April 25, 2019

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HRA-305
Rockville, MD 20852

Re: Citizen Petition—Misbranding by SmileDirectClub, LLC, of Its Orthodontic Plastic Bracket Device and Dental Impression Material Products

To Whom It May Concern:

The basis for this petition is straightforward: SmileDirectClub, LLC, (SDC) is placing the public at risk by knowingly evading the "by prescription only" restriction that the FDA has placed on plastic teeth aligners[1] and on dental impression material.[2] For all intents and purposes, SDC sells its plastic teeth aligner and dental impression material products to consumers over-the-counter.

Clearly, SDC is not patient focused. In lieu of having dentists perform patient exams meeting the applicable standard of care as the basis for prescribing orthodontic treatment, SDC tries to protect its own commercial interests by requiring customers to self-certify their dental condition and then hold SDC harmless from any negative consequences suffered as a result of SDC's aligner "treatment therapy."

A. ACTION REQUESTED

By skirting the "by prescription" restriction with regard to its devices, SDC is misbranding its products and violating labeling laws. Therefore, Petitioner, American Dental Association, requests the FDA to:

- Move for an injunction against SDC's further sale and distribution of its misbranded teeth aligner and dental impression material products in interstate commerce;

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[1] The FDA Classification Name for these aligner devices is Orthodontic Plastic Brackets (Sequential Aligners), 21 C.F.R. § 872.5470. They are referred to as teeth aligners or plastic teeth aligners herein.
[2] The FDA Classification Name for materials for taking dental impressions, which SDC refers to as "putty", is Impression Material, 21 C.F.R. § 872.3660.

- Seek a condemnation and seizure order directed to SDC's misbranded teeth aligner and dental impression material products being distributed and sold in interstate commerce;

- Levy a significant civil penalty against SDC in connection with its misbranded teeth aligner and dental impression material products being distributed and sold in interstate commerce;[3] and,

- Request SDC to voluntarily undertake a Class II recall of its misbranded teeth aligner and dental impression material products being distributed and sold in interstate commerce.

It is prohibited to introduce or cause to be introduced into interstate commerce any device that is misbranded. Federal Food Drug & Cosmetic Act (FD&C Act) § 301(a) [21 U.S.C. § 331(a)]. Further, it is prohibited to misbrand or cause the misbranding of a device in interstate commerce. FD&C Act § 301(b) [21 U.S.C. § 331(b)]. [4]

The law provides, in part, that, "[t]he district courts of the United States [. . .] shall have jurisdiction, for cause shown to restrain violations of § 331." FD&C Act § 302 [21 U.S.C. § 332]. Petitioner requests the FDA to seek, pursuant to FD&C Act § 302(a) [21 U.S.C. §332(a)], an injunction against SDC from manufacturing or continuing to manufacture and from continuing to distribute and sell in interstate commerce SDC's plastic teeth aligner and dental impression material products. Absent such an injunction there is a likelihood that SDC's misbranding violations will continue.

As provided in FD&C Act § 304(a)(1) & (2) [21 U.S.C. § 334(a)(1) & (2)], any misbranded device, "shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found." Petitioner requests that the FDA bring a condemnation and seizure proceeding directed to SDC's teeth aligner and dental impression material products that are shipped and sold in interstate commerce.

Pursuant to FD&C Act § 303(f)(1)(A) [21 U.S.C. §333(f)(1)(A)], "any person who violates a requirement of [Chapter 9 – Federal Food, Drug, and Cosmetic Act] which relates to devices

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[3] In addition to civil penalties, the FDA can impose criminal penalties under FD&C Act § 303(a)(1) and/or (a)(2) [21 U.S.C. § 333(a)(1) and/or (a)(2)].

[4] Petitioner alleges that SDC violated the following misbranding provisions: FD&C Act §§ 502(a)(1), (f)(1), (o), (q)(1), (q)(2), [21 U.S.C. §§ 352(a)(1), (f)(1), (o), (q)(1), (q)(2)].

shall be liable to the United States for a civil penalty." Petitioner requests that the Secretary of Health and Human Services assess a civil penalty in accordance with the factors relevant to determining the amount of a civil penalty in FD&C Act § 303(f)(5)(B) [21 U.S.C. § 333(f)(5)(B)].

Petitioner respectfully requests that the FDA proceed in accordance with 21 C.F.R. § 7.45 and exhort SDC to undertake a voluntary Class II recall of its plastic teeth aligner and dental impression material products that are shipped and sold in interstate commerce.

Further, Petitioner urges the FDA to undertake whatever additional corrective action it deems appropriate in the light of the facts and circumstances detailed herein.

B. STATEMENT OF GROUNDS

Summary

We live during a time of "disruptive technologies" made possible by advances in material science, biology, digitalization, and even newly conceived business models. Where such developments increase efficiencies, lower costs, and expand access to consumers without increasing significant risks to the public such innovations can provide substantial boons.

But just as assuredly, when increased company profits or purportedly lower costs to consumers result from circumventing established, well-considered public health and safety practices, then the true costs, both in terms of injuries to and ultimate expense for those supposed to benefit, can turn out to be far higher than they are worth. In such situations the word "disruptive" loses its salutary glow. SDC's business practices fall into this latter unfortunate category.

Despite describing itself in FDA filings as a mere "re-packager/re-labeler", or "contract manufacturer", and in court papers as "a dental support organization that provides administrative non-clinical support to dentists and orthodontists..."[5], SDC is involved at every level in the manufacture, product sale, and service business of straightening teeth using plastic aligners, which are Class II devices regulated by the FDA. Plastic Aligners and Impression

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[5] *Scott D. Galkin, D.M.D. and New Jersey Dental Association* v. *SmileDirectClub, LLC, Danny Leeds, D.D.S., Robert M. DeRosso, D.M.D. and Isaac V. Perle, D.M.D.*, MID-C-19-19, Brief in Support of Defendant's Motion to Dismiss, p. 3.

Materials are subject to a "by prescription only" FDA restriction, which SDC effectively eludes. To any extent SDC may have lowered costs it has done so by recklessly selling "do-it-yourself dentistry" over-the-counter to its customers (these consumers are most definitely *customers* and not *patients*).

SDC has virtually eliminated from the process any substantive participation by a dentist in a customer's teeth straightening treatment even with respect to the all-important comprehensive oral examination that should precede prescribing treatment in every instance. Instead, SDC "affiliated dentists" allegedly "assigned to your smile" sign-off on aligner orders solely on the basis of plastic impressions and mouth photos made by SDC customers or 3D scans and photos taken at SDC SmileShops. This approach may be commercially rewarding, but it utterly fails to meet the standard of care for a comprehensive oral examination and does not provide a basis upon which a valid prescription for orthodontic care can be written. [See, generally, Exhibit 5, Affidavit of Dr. Randall Markarian]

1. Regulatory History

To fully understand SDC's serious misbranding violations, it is helpful to briefly review the history of the FDA's regulation of plastic teeth aligners and dental impression materials. From the beginning, these devices have been subject to the "by prescription only" restriction because they cannot be used safely "except under the supervision of a practitioner licensed by law to direct the use of such device." As such, they are exempt pursuant to 21 C.F.R. § 801.109 from the "adequate directions for use" requirement of FD&C Act § 502(f)(1) [21 U.S.C. § 352(f)(1)]. This is because for such devices, "'adequate directions for use' cannot be prepared" for lay consumers. See, 21 C.F.R. § 801.109. SDC does not sell its products to consumers on the basis of valid prescriptions and wholly ignores the fact that "adequate directions for use" for its devices "cannot be prepared" for its consumers.

a. FDA regulation of predicates to SDC's plastic teeth aligner devices

In 1998, Align Technology, Inc., (Align) filed a 510(k) request for clearance (number K981095) to market its plastic teeth aligner product sold under the Invisalign® System brand name. [Exhibit 1, PMN K981095] Align sought clearance for use of its product in the treatment of *mild to moderate* malocclusion. In granting clearance, the FDA designated Align's product a

Restricted Device requiring the label to bear, among other information, that its sale and distribution must be by prescription only in accordance with 21 C.F.R. § 801.109.

In 2008, Align filed its "Modified Invisalign® System 510(k) Premarket Notification" (number K081960). Selected pages from the 2008 filing are attached here as Exhibit 2. Align sought clearance for three labeling changes.[6]

Align explained that its system, "is a **doctor-prescribed** [emphasis added] series of removable plastic orthodontic aligners intended as an alternative to conventional wire and bracket technology." [Exhibit 2, p.6]

The 2008 clearance included the contraindication of "active periodontal disease." [Exhibit 2, p. 4] The 2008 submission also includes the "by prescription only" restriction and contains the following labeling language: **"Caution: Federal law restricts this device to sale by or on the order of a dental professional."** [Exhibit 2, p.15]

In keeping with its Section 510(k) clearance, Align has sold its Invisalign® System through orthodontists and general dentists. The company continues to require dentists who prescribe the Invisalign® System to be trained in the use of the device. Align's *Instructions for Use* are also consistent with the "by prescription only" restriction. [Exhibit 2, pp. 8-14] They are appropriately directed to the treating dentist, and include: A list of conditions to look for or to be aware of in a patient when considering or using the product, a description of various steps the dentist should take during the course of treatment, contraindications, allergy warnings, and reference to the Invisalign dentist training manual. As would be expected, many of these instructions would have very little meaning for lay consumers, and some would be incomprehensible to most.

b. SDC's Plastic Aligner Related FDA Filings

In or around 2014, SDC first registered as a re-packager/re-labeler of Align's Invisalign System plastic aligners under FD&C Act § 510 [21 U.S.C. § 360].[7] [Exhibit 3, Re-packager/Re-labeler

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[6] Align represented that, "[t]he technological characteristics of the modified and currently-marketed predicate device, such as design, raw material, and chemical composition, and their manufacturing process and related software, are identical. [Exhibit 2, p. 7]

[7] It did so under the name Access Dental Lab, LLC.

Registration] It cited Align's 1998 510(k), (No. K981095). As a re-packager/re-labeler SDC should not have modified the indications for use or the restriction that such devices are "by prescription only."

But SDC did so by selling the aligners without a valid prescription, thereby rendering their product an over-the-counter item.

In March 2019, SDC registered itself as a contract manufacturer of aligners. [Exhibit 4, Contract Manufacturer Registration, 3/19] But it appears that SDC is actually a manufacturer of plastic aligners. Whereas a contract manufacturer is defined as an establishment that "[m]anufactures a finished device to another establishment's specifications", and so must merely register with the FDA"[8], SDC manufactures its SmileLab finished aligners in accordance with its own specifications, including information derived from its customers' impression molds or the 3D scans taken of SDC customers at SDC's SmileShops.[9]

As a manufacturer of clear aligners for its own customers, SDC was legally obligated to seek 510(k) clearance, and it would have undoubtedly been subject to the same "by prescription only" restriction as the predicate devices. If SDC then decided to flout the restriction, as it has, it would have put its clearance in serious jeopardy. On the other hand, if SDC believed in good faith that the prescription restriction was somehow unnecessary, it could have explained in its clearance request why that was so.

As either a re-packager/re-labeler or a manufacturer changing the device from "prescription only" to OTC, which is what SDC has done, SDC was required to submit a pre-market notification informing the FDA of the prescription to OTC switch. This switch changed the environment of use of the aligners from use in a professional healthcare setting to that of home use. The FDA's guidance document, *Deciding When to Submit a 510(k) for A Change to an Existing Device*, states at p. 20 that, "changes from professional use to home use [...] are more likely to affect the device's risk profile and require submission of a new 510(k) because the

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[8] See, https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/registrationandlisting/ucm053165.htm

[9] See, Exhibit 15, Q&A #5, "[s]ome aligners are produced by Invisalign and some by SDC's Smile Lab..."

different environments have different levels of professional healthcare supervision and offer different environmental challenges."

Moreover, SDC was legally bound to submit in its 510(k) proposed consumer oriented adequate directions for use in accordance with 21 C.F.R. § 801.5, since its device would no longer fall under the exemption of 21 C.F.R. § 801.109. As the FDA explains: "Directions for use necessary for health care professionals to use a device safely and effectively can be significantly different from the directions for use necessary for lay users to use that same device safely and effectively." *Id.* at 17.

SDC failed to submit a premarket notification with proposed adequate directions for use in connection with its "by prescription" to OTC switch. SDC's aligners are therefore misbranded in violation of FD&C Act §§ 502(f)(1) and (o) [21 U.S.C. §§ 352(f)(1) & (o)]. And, because SDC has circumvented the "by prescription" restriction set forth in 21 U.S.C. § 360(j)(e), instead selling the device OTC, the company is also violating FD&C Act § 502(q)(2) [21 U.S.C. § 352(q)(2)]

c. FDA regulation of dental impression material

Impression material is used to provide models for study and for production of restorative prosthetic devices and the like. Although dental Impression Material is designated a Class II Device under 21 C.F.R. § 872.3660(b), Petitioner has found no evidence that SDC ever communicated at any level with the FDA about the Impression Material it sells to customers through the mail so they can make their own dental impressions that form the basis for the fabrication of their SDC aligners.[10] Such products are definitely subject to 510(k) review and from what Petitioner can determine all of them that have been submitted are covered by the "prescription use" restriction.[11] Presumably, this is due at least in part to the allergy, gagging, and choking risks they pose. [See, infra.]

SDC did not register itself as a distributor, manufacturer, or re-packager/re-labeler of the Impression Material, nor did it submit a new 510(k) clearance upon switching the impression

[10] This is one of two routes available to consumers purchasing SDC aligners, the other is to visit a SDC SmileShop for 3D scans. See, *infra*.
[11] See, e.g., 510(k) Numbers: K082560; K013129; K973781; K972239.

device from prescription use to OTC use. SDC's failures in these regards rendered the device misbranded in violation of FD&C Act § 502(o) [21 U.S.C. § 352(o)] for failure to duly register under § 510 [21 U.S.C. § 360], failure to be included in a list required by § 510(j) [21 U.S.C. § 360(j)], and failure to provide notice and other information as required by § 510(k) [21 U.S.C. § 360(k)].

2. Orthodontic Exam Requirements for a Valid Prescription

Teeth are complex living organs comprising many elements. They have nerves and require blood circulation. Moving teeth that are next to other teeth, are rooted in bone, and are held in place by ligaments is often a complicated procedure dependent on multiple individual variables. There really isn't a "one-size-fits-all" methodology for providing competent, professional orthodontic treatment. Done improperly and without sufficient information the patient may not receive any benefit at all from treatment. Even worse, patients may be severely injured, suffering tooth loss, bone damage, nerve damage, jaw pain, exposed teeth roots, receded gums, aggravated or entirely new bite maladjustments, and other related injuries. [Exhibit 5, ¶ 17]

Without a comprehensive oral examination customers are at significantly higher risk for injuries attributable to their orthodontic treatment. This is why dentists are ethically and professionally obligated to know firsthand, before they prescribe treatment, the state of their patients' oral health. The information needed and the planning required cannot be reliably obtained merely from *customer* made dental impressions, photos, or 3D scans, and it certainly cannot be based primarily on patient self-reporting, which how SDC does things.

It is appalling that a dentist SDC spokesperson minimizes the very real health issues, and denigrates those who raise them with comments like, "[l]ook, this isn't rocket science or brain surgery, this is just moving teeth. Teeth move on their own all the time..."[12] The FDA clearly sees things differently from the SDC spokesperson, recognizing that "just moving teeth" requires expert knowledge and experience. That is why the FDA has designated plastic aligners and impression materials as "by prescription only" devices.

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[12] See, page 18, infra. This spokesperson goes on to say that dentists who raise these potential problems are "fearmongering", page 19, infra.

If a patient has had a dental checkup in the recent past, the dentist evaluating the patient for orthodontic treatment can obtain a great deal of necessary information from reviewing the patient's dental record. It will show the last time the patient had a teeth cleaning, state whether the patient has active caries, which aligner therapy can aggravate, identify any crowns, bridges, implants, or other restorations and the state of those restorations (e.g., loose, broken, or missing fillings), which aligners can break, indicate whether an oral cancer screening was performed and its results, list any medications the patient is taking, detail any restricted airway issues caused by the patient's tonsils or otherwise, which can present problems for orthodontic treatment, note the presence of chronic dry-mouth conditions, which can combine with orthodontic treatment in promoting tooth decay, and note whether the patient exhibits periodontal disease. [Exhibit 5, ¶¶ 8, 9]

A dentist evaluating a patient for orthodontic treatment will confirm what is in the patient's dental record by conducting his or her own examination of the patient. Of course, the treating dentist is responsible for filling in any relevant gaps in the record. This is a fundamental step in meeting the standard of care prior to prescribing treatment. For example, because the presence of periodontal disease is such a strong contraindication for aligner or other orthodontic treatment, the dentist should conduct a periodontal exam, including probing the patient's gums to discover any bleeding or tissue swelling, loss of attachment or bone loss, and to check for any loose teeth. The examining dentist will also take into account the shape and dimensions of the patient's palate. [Exhibit 5, ¶¶ 10, 22]

Reviewing radiographs is essential and not optional as well. With regard to periodontal health and related issues, orthodontic treatment should never be commenced until the health of the patient's maxillary and mandibular bones are assessed. Any bone deterioration, whether caused by trauma or infection, will profoundly affect the nature of the patient's treatment, unless treatment is ruled out entirely. Radiographs are central to this inquiry, unless the severe state of periodontal disease and bone loss is so evident from close visual observation and probing that treatment can be ruled out on that basis alone. [Exhibit 5, ¶¶ 11-14]

Correcting the results of poor treatment, to the extent it can be corrected, can be very expensive, time consuming, and sometimes painful. These conditions can be very difficult, painful, and expensive to correct, to the extent correction is even possible [Exhibit 5, ¶¶ 17] as

some SDC patients have learned to their chagrin. [Exhibit 6, Better Business Bureau complaint, 8/6/18, "excruciating pain, possible nerve damage"; Exhibit 7, Better Business Bureau complaint, 10/30/18, teeth fanned out, roots showing through gums; Exhibit 8, Better Business Bureau complaint, 8/20/18, after treatment mouth doesn't close all the way, back teeth don't touch, jaw pain from bite problem; Exhibit 9, Better Business complaint, 11/9/18, cannot fully close bite, have problems with chewing]

It is impossible for Petitioner to know with certainty how many similar injuries to patients have occurred. One of the reasons for this is that a condition for settling a complaint against SDC is that the customer agrees not to discuss the issue with third parties, and the other is that Petitioner has not taken formal discovery of SDC. And, of course, some customers may not bother to report problems because of the disclaimer language contained in the SDC contract documents (see, infra.)

The risk of severe patient discomfort and injury are greatly decreased, or can be swiftly corrected, if a) the patient undergoes a complete orthodontic exam prior to being prescribed orthodontic treatment or, b) the patient receives follow-up care from the prescribing dentist. [Exhibit 5, ¶ 18] The whole reason for developing a doctor/patient relationship and providing professional care to a patient is the recognition that every patient is an individual and so prescription of treatment is based on that patient's unique set of oral health issues. [Exhibit 5, ¶ 17] The cold business calculation that a percentage of bad outcomes is just a cost (for the customer affected) of doing business is inimical to professional healthcare.

Moreover, it is not just the relatively rare conditions that SDC and its affiliated dentists overlook. Without really knowing whether a customer has unerupted wisdom teeth or supernumerary teeth, or periodontal disease, or shortened or reabsorbed roots, or loose fillings, crowns, and bridges, or temporomandibular joint dysfunction (TMJ),[13] SDC and its affiliated dentists are just taking a shot-in-the-dark when they sell aligners to customers. It is the customers, not they, who pay the price.

[13] This painful jaw condition can be aggravated by orthodontic treatment or may even be caused by poorly fitting devices.

3. SDC's Marketing and Customer Service Business

SDC's regulatory shortcuts and failure to ensure that its products are only sold subject to a valid prescription have certainly not hindered SDC's sales efforts across the country. SDC has created a huge market presence for itself. The company advertises extensively in broadcast and print media and is prominent on social media. Although it based its re-packager registration on Align Technology's superseded 1998 PMN, which was limited to using plastic aligners to correct mild to moderate malocclusion, and has represented in court proceedings that its product is limited to such applications[14], its advertising does not appear to conspicuously explain that limitation and its marketing photos strongly imply otherwise.

In fact, any number of photos (including "before and after photos") SDC displays on its website, product packaging, and social media either show examples of severe malocclusion, or misleadingly suggest that its product can be used to treat severe malocclusion. [Exhibit 10, SDC photos] One photo shows a customer with active periodontal disease [Exhibit 11] which is the listed contraindication for Align's predicate device.

On SDC's website, customers are asked to fill out a short questionnaire. The questionnaire asks for seven pieces of information, three of which pertain to a customer's teeth. The consumer is asked to compare his or her teeth to three photos showing mild to extreme teeth crowding and to three others showing mild to extreme gaps between teeth. An individual self-reporting that he has both extreme crowding and extreme gaps received the almost immediate reply from SDC that "You're a great candidate." [Affidavit of Nicholas Lewis Ramirez, Exhibit 12, ¶¶ 8,10; Aff. Ex. A]

A follow up email from SDC urges the potential customer to either visit a SDC SmileShop for 3D scans, or to register with SDC to receive dental impression material from which to make his own dental impression. The email states, **"[SDC] has helped thousands of people who had bite issues like yours."** [Emphasis added] [Exhibit 12, ¶ 11; Aff. Ex. B]. Yet the Informed Consent section of SDC's "Consent and History" form, which the customer must sign before receiving aligners, requires acknowledgement that, "I further understand that my invisible aligner therapy

[14] *Scott D. Galkin, D.M.D., et al.* v. *SmileDirectClub, LLC, et al.*, MID-C-19-19, Brief in Support of Defendant's Motion to Dismiss, p. 3.

treatment will address only the alignment of my teeth **and will not correct my existing bite condition**." [Emphasis added] [Exhibit 13, SDC "History and Informed Consent Form, p. 4] Neither in the first follow-up email or in a subsequent marketing email from SDC's Chief Dental Officer is the potential customer told that a dentist will *prescribe* the customer's aligner treatment. Instead, SDC uses words like "guide your smile", and "approve your treatment plan." [Exhibit 12, Aff. Ex's B and C]

The most egregious example of SDC's false and misleading advertising is the representation made through SDC's Chief Dental Officer, Dr. Jeffrey Sulitzer, that:

> An individual who is requesting treatment by using SmileDirectClub' aligners is receiving the same level of care from a treating dentist or orthodontist as an individual visiting a traditional orthodontist or dentist for treatment.

Dr. Sulitzer continues:

> We define quality as the intersection of customer satisfaction and the Standards of Care. ... We utilize the Standard of Care established by the dental professional community.

[Exhibit 14, *The Grin Life,* SDC Blog, 4/3/2018, p. 10]

Of course, this is not true because there is no patient exam and so no valid prescription for treatment, and no follow up care, which are requirements of the minimum standard of care. With respect to the issue of follow up care, SDC even leaves it to customers to cut and reshape their aligners if they don't fit. [Exhibit 15, Facebook Q & A with Dr. Ben Burris, member SDC Clinical Advisory Board, 5/13/17, Q&A #19] Some SDC customers have bristled at this. [Exhibit 16, Better Business Bureau complaint, 7/10/2018]

SDC has made seriously false and misleading statements to its customers, some of whom have provided their specific examples. One concerns the issue of "bite correction." The customer told SDC that his goal was to have his underbite corrected, and was told that he was good candidate for SDC aligner treatment. But when the treatment failed and he protested, SDC directed him to the fine print of the Consent and History form stating that its aligners cannot correct bite problems. [Exhibit 17, Better Business Bureau complaint, 8/9/17; see, also, p.11, supra.].

These examples of false and misleading advertising statements violate FD&C Act § 502(a)(1) [21 U.S.C. § 352(a)(1)] because they, "fail to reveal facts material in light of such representations or material with respect to the consequences which may result from the use of the article to which the labeling or advertising relates under the condition of use prescribed in the labeling or advertising thereof." FD&C Act § 201(n) [21 U.S.C. §321(n)]. They also violate FD&C Act § 502(q)(1) [21 U.S.C. § 352(q)(1)] because the advertising for the aligner, a restricted device, was false and misleading.

a. The impression kit route to obtaining SDC aligners

SDC sells "New Smile Kits" in retail stores including Macy's, CVS, and Bed Bath and Beyond that customers must register with SDC. It also sells kits directly to consumers on its website, in which case the kits "come preregistered." [Exhibit 18, SDC document] These kits are cube shaped boxes containing on their exteriors large print marketing language and photos. [Exhibit 19, picture of a portion of a "New Smile Kit"] On the upper right hand corner of one side of the box "rx" appears in very small print, especially when compared to the other printing on the box. [Exhibit 20, picture of side of box with "rx" in corner] The kits are shipped to customers or purchased at point of sale with no waiting time or prescription required. [Exhibit 12, ¶¶12,13] "New Smile Kits" contain a number of items, including three sizes of impression trays "for sizing", a "premium whitening pen", lip balm, "a Smile Stretcher for photos", and *New smile guide* booklet [Exhibit 21, SDC booklet], and a registration card. [Exhibit 22, SDC Registration Card] There is also promotional material for a tooth whitening light that can be plugged into a cell phone, for use with the "premium whitening pen".

Once the customer sends in the registration card with his or her best guess as to the size impression tray he or she needs, the Smile kit becomes "registered" and the customer receives by overnight delivery the SDC Impression Kit comprising the impression material and the actual impression trays provided in the size designated by the customer. [Exhibit 23, screen grab of SDC Impression Kit website page,] The registration card includes the extremely misleading statement that the impression material is being sent, "on your doctor's behalf." The SDC "affiliated dentist" who is allegedly "assigned to oversee [the customer's] smile" [Exhibit 22] and on "whose behalf" the impression kit is sent, knows nothing about the customer, and certainly has no information needed to write a legitimate prescription.

After mixing the two-component "putty", the customer loads it into the trays and makes two impressions each of his or her upper and lower teeth.[15] The upper impression tray does not include the portion needed for taking an impression of the customer's palate. This renders the tray incomplete because a palate impression is an important tool used to properly register the molds of the upper and lower bites with each other and helps in determining the nature and full extent of an individual's orthodontic issues. [Exhibit 5 ¶¶ 23] The SDC customer's amateur mouth photographs (see, *infra*), may fail to reveal the extent of the problem or its existence at all. [id.]

At the same time the customer provides SDC with the impressions, she or he must upload photos, taken by cell phone or other camera, of the customer's mouth. Instructions on how to use the Smile Stretcher for this activity are included in the *New smile guide* booklet. [Exhibit 21, pp. 10-13; Photocopy of Smile Stretcher device, Exhibit 24]

As Dr. Markarian explains, it is difficult for a trained, experienced professional to make good dental impressions of a patient's teeth even in the controlled environment of an office equipped to take and retake such impressions, and it is important to be able to see and examine the patient while the impressions are being taken. [Exhibit 5, ¶¶ 19, 20] In addition, there is the possibility that a person will experience an allergic reaction to the impression material, sometimes serious enough to require medical intervention. If a person suffers an allergic reaction, or gagging, or choking while trying to self-take his or her own dental impression, the quality of the impression will likely be compromised and either have to be taken again somehow, or an alternative method will have to be used. [Exhibit 5, ¶¶ 21, 22]

As for the required customer taken photos, because of lighting issues, the photographer's lack of skill, and the fact that the photos cannot be compared to the live customer either in person or via a suitable teledentistry platform, they are almost inherently of little clinical value. For example, they may not properly show the position and alignment of the customer's molars, which should be a major factor in determining whether to provide a customer with SDC plastic aligners, which only move front teeth. Customers are likely to take misleading, unrevealing

[15] Since the "affiliated dentist" assigned to "oversee" the customer's "new smile" never actually sees or talks to the customer, not even via SDC's purported "teledentistry platform," one wonders how SDC knows which impressions to choose for manufacturing the aligners.

photos, in spite of SDC's brief instructions to the customer on the subject. Even experienced dentists can have issues evaluating photos they have taken in their offices using special equipment, which is why access to other information and to the patient is so important. [Exhibit 5, ¶ 24]

For those customers who choose the "make your own dental impression route" the steps described above comprise the sum total of the "examination" the customer undergoes prior to receiving SDC's "clear aligner therapy treatment". There is virtually no information provided to SDC from which an informed, valid prescription for orthodontic treatment can be written.

b. SDC's "SmileShops" route to obtaining SDC aligners

SDC also sells its plastic aligners through its "SmileShops". These are brick and mortar locations where customers have their mouths scanned by SDC "SmileGuides" using 3D hand-held scanners, which provide the digital equivalent of a physical dental impression. SDC promotional literature clearly shows that, just like SDC's incomplete upper impression trays, its scans do not provide any information about the state of a customer's palate. [Exhibit 25, post from SDC's Instagram page]

It is unclear what level of training or expertise the "SmileGuides" have, but SDC represents that at least some are dental assistants or dental hygienists. The SmileGuides also take photos of the customers' mouths.

Scans and photos, just like impressions and photos, can be two valuable tools used in the fabrication of plastic aligners. Looking at them does not constitute an orthodontic examination, however, and provides very little, if any, reliable information about a patient's underlying oral health. Writing prescriptions, if that is really even done, on the basis of such insufficient medical information is a sham.

4. SDC's Business Model Does Not Include the Use of Valid Teledentistry

SDC tells its customers that they are served through teledentistry. [See, e.g., Exhibit 21, p. 8, Exhibit 22] Photos and scans are reportedly uploaded and sent electronically to SDC for alleged review by "affiliated dentists", and aligners are produced and sent to the customer as a result. That seems to be pretty much it. No doctor-patient interaction takes place. Customers are not

required to upload or otherwise provide their existing dental records and, of course, there is absolutely no dental examination, remote or otherwise, conducted by the SDC affiliated dentists.[16] SDC never states that it provides environments where true teledentistry can be conducted because it doesn't provide them and the company does not claim that the "affiliated dentists" do either. What SDC does is not valid teledentistry first and foremost because it is not valid dentistry.

Without a doubt, sufficiently robust teledentistry platforms make it possible to expand patient access to quality care. Petitioner's support for safe and effective teledentistry modalities is one of its Current Policies. [Exhibit 26, Comprehensive ADA Policy Statement on Teledentistry, Current Policies, Adopted 1954-2018] Included among the important elements of an acceptable telehealth platform, but which are not part of what SDC offers, is "live, two-way interaction between a person (patient, caregiver, or provider) and a provider using audiovisual telecommunications." It should also require that patient dental records be furnished for review over a secure system.

The ADA policy points out that:

> The dentist is responsible for, and retains the authority for ensuring, the safety and quality of services provided to patients using teledentistry technologies and methods. **Services delivered via teledentistry should be consistent with in-person services,** and the delivery of services utilizing these modalities must abide by laws addressing privacy and security of a patient's dental/medical information. [Emphasis added] [17]

SDC's claims that it serves customers through "teledentistry" cannot paper over the non-existent orthodontic examination and care its customers receive from SDC's "affiliated dentists." They do not interact with customers in real time or in any other way despite SDC representations to customers that they are able to "chat with your dental team whenever you'd like."

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[16] Petitioner knows of exactly *one* (1) instance where a patient's general dentist was asked to clear him for SDC aligners.

[17] The ADA Policy supporting teledentistry is consistent with the views of both the U.S. Federal Trade Commission (see, e.g., 8/3/16 FTC Opinion Letter to Delaware Board of Occupational Therapy Practice) and U.S. Department of Justice (see, e.g., 11/29/16 Opinion Letter from the DOJ Antitrust Division to Senator Peter MacGregor, Michigan State Senate).

What SDC means by "chatting with your dental team" is engaging in on-line exchanges with SDC's customer services department or social media team. The responses often appear to be automated and sometimes extremely frustrating. [Exhibit 27, 4/5/19 exchange on SDC website between customer Jessica Cheaves and SDC's "dental team"]

Customer "chats" included here confirm that: a) customer dental exams are not conducted by the affiliated dentists; b) submission of dental records to the affiliated dentists is not required in order to buy aligners from SDC; and, c) customers deal almost exclusively with sales representatives or marketing teams and not dentists in connection with their SDC "treatment." [Exhibit 28, 1/28/19 Yelp Review by ZY reporting that his wisdom teeth erupted during treatment and SDC response; Exhibit 29, 4/6/19 Facebook post by Myhoa Tran showing ill fit of aligners and efforts at resolution; Exhibit 30, 2/5/19 Yelp Review by Garrett F. concerning dental issues and SDC response; Exhibit 31, Facebook post 4/11/19 by Nicholas Stevens about treatment problems and SDC response][18]

Of course, doctor-patient interactions would not occur on public forums, but there is no indication that the social media team's invitation to "please send us a private message" ever leads to a dentist-patient interaction. This is consistent with SDC's business model. If SDC actually did provide a teledentistry platform the patient could make an appointment with the "dentist assigned to your smile" and not have to post on social media at all.

5. SDC's "Consent and History" Form is an Attempt to Disclaim Liability for Failing to Conduct a Patient Exam that Approaches the Standard of Care

As members of a learned profession, dentists are bound by ethical considerations and duties that are not generally imposed on commercial enterprises. It is their professional responsibility to satisfy themselves with sufficient evidence and information that the treatments they are prescribing for their patients are appropriate and safe. In order to make this determination they can review patient records compiled by other dentists and they should conduct their own patient examination as well.

[18] Petitioner acknowledges that SDC also receives positive customer reviews.

SDC and its affiliated dentists do not follow this approach, and perhaps the most damning evidence disproving SDC's advertising claim that its customers get the "same level of care from a [SDC] treating dentist or orthodontist as an individual visiting a traditional orthodontist or dentist for treatment" [Exhibit 14], is its own Consent and History form that it makes customers sign. Instead of conducting a competent orthodontic exam SDC affiliated dentists rely on customer self-reporting. The form provides that:

> By signing this Informed Consent, I understand that I am certifying that: My dentist cleaned my teeth. My dentist took x-rays of my teeth. My dentist checked for and repaired cavities, loose or defective fillings, crowns or bridges. My dentist checked my x-rays and I have no shortened or resorbed roots. My dentist checked my x-rays and I have no impacted teeth. My dentist has probed or measured my gum pockets and says I do not have periodontal or gum disease. My dentist preformed a full oral-cancer screening in the last 6 months and I do not have oral cancer. I have no pain in any of my teeth. I have no pain in my jaws. I have no loose teeth. I have no "baby teeth" and all of my permanent teeth are present.

[Exhibit 13, pp. 3-4] This self-certification is SDC's and the affiliated dentists' substitute for an exam. The customer is not asked to produce any of these records or any other evidence of oral health. Lay self-reporting does not meet the examination Standard of Care for writing a prescription for orthodontic treatment. Lay people are not expected to be familiar with specialized technical or medical vocabularies. Some may think that "periodontal" refers to a type of flying dinosaur.

Apparently, however, SDC and the affiliated dentists believe they are professionally off the hook once the customer signs the form. Dr. Burris explained in his Q & A's that one of the things that really impressed him about SDS's business is, "how brilliant and **legal** it was..." [Emphasis added] [Exhibit 15, Q&A #1] The following shows how important Dr. Burris considers the Consent form:

> 12. What would you say we have to be most vigilant about, knowing we don't see a dentist in person specifically about the aligners? What would be the red flags to look out for?
>
> 1. **Well first, every SDC patient signs a document** saying they are under the care of a dentist and I'd recommend cleaning and checkups every 6 months or every three months while in treatment just like I do with in office patients...Look, this isn't rocket science or brain surgery this is just moving teeth. Teeth move on their own

> all the time and despite all the fearmongering from dentists and orthodontists trying to scare people out of SDC "**there is very little that can go wrong if you are honest on your health history** and keep your teeth clean." [Emphasis added]

[Exhibit 15, Q&A #12]

The Question contains an unambiguous statement that customers are not examined by SDC affiliated dentists (whether face-to-face or via teledentistry), and the Answer includes the admission that SDC affiliated dentists don't review any customer dental records. So how can they write a professionally valid prescription for orthodontic treatment? They can't.

The SDC affiliated dentists don't get paid much. In 2017 this exchange took place with Dr. Burris:

> Q. I have one nagging question. Do you have a financial interest as an investor in SDC?
>
> A. Yup. I get paid 50 whole dollars **for each case that I approve** and the customer accepts (buys) just like every other ELP! ... [emphasis added]

[Exhibit 15, unnumbered Q&A, p.9). It is disappointing, but perhaps not surprising, that the SDC affiliated dentists may not endeavor to meet the standard of care because of the small amount of money they make on a per customer basis. What is shocking is that they only get paid if they "approve treatment" (n.b., he doesn't say "prescribe treatment"). This presents a conflict of interest, suggesting the possibility that treatments are being approved that should not be. The affiliated dentists also have the incentive to spend as little time as possible on each case in order to maximize their "approval" volume. This is consistent with the no-exam/patient self-certify model SDC has chosen.

One other aspect of the form helps to illustrate SDC's approach to its customers. Although it is not directly related to the violations by SDC of the FDA's "by prescription" restriction, it is telling. Specifically, the form includes a section titled in bold, large type, "AGREEMENT TO ARBITRATE". This provision appears to provide recourse to customers who believe they have an actionable dispute against the company or the affiliated dentists. [Exhibit 13, p. 3] But, in the second to that last paragraph of the document, which otherwise seems to be exclusively

directed to a photo release, appears the following sentence, tucked into the middle of the paragraph:

> I release SmileDirectClub from liability or any claims by me or any third party in connection with my participation or use of the invisible aligner therapy treatment.

[Exhibit 13, p. 4] This blanket waiver, hidden in a photo release, is an attempt to bar actions against even malpractice, which is prohibited virtually everywhere. Physicians and dentists cannot shirk their duty to their patients to meet the applicable standard of care and then escape the consequences by disclaiming liability through use of an illegal contract provision. But SDC, in small print, tries to do just that and may be counting on the fact that their customers will be fooled.

Whereas the motto of the health professions is, "first, do no harm," it is apparent from SDC's "Consent and History" form that SDC's motto is "buyer beware." That is not acceptable in the healthcare arena.

CONCLUSION

SDC's process for providing teeth aligners to its customers to correct malocclusion falls far short of even the most minimally acceptable standard of care. It is so woefully deficient in this regard that any putative "prescriptions" generated as part of its customer transactions are no more than technical formalities without medical support or basis. They are pretexts, mere fig leaves intended to hide the company's substantial, knowing non-compliance with the pertinent labeling and safety laws.

The instant Petition is submitted in an effort to vindicate important regulatory principles, namely, that it is a serious violation of the law for a company distributing a restricted Class II medical device in interstate commerce to use false and misleading statements to entice consumers and to skirt restricted device prohibitions by declaring technical compliance with the statutes and regulations without substantive compliance. Enforcement against SDC will deter others in the industry from engaging in the same or similar conduct as SDC.

C. ENVIRONMENTAL IMPACT

The action(s) requested are categorically excluded from the requirement to provide an Environmental Assessment or Environmental Impact Statement under 21 C.F.R. §§ 25.30(a)-(d).

D. ECONOMIC IMPACT

It is our understanding that detailed information on this subject is to be submitted only when requested by the Commissioner following review of the petition.

E. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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Sincerely,

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