United States Senate

WASHINGTON, DC 20510

March 31, 2026

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

Dear Commissioner Makary:

Thank you for your recent efforts to enhance the Food and Drug Administration's (FDA) enforcement activities against direct-to-consumer (DTC) pharmaceutical advertisements that fail to comply with statutory requirements to be truthful, not misleading, and balanced. Over the past six months, the FDA has issued hundreds of warning letters to manufacturers and telehealth platforms for false or misleading promotions in television commercials and social media. As authors of the *Protecting Patients from Deceptive Drug Ads Act* (S. 652), we applaud this renewed attention to protect public health.

However, as you have noted, the airwaves are flooded with misleading pharmaceutical promotions. For some firms, airing a deceptive advertisement achieves its commercial aim of reaching customers, and any subsequent FDA enforcement (typically resulting in the cessation of such false or misleading advertising) may be considered an acceptable cost of doing business. The unsubstantiated claim or dangerous omission nevertheless shapes patient behavior and expectations.

FDA can enhance its regulatory oversight and more effectively restrict false and misleading pharmaceutical advertisements by being proactive and sending a message to bad actors. Specifically, we write to urge the agency to use its existing authority under 21 U.S.C. 353c to require certain advertisements to undergo pre-submission to FDA before dissemination. Under the law, FDA has the tools to seek changes on the front end, before patients are inundated with harmful content, to ensure information on side effects, contraindication, and effectiveness is appropriately conveyed. The use of this authority would be particularly critical for a class of high-risk products and those with the greatest population health impact.

While almost every other country on earth prohibits DTC drug advertisements, American patients are bombarded with Super Bowl commercials and incessant social media advertisements about specific medications. In many instances, the advertised product is not even approved by FDA, or omits basic safety and side effect information, creating risk for patients. While the agency has yet to exercise its authority under 21 U.S.C. 353c, the current landscape and sheer volume of deceptive advertisements necessitate consideration of this gatekeeping tool.

Thank you for your attention to this matter, we look forward to working together.

Sincerely,

Richard J. Durbin
United States Senator

Roger Marshall, M.D.
United States Senator