
Case No: 1080780

IN THE
SUPREME COURT OF ALABAMA

WHITE SMILE USA, INC AND §
D'MARKOS, LLC, §
§
Appellants §
§ On Appeal from The Circuit
vs. § Court of Montgomery County
§ Case No. CV-2008-000153.00
BOARD OF DENTAL EXAMINERS OF §
ALABAMA, §
§
Appellee. §

AMICUS CURIAE BRIEF FILED CONDITIONALLY BY
THE ALABAMA DENTAL ASSOCIATION
IN SUPPORT OF APPELLEE

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**STATEMENT OF THE ISSUE
ADDRESSED BY AMICUS CURIAE**

Whether the trial court erred in determining that Appellants' teeth whitening procedure, administered to members of the public in a beauty salon by persons with no formal dental training, falls within the practice of dentistry as set forth in the Alabama Dental Practice Act, Ala. Code 1975, § 34-9-6, and is subject to the regulatory supervision of the Board of Dental Examiners of Alabama.

STATEMENT OF INTEREST

The Alabama Dental Association is a membership organization of Alabama dentists and is part of a tripartite system with the American Dental Association and nine component district dental societies. The Alabama Dental Association represents over 1,800 Alabama dentists in their efforts to provide quality dental care to the citizens of Alabama.

This case is of significant interest to the Alabama Dental Association and its members, but the Association and its undersigned counsel have no direct pecuniary interest in the case. The Board of Dental Examiners of Alabama has consented to the filing of this brief in support of its position. The Association appreciates the opportunity to submit the following for the Court's consideration.

STATEMENT OF THE FACTS

Appellant White Smile, Inc. ("White Smile") is a Georgia Limited Liability Company owned by non-dentist entrepreneurs who have no experience or knowledge in any aspect of dentistry. (Supp.C.880,895-899). The White Smile teeth whitening process includes a teeth whitening gel, a bite registration apparatus into which the teeth whitening gel is placed, and a light which activates the gel and speeds up the whitening process. White Smile sells through company-owned retail locations and distributes to individuals or entities for resale to retail locations. Through a license agreement, White Smile sells license rights to be an authorized distributor or licensee of White Smile. (Supp.C.899-903). Many of White Smile's locations are within Sam's Club facilities. (Supp.C. 907, 915). Jim Valentine is one of three shareholders of White Smile, is on its board, and is its Vice President of Sales. (Supp.C. 50,1154). White Smile began operations in 2007 and is doing business in twenty-four states. (Supp.C.881, 900).

D'Markos LLC d/b/a Randall's ("Randall's") is a beauty salon located in Montgomery, Alabama owned by Kelly Markos and

her husband. Ms. Markos is licensed by the State of Alabama as a cosmetologist. Randall's offers hair cuts and hair styling and must be licensed or the individuals working there must be licensed by the applicable board. (Supp.C.694-697; 701-704).

Ms. Markos is not involved with the teeth whitening process because she was not trained or certified. (Supp.C. 727). Two ladies who work at Randall's salon were trained and certified; Ruthie Thomas, a licensed cosmetologist, and Aly Russell, a licensed nail technician. Ms. Russell must be licensed because she uses chemicals in connection with the application of nail polish. (Supp.C.729-731).

The Board of Dental Examiners of Alabama (the "Board") is a legislatively created entity and its duties and responsibilities are set forth in the Alabama Dental Practice Act ("ADPA" or the "Act"), Ala. Code 1975, § 34-9-1, et seq.

The White Smile Product, Process and Training

White Smile's process is referred to in its Training Manual as "dental power bleaching." (Supp.C. 1113). The teeth whitening gel used in the process is manufactured by a California company, Da Vinci, and contains 12% hydrogen peroxide. This concentration of hydrogen peroxide was arrived at by informal testing on the owners, their family and friends with the idea of maximizing the results yet minimizing the

side effects, which Mr. Valentine claims are only teeth sensitivity and gum irritation. (Supp.C. 947-950).

White Smile made much in the trial court, and argues here, that the Food and Drug Administration does not consider the hydrogen peroxide as contained in teeth whitening products to be a drug.¹ However, Exhibit 17 to Mr. Valentine's deposition reveals that the FDA's position relative to teeth whitening products is not so clear. Exhibit 17 is an email from Robert Eschelmann at the FDA to Mr. Valentine dated July 26, 2007 which states:

Per our discussion, the following information gives some background on the status of teeth bleaching agents.

Various tooth whitening preparations were introduced into the market without the approval or sanction of the Food and Drug Administration. In late 1991 the Food and Drug Administration sent letters to various manufacturers and/or distributors of tooth whitening preparations advising them that we considered the products drugs, and "new drugs" as defined in the Federal Food, Drug and Cosmetic Act (Act). Under the provisions of the Act, a "new drug" may not be legally marketed in this country unless it is the subject of a New Drug Application (NDA). The NDA must contain adequate scientific data, including clinical trials, which establish that a product is safe and effective for its intended use.

¹ White Smile states in its brief that the FDA "considers the White Smile product a cosmetic. In other words, the FDA does not regulate this product or consider it a drug." Appellant's brief at p. 6-7.

As a result of a court case brought by one of the manufacturers, the agency agreed to further evaluate the status of tooth whitening preparations to determine if they should be regulated as "new drugs" or as cosmetics. The agency has not yet completed that further evaluation. Marketing of a tooth whitening preparation containing carbamide peroxide or hydrogen peroxide as the bleaching ingredient is on the manufacturer's own responsibility at this time.

(Supp.C.1148).

White Smile's teeth whitening process also includes a mouth piece, which is described as a "bite registration tray." The whitening gel is inserted in the bite registration tray after the patient bites into the apparatus to make an impression of his teeth in the tray. (Supp.C. 945).

The last main component involved in the process is a teeth bleaching light. (Supp.C. 1085). The purpose of the light is to accelerate the whitening process. The whitening gel that is placed in the bite registration tray is formulated with hydrogen peroxide and a photo accelerator, with the light acting to accelerate the ingredients in the gel.² (Supp.C. 1086-1092, 1096-1097, 1098-1099). The light is touted by the

² The White Smile Training Manual states, "-LightWhite®'s peroxide gel is enhanced with silver-ionic photo initiators. When exposed to the Blue LED Whitening Light, it causes millions of "mini-explosions" on the teeth, oxidizing the discoloration away. (Supp.C. 1112).

manufacturer as having a control panel, the "intuitive interface" of which is sure to help the "dental clinicians" concentrate on their patients. (Supp.C. 1085). The light manufacturer states that the light should only be used by trained personnel but Mr. Valentine says that the use of the light requires no training. (Supp.C. 945). The light has not been approved by the FDA; the FDA has been provided only with pre-market notification. (Supp.C. 951-952).

White Smile produces marketing materials in which it describes White Smile as a "Salon & Spa Business Opportunity." (Supp.C. 1086). In discussing the "Cosmetic Teeth Whitening-Industry at a Glance" it states that "Dentists offices provide in-office or "chairside" whitening as well as custom take home trays while "OTC [over-the counter] products consist primarily of strips and trays, but many variants of these exist in many forms." (Supp.C. 1087). The marketing materials used to sell the public on White Smile's procedure touts it repeatedly as "Fast, Effective, Safe, Affordable." (Supp.C. 1091, 1094, 1095, 1098). One such brochure states, "**SAFE** . . . Our cosmetic teeth whitening specialists are trained to consult with you on an individual basis to identify any potential issues you may have." (Emphasis original) (Supp.C. 1095).

One of the marketing brochures entitled "The Teeth-Whitening Industry- an explosive opportunity" states in part:

While teeth whitening has been a popular cosmetic procedure for almost two decades, systems that offer professional results have proven to be cost prohibitive for the average consumer. . . WhiteSmile USA offers salon and spa owners a proven system to operate responsibly and generate healthy profits.. . .How do you decide which is the best system for you? Is it safe? Is it legal? . . . WhiteSmileUSA Authorized Retailers benefit from our revolutionary product line, national brand awareness, comprehensive training program, regulatory experience and protection, and our customer care infrastructure. There is much more to teeth whitening than blue LED lights, peroxide, and white chairs.

(Supp.C. 1096).

White Smile produces a Training Manual which states, beginning on page 1:

Cleanliness/Sanitation Procedures

1) Gloves - It is imperative that we use the gloves in such a way as to never cross contaminate. The way to accomplish this is to never touch the equipment or cabinets wearing gloves. The application instructions in the WhiteSmile USA Training Manual are designed with avoidance of cross contamination in mind. . . .

2) Overall sanitation of the booth or kiosk (The Cleaning Show) ...

h) Trash cans need to be emptied regularly so we do not run the risk of overflow and thus cross contamination. Gloves should be worn when emptying trash to avoid any contamination risks.

(Supp.C. 1110-1111). The "sanitation procedures" also include wiping down the chairs with a clorox wipe after each customer, removing the cone on the light and sanitizing it with Lysol following each customer, spraying the amber eye glasses with Lysol and drying with a paper towel, cleaning the mirrors, including the handles, as well as the teeth shader, with Lysol. Cabinets must be wiped down from top to bottom several times per day "to minimize the effects of any inadvertent cross contamination." (Supp.C. 1111).³

The Training Manual then discusses the consent form which the customer is asked to sign. The Training Manual states:

When a customer sits down in the chair, the following questions need to be asked before having them sign the consent form. . . .

- 2) If it is a woman, we need to ask if they are pregnant or lactating. We cannot sell the product to them if that is the case. . . .

³ In accordance with applicable regulations, dentists and dental offices must conform to the current recommendations and guidelines of the Centers for Disease Control and Prevention relating to infection control practices for dentistry, which are much more stringent than the sanitation procedures set forth in the While Smile Training Manual. Ala. Admin. Code § 270-x-2-.15.

See also Centers for Disease Control and Prevention, Recommended Infection Control Practices for Dentistry, <http://www.cdc.gov/oralhealth/InfectionControl/guidelines/index.htm>.

- 4) Ask the customer when was the last time they had their teeth cleaned. (We don't recommend the product until 7 days after cleaning.)
- 5) Explain that there is a chance of uncomfortable side effects and that the poorer their dental health, the greater the risk for side effects. If they have any questions about their dental health, have them consult a dentist.

(Supp.C. 1111-1112).

The "Lightwhite™ Informed Consent for Cosmetic Teeth Whitening Application" states in part that the "shade of your teeth will be assessed and recorded." The consent form also explains that "all forms of cosmetic treatments, including teeth whitening, have some risks and limitations" and proceeds to discuss tooth sensitivity, gum and soft tissue irritation, and advice to refrain from using the "aftercare product" within 24 hours of the in-store application. (Supp.C. 1125).

The Training Manual further provides:

Teeth Sensitivity - A Major Issue to Point Out to Your Clients: (emphasis original)

Teeth sensitivity is a major issue with the current whitening products on the market. In-office processes such as BriteSmile and Zoom use a high percentage of peroxide (up to 35%), which can cause severe teeth sensitivity (zingers). Take home products such as the trays and Crest Whitestrips use a lower peroxide level, but require continued long-term exposure to the peroxide. This can cause severe sensitivity as well. Many people polled on this issue complained of teeth sensitivity so severe, they had discontinue [sic] using any whitening products. **For some, the pain was so sever after**

dental power bleaching, they [sic] to go to the emergency room to get prescription pain medication after using WhiteSmileUSA. (emphasis added).

The Training Manual also discusses the "competitive advantages" of the Lightwhite® System and states that "[o]ur proprietary formula maximizes results while minimizing teeth sensitivity and soft tissue blanching." (Supp.C. 1113).

The Training Manual contains a section on "Setting Expectations" which states in part that:

Results will vary from person to person because people have genetically different teeth. . . .

Some people will have great results, some will have good results, some will have mediocre results, and some will have poor results. This is true with every teeth whitening product on the market. We have heard from customers who have visited their dentist and been advised that Zoom and Britesmile would probably not produce good results because of their type of teeth.

(Supp.C.1114).

The Training Manual then details White Smile's 27 step procedure that the "certified cosmetic teeth whitening specialist" is to go through when performing the service of whitening teeth. These steps include:

2. Ask the customer if they are taking any medication that reacts adversely with sunlight. If they answer yes, then instruct them [to] seek their doctor's advice before going through with the teeth whitening application.

3. Ask the customer when they had their teeth cleaned by a dentist. If they have been cleaned within 7 days, reschedule whitening process for a later date.
4. Explain to customer the possible side effects from this process and make sure the customer understands the customer should seek advice from their dentists before the whitening, especially if they don't get regular checkups from the dentist. The most common side effects are:
 1. Blanching of gums and gum irritation - in rare cases some will experience blanching of the gums. This is a temporary side effect that will normally subside in 10-15 minutes. In extremely rare cases, the customers can be hypersensitive to peroxide and can experience swelling and blistering of the soft tissues. This can take days to subside. If you have a customer who experiences these side effects, have them call the Customer Care Line and consult a dentist.
 2. Teeth sensitivity - The most common side effect of all whitening products. This will normally subside after 24-48 hours.

* * *
6. Have customer use provided Vita Pan Tooth Scale to determine customer's pre-use teeth shade. Have customer look in mirror for agreement of current teeth shade. Once the shade is decided, raise-up the appropriate teeth color on shade guide and place next to customer's chair for comparison after whitening process is complete.
7. Prepare for whitening . . .
 - a. Lay our new paper towel on cabinet
 - b. Absorbent bib
 - c. Mouthpiece & syringe
 - d. Brush-ups (2)
 - e. Beverage napkin
 - f. Absorbent lip protector(2) . . .

8. PUT ON 1ST SET OF LATEX OR NITRILE GLOVES
9. Place absorbent bib around customer's neck and attach with provided bib chain clip.

* * *
11. Remove Bite Registration Tray [BRT] from packaging. Use your finger to manipulate the silicon so that it slopes toward the upper front edge of the BRT on both top and bottom.
12. Hand BRT to customer to self administer, ensuring the mouthpiece is inserted correctly before customer bites down into the soft silicone. The customer's teeth should come close to the front edge of the mouthpiece before they bite down.
13. Have customer gently rock jaw from front to back.
14. Fill BRT with whitening gel. Ensure that each teeth cavity is no more than ½ full with gel. Start filling from the front teeth to the back using less gel per cavity as you move towards the back teeth. Repeat process for the top and bottom teeth registrations. Once gel is applied, spray one (1) squirt of provided Photo Initiator to the top and bottom tray. IMPORTANT: Do not over fill the tray. The biggest cause of gum and soft tissue irritation is due to excess gel in the tray.

* * *
16. Hand customer foam lip/gum protectors and instruct them to place one under top lip and one under bottom lip.
17. Hand BRT with gel to customer to self-administer, ensuring that mouthpiece is inserted correctly (make sure the mouthpiece is lined up properly with existing registration) before customer bites down into tray with gel.
18. REMOVE GLOVES - DISCARD IN TRASH

* * *

20. Have customer get comfortable in chair and provide them with the eye glasses supplied to wear during whitening process.
21. Adjust LED light into proper position (approximately 1-2 inches away from customer's mouth).
22. Check timer on whitening light to ensure that it is set correctly on 12 minutes . . .
23. Check with customer periodically for signs of discomfort. If issue arises, have customer discontinue use of the product.⁴

* * *

25. . . .Quickly remove the light apparatus, then put on **2nd Set of New Gloves.**
26. Have customer sit up and instruct them to remove BRT from mouth into provided bib. Provide customer with a Kleenex to wipe their mouth. Immediately place BRT in bag from which it was removed. This applies whether it is a single or double application. The BRT should never touch the counter. It will either be in your gloved hand, in the customer's mouth, or in the bag.
27. Provide customer with (1) empty 3 oz. cup to expel any excess saliva before rinsing. Provide customer with 1 ounce water cup to wash out mouth. Have customer rinse and spit contents of mouth back into provided 3-ounce cup. Repeat this step with 2nd 1

⁴ An earlier version of the training manual discussed in Ms. Markos' deposition describes this step as, "Check with client periodically for signs of discomfort. If issue arises, discontinue process and determine reason for discomfort. Very few clients ever have discomfort, but it will happen from time to time. Mostly due to an exposed root (cavity) that client is unaware of." (Supp.C. 829).

ounce cup of water. Carefully place the cups in the trash.

(Supp.C. 1114-1116).

After the whitening is complete, the "whitening specialist" is to review the result with the customer using the raised teeth on the Vita Teeth Shade. This process determines the number of shades the customer's teeth moved during the initial application which should be at least 2 - 5 shades with the initial application. Then it is determined if a second application is "necessary." The trainee is instructed as follows: "IMPORTANT: If the customer experienced ANY side effects during the 1st application, have them discontinue the 2nd application until side effects fully subside. (Supp.C. 1116).

White Smile requires that its authorized distributors participate in its corporate training program. (Supp.C. 1001).

The Expert Testimony

The Board's expert, Dr. Donald Busby, has been a practicing dentist for twenty six years in Lafayette, Alabama. Dr. Busby has twice served as the President of the Board of Dental Examiners and was serving in that capacity at the time of his deposition. (Supp.C.13 - 150).

Dr. Busby testified that the risks to the public by unregulated teeth whitening services include:

(a) People with undiagnosed decay or rampant decay in their mouths who are exposed to hydrogen peroxide, wherein during the oxidation process of the hydrogen peroxide breaks down into carbon dioxide and urea and oxygen, that all can enter the pulp of the tooth. If that occurs, there is a high probability that the pulp tissue will necrose and die which could result in an abscessed tooth and/or loss of tooth. (Supp.C. 40-41).

(b) Barrier techniques, i.e. guarding the gums. If barrier techniques utilized are not complete, are not watched and addressed, there can be damage to the gums. (Supp.C. 41-42).

(c) The situations where there is resulting sensitivity or post procedure complications. As explained by Dr. Busby: "If it's an unregulated procedure and there is no dental practitioner that's available at the kiosk or the salon or whatever it may be offered, who's going to take care of that patient? What if they don't have a regular practitioner? Who are they supposed to call? That's a concern from a regulatory standpoint, and from a public protection standpoint, and being a member of the

Board; that's my main concern is that's who's going to take care of the public if something goes wrong?" (Supp.C. 42). Further, "if you have somebody who, is in my opinion, performing a dental service and being remunerated for it, is offering a diagnosis or prognosis, and then can't perform the follow-up care, or give somebody information on how to get follow-up care, that could presume a danger to the public." (Supp.C. 42-43).

Dr. Busby testified that in his opinion, the procedure performed by White Smile constitutes the practice of dentistry because it is a dental operation or dental service within the language of § 34-9-6 because it includes a diagnosis or the professing of a diagnosis of a deficiency or physical condition of the human teeth or jaws. (Supp.C. 27-28). In his opinion, when a person goes into a kiosk where teeth bleaching is being advertized and the person asks "Can I have my teeth whitened?" and whoever is there says, "yes, you can", that is professing a diagnosis that the person is physically able to undergo the procedure. (Supp.C. 28-29).

Dr. Busby was not persuaded that there is no difference between the products available at retail stores and the whitening service provided by White Smile. Dr. Busby testified:

So that to me is the difference. One is a product that's being bought by a consumer to be used at his or her discretion. And the public then they have to depend on the FDA or other entities to make sure that those products have a semblance of safety and efficacy, otherwise they would not be able to be purchased by the over the counter.

The other situation is: You have an entity of whatever the product is. And it really doesn't matter to me what the product is that is being used at these kiosks. When you're purporting that I'm going to bleach your teeth' and you're going to sit here we're going to do it; it is going to be this long; and we're going to give you this many shades of difference; and I'm providing this service for you and you're going to give me a remuneration. Based on the statute in my opinion that renders that as being the practice of dentistry.⁵

(Supp.C.33-34).

Dr. Kenneth Tilashalski is the current Director of Academic Affairs and Associate Professor in the Department of Diagnostic Services at the University of Alabama School of Dentistry. He is also an adjunct professor and scientist at the UAB School of Medicine, Department of Pathology and the UAB School of Medicine. Dr. Tilashalski is also Board Certified in Endodontics and in Oral Pathology. He has

⁵ Dr. Busby analogized to hair coloring. He testified, "You can buy all kinds of hair coloring products at supermarkets, or wherever. And you can do it, but if you profess that you're going to color someone's hair, and you do so in whatever setting, and you charge a fee for it, based on Alabama statute and law you're a cosmetologist and have to be licensed to perform those services." (Supp.C. 33).

published over twenty full length manuscripts that have been peer reviewed. Dr. Tilashalski also practices privately at the Dental School one day a week in the area of Endodontics. (Supp.C. 81-86).

Dr. Tilashalski reviewed the White Smile website, did an extensive literature search, and spoke to several dentists who perform teeth whitening procedures. Dr. Tilashalski emphasized that there are various conditions in which teeth bleaching is contraindicated. These include:

1. Inflamed teeth with inflamed pulpal status or necrotic pulp;
2. Teeth with restorations, especially leaky restorations;
3. Teeth with hypo calcifications;
4. Teeth with calculus or plaque;
5. Teeth with exposed dentin;
6. Teeth with active decay;
7. The presence of periodontal disease, gingivitis or any soft tissue inflammatory conditions. (Supp.C. 91).

Dr. Tilashalski observed that the "informed consent" document which customers of White Smile are asked to sign before receiving their treatment did not mention any of these

conditions in which whitening is contraindicated and did not include a general admonition that a person should first have a dental examination to make sure that teeth whitening was appropriate for them. Dr. Tilashalski concluded that the consent form did not constitute an "informed" consent because it did not completely inform a person of all the risks inherent with teeth bleaching. (Supp.C.158-160).

Dr. Tilashalski testified that according to the Centers for Disease Control, the amount of untreated decay in the United States is high.⁶ Certain categories of the population, such as smokers, have an even higher rate of untreated decay. Twenty one percent of adults age 20 to 64 have recession greater than 2 millimeters with exposed dentin and nine percent are affected by periodontal disease. (Supp.C. 92).

Dr. Tilashalski testified that the direct application of whitening material to any degree of decay is contraindicated. (Supp.C. 95).

Dr. Tilashalski was asked whether or not there is a "diagnosis" if a person goes to Randall's salon and asks if

⁶ One CDC study of over 28,000 participants found that untreated tooth decay was present in over 27% of 20-34 year olds; in 25% of 35-49 year olds; and 22% of 50 to 64 year olds. (Supp.C. 92, 252-354).

their teeth can be whitened and is told by the teeth whitening specialist that they can be. He explained that it is professing to be able to perform a service but that there is also a problem with a lack of diagnosis. He testified that

You have to be able to look at the teeth. Not all teeth can be whitened. Not all teeth are suitable for whitening. To be able to say, I can whiten that tooth on someone that asks the question without doing an exam and a proper diagnosis is really a disservice to the patient.

(Supp.C. 100).

Dr. Tilashalski testified that the teeth whitening process utilized by White Smile constitutes the practice of dentistry because it is providing a dental service. He stated that:

Tooth - teeth whitening is - - should be part of a comprehensive dental plan, which should include other options than cosmetic bleaching, veneers, crowns. There is certainly many conditions that preclude the whitening of teeth and to provide that service for remuneration is the practice of dentistry.

(Supp.C. 105).

[C]osmetic bleaching is an irreversible dental procedure done to the dental tissues that carries risks and requires a dental examination prior to its use.

(Supp.C. 115).

The American Dental Association approves teeth whitening products for at home use which contain no more than 10%

carbamide peroxide which equates to about 3.5% hydrogen peroxide. The hydrogen peroxide content of the product used by White Smile and Randall's salon is 12% hydrogen peroxide, which equates to a carbamide peroxide level is 42%, and is much greater than what is approved by the American Dental Association. (Supp.C. 160-168). Dr. Tilashalski testified that the concentration of the hydrogen peroxide is important because, according to two peer reviewed journal articles, the type of light being used by White Smile and Randall's Salon, with a much lower concentration of hydrogen peroxide, can increase the temperature of the pulp which can result in tooth necrosis - the death of the tooth - which would require extraction or a root canal. (Supp.C. 172-173).

Dr. Tilashalski was shown at his deposition a tray used by White Smile and Randall's Salon. He testified that it was not an effective barrier to protect the tissues or tooth structure from the risk of irritation. He testified that if a whitening procedure is done at a dental office, a rubber dam or a painted on protective material would be used to isolate the soft tissues so the whitening gel would be placed only on intact, non-restored, non-decayed, non-hypo-calcified, healthy tooth structure on teeth with healthy pulps only. Also, at a dental office, there would be a diagnosis that teeth whitening

was adequate and appropriate for the particular patient. If the dentist chose to offer a whitening product for home use, a custom tray would be prepared that would not extend into the soft tissues so that the gel would not be extended to the soft tissues. (Supp.C. 178-180).

Dr. Tilashalski testified that the White Smile bleaching process bleaches both the enamel, the outer layer of the tooth, and the dentin, the inner layer and the one next to the pulp. Consequently, he explained, if the dentin is exposed, by virtue of tooth recession or cavity decay or leaky restorations, these are all potential conduits of material from the outside of the tooth to the inside of the tooth, which exposes the living part of the tooth, the pulp, to adverse and serious consequences. (Supp.C. 187-188). Obviously, only a dentist is capable of diagnosing the presence of decay, periodontal problems, gingivitis, etc. (Supp.C. 183).

The White Smile website literature boasts: "most clients see great results with just one 12-minute procedure. Depending on the level of discoloration, **we may recommend an additional 12-minute procedure.**" (Supp.C. 434) (emphasis added). In Dr. Tilashalski's opinion, this constitutes the practice of dentistry because there is a diagnosis being made, even a

prognosis, and a dental service is applied to a patient. (Supp.C.192-193).

The expert proffered by White Smile and Randall's Salon, Frank R. Recker, DDS, JD, is licensed as a dentist in Ohio and Florida and as a lawyer in Ohio, Kentucky and Florida. The last time he was regularly and actively engaged in the practice of dentistry was in 1986. Since 1986, Recker's main concentration has been the practice of law. (Supp.C.540, 619). Recker has never practiced dentistry or law in Alabama.

Prior to his deposition in this case, Recker had never testified as to whether a certain act does or does not constitute the practice of dentistry. (Supp.C. 548). In addition to serving as an expert witness for Appellants, Recker has corresponded with various regulatory agencies on behalf of Jim Valentine and White Smile advocating for the unregulated "consumer assisted application" of tooth whitening products in salon or spa settings, and previously served as legal counsel for at least one distribution company for a tooth whitening product similar to the one at issue in this case. (Supp.C.572-575).

Despite the fact that Recker has never practiced dentistry or law in Alabama and has never been subject to the provisions of the Alabama Dental Practice Act, Recker

testified that in his opinion, White Smile and Randall's teeth whitening process does not constitute the practice of dentistry. Basically, Recker testified that if the product being used on the teeth does not require a prescription and the consumer himself applies the product, the environment in which the product is applied is irrelevant. (Supp.C. 579-581). Recker opined that the consent form used by White Smile is "totally unnecessary" because "with the materials we're talking about, I don't see any foreseeable risk to the process." (Supp.C. 585).

However, Recker would not "countenance a nondentists hands being in somebody's mouth, you know, or saying, your gums are this or you need that. That in my view in my world, be making a dental diagnosis." (Supp.C.583). He testified that "as soon as my hands go into that oral cavity, I could do things that could potentially injure the patient or the consumer. . . (Supp.C. 610). Having acknowledged these dangers, Recker nevertheless later testified, in contrast to his earlier testimony, that a non-dentist putting the whitening product in another person's mouth would not constitute the practice of dentistry. He testified:

The question in my mind would be, does the presence of somebody's hand, assisting putting a tray in my mouth, crossover into the realm of a

dental procedure as contemplated by the legislature when the statute was drafted?

As a dentist, I can't think that the legislature was worried about that being dentistry . . ."

(Supp.C. 613).

White Smile's Experience With Other State Dental Boards

White Smile's overall strategy to end what Mr. Valentine described as "senseless attacks" by state dental boards is to file suits like this one. (Supp.C. 921). Valentine testified that "we figure if we win in two states, then the other states will eventually just let it be. At least that's our strategy." (Supp.C. 921).

White Smile has been contacted by the dental boards of New Mexico, Oklahoma, and Georgia. (Supp.C. 905). The Oklahoma Board advised that the teeth whitening process constituted the practice of dentistry. (Supp.C. 908). White Smile ignored this letter because they had set up in Sam's Clubs in Oklahoma only as a "road show." (Supp.C.907-909). Likewise, the New Mexico Dental Board informed White Smile that the teeth whitening process was the practice of dentistry and in response, White Smile intends to file a declaratory judgment action there. (Supp.C. 911-913). The Mississippi Dental Board also has taken the position that White Smile's

procedures constitute the practice of dentistry. (Supp.C. 917-918).

In White Smile's home state of Georgia, White Smile was contacted in July of 2008 by the Dental Board, which Mr. Valentine referred as the "dental cops." White Smile was asked to sign a Voluntary Cease and Desist to which Mr. Valentine responded:

We told him- we laughed at him and told him no and explained to him what we did and then that was that.

(Supp.C.931).

The Ohio State Dental Board rendered an opinion (with which the Alabama Dental Association disagrees) that as long as the consumer applies the whitening material to his own teeth and no one else places their hands in the consumer's mouth, the procedure is allowable. (Supp.C. 1084). However, this opinion assumes that the consumer applies the light to his own teeth, which the evidence in this case shows not to be the case.⁷ The Ohio Dental Board then goes on to state:

Issues can arise with the materials being provided at the kiosk/salon. The unregulated and unsupervised use of these products can be harmful to the

⁷ See step number 21 in the White Smile training manual which states, "21. Adjust LED light into proper position (approximately 1-2 inches away from customer's mouth)." (Supp.C. 1116).

consumer. Further, the safety and efficacy of products not distributed by a licensed dentist cannot be assured, and should not be used, or should be used with extreme caution.

(Supp.C. 1084).

SUMMARY OF THE ARGUMENT

The evidence offered in this case shows that the teeth whitening services offered by Appellants have a potentially detrimental impact on the health, safety and welfare of the citizens of Alabama. The Alabama Dental Practice Act was enacted to protect the public health, safety and welfare, and the provisions of the Act - including the already-broad definition of "practice of dentistry" - must be construed liberally to effect that purpose. The services Appellants perform pursuant to the White Smile teeth whitening system plainly fall within the broad definition of the practice of dentistry.

The White Smile teeth whitening system utilizes a bite registration tray that is placed in the customer's mouth to create an impression of the teeth. The whitening gel is then placed in the tray, and the tray is returned to the customer's mouth to complete the whitening process. Clearly, Appellants "directly or indirectly, by [some] means or method, make an impression of the human ... teeth." Ala. Code §34-9-6(1). That constitutes the practice of dentistry within the ADPA.

Likewise, Appellant's diagnose, profess to diagnose, prescribe for, profess to prescribe for, treat or profess to treat "a deficiency .. or physical condition of the human teeth." Ala. Code § 34-9-6(4). The evidence in this case demonstrates that in providing teeth whitening services pursuant to the White Smile process, Appellant' "teeth whitening specialists" - among other things - consult with customers "on an individual basis to identify any potential issue" the customer may have and make recommendations as to further services or procedures. A diagnosis and prognosis is being made by the "specialist" and a treatment is provided - **that** constitutes the practice of dentistry.

Performing, attempting to perform, or professing to perform "a dental operation or a dental service of **any** kind" constitutes the practice of dentistry. Ala. Code § 34-9-6. Certainly, the evidence in this case shows that Appellants attempt or profess to perform a dental service of some kind.

The trial court properly determined in this case that the teeth whitening services Appellants provide fall within the broad definition of the practice of dentistry in the ADPA. The judgment of the trial court should be affirmed.

ARGUMENT

I. The trial court did not err in determining that Appellants' teeth whitening procedure, administered to members of the public in a beauty salon by persons with no formal dental training, falls within the practice of dentistry as set forth in the Alabama Dental Practice Act, Ala. Code 1975, § 34-9-6, and is subject to the regulatory supervision of the Board of Dental Examiners of Alabama.

The Alabama Dental Association (ADA) supports the position taken by the Board of Dental Examiners that the teeth whitening services performed by Plaintiff D'Markos, LLC in its Montgomery Salon pursuant to its relationship and agreement with White Smile USA, Inc. constitutes the practice of dentistry within the scope of the Alabama Dental Practice Act, Ala Code 1975, § 34-9-1, et. seq.

Pursuant to the ADPA, it is unlawful for any person to practice dentistry in this State unless he is a duly licensed dentist. Ala. Code 1975, § 34-9-3. The ADPA includes a broad definition of what constitutes the practice of dentistry, providing in pertinent part:

Any person shall be deemed to be practicing dentistry who performs, or attempts or professes to perform, **any dental operation or dental service of any kind**, gratuitously or for a salary, fee, money or other remuneration paid, or to be paid, directly or indirectly, to himself, or to any person in his behalf, or to any agency which is a proprietor of a

place where dental operations or dental services are performed; or

(1) Who directly or indirectly, by any means or method, makes impression of the human tooth, teeth, jaws or adjacent tissue ...; or

* * *

(4) Who professes to the public by any method to furnish, supply, construct, reproduce or repair any prosthetic denture, bridge, appliance or other structure to be worn in the human mouth, or **who diagnoses, or professes to diagnose, prescribe for, professes to prescribe for, treats or professes to treat** disease, pain, deformity, **deficiency, injury or physical condition of the human teeth** or jaws, or adjacent structure, or who extracts or attempts to extract human teeth, or remove tumors, abnormal growths or other lesions from the human gums, jaws and adjacent structures, or who operates for harelip or cleft palate; or who treats surgically or mechanically fractures of the human jaw; or who administers local or general anesthetics in the treatment of any dental lesion;

Ala.Code 1975, § 34-9-6 (emphasis added).

The ADPA was enacted to protect the health, safety and welfare of the public. Indeed, the Act specifically provides:

(a) The Legislature hereby declares that the practice of dentistry affects the public health, safety, and welfare and should be subject to regulation. It is further declared to be a matter of public interest and concern that the dental profession merit and receive the confidence of the public and that only qualified dentists be permitted to practice dentistry in the State of Alabama. All provisions of this chapter relating to the practice

of dentistry and dental hygiene shall be liberally construed to carry out these objects and purposes.

Ala. Code 1975, § 34-9-2 (emphasis added). Thus, the already-broad definition of "practice of dentistry" must be liberally construed to effect the Act's goal of protecting the health, safety and welfare of the citizens of this State.

Appellants and the Institute for Justice essentially argue that the services they provide cannot be the practice of dentistry because the evidence submitted to the trial court shows that there is no difference between the activities performed by Randall's Salon using the White Smile system and a consumer's use at home of an over-the-counter teeth whitening product, such as Crest White Strips. Whoever, whether the activities performed by Randall's Salon using the White Smile system constitute the "practice of dentistry" within the scope of § 34-9-6 cannot be determined by comparing Appellants' activities to other activities - like the sale of over-the-counter teeth whitening products for use by consumers at home - that might, or might not, be held to constitute the practice of dentistry were that issue presented to the Court. Whether Appellants' activities constitute the practice of dentistry must be determined based upon the plain language of

the ADPA and the evidence presented as to Appellants' activities.

Based on the evidence presented in this case as to Appellants' teeth whitening process, the trial court properly denied Appellants' request that the court declare that the teeth whitening services do not constitute the practice of dentistry within the scope of the ADPA.⁸ The trial court relied particularly on White Smile's own literature which reflects a process of twenty-seven different steps, "many of which call for active participation by the technicians identified in White Smile USA's own literature as 'cosmetic teeth whitening specialists.'" (C. 117). The trial court noted that these "specialists" are touted throughout White Smile's literature as "Fast, Effective, Safe, Affordable" and "trained to consult with you on an individual basis to identify any potential issues you may have." (C. 117) (emphasis

⁸ Citing *Ex Parte State Health Planning and Development Agency*, 855 So. 2d 1098 (Ala. 2002) White Smile argues that this Court should not defer to the Board's interpretation of § 34-9-6. The trial court did not "defer" in any sense to the Board's interpretation of the statute. The trial court did exactly what it was supposed to do - it applied the unambiguous provisions of the statute in question to the facts before it and correctly concluded that Appellants' activities constitute the "practice of dentistry" within the meaning of the ADPA.

added). White Smile produces a twelve page "Training Manual" which the court concluded "underscores the significant differences between the processes by which the Plaintiffs provide teeth whitening services and any teeth whitening products approved by the FDA for 'over the counter' sale." (C. 117). The trial court found that White Smile's "numerous proclamations regarding the safety of its product and processes" contained in its own literature "accentuates what is clearly an important aspect of this case: the health, safety and welfare of the citizenry of the State." (C. 117).

The ADPA's goal of protecting the health, safety and welfare of Alabama citizens distinguishes this case from *State v. Lupo*, 984 So. 2d 395 (Ala. 2007), wherein this Court declared unconstitutionally over broad a statutory definition of "interior design" which prohibited "offering advice to a client regarding the selection of paint colors and sofa pillows." 984 So. 2d at 404. Obviously, a non-dentist assisting a consumer to put some substance into his or her body directly impacts the health, safety and welfare of the public, unlike a person assisting a consumer in the choice of paint colors or throw pillows.

The public health and safety issues are particularly concerning when the teeth whitening process is performed in a

hair salon setting. Dental offices must comply with CDC infection control practices and utilize strict sanitation standards. Ala. Admin. Code §270-S-2-.15. A dental office has hand-washing stations, contamination barriers on the chairs, and follows uniform sterilization and sanitation procedures. A hair salon does not provide such equipment or follow such procedures. Further, Appellants' teeth whitening process provides for customers to spit into paper cups that are merely tossed away; it does not provide for barriers on the chairs; it does not require frequent and thorough hand-washing either by the customer, who is putting his hands in his mouth, or by the "teeth whitening specialist," who at the very least is handling the equipment and handing it to the customer. And, all of this is done in a setting where there are hair and nail chemicals in use, not to mention the presence of copious amounts of loose hair, dandruff and other potential contaminants. Certainly, providing teeth whitening services in a salon setting poses serious health and safety concerns.

Appellants and The Institute For Justice argue that because teeth whitening products are available to consumers through drug stores for home use, the Board has no business attempting to regulate a service which supplies a similar

product when administered in a beauty salon.⁹ The Institute for Justice argues that the "Dental Board has not identified any risks presented by White Smile's services that are not also present when consumers use these products at home."¹⁰ (Amicus Brief of The Institute for Justice at p. 1-2). As noted above, however, whether the services Appellants offer

⁹ The most obvious distinction between the two is that Appellants are providing a dental service or dental operation, not just selling a product. The provision of dental services falls squarely within the definition of the practice of dentistry. The sale of a dental related product does not. In fact, the only obvious circumstances in which the sale or provision of a "product" constitutes the practice of dentistry is when someone supplies artificial substitutes for the natural teeth, or furnishes, supplies or delivers prosthetic dentures, bridges, appliances or structures to be worn in the human mouth. See Ala. Code § 34-9-6(2) & (3).

¹⁰ While Dr. Tilashalski testified that both the over the counter whitening strips as well as Appellants' teeth whitening process can potentially cause irreversible damage to teeth, he did note that Appellants process uses a more concentrated hydrogen peroxide than is contained in the over the counter products. (Supp.C. 118-119). The American Dental Association approves teeth whitening products for at-home use which contain no more than 10% carbamide peroxide which equates to about 3.5% hydrogen peroxide. White Smile's product is 12% hydrogen peroxide, the equivalent of 42% carbamide peroxide, and is some four times more concentrated than what is approved by the ADA. (Supp.C. 160-166). Dr. Tilashalski testified that based on peer reviewed articles in the Journal of the American Dental Association, the type of light being used by Appellants can - even when used with a much lower concentration of hydrogen peroxide than used in the White Smile process - increase the temperature of the tooth pulp, which can result in tooth necrosis. (Supp.C. 172-174).

constitute the practice of dentistry must be determined based on the evidence as to the services Appellants are offering, not by comparing those services to other activities. The trial court noted that it was making no findings as to "whether the sale of teeth whitening products such as have been approved by the FDA for 'over the counter' sale in retail settings is permissible under the Alabama Dental Practice Act, as that issue is not before the Court." (C. 118). The trial court correctly concluded that:

[t]he processes by which the Plaintiffs provide teeth whitening services constitute the performance of a dental operation and not merely the sale of a product. Simply put, the fact that citizens of this State may purchase and apply tooth whitening products approved by the FDA for 'over the counter' sale in their own homes does not permit Plaintiffs or others not properly licensed to advertise and perform dental services or operations which affect the public health, safety and welfare.

(C. 118).

Contrary to Appellants' argument, the trial court's conclusion that the teeth whitening service offered by Randall's Salon falls within the practice of dentistry is fully supported by the evidence. One of the Board's experts, Dr. Busby, testified that the risks to the public by unregulated teeth whitening services include:

(a) People with undiagnosed decay or rampant decay in their mouth who are exposed to hydrogen peroxide, wherein during the oxidation process of the hydrogen peroxide breaking down into carbon dioxide and urea and oxygen, that all can enter the pulp of the tooth. If that occurs, there is a high probability that the pulp tissue will necrose and die which could result in an abscessed tooth and/or loss of the tooth. (Supp.C. 40-41).

(b) Barrier techniques, i.e. guarding the gums, during application of the teeth whitening product. If barrier techniques utilized are not complete, are not watched and addressed, there can be damage to the gums. (Supp.C. 41).

(c) The situations where there is resulting sensitivity or post procedure complications. (Supp.C. 42). As explained by Dr. Busby:

If it's an unregulated procedure and there is no dental practitioner that's available at the kiosk or the salon or whatever it may be offered, who's going to take care of that patient? What if they don't have a regular practitioner? Who are they supposed to call? That's a concern from a regulatory standpoint, and from a public protection standpoint, and being a member of the Board; that's my main concern is that who's going to take care of the public if something goes wrong?

* * *

And if you have someone who, is in my opinion, performing a dental service and being remunerated for it, is offering a diagnosis or prognosis, and then can't perform the follow-up care, or give someone information on how to get follow-up care, that could presume a danger to the public.

(Supp.C. 42-43).

Dr. Tilashalski testified that teeth bleaching is contraindicated for people with inflamed teeth, with inflamed pulpal status or necrotic pulp; teeth with restorations, especially leaky restorations; teeth with hypo-calcifications; teeth with calculus or plaque; teeth with exposed dentin; teeth with active decay; the presence of periodontal disease, gingivitis or any soft tissue inflammatory conditions. (Supp.C. 91). Dr. Tilashalski cited a Center For Disease Control study which shows that a significant percentage of the American population has untreated tooth decay. (Supp.C. 92; 252-354).

Dr. Tilashalski testified that Appellants' bleaching process bleaches both the enamel, the outer layer of the tooth, and the dentin, the inner layer and the one next to the pulp. If the dentin is exposed, by virtue of tooth recession or cavity decay or leaky restorations, these are all potential conduits of material from the outside of the tooth to the inside of the tooth which exposes adverse and serious

consequences to the living part of the tooth, the pulp. (Supp.C. 187-188). Obviously, only a dentist can properly diagnose the presence of decay, periodontal problems, gingivitis, etc. (Supp.C. 183).

The Board's experts agreed that Appellants are making a diagnosis and providing a dental service or dental operation. (Supp.C. 21, 22, 27, 30, 100-105, 113). The White Smile marketing materials specifically state that "Our cosmetic teeth whitening specialists are trained **to consult with you on an individual basis to identify any potential issue you may have.**" (Supp.C. 1095) (emphasis added). The website literature states that "most clients see great results with just one 12-minute procedure. Depending on the level of discoloration, **we may recommend an additional 12-minute procedure.**" (Supp.C. 434) (emphasis added). As Dr. Tilashalski noted, a diagnosis and prognosis is being made by the "specialist" and a dental service is being provided - **that** constitutes the practice of dentistry. (Supp.C.192-193).

In support of their position that the practice of dentistry is not implicated here, Appellants tendered the deposition testimony of Dr. Recker, a dentist/lawyer from Ohio/Florida who has not practiced dentistry in over twenty

three years and who has never practiced either dentistry or law in Alabama.¹¹ Even Dr. Recker, however, testified that he could not "countenance a non-dentist ... saying, your gums are this or **you need that**. That in my view in my world, be making a dental diagnosis." (Supp.C.583). As reflected above, the White Smile literature specifically notes that the White Smile "specialists" do exactly that - make a diagnosis and recommend treatment. Thus, even Appellants' expert agrees that that constitutes the practice of dentistry.

The services Appellants perform pursuant to the White Smile teeth whitening system plainly fall within the broad definition of the practice of dentistry. Performing, attempting to perform, or professing to perform "a dental operation or a dental service of **any** kind" constitutes the practice of dentistry. Ala. Code § 34-9-6. Certainly, Appellants attempt or profess to perform a dental service of

¹¹ If this were a medical malpractice action under the Alabama Medical Liability Act, §6-5-548, Ala. Code 1975, Dr. Recker would not have even been allowed to testify at all because he is not an expert practicing the same discipline during the year preceding the date of the alleged breach of the standard of care. See *Sherrer v. Embry*, 963 So. 2d 79 (Ala. 2007) (a medical doctor who practiced plastic and reconstructive surgery was not allowed to testify against a dentist where he had not practiced dentistry within one year of the alleged breach of the standard of care.)

some kind. Appellants "directly or indirectly ... make an impression of the human ... teeth." Ala. Code §34-9-6(1). Likewise, they diagnose, profess to diagnose, prescribe for, profess to prescribe for, treat or profess to treat "a deficiency ... or physical condition of the human teeth." Ala. Code § 34-9-6(4).

The trial court did not err in denying Appellants' request for declaratory relief in this case. Based on the evidence presented in this case, the trial court properly concluded that Appellants' teeth whitening services constitute the practice of dentistry within the ADPA.

CONCLUSION

For the reasons set forth above, the Alabama Dental Association submits that the judgment of the trial court is due to be affirmed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

TO: The Clerk of the Supreme Court of Alabama
Case No. 1080780

WHITE SMILE USA, INC AND §
D'MARKOS, LLC, §
Appellants §
vs. § On Appeal from The Circuit
§ Court of Montgomery County
§ Case No. CV-2008-000153.00
BOARD OF DENTAL EXAMINERS OF §
ALABAMA, §
Appellee. §

I certify that I have this the 1st day of July, 2009, served a copy of the foregoing brief and argument on counsel of record for all parties via email and by placing a copy of same in the United States mail, first class postage prepaid and addressed as follows:

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