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The Honorable Maura Healey
Attorney General of Massachusetts
Office of the Attorney General
One Ashburton Place, 20th Floor
Boston, MA 02108

Dear Attorney General Healey:

I write on behalf of the Massachusetts Dental Society (MDS), which represents 80% of dentists in Massachusetts, to express the growing concerns of MDS member dentists regarding the consumer safety risks posed by certain retail and virtual orthodontic companies—specifically, those selling “do-it-yourself” (DIY) orthodontic clear aligner therapy. Many licensed dentists in Massachusetts are seeing firsthand the damage caused to patients by these DIY orthodontic products, including pain, loose teeth, and the diminished ability to bite and chew properly.

Since 1841, when Alabama became the first state to regulate dentistry, the American public has broadly accepted laws and regulations governing oral health care. The profession’s regulatory framework, established by state and federal law, has long ensured standards of care, adequacy of training and education for providers, and, above all, safeguards to protect patients. Recently, a new breed of DIY dental companies has exploded into the marketplace. Whether online or at pharmacies, department stores, or other retail outlets, DIY dental companies sell prescription-only devices and teeth straightening services directly to consumers over-the-counter, in apparent violation of federal regulations and state law.

On June 5, 2019, the MDS wrote the Board of Registration in Dentistry to express our concerns that one such company’s ecommerce model of diagnosing, prescribing, and supplying devices for orthodontic treatments constitutes the unauthorized practice of dentistry, presenting significant risks to the health and wellbeing of Massachusetts citizens.¹ On May 8, 2019, a federal court dismissed a claim brought by this same company against the Georgia Board of Dentistry seeking a declaratory judgment that its practice of taking digital images of patients’ teeth in retail locations without an onsite dentist does not constitute the “practice of dentistry or dental hygiene.” The court called the argument “incorrect,” stating that the company’s “acts of taking digital scans of a patient’s mouth for the purpose of having a dentist or orthodontist approve a treatment plan for correcting a malposition of the patient’s teeth falls squarely within the definition of the practice of dentistry” in that state.²

¹ <https://www.massdental.org/~media/MassDental/Members/Advocacy/MDS-TESTIMONY/MDS-Letter-to-BORID6519.ashx>

² <https://www1.aaoinfo.org/wp-content/uploads/2019/05/SDC-v-GA-Board-of-Dentistry-Doc-51-Order-on-Defendants-Motion-to-Dismiss.pdf>

Citing innovation and disruption, DIY dental companies tout their products as the future of the dental profession. Armed with 3D printer technology and digital access to consumers, entrepreneurs have launched retail and virtual platforms to sell relatively inexpensive plastic orthodontic aligners to hundreds of thousands of patients. Consumers can purchase orthodontic aligners online, taking photos and impressions of their teeth at home, or visit a retail shop where an employee helps take 3D scans of their teeth. The availability of these services is only expected to grow, with CVS announcing plans in April to partner with one large DIY dental company to open “hundreds” of their shops within its stores.

Targeting younger adults, DIY dental companies offer a seemingly simple solution to those seeking straighter teeth: snap a picture on your smartphone; bite down on an impression tray; answer some questions; and “snap,” you’ll have access to plastic teeth aligners. At least one DIY business asks seven questions as part of its assessment protocol—and only three have anything to do with teeth. Customer service representatives—not dentists—have near-exclusive control of interaction with patients. Despite advertising claims that DIY dental customers will enjoy the same level of care as they would as patients at their local dentist or orthodontist, the prescription of aligners is predicated on customers signing consent forms certifying that their dentist conducted a mandatory comprehensive oral examination.

This over-the-counter dentistry model reportedly includes “remote” case review for each customer by a licensed dentist. The process is described as “cost-effective” and “convenient.” By any measure, however, these companies promote a standard of care that lacks adequate transparency regarding diagnosis and treatment planning, putting patients at risk for irreversible harm.

The appropriate standard of care for determining the suitability of a person to receive orthodontic treatment requires the performance of a clinical examination and the review of current X-rays by a licensed dentist. Dentists take X-rays in these instances to identify cavities that cannot be seen by simply reviewing a 3-D scan, as well as to determine if there is sufficient supporting bone of adequate density. Without an in-person evaluation including X-rays that could identify undiagnosed dental disease or underlying issues that would make a patient an unsuitable candidate for clear aligner orthodontic therapy, a patient may be exposed to irreversible harm, including potential bone loss, receding gums, changed bites, and other issues. Absent direct oversight and monitoring of a licensed practitioner, increased access to DIY “dentistry” will place members of the public on a path toward unnecessary risk and possible adverse consequences based on marketing promises of easy fixes to complex oral health issues.

While every licensed dentist has an ethical and professional obligation to prevent injury whenever possible, there is no such standard met by DIY dental companies. I have seen firsthand the devastating results of a patient who used mail-order orthodontic aligners and suffered the consequences. She came to my office after many months of using the aligners with “remote” monitoring by a provider, complaining that her teeth were moving. The mobility of this patient’s teeth was so severe that she was referred to a periodontist (gum specialist) for splinting. This damage is irreversible and will require lifelong maintenance. Sadly, I have heard many similar stories from other licensed dentists across Massachusetts. For example, members of the MDS have reported the following cases:

- A pediatric dentist saw a 16-year-old patient who used a remote orthodontic provider to save money. He came in for a routine cleaning and exam after finishing clear aligner therapy and presented with a misaligned bite, which would require repeated orthodontics to fix (at a likely cost of \$5,000 to \$6,000). The dentist reports that the father has contacted the DIY provider several times and they are refusing to help. They have concluded that the case is complete. No refund or attempts to repair will be made.

- A dentist saw a patient who had “finished” her DIY orthodontic treatment, who after treatment stated her front tooth started chipping. The dentist noted fremitus (traumatic mobility or vibration upon closing) upon examination. The patient had trouble reaching anyone at the company who could help set up a refinement of the treatment. The patient required a significant occlusal (bite) adjustment and subsequent bonding, which will require lifelong maintenance.
- An orthodontist frequently sees patients that have quit DIY orthodontic treatment and come to him indicating that they have not seen a dentist and are unclear on how to deal with problems. The orthodontist reports that these patients resort to reading Facebook forums for advice. The patients have described tooth pain and TMJ (jaw) pain prior to discontinuing care.
- An oral surgeon saw a patient who came in because her teeth were not moving during aligner therapy. The patient had implants, which could have been detected with an X-ray and in-person exam, but the patient reported that she never had X-rays prior to treatment.
- An orthodontist saw a patient in his late 30s who had tried DIY direct-to-consumer aligners and, after completing the course of aligners, his teeth were still not straight. He came to the orthodontist asking to have his teeth straightened. Upon examination, the orthodontist said the patient could have benefited from extractions to alleviate the crowding, attachments bonded to his teeth, and IPR (interproximal reduction—mechanically removing enamel from between the teeth to achieve orthodontic ends, such as to correct crowding or to reshape the contact area between neighboring teeth) due to tooth size discrepancies—all solutions that are not available to a consumer using DIY aligners at home.
- A dentist saw a 31-year-old female patient with mild crowding who showed the dentist the digitally projected outcome provided by a DIY orthodontics provider’s website after getting her teeth scanned. The dentist determined that if she moved forward with the treatment shown, it would have caused serious gingival recession and possibly periodontal issues due to her “thin buccal plate and thin biotype and facial movements of the lower anteriors.” The dentist recommended against the treatment and she did not go through with it.
- An orthodontist saw a middle-aged male patient who presented with skeletal class III malocclusion (under bite) and spacing between his teeth. Remote DIY orthodontic treatment to address space closure led to TMD (temporomandibular joint dysfunction, meaning problems with the jaw joint and the muscles around it) and occlusal (bite) issues causing tooth attrition (tooth wear caused by tooth-to-tooth contact, resulting in the loss of tooth tissue). The orthodontist indicated that it should have been a surgical case.
- A general dentist saw a female patient in her mid-twenties who came in for her periodic exam. She had started DIY orthodontics and had developed an anterior overbite due to supraeruption of her posterior teeth as the treatment was possibly not monitored, according to the dentist. She was referred to an orthodontist to correct the issue.
- A general dentist saw a male patient in his early 30s who asked if she could “grind down” a tooth because it was the only tooth in his mouth contacting an opposing tooth after undergoing DIY orthodontic treatment, and it was bothering him to bite this way, i.e., he couldn’t properly chew. The patient had open contacts between all of his teeth and a bite problem. The dentist declined to make any occlusal (bite) adjustment and advised him to contact the company for revision trays or see an orthodontist in person.

The MDS and its member dentists are not alone in expressing concerns over DIY orthodontic services. The Better Business Bureau®’s online portal shows nearly 900 complaints against a single DIY dental company, including patients who reported enamel damage, jaw pain, and tooth loss after using DIY aligners. There are Facebook groups and Twitter handles dedicated to consumer complaints of DIY orthodontics gone wrong. State dental associations are asking tough questions and seeking enhanced scrutiny by state dental boards. Last month, the American Dental Association (ADA) wrote the Federal

Trade Commission to request an investigation of the false and misleading claims made by one DIY orthodontic company to entice consumers to purchase its products and services.³ And, in April, the ADA filed a citizen's petition with the U.S. Food and Drug Administration (FDA) seeking an injunction on the sale and distribution of one leading company's teeth aligners and dental impression material products, asserting that the company is skirting the FDA's "by prescription only" restriction on the sale of plastic teeth aligners.⁴

It's becoming clear that DIY dental companies act as dentists in everything but name. Absent direct oversight and monitoring of a licensed practitioner, increased access to DIY "dentistry" and the promise of an easy fix for complex oral health issues will place too many members of the public on a path fraught with painful, costly, and lasting consequences. With increased access and marketing of these teledentistry platforms at retail locations throughout New England, licensed dentists in Massachusetts expect to encounter more patients whose oral health has been jeopardized by DIY orthodontic devices and the lack of adequate supervision by licensed practitioners.

The MDS believes that it is appropriate and urgent for the Office of the Attorney General to do its part to protect consumers and preserve public confidence in the profession by declaring DIY dentistry what it is—dentistry—and ensuring that this new breed of practitioner is properly licensed and regulated.

On behalf of 5,000 licensed dentists in Massachusetts and the millions of patients we serve, we respectfully ask your office to investigate the practices of DIY dental companies and whether the services offered by these retail and virtual orthodontic companies constitute the practice of dentistry in Massachusetts. If these companies are in fact practicing dentistry, what is the appropriate regulatory framework to ensure consumers are protected?

Sincerely,

Dr. Janis Moriarty
President
Massachusetts Dental Society

³ https://www.ada.org/~media/ADA/Advocacy/Files/190627_ftc_smiledirect_nosig.pdf?la=en

⁴ <https://www.regulations.gov/document?D=FDA-2019-P-2038-0001>