

Testimony of Dr. Jeffery Sulitzer, DMD
Chief Clinical Officer, SmileDirectClub
Kansas Senate Committee on Public Health and Welfare
Senate Bill 121 - Opposition
January 25, 2021

Mr. Chairman and members of the Committee:

My name is Jeffery Sulitzer. I am here today as the chief clinical officer at SmileDirectClub in opposition to Senate Bill 121. I appreciate the opportunity to appear here today.

By way of background, I am a general dentist and have been practicing for nearly 40 years. My career has taken me from private practice, to the dental health insurance industry where I was Vice President of US Healthcare's dental division, to chief clinical officer and executive officer of a dental support organization, and now as chief clinical officer at SmileDirectClub, an international oral care leader which has hundreds of SmileShops, more than 1,000 SmileDirectClub Partner Network dental offices, a network of hundreds of affiliated, certified dentists and orthodontists, and thousands of team members across the globe. SmileDirectClub is publicly traded and headquartered in Nashville, Tennessee, along with our manufacturing facility for clear aligners.

SmileDirectClub provides the med-tech platform over which Kansas licensed dentists and orthodontists diagnose and treat Kansas patients for mild to moderate malocclusion of teeth with clear aligner therapy. In common language, this is adjusting the crowding and spacing of teeth. Over 1.5 million patients across the country have been successfully treated over this platform. The cost for this therapy is fixed at \$1950. This is a significant cost saving for Kansas consumers who would otherwise have to pay on average \$5,000 to \$8,000 for other therapies. Because the clear aligner therapy is rendered remotely to the patient while at home it expands access to oral health care to Kansans who may not live in proximity to a dentist or orthodontist. In Kansas, only 18 out of 105 counties are fortunate enough to have an orthodontist practicing there.

Not surprisingly, dentists and orthodontists in traditional bricks and mortar practices consider an effective alternative therapy at more than 60% cost savings to patients a transcendental economic threat to their business model. The provision in Senate Bill 121 that mandates radiographs for orthodontia is a common request by organized dentistry to legislatures that attempts to undermine the unique innovations of remote oral health care technologies by requiring a prior in-office visit in order to secure x-rays that may not provide any diagnostic benefit whatsoever.



The proponents of this legislation propose to create a standard of care in statute that mandates x-rays for orthodontic treatment, but not for extractions, placement of dental implants, or periodontal surgery when orthodontics is the least invasive of these types of treatments.

Further, a standing order for x-rays on a patient is dangerous and simply unethical. The FDA and ADA released guidelines back in 2012 that x-rays should be taken only when there is an expectation that the diagnostic yield will affect patient care. The dentist should make the decision regarding x-rays for each patient based on professional discretion and patient presentation. That is the standard of care today and there is no clinical reason to legislate a statutory standard of care of standing order for x-rays. In fact, the clinical evidence argues the opposite – the demonstrated harmful effects of excessive x-rays call for professional discretion.

For the reasons stated above, SmileDirectClub respectfully requests you not support SB 121. Thank you for your time and consideration.

Customer Name	- Inding	BoT or Eo	T Feedback Easy to get started, 24/7 help if needed, fast delivery after doing your at-home	Source
tohnjua s.	10	ВоТ	impressions, and great quality aligners. Loving the changes already!	NPS
christine b.	10	ВоТ	Packet is easy to use and well organized. Reminders sent to change aligners and products have specials running which save money while providing items needed to help you succeed in your smile journey.	NPS
kathy c.	10	BoT	I've already recommended to a friend.	NPS
	10	D - T	I already feel so much more confidence. I feel my teeth slightly aligning already and its	
neather c.	10	ВоТ	only been 3 weeks.	NPS
amber b.	10	ВоТ	Great experience so far! Started my treatment havent had any problems its been a quick and easy process plus it has its perks of always having clean teeth! Love smile direct club!	NPS
terri b.	10	ВоТ	I have made only minimal adjustments to my aligners, they seem to be doing their job and they are very affordable!!	NPS
thelma b.	9	ВоТ	I can already see improvement in week 3. the pain is only for a short time and the outcome is amazing	NPS
			I have been very impressed by the whole process up to this point. It was very simple to	
chrissy b.	10	ВоТ	have the scans done of my teeth, and after only three weeks of wearing the aligners, I am already seeing a big difference.	NPS
austin g.	10	ВоТ	I think all around what you guys are doing is very awesome	NPS
kathryn I.	10	ВоТ	Easy, extremely user friendly, great customer service, it really IS as simple as it sounds!!	NPS
patricia g.	10	ВоТ	So far everything has been quick and easy! We love that every week all we have to do is change out the retainers and put them in!	NPS
iayden a.	10	ВоТ	The process was a lot more simple than I thought it would be and the aligners really work great.	NPS
connie r.	10	ВоТ	I think it is great that they send you all of the aligners all at once. Don't have to go to an	NPS
WE WE	11 15 15 15	501	office.	
amanda s.	9	ВоТ	So far everything is great. It has not quite been a month. The app is great to have to keep track and the phone call check ups as well.	NPS
chrisg.	10	ВоТ	The consultation was fast, friendly and safe. They answered all my questions and got me going in the right direction to let me achieve a better smile!	NPS
ammie h.	10	ВоТ	l'm on my 3rd week of wearing my aligners and love them! I have had several friends that are interested in them and I highly recommend them! I love that they are affordable and I have send 8 people the link as to refer a friend! Hopefully they give it a try! I'm	NPS
roleou I	10	ВоТ	glad that I did!!!	NDC
celsey I. ohn f.	10 10	ВоТ	Easy and convenient to do it all without going into an office.	NPS
Omi i.	10	БОТ	Better pricing and simple process It really works. I can see a difference in my teeth already and I'm only on my 3rd aligner.	NPS
ariel o.	8	ВоТ	The whitening gel is amazing as well. The only thing that I don't like is the first few days	NPS
ehites.	10	ВоТ	after I change my aligner. It's pretty painful but hey no pain no gain! So far I'm loving my aligners and I'm really hopeful for change in my teeth.	NPS
amber k.	10	ВоТ	I love the process so far. The tips and pointers have been wonderful. You thought of everything to make this as easy and painless as possible. I also love the reminders and alerts that it's time to change my aligners. Seriously this process is way easier than I	NPS
			thought it would be! Thank you!	
onya h.	8	BoT	There's so many competitors.	NPS
autym p.	10	BoT	I want Straight teeth and it's working	NPS
sally h.	10	ВоТ	Customer service is wonderful. Had issues with bottom aligner did a video call. She saw the issue and ordered new ones.	NPS
orianna I.	10	ВоТ	I have already told my friends and co workers how great of an experience it has been so far. The price is amazing compared to traditional orthodontic method.	NPS
ulie h.	9	ВоТ	very easy to understand (clear instructions), aligners are clearly marked and simple to use, some discomfort that is expected so would recommend to all friends except those that are very sensitive to pain.	NPS
ill s.	10	ВоТ	The whole process is so easy & convenient just one visit then the kit is delivered to your door. The change aligners reminder is a great feature. There's no excuses for forgetting to start new aligners. One more thing I love the lip balm!!	NPS
			I had an appointment today and it was quick and easy! The lady who greeted me and	
			helped me get signed in was very nice. My smile guide, Kiana, was great! She made me	
			$feel\ comfortable\ and\ she\ was\ super\ nice\ and\ helpful!\ I\ had\ an\ impression\ kit\ and\ did\ the$	
Coral H.	5 stars	ВоТ	molds, but I didn't think they came out very accurate so I booked an appointment with a smile shop and I am happy I did. I highly suggest visiting a smile shop so you can get a	Google - Overland Park Shop
			more accurate assessment of your teeth. Overall, I had a great experience.	

Rachel	5 stars	ВоТ	Dominique H. was AMAZING! Very knowledgeable and informative, great people skills, and just so genuinely sweet! I was nervous going in, but she totally wiped all my worries away! Pricing is very fair; it is a legitimate business that yields REAL results. There are payment options, 30 days to think about it, and the dental experts get back with you in about 72 hours! SO MUCH BETTER THAN "*THE OTHER GUYS*"!	Google - Overland Park Shop
Kimberly K.	5 stars	ВоТ	Lots of giggles and very happy to have gotten started, now to wait to get approved. I would definitely recommend going, especially if your like me and have no confidence what So ever. I feel like this will make a big change for me and make me more confident than ever. I want to say Thank you to both ladles for making me feel comfortable upon my arrival and having great conversation. I love the fact that they don't not judge.	Google - Overland Park Shop
			Went in for my scan when this location was in its CVS location still. Kiana was my smile guide and was incredibly thorough and explained everything I had questions on since I was a little nervous. The "Smile Leader" (which I assume just means manager), Kortney, paired up with Kiana to make sure I had the perfect appointment. And I did!	
Komputer S.	5 stars	ВоТ	Now 2 months into my treatment I've had to be rescanned now because my teeth shifted a lot more than expected, and both remembered me and were super happy to scan me again! Is it a bit of a hassle to get rescanned? A little. I thought it was one scan and done. But these ladies made it worth it and I'm stoked that it's all included in the payment for the entire process. Love the new location by the way!!	Google - Overland Park Shop
			10/10, would recommend SDC and this location.	
Nicholas Turner	5 stars	ВоТ	Besides being competitively priced and substantially cheaper than Braces, I chose Smile Direct Club because they offer an in-person consultation. This consultation also uses a 3D Smile Scanner instead of an impression kit. I only need minor adjustments, as I had braces when I was younger. My in-person experience was terrific, Dominique was super helpful and friendly, all my questions were thoroughly answered, and the whole process was quick and painless. I would highly recommend the Leawood / Overland Park, KS location, and I'm excited to start my Smile Journey with Smile Direct Club!	Google - Overland Park Shop
Elaine D.	10	ВоТ	The price is very good and I can already see progress! SDC has been very good about educating us on the process and there is a dentist who is supervising the process as well.	NPS
Anastasia C.	5 stars	ВоТ	This was by far, one of my best experiences. SmileDirectClub not only has great affordable prices, but you can have the smile you want in less then a year. I tried getting braces before, but was rudely dismissed. It felt as tho they only cared about the money and gave little regard to their patients. It only took me a few seconds to know that this was not the case with SmileDirectClub. Korey, was polite and met with me as soon as I arrived. He walked me through the entire process, while answering any questions I had. I felt comfortable and very confident in my decision to join the club. I'm so excited, I can't wait to see my aligner results and get started. Thankyou Korey!	Google - Overland Park Shop
Amber K.	10	EoT	Great experience. Awesome customer service.	NPS
lindsey v.	10	EoT	I'm very happy with my results and have a friend or two that could benefit	NPS
terri b.	10	ЕоТ	It was inexpensive, I got great results and everyone I dealt with was amazing and very helpful.	NPS
cheryl h.	10	ЕоТ	The service was streamlined-You you either do your own molds or go get 3-D views done then you get all of your aligners at the same time and everything ships very quickly, I enjoyed all the:-) faces, the friendly and funny emails and texts. It was nice to know that you were progressing the way you needed to be and you only had to send pictures to the dentist a couple of times.	NPS
barb d.	10	EoT	I am pleased with my smile now. It still isn't perfect.but is definitely straighter than it was before we started.	NPS
kristele a.	8	EoT	Getting started was easy. My trip to the smile center was pleasant. My straighten process was easy, and straight forward. The cost was affordable and easy for me.	NPS
ashtyn m.	10	EoT	My teeth looked amazing within weeks! The smile direct team provided useful tips and accessories that made the smile journey fun and pleasurable!	NPS
lanesha w.	8	EoT	It was quick and convenient	NPS
angi v.	10	ЕоТ	Great customer service. Willing to reevaluate my progress. All around, fantastic experience.	NPS
lorrie s.	10	EoT	It has been a good experience.	NPS
whitney d.	10	EoT	For the price my teeth look great.	NPS
christopher h.	10	EoT	A super simple, fast and easy process!	NPS

			Smiledirectclub was easy to work with. It is about half the price of invasalign without all	
samantha g.	10	ЕоТ	the doctor visits. It is a good option for a simple straightening of the teeth and it include whitening!	s NPS
luke p.	9	EoT	Really satisfied worth the results and the customer service.	NPS
chumekka f.	10	EoT	Great product, people, and results!	NPS
niah k.	10	EoT	I finally got the smile I've wanted since my teeth grew in	NPS
sherry e.	10	EoT	Great customer service. Working with me on an extension of my treatment plan	NPS
randy h.	10	EoT	1've had a great experience, and I love my new smile!	NPS
			It is a good program and I did see good results. You have to be disciplined to follow the	
dee t.	8	EoT	program. I had a little trouble but Smilebox helped me through it by allowing me extra time. I am getting ready to order my retainers now. \Thanks	NPS
jennifer c.	10	EoT	The process was quick and easy and my results speak for themselves!	NPS
erin e.	9	EoT	It was quick, easy and less expensive. The whole experience was simple.	NPS
tracy f.	10	ЕоТ	All done at home, clear and excellent results. l'm 56 years old and always wanted straight teeth, I would have never gone to a orthodontist.	NPS
			I am happy with my results, and my treatment plan was much less expensive than	
heather a.	10	EoT	traditional braces. SmileDirect Customer Service was also great, which was very helpful	NPS
			when I had questions about my plan.	
connie r.	10	EoT	I am happy with the results	NPS
anny f.	10	EoT	the process was super easy and quick, my results were AMAZING.	NPS



Radiographs and Orthodontics

Radiographs Linked to Increased Rates of Cancer

Twenty-one studies have found a correlation between dental diagnostic X-rays and overall health, with many finding a correlation between X-rays and brain/thyroid cancer.1

The American Cancer Society affirms that x-rays cause cancer. They also cite a study which found that the people who had brain tumors were more likely to have had a dental x-ray.²

"There is **no safe limit or "safety zone" for ionizing radiation exposure** in diagnostic imaging. Every exposure cumulatively increases the risk of cancer induction."3

A Yale study found that dental X-rays also increased the risk of developing a meningioma, the most common and potentially debilitating type of non-cancerous brain tumor.4

Treating Dentists Must Determine if Radiographs are Clinically Justified on a Patient by Patient basis

The FDA and ADA released guidelines stating that "Radiographs should be taken only when there is an expectation that the diagnostic yield will affect patient care."5

"The <mark>dentist is the one who decides if the radiographs are needed</mark> ... They are an important diagnostic tool and it is the responsibility of the treating dentist to determine how often they are needed."6

"The clinical decision about the need to radiography is influenced by many factors. [E]ach radiograph must be clinically justified... it is unethical to take radiographs for medico-legal, administrative reasons or 'just in case' if there is no clinical need."7

The International Commission on Radiological Protection (ICRP) recommends that activities which cause exposure to radiation should be scrutinized and must be justified by a benefit to risk analysis.8

Delta Dental's Utilization Review Guidelines for 2020 state that radiographs "should only be taken for clinical reasons as determined by the patient's dentist."9

Radiographs are Not Clinically Necessary for all Orthodontic Cases

"No benefit for radiography has been demonstrated for patients referred for dental crowding." 10

Upon the review of several studies that examined the efficacy of radiography, "researchers reported the limited effect radiography has on changing orthodontic diagnosis or treatment plans... questions whether the present use of radiography may be excessive."11

"Diagnostic value of orthodontic radiographs and indications for their use are still debatable ... the minimum set of records required for orthodontic diagnosis and treatment planning has never been solidly established or defined in the literature. Consequently, the use of radiation by orthodontists is accompanied by a responsibility to ensure appropriate indication. It must always be justified and delivered in doses 'as low as reasonably achievable."12

^{1 &}quot;Clinical recommendations regarding use of cone beam computed tomography in orthodontics. Position statement by the American Academy of Oral and maxillofacial radiology." American Academy of Oral and Maxillofacial Radiology, Vol. 116 No. 2 (2013).

Do x-rays and gamma rays cause cancer? American Cancer Society. cancer.org/cancer/cancer-causes/radiation-exposure/x-rays-gamma-rays/do-xrays-and-gammarays-cause-cancer.html

³ "Clinical recommendations regarding use of cone beam computed tomography in orthodontics. Position statement by the American Academy of Oral and maxillofacial radiology, "American Academy of Oral and Maxillofacial Radiology, Vol. 116 No. 2 (2013).

Claus EB, Calvocoressi L, Bondy ML, Schildkraut JM, Wiemels JL, Wrensch M. Dental x-rays and risk of meningioma. Cancer 2012, 118:4530-7.
FDA/ADA, DENTAL RADIOGRAPHIC EXAMINATIONS: RECOMMENDATIONS FOR PATIENT SELECTION AND LIMITING RADIATION EXPOSURE(2012)

⁶ Oregon Board of Dentistry, Clarification on Radiographs, https://www.oregon.gov/dentistry/Documents/Clarification_on_Radiographs.pdf

Isaacson KG, (2015), "Guidelines for the Use of Radiographs in Clinical Orthodontics," British Orthodontic Society.
ICRP – International Commission on Radiological Protection, Radiological protection in medicine, Ann. ICRP (2008) ICRP Publication 105 Thomas Correia, DDS - Dental Director, Delta Dental, "Utilization Review Guidelines," Jan 1, 2020

^{10 &}quot;Clinical recommendations regarding use of cone beam computed tomography in orthodontics. Position statement by the American Academy of Oral and maxillofacial radiology." American Academy of Oral and Maxillofacial Radiology, Vol. 116 No. 2 (2013).

11 "Use of Ionising Radiation," Selection Criteria for Dental Radiography, Faculty of General Dental Practice, 2020.

¹² Aldin Kapetanović, Orthodontic radiology: development of a clinical practice guideline, Head, Neck and Dental Radiology, April 2020.



Is an in-person exam really required for teledentistry?

Here is a review of what the clinical studies indicate.

"Teleorthodontic treatment with clear aligners is clinically effective in the correction of maxillary and mandibular incisor alignment problems."

"This systematic review identified a substantial amount of scientific literature in the relatively new area of teledentistry ... there is a consistent trend supporting the efficacy and effectiveness of teledentistry. Teledentistry seems to be a promising path for access to care in rural and urban settings."²

"Teledentistry has the potential to be part of a paradigm shift in healthcare delivery that can play a key role in mitigating barriers and improving health for populations with traditionally poor access to dental care and oral health services. The Association of State and Territorial Dental Directors supports the development of teledentistry as an approach to enhance the delivery of efficient and cost-effective oral health care, allowing providers to overcome traditional barriers to care faced by underserved communities."

"Teledentistry could be comparable to face-to-face for oral screening. Identification of oral diseases, referrals, and teleconsultations are possible and valid."

"[The] use of monitoring software can be reliable for making clinical decisions."5

"We can conclude that apical root resorption during and after the orthodontic treatment with clear aligners is not unavoidable. But both incidence and severity of ARR are lower after clear aligner therapy compared with ARR results with fixed orthodontic treatment."

"Remote diagnosis using transmitted photographic images of dentition (teledentistry) may be an alternative to visual inspection. Three studies found image analysis to be superior to visual inspection."

"Clear aligners showed improved periodontal status indices when compared to fixed orthodontics. Our results showed increases in supragingival plaque, higher number of probing

¹ Marc B. Ackerman, *Teleorthodontic treatment with clear aligners: An analysis of outcome in treatment supervised by general practitioners versus orthodontic specialists*, Journal of Dental Research and Reports, 2019, Vol. 2 1-4.

² Susan J. Daniel, RDH, PhD; Lin Wu, MLIS, AHIP; Sajeesh Kumar, PhD, *Teledentistry: A Systematic Review of Clinical Outcomes, Utilization and Costs,* The Journal of Dental Hygiene, Vol. 87, No. 6. December 2013

³ ASTDD, Teledentistry: How Technology Can Facilitate Access To Care, March 2019.

⁴ Jafar H. Alabdullah and Susan J. Daniel, *A Systematic Review on the Validity of Teledentistry*, Telemedicine and e-Health VOL. 24, NO. 8, 2018.
⁵ Heather B. Moylan: Caroline K. Carrico: Steven J. Lindauer: Eser Tufek. Accuracy of a smartphone based orthodoxic treatment—monitoring.

⁵ Heather B. Moylan; Caroline K. Carrico; Steven J. Lindauer; Eser Tufek, Accuracy of a smartphone-based orthodontic treatment–monitoring application: A pilot study, Angle Orthod., Epub 2019 Mar 19.

⁶ Ugne Sadauskiene, Orthodontic treatment with clear aligners and apical root resorption, Journal of Medical Sciences, Vol. 8 Issu. 14 (2020)

⁷ Inês Meurer M, Caffery LJ, Bradford NK, Smith AC., Accuracy of dental images for the diagnosis of dental caries and enamel defects in children and adolescents: A systematic review, J Telemed Telecare. 2015;21(8):449-458.

depths greater than 3mm, higher number of bleeding sites on probing, and a higher amount of gingival recession in the subject treated with fixed orthodontics."8

"Clinical factors are detectable from electronically transferred clinical photographs only, particularly, since the use of full records has not been shown to make large differences to clinical decision making. Clinician agreement, for screening and accepting orthodontic referrals based on clinical photographs, is comparable to that previously reported for other clinical decision making (such as in-person exam)."

"For most dental applications, the store-and-forward method provides excellent results without excessive costs. [T]he purpose of the study was to test the validity of diagnoses made in the absence of modern dental facilities. Mobile phone teledentistry offers acceptable reliability for the initial diagnosis." 10

"Outcomes for treatment of mild malocclusions in adolescents (teenagers) showed equivalent effectiveness of clear aligners compared to fixed appliances, with significantly improved results for clear aligner treatment in terms of tooth alignment, occlusal relations, and overjet." 11

"Teledentistry had excellent sensitivity (93.8%) and specificity (94.2%) for diagnosing dental pathologies [when compared to] using face-to-face examination as a 'gold standard.'

Teledentistry was not associated with any serious adverse events, and the acceptability rate (95.3%) among residents and their families was excellent. Teledentistry has excellent accuracy for diagnosing dental pathologies, and good accuracy for assessing the rehabilitation of dental prostheses and chewing ability."¹²

"Teledentistry is a valid system for positively identifying appropriate new patient orthodontic referrals." 13

"There is a consistent trend in the literature supporting the validity and reliability of teledentistry applications in comparison to non-telemedicine alternatives. A growing body of evidence supporting the efficacy of teledentistry is provided by some of the studies on paediatric dentistry, oral medicine, orthodontics and periodontics. The majority of the research in these areas reported that teledentistry had similar or better outcomes than the conventional alternative." 14

⁸ Mark Jones, Comparison of Periodontium among Subjects Treater with Clear Aligners and Conventional Orthodontics, Creighton University (2020).

⁹ Mandall NA, Bearn D, Chadwick S, et al. Are photographic records reliable for orthodontic screening? J Orthod 2002; 29: 125–127.

¹⁰ Mohammad Alshaya, *Reliability of mobile phone teledentistry in dental diagnosis and treatment planning in mixed dentition*, Journal of Telemedicine and Telecare 26(3) · August 2018.

¹¹ Borda et al, *Outcome assessment of orthodontic clear aligner vs fixed appliance treatment in a teenage population with mild malocclusions*, The EH Angle Education and Research Foundation, 2020

¹² Queyroux, Alain et al., Accuracy of Teledentistry for Diagnosing Dental Pathology Using Direct Examination as a Gold Standard: Results of the Tel-e-dent Study of Older Adults Living in Nursing Homes, Journal of the American Medical Directors Association, Volume 18, Issue 6, 528 – 532.

¹³ Mandall NA, O'Brien KD, Brady J, Worthington HV, Harvey L. Teledentistry for screening new patient orthodontic referrals. Part 1: A randomised controlled trial. Br Dent J. 2005;199(10):659-653.

 $^{^{14}}$ Mohamed Estai, A systematic review of the research evidence for the benefits of teledentistry, Journal of Telemedicine and Telecare, 24(3):147-156 · April 2018