, both the FDA and FTC have issued guidelines.[5]

The FDA's guidance, which has not been updated since June 2014, suggests that manufacturers, packers and distributors should consider the following provisions, among others, when using the internet or social media to promote prescription drugs or restricted devices:

- Any advertising that makes representations about the use of a firm's prescription drug must include certain risk information.

- Prescription drug advertisements must present a fair balance between information relating to risk and information relating to benefit.

- Risk information should be comparable in content and prominence to benefit claims within the product promotion (i.e., a balanced presentation).

The FDA takes the position that if a manufacturer, or an influencer on its behalf, cannot represent both the desired benefit claims and the risk profiles for their drug or device in a single post, then the manufacturer should not use that social media platform to advertise its product.

The character space limitations guidance, however, like the FDA's other communications, is only a draft guidance to describe the FDA's current thinking on this topic, which does "not establish legally enforceable rights or responsibilities," and "does not operate to bind [the] FDA or the public."[6]

The FTC's guidance is more comprehensive and direct, with the newest guidance published in November 2019. The Disclosures 101 guidance provides that an influencer's endorsement has to represent their actual experience and opinion. Influencers cannot post about their experience with a product or service if they have not tried it, and cannot claim it was effective or great when it was in fact not.

Specifically, influencers "can't make up claims about a product that would require proof the advertiser doesn't have — such as scientific proof that a product can treat a health condition."

Also, influencers must "make a good disclosure of [their] relationship to the brand," whether they received monetary payment or free or discounted products or services from the brand, or have a personal or employment relationship to the brand. Further, even if influencers are posting from abroad, U.S. law may apply if it is reasonably foreseeable that the post will affect U.S. consumers.[7]

Together, the FDA and FTC operate under a 1971 memorandum of understanding, which dictates the primary responsibilities of the agencies. The agencies have agreed to collaborate to afford maximum protection to the consumer, including in instances where the "same, or similar claims are found in both labeling and advertising" or where "material may be construed as either advertising or labeling or both."[8]

Depending on the product and the published content, internet and social media posts may be subject to both FDA and FTC oversight, making it crucial for the agencies to work together. And recently, they have been collaborating to protect consumers from products falsely characterized as being able to treat COVID-19.

Although the agencies often work together, they still have distinct roles, making it important for the FDA to update its guidance to match the FTC's guidance.

Case Studies

Diclegis

On July 20, 2015, Kim Kardashian posted on her social media accounts the following paid endorsement about Diclegis, a prescription drug used to treat morning sickness in pregnant women:

> OMG. Have you heard about this? As you guys know my #morningsickness has been pretty bad. I tried changing things about my lifestyle, like my diet, but nothing helped, so I talked to my doctor. He prescribed me #Diclegis, and I felt a lot better and most importantly, it's been studied and there was no increased risk to the baby. I'm so excited and happy with my results that I'm partnering with Duchesnay USA to raise awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more www.diclegis.com; www.DicelgisImportantSafetyInfo.com.[9]

The post presented various efficacy claims for Diclegis, but omitted all risk information and failed to indicate limitations of use (e.g., the drug has not been studied in women with hyperemesis gravidarum). Kardashian failed to provide material information regarding the drug, particularly about the consequences that may result from using it, ultimately misleading consumers about the drug's safety. But, Duchesnay Inc., the manufacturer of Diclegis, had preapproved the post.[10]

In response, the FDA issued a warning letter to Duchesnay, finding that the "social media post is false or misleading in that it presents efficacy claims for DICLEGIS, but fails to communicate any risk information associated with its use and it omits material facts." The letter noted that Kardashian's post violated the Federal Food, Drug, and Cosmetic Act and explained that such "violations are concerning from a public health perspective because they suggest that DICLEGIS is safer than has been demonstrated."

Kardashian subsequently deleted the post, which the FDA said was false and misleading, and posted a corrective advertisement with extensive information concerning the risks and limitations of using Diclegis. Kardashian also acknowledged that her previous post did not meet FDA requirements.[11] Kardashian, however, faced no penalties.

Despite the FDA's actions, Kardashian gave Duchesnay the attention it sought — broadcasting the brand to her millions of social media followers. Indeed, there was a

reported 500% increase in digital awareness of Diclegis within the weeks following the post and Duchesnay saw a 21% increase in sales by fall of that year.[12]

Jeuveau

Jeuveau, a prescription drug created to improve the look of wrinkles, has been on the market for over a year, and is already ranked third among neurotoxins. In 2019 alone, Jeuveau made over $34 million in sales.[13] How Jeuveau reached those numbers, though, may be troubling.

In May 2019, immediately before its release, Evolus Inc., Jeuveau's manufacturer, invited top plastic surgeons and cosmetic dermatologists to a weekend retreat at the Ritz-Carlton in Cancun. Billed as an advisory board meeting, the event was in reality an extravagant launch party.

Using Evolus' chosen hashtag, #NewTox, and without disclosing that the company had paid for their trips, these top medical professionals raved about the lavish event, all while promoting the product with social media moments, using an Evolus-themed runway and confetti. Branded items like flip-flops, beach towels and water bottles also saturated doctors' social media pages.

The FTC, however, mandates that influencers disclose whether they received monetary payment or free or discounted products or services. And, the FDA mandates that companies appropriately communicate risk information, which is done in part by balancing a drug's benefits with its risks in any advertising. Arguably, the doctors at the Evolus launch party did neither.

Evolus' CEO, David Moatazedi, said that the event was a standard advisory board meeting and the doctors were not paid or provided any incentives to promote Jeuveau. He claimed that Evolus should be viewed more as a performance beauty company as opposed to a traditional drug maker.

Some disagree, though, given that the product is an FDA-approved drug and comes with serious warnings (i.e., it can potentially cause swallowing and breathing problems in rare cases).[14] This begs the question whether the FDA and FTC should impose heightened burdens on companies like Evolus when it comes to social media posts and endorsements by health professional influencers.

Cyanora

In December 2019, three British social media influencers agreed to promote a fake weight loss drink called Cyanora despite being told that it included hydrogen cyanide — a poisonous chemical — as an ingredient. Cyanora, however, was a hoax.

The BBC, going undercover, filmed the influencers auditioning to promote the weight loss drink as part of an investigation into whether influencers actually use the products they are paid to promote. It turned out the answer was not always.

All three influencers agreed to promote Cyanora despite being informed that it contained hydrogen cyanide and without having tried it. Two of the influencers' agents later clarified that they "would never promote anything that contained poison and proper checks would have been made before any promotion" and they would "not promote a product without trying it first."[15]

Although the products would have been promoted from outside the U.S., the FTC instructs that U.S. law will apply if it is reasonably foreseeable that an advertisement will affect U.S. consumers. Further, the FTC requires influencers to have tried a product or service before posting about their experience with it.

As such, it is likely that these reality stars would have been warned by the FTC had Cyanora been an actual product. The FDA's guidance, however, is silent on whether the agency's power extends to social media posts made outside the U.S. And, unlike the FTC, the FDA does not require influencers to try a product before promoting it.

COVID-19

With the spread of the coronavirus has come the spread of false and misleading health information concerning the same. On March 9, the FDA and FTC announced that, in conjunction, they issued warning letters to seven companies selling unapproved products that violate federal law by making deceptive or scientifically unsupported claims about their ability to treat coronavirus.

The products cited in the warning letters included teas, essential oils, tinctures and colloidal silver, which the agencies found to be unapproved and misbranded products in violation of the FD&C Act and the claims exaggerated in violation of the FTC Act.[16]

The FDA specified that it "is particularly concerned that products that claim to cure, treat or prevent serious diseases like COVID-19 may cause consumers to delay or stop appropriate medical treatment, leading to serious and life-threatening harm" and that there "are currently no vaccines or drugs approved to treat or prevent COVID-19."

The FDA also announced that an "FDA cross-agency task force has been established and dedicated to closely monitor for fraudulent products related to COVID-19."[17] The FDA and FTC continue to issue warning letters to entities and individuals that are selling fraudulent COVID-19 products.

While the initial seven companies and others that have recently received the attention of the FDA and FTC may not be considered influencers (or celebrities), influencers should note that these agencies will not hesitate to take action when it comes to false and misleading information regarding the prevention and treatment of COVID-19.

Recommendations for the FDA

In light of the above, and taking into consideration an increasing number of paid partnerships between influencers and pharmaceutical companies, and the spread of COVID-19 misinformation, we offer a nonexhaustive list of recommendations for the FDA to consider in order to better regulate social media influencers when it comes to health care and particularly prescription drugs.

While the FDA announced a proposed study earlier this year to examine how consumers respond to endorsers and payment disclosures in relation to the promotion of pharmaceuticals in print and on social media,[18] more is needed. Among other things, we propose that the FDA look to its recent partner, the FTC.

First, the FDA should update its guidance with respect to social media because it is outdated. While the FTC released a new publication for online influencers in November

2019, the FDA's guidance on social media advertising is from June 2014 — six years ago. The FDA's guidance fails to mention Instagram and incorrectly states that tweets are limited to 140 characters — they are now limited to 280 characters.

The FTC, which published new guidance less than a year ago, recently announced that it is seeking public comment on whether to make changes to its guides concerning the use of endorsements and testimonials in advertising as part of the agency's systematic review of all its current rules and guides. Other than its plan to study influencer marketing, the FDA has not made similar updates or sought public comment with respect to its guidance.

Second, the FDA should follow the FTC's lead and require social media influencers and their partner pharmaceutical companies to disclose any financial relationships. Indeed, an FDA spokesperson explained that the agency "has not issued guidance regarding disclosure of the financial interests of spokespeople in prescription drug or medical device promotion, including disclosures by social media influencers acting on behalf of a medical product manufacturer," and instead directed attention to the FTC's guidance.[19]

Third, the FDA should, like the FTC, require social media influencers to have tried the prescription drugs before posting about their experience. Influencers should not be able to post about their experience with a prescription drug if they have not tried it, and should not be able to claim it was effective or great when it was in fact not.

And fourth, the FDA should provide drug companies with the option to submit their social media posts for approval before influencers post the content. Although the FDA generally does not have the authority to require preapproval for advertisements,[20] a voluntary review and approval system before publication, as opposed to a warning letter and possible litigation after publication, would be more efficient for the FDA and companies and would benefit consumers.

Social media influencers might be disrupting health care, but it is the FDA's responsibility — in addition to the responsibility of other regulatory agencies — to regulate social media posts and protect consumers, particularly when it comes to prescription drugs which can carry significant risks.

Reena Jain and Carly Kessler are associates at Robins Kaplan LLP.

[1] https://www.socialmediatoday.com/news/new-study-shows-celebrities-are-key-distributors-of-covid-19-misinformation/575753/; https://www.insider.com/coronavirus-influencers-celebrities-hoaxes-chris-brown-debunked-conspiracies-misinformation-fake-2020-3.

[2] https://www.socialmediatoday.com/news/new-study-shows-celebrities-are-key-distributors-of-covid-19-misinformation/575753/; see also https://reutersinstitute.politics.ox.ac.uk/types-sources-and-claims-covid-19-misinformation.

[3] https://www.businessinsider.com/coronavirus-surgeon-general-calls-on-kylie-jenner-influencers-millenials-teens-2020-3.

[4] https://www.fda.gov/drugs/prescription-drug-advertising/basics-drug-ads; see also https://www.fda.gov/about-fda/domestic-mous/mou-225-71-8003.

[5] The FDA published: "Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices." See https://www.fda.gov/media/88551/download. And, the FTC published: "Guides Concerning the Use of Endorsements and Testimonials in Advertising"; "The FTC's Endorsement Guides: What People Are Asking"; and "Disclosures 101 for Social Media Influencers."
See https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-publishes-final-guides-governing-endorsements-testimonials/091005revisedendorsementguides.pdf; https://www.ftc.gov/tips-advice/business-center/guidance/ftcs-endorsement-guides-what-people-are-asking; https://www.ftc.gov/system/files/documents/plain-language/1001a-influencer-guide-508_1.pdf.

[6] https://www.fda.gov/media/88551/download.

[7] https://www.ftc.gov/system/files/documents/plain-language/1001a-influencer-guide-508_1.pdf.

[8] https://www.fda.gov/about-fda/domestic-mous/mou-225-71-8003.

[9] https://www.fda.gov/media/93230/download.

[10] https://www.politico.com/story/2015/08/kim-kardashian-fda-duchesnay-121263; see also https://www.documentcloud.org/documents/4593918-Kim-Kardashian-Diclegis-Agreement.html.

[11] https://www.instagram.com/p/7B07j_uSww/?utm_source=ig_embed.

[12] https://www.thecut.com/2015/08/kim-kardashians-run-in-with-the-fda-explained.html; https://www.complex.com/pop-culture/2018/07/kim-kardashian-reportedly-got-500k-for-sponsored-instagram-pill-posts.

[13] https://www.fiercepharma.com/marketing/evolus-leads-beauty-not-pharma-direct-to-millennial-strategy-for-upstart-aesthetic; see also https://investors.evolus.com/news-releases/news-release-details/evolus-reports-fourth-quarter-and-full-year-2019-results-and.

[14] https://www.nytimes.com/2019/05/15/health/evolus-wrinkles-toxin-jeuveau.html.

[15] https://www.vice.com/en_us/article/akwz9e/influencers-unknowingly-promote-fake-drink-made-with-cyanide.

[16] https://www.fda.gov/news-events/press-announcements/coronavirus-update-fda-and-ftc-warn-seven-companies-selling-fraudulent-products-claim-treat-or; https://www.ftc.gov/news-events/press-releases/2020/03/ftc-fda-send-warning-letters-seven-companies-about-unsupported.

[17] https://www.fda.gov/news-events/press-announcements/coronavirus-update-fda-and-

ftc-warn-seven-companies-selling-fraudulent-products-claim-treat-or.

[18] https://www.regulations.gov/document?D=FDA-2019-N-5900-0001.

[19] https://www.vox.com/the-goods/2019/2/15/18211007/medical-sponcon-instagram-influencer-pharmaceutical.

[20] https://www.fda.gov/drugs/prescription-drug-advertising/prescription-drug-advertising-questions-and-answers#approve_advertisements.