Protecting Patients from Deceptive Drug Ads Online Act

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Background: The prevalence of online promotions and direct-to-consumer advertisements for prescription drugs has drastically increased in recent years, notably through influencers and telehealth companies on social media platforms such as TikTok and Instagram.

FDA oversees prescription drug advertisements by ensuring that promotions by manufacturers are accurate, risks and benefits are disclosed, and information on the FDA-approved label is shared. However, there is a gap in FDA's oversight when it comes to advertisements by influencers and telehealth companies. Too many of these promotions provide false information, omit key side effects, or fuel demand for medications that may not be appropriate for a patient.

Problem: Studies show that patients, especially young people, place a significant degree of trust in statements by influencers. But when an influencer is communicating for commercial gain and sharing deceptive or misleading information, this can place consumers at risk of severe and long-lasting side effects. Well-documented instances of deceptive or misleading promotion include communications by influencers recommending drugs like Ozempic for unapproved, off-label purposes, and touting the benefits of the drug to create the impression that others can achieve similar results. In other cases, telehealth companies utilize social media to reach consumers with advertisements that over-simplify complex symptoms and convince consumers they have the condition, then offering truncated diagnosis and treatment services on the company's website.

These promotions fail to disclose potentially harmful side effects and may over-emphasize benefits. Many are specifically designed to use the unique features of social media to exploit the vulnerabilities of patients. FDA can only enforce against deceptive or misleading promotions by influencers or telehealth companies if there is an established financial relationship with the drug's manufacturer. However, in many instances, influencers with no direct tie to the manufacturer are promoting the benefits of specific prescription drugs, which may occur to gain a following or to seek alternative payment arrangements. Other financial relationships also may exist in which it is unclear if the influencer is truly an independent third party.

Legislation: This bipartisan legislation would protect public health and close regulatory loopholes by having FDA issue warning letters, followed by fines for noncompliance, to influencers and telehealth companies for deceptive and misleading promotions. This would be defined as communications that accrue a financial benefit to the speaker and contain false/inaccurate statements, omit facts regarding a prescription drug, or fail to include traditional risk and side effect disclosures.

In addition, this bill also would require manufacturers to report payments to influencers to the Open Payments database—similar to the existing disclosure of payments to physicians and other health providers—to shine light on promotional activities, including through celebrities.

Finally, the legislation would enhance FDA's visibility of social media promotions by utilizing new analytical tools, enhancing public education, coordinating with the Federal Trade Commission, and establishing a process to notify drug manufacturers of violative content.

Endorsers: Generation Patient; American College of Physicians; American Academy of Neurology; American Academy of Family Physicians; American Academy of Child and Adolescent Psychiatrists; American College of Gastroenterology; American Psychological Association Services; Doctors for America; Public Citizen; Public Interest Research Group; Light Collective; Young People's Alliance; Connecting to Cure Crohn's and Colitis.