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## All Eyes on Influencers: FDA and FTC Examination of Endorser Advertising Signals Global Focus on Social Media

Advisory

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In the competition for consumers' attention, savvy companies in the pharmaceutical and consumer products industries not only maintain a social media presence, but also evolve and adapt their promotional campaign strategies to marry marketing with the content their targets are already consuming. Hence the rise in social media campaigns involving partnerships with different types of endorsers, including celebrities, influencers (especially self-made Instagram or YouTube personalities), and increasingly "virtual," computer-generated, personas.

As reflected in recent policy developments and enforcement actions, regulatory agencies, both in the US and abroad, are attuned to companies' use of endorsers and marketing on social media platforms. They are also closely monitoring the evolving nature of endorser advertising and marketing. The first quarter of 2020 has included notable actions both domestically and globally that should be on the radar of any life sciences or consumer health company intending to include influencers in future marketing strategies.

First, both the US Food & Drug Administration (FDA) and Federal Trade Commission (FTC) have recently announced efforts to update the agencies' perspective on the impact of endorsers on consumers. In particular, FDA plans to conduct two studies evaluating different types of endorsers and payment disclosures, while the FTC is requesting comments on its "Guides Concerning the Use of Endorsements and Testimonials in Advertising" (the Endorsement Guides). Separately, activity in this area continues in Europe. For example, Germany continues to evolve its position on use of endorsers, with the introduction of a draft bill by the Federal Ministry for Economic Affairs and Energy intended to modernize the definition of "influencer" in a manner that better distinguishes such persons from private individuals (this against the backdrop of a more restrictive direct-to-consumer marketing regulatory framework than currently exists in the US). Interestingly, while attention on social media and endorser marketing activity appears to be increasing, FDA is itself "endorsing" the importance of the "patient story" in product development - most notably to meet the policy goals of patient-centered drug development espoused in the Cures Act and recent User Fee legislation.

Below we provide an overview of each proposal, prior relevant regulatory enforcement by each body, and important considerations for companies contemplating (or engaged in) advertising campaigns using endorsers, especially influencers.

### I. FDA's Focus on Endorsers and Social Media

#### A. Proposed Studies—Endorser Status and Payment Disclosures

FDA is empowered by statute (Federal Food, Drug, and Cosmetic Act (FD&C Act) (section 1003(d)(2)(C), 21 U.S.C. 393(d)(2)(C) and Public Health Service Act section 1701(a)(4), 42 U.S.C. 300u(a)(4)) to conduct research related to health information, drugs, and other FDA-regulated products. The agency's Office of Prescription Drug Products (OPDP) has a long history of conducting research on issues related to direct-to-consumer (DTC) advertising and drug promotion, which is intended to develop evidence that informs prescription drug promotion policies.<sup>1</sup> Last month, FDA announced OPDP's latest research endeavor, two planned studies on "**Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion**," that will examine how consumers respond to varying types of endorsers and payment disclosures in relation to the promotion of

a health product in print and social media. A driving force behind the proposal of these studies is FDA's awareness of the widespread use of endorsers in DTC drug advertising and prior social science research in this area, and a desire to improve FDA's understanding of how features utilized in advertising affect consumers' understanding of prescription drug risks and benefits.

The proposed studies will evaluate four types of endorsers (celebrity, physician, patient, and influencer) and whether a disclosure of the endorser's payment status influences the study subjects' reactions. The studies will also evaluate two types of disclosure language—"direct" (e.g., "paid ad") and "indirect" (e.g., "#sp" (short for sponsored)). Notably, proposed "Study B" reflects the agency's interest in the impact of Instagram influencers. As part of the protocol, FDA intends to recruit followers of an Instagram influencer with more than 500,000 followers who previously posted about endometriosis, and expose the participants to an Instagram post for a fictitious endometriosis product. By conducting these studies, FDA hopes to learn more about how endorsement and payment status affect the "participants' recall, benefit and risk perceptions, and behavioral intentions."

FDA is currently soliciting comments on the studies, including ways to enhance the quality, utility and clarity of the information to be collected, and how to reduce the burden of information collection on the respondents. Comments will be accepted until March 30, 2020.

## B. FDA Guidance for Industry & Enforcement

FDA's research focus expands upon the agency's existing policy on social media and endorsements, as reflected in guidance and enforcement. Currently, FDA's social media-focused guidance documents are geared towards ensuring that the information disseminated by drug and device manufacturers online is accurate and complete, and that any connection to a manufacturer is disclosed. For example, FDA's January 2014 [Draft Guidance for Industry – Fulfilling Regulatory Requirements for Post-Marketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics](#) describes how firms can comply with postmarketing OPDP submission requirements relating to interactive promotional media (e.g., social media, blogs, and message boards). In this guidance document, FDA clarifies that a firm is responsible for promotional messaging relating to its products—as opposed to user-generated content—when such messaging appears on websites that are "owned, controlled, created, influenced, or operated by, or on behalf of" the firm. Two additional draft guidance documents issued shortly thereafter further address pertinent issues relating to the use of social media: [Guidance for Industry – Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices](#) and [Guidance for Industry—Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices](#). For more information on these social media guidance documents, see our prior [Advisory here](#).

Based on trends in FDA's enforcement actions and research, we anticipate that future iterations of guidance documents may focus on the use of influencers in promoting FDA-regulated products, and FDA's position on effectively disclosing risk information.

Over the past decade, FDA has expanded its enforcement efforts to encompass advertising and promotion occurring on social media platforms. FDA routinely reviews and cites to company-generated social media content in warning letters, and has also focused on content generated by third-parties on the company's behalf.<sup>2</sup> In one particularly high-profile instance, FDA issued a **warning letter** to Duchesnay, Inc. relating to a social media post by Kim Kardashian promoting DICLEGIS, a drug intended to treat morning sickness. In this warning letter, FDA alleged that the post was false or misleading because it included efficacy claims, but did not include any risk information. FDA has also issued warning letters that include citations to companies' conduct on social media, specifically the act of "liking" customer posts on Facebook. For example, in 2014, FDA sent a **warning letter** to Zarbee's, Inc. regarding, in part, Zarbee's "liking" customer posts on its Facebook page. FDA alleged that "liking" the posts constituted endorsing or promoting the posts (which problematically recommended or described the use of the dietary supplement product in the cure, mitigation, treatment, or prevention of disease).<sup>3</sup>

It is reasonable to expect that FDA scrutiny of such campaigns will increase in coming years, as the agency learns from its studies. Companies should also be aware that the FTC and FDA operate under a memorandum of understanding, and thus will cooperate in scrutinizing influencers used to promote health products.<sup>4</sup> For example, in June 2019, the FDA and FTC sent joint warning letters to four e-liquid companies reminding them that social media influencers have to clearly and conspicuously disclose material connections to the brands they are promoting, and noting that brands should inform influencers of their disclosure responsibilities.<sup>5</sup> Notably, these warning letters alleged several other violations, including failure to include required nicotine warning statements in violation of the Federal Food, Drug, and Cosmetic Act and

failure to disclose health and safety risks. In light of these enforcement actions, any company that uses social media influencers to promote its product—but particularly those promoting FDA-regulated or other health-related products—should be careful to ensure that influencers are in compliance with all disclosure requirements.

## II. FTC's Focus on Endorsers—Request for Comments on FTC's Endorsement Guides

In light of the above, it is not surprising that shortly after FDA announced its intent to study influencers, the FTC **announced** its intent to request public comment on its "Guides Concerning the Use of Endorsements and Testimonials in Advertising" (the Endorsement Guides). While the FTC has **supplemented its Endorsement Guides** in recent years to provide guidance to businesses, the FTC last amended the Endorsement Guides in 2009, a different era in the world of social media. The Commission's recent request for public comment on the Endorsement Guides, which was formally published in the Federal Register on February 21, presents an important opportunity for companies to help modernize the FTC's approach to social media and offers insight into areas of particular interest to the Commission. Key questions being considered by the agency include the following:

- whether disclosures of material connections are necessary;
- whether consumers understand that persons promoting products on social media are likely being compensated;
- whether current disclosures of material connections are adequate, especially in relation to children's products;
- how advertisers use incentives to encourage non-influencer consumers to leave positive product reviews;
- whether review websites should be required to disclose how reviews are solicited and generated; and
- whether the Endorsement Guides should address how endorsers are using affiliate links—links through which consumers can purchase endorsed products.

Notably, a **statement by Commissioner Rohit Chopra** suggests that the agency may also codify certain provisions of the Endorsement Guides to allow the Commission to seek civil penalties for violations and consider mechanisms to hold platforms that benefit from influencer activity accountable for compliance as well. The FTC will accept comments until April 21, 2020.

## III. Influencer Marketing—An International Perspective

Ensuring compliance with regulations governing influencer marketing is not just a U.S. problem—companies in other jurisdictions are facing similar requirements and potential changes in regulatory perspectives.

For example, late last year, the German Federal Ministry for Economic Affairs and Energy introduced a **draft bill intended to amend the German Telemedia Act** to modernize the definition of "influencer" in a manner that better distinguishes such persons from private persons. Currently, in Germany, influencer promotions constitute "advertising" under the German Telemedia Act, as well as the German Interstate Broadcasting Treaty (which governs video, including online video streaming).<sup>6</sup> Under German law, when an influencer uses a social media post to promote a product on behalf of a manufacturer, the influencer must ensure that commercial nature of the post is clearly disclosed. The inclusion in an influencer's social media post of a link to a manufacturer's product alone may be sufficient for the post to be considered an advertisement—even if the influencer clearly states in the post that he paid for the product himself (i.e. he did not receive free product in exchange for promoting the product). In addition to regulatory enforcement action, failing to clearly and prominently disclose that a post is promotional can also bring an influencer's activity within the scope of the German Unfair Competition Act, which is aimed at the protection of competitors, consumers and other market participants against unfair commercial practices, specifically including advertisements. An influencer may always be held liable for violations of German requirements relating to influencer marketing. Additionally, a company using an influencer to promote its products may also be held liable as an accomplice or an indirect perpetrator.

The rules in the UK are similar to those in Germany. The Consumer Protection from Unfair Trading Regulations 2008 prohibit misleading actions or omissions when advertising or selling to consumers and provide for criminal offences in cases of breach. Guidance issued by the UK Advertising Standards Association (ASA) and by the UK Competition and Markets Authority have clarified how these provisions apply to advertising through social media including use of influencers. Advertisements must be clearly identified and consumers must be informed of the commercial relationship between an influencer and the brand he or she is promoting; posts must contain identifiers such as "#ad". As illustrated by a June 2019 ASA enforcement **regarding the promotion of a sleep aid by an "influencer,"** use of influencers to promote medicines raises particular problems in view of the prohibition of promotion of medicines to members of the public using

celebrities.<sup>7</sup> But what is a celebrity? The conclusion by ASA in this case was challenged by the company on the basis that the blogger had only a "small and niche following" (approximately 30,000 followers). The ASA disagreed, concluding that consumers would understand the blogger to have used and endorsed the medicine concerned and that 30,000 followers indicated that she had the attention of a "significant number" of people. The decision was generally viewed as harsh in circumstances where the decision to partner with the blogger had been approved in advance by the Proprietary Association of Great Britain (PAGB), the UK consumer healthcare trade association.

In China, it is also important to be aware of emerging legal requirements covering influencer marketing. For instance, an influencer shall not recommend or endorse goods he or she has not used. An influencer's posts shall be clearly marked with "advertisement" if they are published through mass media. Advertisers are not allowed to use in advertisements certain influencers such as children under the age of 10, or people for which a three-year period has not expired for administrative punishment imposed on them for providing recommendation and/or endorsement in false advertising. In addition, influencer endorsements are not permitted in any advertisement for medical treatment, pharmaceuticals, medical devices or health food. For false advertisements of goods not relating to life and health of consumers, an influencer shall be held jointly and severally liable with the advertiser where the influencer is aware or should be aware that the advertisement is false; however, for false advertisements of goods relating to life and health of consumers, the influencer shall always be held jointly and severally liable with the advertiser.

Notably, these developments are occurring against a backdrop of more restrictive marketplace regulations which generally prohibit the promotion of prescription medical products to consumers. On the heels of these developments, companies marketing consumer products (or any other products) internationally must be sure to monitor the influencer marketing requirements of the countries in which they sell products, and their potential liability if influencer marketing does not comply with those requirements.

#### IV. Implications

Regulator interest in endorser and influencer marketing has been growing, and we expect that these issues will remain of interest to regulators for the foreseeable future. Here is what to expect over the next couple of years—and how your company can prepare.

**Expect agency collaboration and monitor developments both domestically and globally.** The FDA and FTC work under a **longstanding memorandum of understanding** and have a history of collaboration. Thus, it should be expected that the agencies will share learnings from their respective information collection activities. In addition to monitoring the agencies' discussion of material connections, companies should monitor FDA's learnings related to consumer understanding of risk information as they may impact the FTC's perspective on effective presentation of disclaimers (e.g., by hyperlink of QR codes). Companies should also be aware of enhanced enforcement globally, including in the UK and Germany.

**Submit comments.** Companies should also take advantage of the opportunity to submit comments to the FTC that can inform the agencies on consumer understanding of material connections and consumer ability to effectively understand risk or other qualifying information available via hyperlink or other mediums. As character space continues to decrease, the importance of evolving the agencies' perspective on effective use of disclosures increases. In conjunction with FDA's studies, this information could potentially enhance **FTC's perspective and guidance on the .com disclosures**. The comment period may also be an opportunity for prescription drug manufacturers in rare or personalized disease spaces to provide their perspectives on the importance of rational and innovation-friendly regulation in this area. The importance of patient influencers, advocates and partners is only likely to increase in this area.

**Anticipate agency scrutiny.** Finally, companies should anticipate a potential shift in FDA and the FTC's enforcement priorities and in particular, a heightened focus on influencer marketing of health products or targeted at "vulnerable populations" (e.g., youth or seniors). It is advisable that companies engaged in either category of marketing reevaluate current and pending social media campaigns against the agencies' focus on ensuring effective communication of risk.

We will continue to monitor developments in this area. In the interim, please feel free to contact us with any questions about the topics discussed in this Advisory.

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<sup>1</sup> See, FDA OPDP Research.

<sup>2</sup> Note that while off-label promotion risks associated with social media and influencer marketing is on FDA's enforcement radar, this advisory does not focus on such enforcement or attendant risks.

<sup>3</sup> See also, FDA **Warning Letter** to AMARC Enterprises, Inc. for, among other issues, "liking" on Facebook a customer's post about the company's dietary supplement that contained drug claims.

<sup>4</sup> Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration.

<sup>5</sup> FDA/FTC **Warning Letter** to Solace Technologies, LLC d/b/a Solace Vapor (June 7, 2019); FDA/FTC **Warning Letter** to Hype City Vapors, LLC (June 7, 2019); FDA/FTC **Warning Letter** to Humble Juice Co. LLC (June 7, 2019); FDA/FTC **Warning Letter** to Artist Liquids Laboratories LLC d/b/a Artist Liquid Labs (June 7, 2019).

<sup>6</sup> Compliance with these regulations is monitored by the state media authorities in each of Germany's federal states. A joint committee of the 14 media authorities in Germany has put together a **guide** for labeling advertisement in social media.

<sup>7</sup> Regulation 289 Human Medicines Regulations 2012; The Advertising Standards Agency's Committees of Advertising Practice (CAP) Code; the Proprietary Association of Great Britain (PAGB) Codes.