Summer is in full swing, which means that the temperature is rising and schedules are getting busier as we push to that magical day when the first yellow school bus drives by and we can cheer that we survived another August crunch!

If you can find a few minutes of downtime, I thought I'd use this newsletter to update you about AAO concerns with Smile Direct Club. Get yourself a nice cold Corona and enjoy reading the update. Since Congress is taking a vacation to recover from months of fighting with each other (er, I mean their many months of tirelessly collaborating to try to pass legislation to improve the state of our country and better the lives of the America people...insert eyeroll emoji), there isn't much to report on the federal legislative front at this time. I will have more updates on that in the fall newsletter, after I attend our COGA meeting in October.

The excerpt below from the AAO summarizes the concerns with Smile Direct Club's treatment model:

ST. LOUIS, July 2, 2019 /PRNewswire/ -- The American Association of Orthodontists ("AAO") has serious concerns about direct-to-consumer orthodontics when it sees over 935 "Customer Complaints" on the Better Business Bureau's website for SmileDirectClub, LLC ("SmileDirectClub" or "SDC"), as well as other reviews and stories where individuals are claiming issues with certain direct-to-consumer companies.¹ Some of the reports of alleged health and/or treatment issues involving direct-to-consumer orthodontics appear to be at odds with SmileDirectClub's claim that "There's nothing really harmful with clear aligners. That's one of the best things about this is you can't really hurt people with this, which is nice."² The AAO disagrees with SmileDirectClub's statement because orthodontic aligners are meant to **move teeth**, which if not done correctly can lead to potentially irreversible and expensive damage such as tooth and gum loss, changed bites, and other issues – some of which may not arise immediately.

The AAO is also concerned about some entities claiming that certain direct-to-consumer activities do not constitute the practice of dentistry. On May 8, 2019, a federal court in Georgia found that a direct-to-consumer company's – SmileDirectClub's – "acts of taking digital scans of a patient's mouth for the purpose of having a dentist or orthodontist approve of a treatment plan for correcting a malposition of the patient's teeth falls squarely within the definition of the practice of dentistry" under Georgia's laws.³ As for SmileDirectClub's argument that its "acts of providing digital scan services" fall "outside the regulatory jurisdiction of the Georgia Board of Dentistry," the Court found SmileDirectClub's argument as being "incorrect."⁴

The AAO believes it is in the best interest of patients to have orthodontic treatment conducted under the direct and ongoing, in-person supervision of a licensed

orthodontist. SmileDirectClub's current Consent and History form even requires a potential patient to agree:

"I further understand that my clear aligner therapy treatment will only address the alignment of my teeth and will not correct my existing bite condition. <u>In order to correct the current condition</u> of my bite, I will need to seek more comprehensive treatment via my local dental professional. Because I am <u>choosing not to</u> engage the in-patient services of a local dental professional, I understand and accept that my <u>teeth will be straighter than they</u> <u>currently are but may still be compromised.</u>" ⁵ (Emphasis added).

The AAO believes there are many questions to consider for those looking into direct-toconsumer treatment, including those found in the AAO's Consumer Alert "<u>Questions to</u> <u>Consider When Researching Direct-To-Consumer Orthodontic</u> <u>Companies.</u>" *See* <u>https://www.aaoinfo.org/_/online-orthodontic-companies/</u>.

As part of this discussion, the AAO is including information on the following:

- Dental Boards' Jurisdiction
- Legal and Advocacy Developments
- SmileDirectClub's Consent and History Form
- Certain SmileDirectClub Representations
- SmileDirectClub's Affiliated Doctors
- SmileDirectClub's Price

DENTAL BOARDS' JURISDICTION

The field of dentistry and dental practices are subject to numerous laws and regulations, many of which have provisions for civil and/or criminal penalties for violations.⁶ When it comes to certain dental issues, individuals and patients can choose to contact their state, territory, or provincial dental boards or authorities (<u>https://www.aaoinfo.org/aao/state-dental-board-info</u>) (last visited June 29, 2019), their state Attorney General's consumer protection office (<u>https://www.usa.gov/state-consumer</u>) (last visited June 29, 2019) or provincial consumer affairs office

(<u>http://www.consumerhandbook.ca/en/contacts/provincial-territorial-offices</u>) (last visited June 29, 2019), regulatory agencies like the Food and Drug Administration ("FDA") – (<u>https://www.fda.gov/about-fda/contact-fda</u>) (last visited June 29, 2019), and their elected officials (e.g. Governor, state representative, etc.) about such issues.

SmileDirectClub even addresses the following question:

"If you are injured or have another dispute involving your orthodontic treatment, how is it handled (litigation, arbitration, etc.)? State dental boards have their own complaint processes for patients who have had issues with orthodontic treatment." ⁷

SmileDirectClub's answer to this question is, "Disputes are handled in the same manner as they are in the traditional setting." ⁸

In May of 2018, SmileDirectClub filed a lawsuit against the Georgia Board of Dentistry (the "Board") in federal court.⁹ The lawsuit arises out of a rule (Georgia Rule 150-9-.02(3)(aa)), which requires "digital scans for fabrication [of] orthodontic appliances" to be performed by an expanded duty dental assistant acting under the direct supervision of a licensed dentist. On May 8, 2019, the Court entered an Order dismissing a majority of SmileDirectClub's claims in the lawsuit, including claims against the Board members seeking monetary relief. The Court also found that "SmileDirect's acts of providing digital scan services" does constitute the practice of dentistry under Georgia law.¹⁰

The Georgia Court's Order aligns with the AAO's belief that dental boards and regulatory authorities have jurisdiction and can regulate SmileDirectClub's "network of affiliated licensed dentists and orthodontists" who SmileDirectClub states "are licensed to treat patients in all 50 states, Washington, DC, Puerto Rico, and the provinces in Canada where [SmileDirectClub's] affiliated dentists and orthodontists treat patients."¹¹ Even SmileDirectClub has said, "doctors that are affiliated with us . . . [are] also regulated by the dental boards."¹² Given the foregoing, the AAO hopes dental boards and regulatory authorities take the appropriate steps as it relates to their dental laws.

LEGAL AND ADVOCACY DEVELOPMENTS

As set forth below, the AAO has advocated for what it believes are safeguards and appropriate oversight for patient health and safety in orthodontic treatment models.

 In a lawsuit filed by SmileDirectClub against the Georgia Board of Dentistry¹³, the Court recently entered an order dismissing a majority of SmileDirectClub's claims, dismissed the monetary claims against the Board's individual members, and found that SmileDirectClub's "taking digital scans of a patient's mouth...falls squarely within the definition of the practice of dentistry" under Georgia law.¹⁴ The AAO filed a brief in support of the Georgia Board's position, including arguing that SmileDirectClub's acts of taking digital intraoral scans of patient's teeth constitute the practice of dentistry.

- 2. SmileDirectClub also filed a lawsuit in federal court against the Board of Dental Examiners of Alabama.¹⁵ The AAO filed a brief in support of the Board's position because the AAO has a significant interest in the outcome of the case as it involves the health, safety, and well-being of patients seeking orthodontic care. On April 17, 2019, the Court dismissed the majority of SmileDirectClub's claims against the Board and no claims are able to proceed against the Board's members in their individual capacities.¹⁶
- 3. The AAO filed complaints with 36 state dental boards and authorities against SmileDirectClub, alleging specific regulatory and statutory violations. For many of those complaints, the AAO is awaiting a final determination.
- 4. The AAO submitted to the United States Federal Trade Commission ("FTC") a twenty-plus page petition to initiate enforcement action against SmileDirectClub. The AAO is awaiting the FTC's response.
- 5. The AAO sent a letter to the Food and Drug Administration ("FDA") regarding SmileDirectClub, asking the FDA to investigate whether SmileDirectClub's sale and distribution of dental aligner devices is consistent with applicable law and that the appropriate action be taken with respect to SmileDirectClub's former and continued sales and distribution of dental aligners. The AAO is awaiting the FDA's response.

SMILEDIRECTCLUB'S CONSENT AND HISTORY FORM

SmileDirectClub addresses the following question on its blog:

"If you are injured or have a dispute involving your orthodontic treatment, what rights do you have against the person or company involved with your orthodontic treatment?"¹⁷

In answering this question, SmileDirectClub states: "Your rights and disputes are handled in the same manner as they are in the traditional setting."¹⁸ At the same time, SmileDirectClub's Consent and History form requires the potential patient to agree to the following:

> • <u>"AGREEMENT TO ARBITRATE – I hereby agree that any</u> <u>dispute regarding the products and services offered through</u> <u>SmileDirectClub and/or by my affiliated dental professionals,</u> <u>including but not limited to medical malpractice disputes, will be</u>

resolved through final and binding arbitration before a neutral arbitrator and **not by lawsuit filed in any court, except claims within the jurisdiction of Small Claims Court**."¹⁹ (Emphasis added).

- "<u>I understand that I am waiving any right I might otherwise</u> <u>have to a trial by jury</u>."²⁰ (Emphasis added).
- "<u>I further agree that any arbitration under this agreement will</u> take place on an individual basis, that class arbitrations and class actions are not permitted, and that I am agreeing to give up the ability to participate in a class action."²¹ (Emphasis added).
- "<u>I release SmileDirectClub from liability for any claims by me or</u> <u>any third party in connection with my participation or use of the</u> <u>clear aligner therapy treatment.</u>"²² (Emphasis added).

CERTAIN SMILEDIRECTCLUB REPRESENTATIONS

"3x faster than braces": SmileDirectClub has advertised "3x faster than braces."²³ Truth in Advertising (TINA.org) has written an article entitled "Smile Direct Club: '3x Faster Than Braces'."²⁴ The article reports that:

Smile Direct Club says it takes an average of six months to complete one of its treatment plans, which by the company's math would mean braces take about 18 months. But no two smiles are the same. . . . TINA.org reached out to Smile Direct Club for comment. Check back for updates."²⁵

The article also reports that "Smile Direct Club says its system is 'designed for minor to moderate teeth correction, including space between teeth, crowding, rotations, and some bite correction.' Yet when TINA.org filled out the company's online questionnaire, selecting options for extreme teeth crowding and extreme teeth spacing, the results came back saying we are 'a great candidate' for its aligners "²⁶

Smile Guarantee: When ordering an impression kit, SmileDirectClub presents "Our Smile Guarantee" where it states: "Getting started is risk free. If invisible aligners aren't a good fit for you, you'll get your money back."²⁷ Yet, further information about SmileDirectClub's Return Policy, on a different webpage, indicates that SmileDirectClub will "refund your risk-free \$79.00 impression kit or SmileShop scan <u>if the dentist or</u> <u>orthodontist determines our clear aligners aren't a fit for you</u>."²⁸ (Emphasis added). Also, "[y]our custom-made SmileDirectClub clear aligners <u>can be returned</u> <u>within the first 30 days of your smile plan</u> if you're not happy for any reason, and all payments you've made for aligners will be refunded. . . . Just remember, <u>you're</u> <u>responsible for any shipping charges when returning your clear</u> <u>aligners</u>."²⁹ (Emphasis added).

SMILEDIRECTCLUB'S AFFILIATED DOCTORS

<u>Identifying Doctors</u>: SmileDirectClub states that it works "with a network of 225 affiliated duly licensed dentists and orthodontists who create and manage treatment throughout their patient's journey. The prescribing dentist's or orthodontist's name is provided to each customer. <u>We do not state the identity of the treating doctor on our</u> <u>website in order to protect the customer's personal health information.</u>"³⁰ (Emphasis added).

SmileDirectClub's reasoning would seem to be at odds with every hospital, clinic, and health practice that states the identities of their treating doctors on their websites. Meanwhile, SmileDirectClub's "Consent and History" form states, "I have had an opportunity to discuss and ask any questions about aligner therapy treatment with a licensed state dentist who engaged SmileDirectClub to facilitate my treatment."³¹

Level of Care: SmileDirectClub states that "[a]n individual who is requesting treatment by using SmileDirectClub's 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."³² At the same time, however, SmileDirectClub's Consent and History form states:

"I further understand that my clear aligner therapy treatment will only address the alignment of my teeth and will not correct my existing bite condition. <u>In order to correct the current condition</u> of my bite, I will need to seek more comprehensive treatment via my local dental professional. Because I am <u>choosing not to</u> engage the in-patient services of a local dental professional, I understand and accept that my <u>teeth will be straighter than they</u> <u>currently are but may still be compromised.</u>" ³³ (Emphasis added).

Doctor's Payment: In looking at one of SmileDirectClub's dentist's agreement ("ELP Participation Agreement 201707" – so perhaps from 2017), it seems dentists participating with SmileDirectClub under that agreement receive \$50 per patient.

SMILEDIRECTCLUB'S PRICE

SmileDirectClub represents that first you "get started with our \$49 at-home impression kit or a 3D image at a SmileShop."³⁴ Next, SmileDirectClub has "Two easy ways to pay" for its teeth straightening which can be a one-time payment of \$1895 or a \$250 deposit

and \$85 per month for 24 months (\$2290 total).³⁵ SmileDirectClub goes on to state "[w]e believe you shouldn't have to pay a small fortune for a smile you'll love. We work directly with customers, avoiding costly office visits and shipping aligners straight to your door."³⁶ Meanwhile, SmileDirectClub's Consent and History form indicates that office visits to a patient's regular dentist (not the patient's SmileDirectClub affiliated dentist) are still required before, during, and after SmileDirectClub aligner treatment, and those visits do not appear to be part of SmileDirectClub's fee:

- "SmileDirectClub aligners are most effective if your teeth and gums are healthy. <u>It is your responsibility to see a dentist within 6</u> <u>months prior to starting SmileDirectClub aligners, to verify that</u> <u>your teeth and gums [sic] healthy prior to using SmileDirectClub</u> <u>aligners. It is also your responsibility to maintain and have</u> <u>follow-up dental care during and after SmileDirectClub aligner</u> <u>therapy.</u>"³⁷ (Emphasis added).
- "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."³⁸
- "The roots of some patients' teeth become shorter (resorption) during use of aligners. . . . Resorption can impact the long-term health of teeth. <u>If resorption is detected by your regular dentist during orthodontic treatment</u>, treatment may need to be discontinued or tooth loss may occur."³⁹ (Emphasis added).
- "Tooth movement may accelerate nerve damage or nerve death, resulting in a root canal, other dental treatment, or loss of the tooth...
 <u>If your regular dentist detects nerve damage prior or during vour aligner therapy treatment, treatment may need to be discontinued or tooth loss can occur</u>."⁴⁰ (Emphasis added).
- "Problems may occur in the jaw joints during aligner therapy treatment, causing pain, headaches or ear problems. . . . <u>In the event</u> that you experience any of these symptoms, please see your regular dentist."⁴¹ (Emphasis added).
- "<u>Further, you agree that you are responsible for having such</u> <u>bonded retainers, attachments or buttons removed by your</u> <u>regular dentist before beginning aligner therapy treatment. You</u> <u>are also responsible for consulting with your regular dentist</u> <u>regarding the potential consequences of their removal and</u>

obtaining, at your expense, all dental care required for their removal."⁴² (Emphasis added).

"Cavities, tooth decay, periodontal disease, gingival recession, inflammation of the gums or permanent markings (e.g. decalcification) may occur or accelerate during use of aligners. . . . In addition, in some circumstances discoloration or white spots may occur; small cavities may increase in size, causing sensitivity and, in some cases, pain or tooth breakage; gingival inflammation may increase, causing soreness and/or bleeding. If underlying periodontal conditions persist unchecked, they may become more prevalent and lead to tooth loss. You may have to discontinue aligner treatment. <u>All of these symptoms will require you to seek care from a dentist of your choice</u>."⁴³ (Emphasis added).

The foregoing level and degree of potential involvement of a patient's regular dentist seems at odds with SmileDirectClub's claim that "[a]n individual who is requesting treatment by using SmileDirectClub's 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."⁴⁴ SmileDirectClub's website does not appear to clarify what another dentist might charge for these dental services in addition to SmileDirectClub's fee. SmileDirectClub has stated - "Although <u>not covered in the fee charged by the dentists and orthodontists who make up our network</u>, we always recommend that every customer see their local dentist or orthodontist in person before beginning any remote aligner therapy treatment and suggest that it continue during and after invisible aligner orthodontic care."⁴⁵ (Emphasis added).

Beyond the foregoing involvement and potential costs of a regular dentist, it also appears that the following services are also not included as part of a SmileDirectClub patient's one-time payment of \$1895 or payment plan totaling \$2290, should the patient need or elect to receive them:

- "Protect your investment! We strongly recommend you safeguard your new smile with our custom-fit SmileDirectClub clear retainers. Without retainers, teeth have a tendency to shift back to their original positions. Keep them from moving back with our custom-fit retainers. One set costs \$99 and is available to purchase toward the end of your treatment. Call our customer care team at 800-688-4010 about 4–5 weeks before you finish your smile plan to place your order."⁴⁶ (Emphasis added). Further, SmileDirectClub "recommend[s] replacing your retainers every six months to keep them fresh."⁴⁷ (Emphasis added).
- "The average person generally wears the aligners for 4 8 months, but your particular rate of tooth movement is impossible to predict and could take longer. <u>If the duration is extended beyond the</u> <u>original estimate, additional fees may be assessed.</u> Difficult cases

may require IPR and/or extractions with traditional braces for ideal results. **Please note that the related additional costs will be your responsibility**." ⁴⁸ (Emphasis added).

"Your bite may change during treatment and may result in temporary discomfort. Your bite may require adjustment after use of the aligners."⁴⁹ "In order to correct the current condition of my bite, <u>I</u> will need to seek more comprehensive treatment via my local dental professional." ⁵⁰ (Emphasis added).

¹ See, e.g., <u>https://www.bbb.org/us/tn/nashville/profile/cosmetic-</u>

dentistry/smiledirectclub-0573-37111672 (last visited July 1,

2019); <u>http://www.fox5atlanta.com/health/fox-medical-team/finding-the-right-braces-proves-tricky-for-atlanta-man</u> (last visited June 28,

2019); <u>https://www.wrdw.com/content/news/Mail-order-braces--Is-your-smile-worth-the-cost-452548583.html</u> (last visited June 28, 2019); *see also* THE CAPITOL

FORUM, June 21, 2019, Vol. 7 No. 227, "SmileDirectClub: Dissatisfied Customers Asked to Sign Release Before Getting Refund; Restrictions on Complaints and Reviews in Release Could Run Afoul of State and Federal

Laws."; <u>https://www.bbb.org/us/ny/new-york/profile/dental-supplies/candid-care-co-0121-174671</u> (last visited June 29, 2019).

² See <u>https://www.bizjournals.com/nashville/news/2019/03/14/fast-growth-harsh-critics-meet-the-nashville.html</u> (last visited June 28, 2019).

³ See Order on Defendant's Motion to Dismiss, *SmileDirectClub, LLC v. Georgia Bd. of Dentistry et al.*, Case No. 1:18-cv-02328, pp. 5-6 (N.D. Ga. May 8, 2019). ⁴ *Id.* at p. 5.

⁵ <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/co</u>nsent/ (last visited June 28, 2019).

⁶ See <u>https://www1.aaoinfo.org/legal-advocacy/state-laws-and-regulations/</u> (last visited June 28, 2019).

⁷ <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/blog/the-benefits-of-teledentistry-and-invisible-aligners/</u> (last visited June 28, 2019).

<u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/blog/the-benefits-of-teledentistry-and-invisible-aligners/ (last visited June 28, 2019).</u>

⁹ See SmileDirectClub, LLC v. Georgia Board of Dentistry et al., Case No. 1:18-cv-02328 (N.D. Ga.).

¹⁰ See Order on Defendant's Motion to Dismiss, *SmileDirectClub, LLC v. Georgia Bd. of Dentistry et al.*, Case No. 1:18-cv-02328, at pp. 5-6 (N.D. Ga. May 8, 2019).

¹¹ See <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.c</u> om/blog/the-benefits-of-teledentistry-and-invisible-aligners/ (last visited June 28, 2019).

¹² See <u>https://www.usatoday.com/story/money/2018/12/21/invisalign-smile-direct-club-</u> <u>braces-teeth-aligners/2378959002/</u> (last visited June 28, 2019).

¹³ See SmileDirectClub, LLC v. Georgia Board of Dentistry et al., Case No. 1:18-cv-02328 (N.D. Ga.).

¹⁴ <u>https://www.prnewswire.com/news-releases/federal-court-dismisses-a-majority-of-smiledirectclubs-claims-and-finds-that-smiledirectclubs-digital-scans-constitute-the-practice-of-dentistry-300850327.html (last visited June 28, 2019).</u>

¹⁵ See D. Blaine Leeds and SmileDirectClub v. Board of Dental Examiners of Alabama et al., Case No. 2:18-cv-01679 (N.D. Ala.).

¹⁶ <u>https://www.prnewswire.com/news-releases/federal-court-throws-out-six-of-smiledirectclubs-eleven-counts-against-the-alabama-dental-board-300834293.html</u> (last visited June 28, 2019).

¹⁷ <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/blog/the-benefits-of-teledentistry-and-invisible-aligners/</u> (last visited June 28, 2019).

¹⁸ <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/blog/the-benefits-of-teledentistry-and-invisible-aligners/</u> (last visited June 28, 2019).

¹⁹ <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/consent/</u> (last visited June 28, 2019).

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²³ See <u>https://www.truthinadvertising.org/smile-direct-club-3x-faster-than-braces/</u> (last visited June 28, 2019).

²⁴ See <u>https://www.truthinadvertising.org/smile-direct-club-3x-faster-than-braces/</u> (last visited June 28, 2019).

²⁵ See <u>https://www.truthinadvertising.org/smile-direct-club-3x-faster-than-braces/</u> (last visited June 28, 2019).

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³² <u>https://webcache.googleusercontent.com/search?q=cache:https://blog.smiledirectclub.com/doctors-behind-your-smile/?referrer=category-ask-the-doctor</u> (last visited June 28, 2019).

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⁴² <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/consent/</u> (last visited June 28, 2019).

⁴³ <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/consent/</u> (last visited June 28, 2019).

⁴⁴ <u>https://webcache.googleusercontent.com/search?q=cache:https://blog.smiledirectclub.com/doctors-behind-your-smile/?referrer=category-ask-the-doctor</u> (last visited June 28, 2019).

⁴⁵ <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/blog/the-benefits-of-teledentistry-and-invisible-aligners/</u> (last visited June 28, 2019).

⁴⁶ <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/fa</u> <u>q/</u> (last visited June 28, 2019).

⁴⁷ <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/fa</u> <u>q/</u> (last visited June 28, 2019).

⁴⁸ <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/consent/</u> (last visited June 28, 2019).

⁴⁹ <u>https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/consent/</u> (last visited June 28, 2019).

⁵⁰ https://webcache.googleusercontent.com/search?q=cache:https://smiledirectclub.com/c onsent/ (last visited June 28, 2019).

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