



October 19, 2022

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,

For over a century, the National Consumers League has fought for access to quality products, honest labeling, and safe, effective medicines for American consumers and workers. We are writing to bring your attention what believe is likely a misleading advertising claim made by a recent FDA-approved drug, DAXXIFY™.

In September 2022, the Food and Drug Administration (FDA) approved Revance Therapeutics, Inc.'s new neuromodulator DAXXIFY™ (DaxibotulinumtoxinA-lanm). This drug promises to reduce the appearance of facial wrinkles for about six months and brings needed competition to an industry with few consumer options. However, consumers need transparent and accurate information to best determine their anti-wrinkle drug of choice. This is where our concerns lie.

The FDA-approved label for DAXXIFY™ verifies that roughly one-third of patients experience no or mild facial lines for six months after injection. However, Revance Therapeutics, Inc.'s [press release](#) promoting the drug claims that about half of patients see positive effects through six months. Twenty percent is a pretty significant discrepancy, in our view, and one that we felt should be brought to your attention, because not only is Revance making claims that are noncompliant with the FDA's guidance, but we are concerned that they are, at the same time, creating unrealistic expectations for consumers.

We know that the FDA has the important responsibility of determining whether a medical product is safe and effective and to what degree. After the FDA approves or clears a medical product, the [FDA-required labeling](#) sets forth the conditions of use under which the product has been shown to meet the relevant standard for marketing. This guidance is not something to be taken lightly and should never be misstated or exaggerated.

The [Sakura study](#), promoted in Revance Therapeutics, Inc.'s press release, makes claims that are not accurate, in our view. The study claims that 50 percent of patients treated with DAXXIFY™ maintained results at the 6-month to almost nine-month mark. The release claims this product is the first and only long-acting neuromodulator that "has the ability to deliver year-long results with as few as two treatments per year." But

according to [the FDA-approved label](#), at the 6-month mark, only a third of patients still see results and virtually no one saw results at the 9-month mark. This discrepancy is a cause for concern as many consumers could make a decision based on hyperbolic and inaccurate information.

We urge the FDA and the FTC to look into this matter and enforce the law. We ask that if our concerns are warranted, your agencies hold Revance Therapeutics, Inc to accurate claims and insist that they correct anything deceptive in advertising claims. Consumers deserve clear, accurate and reliable information when it comes to making the best choices for their overall health. Thank you for your attention to our concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Sally Greenberg". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Sally Greenberg
Executive Director
National Consumers League