

Congress of the United States
Washington, DC 20515

January 6, 2020

Jeff Shuren, M.D.
Director, Center for Devices and Radiological Health
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Mrs. Mary Engle, J.D.
Associate Director, Division of Advertising Practices,
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Director Shuren and Associate Director Engle:

We write to express our concern regarding SmileDirectClub, LLC (“SmileDirectClub”), especially when we see more than 1,350 “Customer Complaints” on the Better Business Bureau’s website for the company, as well as press reports highlighting significant issues with the business model and product. SmileDirectClub’s “Customer Complaints” are coupled with questions and concerns about SmileDirectClub’s 510(k) registration with the Food & Drug Administration (FDA) and SmileDirectClub’s questionable advertising practices that would be subject to the Federal Trade Commission’s (FTC’s) jurisdiction.

Orthodontic aligners, like those sold directly to consumers by SmileDirectClub, are intended to move teeth as part of orthodontic treatment. As health care providers, we know that orthodontic treatment, if performed without the proper diagnosis and supervision by a dentist or orthodontist, could lead to potentially irreversible damage such as changed bites, gum damage, and tooth loss. For patients who experience some of these negative outcomes, they may require additional and costly treatment from dentists and orthodontists to try to correct the damage. We are also concerned by the notion that when medical products, like the ones SmileDirectClub sells, are sold and constantly advertised in normal commercial channels, the general public may assume they are completely safe, because, as we have heard, “If they weren’t safe, they wouldn’t be allowed.” This seems contradicted by the numerous “Customer Complaints” on the Better Business Bureau’s website that appear to be clinical in nature.

Given the foregoing concerns and those voiced by the American Association of Orthodontists, we write to express our strong support of the FDA and the FTC investigating the practices of SmileDirectClub to ensure that it is not misleading consumers or causing patient harm. We

¹ <https://www.bbb.org/us/tn/nashville/profile/cosmetic-dentistry/smiledirectclub-0573-37111672>

¹ See <https://finance.yahoo.com/news/american-association-orthodontists-discusses-patient-114500121.html>

would appreciate, to the extent possible, your commitment to undertake such reviews in a swift manner in order to protect the health and safety of both current and prospective SmileDirectClub customers.

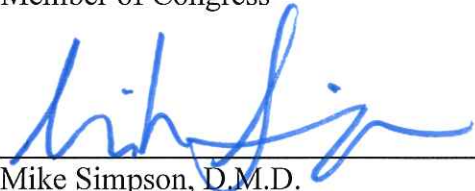
Sincerely,




Brian Babin, D.D.S.
Member of Congress



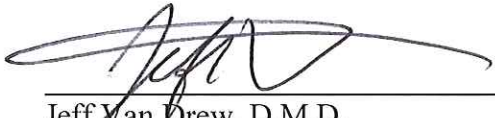
Paul A. Gosar, D.D.S.
Member of Congress



Mike Simpson, D.M.D.
Member of Congress



A. Drew Ferguson, IV, D.M.D.
Member of Congress



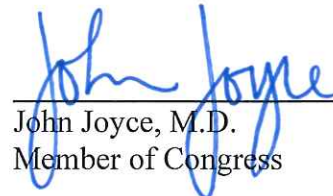
Jeff Van Drew, D.M.D.
Member of Congress



David P. Roe, M.D.
Member of Congress



Andy Harris, M.D.
Member of Congress



John Joyce, M.D.
Member of Congress



Earl L. "Buddy" Carter
Member of Congress