United States Senate

WASHINGTON, DC 20510

February 14, 2024

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Califf:

With the dramatic rise in social media use—especially among youth—there has been an alarming proliferation of dangerous and misleading content promoting prescription drugs. We write to urge the Food and Drug Administration (FDA) to take swift action to update its enforcement tools to reflect the current platforms and methods used to promote prescription drugs and biologics, and to prioritize the protection of children from harmful and inaccurate medical advice.

Studies show that patients are more likely to ask their provider for a particular medication and to receive a prescription if the patient has seen a direct-to-consumer (DTC) advertisement for the drug. This can inflate demand for medications that may not be clinically appropriate, or for which alternative interventions may be available. DTC ads making product claims for disease treatment are only permitted in the United States and New Zealand, and the appeal and potency of DTC ads demand adequate FDA oversight. Unfortunately, it appears there are gaping holes in FDA's oversight of DTC promotions that are being exploited on social media at the expense of children and patients.

First, FDA has not updated its draft guidance on prescription drug promotion for social media since 2014. The social media landscape has evolved dramatically with the skyrocketing amount of time that users—particularly children—spend scrolling on platforms, and the emergence of platforms such as Instagram, Snapchat, X, and TikTok. While we recognize FDA has conducted initial research in this space and supported a one-day workshop, the agency's decade-old guidance must be modernized. FDA's guidance needs to clarify that these platforms are subject to its jurisdiction and should reflect the way that advertisements on these platforms must comply with federal requirements—such as conspicuousness and duration of statements, and size/contrast of imagery, including accounting for character counts and other limitations.

Second, new entrants appear to be exploiting a perceived gap in FDA's jurisdiction. According to reporting from the *Wall Street Journal* (WSJ), telehealth companies have engaged in extensive social media promotion for prescription drugs—without adhering to traditional requirements on accuracy, side effect disclosures, and fair balance of risk information. During a four-week period in 2022, the WSJ found more than 1,800 social media ads promoting prescription drugs without warnings or risks, and 500 ads for product uses that FDA did not approve. The Washington Journal of Law, Technology, and Arts article "*TikTok Told Me I Have ADHD"* examined instances where social media advertisements "simplify complex…symptoms and lead consumers to believe they have the condition," then provide immediate access to a tele-

prescriber who the patient has no prior relationship with. Telehealth companies and other emerging provider entities believe they have identified a regulatory loophole, which can result in unscrupulous actors peddling inaccurate information to patients, creating potential harm.

Third, there has been an explosion of prescription drug promotion by social media influencers, including celebrities, content creators who fail to disclose a financial relationship with a drug's manufacturer, and those with no financial relationship. Often, influencers hold a degree of trust with followers, giving the impression of expertise on a given subject. Consumers can be inundated with promotions for medications from influencers with no expertise, and whether or not the influencer has ever used the medication. Such ads often overstate benefits and minimize harms. Warranting particular attention is the interaction between influencers and their followers via public comment sections—which can further evade appropriate safeguards.

Patients have publicly shared harrowing stories of regret and negative health outcomes from taking medications promoted by influencers, without understanding the possible risks or side effects. A *Bloomberg Law* report highlighted troubling examples of patients asking their doctor to prescribe Ozempic after seeing "good reviews" on TikTok, with representations of "women … losing weight, feeling great, and eating less without severe side effects." However, they quickly experienced vomiting, sickness, bleeding, and lingering pain—side effects that they believe were not adequately acknowledged in the social media promotions they saw.

The power of social media and the deluge of misleading promotions has meant too many young people are receiving medical advice from influencers instead of their health care professional. Only seven of FDA's publicly available warning and untitled letters issued since 2017 relate to social media content. FDA must exercise authority over this dangerous void to ensure truthful, balanced, and appropriate communications that protect public health. To better understand FDA's actions, we request responses to the below questions by March 27, 2024.

1. Will FDA commit to updating its 2014 prescription drug promotion guidance document to reflect the current public health threats and regulatory gaps that exist from the current nature of social media use by December 31, 2024?

2. Are telehealth companies or others who can prescribe medications—but who are not "manufacturers, distributors, or packers"—subject to FDA's regulatory requirements for prescription drug advertisements as enumerated in 21 CFR 202.1?
    a. If not, will FDA commit to issuing proposed regulations to capture this regulatory gap and emerging public health loophole by December 31, 2024?
    b. Does FDA require statutory authority, and if so, would FDA support legislation?

3. Why has FDA only taken public enforcement action in seven instances since 2017 regarding content on social media platforms that fails to comply with 21 CFR 202.1?
    a. How were each of these first cases identified by FDA?

4. FDA has authority to take enforcement action against a social media influencer who is paid by a pharmaceutical manufacturer for a promotion regarding a specific prescription

drug that is false or misleading. Please provide a list of all such enforcement actions that FDA has taken in the past five years.

a. Do you believe FDA needs to clarify its authority to address any ambiguities, or given the sheer lack of compliance on social media platforms?
b. If not, would FDA support legislation to clarify the agency's authority?

5. If a third-party social media influencer—with no financial relationship with a drug's manufacturer, distributor, or packer—promotes a prescription drug by name in a social media post in a false or misleading way, does FDA have enforcement authority?
    a. If so, please provide a list of all such enforcement actions that FDA has taken in such scenarios in the past five years.
    b. If not, would FDA support legislation to clarify the agency's authority?

6. How many staff at FDA's Office of Prescription Drug Promotion (OPDP) and Advertising and Promotional Labeling Branch (APLB) are dedicated to reviewing, monitoring, or conducting systematic and routine regulatory oversight of advertisements on social media, and how has this number changed over the past ten years?

7. Please provide an estimate of the number of staff and associated additional resources needed for OPDP and APLB to adequately oversee content on social media.

8. Please provide a summary of all relevant research findings gathered by FDA on evidence gaps, marketing strategies, trends, key perspectives, vulnerable populations, and other relevant aspects of social media prescription drug advertising landscape.

9. How does the FDA's Bad Ad program support OPDP and APLB in addressing social media content that fails to adhere to FDA's requirements regarding a given medication?
    a. How could the Bad Ad program be adjusted or updated to meet the challenge posed by social media? Please outline the funding, regulatory, or other tools that Congress can provide to assist.

10. Aside from the Bad Ad program, please detail all ways in which FDA is conducting regulatory oversight of advertisements on social media.

11. The Federal Trade Commission (FTC) has issued recent guidance on the use of influencers in social media—including requirements for clear and conspicuous disclosure of a material connection between the marketer and endorser of a product. Please characterize the extent of FDA's current engagement with the FTC regarding prescription drug advertisements on social media platforms.
    a. Please identify what additional actions, collaboration, or information from FTC would further assist FDA in this regard.

12. Do you support the idea of social media platforms being required to list all sponsored influencers for prescription drugs in an easily searchable database, or providing access to such information to FDA for regulatory monitoring?

The threats to children from misleading and unsubstantiated advertisements necessitate action. You have called health misinformation and disinformation a leading cause of death in the United States—and it is time the FDA addresses this challenge.

Sincerely,

Richard J. Durbin
United States Senator

Mike Braun
United States Senator