

American Dental Association

ADACommons

[ADA News Releases](#)

[ADA Archives](#)

2019

ADA Contacts Federal Agencies About Plastic Teeth Aligners

American Dental Association

Follow this and additional works at: <https://commons.ada.org/newsreleases>



Part of the [Business and Corporate Communications Commons](#), [Dentistry Commons](#), and the [History of Science, Technology, and Medicine Commons](#)

Recommended Citation

American Dental Association, "ADA Contacts Federal Agencies About Plastic Teeth Aligners" (2019). *ADA News Releases*. 112.

<https://commons.ada.org/newsreleases/112>

This News Article is brought to you for free and open access by the ADA Archives at ADACommons. It has been accepted for inclusion in ADA News Releases by an authorized administrator of ADACommons. For more information, please contact commons@ada.org.

News Releases

ADA Contacts Federal Agencies About Plastic Teeth Aligners

July 12, 2019

Contact Information:

mediarelations@ada.org

CHICAGO — The American Dental Association (ADA) sent a complaint letter to the Federal Trade Commission's (FTC) Bureau of Consumer Protection raising concerns over aspects of SmileDirect Club, L.L.C.'s (SDC) marketing and direct-to-consumer sales of plastic teeth aligners. The letter was sent approximately two months after the ADA filed a citizen's petition with the U.S. Food and Drug Administration (FDA) in April stating that SmileDirectClub is placing the public at risk by knowingly evading the FDA's "by prescription only" restriction the agency has placed on teeth aligning materials.

The ADA took these actions out of concern for consumer safety and customer recourse when negative outcomes from this direct to consumer dentistry product occur.

The FDA is responsible for protecting public health by ensuring the safety, efficacy, and security of medical devices, while the FTC Bureau of Consumer Protection is responsible for protecting consumers from unfair and deceptive business practices. Plastic teeth aligners are designated by the FDA as a Class II medical device requiring a prescription.

In lieu of having dentists perform patient exams meeting the applicable standard of care as the basis for prescribing orthodontic treatment, SmileDirectClub requires customers to self-report their dental condition. The ADA argues in its petition to the FDA that self-reporting does not meet the standard care of care because it does not satisfy a dentist's required professional due diligence. Lay people are not expected to be familiar with specialized technical or medical vocabularies. SmileDirectClub and the small number of "SDC-affiliated" dentists have no way of knowing whether what the lay consumer attests to is accurate, informed, or true in any respect.

"Moving teeth without knowing all aspects of a patient's oral condition has the potential to cause the patient harm," states ADA President Jeffrey M. Cole, D.D.S., M.B.A. "Orthodontic treatment, if not done correctly, could lead to potential bone loss, lost teeth, receding gums, bite problems, jaw pain, and other issues."

In addition, SmileDirectClub requires customers to hold the company harmless from any negative consequences, a point that was made in both of the communications the ADA sent to the FDA and the FTC.

In its letter to the FTC, the ADA cited the following practices of SmileDirectClub that it believes to be deceptive under section 5 of the Federal Trade Commission Act:

These include:

- Informing purchasers they have recourse against SmileDirect Club via arbitration when in the same document, SmileDirect Club hides a "small print" provision obligating the customer to waive any and all rights the customer "or any third party" may have against SmileDirect Club.
- Encouraging consumers to become customers by telling them individually and directly that SmileDirect Club aligners will correct their overbite, underbite and crossbite conditions or their "extreme" malocclusion. However, when customers complain, SDC invokes other SDC documents that state its aligners cannot

treat bite conditions at all and can only treat mild to moderate teeth misalignment, not “extreme” misalignment.

- Claiming that SDC customers receive the same level of dental/orthodontic care as actual dental patients when actually SDC and its affiliated dentists provide virtually no care and, contrary to its claims, SDC does not use teledentistry.

“The ADA considers it our duty on behalf of the public to make the relevant regulatory agencies aware of what is going on so they can consider whatever actions they deem appropriate,” Dr. Cole said.

The FDA’s [MedWatch voluntary reporting form](#) may be used by both consumers and health care professionals to report poor clinical outcomes associated with medical devices, which include plastic teeth aligners. The FTC also offers consumers an online form to report complaints about unfair and deceptive business practices on their [website](#).

For more information about direct to consumer dentistry, visit the ADA’s consumer website [MouthHealthy.org](#).

About the ADA

The not-for-profit ADA is the nation's largest dental association, representing 163,000 dentist members. The premier source of oral health information, the ADA has advocated for the public's health and promoted the art and science of dentistry since 1859. The ADA's state-of-the-art research facilities develop and test dental products and materials that have advanced the practice of dentistry and made the patient experience more positive. The ADA Seal of Acceptance long has been a valuable and respected guide to consumer dental care products. The monthly The Journal of the American Dental Association (JADA) is the ADA's flagship publication and the best-read scientific journal in dentistry. For more information about the ADA, visit [ADA.org](#). For more information on oral health, including prevention, care and treatment of dental disease, visit the ADA's consumer website [MouthHealthy.org](#)

Related Pages

[Registration open for ADA FDC Virtual Connect...](#)

[Association files complaint with FTC, FDA...](#)

[ADA sets record straight on status of petition...](#)

Copyright © 2020 American Dental Association. Reproduction or republication strictly prohibited without prior written permission.