



JUNTA DENTAL EXAMINADORA DE PUERTO RICO

30 de noviembre de 2018

A todos los dentistas de Puerto Rico:

Colegas:

El 30 de octubre de 2018 se envió la carta al Dr. Jeffrey Sultzer, DMD con aparente licencia en el estado de California. Dicta misiva relacionada a los anuncios en medio sociales por "Smile Shop" respaldado por *Smile Direct Club*. (Carta incluida en este comunicado). También se incluye la contestación a dicha carta por parte de "Smile Direct Club" identificados como "DyKema", así como la acción legal por parte de *American Association of Orthodontists (AAO)* en contra de *Smile Direct Club, LLC*. Además de estar referido y consultado el día 23 de octubre de 2018, con la *American Dental Association, (ADA)* los cuales, han emitido las expresiones que se incluyen en este comunicado.

Un dentista por tener licencia en otro estado no puede practicar la medicina dental, a menos que tenga licencia registrada en Puerto Rico, en cumplimiento con los requisitos estrictos establecidos en la Ley Dental Número 75 del 8 de agosto de 1925 y por parámetros de análisis de la Junta Dental Examinadora de Puerto Rico.

Se han establecido otras acciones referentes a las contestaciones recibidas. Según progresen, estaremos atentos a informarles. No podemos bajo ninguna circunstancia permitir que se violen los altos estándares de practica de nuestra profesión por, los cuales todos hemos luchado. Cualquier sugerencia adicional, será bienvenida.

Gracias por su atención.

Saludos a todos desde la Junta Dental Examinadora de Puerto Rico y todos sus miembros.

Miguel A. Alvarado López, DMD
Presidente Junta Dental Examinadora de Puerto Rico

eBulletin



November 29, 2018



The AAO's Federal Trade Commission (FTC) Petition Regarding SmileDirectClub

The American Association of Orthodontists (AAO) wishes to inform you of the AAO's efforts to protect the public from over-the-internet orthodontic devices. As you may recall, the AAO filed complaints with 36 state dental boards and authorities against SmileDirectClub (SDC), alleging specific regulatory and statutory violations. The AAO also filed with the United States Federal Trade Commission (FTC) a twenty-plus page "Petition to Initiate Enforcement Action Against SmileDirectClub, LLC In Connection with Unfair and Deceptive Practices" in late 2017. There are laws in place to protect the consuming public and as outlined in the FTC Petition, the AAO believes that some of SmileDirectClub's representations and marketing practices during the relevant period did not adhere to those laws. The AAO's FTC Petition is still pending.



GOVERNMENT OF PUERTO RICO

Department of Health
Office of Regulation and Certification of Healthcare Professionals
Dental Board of Examiners of Puerto Rico

October 30, 2018

Dr. Jeffrey Sulitzer, DMD
Lead Dentist at SmileDirectClub
25 Avenida Luis Munoz Rivera
San Juan PR 00901

Dr. Sulitzer,

This is in reference to an advertisement posted on social media by Smile Shop sponsored by SmileDirectClub. The offering includes a free 3D scan starting on October 31st 2018 at Paseo Caribe 25, Ave. Muñoz Rivera.

The advertisement published by the SmileDirectClub offers individuals who receive *"...treatment by using SmileDirectClub's aligners...[are] ...the same level of care from a treating dentist or orthodontist as an individual visiting a traditional orthodontist or dentist for treatment."*

It is further advertised that every customer is assigned a *"state-licensed dentist or orthodontist to oversee their case"* and that the *"doctors affiliated with SmileDirectClub are state-licensed orthodontists, or general dentists with orthodontic experience..."*

The practice of dentistry in Puerto Rico is specifically regulated by Law 75, August 8th 1925, as amended and the Rules and Regulations Number 6591 as approved by the Department of State on March 7, 2003.

The Law requires that all general dentists, dental surgeons, orthodontists, dental higienists, and dental assistants be certified and registered by the Dental Board of Examiners of Puerto Rico. It is illegal to provide diagnosis and/or dental treatment of any kind within the jurisdiction of Puerto Rico, without first obtaining a license



GOVERNMENT OF PUERTO RICO

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Dental Board of Examiners of Puerto Rico

and be registered with the Dental Board of Examiners of Puerto Rico. Each professional is assigned a licence number and in order to provide dental services must also be registered and be in good standing.

The Dental Board of Examiners of Puerto Rico is responsible for the certification of dental health professionals who provide any kind of service to our citizens.

Our inquiry at this time is regarding what kind of dental evaluation, activity and/or services the Smile Shop, SmileDirectClub or any of its subsidiaries or affiliates would be providing. We also inquire on the names and licence numbers of the dental health professions who would be participating in providing these services to the public.

Since this is an urgent matter related to the health of the citizens of Puerto Rico and since your advertise that you will offer services beginning on October 31st 2018, please provide the information requested on the names and licence numbers of the dental professionals who will provide services in Puerto Rico within the next 24 hours of receipt of this communication. This will of course, guarantee that you are providing dental services within the scope of the law and regulations, avoiding any legal procedures which might be initiated for non compliance.

The Dental Board of Examiner's responsibility is to evaluate whether or not the dental professionals are licenced in Puerto Rico to provide the services offered by Smile Shop sponsored by SmileDirectClub.

Cordially,

Miguel Alvarado-López

President

Dental Board of Examiners of Puerto Rico

Norma Torres-Delgado

Executive Director ORCHP



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November 8, 2018

**Via Certified Mail, Return Receipt
Requested**

Miguel Alvarado-Lopez
President
Department of Health
Dental Board of Examiners of Puerto Rico
PO Box 10200
Santurce, PR 00908

Re: SmileDirectClub, LLC

Dear Mr. Alvarado-Lopez:

Please be advised that I and my law firm represent SmileDirectClub, LLC ("SDC"). I am in receipt of your letter to SDC dated October 30, 2018, in which you inquired as to "what kind of dental evaluation, activity and/or services the SmileShop, SmileDirectClub or any of its subsidiaries or affiliates would be providing."

I write to inform you that SDC does not practice dentistry in any way at the SmileShop or anywhere else. SDC does not contract with any dentists to provide dental services on behalf of SDC. Instead, it is the licensed dentists and orthodontists who have requested SDC to enter into a services agreement, pursuant to which SDC provides comprehensive non-clinical, administrative dental support organization ("DSO") services, such as assistance with logistics and supply services, to these dental professionals. As part of those non-clinical administrative support services, SDC owns and operates the SmileShops. The SmileShop is not a dental office. Rather, the trained staff at the SmileShop merely use an iTero scanner to take digital photographs of the customer's teeth and gum line for the benefit of the dental professionals that have engaged SDC to provide this service.

As you noted in your letter dated October 30, 2018, the law in Puerto Rico makes it illegal to provide diagnosis or dental treatment of any kind within the jurisdiction of Puerto Rico without first obtaining a license and becoming registered with the Dental Board of Examiners in Puerto Rico.

California | Illinois | Michigan | Minnesota | Texas | Washington, D.C.

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DyKEMA

Miguel Alvarado-Lopez
November 8, 2018
Page 2

In compliance with the laws of Puerto Rico, the SDC staff working in the SmileShop in Puerto Rico (and elsewhere) are most assuredly not performing any dental services. They simply take digital photographs of the customer's mouth using the iTero, which are used to create a 3D image of the customer's mouth. This image, as well as additional photos, are sent to a dentist or orthodontist who is licensed in Puerto Rico, to evaluate and determine whether clear aligner therapy is appropriate for that particular individual. The evaluation, diagnosis, and all subsequent treatment are always done by a dentist or orthodontist who is licensed and registered in Puerto Rico, and who is solely responsible for exercising his or her own independent professional judgment in all clinical matters. No evaluation, diagnosis, or treatment occurs at the SmileShop or by SDC. Rather, the licensed dentist and/or orthodontist who evaluates the images does so at his or her separate office.

Given that the mere taking of photographs of a person's mouth is not prohibited by Puerto Rico's definition of the practice of dentistry, the SmileShop staff are not practicing dentistry.

As a result, the activities at the SmileShop do not fall within the jurisdiction of the Dental Board of Examiners of Puerto Rico. Please do not hesitate to contact me should you wish to discuss this issue further. Thank you.

Sincerely,

DYKEMA GOSSETT PLLC



Zachary Q. Hoard

California | Illinois | Michigan | Minnesota | Texas | Washington, D.C.

ADA clarifies social media post by SmileDirectClub

November 13, 2018

By David Burger

The ADA will continue to monitor social media while moving ahead with efforts to educate professionals and the public about direct-to-consumer dentistry after a social media post by clear aligner company SmileDirectClub incorrectly stated that its product was approved by the ADA, according to the Association.

The statement, attributed to SmileDirectClub, was made on an Instagram post the week of Nov. 5.

After the ADA called SmileDirectClub's attention to this fact, the Association received a response that the statement on Instagram was unauthorized and made without its knowledge and was removed.

In addition, the ADA was assured by SmileDirectClub that steps will be taken to prevent the recurrence of this type of mistake, the ADA said.

For information on the ADA's direct-to-consumer laboratory services policy statement, visit [ADA.org/en/press-room/news-releases/2018-archives/october/ada-adopts-further-policy-discouraging-direct-to-consumer-dental-services](https://ada.org/en/press-room/news-releases/2018-archives/october/ada-adopts-further-policy-discouraging-direct-to-consumer-dental-services).

Patients and dentists can report issues with medical devices to the U.S. Food and Drug Administration, including any problems they have had with devices related to direct-to-consumer dental laboratory products.

The FDA's MedWatch voluntary reporting form, at <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>, can be used to inform the FDA about problems patients encounter with direct-to-consumer products, such as aligners, partial dentures and snoring appliances. More general information about the FDA medical device reporting program can be found on [the FDA's website, fda.gov](https://www.fda.gov).

ADA Adopts Further Policy Discouraging Direct-to-Consumer Dental Services

Nation's Dentists Concerned about Potential Damage, Irreversible Complications to Patients

October 24, 2018

News Releases

CHICAGO — A new policy from the American Dental Association (ADA) “strongly discourages the practice of direct to the consumer (DTC) dental laboratory services because of the potential for irreversible harm to patients.” The new policy expands upon a 2017 ADA policy entitled “Do-It-Yourself Teeth Straightening” to include the sale of partial dentures, teeth whitening trays, snoring appliances, veneers and mouth guards, in addition to DTC orthodontic services.

The traditional role of a dental laboratory is to manufacture prosthetics and devices at the direction of the dentist. The dentist writes a prescription to the laboratory customized to the specific clinical needs of the patient citing the materials to be used and any special design features requested.

Recently, however, some laboratories have offered to sell such products directly to consumers. Bypassing the involvement and oversight of the dentist eliminates the dentist's essential role in diagnosing oral health conditions, creating treatment plans to meet those needs, and safely managing treatment needs through the course of dental care. Self-delivered, unsupervised dental treatment, in the view of the ADA, creates the risk of damage and irreversible harm to patients.