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November 15, 2021

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D)
Washington, DC 20580
Via online submission at www.regulations.gov

Re: Alabama Board of Dental Examiners, File No. 191 0153

To whom it may concern:

The undersigned group represents orthodontists, dentists, and other medical professionals. We write to express our serious concerns with the FTC's Proposed Order in the above referenced matter (the "Proposed Order").

When the Alabama Board of Dental Examiners (the "Alabama Board") originally passed the rule at issue in this case, it acted pursuant to its mandate, and addressed a subject frequently regulated by dental boards around the nation. In the rule at issue, the Alabama Board required that a certain level of supervision by a dentist (on-site supervision) be present when dental auxiliaries performed a certain task (digital intraoral scanning). These types of rules, known as "scope of practice" rules, are established in every state in the nation. State dental boards (whose members are appointed in reliance on their years of education and experience) seek to ensure that sufficient patient protections are in place when dental tasks are delegated to non-dentists.

The FTC's Proposed Order fails to properly account for the critical role that medical and dental boards play in ensuring patient safety. Second, its provisions go far beyond the issue at hand of on-site supervision by dentists for intraoral scanning. In effect, the Proposed Order significantly restricts the Alabama Board from undertaking *any* further regulation of teledentistry despite clear public health and policy reasons for doing so. In this respect, teledentistry will now be largely unregulated, which is bad for consumers who have come to expect that dental practices are, in fact, regulated. Finally, the Proposed Order does not account for the very real possibility that the structure of the Alabama Board may be changed such that its action may no longer be subject to the antitrust laws. The Proposed Order's failure to account for a potential change in the structure of the Alabama Board renders the Proposed Order directly in

conflict with principles of state sovereign immunity and longstanding Supreme Court precedent.¹ For these reasons, as discussed more below, the undersigned write in opposition to the Proposed Order.²

1. The Proposed Order wrongly ignores the FTC’s duty to protect consumers.

While we understand and acknowledge the FTC’s mandate to enforce the antitrust laws, we have serious concerns about the Proposed Order because it prioritizes antitrust enforcement at the expense of the FTC’s consumer protection mandate to prevent unfair and deceptive trade practices. Indeed, the **protection of patients/consumers is the very reason that Alabama, like every other state, has entrusted** standards of care (as well as licensing and enforcement of the standards of care) to state dental and medical boards.³

State dental and medical boards are comprised of practitioners in their respective fields. The reasoning for reserving matters of clinical practice and standards of care to the judgment of such practitioners is obvious. Dental and medical practice are highly complicated fields requiring many years of education, practice, and specialization. Individuals lacking such background and experience simply do not possess the necessary expertise to establish standards for the profession. It is for this reason that the testimony of an expert witness, most often a practitioner in the relevant field, is nearly universally required to support a medical malpractice claim.⁴

In this case, the procedure at issue (digital intraoral scanning) replaces plaster impressions of the patient’s teeth and is used to create clear aligners that move the patient’s teeth. The digital scans in essence serve as the “blueprint” for creating orthodontic appliances to provide orthodontic treatment. Orthodontic treatment is not a merely cosmetic procedure; it is a complex biological process. Moving teeth improperly through orthodontic treatment (including clear aligners) can result in substantial harm to the patient, including loose teeth, loss of teeth entirely, reduced, or exposed tooth roots, open bite (a condition where the back teeth do not come together), problems with chewing food and other oral function, and temporomandibular joint problems. (These concerns, and the scientific evidence supporting them, are set out more fully in resources published by the American Association of Orthodontists, accessible at orthofacts.org.) This is why states appoint medical and dental experts to regulatory boards, and these are the exact concerns upon which the Alabama Board acted in enacting the rule at issue in this matter.

The Proposed Order, however, essentially ignores the important consumer/patient protection purposes that form the basis of the well-established model of medical and dental boards being entrusted with establishing and enforcing appropriate standards of care. If it is published in final

¹ See *Parker v. Brown*, 317 U.S. 341 (1943).

² The signers of this letter note that they are not expressing an opinion on the clinical advisability of the subject Alabama dental board regulation. That is—consistent with the points raised herein—a discussion best left to the oversight of the Alabama dental board. Rather, the signers of this letter express their concern with the FTC’s overstep into such substantive, clinical matters.

³ See Carlson, D. and Thompson, J., “The Role of State Medical Boards,” American Medical Association, Policy Forum, April 2005, accessible at <https://journalofethics.ama-assn.org/article/role-state-medical-boards/2005-04> (state medical boards establish standards for the profession through their interpretation and enforcement of state medical practice acts).

⁴ See, e.g., *Lang v. United States*, 2018 WL 6011548 at *4 (C.D. Cal. Oct. 31, 2018).

form, it will undercut the clinical expertise of medical and dental boards throughout the United States.

2. The Proposed Order’s prohibitions related to teledentistry are overbroad and restrict the Alabama Board’s ability to ensure patient safety.

According to the Complaint in this matter, the conduct giving rise to a violation of the antitrust laws was limited to: (1) a series of actions taken by the Alabama Board that “operate[d] to prohibit non-dentists from performing digital scans without on-site dentist supervision; and (2) subsequent actions taken to enforce that prohibition.⁵ Section II(A) of the Proposed Order addresses this issue, but Section II(B) goes far beyond, prohibiting the Alabama Board from “[p]rohibiting, restricting, impeding, or discouraging any ... Clear Aligner Platform or [affiliated provider] ... from providing or facilitating the provision of Clear Aligner Therapy through remote treatment.”

The effect of Section II(B) has far reaching consequences beyond the specific rule challenged by the FTC. Most significantly, it effectively prohibits the Alabama Board from regulating teledentistry at all because any generally applicable rule or regulation that applied to teledentistry would, by definition, “restrict” the provision of clear aligner therapy through remote treatment. For example, if the Alabama Board implemented reasonable regulations regarding the security of teledentistry platforms to protect patient health information, such a rule would arguably violate the Proposed Order even though its purpose was entirely legitimate and its effect on responsible clear aligner platforms would be negligible.

Teledentistry is growing rapidly in the United States. This specific trend in dentistry mirrors medical practice in general, where numerous other forms of “telehealth” or “direct-to-consumer” care are growing rapidly. The AAO and other dental associations strongly support the incorporation of teledentistry elements into treatment where appropriate, and where sufficient patient protections are retained, in order to increase access to orthodontic and dental care. However, because of the rapid growth in these areas, and the potential for abuse by providers, medical and dental boards have a strong interest in regulating these areas.⁶ The Proposed Order, however, unnecessarily prevents the Alabama Board from regulating in this area and this could have tangible adverse consequences, namely the physical harm that can potentially result to patients from the misuse of teledentistry.

Adding to this problem is the fact that patients have come to expect that their medical and dental care will be regulated by appropriate authorities. But in the case of teledentistry, this will not be the case if the Proposed Order becomes final, and unscrupulous companies will have an opportunity to take advantage of patients who are unaware that these practices are unregulated.

⁵ See Complaint at P3, 23,24,25.

⁶ Health care professionals are granted license to practice by their state boards. While the U.S. Food and Drug Administration regulates medical devices and has historically limited their use at the prescription and direction of a healthcare professional who has the patient’s best interest in mind. Any therapeutic device, such as clear aligners and intraoral scanners, should fall under this oversight. To the extent that any federal agency has jurisdiction over clinical matters in this area, albeit limited jurisdiction, it is the FDA.

The use of teledentistry in orthodontic treatment—especially in a format where a patient never sees a dentist or orthodontist in person—requires careful supervision by the appropriate regulatory authorities to prevent abuses by treatment providers. This is equally applicable in any other setting in which any type of medical or dental care is administered “direct-to-consumer” and eliminates the direct or in-person supervision by the appropriate medical practitioner.

For this reason, in January 2020, nine members of Congress (including five dentists, three medical doctors and one pharmacist) wrote a letter to the FTC (and the FDA) expressing their “strong support of the FDA and FTC investigating the practices” in the direct-to-consumer orthodontic industry to ensure that providers are “not misleading consumers or causing patient harm.”⁷ In June 2019, the American Dental Association sent a letter to the FTC expressing similar concerns.⁸

In short, Section II(B) of the Proposed Order is overbroad, unnecessary, and potentially harmful to consumers. Rather than outright prohibiting regulation in this area (essentially a “prior restraint” form of regulation), the FTC should simply continue its current practice of monitoring regulations and intervening when it has a specific concern.

3. The Proposed Order does not properly account for potential restructuring of the Alabama Board and therefore is in conflict with principles of state sovereign immunity and longstanding Supreme Court precedent.

In *Parker v. Brown*, the Supreme Court held that states are immune from anticompetitive conduct when acting in their sovereign capacity.⁹ More recently, in *North Carolina Bd. of Dental Examiners*, the Court held that medical and dental boards comprised of market participants are not entitled to such immunity unless acting pursuant to clearly articulated and actively expressed state policy and actively supervised by the state.¹⁰

Given the current structure of the Alabama Board, we understand the FTC’s position that antitrust immunity does not currently apply. This may not, however, always be the case. For example, the Alabama legislature could enact legislation that sets forth specific limitations on teledentistry that are contrary to the Proposed Order. Alternatively, as has been done in a number of states recently, the Alabama Board’s process could be changed so that another government entity makes the final decision on any regulatory changes. The Supreme Court has stated that so long as that entity has the “power to veto or modify particular decisions to ensure that they comply with state policy,” the federal antitrust laws would not apply.¹¹

To properly follow the holdings of *Parker v. Brown* and *North Carolina Bd. of Dental Examiners*, Section II of the Proposed Order should be modified to make clear that the terms of

⁷ See <https://www.prnewswire.com/news-releases/aa-reports-congressmen-write-letter-to-the-fda-and-ftc-regarding-smiledirectclub-while-california-board-of-dentistry-moves-to-dismiss-smiledirectclubs-lawsuit-300993920.html>

⁸ See <https://www.ada.org/en/publications/ada-news/2019-archive/july/association-files-complaint-with-ftc-fda-against-smiledirect-club>

⁹ See 317 U.S. at 350-351.

¹⁰ 574 U.S. 494 (2015).

¹¹ *Id.* at 515, citing *Patrick v. Burget*, 486 U. S. 94, 102-3 (1988).

the Injunction shall only apply to the extent that the Alabama Board is not operating pursuant to a clearly articulated and affirmatively expressed state policy and not actively supervised by the State of Alabama.

Conclusion

For all these reasons, the undersigned write in opposition to the Proposed Order in this matter.

Thank you for your consideration.

Sincerely,

American Association of Orthodontists
American Academy of Pediatric Dentistry
Great Lakes Association of Orthodontists
Middle Atlantic Society of Orthodontists
Midwestern Society of Orthodontists
Northeastern Society of Orthodontists
Pacific Coast Society of Orthodontists
Rocky Mountain Society of Orthodontists
Southern Association of Orthodontists
Southwestern Society of Orthodontists
California Association of Orthodontists
Texas Association of Orthodontists
Illinois Society of Orthodontists