

Wednesday, January 18, 2023

Dr. Patrizia Cavazzoni
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
10903 New Hampshire Avenue
Bldg. 51, Room 5186
Silver Spring, MD 20993-0002

Serena Viswanathan Bureau of Consumer Protection Division of Advertising Practices Federal Trade Commission 600 Pennsylvania Ave., NW Washington, DC 20580

Dear Dr. Cavazzoni and Ms. Viswanathan,

My organization, Consumer Action for a Strong Economy (CASE), serves as the voice of American consumers and advocates for reasonable consumer protections to create more opportunity and prosperity for all Americans.

I write today to express serious concern about the overwhelming evidence that Revance Therapeutics, Inc. is engaging in public advertising by deceiving consumers regarding the efficacy of their neuromodulator DAXXIFY. While <u>FDA testing found</u> roughly one-third (33 percent) of patients had no or mild facial lines after injection, the Revance Therapeutics <u>press release</u> puts this figure at 50 percent, which is a misstatement of the FDA's empirical findings.

This deceit is not only harming consumers by misleading them with regard to the quality and effectiveness of the product they are purchasing and having injected into their skin, but also undermining a free and fair market where companies are properly rewarded for the value that their unique creations impart to their customers. False and misleading advertising is further abuse of consumer trust which could harm other companies and providers in this particular medical specialty.

The FDA has a unique and lifesaving duty to regulate and approve drugs and therapeutics that will improve the public health of our country, but they also must take action to enforce that their approved labels are used correctly. Patients and physicians across the United States are injecting DAXXIFY without accurate information – that is a dangerous precedent to set.

Along with the FDA, the FTC must hold Revance Therapeutics accountable for false advertising. According to <u>federal law</u>, any advertising of a product must "be truthful, not misleading, and, when appropriate, backed by scientific evidence." Revance Therapeutics is failing to comply with the law at every turn.

Thank you for your prompt attention to this issue. My organization stands ready to assist you and your teams as you work to hold Revance Therapeutics responsible and protect American consumers from these fraudulent claims.

Regards,

Gerard Scimeca

Chairman

Consumer Action for a Strong Economy (CASE)