United States Senate

WASHINGTON, DC 20510

February 7, 2025

Sarah Brenner, MD, MPH
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Acting Commissioner Brenner:

As part of the Food and Drug Administration's (FDA) mission to protect public health, the agency conducts regulatory oversight of direct-to-consumer (DTC) advertisements for pharmaceuticals. FDA enforces the law and regulations to ensure prescription drug advertisements are not false or misleading, including by communicating side effects, contraindication, and effectiveness information to the public. 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. We write to draw your attention to an upcoming advertisement that is slated to air during the Super Bowl on Sunday to more than 120 million Americans, which risks misleading patients by omitting any safety or side effect information when promoting a specific type of weight loss medication.

Under Section 502 of the Federal Food, Drug, and Cosmetic Act, as well as its implementing regulations at 21 CFR 202.1, FDA requires that prescription drug advertisements be truthful, not misleading, and balanced.

An upcoming Super Bowl advertisement, which has been publicly posted online, appears to showcase a company's ability to prescribe and dispense GLP-1 medications to patients, including with text and claims about weight loss drugs, and imagery of an injection pen with distinctive characteristics reflective of an existing brand-name medication.

However, nowhere in this promotion is there any side effect disclosure, risk, or safety information as would be typically required in a pharmaceutical advertisement. By comparison, the FDA-approved labels and advertisements for brand-name GLP-1 medications include significant risk disclosures to patients about side effects and contraindications, including warnings about potential gallbladder, pancreas, vomiting, diarrhea, and other implications. Further, for only three seconds during the minute-long commercial does the screen flash in small, barely legible font, that these products are not FDA-approved.

We recognize the important roles that pharmaceutical compounding and telehealth play in the health care delivery system, helping to ensure access to FDA-approved products and filling a need for more customized treatments. However, we believe there should be no disparity in pharmaceutical advertising requirements between regulated entities.

To the extent this falls within a regulatory loophole for the FDA's authorities, we plan to soon introduce bipartisan legislation to close this gap, so that patients are not deceived by

advertisements that glaringly omit critical safety and side effect information. But, we believe FDA may already have the authority to take enforcement action against marketing that may mislead patients about this company's products. Thank you for your attention to this matter.

Sincerely,

Richard J. Durbin
United States Senator

Roger Marshall, M.D.
United States Senator