UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of NORTH CAROLINA STATE BOARD OF DENTAL EXAMINERS, Respondent.	**PUBLIC** Docket No. 9343

COMPLAINT COUNSEL'S OPPOSITION TO RESPONDENT'S MOTION FOR LEAVE TO SUBMIT SURREBUTTAL EXPERT WITNESS REPORT AND TO STRIKE (IN PART) EXPERT WITNESS REBUTTAL REPORT OF MARTIN GINIGER, D.M.D.

Pursuant to Commission Rules of Practice 3.22 and 3.31A, Complaint Counsel respectfully submits this opposition to Respondent's Motion for Leave to Submit Surrebuttal Expert Witness Report and to Strike (In Part) Expert Witness Rebuttal Report of Martin Giniger, D.M.D. Respondent's motion to strike is without merit and should be denied.

Dr. Martin Giniger is trained in dentistry, oral medicine, and oral biology, and has developed, formulated, and clinically tested the safety and effectiveness of many oral care products, including teeth bleaching products. Dr. Giniger's Expert Report was served on Respondent on November 26, 2010 (Attachment A). The Report of Respondent's expert, Dr. Haywood, was served on Complaint Counsel on December 20, 2010 ("Haywood Report") (Attachment B). And Dr. Giniger's Rebuttal Report was served on Respondent on January 8, 2011 ("Giniger Rebuttal Report") (Attachment C).[1] On January 13, Respondent filed its motion

[1]On January 12, 2011, one and a half days before Complaint Counsel's scheduled deposition of Dr. Haywood, Complaint Counsel received a draft of Respondent's Motion requesting leave to submit a surrebuttal. Given the prejudice that might result to Complaint

requesting leave for Dr. Haywood to submit a surrebuttal report on January 21, 2011.

In its motion, Respondent nakedly asserts that various sections of the Giniger Rebuttal Report are improper and should be stricken. Respondent provides this Court with no rationale, no explanation, and no analysis. For this reason alone, Respondent's motion should be denied.[2]

But further, Respondent's motion does not satisfy the applicable legal standard. An expert may properly include within his rebuttal expert report any information that will "explain, repel, counteract or disprove" the expert testimony offered by the opposing party. *United States v. Finis P. Ernest, Inc.*, 509 F.2d 1256, 1263 (7th Cir. 1975), *cert. denied*, 423 U.S. 893 (1975); *Crowley v. Chait*, 322 F. Supp. 2d 530, 551 (D.N.J. 2004); Wright & Miller, *Federal Practice and Procedure*, § 2031.1 at 79 (2010). Measured by this standard, the Giniger Rebuttal Report is proper in its entirety. Because it is proper, surrebutal, or striking of material in the Rebuttal Report, is not.

Below, we discuss the sections of the Giniger Rebuttal Report for which the Board seeks leave to submit surrebuttal.

1. **Page 7, the first two full paragraphs and last partial paragraph through the first partial paragraph on page 8; page 10, last paragraph, through page 13, first partial paragraph**. On page seven, Dr. Giniger notes that the Haywood Report failed to dispute

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Counsel if it deposed Dr. Haywood only to have him then submit an additional report, Complaint Counsel withdrew it's notice of deposition. On January 14, Complaint Counsel and Respondent jointly filed a motion to extend the deadline for deposition of Dr. Haywood until after Your Honor's ruling on this motion, which Your Honor has indicated will be granted.

[2]In a further example of disruptive overreaching, Respondent is asking for 13 full days to prepare a surrebuttal report dealing with only part of Dr. Giniger's rebuttal report, whereas the court's initial scheduling order (modified by the court in response to problems that Respondent had in producing a timely expert report) had allowed only ten days to prepare Dr. Giniger's Rebuttal Report in the first instance.

specific claims in the Giniger Report, stating that Dr. Haywood has thus conceded these points. This seeks to **repel and counteract** Dr. Haywood's report by **explaining** that Dr. Haywood's broad assertions regarding the safety of teeth bleaching are unsupported by specific detail. Dr. Giniger then notes that the Haywood Report makes six claims that purportedly support his assertion that non-dentist teeth whitening poses material safety risks to consumers. Subsequently in pages 7 through13, Dr. Giniger systematically rebuts, **counteracts** and **disproves** each of Dr. Haywood's claims by analyzing the claims, exposing weaknesses in, or inapplicability of, materials cited by Dr. Haywood as support for his claims, and noting contradictory evidence. This is textbook rebuttal, of proper scope, and provides no basis for surrebuttal.

2. **Page 17, last full paragraph through page 18, first partial and first full paragraph**. In this portion Dr. Giniger summarizes his understanding of a portion of Dr. Haywood's report regarding the safety of non-dentist teeth whitening. He then proceeds to **repel** and **disprove** Dr. Haywood's assertion through citations to contrary sources and noting the lack of support provided in the Haywood Report. Specifically, Dr. Haywood identifies specific risks relating to the inability to diagnose certain pathologies or conditions in the event of wholly successful lightening of certain discolored teeth by non-dentist teeth whitening. On pages 17 and 18, Dr. Giniger simply debunks Dr. Haywood's premises and conclusions by **explaining** that the pathologies and conditions referred to by Dr. Haywood are readily diagnosable in routine dental check-ups notwithstanding prior lightening of discolored teeth; that consumers of non-dentist teeth whitening do not avoid dentists they otherwise would have seen because they have had non-dentist teeth whitening; and that noone is aware of any real-world instance in which the harm at the

very center of Dr. Haywood's opinion has ever come to pass. This is textbook rebuttal, of proper scope, and provides no basis for surrebuttal.

3. **Page 21, last partial paragraph through page 22 in its entirety**. Again, Dr. Giniger refers to specific arguments in Dr. Haywood's report this time Dr. Haywood's claims that non-dentist-provided teeth whitening is ineffective/a bad value, and that consumers are misled into confusing non-dentist-providers with dentists and provides substantial information to the contrary, **repelling** and **counteracting** Dr. Haywood's arguments. Once again, this is textbook rebuttal, of proper scope, and provides no basis for surrebuttal.

The FTC rules and the Scheduling Order limit surrebuttal to material in the rebuttal report that is outside the scope of fair rebuttal i.e., material that does not explain, repel, counteract or disprove material in the report subject to rebuttal. All of the material in Dr. Giniger's report does just that it explains, repels, counteracts or disproves material in Dr. Haywood's report. Perhaps Respondent believes that in his report, Dr. Haywood could or should have expressed additional opinions, offered additional bases for those opinions he did express, or just presented his opinions and their bases more effectively. But the wish for a "do-over,"despite the proper scope of Dr. Giniger's Rebuttal Report, is not sufficient grounds for Dr. Haywood's submission of a surrebuttal report. Granting such a do-over in the guise of surrebuttal necessarily would advantage Respondent and prejudice Complaint Counsel, to no lawful purpose. Any surrebuttal by Dr. Haywood must either retread previously traveled territory, or itself be beyond the bounds of proper surrebuttal. Accordingly, Respondent's request for leave to submit a surrebuttal expert report should be denied.

As previously indicated, Respondent seeks to have other portions of Dr. Giniger's

Rebuttal Report stricken. However, those portions of the Giniger Rebuttal Report similarly are fair rebuttal, explaining, repelling, counteracting or disproving material in Dr. Haywood's report, or providing contextual information enabling the reader to understand and weigh Dr. Haywood's claims and Dr. Giniger's information and opinion in rebuttal.[3] Below, we discuss the sections of the Rebuttal Report that the Board asks Your Honor to strike.

1. **Page 1, first paragraph**. Dr. Giniger begins his report by introducing himself, and briefly stating the purpose of the report. He then summarizes Dr. Haywood's report generally and then states why he disagrees, overall, with Dr. Haywood's conclusions. Such a summary **explains** the Haywood Report, and provides context for the reader to understand Dr. Giniger's overall effort to **repel** and **counteract** the Haywood Report. This is within the proper scope of rebuttal, and there is no basis for striking this material.

2. **Page 4, second full paragraph; page 5, first paragraph under heading III**. In this portion, Dr. Giniger briefly summarizes his qualifications as an expert and refers the reader to his initial report for a more detailed description of those qualifications, in addition to the scope of his work in preparing the report and his compensation. Recognition of Dr. Giniger's credentials provide context for the reader, and provide an understanding as to Dr. Giniger's ability to opine on matters contained within his report. Where not important to the reader in understanding or weighing Dr. Giniger's rebuttal information, Dr. Giniger has simply referred the reader to his initial report to avoid

[3]Rule § 3.31A(c) provides that a "rebuttal report . . . need not include any information already included in the initial report of the witness." The rule does not preclude the inclusion of such material in a rebuttal report where otherwise appropriate, and summary and contextual information is plainly useful to the reader in understanding, appreciating, and assessing the expert's opinions in rebuttal.

gratuitous provision of cumulative information; where, however, information was needed in the Rebuttal Report to provide the reader with necessary context for the understanding or weighing of proper rebuttal material, Dr. Giniger has added that contextual information. This is within the proper scope of rebuttal, and there is no basis for striking this material.

3. **Page 23 in its entirety through page 24, first partial paragraph**. Dr. Haywood claims that non-dentist provided teeth whitening does not provide results that are commensurate with its cost, and can cause consumers to be confused or deceived when non-dentists employ hygienic measures such as donning gloves. However, the Haywood Report provides no evidence for those propositions and ignores evidence of measures taken to prevent any confusion or misunderstanding. Dr. Giniger disagrees with these assertions, points out the lack of support for them and at the top of page 23 provides support that **repels** and **counteracts** Dr. Haywood's claims. Then, at the bottom of page 23, Dr. Giniger notes that Dr. Haywood refers to teeth bleaching as "the removal of stains" multiple times throughout his report. Dr. Giniger then proceeds to refute this assertion, **explaining** that teeth bleaching is actually an alteration of bonds at the molecular level which result in the lightening, but not removal, of stains and provides support for this alternate opinion. This is textbook rebuttal, of proper scope, and provides no basis for striking this material.

The FTC rules and the Scheduling Order limit the striking of material in rebuttal reports to material that is outside the scope of fair rebuttal. The material Respondent asks Your Honor to strike from Dr. Giniger's Rebuttal Report is fair rebuttal, explaining, repelling, counteracting or disproving material in the Haywood Report, and providing the reader with contextual

information that assists in understanding and weighing that rebuttal material. It is entirely proper in scope and none of it should be struck.

Because nothing in Dr. Giniger's report stands outside the scope of fair rebuttal, Respondent's Motion for Leave to Submit Surrebuttal Expert Witness Report and to Strike (In Part) Expert Witness Rebuttal Report of Martin Giniger, D.M.D. should be denied.

Respectfully submitted,

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Dated: January 18, 2011

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	DOCKET NO. 9343
NORTH CAROLINA BOARD OF DENTAL EXAMINERS,	)	
Respondent.	)	

[PROPOSED] ORDER

It is hereby, ORDERED, that Respondent's Motion for Leave to Submit Surrebuttal Expert Witness Report and to Strike (In Part) Expert Witness Rebuttal Report of Martin Giniger, D.M.D., is hereby, DENIED.

ORDERED:

_____
D. Michael Chappell
Chief Administrative Law Judge

DATE:

Attachment A

EXPERT WITNESS REPORT OF
MARTIN GINIGER, D.M.D., M.S.D., Ph.D., F.I.C.D.

[FTC v. North Carolina Board of Dental Examiners; Docket No. 9343]

I. BACKGROUND AND QUALIFICATIONS

I am Dr. Martin Giniger. My Curriculum Vitae is attached as Exhibit 1. I have been engaged by Complaint Counsel as an expert in the history, practice, and safety of dental stain removal and vital teeth bleaching. "Vital teeth bleaching" refers to the application of a peroxide gel or peroxyl analog to live teeth for the cosmetic enhancement of tooth color principally the lightening of stain color.[11] (Teeth are living organs that may be killed by disease or trauma, in which the event is referred to as "non-vital." Unless noted, I use the terms "vital teeth bleaching" and "teeth bleaching" interchangeably.) I briefly summarize my relevant qualifications below:

- I am and have practiced as a licensed dentist, having obtained my DMD in 1984;
- I subsequently obtained an MsD in Oral Medicine (1993) and a PhD in Biomedical Science, concentrated in Oral Biology (1993). In addition, I have had significant other training, including Clinical Rotations at prestigious institutions in such subjects as Oral Pathology.
- I have taught and directed programs first as a Clinical Scholar and Teaching Assistant and then as an Assistant Professor at well regarded Schools of Dentistry. For example, I have taught basic and advanced courses in Oral Diagnosis, Diagnostic Sciences, and Treatment Planning at Louisiana State University Medical Center School of Dentistry (LSU) and the University of Medicine and Dentistry of New Jersey School of Dentistry (UMDNJ). I also have held numerous hospital appointments including at LSU, where I

was Director of the Medical Diagnostic Laboratory, and at UMDNJ, where I was Director of Diagnostic Services and at UMDNJ School of Dentistry, where I was Director of Community Services.

- I have done extensive research which has been published in leading scientific journals. For example, my articles relating to my discovery of a previously unknown way in which melanoma cells spread using Laminin as a signaling molecule have been published in, among other journals, the Journal of Biological Chemistry and the Journal of Dental Research. My clinical research can be gleaned from my publications list in my CV.
- I have received numerous grants and honors for my work, including the National Institutes of Health Physician-Scientist Award and the Academy of Oral Medicine's Lester Burket Memorial Award (which seeks to promote basic and clinical research in oral medicine).
- I have been employed by or consulted for numerous professional and consumer oral care companies, developing and/or testing the safety and effectiveness of a variety of oral care products including teeth bleaching products. For example, I served as Colgate-Palmolive Company's Director of Professional and Academic Marketing and as Vice President of Clinical research for Dexcel Pharma, among other employments, and provided consulting services to numerous others providers of teeth whitening products including, among others, Discus Dental Corp., the manufacturer of the Zoom in-office teeth whitening system among other products, and BriteSmile, formerly a leading independent provider of teeth whitening products/systems to dentists and non-dentist teeth whitening service providers and now a part of Discus Dental. The products that I have helped to develop including, among others, Colgate Whitening Toothpastes and Systems, Discus Dental

NiteWhite with ACP, a take-home teeth whitening product, and the Discus Dental Zoom2 in-office whitening system, have had aggregate sales of more than $10 billion.

- I currently am Chief Scientific Officer of the Power Swabs Corporation and the PSC Research Institute. My recent work has emphasized the development of novel teeth whitening formulations for professional and consumer application.
- My education, training, and experience have provided me with a thorough understanding of oral medicine, including diagnosis and management of diseases and conditions that may affect the oral cavity, proper practice and procedures, including those directed toward infection control, and the history, practice, formulation, and safety of dental stain removal and teeth bleaching.

II. MATERIALS CONSIDERED IN FORMULATING OPINIONS

In formulating my opinions in this matter, I have considered the materials identified in the References section of this Report (Section 6) and Exhibit 2 of this Report, List of Additional Reviewed Materials. In addition, I have drawn on my extensive and unique personal knowledge (see the Background and Qualifications section of this Report (Section 1)), and have consulted some of my own publications, which are identified in Exhibit 1 of this Report (my CV), as I thought helpful.

I expect to continue reviewing relevant materials and new submissions as this case progresses, and I reserve the right to modify my conclusions based on these materials and submissions. I also reserve the right to supplement this Report based on any additional work that I may be asked

to do.

III. SCOPE OF WORK AND COMPENSATION

I have been retained by Complaint Counsel to review materials including, for example, relevant scientific texts, journal articles, and matters of record in this litigation as appropriate, and based on those materials and my own extensive knowledge and experience to describe the history, practice, and safety of teeth whitening. In particular, I have been asked to research as necessary and opine as to how the term "stain removal" would have been understood in the context of dentistry prior to and during the 1930s, during which time some legislatures, including North Carolina's, limited the practice of stain removal to licensed dentists; explain whether as a matter of fact teeth bleaching is the removal of stains; compare and contrast the teeth bleaching alternatives available to consumers chairside and take home bleaching provided by dentists, chairside bleaching provided by non-dentists, and personal use of over-the-counter (OTC) products; to determine whether the public safety is threatened by non-dentist-provided teeth whitening products and services; and to formulate an opinion as to whether the public interest is served by the North Carolina State Board of Dental Examiner's (NC-SBODE's) exclusion of non-dentists from the market or by permitting consumers a choice of teeth bleaching providers and products, including dentists and non-dentists.

In addition, the scope of my work included consultation with Complaint Counsel as required, the drafting of Reports as necessary, and the presentation of testimony at deposition and trial as required.

I am being compensated for my work in this matter at a rate of $225.00 per hour.

IV. SUMMARY OF OPINIONS

Consumers are best served by having a variety of teeth bleaching alternatives, including dentist-provided and non-dentist provided products and services. Teeth bleaching, by whomever provided, is safe and effective.[17, 24, 27, 28, 29, 37] Products/services differ, however, in such things as number of bleaching sessions required, support provided to the consumer, and price. Chairside bleaching, whether provided by dentists or non-dentists, is quick and convenient, requiring only a single bleaching session. In contrast, take-home products, whether provided by dentists or over-the-counter, require numerous bleaching sessions over many days. Dentists provide professional service, support, and advice, while non-dentists typically provide service, support, and advice as allowable under applicable laws based on training by the manufacturers of the bleaching products/services they provide and their own experience, which may be considerable in that teeth bleaching may be the sole service they offer. In contrast, take-home products come with instructions and little, if anything, more. As one might expect, dentist-provided teeth bleaching typically is appreciably more expensive than non-dentist-provided teeth bleaching. However, non-dentist- provided chairside teeth bleaching is a particularly good substitute for dentist-provided chairside teeth bleaching for consumers interested in getting quick results. In contrast, OTC products available for self-application at home are the least expensive alternative for consumers.[40] These products may be fine for cost-conscious consumers who are willing to self-apply bleaching products numerous times over numerous days aided only by written instructions, but plainly they are not a good substitute for chairside teeth bleaching for

consumers intent on quick results or wary about self-application of OTC products without supervision or support.

Beyond this, my opinions may be summarized as follows:

- There are several ways to whiten teeth. The use of cosmetic dental restorations is one way. Stain removal is another way. And a third way is teeth bleaching, commonly known today as "teeth whitening," in which peroxide-containing gels or serums are applied to the teeth using any of a variety of delivery systems that are available from dentists, non-dentists, and OTC.
- Prior to and during the 1930s, the removal of dental stains would have been understood by legislators as involving the scratching off of dental stains using pick-like instruments or abrasives, which might be applied using then relatively new rotary instruments. It likely would not have been understood to refer to use of bleaching agents. The principal bleaching agent then in use, Superoxol, was infrequently used and only to lighten darkened non-vital teeth or teeth that soon would become non-vital.[50] Certainly, the legislators could not have understood dental stain removal to include the use of safe bleaching agents to achieve a generalized whitening/brightening of the smile (modern vital teeth bleaching), as that use would not be developed for another 50 odd years.
- Moreover, as a matter of scientific accuracy, teeth bleaching does not remove stains. In contrast to stain removal, which literally removes stains, teeth bleaching causes a chemical reaction that temporarily lightens the color of stains; but it does not remove them the stain persists, and its color typically rebounds (*i.e.,* the appearance of the stain again becomes more intense).

- The public safety is not threatened by non-dentist-provided teeth bleaching products and services. Literally millions of people have whitened their teeth in this way over the last 20 years, yet published clinical reports do not demonstrate any appreciable incidence of significant or non-transient harm resulting from non-dentist-provided teeth whitening in fact, I am aware of none at all.
- I have reviewed the materials referred to by NC-SBODE counsel as supporting the exclusion of non-dentists from the market, and I find it wanting. For example, the EU's limitation of use of hydrogen peroxide as a teeth bleaching agent is based on toxicity studies in which rats or other non-human test subjects were administered extreme and prolonged doses of hydrogen peroxide. These studies have no bearing on risk to humans from teeth bleaching. That is reflected in the fact that the United States Food and Drug Administration (FDA) has determined that hydrogen peroxide and other teeth bleaching agents are cosmetic products not requiring regulation. Moreover, NC-SBODE's position overlooks the fact that if the EU's extrapolations are correct and again, I believe they are not , limitation of use of hydrogen peroxide would be warranted for non-dentists and dentists alike. To the best of my knowledge, the NC-SBODE has never proposed limiting dentists' use of hydrogen peroxide.
- I have also reviewed the NC-SBODE and other materials relating to Mr. Brian Runsick's claim that he was significantly harmed by a non-dentist-provided teeth whitening. The available evidence especially the elapse of four days between his teeth bleaching and the onset of Mr. Runsick's self-reported symptoms is inconsistent with any claim that the bleaching caused Mr. Runsick's problems. A more likely explanation given available evidence is that Mr. Runsick suffered from a periodontal abscess that just happened to

occur within a few days of his teeth bleaching. The questionable nature of Mr. Runsick's claim, and the extraordinary lack of similar complaints, demonstrates, among other things, that a few anecdotal reports are not a substitute for reliable clinical or empirical evidence of product/service safety and efficacy.[48,49]

- In addition to unwarranted concerns about the teeth bleaching itself, representatives of the NC-SBODE have expressed concerns about sanitary conditions in non-dentist-operated teeth whitening establishments, such as kiosks in malls. I have reviewed the operating protocols[1,2,3,5,53] used by many such establishments. Based thereon I see no reason why appropriate sanitary conditions cannot be maintained in non-dentist-operated teeth whitening establishments, including kiosks without running water. If regulation were warranted, regulatory regimes such as are applicable to numerous other endeavors (food-handling, for example) seem practicable and would be far less draconian and anti-consumer than the wholesale exclusion of non-dentist-provided teeth whitening services. Moreover, I find it telling that, as I have been informed, the NC-BODSE never has complained about sanitary conditions at a kiosk or like establishment to any public health agency in or outside of North Carolina.
- Based on my searches of the literature and my experience, there is no evidence that non-dentist-provided teeth whitening poses any greater risk than dentist-provided teeth whitening. Indeed, as I have said, I am aware of no credible evidence that non-dentist-provided teeth whitening poses any public safety risk at all.
- Indeed, the availability of retail teeth whitening establishments may actually contribute to dental health by encouraging consciousness of teeth appearance and, consequently, dental

health. This may help people overcome fear of dentists and seek dental care for dental conditions.[6]

- Given differing consumer wants and willingness to pay, a variety of safe alternatives has to be seen as a good thing. For example, some consumers appreciate the quick results that can be had only with chairside teeth whitening, want more or less support and advice, and are more or less sensitive to costs. Therefore it seems self-evident that the availability of chairside teeth whitening from dentists and non-dentists, with differing service and support, and at different prices, would be good for consumers if those alternatives are equally safe and they are equally safe, subjecting consumers only to comparable risks of minor side effects, principally transient tooth sensitivity or gingival irritation.
- Accordingly I conclude that actions of the NC-SBODE in excluding non-dentists from the market have injured consumers needlessly.

V. STATEMENT OF OPINIONS TO BE EXPRESSED AND REASONS THEREFORE

The demand for teeth whitening products and services keeps growing and growing. A 2002 survey conducted by the American Dental Association (ADA) and Colgate-Palmolive Company showed that the fastest the growing segment of dentists' business was teeth whitening, increasing 25% in that year.[8] Over the last seven years, the demand for dentist-provided teeth whitening has grown over 300%.[9,10] Apparently we all want a bright white smile. However there are different ways to achieve this result: (1) use of prosthetic/aesthetic dental restorations such as crowns and veneers (about which I shall say no more in this report); (2) dental stain removal; and (3) teeth bleaching. Each way is distinctly different from the others, employing different

implements and materials in a variety of settings.

A. Who Can Perform "Teeth Whitening" Procedures

Dentists and hygienists commonly perform both dental stain removal and teeth bleaching procedures. Consumers also can perform these procedures on themselves in their homes, for example, through teeth picking or brushing and use of OTC teeth bleaching products. According to the NC Dental Practices Act, N.C. Gen. Stat. 90-29[7], no person other than a licensed dentist or a hygienist acting under his or her supervision can remove another person's dental stains. The NC-SBODE presumes that in-home self-application of these procedures and products is lawful, but interprets the Act such that an unlicensed person may not so much as assist another person to remove teeth stains even by simply offering information or advice. *See* Ref. 44, No. 9-10 (NC-SBODE asserts that it is unlawful to read instructions or provide "services and or advice attendant to the sale of a teeth whitening product"). The NC-SBODE also takes the position, contrary to fact, that teeth bleaching is stain removal.

I note, however, that: (1) the NC Dental Practices Act does not mention teeth bleaching at all; (2) the statute, and in particular the prohibition concerning the removal of stains, pre-dates the discovery of modern vital teeth bleaching by some 50 years; and (3) the mechanism of action of teeth bleaching involves only the lightening of stain color not the actual removal of the stain. I will discuss this further below. For present purposes it is enough to state that the teeth whitening services delivered by non-dentists to consumers in mall kiosks and other similar locations are related to teeth bleaching, not dental stain removal. I therefore believe that the NC-SBODE has

misinterpreted the Dental Practices Act, and that teeth bleaching is not the practice of dentistry under that Act.

B. N.C. Gen. Stat. 90-29 Pre-Dates the Invention of Modern Vital Teeth Bleaching

The state dental practice statutes pertaining to the regulation of dental stain removal pre-dated the invention of modern vital teeth bleaching products and procedures by more than 50 years. The first report of modern teeth bleaching technique was published in 1989,[20] while the part of the NC Dental Practices Act that designates stain removal as the practice of dentistry was written in the mid 1930s. It is interesting to note that the adoption of the stain removal provision coincides with the wide-spread adoption of mechanical dental stain removal devices created for use in dental offices. The use of these devices in dental stain removal, like the use of picks and abrasives, was and is known to pose significant safety risks, and it is reasonable to conclude that the Act's limitation of dental stain removal was a reasonable reaction to legislators' concerns about the risks attending dental scraping and polishing procedures and had no relation to chemical bleaching.

C. Dental Stain Removal versus Teeth Bleaching

"Dental stain removal" and "teeth bleaching" are entirely different things. Although either can be used to give a person a brighter-whiter smile, that brighter-whiter smile is accomplished through entirely different mechanisms. The use of dental picks and abrasive polishes, for example, physically removes stains. However, the non-controversial scientific fact is that teeth bleaching does not physically remove stains at all; rather the active ingredients in teeth bleaching

products instead work by temporarily lightening the color of dental chromagens stain particles.[25]

Dental stain removal and vital teeth bleaching also have entirely different safety profiles. For example, use of dental stain removal products can permanently damage the enamel of teeth.[19] Use of vital teeth bleaching products cannot. In fact, there is a considerable literature addressing the potential risks attending use of dentifrices, toothbrushes, and professional teeth polishing services, [12,13,14,15,16,18,19] while not one scientific article of which I am aware has shown any permanent damage from any vital tooth bleaching procedure performed on a human being. That is an amazing point to consider given that millions of teeth bleachings have been done in a variety of environments in the past twenty years. Teeth bleaching products/procedures do cause transient dentinal hypersensitivity in some people, and there can be soft tissue reactions such as gingival irritation or blanching as well. But in all cases these side-effects are temporary lasting only a matter of days and clinically insignificant. In contrast, the abrasion damage caused by dental stain removal is irreversible: once enamel has been scratched off of teeth, it cannot be replaced, and once the gingival marginal tissue is abraded away, it will not grow back. It is no wonder, therefore, that many legislatures and state dental boards have sought to limit dental stain removal to qualified dental personnel, but vital teeth bleaching is an altogether different matter.

1. Understanding Dental Stains and Dental Stain Removal

Tooth staining can be caused by many local and systemic conditions. Tooth stains can be either "intrinsic" or "extrinsic." Intrinsic stains are stains located within the tooth structure. They are caused by such things as dental cavities; various dental materials, such as are used in some

restorations and in the treatment of certain disorders, including, among others, complications of pregnancy, bleeding disorders, bile duct problems, and genetic defects and hereditary diseases that affect enamel and dentin development or maturation. Most often the appearance of deep intrinsic stains can be remedied only through use of non-vital bleaching procedures to lighten the stains, or cosmetic restorations, such as crowns or veneers, to mask them.

Extrinsic stains are defined as stains located on the outer surface of the tooth structure. Extrinsic stains are categorized under the Nathoo classification system as follows:

- Nathoo type 1 (N1): N1-type colored material (chromagen) binds to the tooth surface. The color of the chromagen is similar to that of dental stains caused by tea, coffee, wine, chromogenic bacteria, and metals.
- Nathoo type 2 (N2): N2-type colored material changes color after binding to the tooth. The stains actually are N1-type food stains that darken with time.
- Nathoo type 3 (N3): N3-type colorless material or prechromogen binds to the tooth and undergoes a chemical reaction to cause a stain. N3-type stains are caused by carbohydrate-rich foods (e.g., apples, potatoes), stannous fluoride, and chlorhexidine.

The use of dentifrices with inadequate cleaning and polishing actions is a significant factor in dental staining, but the most common determinant of extrinsic stains is poor oral hygiene.

2. Consumer Stain Removal

Home dental stain removal is achieved most typically through use of a toothbrush and abrasive dentifrice. Even though this method is used universally, it should be noted that both the toothbrush and dentifrices can damage teeth and gum tissue by abrasion. Toothpaste is

intentionally abrasive, containing as much as 40% hydrated silica (*i.e.*, sand). So-called "whitening toothpastes" are even more abrasive, using a greater quantity of sand, albeit of finer particle size, to better abrade and physically remove dental stains. In addition, these finer particles leave a fine abrasion pattern, which is more reflective of ambient light leading to more lustrous and whiter-appearing teeth. Note however that this whitening effect is achieved by the use of damaging abrasives, and that "whitening toothpastes" typically contain no bleaching agents.

The toothbrush and tooth brushing technique also matter. It is generally agreed that the prevalence and severity of abrasion is correlated strongly with tooth brushing frequency, firmness of bristles, and improper horizontal brushing technique.[12,13,14,16,18]

Despite a general lack of regulation, home stain removal products carry significant risk of damage to the teeth and surrounding soft tissues. The first report concerning the abrasive properties of dentifrice cleaning and polishing agents and related dental harm was made by Miller.[14] Subsequent findings by other investigators were to similar effect.[12,13,16,18] The most common damage is the abrasion and thinning of enamel, which is why our teeth become more yellow with age. During our youth, our enamel is thick and pearly translucent white, covering the underlying dentin which is bright yellow. As we age, mostly due to toothbrush/toothpaste abrasion, our enamel becomes thinner and less able to mask the underlying dentin, as a result of which our teeth appear yellowed.

3. Professional Stain Removal

Abulcasis (1050-1122 AD), an Arabian surgeon, described, illustrated, and recommended use of dental stain-removal scrapers for the first time in "De Chirurgia," a work that remained a standard surgical text book for centuries. Abulcasis wrote: "Sometimes on the surface of the teeth, both inside and outside, are deposited rough ugly looking scales, black, green and yellow; this corruption is communicated to the gums, and the teeth are in process of time denuded. Lay the patient's head on your lap and scrape the teeth and molars."[15] By the 15th century, English barber-surgeons were performing dental stain-removal procedures, scraping the teeth with various metal instruments and rubbing them with a stick dipped in "aqua fortis," a solution of nitric acid. The acid certainly made teeth white before eating away the enamel and rendering the teeth non-vital.[36]

The father of modern dentistry, Pierre Fauchard, was the first to describe the removal of dental stains by a method similar to that used today. He described polishing of the teeth with various abrasive compositions made of finely ground coral, egg shells, ginger, or salt. This early version of tooth polishing using a prophylaxis (prophy) paste has evolved into one of today's most widely performed dental hygiene procedures. Not unlike the procedure developed by Fauchard, dental hygienists today use a rotating rubber cup to apply prophy pastes with varying levels of coarseness to remove stains from tooth surfaces.[14, 15]

Today's prophy pastes range in grit abrasiveness from low abrasive fine grit (2 μm) to coarse grit (5 μm), the most abrasive. According to Putt, these professional polishing agents are 10 times more abrasive to dentin and 20 times more abrasive to enamel than the polishing agents found in

commercial toothpastes.[16] Because of this, some authorities recommend the use of toothpaste alone to polish teeth.[16] Nevertheless, many dental professionals choose polishing agents based on how efficiently they remove extrinsic dental stains. Rather than take the additional time and effort needed to remove the same stains using a less destructive, fine prophy paste, they opt for coarser, more "efficient" pastes,[16] which have the greatest potential for causing excessive abrasion, scratching the enamel, and contributing to an increased rate of exogenous stain reformation and bacterial plaque retention.

Other factors that contribute to the "efficiency" of extrinsic stain removal from tooth surfaces include: (1) rotations per minute (rpm) of the rubber cup polisher; (2) rubber cup-to-tooth pressure, or load; and (3) the time spent polishing each stained area. Unfortunately, as each of these factors increases, so too does the potential for tooth enamel and dentin damage via surface abrasion, friction, and heat generation.[16,18] And again, there is a trade-off made between "efficiency" of stain removal and risk of harm.

Additional care must be exercised to avoid scratching restorations and wearing away incompletely mineralized tooth surface from newly erupted teeth.[18] And polishing sensitive root areas must be avoided to prevent removal of protective mineral layers from root surfaces and exposing the ends of dentinal tubules in cementum and dentin.[18] As a result of the varied risks of irreversible damage associated with teeth polishing, the American Dental Hygienists' Association (ADHA) published a statement stipulating that teeth polishing should not be performed routinely to smooth and polish teeth surfaces, but only as needed in the "removal of

plaque, calculus, and stains . . . by scaling and polishing as a preventive measure for the control of local irritational factors."[19]

In short, stain removal, which uses dental instruments and abrasive pastes, is difficult, potentially harmful, and often unwarranted. Therefore, it is no wonder that some legislatures and dental boards restricted the practice of stain removal to licensed dentists and hygienists. On the other hand, vital teeth bleaching an appreciably later development is not stain removal, and entails no similar risk of permanent harm.

D. Understanding Vital Teeth Bleaching, Commonly Known As "Teeth Whitening"

Vital tooth bleaching can be achieved through a variety of means. Consumers have traditionally been able to choose between being treated by a licensed dental professional with "professional grade" teeth bleaching preparations, or they could choose to treat themselves as part of an OTC regimen using less potent home products. However, over the last few years a new industry has developed that gives consumers a third option. This industry encompasses the sale of professional-style teeth whitening preparations to consumers along with specialized support (sometimes including use of a light source intended to accelerate whitening) and advice as to how to best self-apply bleaching gel (and light, where part of the teeth bleaching protocol) safely and effectively. The specialized support and advice is provided in a spa-like setting by lay people who typically have been trained, or using training materials provided, by the manufacturers of the bleaching products/systems. These spa-like, lay-operated bleaching centers largely operate out of larger day spas, cruise ship spas, or shopping mall kiosks. The take-home and in-office methods achieve varying degrees of "whitening" for a period of time. The degree

of whitening depends upon such factors as the initial condition of the consumer's teeth, the etiology of the stains, the concentration of oxidizer in the bleaching gel, the length of treatment, and the consumer's protocol compliance and subsequent diet.

Licensed dental professionals and lay-operated bleaching facilities may offer two methods of teeth bleaching. The most popular teeth bleaching method offered by dental professionals requires consumers to wear a dental tray containing bleach for up to an hour daily for a number of days. Tray-based bleaching products and systems also are available to consumers through brick-and-mortar retail outlets such as pharmacies as well as through the Internet. The other alternative offered by licensed dental professionals and lay-operated bleaching facilities is chairside, same day treatment, which offers patients/customers more immediate results and gratification usually in less than two hours.

Whatever the formulation, the mechanism of action is similar for all of these products. The break-down of hydrogen peroxide temporarily converts colored particles in teeth stains into non-colored particles by oxidizing organic compounds within the teeth's enamel and dentin. The hydrogen peroxide functions as a chemical sink for the generation of free radicals of oxygen. These free radicals break the carbon: carbon double bonds in organic stains, causing the stain particles to slowly, and only temporarily, de-colorize. The stain particles remain, lightened in color for a time, but they remain and the color before long rebounds.

1. Tray-Based Systems

As I have indicated, tray-based teeth bleaching products and services are offered by dentists and lay-person bleaching centers and can also be purchased by consumers OTC. They typically utilize carbamide peroxide or hydrogen peroxide as the bleaching agent. Carbamide Peroxide has the advantage of being very stable in anhydrous formulations and breaks down into hydrogen peroxide (three parts carbamide peroxide yielding approximately one part hydrogen peroxide) and urea only by exposure to water and salivary enzymes. Hydrogen peroxide systems are much less stable and require a more acidic pH to prevent unwanted oxygen release. Other stabilizers also are used to promote stability at a variety of ambient temperatures. When carbamide peroxide is exposed to saliva, it breaks down to release hydrogen peroxide and urea. A bleaching gel consisting of 10% carbamide peroxide, for example, would yield roughly 3% hydrogen peroxide and 7% urea. The urea is thought to further assist in the whitening process, because it is itself a mild bleaching agent. Higher concentrations of carbamide peroxide may result in faster whitening of teeth. However, the literature suggests[24] that there is no difference in whitening effect after six weeks of use irrespective of whether a 10% carbamide peroxide formulation or a more concentrated formulation is used. A variety of concentrations of hydrogen peroxide and carbamide peroxide are available for use in tray-based bleaching systems.[40]

In tray-based systems, in addition to the bleaching agent, anhydrous glycerin and/or polyethylene glycol typically is used in the bleaching gel as thickening agents. The thickening agents also impart to the gel a dehydrating effect that increases whitening, but also increases transient dentinal hypersensitivity. The pH of these preparations is either acidic or near neutral (*i.e.*, pH 7.0). If the pH is acidic, the tooth enamel will be etched to some degree, further temporarily

making the teeth appear whiter. However once treatment is discontinued, the tooth rehydrates and recalcifies. As a result, much of the whitening effect caused by desiccation and acidification is lost and stain color rebounds. The literature and my own experience show that effect of acidic bleaching gels on dental enamel is not problematic, it being no greater than would be found in a person drinking orange juice.[25] If the bleaching treatment is per the product manufacturer's instructions, the teeth will recalcify within days after the therapy has ceased.[24]

As I have said, consumers readily can purchase tray-based OTC products. These products are available in the form of bleaching pastes or gels that are applied in trays, as paint-on liquids, in strips, and in rinses (all of which are in most important respects similar to tray-based systems and which I include in my discussion of tray-based systems). Tray-based teeth bleaching products of the 1990's typically contained 10% carbamide peroxide, equivalent to a little more than 3% hydrogen peroxide, they now have concentrations of up to 21% carbamide peroxide, equivalent to 7% hydrogen peroxide. Some contain hydrogen peroxide itself, in concentrations of as much as 9.5%. In addition to bleaching agent concentration, tray-based products differ from chairside products in that they typically contain no peroxide activator, and thus work more slowly and less efficiently. Although some OTC systems are sold to consumers with lights, these lights generally appear to be of very low output and not true photo-initiators of teeth whitening as are typical in chairside systems.

2. Chairside Systems

Chairside teeth whitening offered by dental professionals typically uses bleaching products containing 25% to 35% hydrogen peroxide.[40] At these concentrations, use of a gingival barrier is

recommended to prevent gingival irritation. However, use of a barrier may not be necessary if the bleaching gel does not grossly overflow treatments onto the soft tissue and the bleaching session is kept brief. Lay-operated teeth bleaching facilities use chairside bleaching products at somewhat lower hydrogen peroxide/carbamide peroxide concentrations, typically equivalent to 16% or less of hydrogen peroxide,[40] obviating any need for a gingival barrier. In these facilities too, a light may be used as a secondary photo-initiator to speed whitening.

Most chairside teeth bleaching formulations do not use anhydrous glycerin and/or polyethylene glycol as thickening agents, rather they use carbomer or a close analog to provide a viscous, water-based gel delivery system. Chairside formulations typically have a moderately acidic to extremely acidic pH. This is primarily because peroxide analogs are unstable in aqueous solution, and without acidification the bleaching preparations would have very short shelf-lives and potentially cause their containers to explode. The higher peroxide concentration formulations sometimes used in dental offices may require even more acidification to make them stable. As I noted previously, acidity also temporarily enhances whitening effects: they decalcify and opacify teeth through etching, causing them to look chalky white and temporarily masking underlying discolorations. Chairside teeth bleaching typically relies upon secondary and often even tertiary and quaternary means to activate or speed whitening. These include enhanced formulations chemical activators used in dual component delivery systems as well as light and heat sources to be directed at the teeth during the bleaching session. Most often the chemical activator in dual component systems is a transition metal-containing ingredient or an alkaline pH adjuster. Combination of the two components destabilizes the bleaching agent, resulting in more rapid and greater free radical formation and, hence, whitening effect.

3. Comparing Teeth Bleaching Products and Services

Teeth bleaching, whether provided by dentists, at lay-operated teeth bleaching centers, or done at home by consumers using OTC products/systems, is safe and effective.[24,17,27,28,29,37] But available products and services differ in ways that appear to be important to consumers. These include number of bleaching sessions required, support provided to the consumer, and price. Chairside bleaching, by whomever provided, is quick and convenient, requiring only a single bleaching session. In contrast, take-home products, by whomever provided, require numerous bleaching sessions over many days, perhaps weeks. Dentists provide professional service, support, and advice, while non-dentists typically provide service, support, and advice as allowable based on training by the manufacturers of the bleaching products/services they provide and their own experience, which may be considerable in that teeth bleaching may be the sole service they offer. *See, e.g.,* Ref. 2 (White Science training manual for non-dentist teeth whitening system); Ref. 42 (BriteWhite training manual for non-dentist teeth whitening system). For example, non-dentist-providers may give written information/cautions to consumers to assist them in determining whether they are appropriate candidates for teeth bleaching; may provide encouragement, instruction, and reassurance to consumers as they apply the products; and leave the consumer with no-clean up burdens when the bleaching is concluded.[2,44] In these respects, and others, non-dentist-provided teeth bleaching is quite like that offered by dentists. In contrast, take-home products come with nothing more than instructions. And as one might expect, dentist-provided teeth bleaching typically is appreciably more expensive than non-dentist-provided teeth bleaching. For example, in Non-dentist teeth whiteners in North Carolina advertise themselves as a lower cost substitute for dentist teeth whitening. *See, e.g.*, Ref. 44 (advertisement from SheShe studio spa) ("Teeth whitening has also always been offered in

dental offices . . . and delivers the same results that we offer at a fraction of the cost."); Ref. 47 (Bleach Bright advertisement - $99 - side-by-side with "Dentists $350-$500").

Different consumers will have different preferences. OTC products available for self-application at home are the least expensive alternative for consumers. These products may be fine for cost-conscious consumers who are willing to self-apply bleaching products numerous times over numerous days aided only by written instructions, but plainly they are not a good substitute for chairside teeth bleaching for consumers intent on quick results or wary about self-application of OTC products without supervision or support. Those consumers' requirements can be met only by dentist-provided or lay-provided chairside bleaching. The availability of a variety of teeth bleaching alternatives allows consumers to make their own trade-offs and safely satisfy their preferences.

E. A Brief History of Vital Teeth Bleaching

People have sought to mask or remedy tooth discoloration for hundreds of years. Over time dentists and others have experimented with a variety of chemicals, thermal techniques, abrasive procedures, veneers, and other approaches. However, until 1989, chemical bleaching, increasingly based on use of hydrogen peroxide,[1,20] was reserved almost entirely for non-vital teeth and teeth that were soon to become non-vital.[36, 51] Harlan first wrote of chemical bleaching of non-vital teeth in various articles published in 1891. His article in Dental Cosmos, for example, was entitled, "The Dental Pulp, Its Destruction, and Methods of Treatment of Teeth Discolored by Its Retention In The Pulp Chamber or Canals."[21] Superoxol, a concentrated hydrogen peroxide solution, became the product of choice for lightening teeth that as a result of

trauma or disease had or were about to become non vital. But Superoxol could not be used to lighten vital teeth intended to remain vital because its mode of application directly to the affected teeth as a heated liquid could destroy the dentin and render those teeth non-viable.[50]

By the 1960s hydrogen peroxide was increasingly available as an oral antiseptic.[23,24] Then, in 1989, a dentist observed that when a hydrogen peroxide oral antiseptic was administered by dental tray to address gingival irritation and inflammation, vital teeth also became whiter.[20] Haywood and Heymann published a description of this tray-application of hydrogen peroxide for vital tooth whitening.[20] This was quickly followed by development of the first commercial products for vital teeth whitening, using trays to deliver hydrogen peroxide or carbamide peroxide. *See also* Ref. 51 (According to the ADA, while teeth whitening for diseased or distressed teeth dates back to the 1800s, its cosmetic emphasis began in the late 1980s "with the development of ...products and techniques for vital tooth bleaching that could be applied both in the dental office and at home."). These products were and continue to be labeled and sold to dental professionals and to consumers as cosmetics as that term is defined in Section 201(i) of the Food, Drug, and Cosmetic Act of 1938 (the FDA Act).[33]

1. Hydrogen Peroxide and the Domestic Regulatory Environment

Hydrogen peroxide was discovered by Louis Jacques Thenard in 1818.[24] Today it finds widespread use industrial, agricultural, and consumer product applications. Its safety in numerous such applications has been reviewed by domestic scientific bodies and regulatory agencies, including the FDA, and its use in those applications has been approved.

A solution of 30% hydrogen peroxide has been continuously sold in the United States, since long before 1938,[22] principally as an anti-bacterial agent and antiseptic. As a result of its early entry into the market, it has not been subject to the requirement that the FDA approve its sale through the new drug application (NDA) process, nor has its sale been reviewed under the FDA Drug Efficacy Study Implementation (DESI) program or the FDA OTC Drug Review. However, in lower concentrations hydrogen peroxide has been the subject of scientific evaluation under the OTC Drug Review and found by expert evaluators and the FDA to be safe for diverse oral and dermatological medical uses including: (1) in a 3% aqueous solution as an oral wound cleanser; (2) in a 3% aqueous solution as an oral debriding agent/wound cleanser; (3) in a 3% aqueous solution as a general dental first aid antiseptic; and (4) in a 3% alcohol-based aqueous solution in a mouthwash.[24]

Based upon a review by the Life Sciences Review Office of the Federation of American Societies of Experimental Biology, the FDA has found that hydrogen peroxide is generally recognized as safe (GRAS) for use in the production of various foods.[24] Similarly, the United States Department of Agriculture has determined that hydrogen peroxide is safe and suitable for use in the production of meat and poultry products and may be used in the production of organic crops and livestock. And the United States Environmental Protection Agency has authorized the application of hydrogen peroxide to foods as a pesticide.[24]

Vital teeth bleaching products have been and are labeled and sold as cosmetics as that term is used in the FDA Act. And in May 1991 the Canadian Health Protection Branch concluded that products containing hydrogen peroxide labeled to whiten or brighten teeth were indeed cosmetic

goods. In September 1991, however, the FDA sent warning letters to manufacturers stating that the FDA considered teeth whiteners to be "drugs" under the FDA Act. The manufacturers disagreed, submitted citizen petitions to the FDA asking the FDA to change its position and affirm that teeth bleaching products are cosmetics, and began a declaratory judgment action seeking a determination that bleaching products were cosmetics rather than drugs.[24]

Facing trial, the FDA advised the manufacturers that the agency was reviewing the information they had submitted in their petitions "to determine whether it will affect the agency's original assessment" and that "FDA will take no enforcement action during this deliberation period." Following this assurance, the manufacturers withdrew their lawsuit. In May 1998 the FDA asked the manufacturers to withdraw their citizen petitions as well. Following further discussions with FDA, the manufacturers withdrew their petitions, noting in October 1998 correspondence:

> In telephone conversations with CDER representatives regarding the pending petitions, the Coalition has been informed that the Agency does not at this time or in the foreseeable future intend to expect to [sic] take any enforcement action against the marketing of the products, which are the subject of the Citizen Petition, based upon their regulatory status (as cosmetics). The Coalition further has been informed that should the Agency consider any change of its policy regarding these products, it would receive sufficient prior notice and would be afforded appropriate time and a meaningful opportunity to present its views to the Agency.[24]

To this day the FDA continues to allow the unfettered sale of vital teeth bleaching products to dental professionals, lay-operated dental bleaching facilities, and consumers as recognizedly safe cosmetic products.

F. Possible Side-Effects of Vital Teeth Bleaching Treatment

Vital teeth bleaching has become a mainstream treatment in the United States and is generally regarded as safe and effective. That is not to say that there are no side effects there are, but

they are minor and nonpermanent, the most common being transient dentinal hypersensitivity (*i.e.*, temporary tooth sensitivity). Moreover, these transient adverse side effects are not specific to any class of provider indeed, they may be most frequent and pronounced with dentist-provided chairside bleaching due to the greater concentration of hydrogen peroxide and more intense light/heat activation often used in dental offices. For example, Dr. Owens, a member of the NC-SBODE testified at his deposition that he cannot always tell whether a patient will react adversely to teeth bleaching, and that he has had patients on whom he has done chairside whitening who have, as a result, suffered dentinal sensitivity "for several months to close to a year." Reference 41, p. 85. Based on the literature and my own research and observations, Dr. Owens' experience is not at all extraordinary among dentists.

Transient Dentinal Hypersensitivity: Some dentinal sensitivity or minor soft tissue irritation are variously reported as occurring in 50% or more of people undergoing teeth bleaching. However, these are transient and short-lived.[34] Lesser concentrations of hydrogen peroxide are associated with lesser sensitivity. Notwithstanding transient sensitivity, testing has never shown hydrogen peroxide or carbamide peroxide to induce permanent pathological pulpal changes. Rather, studies have shown that use of hydrogen peroxide or carbamide peroxide in reasonable amounts resulted in mild, reversible histological changes.

The transient sensitivity experienced is believed to be due to an unfavorable osmotic gradient (see Brannstrom's hypersensitivity theory). Dehydration of the teeth and tissues is caused by the acidified and thickened bleaching gels which, when held against the teeth, create a negative osmotic pressure drawing odontoblastic processes into the dentinal tubules. The use of intense

lights and heat during the bleaching process may contribute to this dehydration and the resulting sensitivity. Again, these effects typically are mild and invariably transient. Moreover, there are no reports in the literature to suggest that non-dentist-provided teeth bleaching causes a greater or more severe incidence of transient dentinal sensitivity than dentist-provided bleaching or bleaching through self-application of OTC products.[25]

Rebound: I've previously referred to color rebound following teeth bleaching. Stain color returns over time because the stain was never removed in the first instance; it was only temporarily lightened. Studies report varied times between bleaching and rebound, from a few days or weeks to as much as 47 months. One study found a rebound in 40% of patients at six months with use of concentrations ranging from 16% to 18% carbamide peroxide. An additional cause of rebound is the reversal of the enamel etching and dehydration that occur during teeth whitening, and which imparted an appearance of greater whiteness. There are no reports in the literature to suggest that the incidence or extent of rebound is greater in instances of non-dentist-provided bleaching than in instances of dentist-provided bleaching or bleaching through self-application of OTC products.[25]

Surface Changes: Use of hydrogen peroxide and carbamide peroxide has been found *in vitro* testing to result in minor reversible surface changes in. However, other studies have found that the normal morphological variation in enamel exceeds surface changes induced by use of up to 35% hydrogen peroxide. One study testing varying concentrations of carbamide peroxide found no differences in the decreased surface microhardness between 10% and 35% concentrations. Another study found changes in the absence of saliva, but not in the presence of saliva. Other

studies point out the surface changes are no different from those that occur after drinking a glass of orange juice, and any decalcification is quickly reversed when teeth are exposed to saliva. And in any event, there are no literature reports that suggest that bleaching in lay-operated bleaching facilities results in any more "surface changes" than are found with dentist-provide bleaching or bleaching through self-application of OTC products.[25]

Soft tissue irritation: The peroxides in teeth bleaching products are regarded as safe at low concentrations. Although they have the potential to induce cell changes at high concentrations over extended periods of time, teeth bleaching exposures do not remotely approach those conditions. Systems using higher concentrations of hydrogen peroxide or carbamide peroxide results in more gingival irritation. While some studies suggest that this may be due to tray design, a study conducted using a split-mouth design comparing 10% and 16% carbamide peroxides used in an overnight system nevertheless found gingival irritation to be greater with the 16% concentration. However, the reported literature finds that all soft-tissue irritation abates within days of completion of vital teeth bleaching. No study of which I am aware has shown long-term adverse effects of teeth bleaching on the oral soft tissues. Moreover, there are no literature reports that suggest that soft tissue irritation is more prevalent or severe with non-dentist-provided teeth bleaching than with dentist-provided teeth or bleaching through self-application of OTC products.[25]

1. Safety of Vital Teeth Bleaching – Potential For Systemic Side Effects

The potential for systemic adverse effects from exposure to a chemical is dependent on several variables. One of these is the extent of systemic exposure. Systemic exposure to hydrogen

peroxide or carbamide peroxide through vital teeth bleaching is quite low.[30, 51] For example a recent independent review[24] of the safety profile of Crest WhiteStrips® concluded that the maximum daily exposure to hydrogen peroxide from use of its retail product is 42 mg, and from use of its professional product often sold through dental offices , 49 mg.[24] This exposure is well below any known risk level for humans.[24,30] In chairside bleaching, whether performed at a dentist's office or a lay-operated teeth bleaching facility, one would expect the total exposure to hydrogen peroxide to be substantially less than that found benign in the WhiteStrips® review. For example, the most popular professional chair-side bleaching preparation would expose a person to three 3mL (15mg) applications of 25% hydrogen peroxide.[40, 52] Potential exposure, therefore, would be 11.25mg (3 x 15mg x .25) of hydrogen peroxide per bleaching treatment.[52] Alternatively, the most popular non-dentist-provided chair-side bleaching preparation would expose a person to one application of 10mL (50mg) of 30% carbamide peroxide.[4,40] Potential exposure would be only 5.00mg (1 x 50mg x .10) of hydrogen peroxide per bleaching.[4] From these calculations, it is easy to see that chair-side exposure is much less than what a consumer would be exposed to with an OTC bleaching product**.**

Another factor affecting the potential for systemic effects from exposure to a chemical is conditions of use. The conditions of use of hydrogen peroxide or carbamide peroxide in teeth bleaching work against any material systemic exposure. The independent review of the safety profile of Crest WhiteStrips® noted in the prior paragraph found that under typical conditions the peroxide in saliva of test subjects was less than 0.01%. While systemic exposure to hydrogen peroxide as a result of swallowing of saliva during teeth bleaching would be difficult to quantify, it is considered to be quite small. Among other reasons, the abundance of peroxidases in the

saliva and oral cavity would be expected to break down hydrogen peroxide, allowing little systemic absorption through the gingiva or other structures in the buccal cavity.[24]

Hydrogen peroxide has been extensively studied for systemic toxicity in experimental animals. Numerous drinking water and gastric gavage studies using rats and mice as test subjects indicate that, although adverse effects are observed at repeated high exposures (100 mg/kg), no adverse effects occur at doses of less than 36 mg/kg. Very conservatively that is to say, ignoring the very consequential differences between the methods of administration in these animal studies and the exposure of consumers to hydrogen peroxide having their teeth bleached , these studies would suggest that for a 70 kg person (one weighing 154 lbs), no adverse affects are plausible unless systemic exposure exceeds two grams. As I noted previously, potential exposure from chairside bleaching using the most popular preparations would be a small fraction of that 11.25 mg for dentist-provided bleaching and five mg for non-dentist-provided bleaching. Based on these findings, it would be expected that use of peroxide-based teeth bleaching systems could not result in any systemic toxicity under normal conditions.[24, 30]

In addition to hydrogen peroxide or carbamide peroxide, teeth bleaching preparations contain such ingredients as water, glycerine, carbopol, sodium hydroxide, sodium acid pyrophosphate, sodium saccharin, flavorings, and the like. All of these ingredients are considered safe inactive ingredients for various OTC drug and cosmetic products. They all have been rigorously evaluated for toxicity, and as present in bleaching gels present no safety concern, even if accidentally ingested.[24]

In sum, systemic toxicity of hydrogen peroxide or carbamide peroxide when used in teeth bleaching is not a realistic concern. Moreover, if it were, it would provide a basis for limiting the use of those bleaching agents whether sold for in-home self-application, by non-dentist-providers of teeth bleaching products and services, and by licensed dentists. The NC-SBODE has proposed no such limitation.

2. Safety of Vital Teeth Bleaching – Potential For Dental Enamel Side Effects

As I have explained, teeth bleaching products often are formulated with an acidic pH for a variety of reasons. This might give rise to a concern as to the potential for adverse consequences due to acidic exposures of dental enamel surfaces. However, experiments have been conducted looking for such consequences under normal conditions of use and in the presence of plainly excessive conditions of usage. Even in conditions of plainly excessive usage, little or no damage to enamel surfaces was observed. It appears that teeth whitening formulations are mostly unreactive with the mineral surfaces of the teeth (*i.e.*, the enamel, dentin, and any exposed root). Most investigators agree that *in vivo* salivary buffering and dilution substantially neutralize bleaching formulations at the tooth surface.[24]

G. The European Union Directive Limiting Hydrogen Peroxide in Oral Products Is Over-Cautious

Currently the sale of most peroxide containing teeth bleaching products are banned in the European Union because they contain hydrogen peroxide above limits set by the European Commission's Scientific Committees of Consumer Products (SCCP). In its report of 15 March 2005 (SCCP/0844/04), the SCCP concluded that:

- The proper use of tooth whitening products containing > 0.1 to 6.0 % hydrogen peroxide (or equivalent for hydrogen peroxide releasing substances) is considered safe after consultation with and approval of the consumer's dentist.
- There is an absence of good clinical data and long-term epidemiological studies that assess the possible adverse effects within the oral cavity.
- The new additional data supplied does not provide the necessary reassurance in terms of risk assessment to support the safety of hydrogen peroxide up to 6 % in tooth whitening products freely and directly available to the consumer in various application forms (strips, trays, etc...).

In this 100+ page report, the SCCP justifies its position by citing a large number of *in vitro* and *in vivo* studies that show that hydrogen peroxide can be a potent mutagen. But the SCCP report fails to adequately consider the circumstances under which mutagenicity was demonstrated. The evidence on which the SCCP founds its conclusions consists primarily of rat/mice drinking water and gastric gavage studies in which pre-cancerous or other adverse effects are observed at high exposures (100 mg/kg) of hydrogen peroxide. For example, the SCCP report cites the following:

1. Mice drinking 0.15% hydrogen peroxide (about 150 mg/kg/day) *ad libitum* grew normally and developed no visible abnormalities during a 35-week test period (FDA, 1983). Necropsy results show changes in the liver, kidney and stomach and small intestine. Hydrogen peroxide solutions at >1% (> 1 g/kg/day) caused pronounced weight loss and death of mice within two weeks.[26,38]
2. When Wistar rats were administered 5% hydrogen peroxide by oral gastric tube six days weekly for 90 days with a dose range 56.2 to 506 mg/kg bw/day, the dose of 506 mg/kg

suppressed bodyweight gain, decreased food consumption, and caused changes in haematology, blood chemistry, and organ weights. Principal organ affected was gastric mucosa, and the effect was local. The no-observed-effect-level (NOEL) of hydrogen peroxide was 56.2 mg/kg/day.[26,39]

But men are not mice, and hydrogen peroxide exposure through teeth bleaching entails neither the drinking of hydrogen peroxide at liberty nor its continuous infusion directly into the stomach by gastric tube for periods ranging from 20 to 100 week, shorter exposures having not shown any carcinogenic effect even given the inhuman dosing regimen. Apparently the SCCP and the EU have opted to err on the side of extreme caution; but that caution seems far too extreme. In fact, the very same database of studies that the SCCP/EU directive relies so heavily on, also says the following:

- There is an absence of good clinical data and long-term epidemiological studies that assess the possible adverse effects within the oral cavity.
- Several *in vivo* studies on peroxide containing tooth whiteners detected absolutely no genotoxicity. No increased frequency of micronuclei was observed in bone marrow cells of mice that were gavage-fed with two solutions containing 10% carbamide peroxide.
- Three tooth whiteners containing 10% carbamide peroxide did not have any mutagenic effects to the bone marrow cells of Chinese hamsters and mice after the animals received doses up to 10 g/kg.[26] A tooth whitener paste containing 10% carbamide peroxide was found to be non-genotoxic when administered to rats at doses ranging from 0.1 to 1.0 g/kg for five days.[26, 30] Munro et al. are of the opinion that the available genetic toxicity

and animal toxicology data do not indicate that hydrogen peroxide poses a carcinogenic risk to the human oral mucosa. [26, 30]

- According to industry, market experience indicates that hydrogen peroxide tooth whitening products are well tolerated by consumers, with an adverse event incidence rate of 0.1%. The top five complaints received by consumers have been mouth irritation, oral miscellaneous, tooth hypersensitivity, gastrointestinal, and stained teeth. Oral cavity related effects represent the majority of health effects reported, with 58% of symptoms reported being tooth sensitivity and 56% of symptoms reported being oral soft tissue irritation. Whitening products that contain peroxide are known to have the potential to produce oral irritation and tooth hypersensitivity. These effects have usually been transient in nature and resolved shortly after cessation of product use.[26]

In addition, I note that in teeth bleaching using hydrogen peroxide or carbamide peroxide, consumers are exposed to concentrations far below the determined toxic limit,[24] and as I previously have explained, systemic exposure is further mitigated by salivary dilution and the action of the many peroxidases present in saliva. Munro et al., [26, 30] who, in response to the SCCP report, undertook a review of available safety data and "intended and exaggerated" hydrogen peroxide exposure, including a large number of published and unpublished studies and clinical trials on teeth whitening procedures, and concluded that they do not indicate a genotoxic or carcinogenic risk.[30] Munro et al.also concluded, in another article, that "dosimetric exposure analyses from tooth whitening product users show[ed] margins of safety on the order of 100- to 1,000-fold or more between no effect levels in animal studies and transient peak hydrogen peroxide concentrations in saliva at the floor of the mouth."[30] And again, the FDA, with access

to the SCCP report and all of the data and studies on which it was based, has concluded that the action and safety of hydrogen peroxide and carbamide peroxide when used in vital teeth bleaching is such that it is properly classified not as a drug subject to the FDA approval requirements, but rather as a readily saleable cosmetic.

A similar critique can be made of the journal article written by Goldberg, Grootveld,and Lynch[35] cited by NC-SBODE in its legal papers in support of its exclusion of non-dentists from the vital teeth bleaching market. Moreover, neither the SCCP/EU nor Goldberg et al. purport to find that teeth bleaching by non-dentists or consumer use of OTC products poses safety risk different in kind or degree from those they believe are posed by dentist-provided teeth bleaching. If their position were to be accepted, the proper response would not be to exclude certain practitioners from the market, but rather to limit teeth bleaching entirely, as the EU has done and the FDA purposefully has declined to do.

H. Considerations of Sanitation and Infection Control

The NC-SBODE has suggested that the practice of vital teeth bleaching by non-dentists and in environments like mall kiosks poses sanitation and infection control risks. As I have noted in a previous section of this Report, at lay-operated bleaching facilities consumers typically are directed to self-apply their purchased tooth bleaching products using the information and advice supplied by the product manufacturer and bleaching center personnel. Even so, it appears that typically bleaching facility personnel freshly glove up for each customer (likely using the same non-sterile latex gloves used in dental offices throughout the country). Moreover, hydrogen peroxide is itself a potent antimicrobial agent and likely helps prevent any possible cross

contamination. Accordingly, there seems to be little opportunity for cross contamination between bleaching center personnel and the consumer.

One might properly be concerned about sanitation and infection control if, for example: (1) a kiosk operator used unsanitized re-usable trays; or (2) unsanitized re-usable lip and cheek retractors to aid in the delivery of the teeth bleaching gel; or (3) bleaching gel dispensed from a multi-use container that is used by multiple consumers. However, it appears to me that the vast majority of kiosk operators do none of these things.[1,2] There may be periodic breaches of proper sanitation and infection control in lay-operated bleaching facilities, but that will be true in dental offices as well. The findings of a study reported in the May 2009 Journal of Dental Education "indicate a lack of understanding of the basics of infection control and the prevention of transmission of communicable infectious diseases not only in large percentages of dental and dental hygiene students, but also in graduate students and among the dentists and dental hygienists who responded to this survey."[32] Any breach of proper sanitation and infection control practices might warrant action against the specific dentist or non-dentist teeth bleaching facility involved. It hardly seems to warrant exclusion of all non-dentist providers from the market. Indeed, it appears that although bent on excluding non-dentist providers from the market, the NC-SBODE has never complained of unsanitary practices at a non-dentist operated teeth bleaching facility to a state or local health department or to any other responsible official.

I. Consumer Options for Vital Teeth Bleaching

At the present time there are three basic options available to the consumer for vital teeth bleaching. The first option is bleaching that is performed by a dentist in a dental office, or by a

hygienist or dental assistant at the dentist's office under his or her direct supervision. There are a few variations as to how the dental office does the actual treatment, and those options will be discussed in detail below.

The second option is the OTC option. There are many products available in pharmacies and the Internet for consumers to explore. These products generally provide a product that has a lower concentration of peroxide, and they usually lack sophisticated formulations, however in this market segment there are many novel delivery systems including dual sided pre-filled trays, strips, pens, and even small hand-held LED light sources with headphones for music.

The third alternative involves teeth bleaching using some the same techniques and materials that the dentist would use, but without the bother and expense of having to go to the dental office. Instead this option is typically made available in convenient shopping mall and other locations, or even in day spas and on cruise ships. These consumer-friendly cosmetic bleaching centers use lay personnel who have particular knowledge about the products that they sell to the public and offer advice to the consumer on how to self-apply a professional style teeth bleaching gel to their own teeth to maximize performance and minimize any potential temporary side effects.

1. The Dentist Option

Some twenty-one years ago,[20] VB Haywood and HO Heymann described in Quintessence International, a popular dental journal of the time, what they called "Nightguard Vital Bleaching." It used dentist-fabricated custom bleaching trays, made in a manner similar to

nightguards used for people who ground their teeth, as a delivery system for carbamide peroxide. The trays and bleaching agents were given to the patients for use at home while they slept.

As described by Haywood and Heymann, patients usually would treat their upper teeth first. The patients were instructed that before going to bed they should brush their teeth, apply a small amount of 10% carbamide peroxide bleaching gel to the inside of the tray for the upper teeth, insert the tray to cover the teeth, wipe off any excess bleaching gel that flowed out, and then sleep with the tray in their mouth all night long. Upon arising, they were to remove the tray, rinse it and their mouths with water. The process was to be repeated daily for two weeks. Then, patients would start again, this time using the tray for the lower teeth until the regimen was completed.

The results were usually very good, with shade changes reported of five to eight shades whiter as measured by a dental shade guide. The system was so effective that, with some updating (for example, most dentists now fabricate the trays using a thinner, silicone material), it still is used by the majority of dentists despite the availability of alternatives. It is sold by many dental offices to patients for $200-$600 or more. Over the years, professional products companies have modified the original 10% carbamide peroxide formula, changing its strength and the "wear instructions." This technique, done almost exclusively by dentists, is commonly known as the "Custom Take-Home Tray" method of bleaching. The safety and efficacy of this tooth-whitening method has been well documented in clinical studies.

The other technique that dentists use to bleach vital teeth is known as “In-Office” or “Chairside” whitening. Chairside whitening, also known as “Power Bleaching,” can be done with or without the use of an accelerator light. The cost to the patient typically is $500-$800 per session. In this procedure, all of the bleaching is performed by a dentist or supervised assistant in a dental chair at the dentist’s office. The procedure usually takes one to two hours to complete. The results are generally good, similar to those achieved using the Custom Take-Home Tray method, but they are achieved much more rapidly, albeit usually at much greater cost to the patient.

The most popular systems use a high concentration of hydrogen peroxide, usually in the 20%-35% concentration range.[40] During a lengthy prep time of up to a half hour, the patient’s teeth are exposed using cheek retractors and the gums are isolated using a brushed-on plastic polymer that is hardened by light curing so as to prevent the gums from being exposed to the high peroxide concentration of the whitening gel. The gel is painted on the front surface of the teeth and left to work, usually for a 20-minute period. At this point an accelerator light, such as the ones in the Sapphire™, BriteSmile™, LumaArch™, or Zoom 2™ (the most popular among dentists) systems, may be employed to hasten the chemical reaction of the bleaching process. After 20 minutes, the gel is usually suctioned off the teeth using a dental vacuum. The gel is re-applied, the light, if used, is set again, and the treatment is repeated up to two more times for a total of 60 minutes of actual bleaching time. Again, the results are usually very good with a six shades whiter or more change occurring.

One common undesirable side effect of Power Bleaching is post-procedure teeth sensitivity that can last two weeks or more. Patients using the popular Zoom 2™ system often experience

quick, sharp, electrical-type, short duration pains that gradually subside with time. Use of a professional product known as Power Swabs™, in conjunction with Power Bleaching can help minimize these transient discomforts and pains. The literature, including my own research, suggests that this transient dentinal hypersensitivity is due to the fact that while the isolated teeth are being bleached in the open air for a prolonged time using very high bleach concentrations, they become desiccated, or dried out, and that, coupled with the oft-times high heat output of the accelerator light, causes a temporary inflammation of the inner tooth nerve, known as a pulpitis. This pulpitis manifests itself in the form of the painful transient teeth sensitivity.

2. The OTC Option

As I stated above, there are many teeth bleaching products available as OTC preparations and kits. These products generally use a lower concentration of hydrogen peroxide or carbamide peroxide. They often use relatively unsophisticated formulations, but employ a variety of novel delivery systems that make the system easy to self-apply. In recent years, manufacturers have developed unique tray-less methods for OTC at-home bleaching. Crest Whitestrips® from Proctor and Gamble was one of the first OTC teeth bleaching products on the market, and it remains the number one selling product today. When first made available to consumers in the year 2001, Whitestrips® contained approximately 5% hydrogen peroxide. Now, almost 10 years later, the most popular Whitestrips® contain almost three times that amount of bleaching agent. Other manufacturers have also developed generic whitening strips as well, and the concentration of hydrogen peroxide in these strips have also increased significantly over the years. In all cases strips are relatively inexpensive, usually costing between $25 and $80 per box of strips, depending on the amount of strips supplied in the kit and the concentration of the bleach. The

whitening results with these strips are highly variable because user compliance is variable; a great many consumers will not complete the whitening regimen, which may require as much as 30 days of daily use.

There are many other OTC products on the market today, including toothpastes, chewing gums, and oral rinses, that are described by their respective manufacturers as "whitening" products despite the absence of any bleaching agent. These are not teeth bleaching products, however, and only minimally remove exterior stains through detergency and, mostly, abrasion.

3. Retail Non-Dentist Teeth Bleaching Center Option

In many ways, lay-operated teeth bleaching centers offer the best of all options to the cosmetic beauty-conscious public. These facilities typically are highly accessible, located most often in large shopping malls. No appointment is required. Many offer both light-activated, single session chairside systems and OTC take home products for the consumer to choose from. The key difference between this option and the OTC option is that in lay-operated teeth bleaching centers consumers are offered professional or near-professional strength products that can be self-applied in ways similar to those used by dental professionals. In this way consumers can achieve the white teeth they desire at much less cost than dentist-provided chairside bleaching, with much less time and hassle than is involved in achieving comparable results with OTC products.

Most often these consumer-friendly cosmetic lay-owned bleaching centers use lay personnel who have particular knowledge about the products and services they sell to the public and who offer

advice to the consumer on how best to self-apply the products. Their insights and advice may very important, because the higher concentration products are more technique sensitive. Also because higher concentration products carry greater risk of transient side-effects, it is very helpful to have a live person review proper usage. The cost of a complete chairside teeth bleaching session in a lay-operated bleaching center is typically about $100.

Most frequently, the flagship product that is offered by these centers is a 20 to 60 minute light-accelerated "power bleaching" using hydrogen peroxide or carbamide peroxide at levels somewhat lower than those used in dental offices, typically equivalent to 16% or less of hydrogen peroxide,[40] obviating any need for a gingival barrier. However instead of using products that are only available to licensed dentists, these facilities typically use a proprietary photosensitive peroxide bleaching gel purchased from one of many small manufactures that have carved out a niche supplying non-dentist-operated teeth bleaching businesses throughout the world.

The lay-operated bleaching centers may also sell a line of take home bleaching kits, some of which include self-adapted, self-customized bleaching trays, and others of which are sold with silicone stock trays. These kits typically include a moderate strength carbamide peroxide gel or a slightly stronger hydrogen peroxide gel. They typically are only slightly more expensive than Crest Whitestrips®, usually costing between $40 and $80. Consumers most frequently are instructed to use the at-home kits for up to 30 minutes per day for 14 days. Regardless of whether a chairside power bleaching or take-home kit is chosen, most consumers will achieve

their desired whiteness level, have minimal, if any, transient adverse side effects, and have a high level of satisfaction.

Indeed, the availability of retail teeth whitening establishments may actually contribute to dental health by encouraging consumers' consciousness of teeth appearance and, consequently, dental health. This may help some of the many people who avoid dentists out of fear to overcome that fear and seek dental care for dental conditions.

J. The NC-SBODE'S Reliance on the Self-Reported Experience of Brian Runsick

There is a complete absence of evidence in the literature that vital teeth bleaching by non-dentists poses material risks to consumers greater than those posed by similarly engaged dental professionals. Notwithstanding, or perhaps because of that fact the NC-SBODE seemingly has placed heavy reliance on the self-reported adverse experience of Mr. Runsick following his teeth bleaching at a North Carolina mall kiosk.

The details of Mr. Runsick's complaint are on file with the NC-SBODE. In brief, Mr. Runsick had his teeth bleached a few days before setting off on a cruise. He reported that while on the cruise, four days after having his teeth bleached, he developed, for the first time, pain in his mouth which worsened as his gums deteriorated over a period of several additional days. He was treated by a cruise line-recommended dentist, who, according to Mr. Runsick, joined Mr. Runsick in attributing his misfortune to improper technique and/or materials at his teeth bleaching. Mr. Runsick then took a broad spectrum antibiotic, and felt 80% better within 24 hours later.[42]

The available evidence especially the elapse of four days between his teeth bleaching and the onset of Mr. Runsick's self-reported symptoms is inconsistent with any claim that the bleaching caused Mr. Runsick's problems. A consulting physician for the NC-SBODE later examined Mr. Runsick and found that the tissue between two of Mr. Runsick's teeth "did not completely fill the interdental space," but that his teeth and gums were healthy.[43] He also noted a build-up of tartar between Mr. Runsick's mandibular incisors "with no evidence of any recent attempts to remove the tartar,"[43] which is suggestive of inadequate prior dental care and possible prior periodontal disease. Having never seen or documented Mr. Runsick's "original condition" or his condition while he was symptomatic, Dr. Tilley "[felt] that all the gingival tissue will return to 90% of the original condition."[43] Dr. Tilley sought to explain how it might be that Mr. Runsick's pain his very first symptom of injury took four days to develop, but his attempted explanation is contrary to science and experience.[44] I know of no possible mechanism, aside from a delayed hypersensitivity reaction (which this could not have been, among other reasons, because our immune systems could not mistake hydrogen peroxide for a foreign pathogen given that it is found abundantly in our bodies as a normal by-product of cellular metabolism), in which someone can be exposed to a chemical erosive agent on one day and then experience the harmful effects four days later with none appearing in the interval**.** The more likely explanation given available evidence is that Mr. Runsick suffered from a periodontal abscess that just happened to occur within a few days of his teeth bleaching. Indeed, Mr. Runsick may have worsened his condition in his effort to remedy it with constant teeth brushing and other attempted therapies. The questionable nature of Mr. Runsick's claim, and the extraordinary lack of similar complaints, demonstrates that isolated anecdotal reports are not a substitute for reliable

clinical or empirical evidence of product/service safety and efficacy. [48,49] The available clinical and empirical evidence is that vital teeth bleaching is safe and effective, and no less so when performed at bleaching centers or using OTC products than when performed by dentists.

VI. Conclusion

I believe the NC-SBODE's has sought to eliminate a teeth whitening alternative that is valued by consumers. The NC-SBODE's actions preserve vital teeth bleaching as a dentists' domain, but does so to the disadvantage of consumers who want a speedy teeth whitening experience but would prefer not to pay the considerable sums that dentists charge for chairside bleaching.

The NC-SBODE's efforts to exclude alternative practitioners of vital teeth bleaching from the market is neither authorized by the North Carolina Dental Practices Act's condemnation of stain removal by unlicensed persons nor warranted by public health considerations. Teeth bleaching is not the removal of stains. Plainly, vital teeth bleaching can produce transient adverse side effects, but those are not specific to any class of provider indeed, they may be most frequent and pronounced with dentist-provided chairside bleaching owing to the greater concentration of hydrogen peroxide often used in dental offices. But both the experience of millions upon millions of consumers and the relevant literature indicate that vital teeth bleaching is safe and effective, irrespective of how and by whom done.

Respectfully submitted,

Martin Giniger, D.M.D., M.S.D., Ph.D., F.I.C.D.

REFERENCES

1. Document Number BEK-FTC-000264-000276: Council for Cosmetic Teeth Whitening Best Practices and Information for Cosmetic Teeth Whitening Product Manufacturers and Distributors, dated 2008

2. Document Number CX0108: Letter from Attorney Frank Recker, Esq. to Carolin Bakewell discussing the legality of teeth bleaching materials, and also containing training manuals and instruction sheets, and other attachments supporting the rights of his client, Whitescience, presumably drafted in 2007

3. Instruction sheets provided by Sunshine Health Products to clients who purchase Peroxide Bleaching Gel from them, dated 2010

4. Beauty Clinic/BleachBright Teeth Whitening of Central Florida LLC, Double Blind Study, *available at* http://www.bleachbrightwhitening.com/doubleblindstudy.htm

5. Bleach Bright BB-Cool teeth whitening accelerator light, *available at* http://www.alibaba.com/product-tp/103979074/Bleach_Bright_BB_Cool_teeth_whitening.html

6. G.J. Christensen, The Tooth Whitening Revolution, J Am Dent Assoc, dated 2002

7. Document Number CX0019: NCGS: 90-29. Necessity for license; dentistry defined; exemptions; N.C. General Statutes, Chapter 90, Article 2, Dentistry

8. Document Number CX0384: Gareth Marples: The History of Teeth Whitening Smiles Through the Miles, dated September 11, 2009, *available at* http://www.thehistoryof.net/the-history -of-teeth- whitening.html

9. Jason Meyers, The Growth of Teeth Whitening Procedures Over Recent Years, dated October 21, 2009, *available at* http://ezinearticles.com/?The-Growth-of-Teeth-Whitening-Procedures-Over-Recent-Years&id 3131967

10. Ryn Gargulinski, History of Teeth Whitening, *available at* http://www.ehow.com/about_4687154_history-teeth-whitening.html

11. Andrew Joiner, The bleaching of Teeth: A Review of the Literature, Journal of Dentistry, Vol. 34, 412-419, dated 2006

12. Richard S. Manly, The Abrasion of Cementum and Dentin by Modern Dentifrices, Journal of Dental Research, Vol. 20, 583, dated 1941

13. Michelle Darby and Margaret Walsh, Chapter 27 - Management of Extrinsic and Intrinsic Stains In: Darby M, Walsh MM, eds. Dental Hygiene Theory and Practice, 3rd ed., St Louis: Saunders, dated 2010

14. W.D. Miller, Dental Cosmos, Vol. 49, 109 124, dated 1907

15. The Toothbrush: An Oral Hygiene Story, *available at* http://www.dentistry.com/daily-dental-care/dental-hygiene/the-toothbrush-an-oral-hygiene-history

16. Imma LaCross, Posing the Polishing Question, The Journal of Professional Excellence, Dimensions of Dental Hygiene, 5(6):20, 22-23, dated June 2007

17. M. Cadenaro, et al., Effect of Two In-office Whitening Agents on the Enamel Surface In Vivo: A Morphological and Non-contact Profilometric Study, Operative Dentistry, Vol. 33, No. 2,127-134, dated 2008

18. Esther M. Wilkins and Caren M. Barnes, Extrinsic Stain Removal In: Wilkins EM and Barnes CM, Clinical Practice of the Dental Hygienist, 10th ed., New York: Lippincott, Williams, & Wilkins, 726-741, dated 2009

19. American Dental Hygienists' Association Position on Polishing Procedures, dated 2007, *available at* http://www.adha.org/profissues/polishingpaper.htm

20. Van B. Haywood, Current Status of Nightguard Vital Bleaching, Quintessence International, Compendium, Vol. 21, Supplement No. 28, dated June 2000

21. A.W. Harlan, The Dental Pulp, its Destruction, and Methods of Treatment of Teeth Discolored by its Retention in the Pulp Chamber or Canals, Dental Cosmos, Vol. 33, 137 41, dated 1891

22. 30% Hydrogen Peroxide Concentrate, United States Pharmacopoeia Pharmacopeial Forum Vol. 34(2), dated Mar. Apr. 2008

23. Van B. Haywood, Orthodontic Caries Control and Bleaching, Inside Dentistry, 36-48, dated April 2010

24. Document Number CX0400: Carl C. Peck, Critical Assessment of Safety and Regulatory Status of Crest Whitestrips: Report of a Scientific Advisory Group Internal Unpublished Report, dated November 28, 2003

25. Robert Margeas, New Advances in Tooth Whitening and Dental Cleaning Technology, PenWell CDE Course, dated 2006

26. Document Number 000271-000381: Scientific Committee on Consumer Products, European Commission Health & Consumer Protection Directorate-General, Opinion on

Hydrogen Peroxide, in its free form or when released, in oral hygiene products and tooth whitening products, SCCP/1129/07, dated December 18, 2007

27. Susham Nachnani, et al., ADA Seal of Acceptance Certification Study for Discus Dental, Inc., Efficacy of Nite White® Whitening Gel: A Clinical Trial Final Report, dated March 22, 1997

28. Howard Strassler, Vital Tooth Bleaching: An Update, University of Maryland Dental School Continuing Education Insert, dated December 2006

29. Ghassan R. Mokhlis, et al., A Clinical Evaluation Of Carbamide Peroxide And Hydrogen Peroxide Whitening Agents During Daytime Use, J Am Dent Assoc, Vol. 131, 1269-1277, dated 2000

30. Document Number 000978-000992: I.C. Munro, G.M. Williams, H.O. Heymann, R. Kroes, Tooth whitening products and the risk of oral cancer, Food and Chemical Toxicology, Vol. 44, 301-315, dated 2006

31. United States Department of Labor, Occupational Safety and Health Administration, Safety and Health Topics, Dentistry, *available at* http://www.osha.gov/SLTC/dentistry/index.html

32. Kanjirath, P.P. et al., Effectiveness of Gloves and Infection Control in Dentistry: Student and Provider Perspectives, Journal of Dental Education, Vol. 73, No. 5, 571-80, dated May 2009

33. United States Federal Food, Drug, and Cosmetic Act, Chapter 1, Section II Definitions

34. Michael G. Jorgensen and William B. Carroll, Incidence of Tooth Sensitivity After Home Whitening Treatment, J Am Dent Assoc, Vol. 133; 1076-1082, dated 2002

35. Document Number 001092-001101: Michael Goldberg, Martin Grootveld, and Edward Lynch, Undesirable and Adverse Effects of Tooth Whitening Products: A Review, Clinical Oral Investigations, Vol. 14, 1-10, dated 2010

36. Document Number CX0402: Van B. Haywood, History, Safety and Effectiveness of Current Bleaching Techniques: Applications of the Nightguard Vital Bleaching Technique, Quintessence International, Symposium on Esthetic Restorative Materials, 82-92, dated 1991

37. J. Bowman, et al., Efficacy and Safety of Three Liquid Tooth Whitening Products, Journal of Dental Research (Supplement) Abstract 2119, dated 2005

38. FDA: Hydrogen Peroxide: Proposed Affirmation of Gras Status as a Direct Human Food Ingredient With Specific Limitations, Federal Register 48: 52323-53333, dated 1983

39. Document Number 000027-000039: J.E. Dahl and U. Pallesen: Tooth Bleaching A Critical Review Of The Biological Aspects, Critical Reviews in Oral Biology & Medicine, Vol.14, No. 4, 292-304, dated 2003

40. Spreadsheet showing data about teeth whitening manufacturers provided by Complaint Counsel on November 16, 2010

41. Deposition transcript of Dr. Ronald K. Owens, dated November 8, 2010

42. Document Number CX0049: Letter from Carolin Bakewell, Britewhite training manuals, and instruction sheets, presumably drafted in 2006

43. Rough deposition transcript of Dr. Larry Tilley, dated November 12, 2010

44. Respondent's Objections and Responses to Complaint Counsel's First Set of Requests for Admissions, dated Oct. 27, 2010

45. Document Number CX0096-003-004: Advertisement from SheShe Studio Spa, presumably drafted in 2007

46. Document Number CX0102-015: BriteWhite advertisement, presumably drafted in 2008

47. Document Number CX0043-005: Bleach Bright advertisement, presumably drafted in 2008

48. Gary R. Goldstein, What is Evidence Based Dentistry?, Dental Clinics of North America,Vol. 46, No. 1, 1-9, dated January 2002

49. Alex Loh, et al., Evidence-based Assessment: Evaluation of the Formocresol Versus Ferric Sulfate Primary Molar Pulpotomy, Pediatric Dentistry, Vol. 26, No. 5, 401-409, dated 2004

50. Gianluca Plotino et al., Nonvital Tooth Bleaching: A Review of the Literature and Clinical Procedures, Journal of Endodontics, Vol. 34, No. 4, 394-406, dated April 2008

51. Document Number CX00392: Document Number CX0392: Tooth Whitening/Bleaching: Treatment Considerations for Dentists and Their Patients, ADA Council on Scientific Affairs, dated September 2009

52. The Zoom! Teeth Whitening System, *available at* http://www.animated-teeth.com/dentist_laser_whitening/a9_zoom_teeth_whitening.htm

53. Bleachbright LED Whitening Protocol and Best Practices Manual

EXHIBIT 1: CURRICULUM VITAE

CURRICULUM VITAE
MARTIN STEVEN GINIGER

PERSONAL INFORMATION

Citizenship:	USA
Home Address:	101 Briny Avenue, Apt 2206 Pompano Beach, Florida 33062
Office Telephone: Mobile Telephone:	(561) 865-5499 (954) 501-9005
Office Address:	Power Swabs Corporation 100 East Linton Blvd, Suite 105-B Delray Beach, FL 33483

EDUCATION

Pre-doctoral Degree:	Rutgers College, Rutgers University New Brunswick, New Jersey BA in Biology, With Honors, 1980 Minor in Economics and Marketing
Doctoral Degree:	Fairleigh Dickinson University School of Dental Medicine Hackensack, New Jersey DMD with Basic Science Award, 1984
Postdoctoral Degree:	University of Connecticut School of Dental Medicine Farmington, Connecticut PhD in Biomedical Science (Oral Biology), 1993 3.99 GPA
Postdoctoral Certificate:	University of Connecticut School of Dental Medicine Farmington, Connecticut MsD in Oral Medicine, 1993

EMPLOYMENT HISTORY

2008	2010	Chairman & Chief Science Officer Power Swabs Corporation & PSC Research Institute Beaverton, OR and Delray Beach, FL
2007	2008	Vice Chairman & Founder GRINrx Corporation New York, NY and Kirkland, WA
2006	2007	Chief Formulation Chemist (independent Contractor) Discus Dental Corporation Culver City, CA
1996	2006	Associate Professor and Vice Chairman Department of Diagnostic Sciences University of Medicine & Dentistry of New Jersey Newark, NJ
2002		Director of Professional Relations (Part-time) Dexxon Corporation Edison, NJ 08837
1994	1996	Director of Academic Marketing and Research Colgate-Palmolive Company Canton, MA and New York, NY
1993	1994	Director of Medical Laboratory Services Louisiana State University School of Dentistry
1993	1994	Assistant Professor Joint Appointment: Oral Medicine / Physiology Louisiana State University School of Dentistry Louisiana State University School of Medicine
1989	1993	Clinical Scholar & Teaching Assistant Department of BioStructure and Function University Connecticut School of Dental Medicine

Note: Also served as chief scientific consultant for Colgate-Palmolive Company from 1996 to 2005 and Go Smile, Inc from 2009 to the present time.

PROFESSIONAL LICENSURE (DENTISTRY)

New York, 051946
New Jersey, DI1476
Connecticut, 7102
Louisiana, P38 (Restricted Teaching License)

PRIVATE PRACTICE

1995	2006	Center for Oral and Dental Health Faculty Practice
1993	1994	LSU Medical Center, New Orleans, Louisiana Faculty Practice
1985	1987	Iselin Dental Group, Iselin, New Jersey General Practice
1984-1985		Staff Dentist Trenton State Prison / Yardville Youth Correction Center

HOSPITAL APPOINTMENTS

1993	1994	Charity Hospital - Medical Center of Louisiana at New Orleans - Medical Visiting Staff
1993	1994	LSU Medical Center - School of Dentistry - Director, Medical Diagnostic Laboratory
1989	1993	UConn John Dempsey Hospital Oral Medicine Resident
1984	1985	Beth Israel Medical Center, Newark, New Jersey General Practice Residency

OTHER TRAINING & CLINICAL ROTATIONS

UConn John Dempsey Hospital	Hematology/Laboratory Medicine Dermatology/Dermatopathology Bone Marrow Transplant Unit Head and Neck Cancer Clinic Infectious Diseases
Saint Francis Medical Center	Physical Diagnosis/Internal Medicine

LSU Charity Hospital	Outpatient/Inpatient Leukemia Unit Bone Marrow Transplant Unit
Armed Forces Institute of Pathology	Oral Pathology

TEACHING RESPONSIBILITIES

UMDNJ School of Dentistry	Course Director: Treatment Planning Clinic I Course Director: Treatment Planning Clinic II Course Director: Diagnostic Sciences Seminars I Course Director: Diagnostic Sciences Seminars II Director, Prevention Section, GPR program Intro to Oral Epidemiology Diagnostic Sciences I, II, III and IV Sophomore Operative Dentistry
LSU School of Dentistry	Course Director: Internal Medicine Course Director: Oral Diagnosis Screening Clinic Course Director: Oral Diagnosis I Clinical Preceptor: Oral Diagnosis III Mini-Clinic Faculty Advisor
UConn School of Dentistry	Lectures Given: Oral, Physical & Lab Evaluation Lectures Given: General Pathology Lecture Clinic: Oral Diagnosis Screening Clinic Clinical Lecture Given: Nutrition in Public Health Policy

GRANTS

2004 2005	Healthcare Foundation of NJ ($150,000) to cover all NJDS based Community Activities
2003 2004	Healthcare Foundation of NJ ($150,000) to cover all NJDS based Community Activities
2001 - 2002	Healthcare Foundation of NJ ($54,000) to cover all NJDS based Community Activities
1999 2000	UMDNJ Foundation to fund UMDNJ Special Olympics ($17,000)
1998-1999	UMDNJ Foundation Grant ($25,000) Community Service activities
1989 1993	N.I.H. Dentist /Scientist Award $250,000 (4 years)
1987 1989	N.I.H. Oral Biology Training Grant $20,000 per year (2 years)

Other Grants

2005 Colgate Palmolive Company: Dentifrice, Mouthrinse and Toothwhitening Monetary and In-Kind Grants totaling approximately $100,000

SPECIAL AWARDS

2000	2005	Special Olympics Community Service Awards
2004		UMDNJ Community Service Award
2001		Fellowship, International College of Dentists
2000		Awarded Faculty Membership in O.K.U. Honor Society
1993		Lester Burkett Award - American Academy of Oral Medicine
1984		Basic Medical Science Award - F.D.U. School of Dental Medicine

PROFESSIONAL MEMBERSHIPS

1984	Present	American Dental Association
		International Association of Dental Research
		American Dental Education Association
2000	Present	Omicron Kappa Upsilon
2001	Present	Fellowship into the International College of Dentists
1989	2000	Organization of Teachers of Oral Diagnosis
		American Society of Cell Biology
1993	1995	American Academy of Oral Medicine
		American Association of Dental Schools

UNITED STATES PATENTS & PENDING PATENTS

1	20090004629	AESTHETIC DENTAL ARCH LAMINATES AND ADHESIVE
2	20080213719	Temperature Modified Oral Cleaning Device
3	20070122363	CORPOREAL DELIVERY OF CAROTENOIDS
4	20070122362	HYDROGEL SHEETS AND SHAPES FOR ORAL CARE
5	20060239757	Application and/or carrying devices for oral care compositions
6	20060229226	Foaming compositions and methods
7	20060216256	Foaming oral care compositions of baking soda and vinegar
8	20060204455	Compositions for enhancing effects of other oral care compositions
9	20060204453	Oral care cleaning compositions and methods
10	20060198803	Whitening system capable of delivering effective whitening action
11	20060198799	Tooth glossing or finishing compositions for oral care
12	20060198797	Stand-alone or enhancer composition for oral care
13	20060198796	Whitening compositions and methods involving nitrogen oxide radicals
14	20060198795	Multi-component oral care compositions

PUBLICATIONS

Giniger M, Spaid M, MacDonald J, Felix H.A 180-day clinical investigation of the tooth whitening efficacy of a bleaching gel with added amorphous calcium phosphate. J Clinical Dentistry 2005(1):11-16.

Giniger, M. Spaid M. Felix H. MacDonald J. Ziemba S. A 180-Day Clinical Investigation of the Tooth Whitening Efficacy of a Bleaching Gel with Added Amorphous Calcium Phosphate. Journal of Clinical Dentistry. Volume 16, Issue 5, May 2005.

Giniger M, Macdonald J, Ziemba S, Felix H. The clinical performance of professionally dispensed bleaching gel with added amorphous calcium phosphate. JADA 2005 Mar;136(3):383-92.

Hu D, Zhang YP, Petrone M, Volpe AR, Devizio W, Giniger M. Clinical effectiveness of a triclosan/copolymer/sodium fluoride dentifrice in controlling oral malodor: a 3-week clinical trial. Oral Dis. 2005;11 Suppl 1:51-3.

Silva MF, Giniger MS, Zhang YP, DeVizio W. The effect of a triclosan/copolymer/fluoride liquid dentifrice on interproximal enamel remineralization and fluoride uptake. J Am Dent Assoc. 2004 Jul;135(7):1023-9.

Ayad F, Giniger M, Stewart B, Proskin HM, Petrone M, Volpe AR, DeVizio W: Clinical comparison of the stain-removal efficacy of a novel liquid whitening gel containing 18% carbamide peroxide and a commercially available whitening dentifrice. Compendium of Continuing Education, October Special Issue 2002

Nathoo S, Giniger M, Proskin HM, Petrone M, Volpe AR, DeVizio W: Efficacy of a novel non-tray, paint-on 18% carbamide peroxide whitening gel. Compendium of Continuing Education in Dentistry, October 2002 Special Issue

Giniger M, Nathoo S, Chaknis P, Proskin HM, Petrone M, Volpe AR, DeVizio W:: Comparative three-week clinical tooth-shade evaluation of a novel liquid whitening gel containing 18% carbamide peroxide and a commercially available whitening dentifrice. Compendium of Continuing Education in Dentistry. Accepted for publication , October 2002 Special Issue

Triratana T, Rustogi KN, Volpe AR, DeVizio W, Petrone M, Giniger M: Clinical effect of a new liquid dentifrice containing triclosan/copolymer on existing plaque and gingivitis. Journal of the American Dental Association. 133(2):219-25, 2002 February

Nathoo S, Santana E, Zhang YP, Lin N, Collins M, Klimpel K, DeVizio W, Giniger M: Comparative seven-day clinical evaluation of two tooth whitening products. Compendium of Continuing Education in Dentistry. 22(7):599-604, 606; quiz 608, 2001 July

Singh SM, Battista GW, Petrone ME, Proskin HM, DeVizio W, Volpe AR, Giniger MS: The Comparative Plaque Removal Efficacy of Two Advanced Manual Toothbrush Designs in Two

Independent Clinical Studies. Submitted to American Journal of Dentistry Accepted for Publication 2002

Nathoo S, Santana E, Zhang YP, DeVizio W, Volpe AR, Giniger MS: Comparative Seven-Day Clinical Evaluation of Two Tooth Whitening Products. Compendium, 22(7):599- 608, 2001

Feldman, CA, Giniger, MS, Sanders, RM, Saporito, RA, Zohn, HK, Perlman, S: Special Olympics, Special Smiles: A Field Report of an Oral Care Program at the Special Olympics, JADA, 128: 1687-1695, 1998

Giniger MS, Chandrasekaran S, Tanzer ML: Oligomannosides initiate cell spreading of laminin-adherent murine melanoma cells, J Biol Chem, 269: 3356-3366, 1994

Giniger MS, Chandrasekaran S, Tanzer ML: Characterization of oligomannoside binding to the surface of murine melanoma cells. Potential relationship of oligomannoside-initiated cell spreading, J Biol Chem 269: 3367-3373, 1994

Barasch, A, Mosier, KM, Giniger, MS, Ascensao J, Peterson DE: Postextraction osteomyelitis in a bone marrow transplant patient, OOO, 75(3):391-396, 1993

Tanzer ML, Giniger MS, Chandrasekaran S: Laminin oligosaccharides play a pivotal role in cell spreading, Cell Behavior: Adhesion and Motility 2(1):147-154, 1993

Giniger MS, Chandrasekaran S, Dean JW, Tanzer ML: The role of laminin carbohydrates on cellular interactions, Kidney International, 43(1):66-72, 1993

Giniger MS, Bronner FA, Lorenzo JA, Sousa S, Norton L: A human periodontal ligament fibroblast releases a bone resorption inhibition factor in vitro, J Dent Res, 70(2):99-101, 1991

Chandrasekaran S, Dean JW, Giniger MS, Tanzer ML: Laminin carbohydrates are implicated in cell signaling, J Cell Biochem, 40:115-124, 1991

BOOKS / CHAPTERS

Giniger, MS: Dental Caries Prevention, Nutrition Policy in Public Health, Ed. Felix Bronner, pp. 207-231, Springer Publishing Company, New York, 1997

Tanzer ML, Giniger MS, Dean JW, Chandrasekaran S: The role of glycosylation in adhesive protein function, In Cell Surface and Extracellular Glycoconjugates; Structure and Function, Eds Roberts DD and Mecham RP, pp. 271-308, Academic Press, San Diego, 1993

ABSTRACTS

M. GINIGER, M. SPAID, M. GREENE, and B. OLSON. Whitening and Extrinsic Stain Removal Efficacy of Portable Liquid Toothbrush. Abstract 2006. Brisbane, Australia.

M. SPAID, and M. GINIGER. Effect of Adjunctive Universal Whitening Enhancer on Enamel and Dentin. IADR Abstract 2006. Brisbane, Australia.

M. GINIGER, H. FELIX, J. MACDONALD, S. ZIEMBA, and M. SPAID. Tooth Surface Enhancement By a 16% Carbamide peroxide Take-Home Bleaching Gel. Journal of Dental Research. 84 (Spec Iss A): 1793, 2005

M. SPAID, and M. GINIGER. Whitening Efficacy of an Alkaline Effervescent Peroxide Foam. IADR Abstract 2006. Brisbane, Australia.

M. GINIGER, H. FELIX, J. MACDONALD, S. ZIEMBA, and M. SPAID. Clinical Performance of Professional Tray Bleaching Gel with Added ACP. IADR Abstract 2005. Baltimore, Maryland.

Drew, CP, Giniger MS, Matheson P, Perlman S, Feldman CA: Evaluating Tobacco Use Among Special Olympics Athletes. J Dent Ed 65 (1), p.38 #73, 2001

Matheson P, Slifer M, Feldman CA, Giniger MS, Perlman S: The Oral Health of Special Athletes and Dental Care. Submitted to J Dent Res (IADR Abstract), 2000

Drew C, Matheson P, Giniger MS, Perlman S and Feldman CA: Evaluating Tobacco Use Among Special Olympics Athletes. Submitted to ADEA for poster presentation in September 2000

Panagakos FS, Holtzman JM, Sanders RM, Giniger MS, and Desjardins P: Attitudes of First Year Dental Students Regarding Bloodborne Pathogens. J Dent Res 77 (special issue B), p.790 #1266, 1999

Holtzman JM, Panagakos FS, Sanders RM, Giniger MS, and Desjardins P: Dental Education, Dental Fear and Critical Thinking Skills: a baseline report. J Dent Res 77 (special issue B), p.834 #1622, 1999

Matheson P, Feldman CA, Giniger MS, and Perlman S: Oral Health Status of a Population of Special Olympics Athletes. J Dent Res 77 (special issue B), p.702 #564, 1999

Calem B, Giniger MS, Feldman CA: Comparative Assessment of Methods of measuring Tooth Lightness . J Dent Res 76 (special issue), p. 71 #464, 1999

Zohn HK, Feldman CA, Sanders M, Saporito RA, Perlman SP, and Giniger MS: New Jersey Special Olympics: Special Olympics, Special Smiles. J Dental Education 61 (2), p. 208 #95, 1998

Giniger MS, Chandrasekaran S, Dean JW, Tanzer ML: Oligomannosides initiate cell spreading of laminin-adherent murine melanoma cells, 33rd Annual Meeting of the American Society for Cell Biology, November, 1993

Giniger MS, Chandrasekaran S, Dean JW, Tanzer ML: Melanoma cell spreading is initiated by cellular recognition of high mannose oligosaccharides, Annual Meeting of the American Academy of Oral Medicine, May, 1993

Giniger MS, Chandrasekaran S, Dean JW, Tanzer ML: B16F1 Melanoma cell spreading on laminin is initiated by cellular recognition of high mannose oligosaccharides, 13th Annual Meeting of the East Coast Connective Tissue Society, March, 1993

Giniger MS, Chandrasekaran S, Dean JW, Tanzer ML: High mannose oligosaccharides restore melanoma cel spreading, 32rd Annual Meeting of the American Society for Cell Biology, November, 1992

Tanzer ML, Giniger MS, Chandrasekaran S: Cell spreading is medicated by mannosyl oligosaccharides, 46th Annual Society for Experimental Biology Symposium, September 28, 1992

Giniger MS, Chandrasekaran S, Dean JW, Tanzer ML: Cell spreading is restored by laminin carbohydrates, 12th Annual Meeting of the East Coast Connective Tissue Society, March 13, 1992

Giniger MS, Chandrasekaran S, Dean JW, Tanzer ML: Cell spreading is restored by laminin carbohydrates, 11th Annual Meeting of East Coast Connective Tissue Society, March 23, 1991

Giniger MS, Chandrasekaran S, Dean JW, Tanzer ML: Cell spreading is restored by laminin carbohydrates, J Dent Res, 70(abstracts):193, 1989

Giniger MS, Bronner FA, Lorenzo JA, Sousa S, Norton LA: Cloned human fibroblasts J from the periodontal ligament release a bone resorption inhibition factor, J Dent Res, 68(abstracts):193, 1989

Giniger MS, Bronner FA, Lorenzo JA, Sousa S, Norton LA: Cloned human fibroblasts J from the periodontal ligament release a factor that inhibits bone resorption. J Bone Mineral Res, 3:s222, 1988

EXHIBIT 2: LIST OF REVIEWED MATERIALS

- Initial Complaint of the Federal Trade Commission (with Anticipated Relief) against the North Carolina Board of Dental Examiners (Docket No. 9343), dated June 17, 2010
- Respondents Response to Complaint (Docket No. 9343) filed by Noel L. Allen, Esq. on behalf of the North Carolina State Board of Dental examiners, dated July 6, 2010
- Document Number CX0400: Critical Assessment of Safety and Regulatory Status of Crest Whitestrips, dated November 28, 2003
- Document Number CX0053: Frequently Asked Questions for Professional Teeth Whitening
- Document Number CX0398: Letter from Mr. Michael R. Sudzina to Dr. Daniel Meyer
- Deposition Transcript of Charles Wayne Holland, dated September 17, 2010
- Deposition Transcript of Joseph S. Burnham Jr., dated October 8, 2010
- Deposition Transcript of Clifford O. Feingold, dated October 5, 2010
- Deposition Transcript of M. Alec Parker, dated September 23, 2010
- Deposition Transcript of Millard W. Wester III, dated September 3, 2010
- Deposition Transcript of Brian Runsick, dated November 4, 2010
- Rough Deposition Transcript of Michael L. Hasson, dated November 16, 2010
- Document Number CX0210: E-mail from Ronald Owens to Bobby White et al., dated July 14, 2008
- Document Number CX0206: Minutes from the North Carolina State Board of Dental Examiners Board Meeting, dated August 10-11, 2007
- Document Number CX0201: E-mail from Terry Friddle to Clifford Feingold et al., dated January 4, 2008
- Document Number CX0153: Cease and Desist letter from the North Carolina State Board of Dental Examiners to Serenity Total Body Care (BleachBright), dated September 22, 2009
- Document Number CX0203: Letter from the North Carolina State Board of Dental Examiners to Blue Ridge Mall, dated November 21, 2007

- Document Number CX0211: E-mail from Clifford Feingold to Bobby White et al., dated July 14, 2008

- Document Number CX0212: E-mail from Carolin Bakewell to Ronald Owens et al., dated May 27, 2008

- Document Number CX0213: E-mail from Clifford Feingold to Carolin Bakewell et al., dated May 28, 2008

- Document Number CX0214: E-mail from Stan Hardesty to Carolin Bakewell et al., dated May 27, 2008

- Document Number CX0215: Emails from Clifford Feingold to Carolin Bakewell et al., dated May 19, 2008

- Document Number CX0200: Emails from Clifford Feingold to Line Dempsey et al., dated January 16, 2008

- Document Number CX0218: The Dental Forum Newsletter, North Carolina State Dental Board of Examiners, dated Spring 2007

- Document Number CX0220: Petition signatures supporting the Candidacy of Clifford O. Feingold for the North Carolina State Board of Dental Examiners, dated January 5, 2005

- Document Number CX0124: E-mail from Cassie Goode to Wayne Holland, dated November 14, 2008

- Document Number CX0198: Advertisement for Movie Star Smile, undated

- Document Number CX0106: Closed Session Minutes of the NC State Board of Dental Examiners Board Meeting, dated August 10-11, 2007

- Document Number CX0067: E-mail from Carolin Bakewell to Mr. Van Essen, with attached Board of Cosmetology Notice, dated February 7, 2007

- Document Number CX0056: Minutes of the North Carolina State Board of Dental Examiners Board Meeting, dated February 9, 2007

- Document Number CX0054: Fax from Terry Friddle to Stan Hardesty, with attached Complaint Form, dated September 11, 2006

- Document Number CX0055: Brian Runsick's North Carolina State Board of Dental Examiners Complaint Form, dated April 11, 2008

- Document Number CX0327: Letter from Larry Tilley to North Carolina State Board of Dental Examiners, dated April 24, 2008

- Document Number CX0401: Vital Bleaching With A Thin Peroxide Gel, Journal of the American Dental Association, Vol. 135, dated January 2004

- Document Number CX0100: Cease and Desist letter sent to White Science from the North Carolina State Board of Dental Examiners, dated December 4, 2007

- Document Number CX0068: Cease and Desist letter sent to Joe Willet (BleachBright) from the North Carolina State Board of Dental Examiners, dated February 20, 2008

- Document Number CX0199: E-mail Terry Friddle to Casie Goode, dated January 17, 2008

- Document Number CX0103: Email from Bobby White to Christine Bennett et al., dated April 24, 2008

- Council for Cosmetic Teeth Whitening, *available at* http://www.cctwonline.org/

- Document Number 004428-004430: ADA Meeting Agenda, CSA Report on Whitening/Bleaching (73H-2008) Subcommittee Recommendations, dated November 8-10, 2010.

- Van B. Haywood, A Comparison of At-Home and In-Office Bleaching, Dentistry Today, Vol. 19, No. 4, dated 2000

- 510K Permission to Market, BEKS, Inc., dated February 2007

- 510K Permission to Market, BEKS, Inc., dated April 2004

- 510K Permission to Market, BioLase Technology Inc., dated October 2003

- 510K Permission to Market, Cosmetic Dental Materials, Inc. dated October 2005

- 510K Permission to Market, Dentovations, Inc., dated November 2004

- 510K Permission to Market, Hoya ConBio, Inc., dated March 2007

- 510K Permission to Market, Hoya ConBio, Inc., dated April 2005

- 510K Permission to Market, Hoya ConBio, Inc., dated June 2007

- 510K Permission to Market, Hoya ConBio, Inc., dated October 2003

- 510K Permission to Market, Spectrum International, Inc., dated November 2006
- 510K Permission to Market, Zap Lasers, LLC, dated June 2002
- 510K Summary of Safety, BioLase Technology Inc., dated October 2003
- 510K Summary of Safety, Hoya ConBio, Inc., dated October 2003
- 510K Summary of Safety, Spectrum International, Inc., dated September 2006

Attachment B

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
THE NORTH CAROLINA [STATE] BOARD OF DENTAL EXAMINERS,	)	DOCKET NO. 9343
Respondent.	)	

EXPERT WITNESS REPORT OF VAN B. HAYWOOD, D.M.D.

APPENDIX I	Curriculum Vitae of Van Benjamine Haywood
APPENDIX II	Expert Witness Report Exhibits
APPENDIX III	Statement Pursuant to Rule 3.31A of the FTC Rules of Practice for Adjudicative Proceedings

EXPERT WITNESS REPORT OF VAN B. HAYWOOD, D.M.D.

(FTC vs. North Carolina Board of Dental Examiners; Docket 9343)

I. BACKGROUND AND QUALIFICATIONS:

My name is Van B. Haywood, D.M.D., and I am a Professor in the Department of Oral Rehabilitation, School of Dentistry, Medical College of Georgia. I am a 1974 alumni of MCG, was in private practice 7 years in Augusta, Georgia and taught at the University of North Carolina School of Dentistry in Operative and Prosthodontics for 12 years before coming to MCG in 1993. I teach in the Fixed Prosthodontics courses, the Occlusion course and the Esthetics course, as well as in student clinics. Additionally, since 2005, I have been the Director of Continuing Education for the School of Dentistry.

My most recent CV is attached. I am a member of the American Dental Association, the Georgia Dental Association, the Eastern District Dental Association, and the Augusta Dental Society. I am in the International Association of Dental Research, the Georgia Association of Dental Research, the American Association of Dental Schools, OKU honor society, the Christian Dental Society, and the Christian Medical Dental Association. I am also a member of the Academy of Operative Dentistry, the American Academy of Restorative Dentistry, the Academy of Esthetic Dentistry, and the Hinman Dental Society. I am a Fellow in the American College of Dentists and the International College of Dentists. I am or have been on the editorial board of the Journal of Esthetic Dentistry, Journal of Operative Dentistry, Inside Dentistry, Quintessence International, and I was the Associate Editor of the Esthetics Section of the Journal of the American Dental Association for three years until 2008. I currently serve as an ADA consultant to the Council on Scientific Affairs, as well as consult with several major companies.

In 1989, I co-authored the first publication in the world on Nightguard Vital Bleaching (called NGVB, tray or at-home bleaching) with Dr. Harald Heymann, and in 1997 co-authored the first article on extended treatment (six-months) of tetracycline-stained teeth using this technique. I have completed further research and over 135 publications on the NGVB technique and the topic of bleaching and esthetics, including first papers on treating bleaching sensitivity with potassium nitrate, direct thermoplastic tray fabrication, and bleaching primary teeth, as well as caries control with bleaching materials for elderly and orthodontic patients. My research has involved bleaching, treatment of tooth sensitivity, caries control with bleaching materials and tray designs for delivery of different materials.

In addition to teaching, my involvement with continuing education has spanned a broad base of options. I have lectured in 23 different countries, 27 states and several dental schools, including four schools abroad. Since 2001, I have been listed in the "Top Leaders in Continuing Education" for the United States by Dentistry Today. I have directed or participated in over 65 CE courses at UNC and MCG, and been involved with internet and recorded continuing education CDs. In publications, I have been involved in over 135 articles, 40 abstracts and 7 book chapters. I was associate editor for Dr. Goldstein's "Esthetics In Dentistry: Vol II" in 2002. My book titled "Tooth Whitening: Indications and Outcomes of Nightguard Vital Bleaching", was published by Quintessence International in 2007 and is available at www.quintpub.com online.

II. MATERIALS CONSIDERED IN FORMULATING OPINIONS

The data and materials from which I draw my conclusions include the patient care and research I have performed, the 135 articles, 7 book chapters and book I have written, and a study of the references cited in those articles. I have also reviewed the Expert Witness report of Dr. Martin Giniger, and the economic report of Professor John Kwoka. I have seen the Declaration of Alfred P. Carlton, Jr. with his Respondent (9343), and the North Carolina General Statutes ,

Chapter 90 article 2. I continually review articles and papers on bleaching and related topics, and reserve the right to continually include additional literature as it is found and published and alter my opinions as needed. The opinions expressed in this paper are based on my personal clinical experience, research, and study, and do not reflect any opinions of the Medical College of Georgia School of Dentistry (name changed Feb 1, 2011 to Georgia Health Sciences University, College of Dental Medicine).

III. SCOPE OF WORK AND COMPENSATION

I have been retained by the attorneys of the North Carolina Board of Dental Examiners. I have no financial interest in bleaching products or techniques, and no patents in either area. I have freely shared my bleaching knowledge since the original 1989 article with the dental profession through peer-reviewed journals, teaching publications, lectures, seminars and my personally-funded website www.vanhaywood.com.. I have lectured and consulted with many bleaching companies, but am not or never have been a paid employee of any bleaching company. I have been secured as an expert witness in this case on an hourly rate of $400 with a daily cap of $2000 at home or $3000 away from home plus expenses.

IV. SUMMARY OF OPINIONS

Tooth bleaching treatment should always be preceded by a proper dental examination conducted by a licensed dentist, and may require radiographs to diagnosis the cause of discoloration. Discoloration or staining may be an indication of dental conditions such as abscessed teeth, decay, resorption or faulty restorations. Correctly diagnosed indications for bleaching may require different treatment times or technique approaches, based on the type and depth of the stain/discoloration and the number of teeth involved. Without a proper examination and diagnosis of the cause of discoloration or staining, the disease process

occurring in the tooth may be masked by removing discoloration that is the only clinical symptom of the problem. Additionally, the person may receive bleaching treatment which is not indicated for their condition and wasteful of their finances, or create an unsightly esthetic condition that may be risky or impossible to correct. Non-dentists involved in providing chairside bleaching services are practicing dentistry without the proper training, resources and licensure, and deceiving the public in their ability to diagnosis and treat diseases and conditions of the tooth by their "dentist-like" appearance. A single chairside bleaching treatment by anyone will not resolve the majority of the tooth discolorations/stains, so multiple chairside treatments are generally required. Non-dentist chair side bleaching is practicing dentistry without a license and poses a risk to the general public.

As part of this report, I have included a series of visual examples of concerns and conditions found by the dentist to which I will refer during the report. In order to visually understand the impact of bleaching, color photographs of various patients and conditions are presented, as well as summary points. There is text included on the photographs explaining the purpose of that example. In the report that follows, I will reference this Exhibit by the following parenthesis notation: (see photographs in Exhibits).

EXPERT REPORT:

Discolored or stained teeth create an unsightly and demeaning condition for most people in the United States and the world. The terms discolored and stained are used interchangeably in this report, since some stains/discolorations are on the external surface of the teeth (coffee, tea, etc.), some stains/discolorations are on the internal portion of the tooth (from drugs such as tetracycline, etc.) and some stains/discoloration are both on the outside and inside (like nicotine stains from smoking, fluorosis stains from drinking water, etc.).[1] Discolored or stained teeth are most conservatively treated by bleaching, which removes both internal and external stains and

discolorations from a tooth. The common tooth bleaching materials go through intact enamel and dentin to the pulp (nerve) of the tooth in 5-15 minutes.[2] Hence, the bleaching process is removing stains and discolorations inside the enamel and inside the dentin, as well as on the surface of the enamel. In addition to removing stains and discolorations, bleaching is also changing the genetic color of the tooth by changing the color of the dentin. [3 4] Persons are born with different colored teeth in the same manner as they have different eye or hair color (see photographs in Exhibits). Bleaching is changing the genetic color of the tooth, as some patients are born with very yellow teeth, evident in their teenage years. Also, this situation can easily be seen clinically in persons who have dark canine teeth (eye teeth) compared to their other incisor (front) teeth (see photographs in Exhibits). Those teeth were darker from the time they erupted, not due to external staining. Bleaching will lighten the canine tooth to closer match the other normal colored teeth. Once these stains or discolorations are removed, some removal is permanent, and some regress over time (1-10 years) requiring retreatment.[5 6]

Tooth bleaching started in the late 1800s, and includes the removal of stains or discolorations from both non-vital teeth (no nerve remaining in the tooth) as well as vital teeth (healthy teeth with a nerve, but either genetically dark, or stained by trauma, fluoride, nicotine, caffeine or tetracycline). The traditional bleaching techniques using hydrogen peroxide externally and internally were well described in dentistry and the dental literature (Dental Cosmos) by first decade of the early 1900s.[7] This process was used in dentistry extensively from 1910 into the 80s for vital teeth, but was expensive and risky for the dentist and the patient. With the article in 1989 on Nightguard Vital Bleaching, tray bleaching became available to dentists and patients, making bleaching safer[8] and more cost effective than traditional in-office techniques.[9] However, as was noted then and is still true now, discolored or stained teeth have a number of other possible causes in addition to those listed above which may indicate treatment considerations

different from bleaching, including restorations (fillings), endodontic therapy (root canals) or extraction.

When considering bleaching as a treatment option, the first most critical issue of safety in bleaching relates to the proper dental diagnosis of the cause of discoloration in order to render the proper treatment, whether bleaching or some other treatment. A proper examination prior to bleaching avoids using bleaching when other treatments, such as endodontic therapy, restorations or surgery are needed.[10] For example, dark teeth could be a result of trauma to the tooth at an early age, and the tooth nerve may eventually die (become necrotic or abscess). It may take 1-20 years before this condition occurs (see photographs in Exhibits). During that time, there may or may not be any other symptoms such as pain, swelling, mobility or gum problems. The only sign that the tooth has abscessed is the darkening color.[11] This is also true for teeth which have begun to dissolve internally or externally (called "resorption"). For reasons unknown to dentistry and often related to trauma, the cells in the tooth change and begin to dissolve away tooth structure. This condition is similar to a "cancer of the tooth", where the offending cells must be removed or they will dissolve the entire tooth, resulting in tooth loss. Again, there are no overt symptoms of pain, swelling or mobility in this situation, but only a gradual change in the color of the tooth or teeth. This is most often discovered when radiographs (x-rays) are taken of the teeth, especially if the dissolution is inside the tooth (see photographs in Exhibits). External resorption may be found clinically when carefully exploring at or beneath the gum tissue, as this process generally occurs on the root of the tooth (see photographs in Exhibits). Bleaching discolored teeth for which the color change is the only indication of pathology will change the color of the tooth while not removing the pathology that is causing the discoloration. This masking of the pathology does not stop the pathology from continuing, and can result in the loss of teeth. This would be similar to putting face makeup over facial skin cancer, and believing that the problem is solved. Additionally, tooth decay (caries)

alone or around restorations (fillings) may cause teeth to appear dark (see photographs in Exhibits). Bleaching will not remove the decay from the teeth, which can progress into the nerve or closer to the bone and require more extensive treatments (root canals, gum surgery, crowns, etc.) which is also more expensive. Extensive treatment may include the loss of the tooth and need for replacement with a bridge, implant or partial denture. A dental examination, complete with a screening radiograph of the anterior teeth and any single dark teeth, is recommended prior to initiating any type of bleaching.[12] After a proper examination, the cause of discoloration is diagnosed. Such diagnoses can only be made by a dentist.

The need for the dental examination was the primary focus of the European position on tooth bleaching.[13] Manufacturers were trying to introduce bleaching products over the counter in Europe. After a careful examination of all the literature on all types of bleaching and safety, the European Scientific Committee on Consumer Products (SCCP) commission issued a position paper in March 2005. The position was as follows:

"The proper use of tooth whitening products containing >0.1 to 6.0% hydrogen peroxide (or equivalent for hydrogen peroxide-releasing substances) is considered safe after consultation with and approval of the consumer's dentist." The SCCP, in January 2008, again recommended that up to 6% H_2O_2 is a safe limit to use for at-home tooth bleaching; however, it did not recommend use of such products without dental consultation.[14] Their recommendation affirmed the safety of low concentrations of hydrogen or carbamide peroxide in professionally-supervised situations, but does not support over-the-counter (OTC) sales. Patients must obtain a proper dental examination and obtain a prescription for bleaching products. Then the maximum allowed material concentration of 6% hydrogen peroxide is equivalent to about 17% carbamide peroxide (10% carbamide peroxide is roughly 3.5% hydrogen peroxide and 6.5% urea).

It has been noted that there are several research papers citing the safety of over-the- counter 5.3% and 6% hydrogen products in the United S tates (primarily Crest White Strips, Proctor and Gamble Co).[15 16] However, all those research clinical trials could not be initiated without fi rst having a proper examination by a dentist. The Human Assurance Committees who regulate clinical research on patients and peer-reviewed journal who publish s uch research require both inclusion and exclusion criteria for the patients in order to be included in the r esearch project and report. In other words, the dentist exam ined the patient to determine if they were a suitable candidate for bleaching. Then they were adm itted to the study in which an over-the-counter product was used. T here are no double-blinded clinical trials (where the evaluator does not know the treatm ent received) in refereed journals about over-the- counter products that do not have the examination and inclusion/exclusion factors. This is part of the reason the European Committee could not support over-the-counter sales. T here is no way to know if improper treatment is being render ed unless the dentist establishes the diagnosis through a proper examination. The American Dental As sociation has also taken this pos ition, since there is no way to determine where mis-treatment has occurred without first obtaining a proper dental examination.[17] There are reports in the literature of OTC issues causing damage to the teeth, and those related to product abuse by the patient or improper pH of the m aterial.[18] However, in spite of the possibil ity for consumers to report incidences of harm to governmental agencies, there is no mechanism to know if a patient has lightened an asym ptomatic abscessed tooth until that patient subsequently visi ts a dentist and receives a radiograph an d examination. It is for these unknown si tuations that caution is advi sed, and all professional groups recommend an examination by a dentist prior to using an over-the-counter product. This recommendation is often cited on the package of OT C products.

The additional concern for non-dentist's assisted chairside bleaching as compared to OTC products selected solely by the c onsumer is that their use of dental chairs, dental lights, and

dental apparel creates the illusion of proper dental care when in fact they do not have the proper training, experience, equipment or resources to provide a proper examination prior to bleaching. The non-dentist bleaching relies on the consumer's ability to self-diagnosis their cause of discoloration, remember where all their fillings are located, and recall any significant trauma or root canals. Often the consumer does not remember which teeth have received restorations (fillings, crowns or root canals), so the esthetic outcome of bleaching may actually be worse than the initial state, due to mismatched teeth or yellow-appearing restorations (see photographs in Exhibits). If all the teeth which initially are the same color are bleached the same way, and one tooth in the smile has either a root canal or no nerve, then it often will not bleach as light as the normal teeth. After bleaching, the consumer will have several lighter teeth, but one dark one, which may be less desirable than all the teeth matching one another in a normal smile. If they then visit the dentist, the treatment to match the single dark tooth may be very expensive or impossible to perform. The non-dentist bleaching store seems to be in business for financial gain at the expense of the patient's safety, using the consumer's desire for a beautiful smile and lack of ability to know concerns and contraindications. The non-dental bleaching stores do not seem to exist to provide the best treatment for the patient's conditions and smile, which they are unable to diagnosis. Also, because the bleaching products are not regulated, the consumer (nor often the non-dentist provider) does not have any way to know the composition, the pH, or the total ingredients contained in the product. Products available to dentists have had extensive research, often subject to ADA guidelines for both safety and efficacy. In addition to the reports in the literature of OTC products causing harm to teeth, related to a low pH which etched and dissolved the enamel, there are also concerns about allergies or ingredients such as gluten which may trigger reactions in unsuspecting consumers. With no research or regulations on these products and businesses, there is no safety assurance to the consumer. Additionally, the non-dentist provider is not trained or equipped in emergency procedures for situations from choking to anaphylactic reactions to the ingredients, yet their appearance of similarity to a

dentist would create the illusion of safety, training, and protection. They create the illusion that the consumer is receiving a proper dental examination, and the consumer may not appreciate all that is involved in the dental office when an examination is performed. There are no reports in the literature of any studies of non-dentist bleaching being safe, only those where there was harm, such as the chlorine dioxide bleaching performed on cruise ships and spas as reported in England.[19] There is one report in the literature of a paint-on OTC product etching the tooth, and that product has since been removed from the market by the company.

In order to understand the dental concerns, it is helpful to review the contents of the bleaching examination performed by the dentist.[20] The typical dental examination for bleaching would begin with a health and dental history, including the patient's perception of the cause of discoloration, as well as allergies to bleaching ingredients, or sensitivity issues with their teeth. The exam would include an extra-oral examination of the head and neck, and an intra-oral of the hard and soft tissues of the mouth. This exam would exclude problems such as oral cancer (which might be mistaken for gingival irritation during bleaching), abscessed teeth, periodontal disease and other dental conditions. The occlusion (bite) would be evaluated for para-functional habits like bruxism (grinding of the teeth), or TMJ (jaw joint) problems which may be aggravated by a particular bleaching treatment. If a full mouth series of radiographs are not available or indicated, at least a screening periapical radiograph (x-ray) of the anterior teeth and any dark teeth would be taken to evaluate for abscessed teeth or resorption (internal or external dissolving of the tooth), as well as determine pulp size (height into the tooth of the nerve), presence of calcific metamorphosis (nerve filled in by secondary dentin due to trauma so the tooth becomes dark, with or without an abscess) and root status (exposure of the root may increase sensitivity, but no bleaching technique will significantly change the color of the root) (see photographs in Exhibits). Sensitivity of the teeth would be ascertained from the history and from the dental examination using tactile contact of an explorer or air spray of compressed air.

Since none of the person's restorations would change color from bleaching, the examination would identify all restorations (fillings or crowns) in the esthetic zone, that grouping of teeth which are visible in the full smile (see photographs in Exhibits). The examination would also identify those restorations (fillings) on the lingual (tongue-side) or occlusal (biting surface) of the teeth in the esthetic zone. If these restorations are dark, and the tooth becomes more translucent from bleaching, then they may cause those teeth to appear darker than the other teeth. In that case the patient may look less esthetic after bleaching. Occasionally, those restorations must be replaced prior to bleaching (see photographs in Exhibits). If the dentist waits until after bleaching, sometimes the discoloration cannot be removed,[21] and the patient must consider more extensive and expensive treatments again, such as crowns or veneers (see photographs in Exhibits) . The overall analysis would also indentify translucency in the tips of the teeth which may become more noticeable, cracks in the enamel which may be sensitive, exposed root surfaces which will not bleach well, and defects of form or anatomy in the teeth which will not change from bleaching. The lifestyle and habits of the patient, as well as the presence of removable or fixed appliances will also be considered. Photographs are generally taken to establish the baseline for treatment success and longevity.

The following information may clarify my perspective and position on the safety and simplicity of bleaching only after a dental examination. Because of all these factors involved in a proper examination and diagnosis, if a friend, relative or acquaintance were to contact me by phone or email and ask if they should bleach their teeth, I have never been able to suggest they do so without a proper examination. While the unsuspecting consumer may see this as a non-critical issue, I have taught bleaching for the last twenty years in two different dental schools as a regular part of the dental curriculum. In fact, bleaching is in the dental curriculum in most all of the dental schools in the country as part of training to be a dentist. [22] In their early years of training, it is still very difficult for a junior dental student who has been studying teeth for two

years to discern all the clinical details needed to insure that their patient was a good candidate for bleaching. At the Medical College of Georgia, it is recognized that having a student provide bleaching services to another student without the supervision of a faculty dentist, whether making an impression of the teeth, or delivering a bleaching tray, constitutes the practice of dentistry and is an honor code violation which may involve dismissal from dental school. I have also had incidences when dentists have asked me or colleagues about bleaching their own teeth. Upon examination and radiographs, some of them have required root canals and gum surgery because they were unable to examine and diagnosis their own situation in their mouth (see photographs in Exhibits). If a dentist is unable to diagnosis their own condition without a proper examination by another dentist, and a dental student cannot easily diagnosis their patient's condition due to their lack of experience and expertise, there is no way a non-dentist or consumer can predictably determine if bleaching is indicated without a proper dental examination.

Once a complete dental examination is performed, then the diagnosis of the cause of the discoloration and the appropriate treatment (s) are recommended. Treatment for pathological conditions identified are obviously different from or addition to bleaching. These other treatments may include a root canal followed by a post and core to hold a crown in place or bleaching , the removal of decay and placement of a filling with or without additional bleaching treatment, the replacement of a discolored restoration (filling, veneer or crown), or no treatment due to the danger of replacing a restoration. An example of this no-treatment would be an anterior tooth which has received a crown due to a cracked tooth, possibly with root canal treatment and the root end of the tooth receiving a filling (apicoectomy). Removal of a crown for the sake of color change alone may jeopardize the stable status of the tooth resulting in the crack or root canal failing, causing loss of the tooth. Even teeth which have had root canals and have a silver point filling inside may be contraindicated for bleaching without redoing the root

canal, which can be very expensive and risky for the patient. If bleaching is determined to be indicated, the dental team will select the appropriate technique, the appropriate material, concentration, and the type delivery system to best serve the patient's needs and wants. Some patients may prefer tray or strip application of bleaching materials at night or during the day, which others may prefer in-office treatment with higher concentrations of peroxide. Another option is a combination of in-office following by at-home bleaching.[23] Within the bleaching options, the length of treatment and expected outcome will depend on the diagnosis of the etiology of the discoloration. While bleaching does remove external and internal stains from teeth, it also changes the genetic color of the teeth. Discoloration then could be an inherited trait (the patient had mismatched teeth or genetically more yellow teeth), or be due to aging, associated with extrinsic staining from diet or smoking, or related to intrinsic staining from tetracycline ingestion or other drug ingestion. These bleaching treatments may include tray wear at night, tray wear during the day, in-office bleaching, strip application of materials or some combination of these options.

The dental team can determine which process is most appropriate for the patient, whether in-office, or at-home bleaching, or some combination of the two. They will also determine whether a hydrogen or carbamide peroxide material is more appropriate, and the number of visits or length of wear the patient should expect. These factors affect the financial costs for the patient, and may influence treatment decisions. Determination of the patient's desires and expectations for a successful treatment allow the dental team to counsel the patient as to whether bleaching of any type can meet their desires, or whether bleaching will need to be combined with other treatments for the best smile outcomes or due to other issues identified in the complete examination. These issues often include blue-gray tetracycline stained teeth, dark gingival areas of the teeth; extensive white spots in addition to the sensitivity, TMJ jaw joint) dysfunction, translucent teeth and exposed root surfaces as previously described. The examination also

includes the esthetic potential for the patient, and whether additional restorations would need to be replaced since they do not change color. While sometimes this is merely an additional financial burden for the patient to consider (see photographs in Exhibits), occasionally a dental situation is not advisable to replace the crown or filling, either due to deep previous decay which may require a root canal, or due to a previous crack and root canal that the existing crown is maintaining adequately, but replacement may cause loss of the tooth.

After the examination is completed, and it has been determined that the patient is a good candidate for bleaching, then the appropriate delivery method and material is chosen. Materials from reputable manufacturer with appropriate pH to avoid damage to the teeth and safety of products insure the best outcome. Patients can also be informed of the expected duration of the treatment as well as the expected longevity of the color stability. Plans for re-treatment intervals can be discussed, as well as cost and versatility of retreatment options. If the patient has a history of sensitive teeth, or experiences sensitivity during bleaching treatment, the appropriate pre-treatment, during treatment and post-treatment measures may be addressed.[24] [25] Pre-treatment issues especially for in-office bleaching may include NSAIDS, fluoride or potassium nitrate administration prior to bleaching with tray and toothpaste models.[26] Treatment issues may include a change in brand or product, change in delivery system, change in duration of treatment, change in interval of treatment or cessation of treatment. Application of medications for treatment during bleaching and the appropriate time intervals are also addressed. Other side effects that occur during treatment must be determined as to whether related to the bleaching process, or coincidental with the treatment. All these issues, as well as the appropriate materials for bleaching and a delivery system, are essential for a safe, comfortable and effective bleaching experience.

There is a misconception that one in-office bleaching treatment, with or without the light, will replace the more extended time of at home bleaching. Research has shown that one in-office bleaching will only be successful in 24% of the patients, and those are patients with light teeth (A2, which is the normal color of the dentin of teeth).[27] The range of in-office treatments required can be from 1 to 6, with each treatment requiring additional financial investment.[28] Hence the concept of "quicker" treatment by in-office is not totally true. There is less time at the one appointment, but the cost is greater and the average number of visits is three.[29] Often patients are excited about the immediate whitening they see upon completion of the in-office bleaching. However, a large part of this whitening is due to the dehydration or drying-out of the tooth during the procedure.[30] Research has shown that you must wait at least two weeks and sometimes as much as six to see the actual color change accomplished by in-office bleaching. And this is with the highest concentrations of hydrogen per oxide available to the dentist, not the lower ones used in the non-dentist chairside bleaching treatment centers. This means a consumer may be excited when they leave a non-dental center due to the dehydration effect of the procedure, but in a matter of days, they will have lost the color shift and the financial investment is lost as well. There is also a lot of marketing using light-activated in-office bleaching. With in-office bleaching, research has shown the light does not change the final outcome.[31] [32]The light is used as a motivational tool to encourage patient to continue the process after seeing the immediate results of dehydration from the heat and drying effects of the light. This phenomenon is similar to that seen in a skull you might see at Halloween. The skulls never have dark teeth because human teeth dehydrate when removed from the body fluids. Isolation techniques for fillings and for bleaching have both demonstrated the color change from dehydration[33], so color matches must occur prior to this dehydration, or wait days or weeks to see if the outcome was correct.[34] [35]Hence, the average number of in-office visits for maximum whitening is three with a range of 1-6, so the patient needs to be prepared for additional in-office treatments or combining at home delivery to complete the process. If a consumer leaves a non-dentist chairside treatment center

with the idea their teeth will remain that white dehydrated appearance, they will be very disappointed in a matter of days. Since this is true for dental in-office bleaching with higher concentrations of peroxide, it is even more true if lesser concentrations of peroxide are used in the same manner by the non-dentist.

The safety of the actual bleaching products provided by the dentist has been addressed since the beginning of tray bleaching[36], both from biological safety[37 38 39]as well as clinical safety[40 41 42 43]. After a proper dental examination has determined that bleaching is indicated, then if the proper dental material is used and in the appropriate manner[44], bleaching is very safe. There is no data, nor ADA regulations to control non-dentist chairside bleaching products, and no research to demonstrate either safety or efficacy. All research on OTC products was initiated by a dental examination.

Sensitivity is also a problem with bleaching of any type, and more so with in-office bleaching than with take home materials.[45] While typical tooth sensitivity is often related to the Brännström's theory of hydrodynamic theory of fluid flow, the sensitivity associated with bleaching seems to have a different origin.[46] In the Brännström's hydrodynamic theory, open dentinal tubules are needed to generate a fluid flow[47]. In bleaching situations, the teeth may be in excellent condition, with no open tubules, no cracks , no exposed dentin, or deep restorations, but after a few days of bleaching, the tooth may experience severe sensitivity. This sensitivity seems to be related to the easy passage of hydrogen peroxide and urea through the intact enamel, through the dentin in the interstitial spaces into the pulp within 5 to 15 minutes. In effect, the tooth is a semi-permeable membrane that is quite open to the easy passage of certain-sized molecules. Once it is understood how easily the peroxide penetrates the tooth, the resultant pulpal response of sensitivity may be considered a reversible pulpitis. Tooth sensitivity is the main side effect of bleaching, and may be caused primarily by the peroxide penetration to

the pulp well as temperature rise in the pulp (nerve) from heat or light.[48] The bleaching provider has to be prepared to treat sensitivity that may occur up to 8 hours after the initial bleaching treatment. [49] Sensitivity may be related to higher concentrations of peroxide as well as the inherit sensitivity of the patient.[50] This painful situation requires an additional training need for the bleaching provider which is not addressed by the non-dentist bleaching center. A toothache also requires the ability to distinguish between tooth sensitivity related to bleaching, and tooth sensitivity related to other dental causes, such as tooth decay, improper brushing, periodontal disease (gum problems), and abscessed teeth.[51] The non-dental treatment center does not have the training, expertise, resources and equipment to address such issues and occurrences.

Summary:

Bleaching or whitening is best performed in a professionally-supervised manner, with a proper examination and diagnosis performed by a dentist, using appropriate materials for the patient and situation, with a fair fee for service. Low concentrations of peroxide, often in a custom-fitted tray, provide the safest, most cost-effective whitening treatment available for the largest number of different clinical situations[52]. Other bleaching treatments, such as in-office bleaching by the dentist, may be indicated based on patient preference, lifestyle, finances, or other limitations, but require informed consent after presenting cost/benefit and risk/benefit ratio[53]. There is always a certain amount of risk for the patient[54] [55] [56]which must be adequately determiner prior to the bleaching process. Bleaching should not be performed without a proper dental examination by the dentist. Non-dentist chairside bleaching has less potential for color improvement for the cost, with greater chance for risk to the consumer from improper treatment and masking of conditions that need proper dental care.

Respectively submitted,

Dr. Van B. Haywood

Van B. Haywood D.M.D.

EXHIBITS:

Clinical photographs of various pati ent situations involving bleaching indications and cautions, with text explanations and summary points.

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[1] Haywood VB, Caughman WF, Goldstein RE. Chapter 16: Stains and Discolorations in Esthetics in Dentistry 2nd Edition, RE Goldstein, Editor, VB Haywood, Associate Editor, BC Decker. 2002

[2] Cooper JS, Bokmeyer TJ, Bowles WH. Penetration of the pulp chamber by carbamide peroxide bleaching agents. J Endod. 1992; 18:315-317.

[3] Haywood VB. Tooth Whitening: Indications and outcomes of Nightguard Vital Bleaching. Hanover Park, Il: Quintessence Publishing Company Inc; 2007.

[4] McCaslin AJ, Haywood VB, Potter BJ, Dickinson GL, Russell CM. Assessing Dentin Color Changes from Nightguard Vital Bleaching. JADA 1999;130:1485-1490.

[5] Haywood VB. Considerations for Vital Nightguard Tooth Bleaching with 10% Carbamide Peroxide after nearly 20 Years of Proven Use. Inside Dentistry 2006; Sept: 2-5.

[6] Goldstein RE. Esthetics in Dentistry 2nd Edition, RE Goldstein, Editor, VB Haywood, Associate Editor, BC Decker. 2002.

[7] Haywood VB. History, safety and effectiveness of current bleaching techniques: applications of the Nightguard Vital Bleaching technique. Quintessence International, 1992;23:471-488.

[8] Haywood VB, Heymann HO: Nightguard Vital Bleaching: How Safe Is It? Quintessence Int 1991;22:515-523.

[9] Haywood VB, Heymann HO. Nightguard Vital Bleaching. Quintessence Int 20: 173-176, 1989.

[10] Haywood VB. The "Bottom Line" on Bleaching 2008. Inside Dentistry 2008; 4(2): 82-89.

[11] Haywood VB, DiAngelis AJ. Bleaching the Single Dark Tooth. Inside Dentistry 2010;6(8):42-52.

[12] Haywood VB, Berry TG. Chapter 15: Bleaching Teeth. In Fundamentals of Operative Dentistry: A Contemporary Approach. 3rd Edition. JB Summitt, JW Robbins, TJ Hilton, RS Schwartz, editors. Quintessence Books 2006.

[13] Scientific Committee on Consumer Products (SCCP), European Commission. Opinion on Hydrogen Peroxide in Tooth Whitening Products. Adopted 15 March 2005 (SCCP/0844/04). Available at: http://ec.europa.ed/health/index_en.htm.

[14] Scientific Committee on Consumer Products (European Commission). Opinion on hydrogen peroxide, in its free form or when released, in oral hygiene products and tooth whitening products. SCCP/1129/07, December 18, 2007.

[15] Gerlach RW, Sagel PA. Vital bleaching with a thin peroxide gel: The safety and efficacy of a professional-strength hydrogen peroxide whitening strip. J Am Dent Assoc. 2004; 135(1):98-100.

[16] Gerlach RW, Zhou X. Comparative clinical efficacy of two professional bleaching systems. Compend Contin Educ Dent 2002; 23: 35-41.

[17] American Dental Association Council on Scientific Affairs. Statement on the effectiveness of tooth whitening products. February 2008. Retrieved from http://www.ada.org/1902.aspx

[18] Cubbon T, Ore D. Hard tissue and home tooth whiteners. CDS Review 1991;June:32-35.

[19] Greenwall L. The dangers of chlorine dioxide tooth bleaching. Aesthetic Dentistry Today 2008; 2:20-22.

[20] Haywood, VB. Update on Bleaching: An Examination for Nightguard Vital Bleaching. Esthetic Dent Update 1995;6(2):51-52.

[21] Haywood VB. Greening of the Tooth-Amalgam Interface during Extended 10% Carbamide Peroxide Bleaching of Tetracycline-Stained Teeth: A Case Report. J Esthet Restor Dent 2002;14:12-17.

[22] Frazier KB, Haywood VB. Teaching Nightguard Bleaching and Other Toothwhitening procedures in North American Dental Schools. Journal of Dental Education 2000;64(5):357-364.

[23] Matis BA, Cochran MA, Wang G, Eckert GJ. A clinical evaluation of two in-office bleaching regimens with and without tray bleaching. Oper Dent 2009; 34:142-9.

[24] Haywood VB, Caughman WF, Frazier KB, Myers ML. Tray delivery of Potassium nitrate-fluoride to reduce bleaching sensitivity. Quintessence Int 2001;32:105-9.

[25] Haywood VB, Cordero F, Wright K, et al. Brushing with potassium nitrate dentifrice to reduce bleaching sensitivity. J Clin Dent 2005; 16(1):17-22.

[26] Charakorn P, Cabanilla LL, Wagner WC, Poong WC, Shaheen J, Pregitzer R, Schneider D. The effect of preoperative ibuprofen on tooth sensitivity caused by in-office bleaching. Oper Dent 2009; 34:131-135.

[27] Gottardi MS, Brackett MG, Haywood VB. Number of in-office light-activated bleaching treatments needed to achieve patient satisfaction. Quintessence International, 2006; 37(2):115-120.

[28] Blankenau R, Goldstein RE, Haywood VB. The Current Status of Vital Tooth Whitening Techniques. Compendium 1999;20(8):781-796.

[29] Auschill TM, Hellwig E, Schmidale S, Sculean A, Arweiler NB. Efficacy, side-effects and patients' acceptance of different bleaching techniques (OTC, in-office, at-home). Oper Dent 2005; 30:156-63.

[30] Hein DK, Ploeger BJ, Hartup JK, Wagstaff RS, Palmer TM, Hansen LD. In-office Vital Tooth Bleaching-What do Lights Add? Compendium 2003;24(4A):340-352.

[31] Haywood VB. In-Office Bleaching: Lights, Applications, and Outcomes. Current Practice 2009; 16(4):3-6.

[32] Marson FC, Sensi LG, Vieira LCC, Araújo E. Clinical evaluation of in-office dental bleaching treatments with and without the use of lightactivation sources. Oper Dent 2008;33:15–22.

[33] Russell MD, Gulfraz , Moss. In vivo measurement of colour changes in natural teeth. J Oral Rehab 2000; 27: 786-792.

[34] Kugel G, Papathanasiou A, Williams AJ 3rd, Anderson C, Ferreira S. Clinical evaluation of chemical and light-activated tooth whitening systems. Compend Contin Educ Dent 2006;27:54-62.

[35] Matis BA, Cochran MA, Franco M, et al. Eight inoffice tooth whitening systems evaluated in vivo: a pilot study. Oper Dent 2007;32:322–7.

[36] American Dental Association. Guidelines for the acceptance of peroxide-containing oral hygiene products. J Am Dent Assoc 1994; 125:1140-1142.

[37] Li Y. Biological properties of peroxide-containing tooth whiteners. Food and Chem Toxicology 1996; 34:887-904.

[38] Munro IC, Williams GA, Heymann HO, Kroes R. Use of hydrogen peroxide-based tooth whitening products and the relationship to oral cancer. J Esthet and Rest Dent 2006; 18:119-125.

[39] Dahl JE, Pallesen U. Tooth bleaching-a critical review of the biological aspects. Crit Rev Oral Biol Med 2003;14:292-304.

[40] Ritter AV, Leonard RH, St. Georges AJ, Caplan DJ, Haywood VB. Safety and stability of Nightguard Vital Bleaching: 9-12 years post-treatment. J Esthet Restor Dent 2002; 14275-285.

[41] Browning WD, Swift EJ. Critical appraisal: comparison of the effectiveness and safety of carbamide peroxide whitening agents at different concentrations. J Esthet Restor Dent. 2007;19(5):289-296.

[42] Leonard RH Jr, Bentley C, Eable JC, Garland GE, Knight MC, Phillips C. Nightguard Vital Bleaching: a long-term study on efficacy, shade retention, side effects, and patients' perceptions. J Esthet Restor Dent 2001; 13:357-369.

[43] Matis BA, Mousa HN, Cochran MA, Eckert GJ. Clinical evaluation of bleaching agents of different concentrations. Quintessence Int 2000; 31: 303-310.

[44] Matis BA, Cochran MA, Eckert GJ. Review of the effectiveness of various tooth whitening systems. Oper Dent 2009;34:230–5.

[45] Christensen GJ. Bleaching teeth: which way is best? J Esthet Dent. 2003;15(3):137-140.

[46] Haywood VB. Treating Sensitivity during Tooth Whitening. Compendium 2006;26(9):11-20

[47] Pashley DH, Tay FR, Haywood VB, Collins MA, Drisko CL. Consensus-based recommendations for the diagnosis and management of dentin hypersensitivity. Comp Contin Edu Dent (Spec Iss) 29(8): 1-35, 2008.

[48] Baik JW, Rueggeberg FA, Liewehr FR. Effect of light-enhanced bleaching on in vitro surface and intrapulpal temperature rise. J Esthet Restor Dent 2001; 13:370-8.

[49] Browning WD, Blalock JS, Frazier KB, et al. Duration and timing of sensitivity related to bleaching. J Esthet Restor Dent. 2007;19(5): 256-264.

[50] Haywood VB. Frequently asked questions about bleaching. Compend Cont Educ Dent. 2003;24(4A):324-338.

[51] Haywood VB. Dentine hypersensitivity: bleaching and restorative considerations for successful management. Int Dent J 2002,52(5) supp1:376-384.

[52] Li, Y, et al. Comparison of Clinical Efficacy and Safety of Three Professional at-Home tooth Whitening Systems. Compendium 2003

[53] Zekonis R, Matis BA, Cochran MA, et al. Clinical evaluation of in-office and at-home bleaching treatments. Oper Dent. 2003; 28(2):114-121.

[54] Attin T, Hannig C, Wiegand A, Attin R. Effect of bleaching on restorative materials and restorations—a systematic review. Dent Mater 2004. 20:852-61.

[55] Dahl JE, Pallesen U. Tooth bleaching-a critical review of the biological aspects. Crit Rev Oral Biol Med 2003;14:292-304.

[56] Goldberg M, Grootveld M, Lynch E. Undesirable and adverse effects of tooth-whitening products: a review. Clin Oral Invest 2010;14:1-10.

APPENDIX I

Revision Date: April15, 2010

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Sex	Male
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Marital Status	Married
Spouse	Lillie Angelyn Berry (Angie)
Date of Marriage	December 27, 1978
Children	Lisa Angelyn 8-17-80
	David Wesley 7-5-82
	Michael Christopher 2-11-86

EDUCATION

Institution and Location	Degree	Date Conferred	Degree Major
Dublin High School Dublin, GA	Diploma	1962-67	College Preparatory
University of Georgia Athens, GA	B.S.	1967-71	Mathematics
School of Dentistry Medical College of Georgia Augusta, GA	D.M.D.	1971-74	Dentistry

STATE LICENSE

1974	Georgia Dental License, #8274
1975	North Carolina, #4002
2006	South Carolina #4186

PROFESSIONAL

Academic Appointments

1974-1976	Instructor; Department of Operative Dentistry, School of Dentistry, University of North Carolina Chapel Hill, NC
1978-1983	Assistant Professor (20% time), Restorative Department, School of Dentistry, Medical College of Georgia, Augusta, GA
1983-1990	Assistant Professor; Department of Fixed Prosthodontics (became Department of Prosthodontics effective July 1, 1988), School of Dentistry, University of North Carolina, Chapel Hill, NC
1990-1992	Associate Professor; Department of Prosthodontics, School of Dentistry, University of North Carolina, Chapel Hill, NC
1992-1993	Associate Professor; Department of Operative Dentistry, School of Dentistry, University of North Carolina, Chapel Hill, NC
1993-1998	Associate Professor, Department of Oral Rehabilitation, School of Dentistry, Medical College of Georgia, Augusta, GA
1998-present	Professor, Department of Oral Rehabilitation, School of Dentistry, Medical College of Georgia, Augusta, GA
2004	Professorship confirmed: Post-tenure Review
2009	Professorship confirmed: Post-tenure Review

Administrative Responsibilities/Appointments

Major Teaching Administrative Responsibilities

University of North Carolina:

1975, 1976	Course Director, Elective course: "Direct Gold"
1984-1990	Course Director, Elective Course: "Fixed Prosthodontics in Private Practice", Fall &/or Spring Semesters, Junior/Senior Students
1987-1990	Course Director, Single Tooth Cast Restorations Course 204
1990-1992	Course Director, Introduction to Occlusion Course
1990-1992	Director of Occlusion, Prosthodontic Department
1991	Course Director, Occlusion 304: Junior Occlusion course
1991-1993	Instructor of Occlusion; Academy of General Dentistry Mastership Program

Medical College of Georgia:

1994-1995	Course Director, RES 523 Inlays & Onlays, Post & cores, Resin Bonded FPDs
1994-1998	Course Director, RES 514: Introduction to Cast Restorations: Single Gold crown/ FPD
1999-2004	Course Director, RES5002: Introduction of Cast Restorations: Single Gold Crown, Inlays & Onlays, Gold FPD (combined 514-523 courses).
2003-present	Course Director, Occlusion 5002 sophomore didactic/clinical occlusion course
2003-present	Course Director, Occlusion 5901, clinical junior occlusion course (5902, senior to 2006)
2003-present	Director of Occlusion
2004-present	Course Director FIXP 5001: Introduction to Castings:(FIX5001;RES5002 less FPD)
2005-present	Course Director for Continuing Education courses: Goldstein Lecture (May), Hinman/MCG Fellow (August2005-2008), Update for General Practitioners (October 2005-2007), Last Chance CE (December)

Editorial Boards/Reviews/Consultant

1989-present	Reviewer for "Quintessence International Journal", Operative section
1991-1993	Reviewer for "Current Opinion in Dentistry"

1991-1996	Editorial Board for "Esthetic Dental Update"
1993	Reviewer for "Dental Materials"
1993	Consultant to Perfect Smile
1994,2000	Consultant to Block Drug Company on Proxigel, Sensodyne
1994-2007	Consultant to Colgate on Colgate Platinum
1994-2002	Consultant to Discus Dental on NiteWhite/Contrast
1994-present	Reviewer for "Journal of Prosthodontics"
1994-present	Reviewer for "Journal of Dentistry"
1995	Reviewer for "Advances in Dental Research"
1995-1996	Expert witness for Ultradent Products Inc. on bleaching
1996	Reviewer: ADA Product Seal; Council on Scientific Affairs
1996	Consultant to Proctor & Gamble on Bleaching systems, OH
1997-present	Reviewer for "Journal of the American Dental Association"
1997-2006	Editorial Board for "Contemporary Esthetics and Restorative Practice"
1998-2010	Editorial Board for "Journal of Esthetic and Restorative Dentistry"
1999-2010	Reviewer for "Journal of Operative Dentistry"
1999-2010	Editorial Board for "Journal of Operative Dentistry"
2000-present	Editorial Advisory Board for "Independent Dentistry: Restorative & Aesthetic Practice"
2000	Consultant to Proctor and Gamble on Crest WhiteStrips
2000	Expert witness for Colgate Oral Pharmaceuticals in Iowa court case
2000	Expert witness for American Dental Association in Iowa court case
2000	Consultant to American Dental Association on bleaching guidelines
2001-2004	Editorial Board "Dental Traumatology"
2002	Consultant to Colgate Oral Pharmaceuticals on OTC Simply White bleaching
2002	Consultant to American Dental Association on OTC bleaching guidelines
2002	Consultant to ArchTek, Inc on bleaching and bruxism tray design
2003	Consultant to American Dental Association on bleaching guidelines (P&G)
2003-2010	Consultant to GlaxoSmithKline on bleaching products and study protocol for sensitivity
2003	Reviewer "International Dental Journal"
2003-2010	Commentary Reviewer, "Journal of Esthetic and Restorative Dentistry"
2004	Outside Expert Reviewer "Journal of Prosthetic Dentistry"
2004	Reviewer "Clinical Oral Investigations"
2004	Consultant to GlaxoSmithKline, England Headquarters
2005-2008	Associate Editor: "Journal of the American Dental Association", Esthetics Section
2005-2007	Reviewer, "Odontology", Japan
2005-present	Editorial Board "Inside Dentistry"
2008-present	Consultant to ADA Council on Scientific Affairs

Major Committees

Medical College of Georgia:

1994-1998	Continuing Education Committee
1994-1997	Georgia Dental Association Continuing Education Committee
1994-1999	Advisory Board to Holiday Dental Conference, Charlotte, NC
1995-1999	MCG representative, "University Conference on Cosmetic Dentistry" committee of American Academy of Cosmetic Dentistry (sub-committee on faculty-student-AACD interactions)
1995-1997	MCG Accreditation Committee Self-Study #3
1995-2004	Membership Committee Chairman, OKU
1995-2001	Alumni Liaison Committee, Chair 1999-2001
1995-1997	Scientific Sessions Committee of Academy of Operative Dentistry
2000-2006	Faculty Development Committee; Dental School
2001	Curriculum Committee; Dental School
2001-2004	Academic Research and Computer Advisory Board, MCG campus committee; dental representative
2002-2004	Continuing Education Committee (reappointed from 1998)

2002-2004	Annual Meeting Clinic Committee of American Academy of Restorative Dentistry
2003-2005	MCG Faculty Grievance Committee
2005-present	MCG Director of Dental Continuing Education
2005-present	Chair: Dental Continuing Education Committee, MCG Dental School
2008-present	Instructional Technical Advisory Committee, MCG campus; SOD representative
2010-present	Educational Strategic Plan MCG SOD

University of North Carolina:

1975-1976	Ad Hoc Committee on Promotions and Tenure
1975-1976	Admissions Committee, D.D.S. Students
1985-1991	Admissions Committee, D.D.S. Students
1983-1987	Instrument Committee, Fixed Prosthodontics Representative
1984	Career Conference for Dental Students Committee; Notebook Editor
1984-1985	Search Committee, Dental Ecology Chairperson
1984-1986	Interdisciplinary Committee on Occlusion, Fixed Prosthodontics Representative
1984-1987	Dental Assisting Academic Performance Committee
1986-1988	Admissions Committee, Dental Hygiene
1986-1987	Chairman: Career Conference for Dental Students Committee
1987-1990	Second Year Teaching Committee - Castings Course Director
1988-1989	Task Force Committee to review TMJ-Facial Pain offerings in D.D.S. curriculum
1988-1991	Faculty Fellows Program Representative to undergraduate UNC campus
1990-1992	First Year Teaching Committee - Introduction to Occlusion 117, Course Director
1989-1992	Infection Control Committee; Dental Faculty Representative
1991-1992	Nominations and Elections Committee, UNC Dental School
1991-1992	Third Year Teaching Committee: Occlusion 304, Course Director
1992	Infection Control Committee representative to Dental Faculty Practice Infection Committee
1992-1993	Hazards Communication Committee

Research and Training Grants

1984 Biomedical Research Support Grant; NIH Grant #RR05333, $1270.00 Tensile Bond Strengths of Dentin Bonding Adhesives to Etched Metal.

1986 Junior Faculty Achievement Award, $3000.00. Etched Porcelain Veneers: Bond strengths, marginal adaptation, polishability.

1987 Small Research Grant Award, NIH Grant 2-S07-RR05333, $1579.40. A Quantitative Analysis of the Surface Roughness of Etched Dental Alloy.

1987 Brasseler Research Grant, $2000.00. Experimental Instrumentation for Polishing Porcelain Intraorally.

1989 Educational Grant from Marion Laboratories, $10,000.00: Haywood, V.B. Nightguard Vital Bleaching Research.

1989 Education Grant from Marion Laboratories to Austin College, Sherman Texas, $2000.00: Woolverton C, Haywood VB. Animal toxicity studies on vital bleaching solutions.

1990 BRSG grant, UNC, $3991.00. "Microhardness of teeth and materials exposed to bleaching solution". McCracken, M., Haywood, V.B.

1991 Educational grant from Block Drug Company for travel to present at IADR in Mexico, $1500.00.

1992 Educational grant from Ultradent Dental Products, $12,000.00: Haywood, VB for bleaching research, UNC.

1994 Educational grant from Colgate Oral Pharmaceuticals, $5000.00: Haywood VB for bleaching research, MCG.

1994 Educational grant from Discus Dental, $3000.00 Haywood VB, MCG.

1994 Clinical Evaluation of Opalescence Tooth Whitening System. $62,792.95 Ultradent Products Inc., MCG (P.I.: Dr. Gene Dickinson).

1995 Educational donation to MCG Department of Oral Rehabilitation for computer upgrades from Colgate, $5000.00.

1995 Educational donation to MCG Department of Oral Rehabilitation for computer upgrades from Ultradent Products Inc. , $4500.00.
1995 Educational pilot grant from Colgate on tetracycline-stained teeth, $1000.00.
1995 "Discoloration Protection for Provisional Restorations during NGVB with 10% Carbamide Peroxide". Research Grant from American Academy of Cosmetic Dentistry for student research, $2000.00.
1995 "NCRR Minority Initiative" grant #1-R25-RR10826. $126,038.00 NIH, National Center for Research Resources, MCG (P.I.: Dr. Tom Dirkson).
1996 "Preliminary Study to determine the Efficacy of a Fluoride-KNO3 gel to reduce tooth sensitivity," $30,392.00. Colgate Oral Pharmaceuticals; MCG.
1998 Renewal of 1996 Colgate Grant., $15,000.00.
2000 Ultradent Products patient care support: $5000.00
2000 Ultradent Products patient care support: $2000.00
2001 Final award to 1996 Colgate Grant, $5000.00
2001 Ultradent Products patient care support: $2000.00
2001 ArchTek patient care support: $2500.00
2003 Colgate Oral Pharmaceuticals $5684.00 patient care support final
2003 Educational donation from Colgate Oral Pharmaceuticals to Oral Rehabilitation Dept. $25,000.00
2004 Ultradent Products patient care support $2000.00
2007 Quintessence International patient care support $3000.00
2007 "A feasibility study to determine bacterial reductions in mature dental plaque following application of 10% carbamide peroxide gel". GlaxoSmithKline $35,830.00 (Dr. Bill Browning, PI) Consultant
2009 Ultradent Products patient care support: $1000.00
2010 Ultradent Products patient care support $1000.00

AWARDS/HONORS

1968 Phi Eta Sigma, Honorary Mathematics, Scholastic Achievement, UGA
1969-1971 Pi Mu Epsilon: Honorary Mathematics Scholastic Achievement, UGA
1973 Eisenberg Scholarship Award, MCG
1974 Oral Medicine Award, MCG
1974 Omicron Kappa Upsilon, MCG
1981 Boss of the Year, CSRA Dental Hygiene Association
1986 Convocation Speaker, Dental Assisting Program, UNC
1987 Student Appreciation Award from Sophomore Dental Class, UNC School of Dentistry
1988 Student Appreciation Award from Junior Dental Class, UNC School of Dentistry
1989 Student Appreciation Award from Junior Dental Class, UNC School of Dentistry
1989 Richard F. Hunt Memorial Award for Teaching Excellence in the Dental School, UNC School of Dentistry
1990 Student Appreciation Award from Sophomore Dental Class, UNC School of Dentistry
1991 Student Appreciation Award from Sophomore Dental Class, UNC School of Dentistry
1991 Class of 1958 Award for single research paper with the most clinic impact, UNC School of Dentistry
1995 Distinguished Alumnus Award from MCG School of Dentistry Alumni Association
1996 Reviewer: ADA Product Seal; Council on Scientific Affairs.
1998 Promotion to Professor with tenure
1999-present Elected "Fellow, American College of Dentists"
2000 Listed in "Guide to America's Top Dentists"
2001 Listed in "Leaders in Continuing Education", Dental Products Report Feb 2001
2002 Listed in "Leaders in Continuing Education", Dental Products Report Feb 2002
2003 Listed in "Guide to America's Top Dentists"
2003 Listed in "Leaders in Continuing Education", Dental Products Report Dec 2003
2003 Awarded patent for disposable cheek retractors
2003 Moderator for International Color Symposium held at MCG Dental School

2004	Listed in "Leaders in Continuing Education", Dental Products Report Dec 2004
2004	"Masters of Esthetic Dentistry" Award. Journal of Esthetic and Restorative Dentistry
2004-present	Elected "Fellow, International College of Dentists"
2005	Listed in "Leaders in Continuing Education", Dental Products Report Dec 2005
2006-present	Elected to Hinman Dental Society, Associate Member, Atlanta, GA
2006	Listed in "Leaders in Continuing Education", Dental Products Report Dec 2006
2007	Listed in "Leaders in Continuing Education", Dental Products Report Dec 2007 (7^{th} year)
2008	Listed in "Leaders in Continuing Education", Dental Products Report Dec 2008
2009	Listed in "Leaders in Continuing Education", Dental Products Report Dec 2009 (9^{th} year)
2009	Hinman Special Lecturer, Thomas P. Hinman Medallion recipient
2009	Lifetime membership British Dental Bleaching Society, London England

PRIVATE DENTAL PRACTICE

1975-1976	Intramural Dental Faculty Practice, Operative Dentistry, School of Dentistry, University of North Carolina, Chapel Hill, NC (20%)
1976-1983	Private Practice of General Dentistry; Solo Practice: 183l Central Avenue, Augusta, GA
1976-1978	Gracewood State Hospital Dental Clinic (l-2 day/week), Augusta, GA
1977-1978	Lawton B. Evans Children's Dental Clinic, Augusta, GA (10%)
1983-1992	Dental Faculty Practice, Department of Fixed Prosthodontics, School of Dentistry, University of North Carolina, Chapel Hill, NC (20%)
1992-1993	Dental Faculty Practice, Department of Operative Dentistry, School of Dentistry, University of North Carolina, Chapel Hill, NC (20%)
1993-present	Faculty Practice, Department of Oral Rehabilitation, School of Dentistry, Medical College of Georgia, Augusta, GA (20% until 2006; 10% 2007; 5% 2009))

SCIENTIFIC AND PROFESSIONAL SOCIETIES (including offices held)

1971-1974	American Student Dental Association, Medical College of Georgia	
	Secretary	1972-1973
	President	1973-1974
	Delegate	1974
1974-1976	Omicron Kappa Upsilon, Upsilon Upsilon Chapter, University of North Carolina	
1983-1993	Omicron Kappa Upsilon, Upsilon Upsilon Chapter, University of North Carolina:	
	Secretary-Treasurer	1985-1987
	Membership Chairman	1988-1990
	Constit & Bylaws Com	1990-1992
	Convocation Com	1991-1992
1976-1983	Omicron Kappa Upsilon, Kappa Lambda Chapter, Medical College of Georgia	
1993-present	Omicron Kappa Upsilon, Kappa Lambda Chapter, Medical College of Georgia	
	Membership Committee Chair: 1995-2004	
	Vice President 2005-2006	
	President 2007-2008	
1974-present	American Dental Association	
1974-present	School of Dentistry Alumni Association, Medical College of Georgia	
	Vice-President	1975-1976
	President	1981-1982
	Chairman 10-year Reunion	1984
	Board of Directors	1994-2001
1974-1976	North Carolina State Dental Society	
1974-1976	Third District Dental Society, North Carolina	
1983-1993	North Carolina State Dental Society	
1983-1993	Third District Dental Society, North Carolina	
	Newsletter Editor	1992-1993

1975-present	Academy of Operative Dentistry Scientific Sessions Committee 1995-1997
1976-1983	Augusta Dental Disaster Group
1976-1983	Augusta Dental Society
1993-present	Augusta Dental Society Advisor/Liaison to CSRA Dental Hygiene Assoc. 1980-1983.
1977-1983	DENTAC Study Club, Fort Gordon, Georgia
1976-1983	Georgia Dental Association
1993-present	Georgia Dental Association Continuing Education Committee 1994-1997 ; Chair 1996-97
1976-1983	Eastern District Dental Association, Georgia Chairman, GDA Disabled Dentist Com, Eastern District 1979-1983 Chairman, Children's Dental Health Week, Eastern Dist. 1980 Committee Member GADPAC Eastern District 1976-1983
1993-present	Eastern District Dental Association, Georgia
1984-present	American Dental Education Association (formerly American Association of Dental Schools)
1987-present	American Association for Dental Research/ International Association for Dental Research
1987-1993	North Carolina Section of the AADR Treasurer: 1992-1993
1991-1993	TMJ Study Club, Durham, NC
1993-present	Georgia Section of the AADR Secretary/Treasurer: 1996-1997 President-elect: 1997 President: 1999
1992-present	United Methodist Volunteer-in-Mission Medical Fellowship
1993-present	American Academy of Restorative Dentistry Clinic Committee 2003-2004
1993-present	Christian Dental Society
1998-2000	Sleep Disorders Dental Society
2003-present	American Academy of Esthetic Dentistry, Associate member
2005-present	Christian Medical Dental Association
2009-present	Charter member of International Toothwhitening Academy

COMMUNITY ACTIVITIES

1985	"Career Opportunities in Dentistry" Health Careers Academic Advancement Program, UNC, Chapel Hill, NC
1987	"The Dental Component of a Middle School Science Program": School of Education, UNC, Chapel Hill, NC
1988	"Career Opportunities in Dentistry" Health Careers Academic Advancement Program, UNC, Chapel Hill, NC
1988	"Private Practice Plans" Panel Discussion, Faculty Moderator, UNC Dental Parents Day, UNC School of Dentistry, Chapel Hill, NC
1989	"Career & Post-Graduate Opportunities" Panel Discussion, Faculty Moderator and Presenter, UNC Dental Parents Day, UNC School of Dentistry, Chapel Hill, NC
1989	"Esthetic Options in Dentistry" Recruitment program to undergraduate UNC students, Chapel Hill, NC
1989-1993	Newsletter Editor, Estes Hill Elementary School, Parents-Teachers Organization, Chapel Hill, NC
1991	"Esthetic Dentistry" Program to undergraduate UNC-CH students interested in dentistry, University of North Carolina, Chapel Hill, NC
1992	United Methodist Volunteer in Mission, Dentist to Santo Domingo, Dominican Republic

1993	"Overview of Restorative Dentistry". Presentation to undergraduate students considering a career in dentistry, University of North Carolina, Chapel Hill, NC
1993	"Oral Rehabilitation Curriculum Content". MCG Family Day, MCG, Augusta, GA
1993-present	Dental Fellowship, Faculty Sponsor, Medical College of Georgia, Augusta, GA (became chapter "MCG Dental Fellowship" of the Christian Medical Dental Association 2005)
1993-2001	United Methodist Youth Fellowship Counselor and Song leader/guitar player, Trinity on the Hill United Methodist Church, Augusta, GA
2001-2006	United Methodist Youth Choir (high school, and middle school) Counselor and Song leader/guitar player, Trinity on the Hill United Methodist Church, Augusta, GA
1995	"Demonstration of new teaching Laboratory", MCG Family Day, Augusta, GA
1995	"Demonstration of new teaching Laboratory", MCG Open House Day, Augusta, GA
1995-present	Adult Sunday School Teacher, Open Door Class, Trinity on the Hill United Methodist Church, Augusta, GA
1995-present	Sanctuary Choir member, 8:45 a.m. service, Trinity on the Hill United Methodist Church, Augusta, GA
1994-1997	Vision 2000 Committee, Trinity on the Hill United Methodist Church, Augusta, GA
1995	MCG Medical Hotline, Augusta Chronicle event, Augusta, GA
1993-present	Television and magazine interviews on bleaching teeth: ABC 20/20, NBC Dateline, American Health Magazine, GQ magazine, Esquire magazine, Forbes, Men's Health, Channel 12 local news, Augusta Chronicle, Columbia County news, Health Facts, NY Times
1996, 1998	Lectures to Fort Gordon Prosthodontic Residents, Fort Gordon, GA
1997-2002	Contemporary Worship Committee and SoulScape Band, Trinity on the Hill United Methodist Church, Augusta, GA
1997	MCG Health Fair, Participant, Augusta Mall, Augusta, GA
1997	Advisee to Ft. Bragg, NC AGD residents
1997	Lecture to University Hospital Dental Group: Oral Appliance Therapy for Snoring and Sleep Apnea, Augusta, GA
1997	Lecture to Veterans Administration Dentists: In-office and Home Bleaching, Augusta, GA
1998	MCG Wives Club: Lecture on Esthetic Dentistry and bleaching, Augusta, GA
1998	Lecture in Fort Gordon "Prosthodontic Short Course" on Bleaching, Augusta, GA
1998	Lecture to University Hospital Dental Group: "Update on Bleaching", Augusta, GA
1999	MCG Health Fair, Participant, Augusta Mall, Augusta, GA
1999	Local nursing home caregivers: Oral care in Nursing homes, Augusta, GA
1999-2000	Board member of Christian Medical Dental Society, Dr. Andy Sanders Regional Director
2000	MCG-Red Cross Health Fair, Participant, Augusta Mall, Augusta, GA
2000	Lecture to University Hospital Dental Group: "Smile Analysis"; Augusta, GA
2001	MCG-Red Cross Health Fair, Participant, Augusta Mall, Augusta, GA
2002	Lecture to Fort Gordon DENTAC meeting, Augusta, GA
2002	MCG-Red Cross Health Fair, Participant, Augusta Mall, Augusta, GA
2003	Dental Volunteer in Mission trip Merida, Mexico , Trinity on the Hill UMC (4/7-11)
2004-2006	Music for "MCG Healing Arts Program" Bluegrass Gospel Band
2004, 2006	Tooth Bleaching Fund Raising Lecture for Gwinett County Dental Society, Atlanta (11/3/04) (1/13/06: Brighter Smiles for Brighter Futures)
2005	Interview Augusta Magazine: How to polish up that Smile, pub Jan 2005
2005	Bleaching lecture to Endodontic residents and Fort Gordon (1/05)
2005	Lecture on Tooth Whitening for Mini-Medical School, MCG
2005	Lecture to Augusta Dental Society: "White Teeth or White Lies" (5/04)
2005-present	Advisory Council of the Christian Medical Dental Association in Augusta, GA; Dr. Andy Sanders Regional Director
2005	Dental Volunteer for Georgia Baptist Dental Van with MCG students in Sandersville, GA
2006	Interview: "Your Health Now
2007	Interview:: "Dr. Bicuspid"
2008-present	Dental Advisory Board for Christian Medical Dental Association, Co-chair national committee

2009 "Bleaching and OTC Concerns". Georgia Dental Association Board of Trustees, Atlanta, GA (1/10)
2009 "Bleaching and Caries Control" Orthodontic Residents MCG, Augusta, GA (6)

2010 Lecture to Augusta Dental Society: "Tray application of bleaching materials for caries control in elderly and orthodontic patients", Augusta, GA
2010-present Lay Leader Trinity on the Hill United Methodist Church
2010 "Bleaching Overview" AEGD & GPR Residents, MCG, Augusta, GA (3)

PRESENTATIONS AT NATIONAL, REGIONAL, AND STATE MEETINGS
(Last Ten Years)

State
1994 "Conservative Restorative Dentistry: From Esthetics and Bleaching to Occlusion and Crowns". Eastern District Dental Society, Athens, GA
1995 "Bleaching of vital and non-vital teeth". Central District Dental Society, Columbia, SC
1995 "Occlusion Principles". Moderator and Speaker for Academy of General Dentistry Mastership Course, 72 hours credit in three sessions, UNC, Chapel Hill, NC
1996 "Participation Course in Esthetic Preparation in the New Teaching Laboratory". Eastern District Dental Society/MCG, Augusta, GA
1996 "Esthetic Options prior to Full Coverage". Georgia Dental Association 129th Annual Meeting, Charleston, SC
1997 "Esthetic Options and Occlusion/Articulators". North Carolina Third District Dental Society Annual Session, Williamsburg, VA
1998 "Nightguard Vital Bleaching". Emory Study Club, Atlanta, GA (8/18)
1999 "Home Bleaching: What to know, what to do, and what to tell patients" Aiken Technical College, Aiken SC. (5/7)
2000 "Overview and current status of bleaching and tooth sensitivity" Block Drug Company, Jersey City, NJ (1/18)
2000 "Update on At-Home bleaching" Georgia Dental Association Meeting, Amelia Island, FL (7/28)
2002 "Bleaching for pediatric dental patients". Scottish Rite Hospital, Atlanta, GA (5/22)
2003 Color Symposium Moderator, Colgate Oral Pharmaceuticals and MCG, Augusta, GA (8/22)
2004 ""Tooth Bleaching Information to make Everyone Smile". Triple-Win Study Club of Seattle Study Clubs, Miami, FL (10/8)
2004 "Tooth Bleaching Information to make Everyone Smile", Fall Symposium, Knoxville, TN (11/3)
2005 "White Teeth or Little White Lies", Greater Columbia Dental Association, Columbia, SC(04/18)
2005 "Bleaching: Before, during and after Orthodontics"; and "Smile Analysis", MCG Orthodontic Alumni Meeting, Augusta, GA (08/19)
2005 "Tooth bleaching information to make Everyone smile", Hinman-Alabama Educational Seminar, University of Alabama at Birmingham, Birmingham, AL (09/22)
2005 "Tooth bleaching and Esthetic information to make Everyone smile", Upstate Seattle Study Club, Greenville, SC (11/11)
2006 "Tooth bleaching information to make Everyone smile", Second District Dental Society Annual Meeting, Montgomery, AL (01/13)
2006 "Tooth bleaching information to make Everyone smile", and "Hands on fabrication of Bleaching Trays" University of Louisville School of Dentistry, Louisville, KY (03/17)
2006 "Tooth bleaching and Esthetic information to make Everyone smile", New Jersey School of Dental Medicine, New Jersey, NJ (04/21)
2006 "Tooth Discoloration and Whitening Options", "Smile Analysis", "Tray fabrication for Bleaching" Northern Kentucky Study Club, Cincinnati, OH (09/15)
2006 "Tooth Discoloration and Whitening Options", "Smile Analysis", "Tray fabrication for Bleaching". University of Kentucky College of Dentistry Alumni Weekend, Lexington, KY. (10/6-7)
2006 "Tooth bleaching information to make Everyone smile", Eames Study Club, Atlanta, GA (11/18)

2007 "Tooth Bleaching and Esthetic Information to make Everyone Smile."and Hands-on Workshop:"Tray fabrication options and Smile Analysis for bleaching". University of Southern Illinois School of Dental Medicine; Central Illinois Academy of General Dentistry, Alton, Il (3/23-24)

2007 "Tooth Bleaching and Esthetic Information to make Everyone Smile."Oral & maxillofacial surgery group. Nashville, TN (4/13)

2008 ""White Teeth or White Lies". Outagamie Dental Society, Appleton, WI (04/18)

2008 "State of the Art Bleaching" South Carolina Dental Association 139th Annual Convention, Myrtle Beach, SC (04/24)

2008 "Tray bleaching overview and Indications", "Bleaching Brown Teeth, White Spots and Tetracycline-stained teeth", "In-office Bleaching and OTC Products", Sensitivity Treatment during bleaching and Caries Control", "Tray Fabrication options for bleaching: Laboratory and office", "Single Dark Teeth: Bleaching and Bonding tips".Ohio State University 64th Annual College of Dentistry Post College Assembly, Columbus, OH (05/09)

2008 "Current Concepts in Bleaching 2008". Monterey Bay Dental Society, Monterey, CA (08/15)

2008 "Bottom Line on Bleaching for 2008" 2nd, 3rd, & 4th District Dental Society Meeting, Wrightsville Beach, NC (09/15)

2008 "Caries Control with Bleaching Materials" A Day with Drake, Drake Dental Laboratory, Charlotte, NC (10/10)

2008 "Bleaching Overview" GPR Residents, Meharry Dental College, Nashville, TN (11/10)

2009 "Tray Bleaching Information: Overview and Indications"(2) Western Regional Dental Convention, Phoenix, Arizona (3/12-14).

2009 "Tooth Discoloration and Whitening Options"; "Restorative Parameters for Esthetic Success: Smile Analysis, Recontouring, Bleaching & Bonding or Crowns, Occlusion & Splints". The Kentucky Meeting, Louisville, KY (4,2-5)

2009 "Bleaching Update 2009" New Jersey Dental School, Newark, NJ (4/8)

2009 "Bleaching options from the youngest to the oldest patient". North Carolina First District Dental Society. Ashville, NC (9/11)

2009 "Treating the Discolored Dentition 2009: Bleaching options from the youngest to the oldest patient". Local dentists; MAYO dentists and residents; hands-on course residents and lab staff. Mayo Clinic, Rochester, Minnesota (10/28-30).

2010 "Tooth Bleaching Options and Recommendations for the Youngest to the Oldest Patient", "Translating Smile Analysis into Restorative Success"; "Restorative Considerations for the Single Crown: Occlusion, Articulation and Provisional Choices". South Western Dental Conference, Dallas, Texas (1/21-23)

2010 "Tray Fabrication Options for bleaching, sensitivity, elderly caries control, and children's orthodontics". Greater Columbia Dental Association, Columbia, South Carolina (3/15)

PRESENTATIONS

National

1994 "Bleaching Vital Teeth". Dental Hygiene Symposium, MCG, Savannah, GA

1994 "Esthetics and recontouring, bleaching of vital and non-vital teeth, composite bonding, porcelain veneers, occlusal considerations for restorative patients, efficient techniques for a single posterior crown". Residents of the Comprehensive Dental Department of the National Naval Dental Center, Bethesda, MD

1994 "Nightguard Vital Bleaching", Block Drug Company, Piscataway, NJ

1994 "Bleaching of vital and non-vital teeth". Saint Clare's Riverside Medical Center, Whippany, NJ

1994 "Bleaching of Vital and Non-Vital Teeth", University of Texas Esthetics Course, Las Vegas, NV

1995 "Update on Nightguard Vital Bleaching", Academy of Operative Dentistry, Chicago, IL

1995 "Nightguard Vital Bleaching: Current Status" and "Bleaching Options for Vital and Non-vital teeth". 18th Annual Conference of Academy of Latter Day Saints Dentists, Brigham Young University, Provo, UT

1996 "Home Bleaching: What to know, what to do, and what to tell patients". A participation course given twice: Hinman Dental Meeting, Atlanta, GA

1996 "Home Bleaching: What to know, what to do, and what to tell patients". A participation course given twice: Greater New York Dental Meeting, New York, NY
1996 "Home Bleaching: What to know, what to do, and what to tell patients". A participation course: Holiday Dental Conference, Charlotte, NC
1996 "Crown and Bridge Quadrant Techniques". Holiday Dental Conference, Charlotte, NC
1997 "What we know about Nightguard Vital Bleaching", Key Educators Conference, Ultradent Products Inc., South Jordan, UT
1997 "Colgate Platinum and the Archtek Tray system". Lecture and Video. Colgate Oral Pharmaceuticals, Piscataway, NJ
1997 "Home Bleaching: What to know, what to do, and what to tell patients". National Dental Association Annual meeting, Scottsdale, AZ
1998 "Home Bleaching: What to know, what to do, and what to tell patients". A participation course given twice: Yankee Dental Congress, Boston , MA
1998 "Tooth Bleaching and Other Esthetic Options". Georgia Dental Alumni Study Group. Steamboat Springs, CO
1998 "Tooth Bleaching and Other Esthetic Considerations". Prosthodontic Short Course, US Army Dental Activity, Fort Gordon, GA (3/)
1998 "Clinical Techniques of Overnight Whitening". Colgate Oral Pharmaceutical Symposium, Atlanta, GA (3/)
1998 "Clinical Techniques of Overnight Whitening". Colgate Oral Pharmaceutical Symposium, Anaheim, CA
1998 "Clinical Techniques of Overnight Whitening". Colgate Oral Pharmaceutical Symposium, New Orleans, LA
2000 "Home Bleaching: What to know, what to do, and what to tell patients". A participation course given twice: Yankee Dental Congress, Boston , MA (1/20)
2000 "Tooth Whitening Answers and Applications". (twice): Thomas P. Hinman Dental Meeting, Atlanta, GA (3/23)
2000 "Nightguard Vital bleaching, and other bleaching options for vital and non-vital teeth" Peninsula Hospital Center, New York, NY (5/12)
2000 "History and overview of the current status of Tooth Whitening". University of Florida School of Dentistry, Orlando FL (6/22)
2000 "History and overview of the current status of Tooth Whitening". Tufts University, School of Dental Medicine, Boston MA (10)
2000 "Nightguard vital bleaching, and other bleaching options for vital and non-vital teeth". Outagamie Dental Conference, Appleton, WI (11/3)
2001 "How does bleaching fit into a pediatric dental practice?". American Academy of Pediatric Dentistry Annual Session, Atlanta, GA (5/28)
2001 "Tooth Whitening: Answers and Applications". Marquette University School of Dentistry, Miilwaukee, WI (10/19)
2002 "Bleaching Overview". Prosthodontic Short Course, US Army Dental Activity, Fort Gordon, GA (3/4)
2002 "Tooth Whitening: Answers and Applications". University of Washington School of Dentistry, Seattle, Washington (5/3)
2002 "Tooth Whitening Symposium: What is the status of Bleaching?". Loma Linda University Dental School, Loma Linda, CA (11/3)
2003 "Special Topics in Dentistry: Vital Tooth Bleaching.", New York University, NY (3/17)
2003 "Tooth Discoloration and Whitening Options", Seattle Study Club, Seattle WA (5/16)
2003 "Conservative Esthetic Dentistry", University of Kentucky, Lexington, KY (11/14)
2004 "Tooth Discoloration and Whitening Options". Pacific Northwest Dental Conference, Seattle, Washington (2X) (7/22,23)
2004 "Current Trends in Tooth Bleaching; Smile analysis, Choosing articulators and Impressions" 20th Annual Prosthodontics and Esthetic Dentistry for General Practitioners (UNC), Hilton Head, SC (7/26-31)
2005 "Tooth Bleaching and Sensitivity Issues", National Meeting for GlaxoSmithKline Sales, Laguna Nigel, CA (1/12)

2005 "The Reality of Smile Makeovers", National Dental Associations 92nd Annual Convention, Las Vegas, NV (07/29)
2005 "White teeth or White Lies" (2X). 93rd Thomas P. Hinman Dental Meeting, Atlanta, GA (03/16)
2006 "Tooth Discoloration and Whitening Options", Texas State Dental Association Meeting (2X) and "Hands on Fabrication of bleaching trays", San Antonio, TX (05/11-13)
2006 "Tooth Discoloration and Whitening Options", and "Smile Analysis". Christian Dental Society Annual Meeting, Hilton Head, SC
2007 "Sensitivity, Single Dark Teeth and Tray Fabrication", "Tooth Discoloration and Whitening Options" "Smile Analysis" and "Restorative Parameters for Esthetic Success" Southwest Dental Meeting, Dallas, TX (01/18-20).
2007 "White Teeth or White Lies?" and "The Reality of Smile Makeovers: Basic Case Selection Considerations". Hinman Dental Meeting, (Featured Clinician), Atlanta, GA (3/15-17)
2007 "White Teeth or White Lies?" and hands-on "Bleaching tray Fabrication Options and Smile Makeover Analysis". Florida National Dental Convention, Orlando, FL (06/15-16)
2007 "Tooth Discoloration and Whitening Options: White and Brown spots, Tetracycline and Single dark teeth", and hands-on "Tray fabrication for Bleaching, Sensitivity and Caries Control" Greater New York Dental Meeting, New York, NY (11/24-25)
2008 "Tooth Discoloration and Whitening Options", "Sensitivity, Single Dark Teeth, Caries Control, and Tray Fabrication: Treatment Options", "Restorative Parameters for Esthetic Success: Smile Analysis, Re-contouring, Bleaching & Bonding or Crowns, Occlusion & Splints" Southwest Dental Conference, Dallas, Texas (01/17-19)
2008 "Tooth Discoloration and Whitening Options", and 2X hands-on "Tray fabrication for Bleaching". Yankee Dental Congress 33, Boston, MA (02/1-2)
2008 "White Teeth or White Lies", "Dental Missions Panel" Hinman Dental Meeting (Special Lecturer), Atlanta, GA (3/13-15).
2008 "Overview of Bleaching" "Tetracycline-Staining and Bleaching", "Sensitivity and Caries Control with bleaching". Christian Medical Dental Society National Meeting, Chicago, IL (06/18-22)
2009 "Bleaching: Tray, In-Office and OTC Options."; Sensitivity During Bleaching and Caries Control"; "Single Dark Tooth Bleaching: Vital and Non-Vital" Thomas P. Hinman Dental Meeting, Atlanta, GA (3/19-21).
2009 "Hypersensitivity: Causes and Treatments; Traditional and Bleaching". Academy of General Dentistry Annual Meeting, Baltimore, MC (7/8-12).
2010 "What every Orthodontist should know about Bleaching" American Academy of Orthodontists Winter Conference on Dental and Facial Esthetics. Indian Springs, California (1/23)
2010 "Maintaining Ethical Standards and Quality Programs in Continuing Education-A CE Speaker's Perspective". American Dental Education Association annual meeting. Washington, DC (3/1)
2010 "Bleaching Update 2010: Bleaching Options for the Young and Older Patients"; "Bleaching Single Dark Teeth"; "Bleaching Answers to Common Questions (Assisting Extravaganza)", Thomas P. Hinman Dental Meeting, Atlanta, Georgia (3/25-27)

PRESENTATIONS

International

1994 "Efficacy of six-months nightguard vital bleaching of tetracycline-stained teeth." International Association for Dental Research (#2358) Seattle, WA
1994 "Current Status of Nightguard Vital Bleaching" American Academy of Esthetic Dentistry, Maui, HI
1995 "Update on Nightguard Vital Bleaching". Academy of Operative Dentistry Table clinic, Chicago, IL
1996 "Tray design and fabrication for NGVB". Academy of Operative Dentistry table clinic, Chicago, IL
1996 "Six and 12-Month Color Stability after 6-months Bleaching Tetracycline Teeth". International Association of Dental Research (#2891) San Francisco, CA
1996 "Nightguard Vital Bleaching: Current Concepts and Research". International Symposium on Non-Restorative Treatment of Discolored Teeth. University of North Carolina, Chapel Hill, NC
1997 "Fabrication of an anti-Snoring device". Academy of Operative Dentistry table clinic, Chicago, IL
1997 "Nightguard Vital Bleaching". University of Rome Dental School, Rome, Italy
1997 "The Whitening of Vital and Nonvital teeth". National Italian Dental Association. Milan, Italy

1997 "Dental Bleaching of Vital and Non-Vital Teeth: Options and Recommendations". XII International Odontology Conclave of Campinas, Sao Paulo, Brazil
1997 "New Frontiers for Nightguard Vital Bleaching". The American Academy of Cosmetic Dentistry, Las Croabas, Puerto Rico
1998 "Nightguard Vital Bleaching: Current Concepts and Research". Ultradent Seminars, Cancun, Mexico
1998 "Immediate Direct Thermoplastic Bleaching Trays". Academy of Operative Dentistry table clinic. Chicago, IL
1998 "Feasibility of Immediate Direct Thermoplastic Whitening Trays". American Association of Dental Research (#1337), Minneapolis, MN
1998 "The Chemistry of Bleaching". Lunch and Learn session of the American Association of Dental Research, Minneapolis, MN
1998 "Vital and Non-Vital Bleaching" , Oral Tech Seminar, San Paulo, Brazil
1998 "Bleaching of vital and non-vital teeth", 29th Brazilian Congress of Dentistry & 10th International Congress of Goias, Goiania, Goias, Brazil
1999 "Treatment options for tooth sensitivity during Nightguard Vital Bleaching", Academy of Operative Dentistry table clinic, Chicago, IL (2/)
1999 "History and Overview of Current Status of Tooth Whitening". At "Tooth Whitening: State of the Art 2000" Symposium. Loma Linda, CA. (11/14)
1999 "Nightguard Vital Bleaching: History and Current Status". Ultradent Educators/Vitalescence Conference, South Jordon, UT. (12/3-5)
2000 "Tray delivery of Potassium-Nitrate Fluoride to reduce bleaching sensitivity". International Association for Dental Research, Washington, DC (4/8)
2000 "Bright Ideas for the 21st Century", (Nightguard vital bleaching, Smile Analysis and non-vital bleaching, Oral Appliance therapy for Snoring and Sleep Apnea.) British Society for Restorative Dentistry, Windsor Castle, England (5/5-6)
2000 "Why and What Prosthodontists need to know about Bleaching" American College of Prosthodontists Annual Meeting, Kona, Hawaii (11/17)
2001 "Tooth Whitening: Answers and Applications" Academy of Operative Dentistry Annual Meeting, Chicago, Il (2/22)
2002 "Tooth Whitening: at-home or in-office? Current Trends and Indications". International Association for Dental Research ,Lunch & Learn; San Diego, CA (3/6)
2002 "Tooth Whitening and Treatment Options"; "Advanced Concepts for Tooth Whitening" World Esthetic Congress, London, UK (6/14-15)
2002 "Tooth Discoloration: Whitening Options" American Academy of Esthetic Dentistry Annual Meeting, Beaver Creek, CO (8/7-10)
2002 "Dentine Hypersensitivity: bleaching and restorative considerations for successful management". FDI World Dental Federation, Vienna, Austria (10/2)
2002 "Current Trends in Bleaching and Esthetic Dentistry" The 4th World Dental Meeting in Japan 2002, Yokohama, Japan (10/18)
2003 "Direct Thermoplastic Bleaching Tray Fabrication". Academy of Operative Dentistry Annual Meeting, Table clinic, Chicago, Il (2/28)
2003 "Tooth Discoloration: Whitening Options". American Academy of Cosmetic Dentistry Annual Meeting, Orlando, FL (5/4)
2003 "Tooth whitening Research Options", GlaxoSmithKline House, London England (6/26)
2003 "Vital Tooth Whitening-An Update on Safety and Efficacy" International Association of Dental Research, Gothenburg, Sweden (6/28)
2003 "Tooth Whitening and Dentin Hypersensitivity" GlaxoSmithKline Symposium, Belfast, Northern Ireland (10/8)
2003 "Tooth Whitening and Dentin Hypersensitivity" GlaxoSmithKline Symposium, Dublin, Ireland (10/8)
2003 "Current Controversies in Vital Bleaching" American Dental Association Symposium, Annual Meeting San Francisco, CA (10/23)
2003 "Bleaching – a participation workshop": Hands on course given twice, American Dental Association Annual Meeting, San Francisco, CA (10/24)

2004 Table Clinic on "Number of In-office light-activated bleaching appointments to achieve patient satisfaction" and "In-office bleaching sensitivity" with Drs. Brackett and Gottarti. Academy of Operative Dentistry Annual Meeting, Chicago, Il (2/28)

2004 "Current Trends in Bleaching" Seattle Study Club Eleventh National Symposium, Laguna Niguel, CA (1/28)

2004 "Tooth Bleaching Information to make Everyone Smile" Tin Grinners Club, Jamaica, Kingston, Jamaica (3/26)

2004 "Tooth Whitening Overview", and "Oral Appliance Therapy for Sleep Apnea", Baku Dental School Medical University and Baku Governmental Children's Hospital, Baku, Azerbajan (4/19-20)

2004 "What's New in Tooth Whitening; Get the White Facts", Seminar and hands on course with Dr. Linda Greenwall and Independent Seminars, The Royal College of Physicians, London, England (4/23-24)

2004 "Aesthetic Options for Vital Tooth Bleaching", Second Annual Symposium on Aesthetic Dentistry, New York Academy of Cosmetic Dentistry, New York University College of Dentistry, NY, NY (5/15)

2005 "Tooth Whitening: Answers about at-home bleaching, in-office and over the counter products." American Academy of Restorative Dentistry, Chicago, IL (02/26)

2005 "Bleaching controversies: "Color Measurements" instead of "Chemistry" ". Lunch and Learn, International Association of Dental Research Meeting, Baltimore, MD (03/08)

2005 "Tooth Whitening of the Single Dark Tooth: Vital and Non-Vital Options". XIV World Congress on Dental Traumatology, Reykjavik, Iceland (05/05)

2005 "Tooth Discoloration and Whitening Options", 9th International Congress of Esthetic Dentistry, Turkish Academy of Esthetic Dentistry, Istanbul, Turkey (09/16)

2005 "Tooth Bleaching: A Current Perspective ", 2005 Tooth Bleaching Symposium, Loma Linda University, Loma Linda, CA (11/05)

2005 "Nightguard Vital Bleaching: Indications and Limitations" & "Tooth Discoloration and in-office Bleaching", 50th Anniversary of the Japanese Society of Conservative Dentistry, Tokyo, Japan (11/25)

2005 "Nightguard Vital Bleaching, and Problems with In-Office Bleaching", Shofu Dental Company, Kyoto, Japan (11/28)

2006 "White teeth or White Lies" Academy of Operative Dentistry Annual Meeting, Chicago, Il (2/23)

2006 "What's your best bet on Bleaching?" and ""Esthetics and bleaching differences for the aging population, management of sensitivity and root caries"". American Dental Association Annual meeting, Las Vegas, NV (10/17-19)

2007 "Contemporary Approach to Bleaching and Hypersensitivity management", Chulalongkorn University, Bangkok, Thailand (02/25)

2007 "Tooth Discoloration and Whitening Options", "Tray fabrication for Bleaching", "Bleaching Tetracycline-stained and Single Dark teeth", "Sensitivity and Caries Control with bleaching", and "Oral Appliance Therapy for Snoring and Sleep Apnea". Twenty-Eighth International Conference, Christian Medical and Dental Education, Chiang Mai, Thailand (02/26-3/2)

2007 "Contemporary Approach to Bleaching and Hypersensitivity management", GlaxoSmithKline Seminar, Manila, Philippines (03/04-05)

2007 "Tooth Discolorations and Nightguard Vital Bleaching". International Federation of Esthetic Dentistry; Seoul Korea (05/4-6)

2007 "Tooth Discoloration and Whitening Options", "Tray fabrication for Bleaching", "Bleaching Tetracycline-stained and Single Dark teeth", "Sensitivity and Caries Control with bleaching", Mexico Seminario del Groups de Estudios USC de Mexico; Ixtapan de la Sol, Edo. De Mexico. (05/ 13-17)

2008 "Tooth Discoloration and Tray Bleaching" 5th International Conference of Aesthetic Dentistry, Hellenic Academy of Aesthetic Dentistry, Thessaloniki, Greece (04/05)

2008 "Status of Tray Bleaching 2008" Dentalite-Ultradent Seminar, Madrid, Spain (04/11)

2008 "What's your best bet on Bleaching?" Les Journees Dentaires Internationals du Quebec 2008, 37th Annual Convention, Montreal, Canada (05/26)

2008 "International Symposium on Tooth Whitening" hungShan Medical College Dental Alumni Association, Taichung, Taiwan (07/06)

2008 "International Symposium on Tooth Whitening", Prince Philip Hospital, Hong Kong, China (07/08)

2008 "Tooth bleaching for elderly and young people", "Oral longevity and aging panel" ADA annual meeting, San Antonio TX (10/17-22)
2009 "Bottom line on Bleaching", Bangkok, Thailand (2/8)
2009 "Bleaching, Smile Analysis, Recontouring, Bonding, Occlusion, Splints" Christian Medical Dental Education program two weeks. Chiang Mai, Thailand (2/9-19)
2009 "Tooth Whitening Information for Children and Youth" (2). American Academy of Pediatric Dentistry 62nd Annual Session. Honolulu, HI (5/21-24)
2009 "Current Status of home bleaching-with 20 years of research knowledge" World Aesthetic Congress: Bleaching Symposium. London, England (6/12).
2009 "Whitening Update 2009". Auckland, Dunedin, Wellington in New Zealand, Cairns, Sidney, Melbourne in Australia for University of Sidney, University of Melbourne, Otago University, IADR Dental Materials Group, & Guntz Dental. Australia and New Zealand. (7/20-31)
2009 "Bleaching: Answers for Patients, questions on tray bleaching, in-office bleaching and OTC materials"; "Tooth bleaching options and recommendations for the youngest to the oldest patient"; "Tray Options for bleaching, sensitivity and caries control: Custom, Boil and Form, and Disposable Trays (Hands-on X2)". Plus Web-based pre-course and GSK Lunch and Learn. American Dental Association Annual Meeting, Honolulu, HI (10/1-4)

MEETINGS ATTENDED (last five years)

2004 Academy of Operative Dentistry, Chicago, IL (2)
2004 American Academy of Restorative Dentistry, Chicago, IL (2)
2004 American Dental Association, Orlando,(10)
2005 Academy of Operative Dentistry, Chicago, IL (2)
2005 American Academy of Restorative Dentistry, Chicago, IL (2)
2005 Hinman Dental Society Meeting, (3)
2005 Academy of Continuing Dental Education, Boston, (8)
2005 American Dental Association, Philadelphia,(10)
2005 2005 Tooth Bleaching Symposium, Loma Linda (11)
2006 American College of Dentists-Carolina's Section (1)
2006 Academy of Operative Dentistry, Chicago, IL (2)
2006 American Academy of Restorative Dentistry, Chicago, IL (2)
2006 Hinman Dental Society Meeting, (3)
2006 American Academy of Esthetic Dentistry, Grand Cayman, (8)
2006 American Dental Association, Las Vegas,(10)
2007 American College of Dentists-Carolina's Section, Kiawah, SC (1)
2007 Christian Medical Dental Education International Conference, Chiang Mai, Thailand (2)
2007 Christian Medical Dental Association National Meeting, Orlando, FL (6)
2007 American Academy of Esthetic Dentistry, Colorado Springs, CO (8)
2007 American Dental Association, Orlando (10)
2008 Academy of Operative Dentistry, Chicago, IL (2)
2008 American Academy of Restorative Dentistry, Chicago, IL (2)
2008 Christian Medical Dental Association National Meeting, Chicago, IL (6)
2008 Academy of Continuing Dental Education Annual Meeting, Chicago, IL (8)
2008 American Dental Association, San Antonio(10)
2009 Christian Medical Dental Education International Conference, Chiang Mai, Thailand (2)
2009 Christian Medical Dental Association National Meeting, Ashville, NC (6)
2009 American Dental Association, Hawaii (10)
2010 Academy of Operative Dentistry, Chicago, IL (2)
2010 American Academy of Restorative Dentistry, Chicago, IL (2)
2010 Christian Medical Dental Association National Meeting, Ashville, NC (4)

PROFESSIONAL EXHIBITS AND AUDIOVISUAL PROGRAMS

CONTINUING EDUCATION COURSES PRESENTED-UNC

1975 Instructor: "Tooth Colored Restorations" UNC, Operative Dentistry course, UNC School of Dentistry, Chapel Hill, NC

1975 "Pins in Restorative Dentistry" Operative Department Continuing Education Course, UNC School of Dentistry, Chapel Hill, NC

1985 Course Director/Lecturer, "Direct Fabrication of Resin Temporary Crowns and Bridges." One day AHEC Lecture/Lab Course for Dental Assistant II -Mountain Area Health Education Center, Asheville, NC

1985 Course Director/Lecturer, "Direct Fabrication of Resin Temporary Crowns and Bridges." One day AHEC lecture/lab course for Dental Assistant II, Fayetteville Technical Institute, Fayetteville, NC

1985 Course Director/Lecturer, "Direct Fabrication of Resin Temporary Crowns and Bridges" One day AHEC lecture/lab course for dental assistant II - private office, Fayetteville, NC

1985 Course Director/Lecturer, "Direct Fabrication of Resin Temporary Crowns and Bridges" CE Lecture/Lab course for Dental Assistant II, UNC School of Dentistry, Chapel Hill, NC

1985 Course Director "Fixed Prosthodontics for General Practitioners." Three day Fixed Prosthodontics Departmental Course, Hilton Head Island, SC

1985 "Triple Tray Impressions, Seating Castings, Walking Bleach, Ortho Extrusion, Temporaries": Fixed Prosthodontics for the General Practitioner, Departmental Course, Hilton Head, SC

1986 Course Director "Fixed Prosthodontics for General Practitioners." Three day Fixed Prosthodontics Departmental Course, Hilton Head Island, SC

1986 "Etched Porcelain Laminate Veneers, Impression Materials, Occlusal Considerations for Restorative Patients" Fixed Prosthodontics for the General Practitioner, Departmental Course, Hilton Head Island, SC

1986 "Etched Porcelain Laminate Veneers": Update in General Practice, Academy of General Dentistry Course, UNC School of Dentistry, Chapel Hill, NC

1986 Course Director/Lecturer, "Direct Fabrication of Resin Temporary Crowns and Bridges" one day lecture/lab course for Dental Assistant II -Private Office, Wilson, NC

1987 "Update in General Dentistry- Fixed Prosthodontics Area": Academy of General Dentistry Course, UNC School of Dentistry, Chapel Hill, NC

1987 Course Director "Fixed Prosthodontics for General Practitioners." Three day Fixed Prosthodontics Departmental Course, Hilton Head Island, SC

1987 "Etched Porcelain Laminate Veneers, Occlusal Splint Construction and Application, Porcelain Repair Kits, Glass Ionomers," Fixed Prosthodontics for the General Practitioner, Departmental Course, Hilton Head Island, SC

1987 Chairman/Moderator "1987 Careers in Dentistry" Conference for Dental Students, Chapel Hill, NC

1988 Course Director/Lecturer, "Temporary Crowns and Bridges for Auxiliaries" one day lecture/lab course for Dental Assistant II-Area L AHEC Center, Rocky Mount, NC

1988 Course Director "Fixed Prosthodontics for General Practitioners." Three day Fixed Prosthodontics Departmental Course, Hilton Head Island, SC

1988 "Update on Etched Metal Resin Bonded Fixed Partial Dentures, Esthetic Options in Fixed Prosthodontics, and Quadrant Techniques/Impression Materials" Fixed Prosthodontics for the General Practitioner, Departmental Course, Hilton Head Island, SC

1988 "Esthetic Options in Fixed Prosthodontics" Academy of General Dentistry Course, UNC School of Dentistry, Chapel Hill, NC

1989 Course Director, "Prosthodontics for General Practitioners." Seven day Prosthodontics Departmental Course, Hilton Head Island, SC

1989 "Nightguard Vital Bleaching, Esthetic Options in Fixed Prosthodontics, Orthodontic extrusion of roots, Non-vital bleaching, and Triple Tray Techniques/Impression Materials" Fixed Prosthodontics for the General Practitioner, Departmental Course, Hilton Head Island, SC

1989 "Esthetic Options in Fixed Prosthodontics" Rowan-Cabarrus Community College, Salisbury, NC

1990 Course Director "Fixed Prosthodontics for General Practitioners." Seven day Prosthodontics Departmental Course, Hilton Head Island, SC

1990 "Nightguard Vital Bleaching Update and Research, Porcelain Laminate Veneers, Porcelain Fracture Repairs, Triple Tray Techniques/Impression Materials, Practice Management Tidbits, Update of Resin Bonded Bridges, and Retention for Amalgam" Fixed Prosthodontics for the General Practitioner, Departmental Course, Hilton Head Island, SC
1990 "Nightguard Vital Bleaching" Academy of General Dentistry Course, UNC School of Dentistry
1991 Course Director "Prosthodontics for General Practitioners." Seven day Prosthodontics Departmental Course, Hilton Head Island, SC
1991 "Occlusion; Triple Tray Techniques and Impression materials; Nightguard vital bleaching update and research." Prosthodontics for General Practitioners, Departmental Course, Hilton Head Island, SC
1991 "Nightguard Vital Bleaching" Academy of General Dentistry Course, UNC School of Dentistry
1991 "Conservative Options: Recontouring and Bleaching". The All Ceramic Restoration, Departmental Continuing Education course, Chapel Hill, NC
1992 Course Director "Prosthodontics and Periodontics for General Practitioners." Seven day Prosthodontics Departmental Course, Hilton Head Island, SC
1992 "Resin Temporaries for Fixed Prostheses, Bleaching, Infection Control in Prosthodontics." Prosthodontics and Periodontics for General Practitioners, Departmental Course, Hilton Head, SC
1993 "Bleaching of Vital and Non-vital teeth" Department of Operative Dentistry course, Myrtle Beach, SC

CONTINUING EDUCATION COURSES PRESENTED-MCG

1993 "Bleaching, Occlusal Considerations, Quadrant Posterior Crowns, Esthetics and recontouring, Veneers, Practice management". Specialize your General Practice, MCG, St. Simons Island, GA
1994 "Bleaching of vital and non-vital teeth, Efficient techniques for a single posterior crown". Treatment Techniques for Fixed-Restorative Patients in General Dentistry, MCG, Atlanta, GA
1995 "Esthetic Options prior to full coverage; Occlusion" MCG Course Director and Lecturer; Calloway Gardens, GA
1996 "Conservative Esthetic Options: A participation course in Preparations". MCG Course Director and Lecturer; MCG, Augusta, GA
1997 "Conservative Esthetic Options: A participation course in Preparations". MCG Course Director and Lecturer; MCG, Augusta, GA
1998 "Bleaching and Other Esthetic Options". MCG Course Director and Lecturer; Lake Lanier Islands, GA (7/31)
1999 "Home bleaching: What to know, what to do & what to tell patients". MCG Dental Hygiene Symposium, Savannah GA. Lecture and participation course (7/16).
2000 "Home bleaching: What to know, what to do & what to tell patients". MCG Dental course lecturer, St. Simons Island, GA (8/6)
2003 "Current Trends in Bleaching; Bleaching and Bonding: Choosing Articulators": Symposium on General Dentistry, MCG, St. Simon's Island (7/3-5)
2005 "Bleaching before, during and after Orthodontics", and "Smile Analysis". MCG Orthodontic Alumni Association, MCG, Augusta, GA (08/19)
2005 "Frequently Asked Questions about Bleaching". Course Director and Lecturer; 2005 Hinman/MCG Esthetic Symposium, Atlanta, GA (8/20-21)
2005 "Tooth Bleaching: Answers about at-home bleaching, in-office and OTC products" . Course Director and Lecturer, Update for General Practitioners, Young Harris, GA (10/21-23)
2005 ""Commonly Asked Questions about Bleaching", Course Director and lecturer, Last Chance Dental Continuing Education, MCG Augusta, GA (12/8-9)
2006 Course Director for "CE with the Masters" Augusta, GA (4)
2006 Course Director for "28th Annual Goldstein Lectureship", Augusta, GA (4)
2006 Course Director for Saturday CE with the Faculty, Augusta, GA (4)
2006 Course Director for "3rd Annual Hinman/Fellow Esthetic Symposium : Dr. Pascal Magne" Atlanta, Albany and Augusta, GA (08)
2006 Course Director for "Dental Update for the General Practitioner" Brasstown Valley Resort, Young Harris, GA (10)
2006 Course Director for "A Day with Pankey: Dr. Irwin Becker". MCG Campus, Augusta, GA (11)
2006 Course Director for "Last Chance Dental Continuing Education" MCG Campus, Augusta, GA (12)

2007 Course Director for 29th Annual Goldstein Lecture: Dr. Gerald Chiche. Augusta Marriott Hotel and Suites, Augusta, GA (4)
2007 Course Director for Saturday CE with Faculty: Drs. Rueggebery and Abreu, MCG Campus, Augusta, GA.
2007 Course Director for 4th Hinman/MCG Fellows Series Dr. Dario Adlofi from Brazil. Atlanta, Augusta and Tifton, GA (08)
2007 "Tray Fabrication Options for Bleaching, Sensitivity and Caries Control". Course Director and Lecturer: Dental Update for the General Practitioner, Brasstown Valley Resort, Young Harris, GA (10/19-21)
2007 "Sensitivity treatment and caries control" & "Tray fabrication options for bleaching" Course Director and Lecturer: General Dentistry Problem Solving, Omni Hotel at CNN Center, Atlanta, GA (11/2)
2007 "Bleaching Single Dark Teeth" "Caries Control with Bleaching". Course Director and Lecturer: Last Chance Dental Continuing Education, Medical College of Georgia campus, Augusta, GA (12/6-7)
2008 Course Director for 30th Annual Goldstein Lecture: Dr. Dennis Tarnow. Augusta Marriott Hotel and Suites, Augusta, GA (4)
2008 Course Director for Saturday CE with Faculty: Drs. Rockman and Kalathingal, MCG Campus, Augusta, GA.
2008 Course Director for 5th Hinman/MCG Fellows Series Dr. Didier Dietschi from Geneva, Switzerland. Atlanta, and Columbus, GA (08)
2008 Co-Course Director: Last Chance Dental Continuing Education, Medical College of Georgia campus, Augusta, GA (12/11-12)
2009 Course Director for 31th Annual Goldstein Lecture: Dr. Cherilyn Sheets. Augusta Marriott Hotel and Suites, Augusta, GA (4)
2009 Course Director for Saturday CE with Faculty: Drs.Siranli & B.Brackett , MCG Campus, Augusta, GA.
2009 Co-Course Director: Last Chance Dental Continuing Education, Medical College of Georgia campus, Augusta, GA (12/3-4)
2010 Course Director for 32th Annual Goldstein Lecture: Dr. Markus Blatz. Augusta Marriott Hotel and Suites, Augusta, GA (4)
2010 Course Director for Saturday CE with Faculty: Drs. Mitchell & Metzler , MCG Campus, Augusta, GA.

AUDIOVISUAL PROGRAMS

1986 Murray HV, Haywood VB. Four video tape series on Making Alginate Impressions, Taking a Facebow, Records, Mounting Study Casts, and Setting the Whip Mix Articulator. UNC
1987 Haywood VB, Phillips K, Paton PE. Two video tape series on Spruing and Investing Wax Patterns, and Casting Gold Alloys. UNC
1995 Haywood VB, Goldstein RE, Heymann HO. "Vital and Non-vital Bleaching: Office and at-home Systems". Academy of General Dentistry AudioDent Series, Atlanta, GA
1997 Haywood VB, Caughman F. "Single Appointment Fabrication of a direct Thermoplastic Tray (Archtek) for use with Colgate Platinum Professional Toothwhitening System. Video tape, MCG
1998 Haywood VB. "Whitening teeth with Nightguard Vital bleaching". Practical Reviews in Pediatric dentistry. Audio tape, American Academy of Pediatric Dentistry.
1999 Haywood VB: "Treatment of Tooth Sensitivity during Nightguard Vital Bleaching". Internet audio/slide lecture. DentalQuest.org.
2000 Haywood VB: "Tooth Whitening Answers and Applications". Thomas P. Hinman Dental Meeting audio tape.
2000 Haywood VB: "Tray fabrication for Nightguard Vital Bleaching". Internet audio/slide lecture. Dentrek.com
2001 Haywood VB: "Bleaching Tetracycline-stained teeth". Internet audio/slide lecture. DenTrek.com
2001 Haywood VB: "Immediate fabrication of direct thermoplastic whitening trays". Internet audio/slide lecture. DenTrek.com
2002 Haywood VB. "Vital Tooth Bleaching". Tape interview with Dr. Tom Berry. Practical Reviews in Cosmetic Dentistry (2)

2003 Dentine Hypersensitivity-general practice considerations for successful management. GlaxoSmithKline CD of Vienna Symposium, with interview
2006 Podcasts on "Bleaching" (2), Ultradent Products Inc, Las Vegas ADA meeting, posted online
2007 Video on "Direct Thermoplastic Bleaching Trays". Website post www.vanhaywood.com
2008 Video on "Direct Thermoplastic Bleaching Trays over Orthodontic Braces".
2009 Haywood VB. "Vital Tooth Bleaching". Tape interview with Dr. Tom Berry. Practical Reviews in Cosmetic Dentistry (2)
2009 Australian Dental Files program on, BLEACHING: Program 6, track 6 Australian Dental Association

PUBLICATIONS in Teaching journals

1. Glawson J, Haywood VB. A New Idea in Dental Education. Dental Student Magazine, May(38) l974.
2. Haywood VB. A Direct Temporary for a Single Tooth Restoration, N.C. Dent Jour 59(3): 12, 1976.
3. Haywood VB. Dent Notes. North Carolina Dental Review:
   Clinical tidbits. Summer: 24, 1984.
   Patient conveniences. Fall: 31, 1984.
   Gift toothbrushes. Winter: 31, 1985.
   TMJ Tapes. Summer: 35, 1985.
   Toothbrush ornaments; Extended Uses for Dental Floss. Winter: 53-54, 1987.
   Staff Uniforms and Office Decor. Fall: 53, 1987.
4. Haywood VB, Wall JT. Restorative Dental Emergencies (Operative and Fixed Prosthodontics), North Carolina Dental Review 4(2):20,25, 1987. Reprinted in Dental Abstracts 33(4): 176, 1988.
5. Haywood VB. Office Emergency Coverage Tips. North Carolina Dental Review 4(2):25, 1987.
6. Currens WE, Haywood VB. Video Review of "Postgraduate Course for Placement of Modern Posterior Composites." Dental Magazine, March: 22, 1987.
7. Haywood VB. Research on Whitening Teeth Makes News. NC Dental Review 1990;7(2):9.
8. Haywood VB. Nightguard Vital Bleaching: History and Products Update, Part 1. Esthetic Dentistry Update 1991;2(4):63-66.
9. Haywood VB. Overview and Status of Mouthguard Bleaching. J Esthetic Dent 1991;3(4):157-161.
10. Haywood VB. Nightguard Vital Bleaching: History and Products Update, Part 2. Esthetic Dentistry Update 1991;2(5):82-85.
11. Haywood VB. Bleaching of Vital and Non-Vital Teeth.Current Opinion in Dentistry 1992;2(1):142-149.
12. Haywood VB. History, safety and effectiveness of current bleaching techniques: applications of the nightguard vital bleaching technique. Symposium on Esthetic Restorative Materials 1993; November: 82-92.
13. Haywood VB. Vitalbleichen mit Nachtschienen, Wissensstand und Technik. Phillip Journal (German) 1993;7-8:331-335.
14. Haywood VB. The Food and Drug Administration and its influence on Home bleaching. Current Opinion in Cosmetic Dentistry 1993;12-18.
15. Haywood VB. Considerations and Variations of Dentist-Prescribed, Home-Applied Vital Tooth-Bleaching Techniques. Compendium Contin Educ Dent 15 (suppl 17);1994:s616-s621.
16. Haywood VB, Heymann HO. Nightguard vital bleaching safety. Letter to the Editor. Quintessence International 1993;24:599-600.
17. Haywood VB, Williams HA. Status and Restorative Options for Dentist-Prescribed Home-Applied Bleaching. Esthetic Dentistry Update 1994;5(3):65-67.
18. Haywood, VB. Update on Bleaching: Material Changes. Esthetic Dent Update 1995;6(1):24.
19. Haywood, VB. Update on Bleaching: An Examination for Nightguard Vital Bleaching. Esthetic Dent Update 1995;6(2):51-52.
20. Haywood, VB. Update on Bleaching: Advice to Patients on Over-the-counter Bleaching Agents. Esthetic Dent Update 1995;6(3):74.
21. Haywood, VB. Update on Bleaching: Bleaching and Microabrasion Options. Esthetic Dent Update 1995;6(4):99-100.
22. Haywood, VB. Nightguard Vital Bleaching: Information and Consent Form. Esthetic Dent Update 1995;6(5):130-132.
23. Haywood, VB. Checklist for Nightguard Vital Bleaching. Ultraedge 1996;1:1-2.

24. Haywood, VB. Bleaching Tetracycline-stained teeth. Esthet Dent Update 1996;7(1):25-26.
25. Haywood, VB. Bleaching and Snoring. Esthetic Dent Update 1996;7(2):56-57.
26. Haywood VB, Myers MI, Dirkson TR. Nightguard Vital Bleaching. GDA Action, MCG Quiz. 1996. September, 20, 28.
27. Haywood VB. Nightguard Vital Bleaching: Construction of NGVB Prosthetic. Dentistry Today 1997;16(6):86-91.
28. Haywood VB, Robinson FG. Vital Tooth Bleaching with Nightguard Vital Bleaching. Current Opinion in Cosmetic Dentistry 1997,4:45-52.
29. Haywood VB. Extended Bleaching of Tetracycline-stained teeth: a case report. Contemporary Esthetics and Restorative Practice 1997;1(1):14-21.
30. Haywood VB. Bleaching Analysis (Quick Tips). Contemporary Esthetics and Restorative Practice 1997;1(2):36.
31. Haywood VB. Guest Editor: Current Opinions on Nightguard Vital Bleaching. Compendium (Special Issue) 1998.
32. Haywood VB. The Pros and Cons of Whitening your Teeth. Atlanta Health & Beauty 1998;Oct:26,33.
33. Pelehach L. Little white lies? Set patients straight on bleaching. Dent Prac &Finan 1999;Jan/Feb:31-35. (interview)
34. Haywood VB. Are Reservoirs Necessary?. J Esthet Dent 1999;11(1):3.
35. Haywood VB. Ask the Experts. J Esthet Dent 1999;11(4):175-6.
36. Haywood VB. Current Status and Recommendations for Dentist-prescribed, at-home Tooth Whitening. Contemporary Esthetics and Restorative Practice 1999;3(1):2-9.
37. Haywood VB. A Comparison of At-home and In-office Bleaching. Dentistry Today 2000;19(4):44-53.
38. Haywood VB. Supervised at-home bleaching is safest, most effective. Dental Products Report 2000;May:82-91.
39. Haywood VB. "More on Home Bleaching". Dental Products Report 2000,June;80-81
40. Illustrations contributor: Stedman's Medical Dictionary 2000; 27th Edition.
41. Andrews LM. Interview for "SMILE". Mature Outlook, 2000 June;32-43.
42. Haywood VB. "Tooth bleaching options raise key questions". GAGD Explorer 2000; Oct:1,4.
43. Haywood VB. Tooth Whitening in your Practice: Treatment time and fee schedules. Contemporary Esthetics and Restorative Practice 2000;4(11):12-15.
44. Haywood VB, Caughman WF, Frazier KB, Myers ML. Fabrication of Immediate Thermoplastic Whitening Trays. Contemporary Esthetics and Restorative Practice 2001;5(9):84-86.
45. Haywood VB, Caughman WF. At-Home Whitening and Selective Bonding of Tetracycline-stained Teeth. Contemporary Esthetics and Restorative Practice 2001;5(10):20-26.
46. Haywood VB, Singh BB, Borke JL. Nightguard Vital Bleaching and tumor promotion. www.oraltech.com.br (Brazilian Dental Supplier website; biblioteca section: 2002).
47. Interview in Goldstein R. Whitening Options: How to Choose. Contemporary Esthetics and Restorative Practice 2002;6(7):12-17.
48. Haywood VB. Interview on Nightguard Vital Bleaching. Dental Products Report 2002, 36(10): 82-86,96. (reprinted in Dental Products Report EUROPE 2003,24(1):8-11)
49. Meeting Van Haywood, world Expert on tooth whitening and sensitivity. Interview with Irish Dentist Magazine, Nov 2003:28-29.
50. Haywood VB. A Brighter Smile. Dimensions of Dental Hygiene 2004; March28,30,35.
51. Haywood VB. Tooth Bleaching: Commentary on Current Concepts. The New Face of Aesthetics: The AACD Monograph 2004; 42-43.
52. Why, When and how to whiten your patient's teeth: Bleaching expert Van Haywood puts you on track. Irish Dentist Sept 2004: 16-18 (reprinted UK Dentistry Jan 2005:48-49.)
53. Haywood VB, Pohjola R. Bleaching and Esthetic Bonding of Tetracycline-stained teeth. Contemporary Esthetics and Restorative Practice 2004; 8(10):16-24. (reprinted Indian Journal 2005)
54. Haywood VB, "Tooth Discoloration and Whitening Options" Seattle Study Club Journal 2004;9(2):25-32.
55. Haywood VB. Whitening Particulars. Dimensions of Dental Hygiene 2006;4(5):22,24.
56. Haywood VB. Bleaching Children's Teeth: Questions and Answers. Georgia Academy of General Dentistry Newsletter 2006; September: 4-7.

57. Haywood VB. Taking the Pain out of Tooth Whitening. Dimensions of Dental Hygiene 2006;4(9): 32-33.
58. Haywood VB. Considerations for Vital Nightguard Tooth Bleaching with 10% Carbamide Peroxide after nearly 20 Years of Proven Use. Inside Dentistry 2006; Sept: 2-5.
59. Haywood VB. Bleaching and caries control in elderly patients. Aesthetic dentistry today October 2007:1(4):42-44.REPRINTED: Dental Economics Jan 2010.
60. DeMatteo AM. The Ethics of Esthetic Dentistry: Interview. 2007 Sept;53-64.
61. Haywood VB. The "Bottom Line" on Bleaching 2008. Inside Dentistry 2008; 4(2): 82-89.
62. Haywood VB. In-Office Bleaching: Lights, Applications, and Outcomes. Current Practice 2009; 16(4):3-6.
63. Haywood, VB. "The tooth's response to bleaching is individualistic and can only be determined by starting treatment". Dental Tribute Asia Pacific 2009; 5:14.
64. Haywood VB. The Safety and Efficacy of Esthetic Tooth Whitening. Dimensions of Dental Hygiene 2010; 8(3):46-47.
65. Haywood VB. Orthodontic Caries Control and Bleaching. Inside Dentistry 2010; 6(4): 36-50.
66. Haywood VB, DiAngelis AJ. Bleaching the Single Dark Tooth.Inside Dentistry 2010;6(8):42-52.

ABSTRACTS

1. Haywood VB, Heymann HO, Andreaus SB. Polishing Porcelain Veneers: An SEM Analysis. J Dent Res 66 (Special Issue, #1455): 288, 1987.
2. Haywood VB, Brantley CF, Bruggers KJ. Thermal Removal of Composite Resin: Effect on Rebonding Etched Metal. J Dent Res 67 (Special Issue, #1541): 305, 1988.
3. Haywood VB, Heymann HO, Scurria MS. Experimental Instrumentation for Polishing Porcelain Intraorally. J Dent Res 67 (Special Issue #2116): 377, 1988.
4. Haywood VB, Heymann HO, Scurria MS. Efficacy of Stones for Polishing Porcelain Intraorally. J. Dent. Res. 68 (Special Issue, #1704): 394, 1989.
5. Scurria MS, Haywood VB, Heymann HO. Effects of Polishing Porcelain Prior to Glazing. J. Dent. Res. 68 (Special Issue, #184) 204, 1989.
6. Haywood VB, Heymann HO. Nightguard used for bleaching discussed. Dental Abstracts 34 (6); 250-251, 1989.
7. Haywood VB, Houck VM, Heymann HO: Effects of various Nightguard Vital Bleaching solutions on enamel surfaces and color change. J Dent Res 1991;70(#0893):377.
8. Woolverton CJ, Haywood VB, Heymann HO: A Toxicologic Screen of Two Carbamide Peroxide Tooth Whiteners. J Dent Res 1991;70(#2335);558.
9. Haywood VB, Leonard RH, Nelson CF. Efficacy of Foam Liner in 10% carbamide peroxide bleaching technique. J Dent Res 1992;71 (#592):179.
10. Leonard RH, Bentley C, Haywood VB. Salivary pH changes during Nightguard Vital Bleaching. J Dent Res 1992;71 (#593):180.
11. McCracken MS, Haywood VB, Kanoy BE. Effects of 10% Carbamide Peroxide on Subsurface Hardness of Enamel. J Dent Res 1992;71 (#430):159.
12. Haywood VB, Leonard RH, Nelson CF. Effectiveness of Nightguard Vital Bleaching. J Dent Res 1992;71 (#591):179.
13. Haywood VB, Houck VM, Heymann HO: Bleaching Solution do not affect enamel surface. Dental Abstracts 1992;37(1):41-42.
14. Haywood VB, Leonard RH, Nelson CF. Nightguard Vital Bleaching Longevity & Side Effects: 13-25 Months Data. J Dent Res 1993;72 (#835):208.
15. Leonard RH, Austin SM, Haywood VB, Bentley C. PH change of plaque and carbamide peroxide during vital bleaching. J Dent Res 1993;72(#895):215.
16. McCracken MS, Haywood VB, Deaton TG. Demineralization effects of 10% carbamide peroxide and cola on enamel. J Dent Res 1993;72(#896):215.
17. Nelson CF, Haywood VB, Leonard RH, Ludlow JB, McCracken MS. Image Analysis of digitized 35mm slides for color evaluation. J Dent Res 1993;72(#1607):304.
18. Haywood VB, Leonard RH, Dickinson GL. Efficacy of six-months nightguard vital bleaching of tetracycline-stained teeth. J Dent Res 1994;73 (#2358).

19. Leonard RH, Nelson CF, Haywood VB, Brunson WD. Retrospective study of Patient's Perceptions with Nightguard Vital Bleaching. J Dent Res 1995;74(#1820):239.
20. Dickinson GL, Russell CM, Downey MC, Curtis JR, Haywood VB, Myers ML, Johnson MH. Placebo/Controled Clinical Trial of 10% Carbamide Peroxide. J Dent Res 1996;75(#121):33.
21. Haywood VB, Leonard RH. Six and 12-month Color Stability after 6-months Bleaching Tetracycline Teeth. J Dent Res 1996;75(#2891):379.
22. Robinson F, Haywood V, Myers M. Effect of 10% Carbamide Peroxide on Color of Provisional Restorations. J Dent Res 1996;75(#2892):379.
23. Leonard RH, Phillips C, Haywood VB. Predictors for Sensitivity and Irritation in Nightguard Vital Bleaching. J Dent Res 1996;75(#2894):379.
24. Sharma A, Leonard RH, Haywood VB. Use of Different Concentrations of Carbamide Peroxide for Bleaching. J Dent Res 1996;75(#2895):379.
25. Leonard RL, Bentley C, Phillips C, Eagle JC, Garland GE, Gari GJ, Haywood VB. ADA Controlled Clinical Trial of a 10% Carbamide Peroxide Solution. J Dent Res 1997;76(#2365):309.
26. Leonard RL, Bentley C, Phillips C, Eagle JC, Garland GE, Gari GJ, Haywood VB. Safety Issues of 10% Carbamide Peroxide in Clinical Usage. J Dent Res 1997;76(#2366):309.
27. Haywood VB, Caughman WF, Frazier KB, Myers ML, Bonita CY, Curtis JP, Christina-Beck L. Feasibility of Immediate Direct Thermoplastic Whitening Trays. J Dent Res 1998;77(#1337):273.
28. Pierson MC, Robinson FG, Haywood VB. Discoloration Protections for Provisional Restorations during 10% carbamide peroxide Bleaching. J Dent Res 1998;77(#1338):273.
29. Leonard RH, Knight MC, Haywood VB, Phillips C. Nightguard vital bleaching-Stability and Side Effects 82 Months Post-Whitening. J Dent Res 1998;77(#1339):273.
30. Haywood VB. Whitening teeth with Nightguard Vital bleaching. Practical Reviews in Pediatric dentistry, American Academy of Pediatric Dentistry.
31. Leonard RH, Haywood VB, Eagle JC, Garland GE, Matthews KP, Tart ND. Nightguard Vital Bleaching of Tetracycline Stained Teeth: 4.5 years post-treatment. J Dent Res 1999;78(#314):145.
32. Frazier KB, Parr GR, Ivanhoe JR, Haywood VB. Teaching Obstructive Sleep Apnea and the Use of Anti-Snoring Oral Devices. J Dent Ed 2000;64(#175):220.
33. Haywood VB, Caughman WF, Frazier KB, Myers ML. Tray delivery of Potassium Nitrate-Fluoride to reduce bleaching sensitivity. J Dent Res 2000;79(#3001):519.
34. Tanner JC, Smith BL, Rueggerberg FA, Haywood VB. Effect of Dentist-prescribed Home bleaching on Orthodontic Bracket Retention. J Dent Res 2001;80(#1359):205.
35. Leonard RH, Haywood VB, Caplan DJ, Tart ND. Nightguard Vital Bleaching of Tetracycline Stained Teeth 7.5 Years Post-treatment . J Dent Res 2002;81 (#1962):254 .
36. Perry AO, Haywood VB, Adair SM. Nightguard Vital Bleaching for the Adolescent Dental Patient. Presented at annual session: American Academy of Pediatric Dentistry, Denver, CO, May 2002
37. Holmes R, Parker M, Haywood V. Computer-Based Real-Time Feedback from Dental Students using Classroom Performance System. J Dent Edu 2003;67(2):162.
38. Haywood VB. Vital Tooth Whitening – An Update on Safety and Efficacy. J Dent Res 2003; 82 (Spec Iss B #2346):B-304.
39. Haywood VB, Cordero R, Gendreau LD, Kotler M, Littlejohn S, Smith SR, Fabyanski J, Rubb R, Fernandez PM. A Study of KNO3/F toothpaste as a pretreatment to bleaching. J Dent Res 2005: (#2126)
40. Holmes RG, Blalock JS, Parker MH, Haywood VB.Student accuracy and evaluation of a computer-based audience response system. J Dent Educ. 2006 Dec;70(12):1355-61.

PUBLICATIONS in Refereed Journals

1. Koth DL, Haywood VB. Articulation of Posterior Quadrant Impressions for Cast Restorations, J Prosthet Dent 1980, 44: 394-397.
2. Haywood VB, Brantley CF, Koth DL. Custom shade tabs for esthetic provisional restorations. J Prosthet Dent 1985, 54: 621-623.
3. Haywood VB, Ricks RB, Wall JT. A single appointment technique for re-use of an existing crown after tooth fracture. J Prosthet Dent 1986, 55: 182-183.
4. Haywood VB. Seating Castings. J Prosthet Dent 1986, 55: 405-406.
5. Haywood VB, Lundeen TF, Taylor DF. Tensile Bond Strengths of Comspan to Electrolytically Etched Metal with and Without Enamel Bonding Agent. Journal of Dental Materials 3: 29-32, 1987.
6. Heymann HO, Haywood VB, Andreaus SB, Bayne SC. Bonding Agent Strengths with Processed Composite Resin Veneers. Journal of Dental Materials 3: 121-124, 1987.
7. Haywood VB, Taylor DF, Lundeen TF, Andreaus SB. Concentration of Solutions for Electrolytically Etching Rexillium III. Journal of Dental Materials 3: 150-152, 1987.
8. Haywood VB, Heymann HO, Kusy RP, Whitley JQ, Andreaus SB. Polishing Porcelain Veneers: An SEM and Spectral Reflectance Analysis. Dent Mater 4: 116-121, 1988.
9. Haywood VB, Kanoy BE, Bruggers KJ Andreaus SB. Thermal Removal of Composite Resin: Effect on Rebonding Etched Metal. J Prosthet Dent 1990;63:289-91.
10. Haywood VB, Heymann HO. Nightguard Vital Bleaching. Quintessence Int 20: 173-176, 1989. (Reprinted: Gouttiere Nocturne Et Blanchiment Vital. Clinic Odontologia 2; 95-98, 1989. Reprinted: Imbiancamento Dedenti not devitalizzati mediante apparecchio notturno. Quintessence Int Dental Digest 1990; 1:37-40.)
11. Haywood VB, Heymann HO, Scurria MS. Effects of Water, Speed and Experimental Instrumentation on Finishing and Polishing Porcelain Intraorally. Journal of Dent Mater 5: 185-189, 1989.
12. Maryniuk GA, Haywood VB. Placement of Cast Restorations over Direct Pulp Capping Procedures: A Decision Analytic Approach. Journal of the American Dental Association, Vol 120; 183-188, 1990.
13. Haywood VB. Using a dentin bonding agent for cementation of etched-metal resin-bonded fixed partial dentures. General Dentistry 37(5); 413, 1989.
14. Haywood VB, Leech T, Heymann HO, Crumpler D, Bruggers K: Nightguard Vital Bleaching: Effects on Enamel Surface Texture and Diffusion. Quintessence Int 1990;21:801-806. (reprinted Blanqueamiento vital nocturno. Efectos sobre la textura de la superficie del esmalte y difusión. Quintessence (Edición Española) 5(2);1992:65-68.)
15. Haywood VB: Nightguard Vital Bleaching: Current Information and Research. Esthetic Dentistry Update 1990;1(2),7-12.
16. Haywood VB, Heymann HO: Nightguard vital bleaching: How Safe Is It? Quintessence Int 1991;22:515-523. (reprinted Blanqueamiento vital nocturno: ¿qué seguridad ofrece? Quintessence (Edición Española) 6(1);1993:3-11.)
17. Haywood VB, Houck VM, Heymann HO: Nightguard Vital Bleaching: Effects of varying pH solutions on enamel surface texture and color. Quintessence Int 1991;22:775-782.
18. Haywood VB. History, safety and effectiveness of current bleaching techniques: applications of the nightguard vital bleaching technique. Quintessence International, 1992;23:471-488. (reprinted in Spanish: Edición Española: Histora, seguridad y efectividad de las tecnicas de blanqueamiento actuales y aplicaciones de la tecnica de blanqueamiento vital nocturno. Quintessence (ed. esp.) 1994;7(9):546-564)
19. Haywood VB, Leonard RH, Nelson CF. Efficacy of foam liner in 10% carbamide peroxide bleaching technique. Quintessence International 1993;24:663-666.
20. Woolverton CJ, Haywood VB, Heymann HO. Toxicity of two carbamide peroxide products used in nightguard vital bleaching. American Journal of Dentistry 1993;6:310-314.
21. Haywood VB. Commonly asked questions about Nightguard Vital Bleaching. Journal of the Indiana Dental Association 1993;Sept/Oct:28-33.
22. Leonard RH, Bentley CD, Haywood VB. Salivary pH changes during 10% carbamide peroxide bleaching. Quintessence Int 1994;25:547-550.

23. Haywood VB, Heymann HO. Response of normal and tetracycline-stained teeth with pulp-size variation to nightguard vital bleaching. J Esthet Dent 1994;6(3):109-114.
24. Haywood VB, Leonard RH, Nelson CF, Brunson WD. Effectiveness, side effects and long-term status of nightguard vital bleaching. JADA 1994;125(9):1219-1226.
25. Leonard RH, Austin SM, Haywood VB, Bentley CD. Change in pH of plaque and 10% carbamide peroxide during nightguard vital bleaching. Quintessence Int 1994;25:819-823.
26. McCracken MS, Haywood VB. Effects of 10% carbamide peroxide on the subsurface hardness of enamel. Quintessence Int 1995;26:21-24.
27. Haywood, VB. Achieving, Maintaining, and Recovering Successful Tooth Bleaching. J Esthet Dent 1996;8(1):31-38.
28. Russell CM, Dickinson GL, Johnson MH, Curtis JW, Downey MC, Haywood VB, Myers ML. Dentist-Supervised Home Bleaching with Ten Percent Carbamide Peroxide Gel: A six-Month study. J Esthet Dent 1996, 8(4):177-182.
29. Curtis JW, Dickinson GL, Downey MC, Russell CM, Haywood VB, Myers ML, Johnson MH. Assessing the effects of 10 percent carbamide peroxide on oral soft tissues. JADA 1996, 127:1218-1223.
30. McCracken MS, Haywood VB. Demineralization effects of 10 percent carbamide peroxide. Journal of Dentistry 1996, 24(6),395-398.
31. Haywood VB, Leonard RH, Dickinson GL. Efficacy of six-months nightguard vital bleaching of tetracycline-stained teeth. J Esthet Dent 1997;9(1):13-19.
32. Haywood VB. Nightguard Vital Bleaching: Current Concepts and Research. JADA supplement 1997;128:19s-25s. (reprinted Archivos De Odonto Estomatologia 1998, 14(2):94-102)
33. Haywood VB. Historical Development of Whiteners, Clinical Safety and Efficacy Evaluation. Dental Update 1997;24:98-104. (Reprinted Oral Health 1999, April: 27-37)
34. Robinson FG, Haywood VB, Myers M. Effect of 10 Percent Carbamide Peroxide on Color of Provisional Restoration Materials. JADA 1997;128:727-731.
35. Heymann HO, Goldstein RE, Haywood VB, Freedman G. Bleaching of Vital teeth. Current Concepts, Quintessence International 1997,28(6):420-427.
36. Leonard RH, Haywood VB, Phillips C,. Risk Factors for developing tooth sensitivity and gingival irritation in nightguard vital bleaching.Quintessence International 1997;28:527-534.
37. Robinson FG, Haywood VB, David TJ. Dental Practices that aid the general dentist and forensic dentist. General Dentistry 1998;46(2):203-205.
38. Haywood VB, Powe A. Using Double-poured Alginate Impressions to Fabricate Bleaching Trays. Operative Dent 1998;23(3):128-131.
39. Haywood VB, Leonard RH. Nightguard Vital Bleaching removes brown discoloration for 7 years: A case report. Quintessence Int 1998;29(7):450-451.
40. Haywood VB. Critical Appraisal: At-Home Bleaching. J of Esthet Dent 1998; 10(2):94-98.
41. Leonard RH, Sharma A, Haywood VB. Use of different concentrations of carbamide peroxide for bleaching teeth. Quintessence Int 1998;29(8):503-507.
42. Frazier KB, Haywood VB. Correcting incisal defects in custom-fabricated bleaching trays. Quintessence Int 1998;29:565-566.
43. Carrillo A, Trevino MVA, Haywood VB. Simultaneous bleaching of vital teeth and an open-chamber nonvital tooth with 10% carbamide peroxide. Quintessence Int 1998;29:643-648. (Reprinted Clinic 1999;20(3):159-165)
44. Caughman WF, Frazier KB, Haywood VB. Carbamide peroxide whitening of nonvital single discolored teeth: Case Reports. Quintessence Int 1999;30:155-161 (Reprinted in Spanish: Edicion Espanola 2000;13(4):219-224.)
45. Oliver TL, Haywood VB. Efficacy of Nightguard Vital Bleaching Technique Beyond the Borders of a Shortened Tray. J Esthet Dent 1999;11(2):95-102.
46. Blankenau R, Goldstein RE, Haywood VB. The Current Status of Vital Tooth Whitening Techniques. Compendium 1999;20(8):781-796 (Reprinted in Bulgarian 2002).
47. McCaslin AJ, Haywood VB, Potter BJ, Dickinson GL, Russell CM. Assessing Dentin Color Changes from Nightguard Vital Bleaching. JADA 1999;130:1485-1490.

48. Haywood VB, Parker MH. Nightguard vital bleaching beneath existing porcelain veneers: a case report. Quintessence Int 1999;30(11):743-7. (Reprinted in J Dent Tech and Pros, Feb 2000 Japan.; Reprinted in German: Die Quintessenz 2000; 51(4):329-334; Reprinted in Spanish: Quintessence 2001)
49. Leonard RH, Haywood VB, Eagle JC, Garland GE, Caplan DJ, Matthews KP, Tart ND. Nightguard vial bleaching of Tetracycline-stained teeth: 54 months Post Treatment. J Esthet Dent 1999, 11:265-277.
50. Haywood VB. Ultralight Composite Resin for Whitened Teeth: Case Reports. Compendium 2000;21(4):340-346
51. Haywood VB. Current Status of Nightguard Vital Bleaching. Compendium 2000;21(suppl#28):s10-s17
52. Frazier KB, Haywood VB. Teaching Nightguard Bleaching and Other Toothwhitening procedures in North American Dental Schools. Journal of Dental Education 2000;64(5):357-364.
53. Robinson FG, Haywood VB. Bleaching and temporomandibular disorder using a half tray design: A clinical report. J Prosthet Dent 2000;83:501-3.
54. Haywood VB, Caughman WF, Frazier KB, Myers ML. Tray delivery of Potassium nitrate-fluoride to reduce bleaching sensitivity. Quintessence Int 2001;32:105-9.
55. Brantley DH, Barnes KP, Haywood VB. Bleaching primary teeth with 10% carbamide peroxide. Pediatr Dent 2001,23:514-516.
56. Haywood VB. Dentine hypersensitivity: bleaching and restorative considerations for successful management. Int Dent J 2002,52(5) supp1:376-384.
57. Haywood VB. Greening of the Tooth-Amalgam Interface during Extended 10% Carbamide Peroxide Bleaching of Tetracycline-Stained Teeth: A Case Report. J Esthet Restor Dent 2002;14:12-17.
58. Ritter AV, Leonard RH, St. Georges AJ, Caplan DJ, Haywood VB. Safety and stability of nightguard vital bleaching: 9 to 12 years post-treatment. J Esthet Restor Dent 2002; 14(5):275-285.
59. Bodden MK, Haywood VB. Treatment of endemic fluorosis and tetracycline staining with macroabrasion and nightguard vital bleaching: a case report. Quintessence Int 2003;34:87-91.
60. Haywood VB. Frequently Asked Questions about Bleaching. Compendium 2003,24(4A):324-338.
61. Haywood VB. New Bleaching Considerations compared with At-Home Bleaching. J Esthet Restor Dent 2003;15(3):184-188.
62. Leonard RH, Haywood VB, Caplan DJ, Tart ND. Nightguard Vital Bleaching of Tetracycline-Stained teeth: 90 months Post Treatment. J Esthet Restor Dent 2003;15(3):142-154.
63. Haywood VB. PERSPECTIVES on "Color Measurement Symposium 2003" J Esthet Restor Dent 2003;15(1):s3-4
64. Haywood VB. COMMENTARY on "Effects of bleaching CP gels on microhardness of Restoration materials. J Esthet Restor Dent 2003;15(3):183.
65. Haywood VB. COMMENTARY on "Comparison of effectiveness of two 10% CP tooth bleaching systems using spectrophotometric measurements. J Esthet Restor Dent 2004;16(6):375-76
66. Haywood VB, Cordero R, Wright K, Gendreau L, Rupp R, Kotler M, Littlejohn S, Fabyanski J, Smith S. Brushing with a potassium nitrate dentifrice to reduce bleaching sensitivity.J Clin Dent. 2005;16(1):17-22.
67. Gottardi MS, Brackett MG, Haywood VB. Number of in-office light-activated bleaching treatments needed to achieve patient satisfaction. Quintessence International, 2006; 37(2):115-120.
68. Haywood VB. Treating Sensitivity during Tooth Whitening. Compendium 2006;26(9):11-20.
69. Haywood VB. Nightguard Vital Bleaching: Indications and Limitations. US Dentistry 2006;18:2-8.
70. Holmes RG, Blalock JS, Parker MH, Haywood VB. Student Accuracy and Evaluation of a Computer-Based Audience Response System. Journal of Dental Education 2006;70(12):1355-1361.
71. Haywood, VB. Commentary on Remineralization Potential of a Fluoridated Carbamide Peroxide Whitening Gel. Journal of Esthetic and Restorative Dentistry 2006;18(4):212-213
72. Haywood, VB. Commentary on Case Report: Interaction of Peroxides with Amalgam. Journal of Esthetic and Restorative Dentistry 2007;19(4):212-213.
73. Baker PS, Haywood VB, Plummer KD. Method for immediate fabrication of an occlusal device. J Prosthet Dent 2007;98(5):411-5.

74. Browning WD. Haywood VB. Hughes N, Cordero R. Prebrushing with a Potassium Nitrate Dentifrice to Reduce Tooth Sensitivity During Bleaching Evaluated in a Practice-Based Setting. Compendium 2010; 31(3):220-225.

BOOKS AND CHAPTERS

1. Goldstein RE, Haywood VB, Heymann HO, Steiner DR, West JD. Chapter 21 entitled: Bleaching of Vital and Pulpless Teeth. In: Pathways of the Pulp, 6th ed. Cohen S and Burns RC, editor., C.V. Mosby Company, St. Louis, MO. 1994.
2. Heymann HO, Sockwell CL, Haywood VB. Chapter 18: Additional Conservative Esthetic Procedures. In: The Art and Science of Operative Dentistry, 3rd Ed., C.M. Sturdevant, editor. C.V. Mosby Company, St. Louis, MO. 1995, 643-647.
3. Haywood VB. Contributions to Chapters on Tooth Discoloration, Tooth Sensitivity, Toothache, Jaw Clicking and Jaw Problems. In: Symptoms: Their Causes and Cures. A. Feinstein, editor., Rodale Press, Emmaus, PA 1994.
4. Heymann HO, Haywood VB. Chapter entitled: Nightguard vital bleaching. In: Complete Dental Bleaching, by Goldstein RE and Garber DA. Quintessence Publishing Co., Chicago IL 1995.
5. Haywood VB. Contributions to chapter on Tooth Stains (528-531), in Home Remedies for Seniors. D Dollemore, editor. Rodale Press, Inc, Emmaus PA 1999.
6. Haywood VB, Berry TG. Chapter 15: Bleaching Teeth. In Fundamentals of Operative Dentistry: A Contemporary Approach. 2nd Edition. RS Schwartz, JB Summitt, JW Robbins editors. Quintessence Books 2001.
7. Haywood VB, Caughman WF, Goldstein RE. Chapter 16: Stains and Discolorations in Esthetics in Dentistry 2nd Edition, RE Goldstein, Editor, VB Haywood, Associate Editor, BC Decker. 2002
8. Haywood VB. Forward to "Bleaching Techniques in Restorative Dentistry", L Greenwall, Editor, Martin Dunitz , England 2001.
9. Haywood VB, Berry TG. Chapter 15: Bleaching Teeth. In Fundamentals of Operative Dentistry: A Contemporary Approach. 3rd Edition. JB Summitt, JW Robbins, TJ Hilton, RS Schwartz, editors. Quintessence Books 2006.
10. Haywood, VB. Tooth Whitening: Indications and Outcomes of Nightguard Vital Bleaching. 2007 Quintessence Publishing Co, Inc. Hanover Park, IL

APPENDIX II

Expert Witness Report Exhibits for FTC vs. North Carolina

12.18.2010

Dr. Van B. Haywood

Why dentist-supervised rather than non-dentist-supervised?

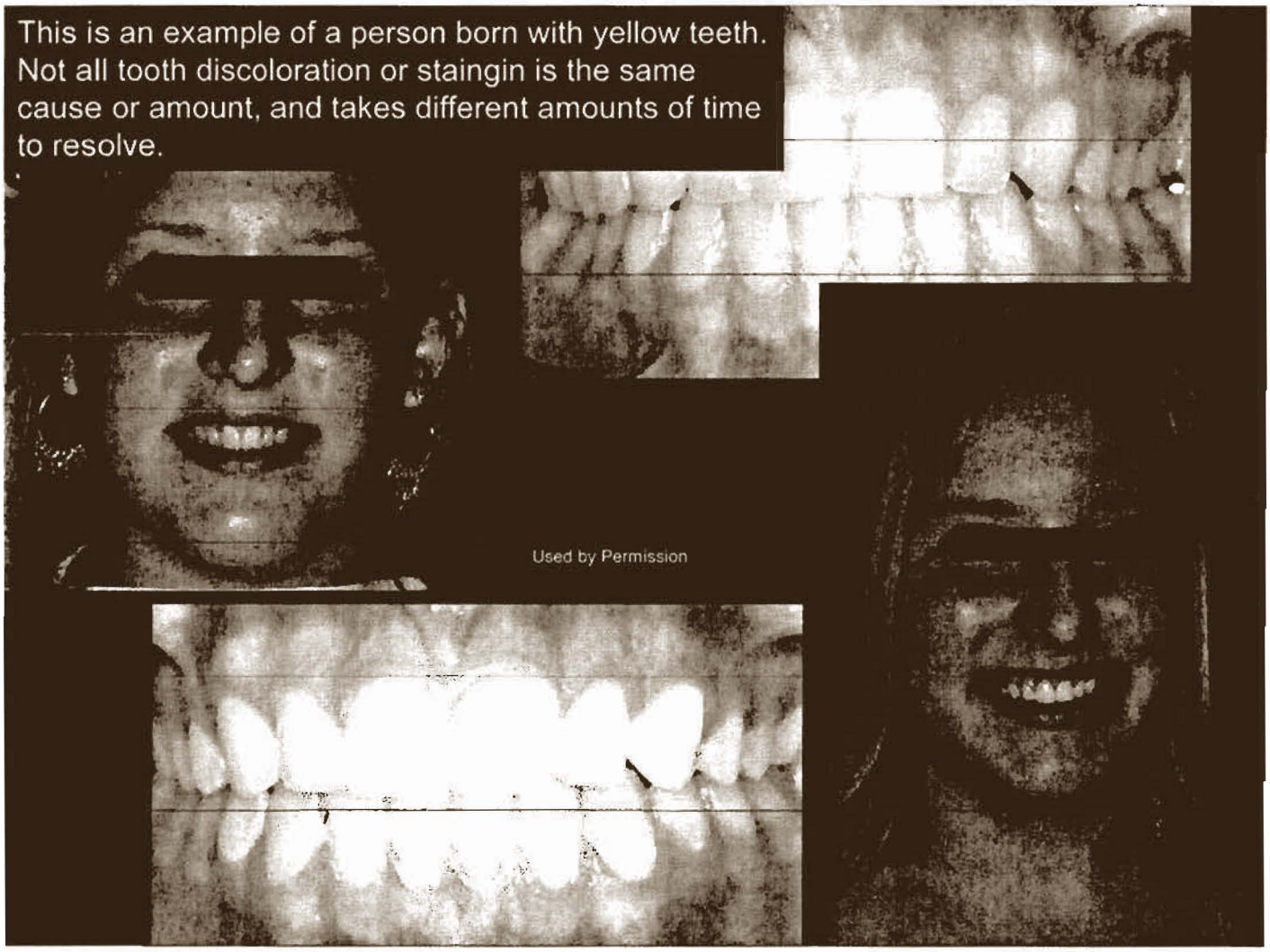
Diagnosis of Correct Cause of Discoloration

Other treatments needed for…

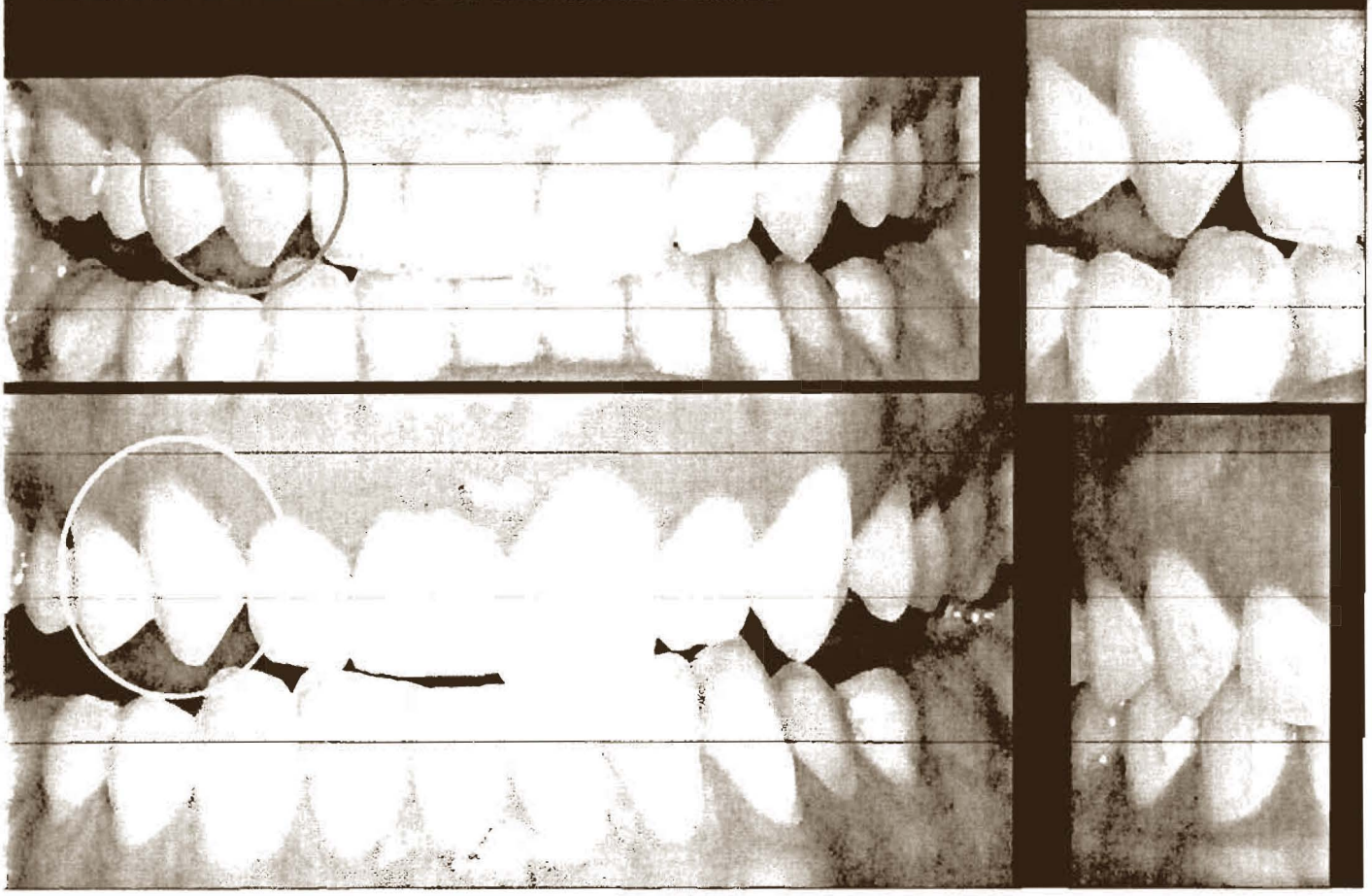
- Non-vital teeth
- Decay
- Internal resorption
- Lingual fillings

Bleaching Tx time varies with…

- Inherited
- Aging
- External Staining
- Nicotine
- Tetracycline


This is an example of a person born with yellow teeth.
Not all tooth discoloration or staingin is the same cause or amount, and takes different amounts of time to resolve.
Used by Permission

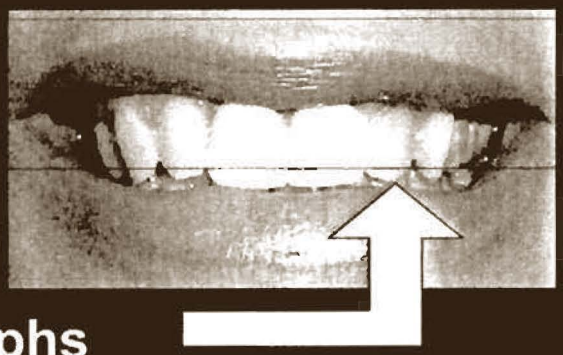
This person has canines (eye teeth) which are darker than normal. These teeth were genetically formed that way. The bleaching process goes into the tooth and changes the color of the dentin as well as removes stains.

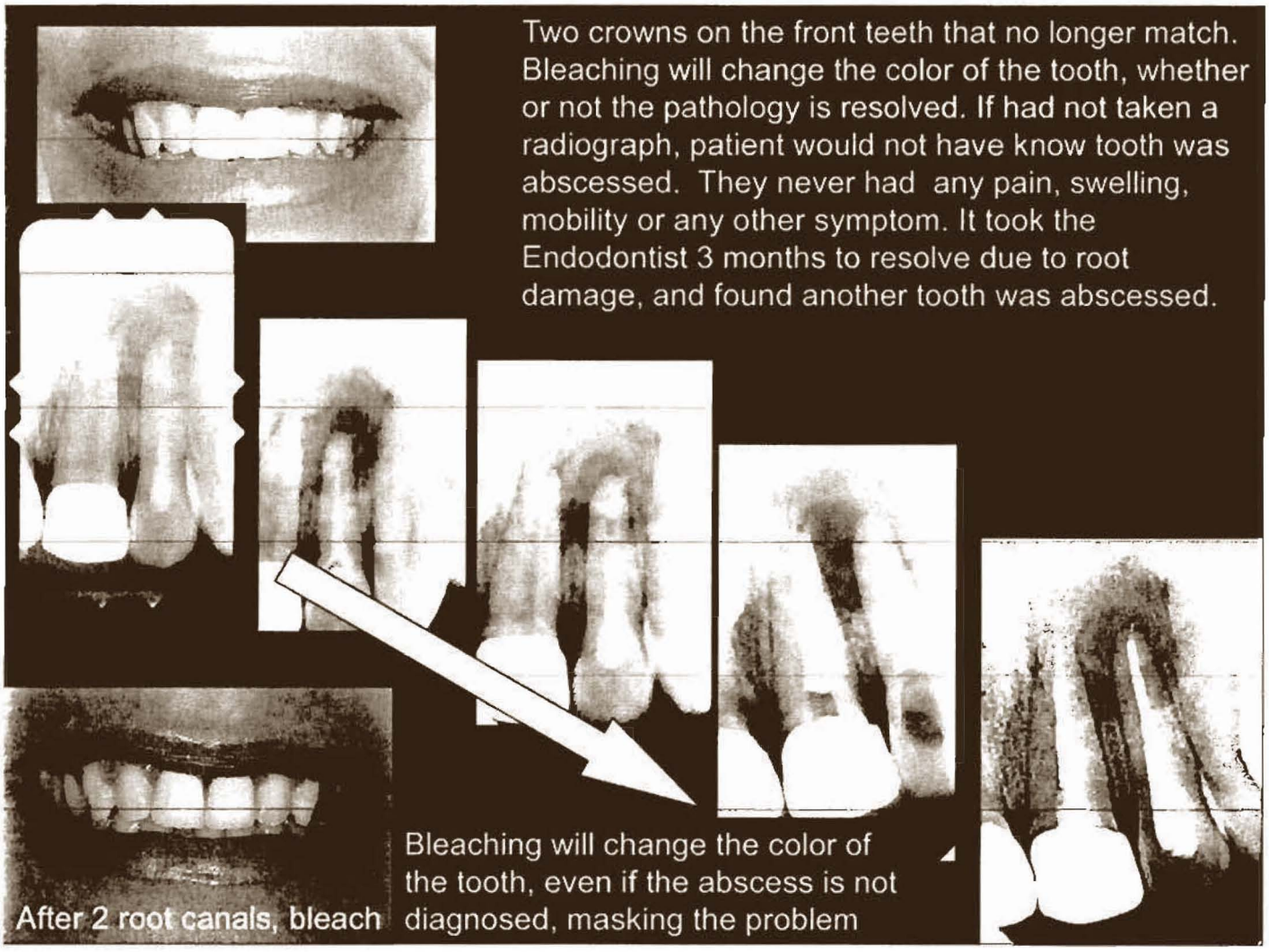


This patient though bleaching would solve the dark tooth, when in fact it was decay that made it dark. Treatment was no bleaching but the placement of a restoration.

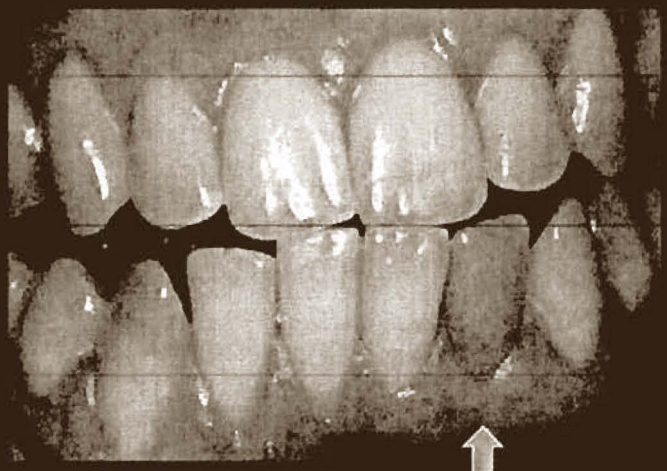
Why Dentist Supervised?

- Correct Diagnosis of Discoloration
  - Inappropriate TX avoided
  - Appropriate TX not delayed
- Baseline status & radiographs

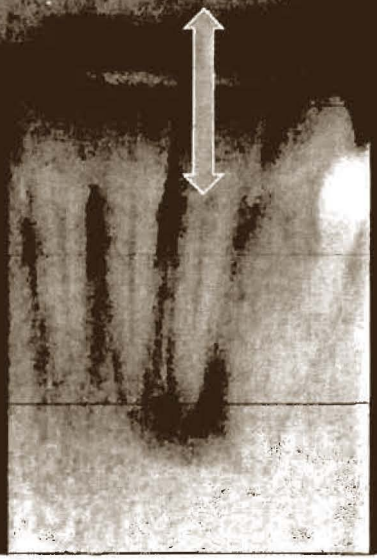


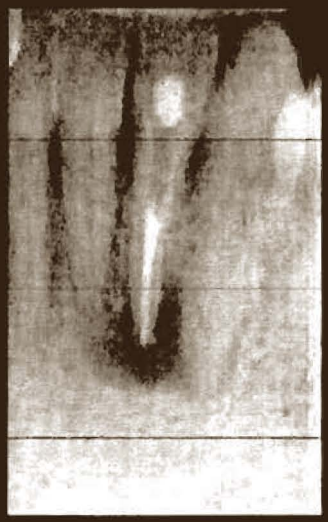

Two crowns on the front teeth that no longer match. Bleaching will change the color of the tooth, whether or not the pathology is resolved. If had not taken a radiograph, patient would not have know tooth was abscessed. They never had any pain, swelling, mobility or any other symptom. It took the Endodontist 3 months to resolve due to root damage, and found another tooth was abscessed.
Bleaching will change the color of the tooth, even if the abscess is not diagnosed, masking the problem
After 2 root canals, bleach

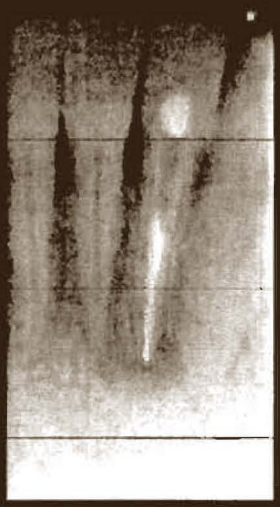
Why take radiographs at the examination?



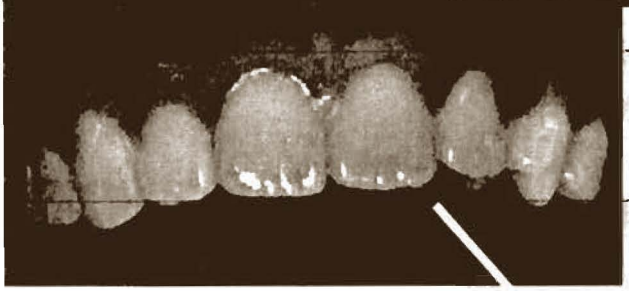
This patient had no pain, no swelling, only a dark tooth, which was abscessed. She did not know it was, and assumed the dark tooth on the left side (orange arrow) was the mirror to the dark canine on the right side (green arrow).



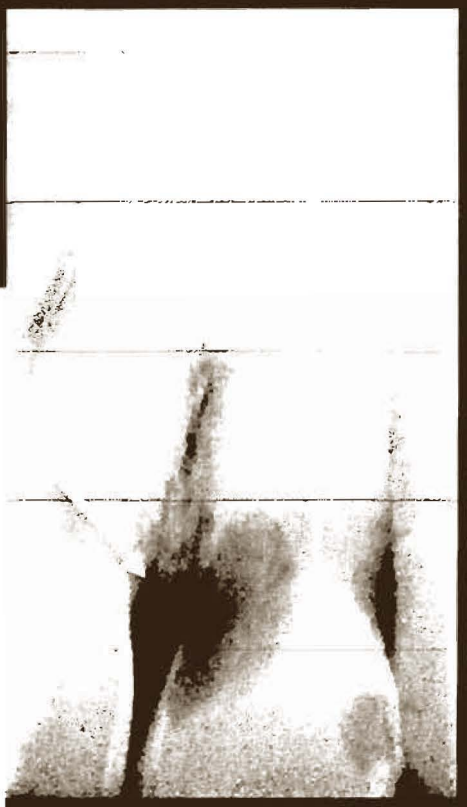




A complete examination for bleaching includes a careful clnical examination, as well as radiographs, especially of single dark teeth.



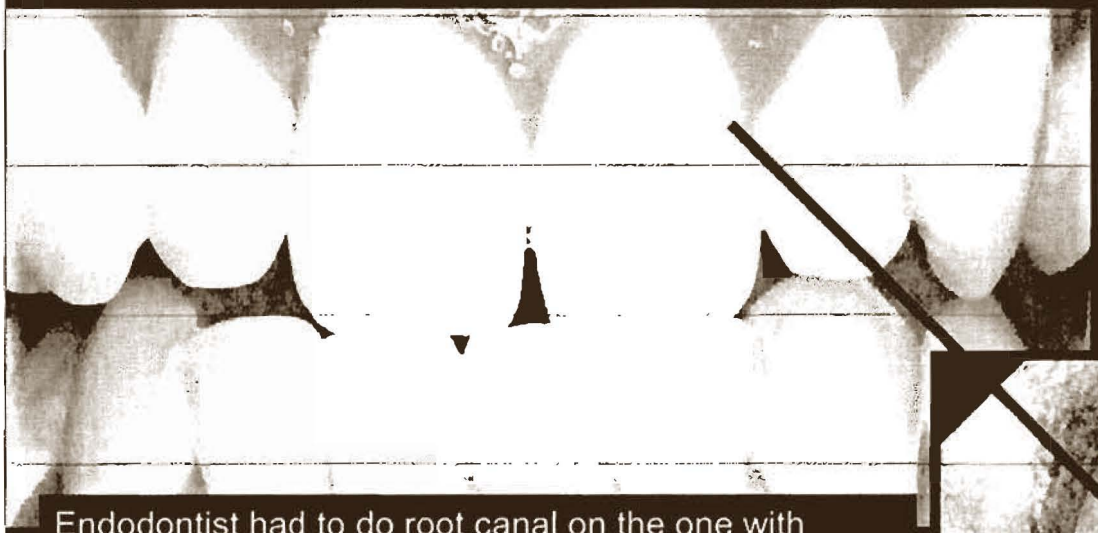
External Resorption: This patient (a dentist) had no pain, swelling or mobility. The only indication was a darkened tooth which was discovered when he had his teeth cleaned



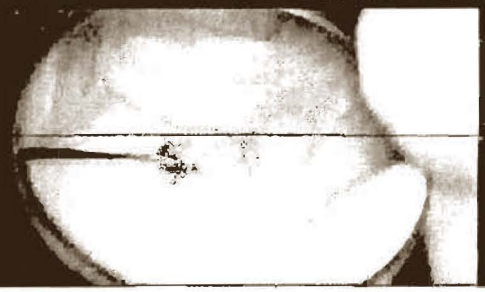
Courtesy of Dr. Tom McDonald

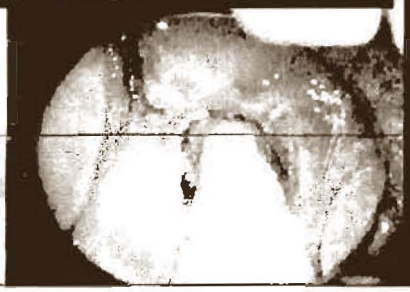
Treatment was a root canal, gum surgery, and a filling to try to save the tooth.

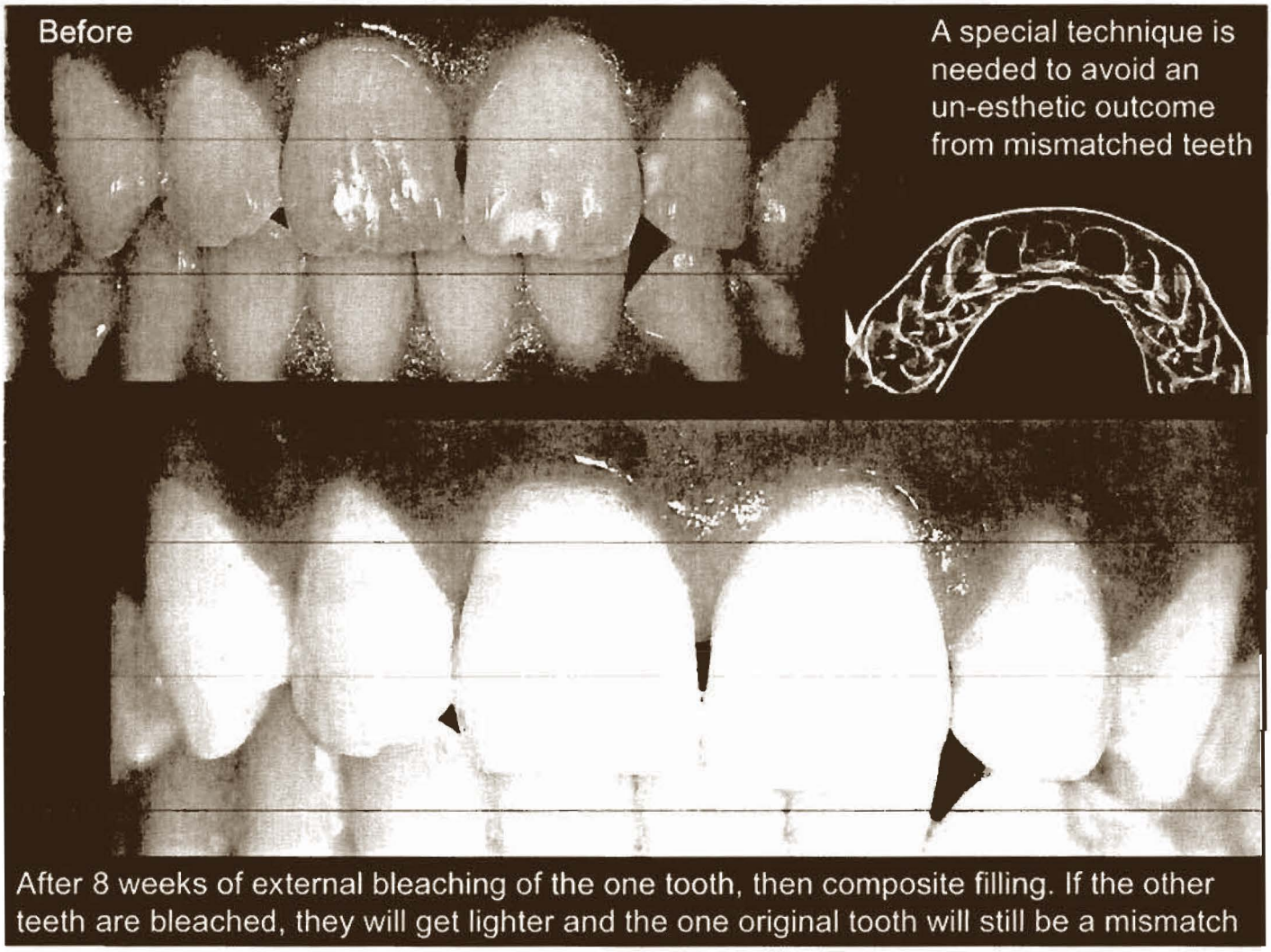
This patient (a dentist) had trauma in teenage years in football; Upon examination and x-ray, we found one tooth darkened and one tooth had external resportion. No pain, swelling, etc. in history. Without an exam and radiograph, this could not be done



Endodontist had to do root canal on the one with external resportion, as well as gum surgery to expose and remove the resorption on the tongue side.



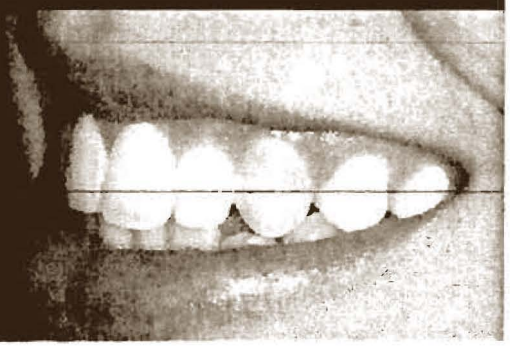


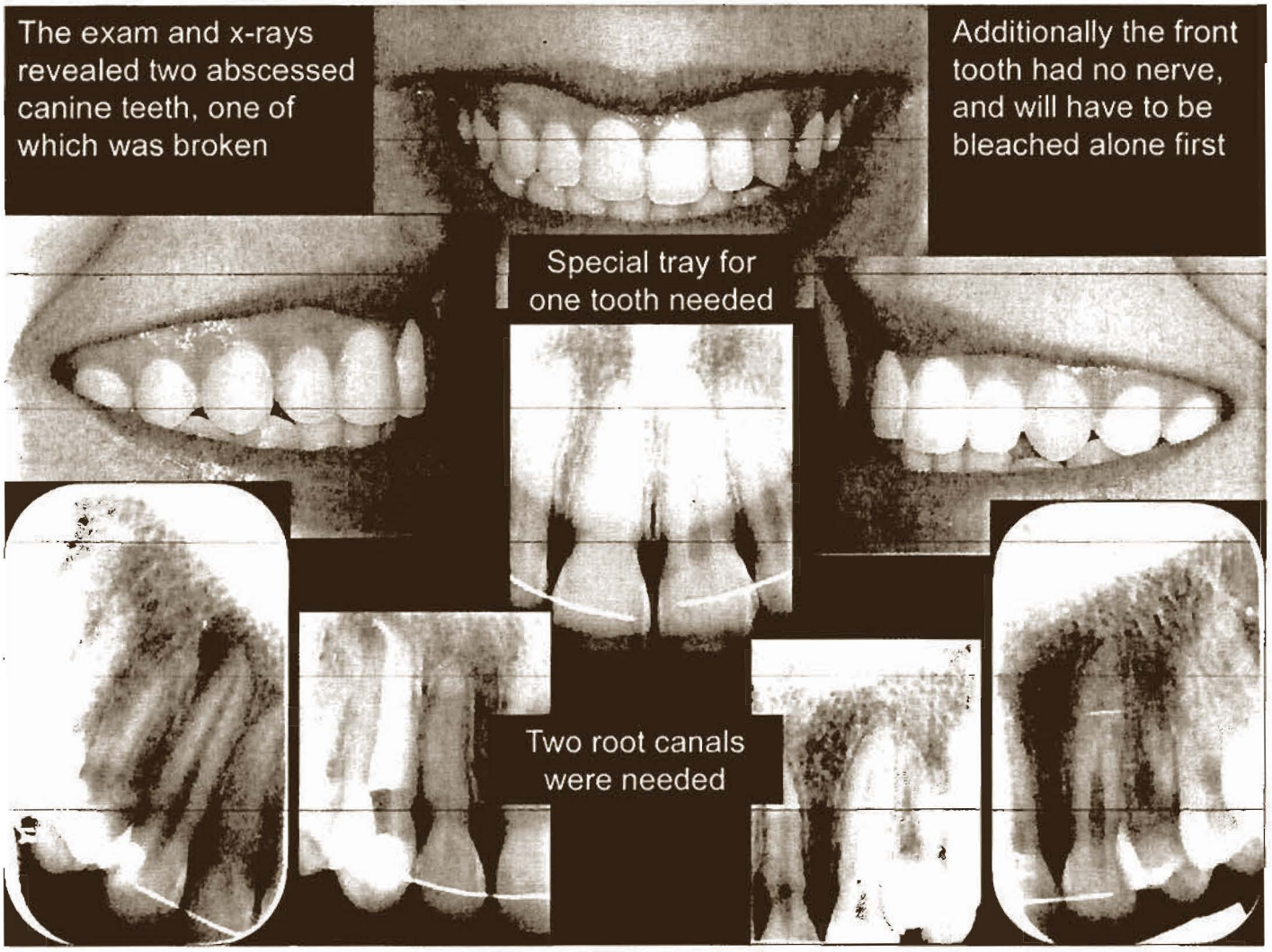

Before
A special technique is needed to avoid an un-esthetic outcome from mismatched teeth
After 8 weeks of external bleaching of the one tooth, then composite filling. If the other teeth are bleached, they will get lighter and the one original tooth will still be a mismatch

This is an x-ray of a young boy whose front tooth has started to dissolve (Internal Resorption). This problem often occurs from trauma, and the darkening of the tooth is the only indication of any problem. This tooth was discolored, but had no other symptoms

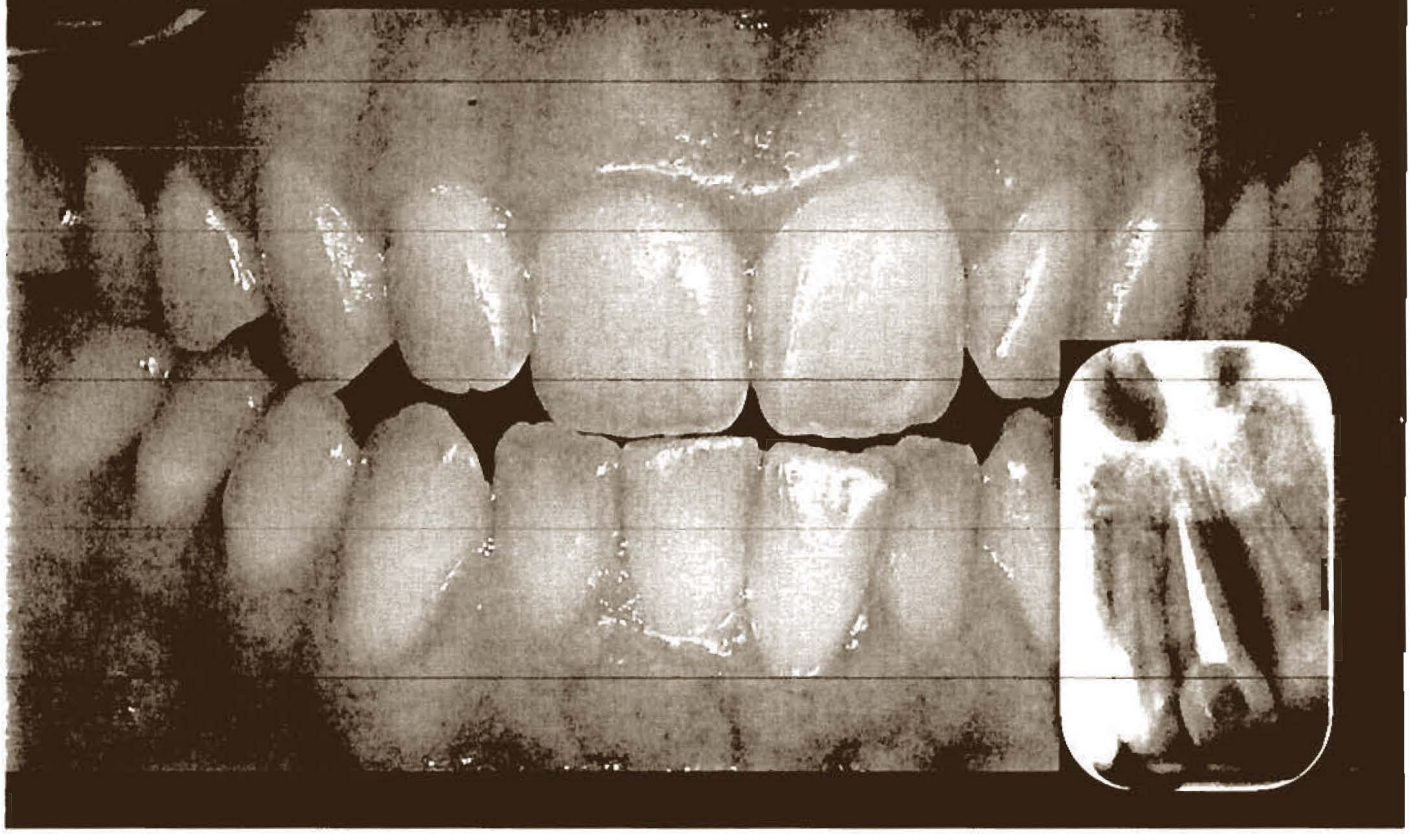
This college student inquired about bleaching, since one front tooth had become darker than the other one. She noticed her teeth had changed since high school.

She also noticed the two eye teeth did not match in color.

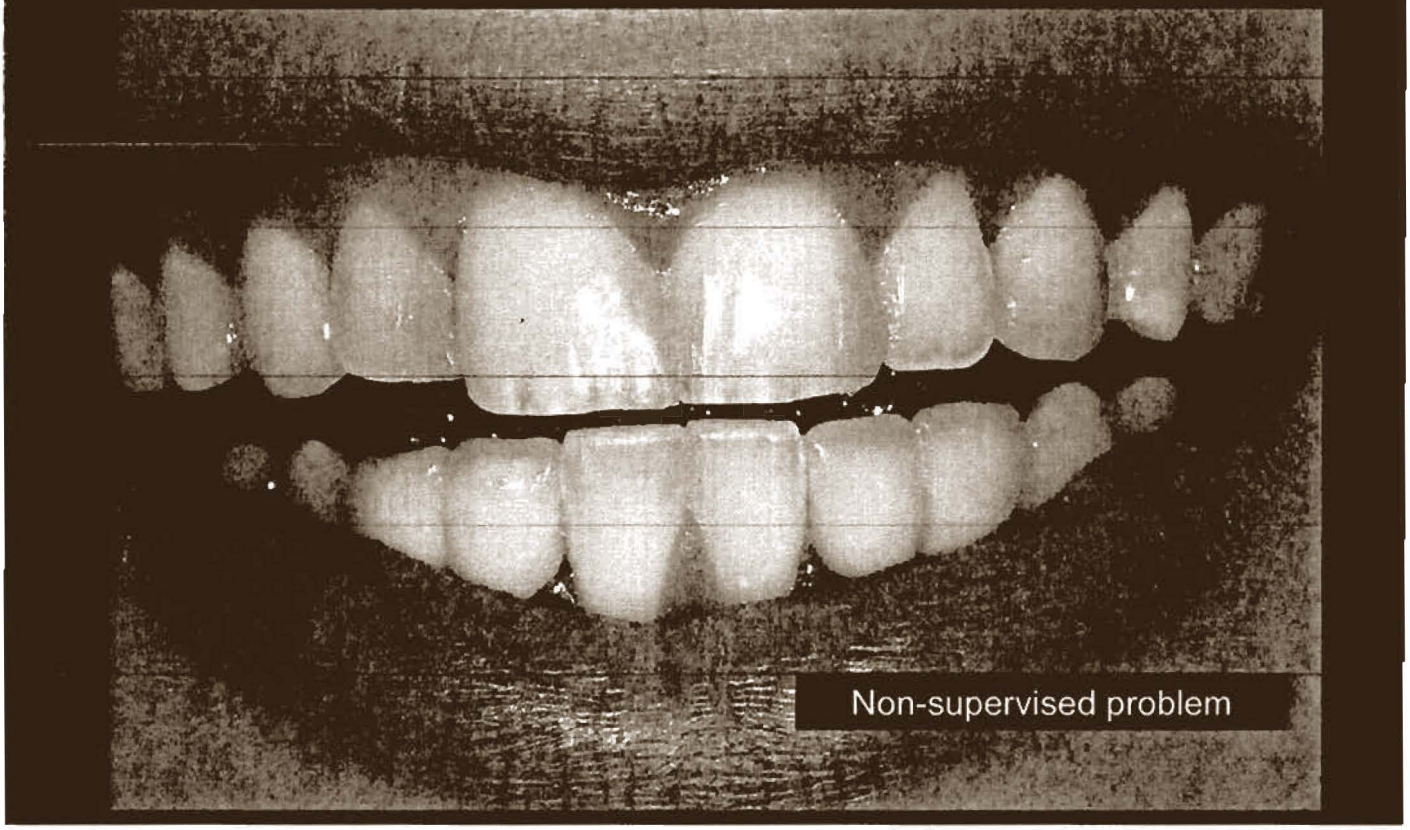


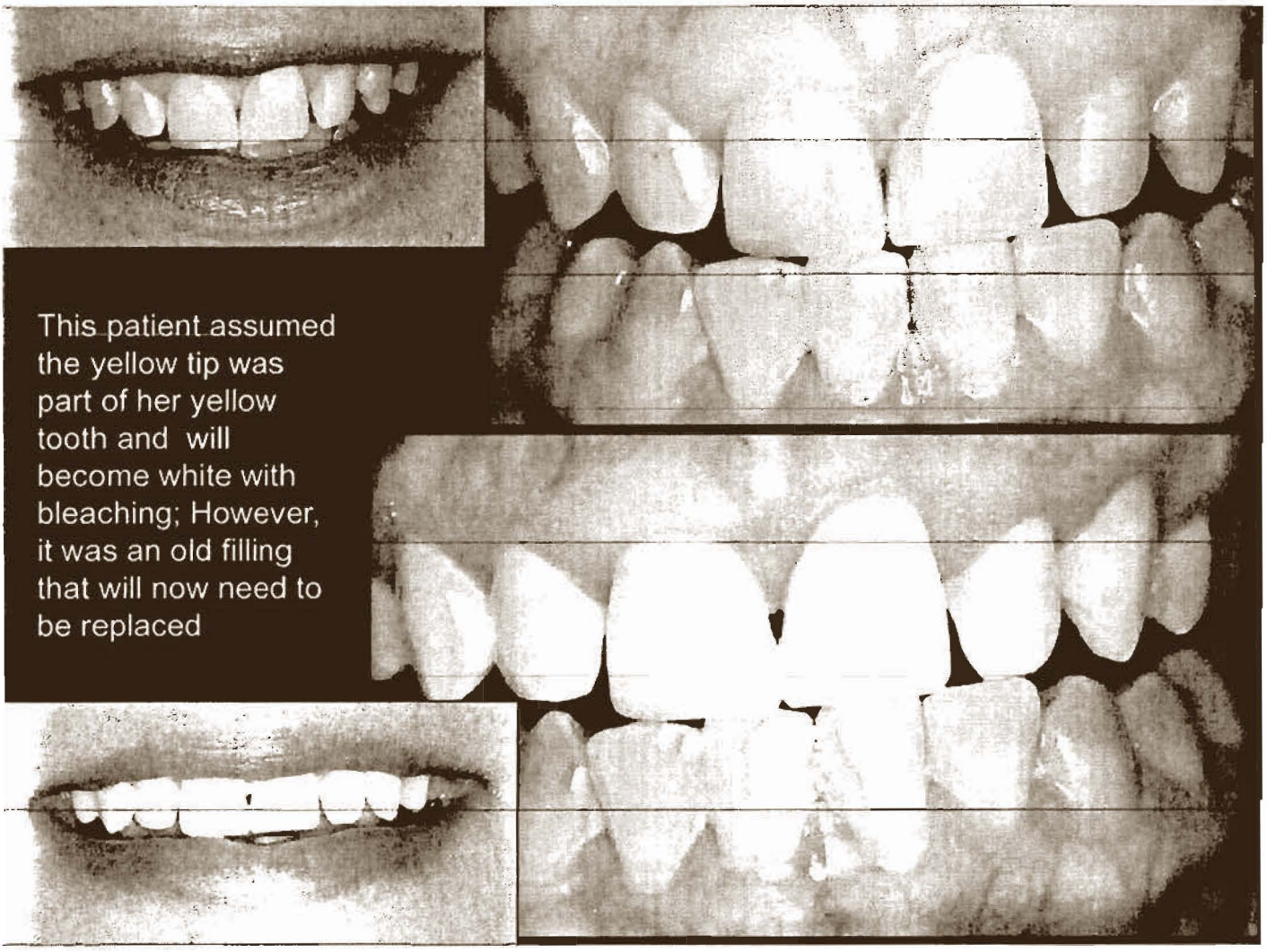

The exam and x-rays revealed two abscessed canine teeth, one of which was broken
Additionally the front tooth had no nerve, and will have to be bleached alone first
Special tray for one tooth needed
Two root canals were needed

This patient wanted to bleach her teeth, which seemed reasonable clinically. However a radiographs revealed she had a root canal on one, which she had forgotten was done when she was young. Bleaching all teeth resulted in the others getting lighter, so a different tray for one tooth was used. Without an exam and x-ray, her teeth after bleaching would have been mis-matched.

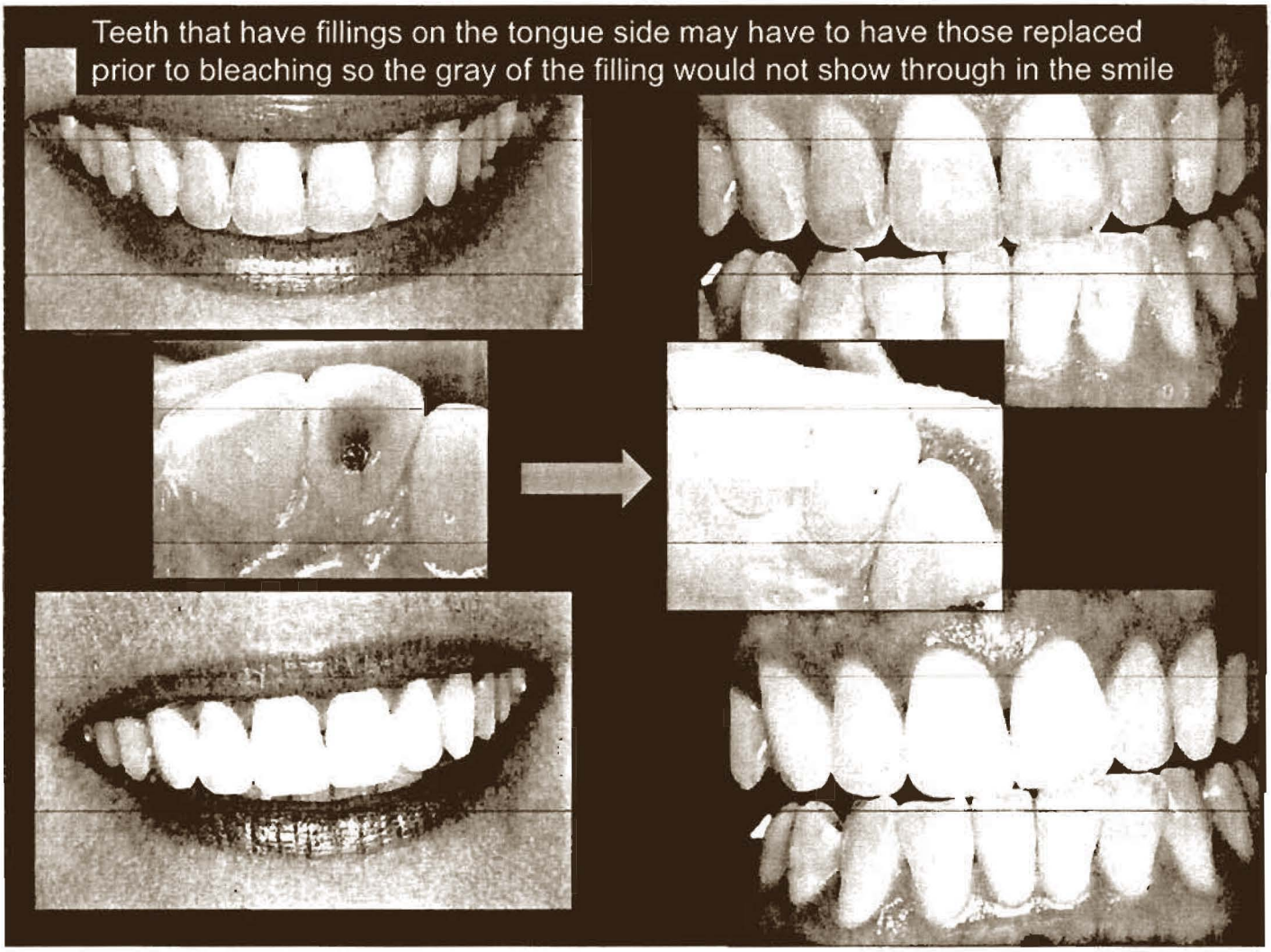


This patient bleached their teeth without dental supervision. She had forgotten that the dentist had closed spaces years ago with composite bonding. Now all the composite bonding looks yellow and needs to be replaced to have an esthetic smile. A proper examination would have alerted the patient to this financial treatment need.

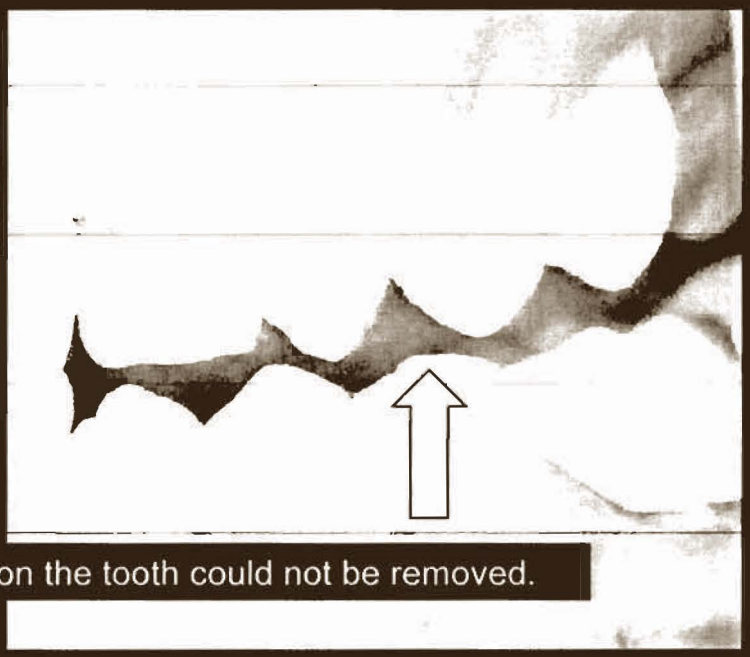




This patient assumed the yellow tip was part of her yellow tooth and will become white with bleaching; However, it was an old filling that will now need to be replaced


Teeth that have fillings on the tongue side may have to have those replaced prior to bleaching so the gray of the filling would not show through in the smile

Consider replacement of the amalgam in teeth in the esthetic zone prior to bleaching due to potential greening or translucency occurring during bleaching



After bleaching, the green discoloration on the tooth could not be removed.

Bleaching Examination Summary of considerations

Intra-oral exam soft and hard tissue (exclude cancer, gum problems, recession, etc.)

Radiograph (for apical abscess and single dark teeth)

Diagnosis tooth color and condition

Identify Esthetic Restorations

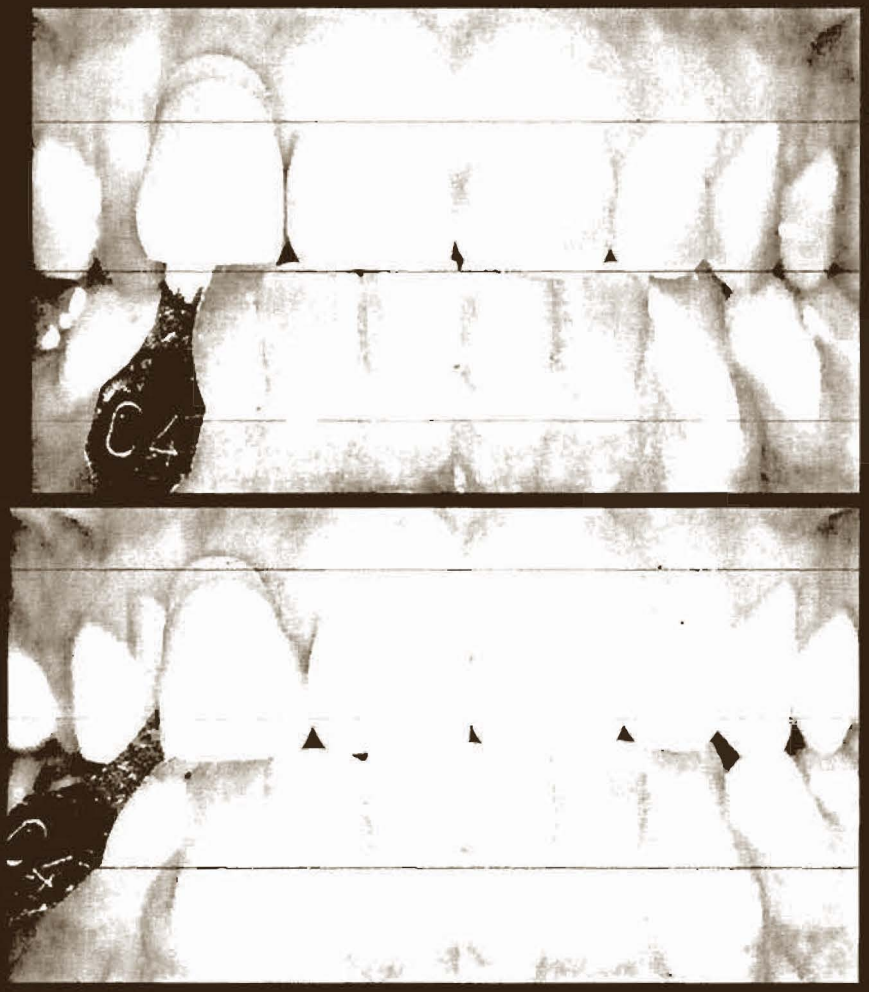
Perform a Smile analysis; Roots; white spots, Cracks; Defects, Esthetic potential, other appliances & lifestyle issues

Complete a Sensitivity history and exam

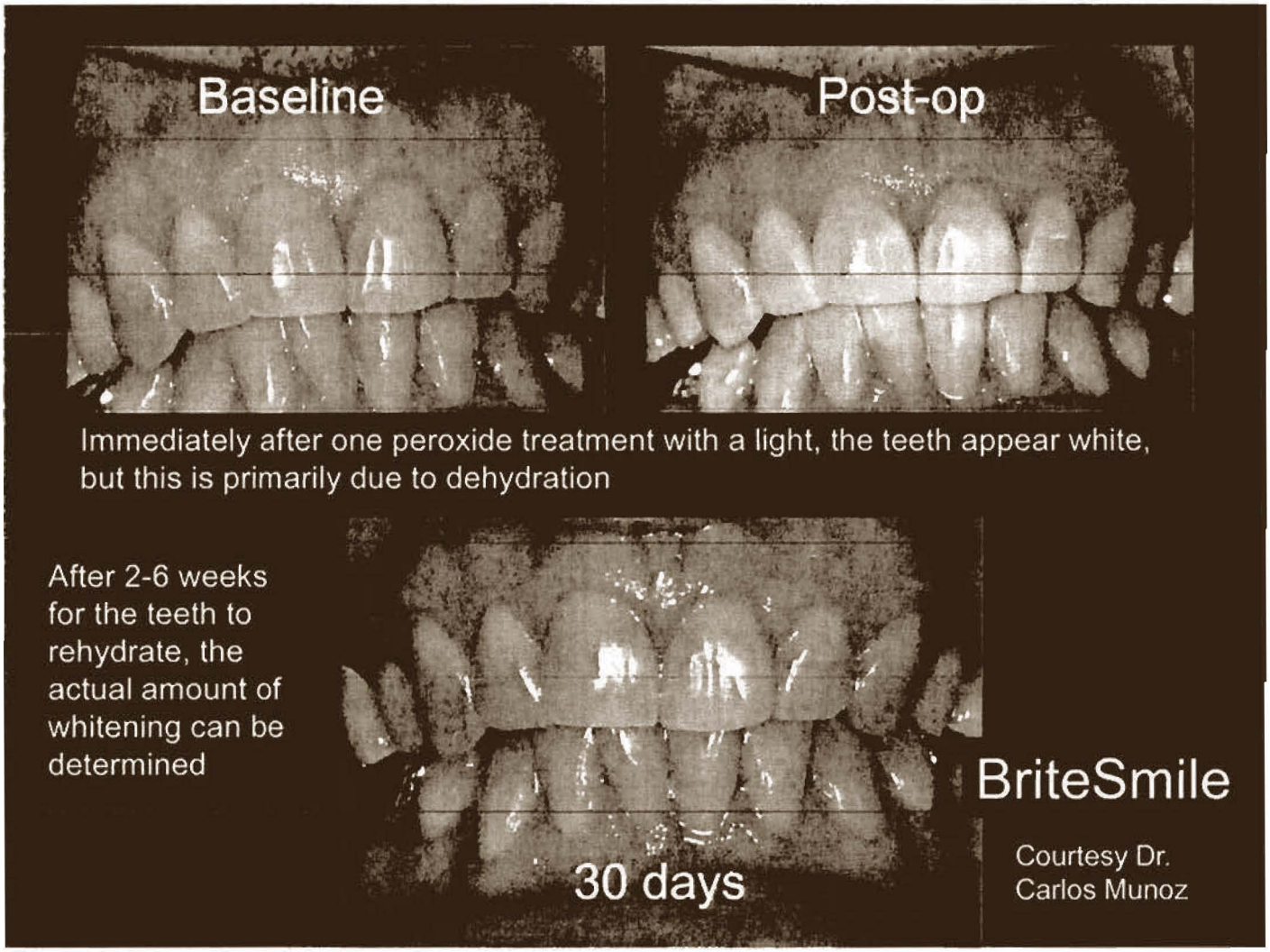
Perform, an Occlusion and TMJ screen

TETRACYCLINE STAINS take…

Six months of nightly treatment with tray bleaching; this cannot be done with one in-office bleaching by the dentist. A lesser concentration by a non-dentist would be less effective, and waste money. A proper diagnosis is needed to determine the cause and prognosis….

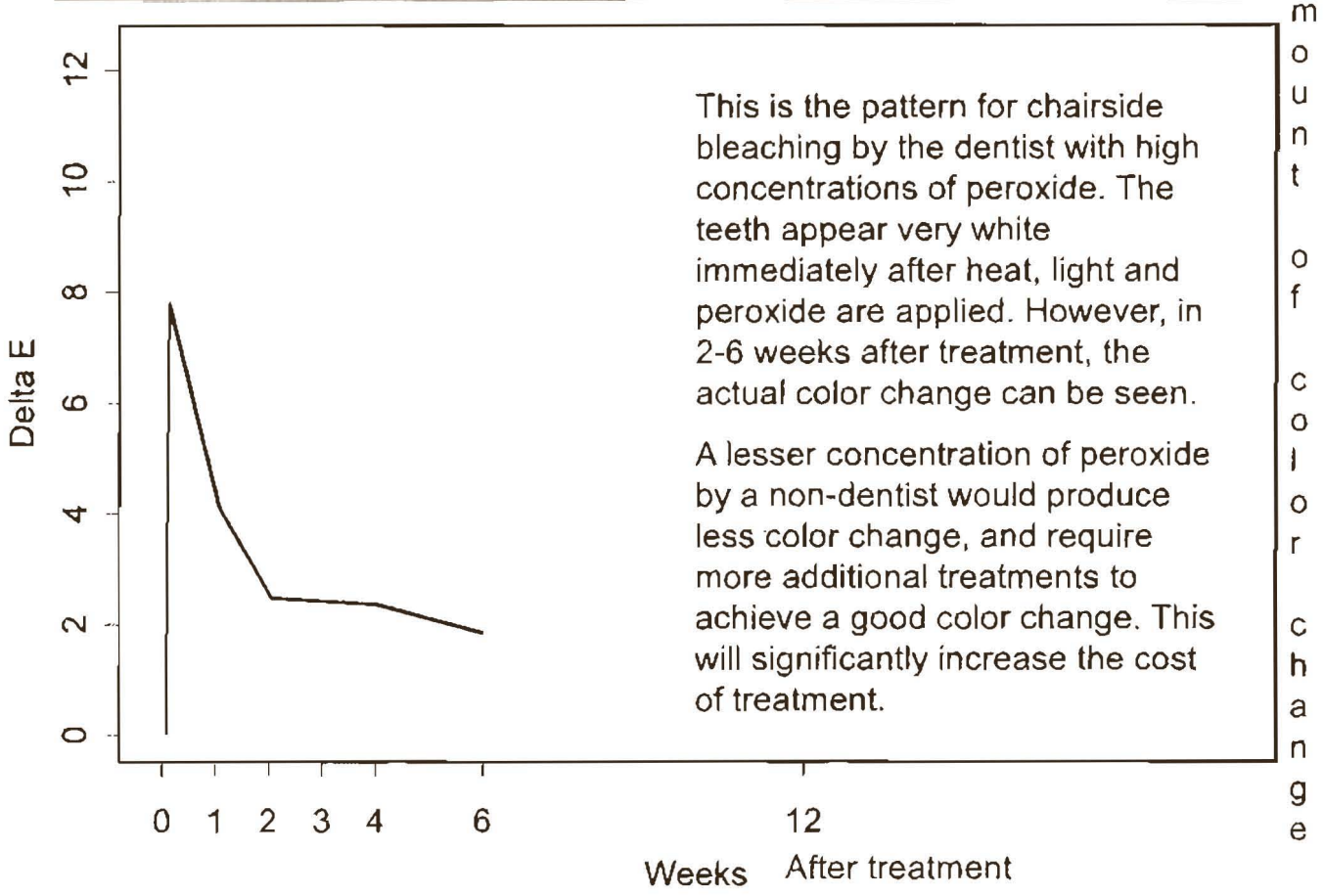


Efficacy of six-months nightguard vital bleaching of tetracycline-stained teeth.
Haywood VB, Leonard RH, Dickinson GL. J Esthet Dent 1997;9(1):13-19.


Baseline
Post-op
Immediately after one peroxide treatment with a light, the teeth appear white, but this is primarily due to dehydration
After 2-6 weeks for the teeth to rehydrate, the actual amount of whitening can be determined
30 days
BriteSmile
Courtesy Dr. Carlos Munoz

Eight in-office Tooth Whitening Systems evaluated in Vivo: A Pilot Study.

Matis, Cochran, Franco M, Al-Ammar, Eckert, Stropes. Operative Dent 2007



Examination: Diagnosis of discoloration and stain causes to decide on treatment options

- Genetic
- Tetracycline
- Smoking/coffee/tea
- Caries
- Discolored restoration
- Leaking restorations

- Single dark
  - Endodontic
  - Abscessed
  - Internal resorption
  - Silver point
  - Calcific metamorphosis

- Crown PFM: gray metal not change

Esthetic & Functional Diagnosis and Treatment

- Color of eyes and color of teeth match
- Gummy smile with short teeth not helped
- Other restorations that show in smile
- Defects in gingival harmony that are changed

- Sensitivity issues
  - Pre treatment
  - During treatment
- Tray design needed
  - Full
  - Single tooth
  - Off tissue or not
- Time of treatment
  - Day: # hours
  - Night
  - In-office

How do you compare the three options?

Efficacy, Side-effects and Patient's acceptance of Different Bleaching Techniques (OTC, in-office, at-home). Auschill TM, Hellwig E, Schmidale S, Sculean, A, Arweiler. Operative Dentistry 2005. 30-2,156-163.

Time to obtain a six-shade change:

7 nights of 10% CP =

16 days of Crest White Strips =

3 treatments of 38% HP

A lesser concentration of hydrogen peroxide by a non-dentist will take more treatments to reach the same amount of color change, and hence cost the consumer more

Concerns for non-dental bleaching bleaching Safety:

1. **Lack of Diagnosis for proper Treatment**
   (mask pathology; bleaching not indicated)

2. **Potential for less esthetic outcome**
   (restorations not identified, root canals not known)

3. **Unknown safety of higher concentrations**
   (no research above 15%HP, unsupervised)

4. **Unknown quality of product for some** (pH, allergic ingredients, etchants, other ingredients)

5. **Patient may not receive any or maximum benefit available for whitening**
   (due to shortened treatment time for difficult stains and discolorations, ineffective product)

Summary

Whitening is best performed in a professionally-supervised manner, with a proper examination and diagnosis, using appropriate materials for the patient and situation, with a fair fee for service.

Low concentrations of peroxide, especially 10% carbamide peroxide in a custom-fitted tray are generally the safest, most cost-effective, best researched whitening treatments available.

Other bleaching treatments such as in-office may be indicated based on patient preference, lifestyle, finances, or other limitations, but require informed consent after presenting cost/benefit and risk/benefit ratio.

Non-dentist bleaching does not have a good risk/benefit or cost/benefit ratio, and misleads the public as to safety and efficacy.

APPENDIX III

Statement Pursuant to Rule 3.31A of the FTC Rules of Practice for Adjudicative Proceedings of Data, Materials and Other Information Considered by Dr. Van B. Haywood, D.M.D. in Forming Opinions:

Reference is made to footnotes 1-56 of the accompanying Expert Witness Report of Van B. Haywood, D.M.D. (pages 19 – 22).

CERTIFICATE OF SERVICE

I hereby certify that the undersigned has this date served copies of the foregoing upon all parties to this cause by electronic mail as follows:

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Dated: December 20, 2010

/s/ Alfred P. Carton, Jr.

Alfred P. Carlton, Jr.

Attachment C

EXPERT WITNESS REBUTTAL REPORT OF
MARTIN GINIGER, D.M.D., M.S.D., Ph.D., F.I.C.D.

In the Matter of North Carolina Board of Dental Examiners, Docket No. 9343

I. INTRODUCTION

I am Dr. Martin Giniger. I have been engaged by Complaint Counsel as an expert in the history, practice, and safety of dental stain removal and vital teeth bleaching. I previously submitted an Expert Report in this matter.[1] I since have been asked to consider and comment on the Report submitted on behalf of the North Carolina State Board of Dental Examiners (the NCSBDE) by Dr. Van B. Haywood. Having now reviewed it, I note that Dr. Haywood's Report—indeed, much of his work—often uncritically accepts and promotes socio-economic agenda of organized dentistry, namely that commercial activity involving the oral cavity (other than the sale, without more, of toothbrushes, dentifrices, and the like) must be the exclusive domain of dentists (or persons "supervised" by dentists), lest the public be injured. His Report frequently relies, at least implicitly, upon the unsupported claim that profit-seeking commercial enterprises are willing to impose harm in order to profit, but that dentists are unaffected by profit-seeking motivation, and hence do not cause harm. This claim is simplistic, not within Dr. Haywood's professional expertise, and in my personal experience, wrong. Indeed, the claim is inconsistent with Dr. Haywood's recognition, elsewhere, that: "The biggest challenge in esthetic dentistry is to maintain the ethics of the dental profession, and to place patient care ahead of financial gain."[25] But seeking to profit, whether by commercial enterprises or by dentists, is not itself improper. What is important here is, as I indicated in my initial Report: teeth bleaching by non-dentists and by consumers themselves is safe and effective—facts demonstrated through study and through millions upon millions of applications over a number of years without evidence of resulting actual harm. Dr. Haywood willfully ignores the significance of these data, but he cannot and does not deny these essential facts.

Indeed, Dr. Haywood does not challenge many of the facts and opinions indicating the safety of teeth bleaching by non-dentists that I set down in my initial Report, at least implicitly conceding them. As for his own assertions of "fact," many are incorrect or incomplete. Some apparently are based on studies of dubious applicability to bleaching of vital teeth, such as studies involving the constant and prolonged administration of concentrated hydrogen peroxide to hamsters via stomach tube[24, 28] or the soaking of removed and de-pulped bovine and human teeth in peroxides.[29] Dr. Haywood ignores questions of the clinical significance of these studies and of other supposed facts that he finds, even where study authors and others have observed that clinical significance has not been demonstrated or that there is no clinical significance to a given finding.[19, 28, 30] And he ignores other critical but "inconvenient" information that is readily available,[16, 20] including even the ADA Frequently Asked Questions on Tooth Whitening safety in which the ADA states that "[w]hether tooth whitening is performed under the care and supervisions of a dentist, self-applied at home or in non-dental setting, whitening materials are generally well-tolerated when used appropriately and according to directions."[31]

Dr. Haywood's assertion that non-dentist-provided teeth whitening is unsafe is in tension, if not in conflict, with his own previous writings, and with the writings of other eminent practitioners and academics. For example, Dr. Haywood previously has written that: "The long-term safety of extended bleaching times using low concentrations of carbamide peroxide is well established"[25]; and that, "When properly supervised and dentist-monitored, vital nightguard tooth whitening with 10% carbamide peroxide is safe and effective, with no long-term post-treatment side effects (e.g., no external cervical resorption, gingival index and tooth vitality findings within normal range, no restorations or root canal therapy required as a result of whitening) reported at approximately 10 years post-treatment.[26] But Dr. Haywood's Report provides no satisfactory explanation as to why one would anticipate a different safety profile for similar uses of similar bleaching formulations just because in one instance they are dentist-applied or –prescribed and in others they are not. As Dr.

Haywood said of his Nightguard Vital Bleaching using a 10% carbamide peroxide formulation, there have been numerous studies with post-treatment recalls of non-dentist-provided teeth bleaching, and millions upon millions of non-dentist-provided teeth bleaching over many years, but there are no reports of long-term post-treatment side effects of vital teeth bleaching by non-dentists.

Working with Dr. Haywood, the professional association of American dentists, the American Dental Association, issued a report[18] that grudgingly concluded that, "published studies tend to suggest that bleaching[, however provided,] is a relatively safe procedure." But that report, like Dr. Haywood's Report , continued at the same time to discount non-dentist-provided teeth whitening because "investigators continue to report adverse effects . . . ." In a critique of the ADA report that appears equally applicable to Dr. Haywood's Report, Dr. Harald Heymann, co-developer of the Nightguard Vital Bleaching technique, noted that many of these "reports of adverse events" were dubious, and that the report ignored other "comprehensive and compelling reviews."[17] As he said with respect to some of the "concerns" noted in the ADA report, "Concerns that have been 'raised' have been totally unfounded, so why raise them in your report."[17] Dr. Heymann concludes that, "the report from the American Dental Association is overly exaggerated with regards to safety concerns and ignores volumes of evidence that indicates that if used as directed, most whitening systems, including at-home, in-office, and OTC bleaching products (from reputable manufacturers) are indeed safe and effective."[17]

Dr. Haywood's Report includes exhibits some of which convey misleading impressions—color photos in which the appearance of post-bleaching cosmetic "defects" is heightened through the photographers' obliteration of natural shadows and the far larger-than-life size of the photographs themselves. In any event, as I explain later in this Report, those photos are not evidence of any harm resulting uniquely from non-dentist-provided teeth bleaching or justifying the exclusion of those providers from the marketplace .

In sum, Dr. Haywood's principal opinions are unreliable at best and at times plainly incorrect. His Report does not in any way undermine my confidence in the opinions I expressed in my initial Report.

In my initial Report, I discussed my education, training, and experience, establishing my expertise in the oral medicine, including the prevention, diagnosis, and treatment of diseases and conditions affecting the oral cavity, and the history, practice, and safety of teeth bleaching. In brief, in addition to being degreed and licensed to practice dentistry (1984), I have a Specialty Certificate in Oral Medicine and a PhD in Biomedical Science with a concentration in Oral Biology (1993). My significant post-doctoral training has included Clinical Rotations at prestigious institutions in such subjects as Oral Pathology, and I have taught such subjects as Oral Diagnosis, Diagnostic Sciences, and Treatment Planning at Eminent Colleges of Dentistry. I have conducted extensive and original scientific research, which has been published such leading scientific journals as the Journal of Biological Chemistry and the Journal of Dental Research. My contributions have been recognized by, among other things, my receipt of the Lester Burket Memorial Award, which seeks to recognize and promote basic and clinical research in oral medicine. I have been employed by or consulted with the leading professional and consumer oral care companies, developing and/or designing, conducting, and evaluating clinical trials testing the safety and effectiveness of a variety of teeth bleaching and other oral care products.

II. MATERIALS CONSIDERED IN FORMULATING OPINIONS

In addition to the materials I considered in formulating my opinions in my initial Report, I now have read Dr. Haywood's Report, considered the references contained therein, and considered the additional References identified at the conclusion of this Report. I have consulted my own publications as I thought useful—see the publications section of my CV, appended to my initial Report—, and I have drawn on my extensive and unique personal knowledge of oral medicine and teeth whitening.

III. SCOPE OF WORK AND COMPENSATION

The scope of my work in this matter and my compensation are as described in my initial Report.

IV. SUMMARY OF OPINIONS

The principal opinions I express in this Report may be further summarized as follows:

- Non-dentist-provided teeth bleaching is not harmful to consumers, whether because non-dentists seek financial gain or otherwise.
- Non-dentist-provided teeth bleaching does not hinder diagnosis and treatment of diseases and conditions underlying discoloration.
- The esthetic-, cost-, and consumer protection-oriented claims expressed in Dr. Haywood's Report are insubstantial, and do not warrant the elimination of non-dentist-providers of teeth bleaching from the market.
- Non-vital teeth bleaching is not "the removal of stains."

V. DISCUSSION

A. Non-dentist-provided teeth bleaching is not harmful to consumers, whether because non-dentists seek financial gain or otherwise.

Dr. Haywood's Report implies that because non-dentist providers of teeth bleaching seek financial gain, the goods and services they provide are harmful to consumers. Dr. Haywood offers no evidence in support of his disparagement of for-profit providers of goods and services. My own experience, as one who has formulated teeth whitening products for use by dentists and non-dentists, is that dentists and non-dentists alike are motivated, at least in important part, by profit-seeking, but that neither dentists nor non-dentists subordinate consumer safety to those concerns. They know that it is neither right nor good for business. My own experience is that products used for dentist-provided teeth bleaching, non-dentist-provided teeth bleaching, and OTC sale are formulated, produced, and applied with care.

Dr. Haywood expresses his confidence in the safety of Nightguard Vital Bleaching using a 10% carbamide peroxide formulation, and then, like the ADA report I previously discussed, largely confines himself to argument of the "concerns have been raised" kind. I agree with Dr. Haywood that Nightguard Vital Bleaching using a 10% carbamide peroxide formulation, which he co-developed, is a fine teeth whitening technique. But his attack on other innovations in teeth whitening, and particularly on non-dentist-provided teeth whitening, is unsupported by facts or analyses. And it is worth special note that if, as Dr. Haywood suggests, the safety of other teeth bleaching techniques is questionable, the practices of dentists, who use the most highly concentrated bleaching agents, the brightest and hottest accelerating lights, etc. is more likely to pose safety risks than non-dentist-provided teeth bleaching. Nonetheless, neither Dr. Haywood, nor the ADA, nor the NCSBDE is on record as supporting prohibitions of any teeth bleaching products/services when used or sold by dentists. This seemingly reflects either the condoning by them of conduct by dentists that Dr. Haywood says may be harmful to consumers, or their lack of commitment to Dr. Haywood's expressed view that teeth bleaching other than Nightguard Vital Bleaching using a 10% carbamide peroxide formulation may be harmful. Whatever, Dr. Haywood's belief, it is apparent to me that vital teeth bleaching, whether by dentists, non-dentists, or consumers using OTC products, is safe and effective. There have been hundreds of millions of vital teeth bleachings over a period of many years, including tens of millions by non-dentists and consumers themselves. And yet, the literature shows no harm—and this despite a concerted ADA effort to identify and collect any and all such instances.[32] At some point, real-world-experience must trump Dr. Haywood's empty arguments of the "concerns were raised" kind.

In my initial Report I discussed the safety of teeth bleaching at length. Among other things, I noted that the FDA has found hydrogen peroxide to be generally recognized as safe for use in foods and cosmetics, and, like its Canadian counterpart agency, deemed peroxide-based teeth bleaching products to be cosmetics. (See my initial Report at 25-16.) I discussed the European Union's

decision to limit concentration and use of peroxides in teeth bleaching products, and the inapplicability to vital teeth bleaching of the studies on which that decision was based—such as studies in which concentrated hydrogen peroxide was constantly and for a prolonged period administered to hamsters via stomach tube. (See my initial Report at 33-35.) I shared calculations demonstrating that peroxide exposure from teeth bleaching is well below any known risk level for humans. (See my initial Report at 33-34.) And I noted that to this day, the FDA continues to allow the unfettered sale of vital teeth bleaching products to dental professionals, lay-operated dental bleaching facilities, and consumers as recognizedly safe cosmetic products. (See my initial Report at 35-36.)

Dr. Haywood's report does not dispute any of this, and it must be taken as conceded. Indeed, given the NCBDS' position, Dr. Haywood's Report says remarkably little about the safety of non-dentist-provided teeth bleaching, which itself must be taken as a concession. Dr. Haywood's Report makes six claims that non-dentist-provided teeth bleaching poses a direct risk of harm to consumers. As I demonstrate below, none of those claims are well founded.

First, Dr. Haywood's Report notes the EU action to which I've referred and the stated reasons for it. As I have said, I addressed the EU action and its antecedent studies in my initial Report (See my initial Report at 33-36). I would now add only that Dr. Haywood neither responds to my critique nor endorses the EU's findings/actions, which restricts dentists' use of peroxides as well as others' use.

Second, Dr. Haywood's Report asserts that, "There are reports in the literature of OTC issues causing damage to the teeth, and those related to product abuse by the patient or improper pH of the material" [sic]. I have three observations with respect to this assertion. First, Dr. Haywood does not provide any evidence, and there is no compelling reason to believe, that abuse of non-dentist-provided at-home teeth bleaching products, if any, is greater than abuse of dentist-provided at-home products. Second, I have substantial experience as a formulator of bleaching products for

use by dentists and non-dentists and as a consultant to manufacturers of these products, based upon which I can state with confidence that the role of pH in providing a stable, effective, and safe formulation are well understood and adhered to. Perhaps that is why Dr. Haywood cites only one article for his claim—an article published in 1991, at which time at-home teeth whitening was in its infancy.[33] In fact, the studies demonstrate that *in* vivo applications of 6% hydrogen peroxide did not affect the surface properties of enamel as compared to water, whereas, "Orange juice treatment reduced surface enamel hardness by 84.4%, and significantly alters surface topography of the enamel."[34] Last, in the period following publication of the 1991 article cited by Dr. Haywood, there have been millions upon millions of teeth bleaching using OTC products, and, and more than a 100 million teeth bleachings in total, and yet the literature is empty of reports of damage to teeth, and replete with studies demonstrating safety and efficacy.[16, 20, 35]

Third, in a related claim, Dr. Haywood's Report maintains that the manufacture and sale of vital teeth bleaching products is not regulated, and that therefore non-dentist-providers of teeth bleaching products/services and their customers have no way of knowing the pH or other compositional aspects of those products. This also is plainly untrue. As Dr. Haywood likely knows, manufacturers of vital teeth bleaching products are required to supply a Materials Safety Data Sheet (MSDS) for each product on request of any purchaser. In many instances, MSDSes are provided routinely to non-dentist-providers by manufacturers of vital teeth whitening products.[10, 11, 13] The MSDS is specifically intended to disclose to interested persons product composition, product properties of potential significance, including pH, and related safety issues. Moreover, based on my experience as a formulator of bleaching products for use by dentists and non-dentists and a consultant to manufacturers of these products, I can state that the quality of products intended for use by dentists and non-dentists is comparable, although products for non-dentists may use simpler formulations; all typically are manufactured in FDA approved labs using food-safe

ingredients, often by the same manufacturers; and FDA labeling guidelines require that such products, when sold directly to consumers, must disclose ingredients in an easily readable format.

More important, Dr. Haywood's claim falsely implies that non-dentist-provided products and services are likely to be harmful. As I demonstrate in this and my initial Report, the literature and the substantial history of non-dentist-provided teeth bleaching demonstrates that that too is untrue.

Fourth, Dr. Haywood's Report claims that there are no reports in the literature of studies proving the safety of non-dentist-provide teeth bleaching, but that there is one report out of England of harm from the use of a chlorine dioxide bleaching product by non-dentists,[36] and one report, nowhere identified by Dr. Haywood, "of a paint-on OTC product etching the tooth," following which, according to Dr. Haywood, the seller removed the product from the market. Apparently Dr. Haywood feels free to disregard numerous studies that demonstrate the safety and efficacy of non-dentist-provided teeth bleaching, which include reports of extensive clinical trials by Procter & Gamble demonstrating the safety and effectiveness of home-use products containing as much as 14.5% hydrogen peroxide.[37] His stated reasons are illogical, at best. He argues that because dentists played a part in the studies and because participants were selected based on defined inclusion/exclusion criteria (none of which Dr. Haywood describes or appear to have assessed), these studies are not relevant. As one with extensive education and training in the scientific method and extensive experience in the design and implementation of studies designed to determine the safety and efficacy of OTC teeth bleaching products, I can state with confidence that the mere participation of dentists in a study and the mere application of inclusion/exclusion criteria in participant selection does not render a study methodologically infirm. It is important that dentists participate in studies of the safety and effectiveness or oral care products, and that those studies have well-designed criteria for inclusion/exclusion of test subjects. However, dental participation and inclusion/exclusion criteria would be problematic only if the manner of dental

participation or the specific inclusion/exclusion criteria selected are poorly designed or executed such that the study is compromised, as where the sample is biased. But these distinctions appear to elude Dr. Haywood. Dr. Haywood's position is tantamount to claiming that studies cannot be designed to test the safety and effectiveness of non-dentist-provided teeth bleaching, and so its safety cannot be established, period. That is nonsense.

The Report's reference to one report out of England of harm from the use of a chlorine dioxide bleaching product by non-dentists and another of an OTC product that was pulled from the market by its seller after a reported instance of its etching a tooth certainly does not evidence a meaningful risk of harm from non-dentist-provided teeth whitening. To the contrary, chlorine dioxide is infrequently, if ever, used for vital teeth bleaching in the U.S., and likely was used in England as a substitute for peroxide because of the EU's unwarranted limitation of peroxide use. And the prompt seller-removal from the market of what may be the only OTC teeth bleaching product found to have etched a tooth suggests both the rarity and lack of clinical significance of any etching as a result of ordinary or anticipatable use of OTC teeth bleaching products and the care and responsibility exercised by sellers of those products and related services.

Fifth, Dr. Haywood's Report resoundingly states that "After a proper dental examination has determined that bleaching is indicated, then if the proper dental material is used and in the appropriate manner, bleaching is very safe" (reference omitted). But it then continues, claiming that there is no research demonstrating safety or efficacy of any bleaching using OTC products where that bleaching was not "initiated by a dental exam". Dr. Haywood's initial observation is true. But it is equally true that non-dentist-provided bleaching is very safe. Formulators of teeth bleaching agents are knowledgeable and cautious, and often the same formulators develop products for use by dentists and for the OTC market; users have information and incentive to use those bleaching agents appropriately; and prior dental examination has no impact on the safety of vital teeth bleaching, as I demonstrate in the following section of this Report.

Last, Dr. Haywood's Report acknowledges the importance of patient preference, lifestyle, finances, etc. in the selection of teeth bleaching modality. In this, it is plainly correct.[20] But it adds, "There is always a certain amount of risk for the patient which must be adequately determiner prior to the bleaching process." [sic] For this proposition, Dr. Haywood provides a general citation to three papers,[19, 28, 30] but without elaboration or discussion of any kind. Given that Dr. Haywood's Report does not rely on those papers for any findings with respect to specific risks and their clinical significance, I do not here "dissect" those papers. Rather, I offer the following observations, which are by no means intended to be inclusive, using Goldberg et al.[19] for illustrative purposes.

Goldberg et al. purports to assess the literature bearing on the potential risks of vital teeth bleaching in its various forms. I say "purports to," because it inexplicably fails to consider a significant literature that would have disturbed the authors' ruminations and conclusions, such as Munro et al.[16] and Sulieman[20]—articles that Dr. Haywood too failed to discuss (a particularly odd failing with respect to Munro et al., which was co-authored by Dr. Haywood's collaborator, Harold Heymann). The potential risks surveyed by Goldberg et al. include, for example, damage to the pulp, subacute and acute systemic toxicity, genotoxicity and carcinogenicity, and allergic reaction.

With respect to the effects of teeth bleaching on the pulp, Goldberg et al. claims that findings are inconsistent and controversial. However, pulpal effects from vital teeth bleaching, if any, are consequences of use of high concentrations of hydrogen peroxide in conjunction with intense light and heat sources as peroxide activators.[20] These intense light and heat sources, to the extent that they are still in use today, are used in dentist-provided chairside bleaching. The peroxide concentrations and light/heat sources used by—indeed, available to—non-dentist-providers of teeth whitening products and services are limited to light emitting diodes and other cool blue and white lights that elevate ambient temperature of 2° F or less. They do not generate even remotely sufficient heat to put pulpal health at risk. [20]

Sulieman[20], in particular, discusses effects of vital teeth bleaching on pulp, and after noting a purely theoretical concern with disruption of pulpal enzyme activity, concludes that the quantities of hydrogen peroxide (when used in conjunction with heat) that would be required to produce this disruption would be about 50 mg. Sulieman then observes that it has been shown that the quantities of hydrogen peroxide that diffuse into the pulp during vital teeth bleaching were only micrograms (an order of magnitude less than mgs)—and thus obviously too low to cause any permanent pulpal damage. Sulieman adds that use of carbamide peroxide, the bleaching agent most often used by non-dentist teeth whiteners, results in even less diffusion into the pulp. (Sulieman also notes that, "A number of studies have reported an increase in gingival health following bleaching procedures," probably because bleaching products are toxic to bacteria within the gingival crevice and persons undergoing bleaching "might take more interest in their teeth and as a result may improve their oral hygiene during the treatment.")[20]

Goldberg et al. does not establish any basis for concern about subacute toxicity, and acknowledges that there are no reports of such effects. With respect to acute cytotoxic effects, Goldberg et al., extrapolating from studies like the hamster study to which I earlier referred, concludes that such effects may be anticipated only at hydrogen peroxide doses of or exceeding 5g/kg/day, equivalent to a dose of 5 or more grams for a person weighing 154 pounds. As I noted in my initial Report, potential exposure from vital teeth bleaching is a tiny fraction of that amount.

With regard to the potential genotoxicity or carcinogenicity of vital teeth bleaching, Goldberg et al. does acknowledge that neither International Agency on Research on Cancer data nor case reports evidence such a risk. But it nevertheless implies that the risks somehow remain. However, Munro et al.[16] reviewed more than 100 published and unpublished studies and concluded, among other things, that: "the available genetic toxicity and animal toxicology data do not indicate that HPO [hydrogen peroxide] poses a carcinogenic risk to the human mucosa. This conclusion is further bolstered by the results of the dosimetric exposure analyses from TWP [teeth whitening

products] users showing margins-of-safety on the order of 100- to 1000-fold between no effect levels in animal studies and transient peak HPO concentrations . . . . Moreover, HPO concentrations are highest in the gingiva, a site where oral cancer is rarely found and humans have sufficient catalase activity in saliva and oral mucosa to effectively detoxicate HPO at such low exposure levels." And Sulieman concludes that, "Hydrogen peroxide has been found not to be carcinogenic, mutagenic , or teratogenic, and concerns of toxicity to soft tissues appear to be unfounded."[20] (references omitted) (It notes that, "The only side effect reported from ingesting large quantities of a carbamide peroxide home bleaching product was a laxative effect from the presence of glycerine found within the gel."[20]) (reference omitted)

However one assesses these risks, it is apparent that use of bleaching agents by non-dentist providers of teeth whitening products creates no greater risk, and may create a significantly lesser risk, than dentist-providers of teeth bleaching products and services. The peroxide exposure associated with the most popular dentist-provided chairside bleaching product is more than double that associated with the most popular non-dentist-provided chairside bleaching product. And it is likely that the greatest peroxide exposures are associated with specialized uses of Nightguard Vital Bleaching that are explicitly advocated by Dr. Haywood: in the bleaching of tetracycline stains,[38] in conjunction with the wearing of braces,[39] each of which involves ongoing daily exposures over months or even years and, in the case of the elderly, "for the life of the patient."[40] Consider, for example, Dr. Haywood's writings advocating the use of Nightguard Vital Bleaching for lightening of tetracycline stains in vital teeth.[21,22,23] Dr. Haywood indicates that it may be necessary—and is safe—to bleach tetracycline stained teeth for up to 12 months.[21] Yet, assuming that such bleaching involved use of a 10% carbamide peroxide gel in a single maxillary tray—that is to say a tray for the upper teeth—, the patient's total peroxide exposure would be more than 200 mg and as much as 1000 mg. This peroxide exposure is far more than the exposure reasonably associated with non-dentist-provided teeth whitening, and comes close to the exposure levels said to be of concern by

Goldberg et al.[19] and the EU[24]. But, as Dr. Haywood rightly notes, there are no reports of clinical harm even from peroxide exposure of this magnitude, and it properly is to be considered safe. The same, then, must be said of non-dentist-provided teeth bleaching products and services.

Goldberg et al., note that no allergic reaction to carbamide peroxide or hydrogen peroxides has been reported. This is hardly surprising given that hydrogen peroxide is a natural product of human cellular metabolism.

Unable to implicate non-dentist-provided teeth bleaching as posing a risk of direct, substantial harm, Dr. Haywood's Report also argues that dentists are better positioned than non-dentists to deal with transient dentinal sensitivity. In addition to the knowledge that I have gained through my education, training, and other work experiences, I have had the unique experience of being specifically engaged to investigate dentinal sensitivity in connection with use of the BriteSmile bleaching system. Dentinal sensitivity affects a large portion of people undergoing teeth bleaching, [20, 43] and no one can predict with a high degree of certainty who will be more or less effected, other than by noting prior instances of dentinal sensitivity. [41, 15] However, there is a well-founded consensus, with which I believe Dr. Haywood agrees, that dentinal sensitivity is nothing more than a brief reversible pulpitis of no clinical significance. [43] To that extent, it seems odd that Dr. Haywood would spill so much ink in discussing it in his Report. Because he did, however, I shall reply.

I disagree with Dr. Haywood's belief that rapid permeation of peroxide through the teeth causes dentinal sensitivity. Evidence of rapid permeation is based on studies of exposure of extracted teeth to peroxides. The salivary, osmotic, and vascular conditions that would limit rapid permeation of peroxide through the teeth of a vital teeth bleaching subject were not present in the extracted teeth studies on which Dr. Haywood relies.[29] The better explanation is that the transient dentinal hypersensitivity is associated with dehydration of the teeth during bleaching. The dehydration itself is caused by such things as: use of highly thickened bleaching gels; use of

powerful light and heat activators; and isolation of the teeth from salivary flow. I note that of all modalities of vital teeth bleaching, it is dentist-provided chairside bleaching that most involves these causes of dentinal sensitivity.[28, 42]

That said, all of the means to help combat transient dentinal hypersensitivity that are discussed in Dr. Haywood's Report are available over-the-counter. NSAIDS include Motrin, Advil, Aleve, and similar products. Potassium nitrate is available as Sesnsodyne brand toothpaste (which contains 5% Potassium Nitrate, the maximum concentration used by dentists), and Fluoride is available in ACT Mouthrinse and Colgate Fluorogard, for example. Consumers regularly avail themselves of NSAIDS and Sensodyne brand toothpaste, in particular, for to prevent transient oral discomfort, without need of a dentist's re commendation or assistance. The very best way to combat transient dentinal hypersensitivity is to temporarily discontinue treatment—a simple, commonsense expedient. It passes in one to a few days, with no residual harm of any kind.

Given the safety of non-dentist-provided teeth whitening and the lack of severe or non-transient side effects, it is not surprising that the greater part of Dr. Haywood's Report shifts to claims that non-dentist-provided teeth bleaching causes indirect, esthetic, and other subjective harms. These claims too, are without merit.

B. Non-dentist-provided teeth bleaching does not hinder diagnosis and treatment of diseases and conditions underlying discoloration.

Perhaps the most surprising of Dr. Haywood's claims is his assertion that because in some instances teeth discoloration may be an indication of a disease or condition, teeth whitening by a non-dentist will mask the disease or condition thereby hindering diagnosis and treatment. It is true that in some instances teeth discoloration may be an indication of a disease or condition, but other indicators of the disease or condition invariably should be detected in routine dental examination, permitting treatment as appropriate. Dr. Haywood's claim that non-dentist-provided teeth

whitening will mask the disease or condition thereby hindering diagnosis and treatment therefore is false.

Of the many diseases and conditions that can affect the oral cavity[5], only a few affect tooth color. These typically involve dental caries (cavities) and/or pulpal disease.[6] In some instances, profound discoloration of a tooth may be an indicator of caries or pulpal disease, but it is never the only indication. Notwithstanding prior lightening of a profoundly discolored tooth, a minimally competent dental examination would identify caries, pulpal disease, and any other disease or condition that had caused profound discoloration of a tooth. And the prior bleaching would in no way hinder subsequent treatment.

Dental examination and diagnosis is accomplished through the taking of a comprehensive dental history, visual inspection, tactile sense, radiography, and, where warranted, use of specialized diagnostic tools.[7] Lightening of teeth would have only a minor effect on diagnosis through visual inspection, because it does not hamper the dentist's ability to visualize chips, cracks, pits, fissures, holes, malocclusions, wear facets, abfractions, abrasion, erosion, defective margins, and other visual cues of dental diseases and conditions. And lightening of teeth would have no affect whatsoever on the dentist's ability to effectively diagnose diseases and conditions using the other tools.

Dental caries is by far the most prevalent disease that affect the teeth[8] And prior teeth whitening has absolutely no impact on the dentist's ability to detect dental caries, which are readily detectable notwithstanding prior bleaching, for example through routinely conducted radiography.

In some instances, physical trauma may result in the devitalization of a tooth's pulp, causing profound discoloration. Again, however, a minimally competent dental examination would identify any need for treatment. The patient may report recent or current pain in the tooth. Cracks in its enamel may be evident. And it is quite unlikely that prior bleaching would entirely have eliminated color disparity between the traumatized tooth and other teeth. But Dr. Haywood says, in effect,

assume all of this away: what then? The answer is that any problem requiring treatment should become evident through the taking of the dental history, examination of routinely taken radiographs, and, if indicated, pulp testing using an electronic meter, for example. Dr. Haywood's Report, perhaps unintentionally acknowledges this in its discussion of internal and external resorption, that is to say the dissolution and loss of bone or dentinal material, resulting from trauma. Resorption, Dr. Haywood's Report notes, most often is discovered as a result of physical examination—"carefully exploring at or beneath the gum tissue"—or radiography—"This is most often discovered when radiographs (x-rays) are taken of the teeth."

Indeed, given consumers' widespread use of OTC teeth whitening products—more than fifty million Crest Whitestrips kits alone have been sold[37]—, dental histories routinely should include the questions, "have you bleached your teeth since your last dental visit," and if so, "prior to bleaching were any of your teeth notably more discolored than the others," etc. By this simple expedient, the dentist would have available from the outset substantially all of the information he or she would have had upon visual inspection of the same teeth prior to bleaching.

All of this reduces Dr. Haywood's claim to the search for some consumer (1) with profound discoloration of a tooth due to trauma-induced devitalization of the pulp, (2) who determinedly avoided dentists prior to undergoing non-dentist-provided bleaching, (3) who had non-dentist-provided bleaching that lightened the profoundly discolored tooth to very near the color of the other teeth, (4) who would have gone to a dentist had the teeth whitening been less effective, (5) but instead continues to determinedly avoid dentists. That consumer may or may not exist. If he or she does exist, ultimately the traumatized tooth may have to be treated endodontically or extracted. But what if an earlier diagnosis been made? The answer is, ultimately the traumatized tooth would have been treated endodontically or extracted.

Dr. Haywood has not cited, nor am I aware of, any literature—not even a published case report—indicating that a non-dentist-provided teeth bleaching resulted in a missed diagnosis with

any serious consequence to the patient. Nor has he offered any evidence that any consumer anywhere believes that non-dentist provided teeth bleaching is a reasonable substitute for regular dental examinations by a licensed dentist. Dr. Haywood's concern is founded in imagination alone. In fact, he is disturbed that some people do not visit dentists for oral care. So am I, but that has nothing to do with the availability to consumers of non-dentist-provided teeth bleaching services and products. Indeed, the availability to consumers of non-dentist-provided teeth bleaching services and products may make it more, not less, likely that consumers will visit dentists for oral care. [26] As Dr. Haywood has written, again on a prior occasion, "Bleaching is often the gateway to other restorative treatment needs."[43] I and others agree.[20]

Safety not being implicated directly or indirectly by non-dentist-provided teeth bleaching, Dr. Haywood's Report stretches on to considerations of esthetics, costs, and consumer protection.

C. The esthetic-, cost-, and consumer protection-oriented claims expressed in Dr. Haywood's Report are insubstantial, and do not warrant the elimination of non-dentist-providers of teeth bleaching from the market.

Dr. Haywood's Report claims that because tooth discoloration may have various causes, only a dentist can determine the amount of bleaching time that will be required to appropriately lighten the teeth. Actually, no person, including dentists, can do this with precision. The most sound procedure is to begin with the bleaching product/system vendor's recommendations, adjusting the time allowed as needed based on the resistance of the stains to lightening and the level of whiteness desired. In this, dentists' have scant advantage over non-dentist-providers of teeth bleaching products and services. Dr. Haywood's Report states that "bleaching is in the dental curriculum in most all" dental schools, but apparently it is not in the curriculum of some dental schools, nor does Dr. Haywood's Report indicate the extent to which it is "in the curriculum." Dr. Haywood omits the facts, well known to him, that 8% of the dental schools *he* surveyed did not teach nightguard bleaching at all.[45] More important, Dr. Haywood found that not one of the schools

he surveyed had clinical requirements for nightguard bleaching.[45] Based on my own experience and observations, it is quite likely that many non-dentist providers will have substantially greater teeth bleaching experience than many dentists. But even were it otherwise, there would be no consequential harm to consumers.

Dr. Haywood's Report claims that in some instances non-dentist-provided teeth bleaching will be ineffective, causing unsightly results or requiring the consumer to incur additional costs. But Dr. Haywood is wrong in asking one to believe that the "problem" he identifies is substantial. For example, Dr. Haywood's Report includes an exhibit showing a person with a tooth that is profoundly discolored due to previous endodontic treatment (a root canal procedure rendering the tooth non-vital). According to the Report, bleaching would result in lightening of all teeth but the non-vital one, resulting in an esthetic mismatch. This example ignores two things: the fact that non-dentist-providers of teeth bleaching products and services typically give consumers disclosures designed, among other things, to prevent such esthetic disappointments,[10, 12, 13] exemplars of which I provide later in this Report; and the fact that, as I have seen in practice, the "problem," should it occur, can be resolved by discontinuing bleaching of the surrounding teeth while continuing bleaching of the endodontically treated tooth until a satisfactory color match is achieved.
Dr. Haywood's Report includes another exhibit showing a person with interproximal (*i.e*, between the surfaces of two teeth) tooth-colored fillings. A post-bleaching photograph shows the interproximal fillings retaining their prior coloration, while the rest of the teeth appear quite white. For Dr. Haywood, this is further proof that non-dentist-provided teeth bleaching should be banned. But again, there are two flaws in Dr. Haywood's presentation. First, non-dentist-providers of teeth bleaching products and services typically give consumers disclosures designed, among other things, to prevent such esthetic disappointments.[10, 13, 44] Second, particularly when considered in natural light and life-size (as opposed to Dr. Haywood's photographic blow-ups of pictures taken using lighting that obliterates natural shadows and gradations, producing a distorted net impression), the

post-bleaching result depicted is one I believe, based on my own experience in bleaching or supervising the bleaching of the teeth of literally thousands of test subjects in safety and efficacy studies, most consumers would be pleased to have. Moreover, Dr. Haywood's photos notwithstanding, it is recognized that some types of composites—restoration materials—display what has been called "a chameleon effect, taking on the shade of the surrounding tooth and blending in well, if not quite perfectly."[20] And finally, Dr. Haywood offers absolutely no evidence to quantify either frequency or degree of consumer disappointment with non-dentist-provided bleaching outcomes. "The evaluation of the esthetic outcome of a bleaching treatment is subjective. And the patient's opinions may differ from that of the dental surgeon."[28] In my experience, consumer satisfaction with all modes of vital teeth bleaching is high.

Another of Dr. Haywood's photos purportedly shows post-bleaching "green discoloration on the tooth [that] could not be removed." The exhibit does not include a pre-bleaching photo, and so the extent to which the pictured discoloration preceded the bleaching cannot be determined. Dr. Haywood writes, in the exhibit, "Consider replacement of the amalgam in teeth in the esthetic zone prior to bleaching due to potential greening or translucency occurring during bleaching." Dr. Haywood's Report does not indicate the frequency with which this occurs, but he previously has referred to "greening of the teeth" as a "rare outlying occurrence."[47] Despite the thousands of vital teeth bleachings that I have done or supervised, I have not encountered this greening effect, at least as described. If it occurs as a result of vital teeth bleaching at all, it must do so in a vanishingly small percentage of instances. On three or four occasions, I have seen discolored teeth pick up a gray or gray-green coloration during the first applications of bleaching materials. In each such instance, continued bleaching resolved that discoloration.

Other exhibits similarly are without real significance. For example, one photograph shows a silver filling on a posterior tooth, but based on my own experience, consumers are most interested in the whitening of their "smile teeth," the incisors and canines, not the posterior teeth. Should

consumers, generally happy with their new smiles, determine that they would like to go further and rid themselves of their posterior silver fillings, they can do so. Indeed, that some might want to do so underscores the fact that non-dentist-provided teeth whitening may stimulate demand for dental services among the many consumers who suffer dentist-anxiety,[44] and improve overall dental health.

Dr. Haywood goes so far as to argue, in effect, that non-dentist-provided teeth whitening just isn't worth its cost to consumers. This argument takes two forms. First the Report claims that non-dentist-provided teeth bleaching is less effective at lightening the teeth than dentist-provided bleaching and is attended by greater safety risks. As I have shown, Dr. Haywood is wrong about relative safety. As for the rest of this claim, it is not clear that dentist-provided teeth bleaching necessarily provides consumers with a more pleasing ultimate outcome than dentist-provided teeth bleaching. Dr. Haywood himself has written on an earlier occasion that, "The eventual outcome of whitening is the same regardless of the material if the time is extended long enough, as the outcome is determined by the tooth not the product."[25] (references omitted) But suppose that Dr. Haywood was incorrect then and is correct now, and that dentist-provided bleaching inevitably is more effective. Who is Dr. Haywood, or the NCSBDE, to decide for consumers that because they can obtain more effective dentist-provided teeth bleaching (in the range of six to eight shades of improvement) for several hundreds of dollars (a mean price of about $366 for an at-home system and $538 for in-office bleaching,[46] they ought not to want, or be permitted to have, effective non-dentist-provided teeth bleaching (in the range of three to five shades of improvement) for about $100?

A variant of this argument is the claim in Dr. Haywood's Report that a single chairside treatment often cannot resolve many discolorations. But the cited references indicate that is true of chairside treatment by dentists as well as non-dentists.[42] And many consumers are satisfied with a single chairside bleaching—Dr. Haywood says more than one quarter of consumers.[43] Moreover,

non-dentist-providers may offer free second chairside bleachings to consumers whose expectations have not been, at the first, met. And many, like dentists, either in addition to or instead of chairside bleaching, send consumers home with at-home bleaching kits. As I wrote in my initial Report, "The lay-operated bleaching centers may also sell a line of take home bleaching kits, some of which include self-adapted, self-customized bleaching trays, and others of which are sold with silicone stock trays. These kits typically include a moderate strength carbamide peroxide gel or a slightly stronger hydrogen peroxide gel. They typically are only slightly more expensive than Crest Whitestrips®, usually costing between $40 and $80. Consumers most frequently are instructed to use the at-home kits for up to 30 minutes per day for 14 days." Dr. Haywood's Report offers no rebuttal.

Dr. Haywood's Report fails to recognize that non-dentist-providers of teeth bleaching services offer consumers value propositions that many consumers want. As I discussed in my initial Report they are trained, experienced, and provide consumers with information, guidance, support, and products/services that address each consumers' preferences, conveniently, ethically, safely, and at prices substantially below those of dentists.[10]

The very fact that non-dentist-providers add value beyond mere sale of a product seems to have led NCBDE members, and others within organized dentistry, to insist that non-dentist-providers are engaged in the unlicensed practice of dentistry. Dr. Haywood's Report puts forward a similar claim. It asserts that non-dentist-providers, by sometimes wearing white coats, appearing knowledgeable, and providing meaningful assistance, pass themselves off as dentists. Dr. Haywood offers no evidence of consumer confusion. Moreover, there is substantial evidence that non-dentist-providers of teeth bleaching products and services work carefully to avoid consumer confusion.

Consider, for example, the following select quotes from the materials given by BleachBright Corp. to all retail businesses that purchase the BleachBright system and products.[11] Among those directed to non-dentist providers and their employees are:

- Never try to pass yourself off as a dentist.
- Never offer advice or opinions to customers about their oral health.
- Cosmetic teeth whitening should only be purchased by clients with healthy teeth and gums. Any abnormal condition raised by a client should be immediately referred to a dentist for further evaluation. If potential customer has any questions about the effects of these products on their teeth or existing dental work, they should be referred to their dentist to have their questions answered or concerns addressed. If in doubt, send to dentist.
- However, cosmetic teeth whitening should be avoided for clients who suffer from any abnormal tooth or gum conditions or have crowns, veneers, porcelain, temporaries, composites or other restorative materials, fillings, bridges or bonds. Always do your best to make sure the customer reads the enclosed directions, warning and aftercare insert. If question arise then encourage them to check with their dentist before considering cosmetic teeth whitening.

And other materials are intended for the guidance of consumers:

- It is recommended to consult your dentist before using any teeth whitening system.
- Product is not for children under 12, and children under 18 must be supervised by a parent. Product is not for people using photosensitive drugs, pregnant, suspected of being pregnant or nursing.
- If you have tooth decay, exposed roots, gum disease, braces, have had recent oral surgery or other dental problems, consult your dentist before using this product.
- This product can be used with but will not whiten caps, crowns, veneers, fillings, dentures, or any other type of dental work.

D. Non-vital teeth bleaching is not "the removal of stains."

Dr. Haywood's Report repeatedly refers to vital teeth bleaching as the removal of stains. As I explained in my initial Report, it is not. Hydrogen peroxide, carbamide peroxide, and in fact all bleaches alter the molecular bonds within stains molecules, causing them to lighten in color, but not removing them.[2] The mechanism of action, as I wrote in my initial Report, is as follows: "The break-down of hydrogen peroxide temporarily converts colored particles in teeth stains into non-colored particles by oxidizing organic compounds within the teeth's enamel and dentin. The hydrogen peroxide functions as a chemical sink for the generation of free radicals of oxygen. These free radicals break the carbon:carbon double bonds in organic stains, causing the stain particles to

slowly, and only temporarily, de-colorize." The mechanism of action of bleaches is in sharp contrast to that of detergents, which lift stain molecules from stained materials enabling them to be wiped or washed away, i.e., removing them. Vital teeth bleaching does no such thing. Although Dr. Haywood's Report refers to teeth bleaching as the removal of stains, it does not dispute any of these facts. Bleaching lightens the appearance of, but does not remove, stains.

V. CONCLUSION

Dr. Haywood's Report does not dispute many of the points I made in my initial Report, effectively conceding them. It unconvincingly asserts that non-dentist-provided teeth whitening may cause direct harm, but offers no compelling evidence for that assertion. The Report identifies six specific safety claims, each of which I have shown to be without substance. It mostly offers "concerns were raised" references to studies that are of no relevance to vital teeth bleaching in humans and/or that have been discredited by later work. And the Report barely acknowledges the literature suggesting safety in experimental and clinical settings. Most important, it ignores the fact that after twenty odd years and hundreds of millions of teeth bleachings, including millions upon millions of non-dentist-provided teeth bleachings, there is no record of direct harm.

Dr. Haywood's Report then argues that post-bleaching sensitivity of the teeth and gingiva somehow justifies the NCSBDE in eliminating from the marketplace non-dentist-providers of bleaching, providers who best satisfy many consumers' personal preferences. But dentist-provided-bleaching actually may increase the likelihood and magnitude of sensitivity. And it is beyond debate that such sensitivity is transient, and amenable to use of OTC remedies to which consumers are not strangers: NSAIDS, Sensodyne brand toothpaste, and the like.

Apparently well-aware of the weaknesses in direct-harm-arguments, Dr. Haywood's Report claims the "most critical issue" is not risk of direct harm at all, but rather the alleged need for dental examination and diagnosis prior to bleaching. The Report asserts that without tooth discoloration as a marker, diagnosis and treatment of various pathologies and conditions would be hindered. But

even assuming that non-dentist-provided teeth bleaching eliminated *all* discoloration of previously profoundly discolored teeth—itself a remarkable proposition given the Report's professed doubt as to the effectiveness of non-dentist-provided teeth whitening—, the pathologies and conditions that the Report refers to would be found during a minimally competent routine dental examination as a result of the taking of an adequate oral history, physical examination, and use of radiography and other regularly applied tools of dentistry. Dr. Haywood apparently believes that non-dentist-provided teeth bleaching leads consumers who otherwise would undergo dental examinations, to forgo, for years at a time, visits to a dentist. There is absolutely no evidence to support that belief. To the contrary, satisfaction and enhanced self-esteem associated with teeth bleaching may increase a consumer's interest in appearance of the dentition, increasing the likelihood that an otherwise reluctant person may visit a dentist to resolve other "issues."

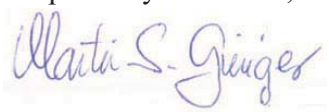
Dr. Haywood's Report then retreats to considerations of esthetics, using photo-exhibits that create a misleading impression of significant post-bleaching mismatches between living natural teeth, discolored non-vital teeth, and restorations. The Report ignores both the information given to consumers about the difficulty in bleaching certain kinds of stains and materials by non-dentist-providers of bleaching products and services, and the fact that despite imperfect teeth matches, consumers are greatly satisfied with teeth bleaching results, however and by whoever performed. Dr. Haywood substitutes his esthetic judgments for those of consumers, making the perfect the enemy of the good. But consumers appreciate affordable lightening of their teeth stains, despite imperfect results. For them, good is good.

In the end, Dr. Haywood's Report is reduced to asserting that non-dentist-provided teeth bleaching is deceptive because non-dentist-providers wear coats and sound authoritative, or that non-dentist-provided teeth bleaching just isn't good value for consumers. Dr. Haywood's Report supports neither assertion with evidence, because there is none. Neither conclusion is within Dr.

Haywood's professional expertise, and each flies in the face of the millions upon millions of consumers who have opted for non-dentist-provided teeth bleaching and been well satisfied.

Non-dentist-provided teeth bleaching is safe and effective. It does not cause indirect harm to consumers, and conveys substantial benefits. It does not remove stains, as do detergents; rather it lightens stains by cleaving some of the molecular bonds that impart color to stains. And it satisfies the personal preferences of many consumers for various combinations of effectiveness, speed, assistance, affordability, and more.

Respectfully submitted,



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REFERENCES

1. Giniger Expert Witness Report, FTC v. North Carolina Board of Dental Examiners, Docket No. 9343, dated November 24, 2010
2. Margeas R, New Advances in Tooth Whitening and Dental Cleaning Technology, PenWell CDE Course, dated 2006
3. Cooper JS, Bokmeyer TJ, Bowles WH, Penetration of the Pulp Chamber by Carbamide Peroxide Bleaching Agents, Journal of Endodontics, Vol. 18, 315-317, dated 1992
4. Tooth Enamel, *available at* http://en.wikipedia.org/wiki/Tooth_enamel
5. Schafer WG, Hine MK, Levy BM (eds), A Text Book of Oral Pathology, W.B. Saunders Company, 4th edition, dated July 1983
6. Dental Caries, *available at* http://en.wikipedia.org/wiki/Dental_caries
7. Bricker SL, Langlas RP, Miller CS (eds), Oral Diagnosis, Oral Medicine and Treatment Planning, B.C. Decker Inc. 2nd Edition, dated 2002

8. Tooth Decay, *available at* http://www.doctorspiller.com/Tooth Decay.htm
9. Dental Caries, *available a*t http://www.answers.com/topic/dental-caries
10. Document Number CX0630: Council for Cosmetic Teeth Whitening Best Practices and Information for Cosmetic Teeth Whitening Product Manufacturers and Distributors, adopted by Council for Cosmetic Teeth Whitening, dated 2008
11. Document Number CX0637: BleachBright Manual: For getting the most out of your BleachBright business
12. Document Number CX0669: Instructions for Use for Beyond Dental Take Home Product
13. Document Number CX0108: White Science Training Manual
14. Document Number CX0400: Critical Assessment of Safety and Regulatory Status of Crest Whitestrips: Report of a Scientific Advisory Group, Internal Unpublished Report, dated 2003
15. Document Number 000392-000397: Haywood VB, Caughman F, Frazier K, et al., Tray delivery or potassium nitrate-fluoride to reduce bleaching sensitivity, Quintessence International, Vol. 32, No. 2, dated 2001
16. Document Number CX0505: Munro IC, Williams GM, Heymann HO, et al., Use of Hydrogen Peroxide-Based Tooth Whitening Products and the Relationship to Oral Cancer, Journal of Esthetic and Restorative Dentistry, Vol. 18, No. 5, 119-125, dated 2006
17. Document Number CX0497: Heymann HO, Review of the ADA Report on Tooth Whitening/Bleaching
18. Document Number CX0587: American Dental Association Council of Scientific Affairs: Tooth Whitening/Bleaching Considerations for Dentists and Their Patients, Draft dated September 2009 and updated August 2010
19. Document Number 001092-001101: Michael Goldberg, Martin Grootveld, and Edward Lynch, Undesirable and Adverse Effects of Tooth Whitening Products: A Review, Clinical Oral Investigations, Vol. 14, 1-10, dated 2009

20. Document Number 000100-000120: Sulieman MA, An overview of tooth-bleaching techniques: chemistry, safety and efficacy, Periodontology 2000, Vol. 48, 148-169, dated 2008
21. Summitt JB, Robbins JW, Hilton TJ, et al. (eds), Fundamentals of Operative Dentistry, A Contemporary Approach, Quintessence books, Third Edition, dated 2006
22. Leonard RH, Haywood VB, Caplan OJ, et al., Nightguard vital bleaching of tetracydine-stained teeth 90 months post treatment, Journal of Esthetic and Restorative Dentistry, Vol. 15, 142-153, dated 2003
23. Leonard RH, Haywood VB, Eagle JC., et al., Nightguard vital bleaching of tetracycline stained teeth: 54 months post-op treatment, Journal of Esthetic and Restorative Dentistry, Vol. 11, 265-277, dated 1999
24. Document Number 000271-000381: Scientific Committee on Consumer Products, European Commission Health & Consumer Protection Directorate-General, Opinion on Hydrogen Peroxide, in its free form or when released, in oral hygiene products and tooth whitening products, SCCP/1129/07, dated December 18, 2007
25. Document Number 000961-000964: Haywood VB, The "Bottom Line" on Bleaching 2008, Inside Dentistry, Vol. 4, No. 2, 82- 89, dated February 2008
26. Haywood VB, Considerations for Vital Nightguard Tooth Bleaching with 10% Carbamide Peroxide After Nearly 20 Years of Proven Use, Inside Dentistry, dated September 2006
27. Bleach Bright Beauty, *available at* http://www.yelp.com/biz/bleach-bright-beauty-new-york
28. Document Number 000027-000039: Dahl JE and Pallesen U: Tooth Bleaching—A Critical Review Of The Biological Aspects, Critical Reviews in Oral Biology & Medicine, Vol. 14, No. 4, 292-304, dated 2003

29. Camargo SEA, Valera MC, Camargo CHR, et al., Penetration by 38% Hydrogen Peroxide into the Pulp Chamber in Bovine and Human Teeth Submitted to Office Bleach Technique, Journal of Endodontics, Vol. 33, No. 9, 1074-1077, dated September 2007
30. Document Number 004092-004101: Attin T, Hannig C, Wiegand A, et al., Effect of bleaching on restorative materials and restorations – a systematic review. Dental Materials, Vol. 20, 825-861, dated 2004.
31. Document Number CX0227: ADA: Frequently Asked Questions about Teeth Whitening, dated July 2010
32. Document Number CX0469: E-mail to Rhodes from Hansen: re: Tooth Whitening w/Attach: 59 Whitening by Retail Staff.docx, dated August 2009
33. Document Number 000256-000261: Cubbon T, Ore D, Hard Tissue and Home Tooth Whiteners. CDS Review, Vol. 84, No. 5, 32-35, dated June 1991
34. Document Number CX0403: Ren YF, Amin A, Malstrom H, Effects of tooth whitening and orange juice on surface properties of dental enamel, Journal of Dentistry, Vol. 37, No. 6, 424-431, dated June 2009
35. Document Number 000593-000598: Gerlach R, Barker M, Karpinia K, et al., Single site meta-analysis of 6% hydrogen peroxide whitening strip effectiveness and safety over 2 weeks, Journal of Dentistry, Vol. 37, 360-365, dated 2009
36. Document Number 003944-003946: Greenwall L., The Dangers of Chlorine Dioxide Tooth Bleaching, Aesthetic Dentistry Today, Vol. 2, 20-22, dated 2008
37. Document Number CX0496: Letter to Margaret Hamburg, MD, from Greg Collier, PhD: re: Procter & Gamble's Comments on the November 20th, 2009 American Dental Association's Citizen Petition, Regulatory Treatment of Tooth Whitening Preparations

38. Leonard RH Jr., Haywood VB, Caplan DJ, et al., Nightguard Vital Bleaching of Tetracycline-Stained Teeth: 90 Months Post Treatment, Journal of Esthetic and Restorative Dentistry, Vol. 15, No. 3, 142-152, dated 2003
39. Haywood VB, Orthodontic Caries Control and Bleaching, Inside Dentistry, 36-48, dated April 2010
40. Haywood VB, Bleaching and caries control in the elderly, dated January 1, 2010
41. Document Number CX0627: Salwiczek C, Interview with Prof. Van B. Haywood, USA, about bleaching sensitivity, dated May 28, 2009
42. Haywood VB, In-Office Bleaching: Light, Applications and Outcomes, Current Practice, dated 2009
43. Haywood VB, Nightguard Vital Bleaching: Indications and Limitations, US Dentistry, dated 2006
44. Elter JR, Strauss RP, Beck JD, Assessing Dental Anxiety, Dental Care Use and Oral Status in Older Adults, JADA, Vol. 128, No. 8, 1066, dated August 1997
45. Frazier KB and Haywood VB, Teaching nightguard bleaching and other tooth-whitening procedures in North American dental schools, J Dent. Educ., Vol. 64, No. 5, 357-364, dated May 2000
46. Document Number CX0513: The 2008 Gallup Study of Dentists' Attitudes Toward Tooth Whitening Products and Services, dated September 2008
47. Haywood, VB, Commentary, Interaction of Peroxides with Amalgam: A Case Report, dated July 2007

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I hereby certify that on January 18, 2011, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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I also certify that I delivered via electronic mail and hand delivery a copy of the foregoing document to:

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January 18, 2011

By: s/ Richard B. Dagen
Richard B. Dagen