

FLORIDA DENTAL ASSOCIATION
COUNCIL ON DENTAL BENEFITS AND CARE

AGENDA

DATE: Monday, March 4, 2019
NOTICED START TIME: 6:00 p.m. EST
PROJECTED END TIME: 7:00 p.m. EST
LOCATION: Conference Call

CONFERENCE CALL DIRECTIONS
CALL 1-951-797-1058
ENTER CONFERENCE CODE: 982799
ANNOUNCE YOUR ENTRY ONTO THE CALL

COUNCIL MEMBERS (11): Dr. Craig Kara, CFDDA- Chair

Dr. Luran Andreolas, NEDDA	Dr. Eddie Martin, BOT Liaison
Dr. Steve Bryan, NWDDA	Dr. Chris Bulnes, Consultant
Dr. Melissa Seden, SFDDA	Justin Norell, UF ASDA Consultant
Dr. Wendy Churchill, WCDDA	Ly Ngo, LECOM ASDA Consultant
Dr. Tiffany Spallone, ACDDA	Vipin Palikuri, Nova ASDA Consultant

STAFF (1):
Casey Stoutamire, Director of Third Party Payer and Professional Affairs

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| 1. Call to Order | Dr. Craig Kara |
| 2. Recognition of Guests, if any | Dr. Kara |
| 3. Opening Remarks | Dr. Kara |
| 4. Meeting Participant Policy Reminders | Dr. Kara |
| A. Conflict of Interest Statement | Exhibit CDBC-4A, Page 2 |
| B. Legal Compliance Statement | Exhibit CDBC-4B, Page 3 |
| 5. Adoption of Agenda | Dr. Kara |
| 6. DIY Dentistry Introduction | Dr. Kara
Dr. Andy Brown
Ms. Stoutamire
Exhibit CDBC-6, Page 7 |
| 9. Announcements | Dr. Kara |
| 10. Next CDBC Meeting | Dr. Kara |
| TBD | |
| 11. Adjournment | Dr. Kara |

CONFLICTS OF INTEREST DISCLOSURE POLICY

For reference purposes at this meeting, all participants are advised of the FDA's policy governing the disclosure of conflicts of interest. This policy is codified as Resolution 92H-022, as adopted by the House of Delegates on January 9, 1993, and reads as follows:

Resolved, that individuals serving as delegates, alternate delegates, officers, trustees, alternate trustees, council or committee members shall, at all times, exercise diligent care and unbiased judgment in assuring that no detriment to the FDA results from conflicts between their personal or business interests and those interests of the FDA. And, be it further

Resolved, that agendas at all official meetings of FDA agencies contain a declaration of conflicts of interest at which time the presiding chairperson will ask all members of that body to express the conflict. And, be it further

Resolved, that if an individual believes that he or she or a member of his or her immediate family may have a conflict of interest, whether personal or business in nature, which pertains to an ownership, contractual, financial or fiduciary interest, then the individual shall promptly and fully disclose the possible conflict to the president of the association and/or chairperson of the body for which the individual serves. And, be it further

Resolved, that failure to disclose a material conflict of interest may be the basis for reconsideration of the question on a given issue according to parliamentary procedure at any further time.

LEGAL COMPLIANCE STATEMENT

BACKGROUND: For reference purposes at this meeting, all participants are advised of the following regarding legal compliance:

Association representatives who act in good faith in compliance with the standards below will be indemnified by the association for actions occurring under the course and scope of their official representation. Defamation, intentional interference with an advantageous business relationship and antitrust violations are the areas the FDA has identified for which strict compliance is necessary.

Defamation occurs when one person makes untrue statements of fact to another person about a third party. Potential examples include disparaging comments about a dentist's ability to practice his or her chosen profession; untruths about claims reimbursement policies regarding an insurer or managed care payer; untrue allegations regarding ability to pay claims, etc.

Intentional interference occurs when one person tries to influence the conduct of another person who is under contract with a third party. Potential examples include influencing dentists to not sign up, or to cancel participating provider agreements with, a payer; encouraging a dentist to break his or her contract with one practice to come to work for another practice, etc.

Antitrust law prohibits the FDA from facilitating agreements between competing dentists that unreasonably restrain trade. Thus, attendees at FDA meetings may not discuss prices they charge for dental services; price-related terms (e.g., their hours of operation, credit policies, salaries paid to ancillary staff, etc.); or the boycott of dental benefit plans (e.g., because of reimbursement policies), suppliers, or other dentists (e.g., by refusing to refer patients to them).

Certain collective conduct by competitors is "per se" or automatically illegal regardless of the group's economic power in the marketplace (i.e., whether the group has the ability to reduce output of dental services or increase the cost of those services). Per se violations are likely to result in criminal sanctions (prison terms and fines) as well as civil damages (triple the amount of the actual loss suffered by a plaintiff plus reimbursement of the plaintiff's court costs and attorneys' fees). Such sanctions and awards can apply to both the dental society as well as its representatives if the alleged conduct is found to have restrained trade. Very importantly, dental society insurance coverage may not apply to indemnify against criminal prosecutions. For these reasons, it is important for all association employees and representatives to follow these standards and avoid any conduct that gives even the appearance of impropriety.

Representatives of organized dentistry should pay close attention to the following areas because they carry high risk of per se violations:

I. *Price-fixing:* Agreements facilitated by dental societies under which competing dentists agree to deal in concert with one another towards third party payers or purchasers of dental services on price or price-related terms are per se illegal. Dental societies and their designated representatives must therefore avoid any action that may constitute price-fixing or a conspiracy among competing

dentists to engage in price-fixing. The term “price” in this context should be broadly construed to include:

- Pricing methodologies, fee schedules or the actual fees to be charged by doctors for dental services, including their criteria for fee waivers.
- Acceptable levels of co-payments, fee withholds, UCR discounts, reimbursement methodology or claims administration procedures should doctors accept assignment of benefits or claim reimbursement from third party payers.
- Terms of credit to be offered to patients by doctors.
- Prices to be paid by doctors for “inputs” necessary to provide dental services such as dental equipment, supplies and office space or ancillary services from hygienists and assistants.

II. Group boycott and market allocation: Agreements facilitated by dental societies under which competing dentists threaten, or actually engage in, collective non-participation or create “barriers to entry” into the marketplace by another actual or potential competitor are per se illegal. In this context, “actual competitor” means another dentist currently in the same geographic and specialty (if applicable) area of practice; “potential competitor” means someone with the present ability to enter the marketplace within one year; “collective non-participation” or “barriers to entry” include agreements that dental society members:

- Will not refer otherwise appropriate patients to targeted actual or potential competitors unless, for example, the targeted competitor limits its hours or the scope of services it provides.
- Will not accept referrals of otherwise appropriate patients from targeted competitors unless, for example, the targeted competitor limits the patients to whom it markets its services, agrees to a policy on fee waivers, or agrees that it will not do business with a managed care payer.
- Will otherwise try to coerce or intimidate competitors from locating their practices where they want or otherwise engaging in lawful conduct.
- Will prohibit or attempt to influence members’ individual decisions about whether to accept or decline offers of participating provider agreements or the scope of the agreements (e.g., what services will be provided, for which patients, how much will be charged for services, etc.). Dental societies must avoid appointing a representative to negotiate participation levels with payers (e.g., whether and under what conditions the dentist-members will participate with [or withhold participation from] payers or patients in general).
- Will refuse to deal with payers based on non-price terms. For example, local societies must not facilitate agreements among members that x-rays or study models needed for claims processing will be withheld from the payer.
- Will all participate with (or withhold participation from) payers regardless of how meritorious (or unmeritorious) the reasons. While this violation is subtle, the essence of it is that the individual judgment (business or otherwise) of members is subverted to the collective will of the dental society.

As representatives of organized dentistry, volunteer-leaders and staff should **DO** the following:

- Self-police against restraint of trade and avoid any conduct that would organize or further a conspiracy to engage in price-fixing, group boycott or market allocation as described above.
- If one becomes aware of prohibited conduct, take all reasonable steps to avoid the perception that the association has encouraged or supported the activity.
- Contact the FDA Department of Legal Affairs before taking any action that violates the standards set forth herein rather than engaging in the conduct until told to refrain.
- Distribute these rules to all representatives of organized dentistry (employees, leadership and “contact dentists”) and encourage them to contact FDA legal staff if there is any question as to what is acceptable before taking the action. If a representative of organized dentistry is unwilling to abide by the standards of conduct, then the dental society should immediately cease using that dentist as an informational resource or volunteer.
- Fairly and truthfully educate members about proposed and known developments in the marketplace.

As representatives of organized dentistry, volunteer-leaders and staff should **NOT DO** the following:

- Meet without FDA support staff in attendance. FDA support staff is expected to notice the meeting, prepare agendas, keep minutes, etc. Further, FDA support staff is expected to work closely with the FDA’s legal department should assistance be needed on risk management practices. FDA legal staff may also sit in on meetings to ensure improper conduct does not occur.
- Meet without approval of the chair.
- Allow one volunteer representative to unilaterally designate another doctor to serve in an official capacity as an informational resource, association representative or “contact dentist.” Rather, all such representatives should be selected and supervised by the FDA agency sponsoring the activity in accordance with the FDA bylaws and these guidelines. Allowing one representative to designate another person to serve (whether temporarily or permanently) as dental society spokesperson or representative about marketplace issues probably violates most societies’ bylaws and policies and, even more serious, may make the society itself responsible for what was said or done by the alternate.
- Publish an article or organize/sponsor a meeting between one or more competing dentists (including dental society meetings) in order to organize or facilitate collective conduct such as price-fixing, market allocation or boycott as described above.
- Promulgate a survey of member-dentists regarding participation levels in, and/or members’ willingness to accept (or to refuse to accept) participating provider agreements from insurers and managed care payers.
- Distribute information to dental society members or others about participation levels in the insurance programs or managed care organizations. For example, it is improper to distribute lists of participating and/or non-participating dentists to the dental community. Similarly, it is improper for the dental society to exchange information among competing dentists about the terms and conditions of other dentists’ participation or refusal to participate.
- Appoint a single individual to collectively provide information to or negotiate and bargain with payers about dentists’ participation levels; fees charged by the dentists to

patients or third-party payers (governmental or otherwise); the scope of services to be provided and to what category of patient (e.g., underserved or indigent only); or price-related terms such as fee waivers, timing of claims reimbursement, and the like.

- Sign letters or sponsor petitions sent to payers or other potential or actual competitors encouraging them not to locate clinics in their dental society's jurisdiction or to locate it elsewhere.

III. Confidentiality Reminder: The following statement shall be added to the written Legal Compliance Statement included with all FDA agendas and, when the agency chair calls for an executive session, FDA support staff (or in the absence of staff, the chair of the executive session) is directed to verbally read the following statement:

Confidentiality is an integral part of how an association works. Agencies often require access to sensitive or potentially embarrassing information and must be able to disclose this information freely in executive session to make recommendations on association policy or candidates for office. To deliberate honestly and openly, the agency must know that the trust they have placed in other agency members will not be broken by an individual improperly disclosing information outside of the executive session. Unauthorized disclosure of information that was provided to the group with the understanding that it will be kept confidential is serious. It impairs the association's ability to function effectively and presents liability risk. Once the group's trust is broken by making improper disclosure, it is very difficult to restore a positive working relationship.

Only information discussed during a formally announced executive session is confidential. The chair must announce the start and end of the executive session and the minutes must reflect this. No official action can be taken during executive session (i.e., the group must come out of executive session before voting). Executive session is mandatory for discussion of personnel matters, Corporate Affiliation Program proposals, dues waivers, legislation or regulatory matters, litigation or when the chair determines information is sensitive.

“Confidential” means the information may not be disclosed at any time in any manner (including but not limited to verbally, in writing, electronically, or through social media) to anyone (including but not limited to friends outside of dentistry; spouses or significant others; business partners or employees; association staff; dental or dental hygiene schools; licensure agencies; accrediting organizations; governmental agencies; association leadership serving on other agencies; associations or specialty groups at other levels of organized dentistry; or public media). It may not be discussed between members who participated in the executive session after the executive session concludes.

STRATEGIC PLAN LINK: This matter relates to Program Goal 5: Ensure that the FDA is organized to effectively carry out its strategic plan.

RECOMMENDATION: Accept for information.

UNBUDGETED IMPACT: None.

Direct-to-Consumer Dental Services

There is a growing presence of direct to the consumer (DTC) dental laboratory services, where patients are instructed in how to independently take their own impressions and order products such as mouth guards, snoring appliances, teeth whitening trays and bleaching products, partial dentures, veneers and aligners. Direct to consumer laboratory services eliminate the role of the dentist in diagnosing the patient's oral health needs, developing a treatment plan to best meet those needs, and safely managing treatment throughout the course of care. Self-delivered, unsupervised dental treatments have the potential to cause damage and irreversible complications for patients.

Every state has regulations that require dentists and hygienists to be licensed in order to provide patient care. The level of oversight for dental assistants varies by state and, while dental assistants may or may not be licensed or registered by the state, they are required to perform their duties under the supervision of a licensed dentist. State dental practice acts define the scope of practice for dentists, hygienists, and licensed or registered dental assistants.

However, dental laboratory technicians and businesses are generally not licensed. While the ADA maintains policy encouraging state boards to register dental laboratories, only seven states currently require dental laboratory registration. No states require registration of dental laboratory technicians.

The traditional role of a dental laboratory has been to manufacture prosthetics or devices in accordance with the written directives (or instructions) provided by a licensed dentist. ADA's policy, Statement on Prosthetic and Appliance Care and Dental Laboratories, specifies that "the dentist-provider is ultimately responsible for the patient's care, the Association believes that he or she is the only individual qualified to accept responsibility for prosthetic care." Dentists are responsible for all aspects of the manufacture of prosthetic devices through ordering or prescribing the prosthetic device, receiving the notifications of materials and country of origin, and delivering prosthetics to patients.

A policy on do-it-yourself teeth straightening [was adopted by the ADA's House of Delegates](#) in 2017 and states ADA's position on self-directed orthodontic treatment. In October 2018, the ADA adopted a policy on direct to consumer dental laboratory services. The policy states that the ADA strongly discourages the practice of direct to the consumer dental laboratory services because of the potential for irreversible harm to patients.

It's also worth noting that dental prosthetics, such as aligners, partial dentures and snoring appliances are considered medical devices by the U.S. Food & Drug Administration (FDA). In case of problems, the FDA encourages consumers as well as health care professionals to utilize and submit the [MedWatch voluntary reporting form](#) to help improve safety by bringing attention to particular issues. More general information about the FDA medical device reporting program can be found [here](#).

ADA discourages DIY orthodontics through resolution

November 10, 2017

By David Burger

Atlanta — The ADA "strongly discourages" the practice of do-it-yourself orthodontics because of the potential for harm to patients, according to a new policy passed by the 2017 ADA House of Delegates.

"Patients are being inundated with direct marketing campaigns encouraging them to initiate and manage their own orthodontic treatment. These campaigns are operating in multiple media outlets, including online, billboards and television ads," said Dr. Craig Ratner, chair of the ADA Council on Dental Practice.

Dr. Ratner continued: "This year's ADA House of Delegates recognized the need for the ADA, as America's leading advocate for oral health, to take steps to educate patients about the potential pitfalls of self-managed orthodontic treatment. This new policy supports the importance of dentists being in charge of diagnosing and treating patients to ensure the safe delivery of appropriate care."

The Michigan Dental Association transmitted Resolution 50H-2017 to the House. The state society's executive director and CEO, Karen Burgess, told the ADA News that members brought the topic to the association's attention. Some research found that there was no policy addressing the issue.

The resolution states that the Association "believes that supervision by a licensed dentist is necessary for all phase of orthodontic treatment including oral examinations, periodontal examinations, radiographic examinations, study models of scans of the mouth, treatment planning and prescriptions, periodic progress assessments and final assessments with stabilizing measures."

The American Association of Orthodontists was not involved in the creation of the resolution, but has been cautioning consumers about the dangers of DIY orthodontics in the past year.

In a survey conducted among its members, according to a news release on the AAO website, the AAO reported that nearly 13 percent of its member orthodontists are seeing patients who have tried do-it-yourself teeth straightening, with some of those attempts causing irreparable damage.

In response, the AAO issued a "consumer alert" on the home page of its website, stating: "The American Association of Orthodontists is urging consumers to beware of Internet videos and websites which encourage people to try and straighten their own teeth. Moving teeth is a medical procedure and needs personal supervision by an orthodontist. Please be wary of any suggestions to move teeth with rubber bands, dental floss or other objects ordered on the Internet. Moving teeth without a thorough examination of the overall health of the teeth and gums could result in the permanent loss of teeth, which may result in expensive and lifelong dental problems. Orthodontists receive two to three years of specialized education beyond dental school and are specialists in straightening teeth and aligning the bite."

Kevin Dillard, AAO general counsel, told the ADA News that the AAO has filed complaints with dental boards and attorneys general in 36 states regarding companies providing aligners through an online service. In addition, he said, at least three dental boards — in Alaska, California and West Virginia — have opened investigations into one of the companies, SmileDirectClub. In August, Alaska's board voted to ask the state's licensing division to send a cease-and-desist letter barring SmileDirectClub from selling there, Mr. Dillard said.

Mr. Dillard said the complaints allege that SmileDirectClub is violating laws that exist to protect the public. The AAO complaints argue that these companies are performing medical work that many state laws reserve for licensed professionals, such as taking bite casts and delivering dental appliances to patients.

Some of the businesses, such as SmileDirectClub, contend that they function as a marketing company for dentists, connecting them to customers, Mr. Dillard said. He said that claim is difficult to accept. Part of their marketing, he said, is that people can skip going to the dentist.

On Oct. 26, attorneys for SmileDirectClub filed suit against the Michigan Dental Association in the U.S. District Court for the Western District of Michigan for "false light" and "trade libel" with regard to an August 2017 article published by the MDA in the Journal of the Michigan Dental Association.

SmileDirectClub did not respond to attempts to reach it by ADA News, but in a SmileDirectClub news release, Alex Fenkell, SmileDirectClub co-founder, said, "The inaccuracies and misrepresentations in the

MDA article are egregious. We're committed to fighting back against this type of anti-competitive activity because we believe people deserve an accessible and affordable option for obtaining a better and healthier smile."

In the same release, co-founder Jordan Katzman added, "The medical industry has been here before. Products like hearing aids, contact lenses, and dialysis supplies faced resistance at first too. We are confident in our product, as well as our process and independent providers, and will not let the opposition keep us from providing more accessible and affordable services."

"The Michigan Dental Association is dedicated to upholding the highest standards of practice for the residents of Michigan so that they receive the best oral care in compliance with the laws of the state of Michigan," the MDA said in its official statement. "MDA denies the allegations contained in the complaint filed by SmileDirectClub, and in that company's recent press release. The MDA sent a letter to SmileDirectClub seeking information to confirm it was complying with the Michigan laws governing dental practice when providing services to patients in the state. SmileDirectClub's response failed to support its representations that it was in compliance with Michigan law. The article published in the August MDA Journal simply informed MDA members of these facts. The MDA stands by the accuracy of the article. The claims made by SmileDirectClub are without merit. If served with the complaint, MDA will vigorously defend itself in court."

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

SMILEDIRECTCLUB, LLC,

Plaintiff

v.

GEORGIA BOARD OF DENTISTRY;
TANJA D. BATTLE, in her official
capacity as Executive Director of the
Georgia Board of Dentistry; and
THOMAS P. GODFREY, GREGORY
G. GOGGANS, RICHARD BENNETT,
REBECCA B. BYNUM, TRACY GAY,
STEVE HOLCOMB, LOGAN
NALLEY, JR., ANTWAN L.
TREADWAY, H. BERT YEARGAN,
and WENDY JOHNSON, individually
and in their official capacities as
Members of the Georgia Board of
Dentistry,

Defendants.

Civil Action No. _____

JURY TRIAL DEMANDED

**COMPLAINT FOR DAMAGES, DECLARATORY, AND INJUNCTIVE
RELIEF**

Plaintiff SmileDirectClub, LLC (“Plaintiff” or “SDC”) alleges the following against Defendants the Georgia Board of Dentistry (the “Board”), Thomas P. Godfrey, Gregory G. Goggans, Richard Bennett, Rebecca B. Bynum, Tracy Gay, Steve Holcomb, Logan Nalley, Jr., Antwan L. Treadway, H. Bert Yeargan, and

Wendy Johnson (each of the foregoing individuals is sued in his or her individual capacity and in his or her official capacity as Members of the Board), and Tanja D. Battle in her official capacity as Executive Director of the Board:

INTRODUCTION

1. This is an action to enjoin the enforcement of an unauthorized and improper rule adopted by the Georgia Board of Dentistry. Specifically, the Board recently approved a rule that purportedly “expanded” the list of duties a dental assistant may perform if directly supervised by a licensed dentist under Georgia Rule of Dentistry 150-9-.02(3). A true and correct copy of Rule 150-9-.02, including the list of ten “expanded” duties, is attached hereto and incorporated herein by reference as Exhibit A. Subparagraph (aa) of the new Rule provides that a dental assistant may perform “[d]igital scans for fabrication (sic) orthodontic appliances and models” only “under the direct supervision of a licensed dentist.” Digital scanning, however, is not the practice of dentistry or dental hygiene and, thus, the Board lacks the authority to regulate this conduct.

2. By including “digital scans” within the framework of Rule 150-9-.02(3), Subparagraph (aa) bars technicians from performing digital scans of a patient’s teeth and gums unless under the direct supervision of a licensed dentist. Notably, the supervision contemplated by the new Rule simply requires that a

licensed dentist be in the building while the digital scanning is performed. It does not require that the licensed dentists perform the digital scan themselves, observe the digital scans, or even be in the same room as the patient when the digital scan is performed. Thus, effectively, Subparagraph (aa) is aimed uniquely at shops that offer digital scan services apart from dental services. As a result, Subparagraph (aa) unlawfully restricts Georgia residents' access to affordable aligner treatment, fails to protect the public in any manner, stifles competition, harms consumers, and makes it virtually impossible for Plaintiff to lawfully conduct business in the State of Georgia without making costly and prohibitive changes to its present business model.

THE PARTIES

3. Plaintiff SDC is a dental service organization that provides non-clinical administrative support services to contractually affiliated dental practices in Georgia that wish to offer doctor-directed at-home clear aligner treatment for cases of mild to moderate malocclusion (*i.e.* improper positioning of the teeth when the jaws are closed). SDC is licensed to practice business in the State of Georgia.

4. The Board consists of eleven members appointed by the Governor to regulate and enforce the standards of the practice of dentistry. By statute, nine

members of the Board must be dentists, one member of the Board must be a dental hygienist who is not a dentist, and one member of the Board must be an individual who is neither a dentist nor a dental hygienist. O.C.G.A. § 43-11-2. Upon information and belief, one of the nine seats allocated to dentists is presently vacant, meaning that the Board presently consists of ten members, eight of whom are dentists. The Board's authority is limited to regulating the practice of dentistry and dental hygiene and those who practice dentistry or dental hygiene in the State of Georgia. The Board has no authority over activities that do not constitute dentistry or dental hygiene or individuals and organizations, such as SDC, that provide non-clinical administrative support services to dental providers.

5. Defendant Tanja D. Battle is the Executive Director of the Georgia Board of Dentistry.

6. Defendant Thomas P. Godfrey, D.M.D., is the President and one of the eight current dentist members of the Board. Upon information and belief, Dr. Godfrey is a licensed, practicing dentist with an office in Atlanta, Georgia.

7. Defendant Gregory G. Goggans, D.M.D., is the Vice President and one of the eight current dentist members of the Board. Upon information and belief, Dr. Goggans is a licensed, practicing orthodontist with offices in various locations throughout Georgia. According to the website for his practice, Dr.

Goggans offers patients clear aligner treatment products and services that compete with the products and services offered by SDC and its affiliated dental practices.

8. Defendant Richard Bennett, D.M.D., is one of the eight current dentist members of the Board. Upon information and belief, Dr. Bennett is a licensed, practicing dentist with an office in Gainesville, Georgia.

9. Defendant Rebecca B. Bynum, R.D.H., is a current member of the Board. Upon information and belief, Ms. Bynum is a registered dental hygienist.

10. Defendant Tracy Gay, D.M.D., is one of the eight current dentist members of the Board. Upon information and belief, Dr. Gay is a licensed, practicing dentist with an office in Dublin, Georgia. According to the website for his practice, Dr. Gay offers patients clear aligner treatment products and services that compete with the products and services offered by SDC and its affiliated dental practices.

11. Defendant Steve Holcomb, D.M.D., is one of the eight current dentist members of the Board. Upon information and belief, Dr. Holcomb is a licensed, practicing dentist with an office in Byron, Georgia.

12. Defendant Logan “Buzzy” Nalley, Jr., D.M.D., is one of the eight current dentist members of the Board. Upon information and belief, Dr. Nalley is a licensed, practicing prosthodontist with an office in Augusta, Georgia.

13. Defendant Antwan L. Treadway, D.M.D., is one of the eight current dentist members of the Board. Upon information and belief, Dr. Treadway is a licensed, practicing oral surgeon with an office in Atlanta, Georgia.

14. Defendant H. Bert Yeargan, D.M.D., is one of the eight current dentist members of the Board. Upon information and belief, Dr. Yeargan is a licensed, practicing dentist with an office in Brunswick, Georgia.

15. Defendant Wendy Johnson is a current member of the Board.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over the claims asserted in this Action pursuant to 28 U.S.C. §§ 1331, 1337, 1343, 1367 and 42 U.S.C. § 1983.

17. The Board was created by the Georgia Legislature to regulate and enforce the standards of the practice of dentistry in the State of Georgia. *See* O.C.G.A. §§ 43-11-1 *et seq.* The Board operates in the State of Georgia and the events giving rise to the claims asserted in this Action occurred in the State of Georgia. Upon information and belief, Defendants Battle, Godfrey, Goggans, Bennett, Bynum, Gay, Holcomb, Nalley, Treadway, and Yeargan are all citizens of the State of Georgia. *See* O.C.G.A. § 43-11-2 (requiring members of the Georgia Board of Dentistry to be citizens of the State of Georgia). Accordingly, Defendants are subject to personal jurisdiction in Georgia.

18. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 15 U.S.C. § 22 because the Board is deemed to reside in any judicial district in which it is subject to personal jurisdiction with respect to this Action, which includes this District. Venue is also proper in this District because a substantial part of the events or omissions giving rise to the claims asserted in this Action occurred in this District.

19. The Defendants' actions substantially and adversely affect interstate commerce in the "Relevant Market" as described herein. Defendants provide services in interstate commerce and certain of the Defendants perform aligner treatment using products that are sold across state lines and from outside the State of Georgia into the State of Georgia. In addition, by restraining competition for aligner treatment in Georgia, the flow of interstate commerce is interrupted because the purchase of supplies needed for such treatment, and any related services, from outside of Georgia is reduced. Thus, Defendants' actions have the effect of reducing the amount of interstate commerce to the detriment of consumers.

FACTUAL BACKGROUND

A. SDC Provides Non-Clinical Administrative Support Services to Licensed Dental Providers.

20. SDC is a dental service organization that provides non-clinical administrative support services to contractually affiliated dental practices that wish to offer doctor-directed at-home clear aligner treatment for cases of mild to moderate malocclusion using the teledentistry platform and portal provided by SDC. A clear aligner is a removable appliance made from a strong plastic material that is fabricated to fit an individual's mouth to move the individual's teeth in increments until the desired positioning is achieved. Teledentistry enables the provision of dental treatment and care via remote technology, rather than on-site personal contact with patients.

21. Through SDC's teledentistry platform, dentists and orthodontists licensed in the state of Georgia who affiliate with SDC are able to offer at-home aligner treatment at a substantially lower price than traditional aligner treatment offered in an established dental office and are therefore able to treat many patients who otherwise would not have access to an orthodontist. The SDC platform is built around its proprietary SmileCheck system, a web-based portal that connects patients and doctors, facilitating timely and convenient interaction.

22. SDC's affiliated practices are revolutionizing orthodontic treatment by dramatically lowering the price of aligner treatment for mild to moderate cases of malocclusion and providing greater access to aligner treatment for the residents of the State of Georgia.

23. SDC's mission of providing affordable aligner treatment to the underserved is important in the State of Georgia, where approximately 63.5% of Georgia counties do not have a licensed orthodontist.

24. Among the suite of non-clinical administrative support services offered by SDC is the provision of a SmileShop to SDC-affiliated licensed dentists and orthodontists.

25. SmileShops are locations where customers may receive digital photographs of their teeth and gums through the use of an iTero scanner to determine if they are a candidate for SDC's clear aligner product. The iTero scanner is cleared as safe and effective by the FDA. And unlike devices that are used for medical or dental procedures, such as x-ray machines, the iTero scanner does not need to be registered with or inspected by the state prior to use. The digital photographs created by the iTero scanner are necessary for SDC's licensed dentists and orthodontists to provide aligner treatment and thereby compete in the "Relevant Market" as defined below.

26. The digital scan at the SDC SmileShops in Georgia is performed by a trained technician or assistant using an iTero scanner, which is essentially a wand with a camera, to take thousands of photographs of a customer's teeth and gums. The photographs are sent to the SDC lab, where trained technicians receive the patient's scans on behalf of the treating dentist or orthodontist, and, if the scans are deemed acceptable, coordinate the creation of a 3D digital model from those scans to create a model treatment plan. This treatment plan, along with the photographs, customer health history, and other required information, is provided to a Georgia licensed dentist or orthodontist for review and evaluation.

27. The digital scan consists of thousands of photographs, which generate a 3D model of the patient's maxillary and mandibular dentition, along with the attached gingiva and supporting oral mucosa, from different perspectives such as maxillary, open, mandibular open, and in centric occlusion. The iTero scanner takes approximately 6,000 photographs per second.

28. The technician also takes standard digital photographs of the customer's teeth and gums which are also provided to the Georgia licensed dentist or orthodontist for review and evaluation to identify periodontal disease, cavities, or any other presentation that would require further clearance or prevent the customer from being a candidate for SDC clear aligners.

29. The Georgia licensed dentist or orthodontist evaluates the customer's digital scans, photographs, and medical and dental history questionnaire to determine if aligner therapy is appropriate for the patient. The Georgia licensed dentist or orthodontist also determines whether any additional information, x-rays, or further photographs are required or appropriate. If so, the dentist indicates what additional information is required before a treatment decision can be made.

30. Throughout the process, the licensed dentist or orthodontist maintains sole responsibility for all aspects of patient care and all clinical decisions, including evaluating, diagnosing, and, if appropriate in the licensed dentist's or orthodontist's independent professional judgment, treating the patient's condition with SDC clear aligners.

31. Each SDC-affiliated dentist or orthodontist who treats a Georgia citizen is licensed and qualified to practice dentistry in the State of Georgia.

32. SDC's entry into the market and offering of top-notch, low-cost clear aligners has been embraced by many in the public and dental community. Through the use of SmileShops and its web-based teledentistry platform, SDC has been able to drastically reduce the cost of expensive (and often overpriced) aligner treatment and increase access to aligner treatment for many unreached segments of the

population, all while ensuring that patients receive treatment from and are closely monitored by Georgia licensed dentists and orthodontists.

33. Since SDC opened its first SmileShop in Georgia in July 2017, SDC has performed thousands of scans for customers in Georgia without a single incident or complaint of physical injury, infection, or other adverse patient outcome associated with the performance of the scan. In addition, SDC has performed hundreds of thousands of scans on a national basis without a single such incident or complaint.

B. The Board Improperly Votes To Regulate Digital Scans.

34. Against this backdrop of lower-cost treatments, increased access to patient care, and direct oversight by Georgia licensed dentists and orthodontists, the Board approved amendments to Georgia Board of Dentistry Rule 150-9-.02 on or about January 24, 2018, which are scheduled to become effective on May 22, 2018.

35. A true and correct copy of the amendments to Georgia Board of Dentistry Rule 150-9-.02 is attached hereto as Exhibit A.

36. The amendments added ten additional duties to the list of “expanded” duties a dental assistant may perform under Rule 150-9-.02(3).

37. One of the additional duties added to the list appears as Subparagraph (aa) of Rule 150-9-.02(3) and states as follows: “(aa) Digital scans for fabrication (sic) orthodontic appliances and models” (hereinafter “Subparagraph (aa)”).

38. As written, Subparagraph (aa) will require digital scans in Georgia to be made in a dentist’s office under the direct supervision of a licensed dentist, rather than in a SmileShop with a trained technician who provides the same digital scans to a Georgia licensed dentist or orthodontist through SDC’s web-based platform.

39. Moreover, when Subparagraph (aa) becomes effective, SDC will potentially be subject to the threat of: (1) Board action seeking to enjoin SDC from conducting business in Georgia, *see* O.C.G.A. § 43-11-2(e); and (2) enforcement action by the State seeking criminal penalties, *see* O.C.G.A. §§ 43-11-50, 43-11-76.

40. Prior to the adoption of Subparagraph (aa), SDC customers could, and did, visit a conveniently located SmileShop and request a digital scan from a qualified technician without requiring the presence or direct supervision of a licensed dentist or orthodontist. At no time prior to the adoption of Subparagraph (aa) did the Georgia Board of Dentistry advise SDC that its SmileShops were in

violation of any law, regulation, or rule regarding the practice of dentistry or dental hygiene.

41. Indeed, such direct supervision is wholly unnecessary because (1) the process is simple, only involving use of a wand with a disposable sleeve and camera, (2) there is no trauma or health or safety risk to a customer, (3) the scan does not emit radiation, (4) the software in all digital scanners on the market prevents the technician from uploading an incomplete scan that has not captured all necessary intraoral structures, and (5) all photographs are later reviewed by a Georgia licensed dentist or orthodontist to ensure the quality of the photographs, a customer's candidacy for treatment, and a proper treatment plan.

42. The adoption of Subparagraph (aa) fails to acknowledge such realities. To the contrary, it places patients last by severely impairing SDC's ability to deliver affordable products and services to affiliated licensed dentists and orthodontists, who in turn pass these savings along to their patients.

43. Indeed, the adoption of Subparagraph (aa) makes it virtually impossible for SDC and its affiliated licensed dentists and orthodontists to lawfully conduct business in Georgia without making costly and prohibitive changes to SDC's current business model.

44. Thus, as set forth in greater detail below, Subparagraph (aa) should be removed from the amendments because it (1) reduces Georgia citizens' access to care, (2) increases the cost of digital scans and overall orthodontic care, (3) does not protect the public, (4) disproportionately regulates a safe procedure, (5) creates an unnecessary barrier to employment for Georgia citizens, (6) is beyond the Board's rulemaking authority, (7) distinguishes between technicians employed by SDC and extended duty dental assistants who perform scans "directly supervised" (within the meaning of Rule 150-9-.01(2)) by licensed dentists and orthodontists, without a rational basis for such a distinction, and (8) deprives SDC of its constitutionally protected liberty and property interests.

45. On April 30, 2018, Georgia Governor Nathan Deal signed a "Certification of Active Supervision," pursuant to the Georgia Professional Regulation Reform Act, O.C.G.A. § 43-1C-1 *et seq.* The context and circumstances, however, demonstrate that the State of Georgia did not actively or adequately supervise the Board with regard to its action in passing Subparagraph (aa). Instead, the Board impeded the State of Georgia's ability to actively and adequately supervise the substance of the Board's actions by failing to fully advise the Governor of the reasons for its action and the objections to its actions in passing Subparagraph (aa). For example, the Board's official minutes fail to

provide a full and complete summary of objections to the Board's action expressed during official Board meetings, thereby depriving the State of Georgia of the information needed to actively and adequately supervise the Board's conduct. The Board also failed to explain to the State of Georgia the impact Subparagraph (aa) will have on consumers in the "Relevant Market" and failed to reveal the conflicts of interest of the Defendants who will benefit monetarily, now or in the future, by restraining trade in the "Relevant Market."

C. The Relevant Market.

46. The "Relevant Market" in which to evaluate the anticompetitive effect of the conduct of Defendants is the market for aligner treatment for mild to moderate malocclusion in Georgia.

47. The relevant products in this market are aligner treatments for mild and moderate malocclusion. The relevant products include clear aligners and traditional braces that use brackets and wires, as well as potentially non-fixed dental braces such as retainers, headgear, and palate expanders. Treatment options, of course, vary based on the particular needs of a patient, but these products are viable substitutes for consumers to consider in the treatment of mild-to-moderate malocclusion. The relevant market properly excludes aligner treatment of severe malocclusion because clear aligners are generally not an option for such treatment,

and as such, consumers who need treatment for severe malocclusion do not regard clear aligners as a viable substitute. Treatment of severe malocclusion is substantially more expensive than treatment of mild-to-moderate malocclusion and may involve surgical services as well.

48. The relevant geographic market is properly limited to Georgia. The Board purports to exercise authority over the provision of digital scan services for aligner treatment in Georgia. Furthermore, consumers in Georgia almost always seek aligner treatment from local providers in the State. Consumers who desire such services in Georgia do not travel out of state in any appreciable numbers to obtain aligner treatment. If the price of aligner treatment for mild-to-moderate malocclusion in Georgia increases as a result of actions of the Board, consumers in Georgia will not seek aligner treatment from providers in other states. Rather, such consumers will be forced to pay the higher prices for aligner treatment and travel long distances within Georgia to seek such services only from licensed dentists in Georgia.

D. The Board Exceeded Its Rulemaking Authority.

49. The Board is limited in its rulemaking authority—it may only regulate the practice of dentistry and those professionals who engage in the practice of dentistry. The Board has no authority to regulate industries or activities that do not

constitute the practice of dentistry or dental hygiene, such as dental support organizations, or those individuals who are not engaged in the practice of dentistry or dental hygiene. *See* O.C.G.A. § 43-11-9.

50. “Dentistry” is defined in the Georgia statutes as the “evaluation, diagnosis, prevention, or treatment, or any combination thereof, whether using surgical or nonsurgical procedures, of diseases, disorders, or conditions, or any combination thereof, of the oral cavity, maxillofacial area, or the adjacent and associated structures, or any combination thereof, and their impact on the human body provided by a dentist, within the scope of his or her education, training, and experience, in accordance with the ethics of the profession and applicable law” O.C.G.A. § 43-11-1(6).

51. The taking of a digital scan, in and of itself, does not constitute an “evaluation, diagnosis, prevention, or treatment” and, therefore, falls outside of the practice of dentistry. Similarly, the taking of a digital scan is not listed as one of the acts that constitute the practice of dental hygiene as that term is used in the Georgia Dental Practice Act. *See* O.C.G.A. § 43-11-74. Moreover, trained technicians do not provide diagnosis or dental advice; instead, they are simply taking a digital scan and uploading this information to a state licensed dentist or orthodontist for review, diagnosis, and preparation of a treatment plan.

Accordingly, the Board has no authority to regulate scans or those technicians who would otherwise be permitted to conduct digital scans, such as SDC technicians.

52. Thus, the Board has impermissibly exceeded the scope of its rulemaking authority in approving Subparagraph (aa) and seeking to regulate activities that do not constitute the practice of dentistry and individuals who are not engaged in providing dental evaluation, diagnosis, prevention, or treatment. The decision of the Board was made without cause or explanation and is merely designed to protect the business interests of traditional orthodontic practices.

E. Subparagraph (aa) Will Reduce Georgia Citizens' Access to Care.

53. Subparagraph (aa) will diminish Georgia citizens' access to care by reducing the number of locations where digital scans may be taken for fabrication of orthodontic appliances and models.

54. At present, only 58 of 159 Georgia counties have a licensed orthodontist.

55. Despite the massive volume of underserved patients in Georgia, the Board seeks to impose a new rule that would needlessly complicate an otherwise safe procedure that an unlicensed person can perform in a variety of locations.

56. Under such a scheme, SDC would no longer be able to provide one of the key elements of the services it currently offers to Georgia licensed dentists and

orthodontists, which allows them to provide affordable treatment to potential patients. The dentist members of the Board, however, would be able to use their dental assistants to continue to provide such scans to patients. Moreover, no law or regulation would prohibit the dentist members of the Board who are not currently providing digital scans to potential patients from providing such scans in their offices in the future.

57. Despite current plans to open additional SmileShops across the State of Georgia, many in areas where people cannot easily access orthodontic care and treatment, SDC would be forced to limit, if not entirely eliminate, its plans for increasing access to affordable orthodontic care across the State of Georgia if Subparagraph (aa) were to take effect.

58. As a result, rather than protect patients, the Board's decision will unnecessarily drive up costs and decrease access to care in the Relevant Market based on the mistaken belief that a 3D scan must be performed by, or directly supervised by, a dentist. Indeed, the Board's decision does not require that a licensed dentist visually monitor or observe the taking of a digital scan; it requires only that a licensed dentist be in the same building at the time the scan is performed.

59. Taking a digital scan of a customer's teeth and gums is neither dangerous nor risky. It is nothing more than the taking of photographs. Nor does it require the knowledge, training, and education of a licensed dentist or orthodontist or an extended duty dental assistant to properly execute.

60. Properly trained technicians such as those employed by SDC are capable of safely and accurately taking a digital scan of a customer's teeth and gums without the need for a dentist to be present. Indeed, the scan is not even a dental procedure, but rather a non-invasive use of digital technology to create an accurate three-dimensional model of a prospective patient's teeth, bite, gums, and palate.

61. There is no known evidence that digital scans taken under the "direct supervision" of a licensed dentist or orthodontist are somehow safer or more accurate than scans taken without such "supervision."

F. Subparagraph (aa) Will Increase The Cost Of Digital Scans And Overall Orthodontic Care.

62. The adoption of Subparagraph (aa) will unnecessarily increase the cost of digital scans and overall aligner treatment for Georgia consumers by requiring highly paid personnel to perform an otherwise safe and simple procedure. Many Georgia consumers also will incur increased costs by needing to travel to and pay for an office visit to a dentist or orthodontist, particularly when the office

visit is not covered by insurance. This increase in cost will be borne by consumers, who will pay more for such services than they otherwise would need to pay.

63. Plaintiff SDC also will suffer significant economic injury and damage as a result of the implementation of Subparagraph (aa). SDC will suffer lost business that it would have obtained by offering lower priced and superior services to those offered by dentists and orthodontists.

64. Indeed, the only parties who benefit from such a rule change are the licensed dentists and orthodontists who offer, or will offer, such services in their offices, because they will be able to demand additional compensation for requiring a photo session to take place in their office. Such requirements drive up costs and entirely eliminate the ability of some citizens to receive convenient, affordable care; indeed, care that has been proven to positively impact many other aspects of a person's overall health.

G. Subparagraph (aa) Does Not Protect The Public.

65. Even if the Board had the authority to impose regulations on the taking of digital scans, which it does not, Subparagraph (aa) would not provide any additional protection to the public.

66. The taking of a digital scan is extremely safe, and the process consists of using a wand with a camera at varying angles to approximate the teeth and

tissue so as to get a more accurate and predictable model of the teeth and gums than physical impressions.

67. The technology of taking digital scans is extremely user-friendly, providing real time feedback to the user regarding the accuracy of the scan and informing the user of where additional scans are needed to complete the full scan.

68. This advanced process does not use any radiation and allows a technician to photograph a patient's teeth and gums without the patient experiencing any trauma, pain, or morbidity.

69. The digital scanners are also easy to clean between patients and thus present no meaningful risk of cross-contamination as long as the technicians remove and discard the disposable cover and wipe the wand with a disinfecting wipe after each use. SDC technicians are carefully trained on these procedures and are required to follow them after each scan.

70. Given that digital scans present virtually no risk to consumers, Subparagraph (aa) unnecessarily complicates a safe procedure by needlessly imposing regulatory burdens that do not provide any additional protection to the public.

71. Indeed, as noted above, SDC has performed hundreds of thousands of customer scans in existing SmileShops nationwide—and thousands of customer

scans in Georgia alone—without receiving a single complaint of physical injury, infection, or other adverse patient outcome associated with the performance of the scan.

H. Subparagraph (aa) Will Disproportionately Regulate A Safe Procedure.

72. Subparagraph (aa) disproportionately regulates an extremely safe procedure by requiring education and certification requirements that are more stringent than the Board's requirements for more invasive and dangerous procedures.

73. The adoption of Subparagraph (aa) results in greater restrictions on digital photographs than the following procedures, all of which are more invasive and dangerous and require more medical/dental training and experience than does a digital scan:

- capturing a radiographic image using ionizing radiation (x-ray);
- removing sutures;
- applying topical anesthetic;
- cementing temporary crowns and bridges with intermediate cement;
- placing intracoronary temporary restorations using intermediate cement;
- polishing the enamel and restorations of the anatomical crown;
- removing dry socket medication;

- cutting and tucking ligatures; and
- performing phlebotomy and venipuncture procedures.

74. Moreover, the current framework and prohibitions within the existing rule evidence a regulatory intent that is at odds with the adoption of Subparagraph (aa).

75. Specifically, virtually all of the procedures that are required to be directly supervised by a licensed dentist involve (1) invasive procedures or (2) the administration of sedation compounds, such as nitrous oxide.

76. Digital scans, however, are not threatening to patient safety.

77. In sum, digital scans do not constitute the practice of dentistry or dental hygiene and are not in need of additional oversight or regulation. Rules that allow trained technicians to perform such scans on their own are sufficient to protect patients while simultaneously promoting increased access to care and lower cost to consumers in the Relevant Market.

I. Subparagraph (aa) Will Create An Unnecessary Barrier To Employment For Georgia Citizens.

78. Subparagraph (aa) will create an unnecessary barrier to employment for Georgia citizens by adopting strict education and certification requirements before a person can perform a digital scan in Georgia. Moreover, because of increased regulatory barriers, SDC, and others like it, would no longer be able to

open shops at which digital scans are conducted throughout the State of Georgia, reducing the number of opportunities for qualified technicians and harming competition in the Relevant Market.

J. Subparagraph (aa) Is Fatally Ambiguous And Confusing As Written.

79. The term “[d]igital scans” in Subparagraph (aa) is not defined, rendering it ambiguous as to what duties, conduct, or procedures are included such that they must be made in a dentist’s office under the “direct supervision” of a licensed dentist. The lack of any definition of the term “digital scans” renders Subparagraph (aa) vague, ambiguous, and confusing.

80. Because Subparagraph (aa) is unenforceable in its current form, it should be deleted from the amendments and the Board enjoined from its implementation.

CAUSES OF ACTION

COUNT ONE: DECLARATORY JUDGMENT

(Brought Against The Board Only)

81. SDC re-alleges and incorporates paragraphs 1 through 80 as if fully set forth herein.

82. This Count is brought pursuant to 28 U.S.C. § 2201.

83. Under the Georgia Administrative Procedure Act, “[t]he validity of any rule . . . may be determined in an action for declaratory judgment when it is alleged that the rule . . . or its threatened application interferes with or impairs the legal rights of the petitioner.” O.C.G.A. § 50-13-10(a). “A declaratory judgment may be rendered whether or not the petitioner has first requested the agency to pass upon the validity of the rule . . . in question.” *Id.*

84. O.C.G.A. § 50-13-10 applies to Subparagraph (aa) of the amendments adopted by the Board. *See* O.C.G.A. § 50-13-1 *et seq.*

85. 28 U.S.C. § 2201 authorizes this Court, “[i]n a case of actual controversy within its jurisdiction, . . . [to] declare the rights and other legal relations of any interested party seeking such declaration.”

86. As set forth above, there is an “actual controversy” between SDC and the Board with respect to the enforcement of Subparagraph (aa) against SDC. SDC’s rights are in actual jeopardy of being abolished by the enactment of Rule 150-9-.02(3)(aa). Application of Subparagraph (aa) immediately, definitively, and adversely affects SDC’s interests because it effectively eliminates SDC’s ability to provide low-cost scans at its SmileShops in the State of Georgia. Subparagraph (aa) will reduce Georgia citizens’ access to care and increase the cost of digital scans and overall aligner treatment, does not protect the public, would

disproportionately regulate a safe procedure, and will create an unnecessary barrier to employment for Georgia citizens. Subparagraph (aa) also exceeds the Board's rule-making authority and is fatally ambiguous and confusing as written. For all of these reasons, detailed above, this Court should declare Subparagraph (aa) invalid.

87. Accordingly, SDC seeks declarations from this Court pursuant to O.C.G.A. § 50-13-10 and 28 U.S.C. § 2201 that (1) the provision of digital scan services by SDC pursuant to the protocol described above does not constitute the practice of dentistry or dental hygiene within the meaning of O.C.G.A. §§ 43-11-1(6), 43-11-17(a), and 43-11-74 and is therefore outside the regulatory jurisdiction of the Georgia Board of Dentistry; (2) Rule 150-9-.02(3)(aa) is an invalid exercise of the statutory authority granted to the Board; and (3) the Georgia Board of Dentistry may not implement or enforce Rule 150-9-.02(3)(aa).

88. A copy of this Complaint is being served on the Office of the Attorney General in accordance with O.C.G.A. § 50-13-10.

COUNT TWO: VIOLATION OF 15 U.S.C. § 1

(Brought Against All Defendants)

89. SDC re-alleges and incorporates paragraphs 1 through 88 as if fully set forth herein.

90. The Defendants, by and through their anticompetitive actions as outlined herein, entered a contract, combination, or conspiracy in restraint of trade and commerce to prevent non-dentists, including, but not limited to Plaintiff, from providing non-clinical administrative support services in the Relevant Market, unless directly supervised by a dentist, and thereby have violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

91. In furtherance of their contract, combination or conspiracy in restraint of trade, the Defendants have agreed and acted upon a policy of excluding non-dentists from providing digital scans without the direct supervision of dentists, thereby harming competition in the Relevant Market. This agreement among Defendants is expressly stated in Subparagraph (aa) of Rule 150-9-.02(3).

92. As is evidenced by Defendants' passage of Subparagraph (aa) of Rule 150-9-.02(3), Defendants demonstrated a unity of purpose, as well as common design and understanding, to reduce or eliminate competition in the Relevant Market.

93. As is demonstrated by Defendants' passage of Subparagraph (aa) of Rule 150-9-.02(3), the Defendants possessed, and still possess, a conscious commitment to a common scheme designed to achieve an unlawful objective.

94. The Defendants' actions constitute a continuing agreement, understanding, and concert of action among market participants that are practicing dentists in the State of Georgia.

95. The Defendants' actions have the purpose and effect of unreasonably restraining trade in the Relevant Market, the net effects of which are anticompetitive, and any purported procompetitive justifications are illegitimate and pretextual. The Defendants' actions have the following anticompetitive effects in the Relevant Market:

- a. preventing and deterring the use of non-dentists for digital scan services needed to provide clear aligner treatment in Georgia;
- b. depriving consumers of the benefits of competition on price and quality for aligner treatment in Georgia by causing new, efficient entrants, like SDC, to shut down or incur higher costs;
- c. reducing consumer choice and the availability of aligner treatment to consumers in Georgia;
- d. reducing incentives for innovation in the provision of aligner treatment in Georgia; and
- e. increasing the prices that customers in Georgia pay for aligner treatment.

96. The Defendants' actions constitute a per se violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

97. Alternatively, the Defendants' actions constitute a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, under the Rule of Reason. On their face, the Defendants' actions restrict, and are intended to restrict, the method of competing in the Relevant Market, thereby restricting the number of competitors and causing prices in the Relevant Market to rise, maintain, or stabilize above competitive levels. Defendants have market power in the Relevant Market and can enforce their output-restricting agreement by using the legal process of the State of Georgia to preclude entrance into the Relevant Market or to restrict the method of competition in the Relevant Market. Defendants can, and do, use investigators of the State of Georgia to locate persons who offer digital scan services in contravention of their agreement that only licensed dentists (or those they supervise) offer the service and threaten to use the office of the Georgia Attorney General to enforce sanctions against any individual or business that operates in contravention of their agreement, which results in harm to competition in the Relevant Market. The Individual Dentist Defendants are actual or potential participants in the Relevant Market and have incentives to restrict competition in

the Relevant Market, and no legitimate business justification exists for Defendants' agreement.

98. The Defendants' actions evidence predatory intent to deprive dentists that utilize a new, more efficient method of competition of a fair opportunity to compete in the Relevant Market. Through their actions, Defendants intend to reduce the number of providers of aligner treatment in Georgia and the output of such services. Defendants' actions do not enhance public health and safety in Georgia and do not serve any legitimate public purpose.

99. As a direct, proximate, and foreseeable result of the Defendants' actions, Plaintiff has or will suffer damages and injury.

COUNT THREE: VIOLATION OF EQUAL PROTECTION CLAUSE

(Brought Against All Defendants)

100. SDC re-alleges and incorporates paragraphs 1 through 99 as if fully set forth herein.

101. This Count is brought pursuant to the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution and 42 U.S.C. § 1983.

102. Under the status quo, technicians employed by SDC are permitted to perform digital scans for fabrication of orthodontic appliances and models. Subparagraph (aa), which the Defendants enacted under color of State law,

prohibits technicians employed by SDC from performing digital scans by requiring that such scans be performed only by licensed dentists or orthodontists or by expanded duty dental assistants, acting under the direct supervision of a licensed dentist or orthodontist. Accordingly, Subparagraph (aa) creates a distinction between persons and entities who offer digital scans by technicians (such as SDC), and persons and entities who offer digital scans by licensed dentists or orthodontists or by expanded duty dental assistants, acting under the direct supervision of a licensed dentist or orthodontist.

103. The Equal Protection Clause of the Fourteenth Amendment does not allow government to treat similarly situated persons differently unless the reason for doing so bears a rational relationship to a legitimate governmental interest.

104. As detailed above, there is no rational basis for Georgia's distinction between persons and entities who offer digital scans by technicians and persons and entities who offer the identical service by licensed dentists or orthodontists or by expanded duty dental assistants, acting under the direct supervision of a licensed dentist or orthodontist. Accordingly, SDC has been denied equal protection of the law.

105. Unless Defendants are enjoined from committing the above-described violations of the Equal Protection Clause of the Fourteenth Amendment, SDC will

suffer great and irreparable harm. As detailed above, in the absence of an injunction, SDC will be prohibited from employing technicians to perform digital scans and will face the possibility of enforcement action and possible criminal penalties if it continues to do so.

106. Accordingly, this Court should grant declaratory and injunctive relief restraining Defendants' denial to SDC of equal protection of the law and award SDC attorneys' fees and costs.

COUNT FOUR: VIOLATION OF DUE PROCESS

(Brought Against All Defendants)

107. SDC re-alleges and incorporates paragraphs 1 through 106 as if fully set forth herein.

108. This Count is brought pursuant to the Due Process Clause of the Fourteenth Amendment and 42 U.S.C. § 1983.

109. SDC possesses liberty and property interests in the ability to conduct a business that provides non-clinical administrative support services to contractually affiliated dental practices, including the ability to offer digital scans for fabrication of orthodontic appliances and models, subject only to regulations that are rationally related to a legitimate government interest.

110. Subparagraph (aa), as applied to SDC, deprives SDC of its liberty and property interests that are protected by the Due Process Clause by imposing restrictions on its ability to offer digital scans for fabrication of orthodontic appliances and models that are not rationally related to any legitimate governmental interest. Indeed, as described above, SDC would be forced to limit, if not entirely eliminate, its plans for increasing access to affordable orthodontic care across the State of Georgia if Subparagraph (aa) were to take effect.

111. As detailed above, Subparagraph (aa), which Defendants enacted under color of State law, is not rationally related to any legitimate government interest.

112. Unless Defendants are enjoined from committing the above-described violations of the Fourteenth Amendment, SDC will suffer great and irreparable harm. As detailed above, in the absence of an injunction, SDC will be prohibited from employing technicians to perform digital scans and will face the possibility of enforcement action and possible criminal penalties if it continues to do so.

113. Accordingly, this Court should grant declaratory and injunctive relief restraining Defendants' denial to SDC of Due Process and award SDC attorneys' fees and costs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff SDC respectfully requests relief as follows:

(a) Declare that: (1) the provision of digital scan services by SDC pursuant to the protocol described above does not constitute the practice of dentistry or dental hygiene within the meaning of O.C.G.A. §§ 43-11-1(6), 43-11-17(a), and 43-11-74 and is therefore outside the regulatory jurisdiction of the Georgia Board of Dentistry; (2) proposed Rule 150-9-.02(3)(aa) is an invalid exercise of the statutory authority granted to the Board; and (3) the Georgia Board of Dentistry may not implement or enforce proposed Rule 150-9-.02(3)(aa);

(b) Declare that proposed Rule 150-9-.02(3)(aa), as applied to Plaintiff, violates the Equal Protection and Due Process Clauses of the Fourteenth Amendment to the U.S. Constitution.

(c) Preliminarily and permanently enjoin the enforcement of proposed Rule 150-9-.02(3)(aa) against Plaintiff;

(d) Award monetary damages for all claims as permitted under statute and law;

(e) Award treble damages, as provided in 15 U.S.C. § 15;

(f) Award reasonable attorneys' fees, costs, and expenses in this action pursuant to 15 U.S.C. § 15 and 42 U.S.C. § 1988; and

(g) Award such further relief as the Court deems just and proper.

JURY DEMAND

In accordance with Rule 38 of the Federal Rules of Civil Procedure, Plaintiff respectfully demands a jury trial of any and all issues in this action so triable of right.

Respectfully submitted this 21st day of May, 2018.

/s/ Jeffrey S. Cashdan

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Letter to Food and Drug Administration sent by a FDA member

I am writing in reference to the new wave of direct to consumer care that is becoming more in vogue within our states, whether referenced in the Statutes or Rules within the respective states that it is being practiced to be "legal", or not. Yes, this is a "State's rights" issue for the most part, but most states are silent on all the new technologies present within their Statutes and Rules. They need to "catch up" if they can, and thus some of my concerns.

With this in mind, I am reaching out in reference to "Class II medical devices" in particular, and what is incumbent within the regulatory environment for the production thereof. Obviously there should be a legal prescription from a licensed provider within the State to start the fabrication of that device(s). The bigger questions I have are:

- is there a definition of "patient of record", or however delineated, that such a Rx can be promulgated and signed?
- is there a responsibility of that Rx signer for the ultimate evaluation and subsequent care of that patient in any manner with examination, monitoring, review of outcomes, etc?
- are there proper 510(k)s for each of these new "processes" in materials and methods already in place for each group producing them?
- probably outside the FDA's scope, but are there any regulations on "telehealth" issues for anything from signing, to care, to review of those same outcomes present outside CMS standards? For instance, within Florida, telehealth, especially for supervision levels of various medical/dental staff, etc, is not "legal". Yet it is being done routinely, and now brought to the homes, and producing Class II medical devices on site, and no State licensed provider has "seen" the patient.

Whenever these questions are asked, be it at the respective Boards of Dentistry, or in the public realm, the specter of the FTC is always invoked. I want to bring the conversation back to "the care of our patients and the public" as it should be as we move into new aspects of materials and care options going forward. As the Mission Statement for the Florida BOD states in part, "protect the public".... even if it is from themselves at times. We know what the community "stand of care" parameters imply within states. Is this setting a "new normal" for health care moving forward?

In essence, I was hoping to get whatever background and baselines the FDA have referenced in place already as we move forward so that I have all the information to start the process delineating this within our state. Dr. Runner has been very helpful in thoughts to date, but she suggested I reach out to you for, perhaps, a "declaratory statement" of sorts with whatever the FDA may have in place as answers to the above if that is something that is available?

Likewise, if not the FDA, are there other federal regulatory parameters in place that may answer some of the above in different departments I should be reaching out to as well?

I know this may seem like a big lift here, but I promise you we are not the only folks contemplating what the new paradigms of healthcare are bringing going forward. I helped write the ADA Telehealth standards while the Council on Dental Practice Chair there years ago. I know all the potential efficiencies that it will bring to the system, but also the opportunity for abuse. We need to focus on the care of the public we should be serving, whether in our offices or remotely. Is it being done with the thought of "protect the public", even if from themselves or potential abusers of the healthcare system in the name of "access".

I would appreciate any feedback on these issues you may have and how best to proceed from here.

Dentists warn of the dangers of DIY dental care

Do-it-yourself dentistry is ruining mouths and costing families a lot of money. Now, a patient and dentist from Southwest Florida are warning you what to watch out for.

Nancy Kate Barr is from Cape Coral and has worn retainers since she was 15 years old. Recently, she needed new ones.

"I was calling around dentists in the area," she told WINK News. "A lot of them were wanting quite a bit of money for retainers."

She made the decision that hundreds of people make every year and sought help online. Eventually, she connected with a company that helps you do it yourself. "They sent a make-your-own-retainer kit in the mail," she explained.

Making the impressions needed for her replacement was not easy.

"They said, 'you made them completely wrong,'" she explained. Instead of trying again, she got a refund and turned to a local expert, Dr. Phillip Kraver.

"When you talk about DIY dentistry, there are a lot of different ways patients take matters into their own hands for their oral health," Dr. Kraver explained. He helped Barr get the retainers she needed without hurting her smile for about \$150. Not everyone is so lucky. Dr. Kraver added, "one of the things that scares me the most right now is orthodontics."

He says online methods that claim to straighten your teeth can actually do a lot of damage. Teens are putting plastic rubber bands around their teeth and promising others it will close any gaps in videos posted online. Serious damage can be done when those rubber bands work themselves into the gum line and the bone. "Even small movements in your teeth can cause a lot of problems to the whole system," Dr. Kraver said.

That's leading to lost teeth and costly repairs, but it's not just straightening.

"In my practice, we've seen a lot of enamel wear and gum recession from aggressive brushing with very strong whiteners," Dr. Kraver went on to say. That includes activated charcoal pastes which claim to give you a whiter smile, but Dr. Kraver says

they actually do the opposite. "It's not really whitening the tooth itself," he explained. "It's just stripping the enamel off and getting to the deeper levels of the enamel."

He says rather than try to aggressively whiten or straighten your teeth, your best bet is to visit an actual dentist's office.

"We can tell you what's good, what's bad and what to look out for. We can guide you through treatment that will give you the best ultimate outcomes," Dr. Kraver concluded. That's exactly what Barr says Dr. Kraver did for her. "I would've just wasted more of my money," Barr said. "Who knows if I would've been able to make the right impression?"

Dr. Kraver says generally, those teeth whitening strips you can buy at the grocery store are safe to use; they're not removing the enamel from your teeth. Just watch out for products containing chlorine dioxide, which can destroy your enamel. To be 100 percent sure, talk to an actual dentist before making any changes to your teeth.

<http://www.winknews.com/2018/11/16/dentists-warn-of-the-dangers-of-diy-dental-care/>

Dentists Warns of Dangers Linked to D.I.Y. Dentistry

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The popular trend of Do-It-Yourself dentistry is popping up in social media and online videos, but the American Dental Association is warning consumers to steer clear of doing at-home dentistry.

The ADA launched a campaign that strongly discourages the practice of D-I-Y orthodontics because of the potential risks to patients. They warn "If teeth are improperly aligned, gum tissue may be impinged or stripped."

“Ask your dentist if it is okay if I do this,” Dr. Monica Gonzalez, a Miami dentist, told us.

Dr. Gonzalez recommends before doing any at-home dentistry you should consult a medical professional.

Dr. Gonzalez says she recently noticed alarming changes to one of her patients who used an at-home teeth straightening system.

“That’s when I noticed they were not fitting properly,” says Johanna Ley.

Ley bought an at home aligner system she saw advertised on T.V. and visited Dr. Gonzalez months after wearing the system.

She found out the aligners weren’t fitting properly and she was at risk of getting an infection.

“There was a tooth in the back that if she was my patient, if she was my sister, I would have never done any form of aligner system on her, period,” Dr. Gonzalez told us.

Dr. Gonzalez says most of the time aligners move teeth safely, but not everyone is a candidate for this type of teeth straightening.

“There are times it will work, we just have to make sure we don’t have consequences that will be worse in the end,” said Gonzalez.

The ADA encourages consumers to look for the ADA seal of Acceptance on Dentistry products.

We reached out to several companies that sell at-home teeth straightening kits directly to consumers.

One company told us:

“Our team completely agrees with the ADA. Generally, DIY dentistry is a bad idea. Unless of course, it's brushing your teeth. Our direct to consumer model is not DIY.” Another company sent us the following statement, stating their company “is not a ‘do-it-yourself’ service... our service is completely doctor prescribed and doctor monitored. All customers are treated by a dentist or orthodontist, licensed in their state, who creates their customized treatment plan and then monitors the process remotely through the platform with regular check-ins. The customer can connect with their treating doctor at any point through the treatment plan.” Their statement when on to say we “have helped over three hundred thousand people get the smile they love, safely and effectively, while bringing access to the over 60% of the US counties that do not have access to orthodontics for mild to moderate spacing and crowding.”

As for Johanna, she wants to share a lesson she says she learned the hard way.

“There was one tooth that was even pushed back so it is worse than when it first started,” she told us. “If I can help someone make an educated decision, then it’s for the better.”

Johanna told us she did call the company she bought the aligners from and they gave her a full refund.

<https://www.nbcmiami.com/news/local/Dentists-Warns-of-Dangers-Linked-to-DIY-Dentistry-503978281.html>

Reporting In Florida:

- Patient has been harmed or there are dental assistants practicing outside their scope/not being supervised properly
 - Report to BOD at <http://www.floridahealth.gov/licensing-and-regulation/enforcement/index.html> or call 850-245-4474
- Report unlicensed activity to the below. This should be done when there is no patient harm and you want the place to be investigated. But also report it here when there has been patient harm because normally the assistant is practicing outside their scope of practice.
 - <http://www.floridahealth.gov/licensing-and-regulation/enforcement/report-unlicensed-activity/index.html>
 - <https://www.flhealthcomplaint.gov/>

Report to the Food and Drug Administration

- <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>