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United States Senate
Washington, DC 20510–1304

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
COMMITTEE ON APPROPRIATIONS
COMMITTEE ON THE JUDICIARY

May 27, 2025

Martin A. Makary, MD, MPH
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Makary:

In light of recent workforce reductions at the Food and Drug Administration's (FDA) Office of Prescription Drug Promotion (OPDP), and your recent public statements expressing an interest in "mak[ing] sure that the information being presented … in those ads … is a complete picture," I write to understand FDA's operational capacity to carry out its mission to regulate direct-to-consumer (DTC) advertisements for prescription drugs.

Drug manufacturers in the United States spend approximately $6 billion annually in direct-to-consumer (DTC) prescription drug advertisements, with approximately one-third of all commercial time across evening news programs consumed with these pharmaceutical promotions. It is a similar story when consumers stream their favorite show or scroll through social media. The United States is one of only two developed countries in the world that permit such pharmaceutical commercials.

Department of Health and Human Services (HHS) Secretary Kennedy previously has expressed concern that DTC drug advertising potentially misleads patients about the benefits and risks of the products, while steering patients to the most expensive medications. You also recently stated that these commercials depict customers "always dancing, always singing, at a certain point you don't even know what the drugs are for, but you feel like, 'I give up', I'll just take it." This may contribute to, as you've stated, how the United States has "the most over-medicated, sickest population."

Indeed, a recent study in the *Journal of the American Medical Association* found that more than two-thirds of drugs advertised on television were considered "low therapeutic value." This creates concern for taxpayers, as a review from the Government Accountability Office that I requested with Senator Grassley found that prescription drugs advertised on television accounted for 58 percent of Medicare's overall spending on prescription drugs between 2016-2018. In 2022, the two most-advertised drugs on television alone accounted for $1.7 billion in Medicare spending.

I have recently introduced bipartisan legislation to cure deceptive prescription drug advertising by requiring price disclosures in commercials, and closing loopholes exploited by telehealth companies and social media influencers to make false or misleading statements or omit critical safety and side effect information.

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As part of the FDA's mission to protect public health, the agency conducts regulatory oversight of DTC advertisements for pharmaceuticals. FDA enforces Section 502 of the *Federal Food, Drug, and Cosmetic Act*, as well as its implementing regulations at 21 CFR 202.1, to ensure prescription drug advertisements are not false or misleading, including by communicating side effects, contraindication, and effectiveness information to the public.

FDA's responsibility has grown to meet the explosion of DTC advertising on new mediums, including social media. In 2012, FDA received submissions from the pharmaceutical industry comprising 78,696 promotional drug communication materials—by 2024, the agency received 149,516 such materials. And in the last six months of 2024, FDA issued four important untitled letters to manufacturers to seek corrections to their false or misleading pharmaceutical advertisements.

According to recent press reports, four top leaders in the FDA's OPDP have departed, including under Reduction in Force notices, including the Office's Director and Deputy Director, as well as the Director and Deputy Division Director for the Division of Promotion Policy, Research, and Operations. Further, the entire Division of Promotion Policy, Research, and Operations also was reportedly laid off. These departures raise major questions about whether FDA has the personnel, expertise, and capacity to fulfill its mission to regulate prescription drug advertisements—especially in light of your and Secretary Kennedy's scrutiny of these pharmaceutical promotions.

Additionally, I am concerned that any gap in regulatory oversight would provide an opening for unscrupulous behavior by industry stakeholders eager to promote medications absent FDA scrutiny. Last month, Novo Nordisk announced a blockbuster partnership to sell Wegovy to patients through telehealth company Hims & Hers. However, there appear to be promotions on the telehealth company's website that may be considered advertisements for off-label uses of the drug and also may fail to adhere to FDA's requirements for providing a "fair balance" of risk information, given the limited safety disclosure that is buried in the text and only accessed via an external link. A telehealth company that has formally partnered with a drug manufacturer to sell the manufacturer's blockbuster medication—citing its trademark and other promotional statements—should be subject to the same misbranding standards as the manufacturer.

To further our legislative efforts to address potential harms from misleading prescription drug advertising, I request responses to the following questions by June 17, 2025:

1. Who is currently in charge of FDA's OPDP?

2. In a letter response to Senators Durbin and Braun last year, FDA stated that OPDP has approximately 70 full-time employees, the majority of whom are responsible for compliance and review activities of promotional drug communications. What is the current number of FDA OPDP employees, broken down by division and function?
    a. Since January 20, 2025, how many total FDA OPDP employees have lost their jobs due to Reductions in Force; the termination of probationary employees; or other avenues of separation? Please provide a breakdown by category.

3. How will the reduction in staff compared to 2024 levels affect OPDP's activities?
    a. Please describe all functions or activities that have been halted or curtailed as a result of the workforce reductions.
    b. In 2024, OPDP received 83 voluntary submissions for review of draft television advertisements from the pharmaceutical industry, and OPDP issued 82 comment letters in response to those submissions. How many such voluntary submissions has OPDP received thus far in 2025, and how many comment letters has OPDP issued in response thus far?
    c. Since the data has not been updated since December 2024, how many complaints for potentially false or misleading promotion has OPDP received in 2025, and how many such complaints has OPDP acknowledged in 2025?

4. Will FDA OPDP obligate its Fiscal Year 2025 funding, provided by Congress in the *Full-Year Continuing Appropriations and Extensions Act, 2025* (P.L. 119-4)?

Thank you for your attention to this matter, I look forward to working with you.

Sincerely,

Richard J. Durbin
United States Senator