Proposed Legislation May Crack Down On Online Drug Ads

By **Dominick DiSabatino and Arushi Pandya** (September 25, 2024)

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This month, Sens. Dick Durbin, D-Ill., and Mike Braun, R-Ind., proposed the bipartisan Protecting Patients from Deceptive Drugs Ads Online Act.[1]

The act comes in the wake of increased online and direct-to-consumer advertisements by social media influencers and telehealth providers, especially as semaglutide and GLP-1 drugs have become pervasive in recent years.

The act proposes a number of mechanisms for increased oversight, including providing a basis for the U.S. Food and Drug Administration to issue warning letters and fines not just to drug manufacturers but to social media influencers and healthcare providers directly, as well as financial reporting requirements for both drug manufacturers and, now, healthcare providers.

The act, if ultimately passed in its current form, would serve as a sea change in the way that the FDA regulates drug-related speech, and would have significant trickle-down effects on various corners of not only the drug industry but also consumers and providers themselves.

To be sure, questions remain on how to interpret the provisions and where the onus of the impact will lie, but for now, folks from drug manufacturing to telehealth technology platforms to healthcare providers should get up to speed on what could happen here.

The Current Social Media and Telehealth Advertising Climate

One of the FDA mandates is to enforce its regulations that govern advertising and promotion of drugs to ensure that the presentation about the drug is not false or misleading.

The FDA has historically been slow to act from an unofficial policy perspective, i.e., via nonbinding guidance, when it comes to social media, but the FDA has been active in enforcement, releasing multiple untitled and warning letters since October 2023 to companies and websites for sale of misbranded drugs.[2]

However, FDA guidance does not, at this time, comprehensively address the many social media platforms that have recently soared in popularity.

Indeed, the FDA's most significant guidance document pertaining to internet and social media advertising and promotion has not been updated since 2014.[3]

To be sure, the FDA did update its 2014 guidance about responding to misinformation on — among other platforms — social media earlier this year.[4] Neither guidance, though, fully tackles today's social media climate and the types of communications occurring on those platforms.

Furthermore, the FDA has not addressed the rising number of social media advertisements created by telehealth companies and even healthcare providers, which have generally been outside of the FDA's regulatory purview, unless they have a financial relationship with a drug's manufacturer.

Against this backdrop, it comes as no surprise that Durbin and Braun proposed the act, after having sent a letter to FDA Commissioner Robert Califf earlier this year, urging the FDA to take swift action against misleading advertising.[5]

The act, among other things, aims to address this gray area and provide increased oversight of advertising activity by influencers and telehealth companies. This represents a foundational shift in enforcement authority for the FDA.

Key Requirements of the Act

The most significant proposals of the act include the following.

Warning Letters and Fines

The act proposes to amend the scope of Title 21 of the U.S. Code, Section 333(g)(1), which addresses violations regarding direct-to-consumer advertising, and provide the FDA with the authority to issue warning letters to social media influencers and telehealth companies who make false or misleading communications regarding an approved drug.

"False or misleading communications," for purposes of the act, mean advertisements or promotional communications on a social media platform that provide a financial benefit to the individual making the communication.

The communication must (1) be made knowingly or recklessly and contain a false or inaccurate statement or material omission of fact regarding a drug or (2) omit information relating to side effects, contraindications and effectiveness as would otherwise be required in prescription drug advertisements.

The definition of "false or misleading communications" carves out statements that describe a person's own experience, opinion or value judgment.

A "social media influencer" is defined to mean a private individual who has perceived credibility or popularity and who expresses their opinions, beliefs, findings, recommendations or experience on social media platforms to an audience, including in a manner conveying trust or expertise on a topic, for the purpose to promoting or advertising certain information or products or inducing behavior by the audience.

The definition of "social media influencer" is broad enough to include celebrities, as well as healthcare providers.

Noncompliance with a warning letter can result in civil monetary penalties ranging from $250,000 to $500,000.

Influencer and Telehealth Payment Reporting Requirements

The act also proposes to amend transparency reporting requirements set forth in Title 42 of the U.S. Code, Section 1320a-7h, to create a new reporting obligation for pharmaceutical manufacturers and healthcare providers, including potentially both telehealth companies

and providers.

Manufacturers and healthcare providers would be required to disclose the following types of payments for the promotion of, or communications regarding, any drug, including a biologic, that is payable by Medicare or Medicaid to the open payments database: (1) payments made by the manufacturer to a healthcare provider, including a telehealth company, or social media influencers; and (2) payments by a healthcare provider, including a telehealth provider, to a social media influencer.[6]

Notably, the act addresses both, and differentiates between, telehealth companies and providers in its definition of reportable payments.

The open payments databases are publicly accessible, and the proposed reporting requirement would dramatically alter transparency reporting obligations for both pharmaceutical manufacturers and healthcare providers.

Applicability of Prescription Drug Advertisement Requirements to Telehealth Providers

The act proposes to expand the applicability of Title 21 of the U.S. Code, Section 352(n), which sets forth specific content requirements for prescription drug advertisements for the manufacturer, packer or distributor of a prescription drug.

The act would revise the definition of "manufacturer, packer, or distributor" to include a person who (1) issues, or causes to be issued, an advertisement or other descriptive printed matter with respect to certain compounded drugs, and (2) who directly or indirectly offers to bring together a potential patient and a prescriber or dispenser through use of electronic information and telecommunication technologies to engage in prescribing or dispensing of such drugs.

This proposal would encompass certain telehealth providers and subject them to prescription drug advertising requirements.

HHS Guidance

The act directs the secretary of the U.S. Department of Health and Human Services to issue guidance on how the new mechanisms for warning letters and penalties will be enforced, including the factors that will be considered when determining whether a communication is false or misleading.

Significance of the Act

The act has received bipartisan support as well as endorsements from a variety of professional medical organizations, including the American College of Physicians.

The American College of Physicians released its own statement supporting the act, noting that it would "tackle the explosion of misleading promotions by new entities."[7]

The support from professional organizations not only suggests support for the act to pass, but also indicates a recognition of the need for greater FDA regulation in this space from within the industry itself.

The scope of the act also raises constitutional questions.

Generally, inaccurate or misleading claims do not receive First Amendment protection, and such claims are already regulated by the FDA.

However, the act greatly expands the amount and types of speech under the FDA's purview, and could face First Amendment constitutional challenges and litigation after it is passed.

Although the act excludes certain communications regarding one's own experiences and opinions and only applies to communications that provide a financial benefit, as described above, such exceptions may also create loopholes.

For example, it remains to be seen whether the statements made by an influencer who has been paid to post about their experiences would be subject to the act.

If passed, the act would represent a significant crackdown on communications by influencers and telehealth companies that many believe is long overdue — especially on the telehealth side.

Telehealth companies — think of the big telehealth technology platforms you see everywhere — have risen to great prominence over the past decade or so, utilizing social media campaigns to extol the benefits of typically generic products — that certainly do not come without risk — for hair loss, sexual dysfunction, depression, anxiety and more.

But FDA and Federal Trade Commission regulations are written to apply in substance to manufacturers or their paid proxies, not so much to telehealth companies.

However, many questions pertaining to the scope of the act remain.

The act, as currently drafted, includes payments involving both telehealth companies and providers as reportable, but imposes the transparency reporting obligation on "health care providers" without clarification on whether both telehealth providers and companies must report, i.e., fall within the scope of the same definition.

Consequently, there could be arguments made both ways about whether telehealth companies have a reporting obligation.

Similarly, the act's regulation of false or misleading communication applies to "health care providers" without clarification on whether both telehealth providers and companies are encompassed. If telehealth companies are, in fact, not subject to the act, a significant amount of social media and online drug advertising would be carved out.

This uncertainty also raises the question of whether novel integrated entities that include telehealth and pharmacies and make drug product advertisements through social media would be subject to the act.

At its core, the act appears to be representative of a broader targeting of activity around weight-loss drugs in the healthcare space, including by insurers focusing on off-label usage of semaglutides and other GLP-1 drugs.[8]

The act's imposition of new obligations on healthcare providers would require significant procedures and protocols for reporting obligations and monitoring social media communications to be implemented.

If passed, manufacturers, social media influencers and healthcare providers engaging in telehealth alike should consider the implications of the act prior to engaging in advertising and promotional activity, as the act may signal an impending rise in enforcement activity by the FDA and other regulatory agencies.

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[1] See S. 5040.

[2] See FDA, "Warning Letter: Ozempen.com" (Jun. 24, 2024).

[3] See FDA, "Draft Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices" (Jun. 2014).

[4] See FDA, "Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers" (Jul. 8, 2024).

[5] See Sen. Durbin & Braun, "Letter to Commissioner Califf" (Feb. 14, 2024).

[6] Currently, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient must report such payment. 42 U.S.C. § 1320a-7h(a)(1)(A). The Act would classify these payments as a payment from an applicable manufacturer to a covered recipient for purposes of 42 U.S.C. § 1320a-7h. The terms "applicable manufacturer" and "covered recipient" have the meanings given in 42 U.S.C. § 1320a-7h.

[7] American College of Physicians, "Letter of Support for the Protecting Patients from Deceptive Drug Ads Online Act" (Aug. 28, 2024).

[8] See Bloomberg Law, "Ozempic's Off-Label Use Sends $1 Million Demand to Prescribers" (Sep. 12, 2024); Fierce Healthcare, "GLP-1 Drugs are still in Demand. Insurers are Cutting Back Coverage in Response, Found Study Shows" (Jul. 26, 2023).