American College of Physicians
Leading Internal Medicine, Improving Lives

August 28, 2024

The Honorable Dick Durbin
United States Senate
Washington, DC 20510

The Honorable Mike Braun
United States Senate
Washington, DC 20510

Dear Senators Durbin and Braun:

On behalf of the American College of Physicians (ACP), I am writing to express our support for your bipartisan legislation, the Protecting Patients from Deceptive Drug Ads Online Act ("Act"). The Act would tackle the explosion of misleading promotions by new entities—social media influencers and telehealth companies—that generally are not subject to the Food and Drug Administration's (FDA's) existing prescription drug requirements of manufacturers to disclose the side effects, be accurate, or provide a fair balance of risk information. The legislation would enable the FDA to strengthen its guidelines to close the regulatory loophole.

ACP is the largest medical specialty organization and the second largest physician membership society in the United States. ACP members include 161,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic care of adults across the spectrum from health to complex illness.

Protecting Patients from Deceptive Drug Ads Online Act

As direct-to-consumer (DTC) advertising has increased, the Act seeks to protect public health and align FDA's regulatory and enforcement authority over prescription drug promotions by social media influencers and telehealth companies with existing rules for manufacturer-sponsored prescription drug ads. The legislation would close this loophole by requiring the FDA to issue warning letters and fines for noncompliance to influencers and telehealth companies for deceptive and misleading promotions 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. The legislation would make it harder for influencers and telehealth companies to promote prescription drug products to consumers without disclosing health and safety risks of consuming those drugs. In addition, the Act 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. Finally, the Act seeks to enhance FDA's visibility of social media promotions by authorizing staffing increases, utilizing new analytical tools, enhancing education and engagement with the public, coordinating with the Federal Trade Commission, and establishing a process to notify manufacturers of violative content.

The Act is consistent with ACP's policy on prescription drug DTC advertising. ACP believes that DTC advertising of prescription drugs is an inappropriate practice that undermines the patient-physician

relationship and often leaves patients confused and misinformed about medications. Since DTC advertising is increasing and in the absence of legislation or regulation to ban DTC advertising, the FDA should play a stronger role in ensuring that complete, valid, and clear information is provided to the public and in making determinations about whether the commercial information in a DTC ad actually will educate and enhance the health of the public. ACP calls on the federal government to expeditiously strengthen regulations governing DTC ads in the following ways:

- Congress should give the FDA authority to issue regulations that require review and approval of the content of any DTC advertisement prior to it being released publicly.
- Congress should provide additional resources for the FDA to carry out enhanced oversight and enforcement duties and to study the effectiveness of DTC advertising.
- Federal regulations should require manufacturers to run corrective ads after receiving both "untitled" and "warning" letters.
- The FDA should take steps toward regulating image selection in ads.
- The FDA should require that information about a drug's effectiveness, side effects, and contraindications, as well as references to where more comprehensive information can be obtained, be prominently displayed in ads and on labeling and be in a language that is clear and understandable to the general public.
- The FDA should require that ads provide key information to consumers on alternative treatments, such as lifestyle changes.
- DTC ads should be required to contain a statement directing patients to report all adverse reactions to a physician and the FDA at MedWatch and give the toll-free telephone number and Web address of MedWatch.
- The FDA should require that ads for those drugs approved on the condition of further studies publicly identify that safety concerns have been identified and are being investigated.

Conclusion

We strongly support this legislation which addresses online prescription drug promotions that target younger users and go unchecked by the FDA, influencing users to seek out the drugs being advertised without appropriate warnings of side effects or other threats to public health. If you have any questions, please contact George Lyons at glyons@acponline.org.

Sincerely,

Isaac O. Opole, MD, PHD, MACP

President