

UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION OFFICE OF ADMINISTRATIVE LAW JUDGES

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

RESPONDENT'S PROPOSED FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER, AS AMENDED

Counsel for Respondent:

Noel L. Allen
Alfred P. Carlton, Jr.
M. Jackson Nichols
Catherine E. Lee
Brenner A. Allen, of counsel
Jackson S. Nichols, of counsel
Allen and Pinnix, P.A.
Attorneys for Respondent
Post Office Drawer 1270
Raleigh, North Carolina 27602
Telephone: 919-755-0505
Facsimile: 919-829-8098

Email: nallen@allen-pinnix.com mjn@allen-pinnix.com acarlton@allen-pinnix.com clee@allen-pinnix.com ballen@allen-pinnix.com jsn@allen-pinnix.com

TABLE OF CONTENTS

I.	PROPOSED FINDINGS OF FACT	1
	A. Absence of Evidence of a Conspiracy or of Collusion	
	i. Complaint Counsel's Absence of Evidence	1
	ii. The Board's Evidence That There Was No Conspiracy and No Collusion	on1
	3. The North Carolina General Assembly Properly Established the Board	
	i. The Dental Practice Act	2
	ii. Other Statutory Authority	4
	C. The Board Operates in Accordance with Its Statutory Authority	
	i. Testimony of Current and Former Board Members	5
	ii. Testimony of the Board's Chief Operating Officer	6
	D. Dentist Board Members Properly Utilized Their Knowledge and Expertise Interpret and Enforce the Unauthorized Practice Statute	
	E. Board Members Are Required to Act Ethically, and There Is No Evidence of Bias	
	Teeth Whitening Is the Unauthorized Practice of Dentistry in North Carolic	na12
	F. The Investigation of Complaints of Teeth Whitening Is an Insignificant Part of the Board's Regulatory Activities	13
	I. Teeth Whitening Cases Are Decided on a Case by Case Basis	13
	The Board's Investigatory Process Is Properly Authorized	
	i. Receipt of Complaints	27
	ii. The Secretary-Treasurer Appoints the Case Officer	28
	iii. The Case Officer, Staff, and Legal Counsel Form the Investigative Pan	el29
	iv. No One Outside the Investigative Panel Knows the Details of a Case, With the Possible Exception of the Complainant	29

	v.	The Case Officer Decides a Course of Action Without Consulting with Other Board Members	.30
	vi.	Dr. Owens Is the Case Officer for Most of the Teeth Whitening Cases	.31
J.		ase and Desist Letters Are Authorized Enforcement Techniques and Are propriately Utilized by the Board	
	i.	The Board's Enforcement Authority Regarding Cease and Desist Letters	.31
	ii.	Cease and Desist Letters in General	.32
	iii.	Options Available to Recipients of Cease and Desist Letters	.34
	iv.	No Member of the Teeth Whitening Industry Sought to Challenge the Board's Letters	.35
K.		e Board's Contact with Third Parties Regarding Teeth Whitening Was dertaken in Furtherance of Its Public Protection Role	
	i.	Letters Sent to Mall Management	.36
	ii.	Communication with the North Carolina Board of Cosmetic Art Examiners	.38
L.		e Board Tendered and the Court Accepted Van B. Haywood as an Expert	.38
M.		mplaint Counsel Tendered and the Court Accepted Martin R. Giniger as an Expert	.39
N.		e Board's Actions Were Taken Pursuant to a Legitimate State Law Forcement Objective	
	i.	Teeth Whitening Is the Practice of Dentistry	.42
	ii.	Teeth Bleaching Is Teeth Whitening	.42
	iii.	The Removal of Stains from Human Teeth Is Teeth Whitening	.43
		The Removal of Stains from Human Teeth by a Non-Dentist Is a Violation of the North Carolina Dental Practice Act	43

О	. Th	ie B	oard's Actions Were Taken Pursuant to Legitimate Public Safety Conce	ms	
	i. Dr. Haywood's Concerns				
		a.	Difference Between OTC Products and Kiosk/Spa Teeth Whitening	43	
		b.	Problems with Kiosk/Spa Teeth Whitening	44	
		c.	Dentist Teeth Whitening Is Safer Because of Superior Training and Professional Obligations	45	
		d.	ADA Concerns about Teeth Whitening by Non-Dentists	45	
		e.	ADA Report to FDA Asking FDA to Classify Bleaching Products as a Medical Device	46	
		f.	Dr. Haywood's Conclusions	46	
	ii.	Dr	. Giniger's Denials as to Dentistry	47	
	iii. Public Safety Concerns Demand That a Proper Dental Examination Precede Teeth Whitening			49	
	iv. Dentists' Concerns as to Sanitation and Other Safety Issues		50		
	v.		orth Carolina Consumers Have Been Injured by Non-Dentist eth Whitening	54	
		a.	Brian Runsick's Injuries	54	
		b.	Other Consumers' Injuries	59	
P.	Eq	ual .	Access to Justice Act	61	
Q.	The	e Bo an E	pard Tendered and the Court Accepted Dr. David L. Baumer Expert	62	
R.			aint Counsel Tendered and the Court Accepted nn E. Kwoka as an Expert	62	
s.	The	e Te	eth Whitening Markets	63	
T.			Enforcement of a State Statute to Exclude Market Participants mited Basis Is a Justifiable Activity		
	i.	Dr.	Baumer's Testimony	64	

	ii.	Rebuttal of Dr. Kwoka's Testimony	66
	U. Th	e Teeth Whitening Industry	68
	i.	Dental Teeth Whitening	68
	ii.	Non-Dentist Teeth Whitening	70
	iii.	Testimony of Teeth Whitening Industry Representatives	70
	iv.	Testimony of Kiosk/Spa Teeth Whiteners	77
II.	PROF	OSED CONCLUSIONS OF LAW	83
III.	PROI	POSED ORDER	88
IV.	EXHI	BIT INDEX	Exhibit A
V.	WITN	ESS INDEX	Exhibit B
VI.	PROT	ECTIVE ORDER	Exhibit C

I. PROPOSED FINDINGS OF FACT

A. Absence of Evidence of a Conspiracy or of Collusion.

i. Complaint Counsel's Absence of Evidence

- 1. There is no testimonial evidence in the record indicating that the members of the North Carolina State Board of Dental Examiners ("Board" or "State Board") were part of a conspiracy or colluded in connection with non-dental teeth whitening operations. (Entire record).
- 2. There is no deposition designation in the record indicating that the Board members were part of a conspiracy or colluded in connection with non-dental teeth whitening operations. (Entire record).
- 3. There is no documentary evidence in the record indicating that the Board members were part of a conspiracy or colluded in connection with non-dental teeth whitening operations. (Entire record).

ii. The Board's Evidence That There Was No Conspiracy and No Collusion

- 4. There is evidence that there have been no conversations between dentist Board members and other dentists (1) about competition between dentists and non-dentists who were performing teeth whitening, (2) about the impact of over-the-counter teeth whitening products on a dentist's practice, (3) about non-dentist teeth whitening hurting a dentist's business, or (4) where another dentist tried to pressure any Board member about non-dentist teeth whitening. (Wester, Tr. 1306-1307; Owens, Tr. 1462-1463; White, Tr. 2236-2237; Hardesty, Tr. 2785; RX52 (Burnham, Dep. at 151-153); RX55 (Efird, Dep. at 42, 68-70, 75); RX56 (Feingold, Dep. at 182-183); RX60 (Hall, Dep. at 47); RX65 (Morgan, Dep. at 25-26, 263-264); RX76 (Parker, Dep. at 249)).
- 5. The evidence shows that, other than very few informal, random and insignificant instances, there were no conversations or other communications about the investigation of teeth whitening complaints between dentist Board members and non-dentist Board members. CX564 (Hall, Dep. at 15-16); RX60 (Hall, Dep. at 61)).
- 6. The evidence shows that, other than very few informal, random, and insignificant instances, there were no conversations or other communications about the investigation of teeth whitening complaints between Board staff and non-dentist Board members. (CX559 (Efird, Dep. at 10-12)).

- 7. The evidence shows that Board members never discussed among themselves the amount of teeth whitening that they did in their practices. (RX51 (Brown, Dep. at 104)).
- 8. The evidence shows that, other than very few informal, random and insignificant instances, there were no conversations or other communications about teeth whitening complaints between Board members or Board staff and the North Carolina Dental Society or other national dental associations. (RX51 (Brown, Dep. at 192-193); RX52 (Burnham, Dep. at 168-169); RX56 (Feingold, Dep. at 39); RX63 (Holland, Dep. at 205, 228); RX65 (Morgan, Dep. at 125, 127, 167); RX75 (Oyster, Dep. at 36-37, 57); RX76 (Parker, Dep. at 67-68, 73-74, 83)).
- 9. The evidence shows that there were no conversations or other communications about teeth whitening at Tripartite meetings including representatives of the State Board, the N.C. State Dental Society, and University of North Carolina School of Dentistry. (RX52 (Burnham, Dep. at 236); RX56 (Feingold, Dep. at 258); RX75 (Oyster, Dep. at 73-74); RX76 (Parker, Dep. at 231)).
- 10. Complaint Counsel has failed to meet its burden of proof. (Entire record).

B. The North Carolina General Assembly Properly Established the Board.

i. The Dental Practice Act

- 11. The North Carolina State Board of Dental Examiners is an agency of the State of North Carolina, and is charged with regulating the practice of dentistry in the interest of the public health, safety, and welfare of the citizens of North Carolina. The Board is organized, exists, and transacts business under and by virtue of the laws of the State of North Carolina, with its principal officer and place of business located at 507 Airport Blvd., Suite 105, Morrisville, NC 27560. (Joint Stipulations of Law and Fact ("Joint Stipulations") ¶ 1; CX19 at 1; RX60 (Hall, Dep. at 35)).
- 12. The State Board is authorized and empowered by the Legislature of North Carolina to enforce the provisions of the Dental Practice Act. (Joint Stipulations ¶ 12; N.C. Gen. Stat. § 90-22(b), CX19 at 1; White, Tr. 2203-2204; RX50 (Bakewell, Dep. at 182); RX51 (Brown, Dep. at 48); RX52 (Burnham, Dep. at 74-75)).
- 13. The North Carolina Dental Practice Act was enacted in 1879. (White, Tr. 2203-2204; CX19 at 1).
- 14. Pursuant to N.C. Gen. Stat. § 90-22(a), the Dental Practice Act should be liberally construed to protect the public and to enforce the unauthorized practice of dentistry provision. (CX19 at 1; RX65 (Morgan, Dep. at 191-192)).

- 15. Individual members of the State Board are sworn officers of the State of North Carolina. (N.C. Gen. Stat. § 11-7; White, Tr. 2197).
- 16. The election of dentist and hygienist Board members is governed by N.C. Gen. Stat. §90-22(b), (c). (Joint Stipulations ¶ 5).
- 17. N.C. Gen. Stat. § 90-22(b) provides that the Board shall consist of six practicing dentists, a hygienist, and a consumer representative. (CX19 at 1; White, Tr. 2194; Joint Stipulations ¶ 2).
- 18. N.C. Gen. Stat. § 90-22(b) provides that of the eight Board members, the consumer representative is appointed by the Governor. (CX19 at 1). Of the eight Board members, only the consumer representative is selected by North Carolina officials. (Joint Stipulations ¶ 3).
- 19. N.C. Gen. Stat. § 90-22(b) and (c) provide that the dental hygienist Board member is elected by other dental hygienists licensed in North Carolina. (CX19 at 1-2; White, Tr. 2242-2243).
- 20. N.C. Gen. Stat. § 90-22(b) provides that the six dentist Board members are elected by other dentists licensed in North Carolina. (Joint Stipulations ¶ 6; CX19 at 1; White, Tr. 2242; Hardesty, Tr. 2761).
- 21. N.C. Gen. Stat. § 90-22(b) and (c) provide that the dentist members of the Board are elected for three year terms and can run for re-election, but "[n]o person shall be nominated, elected, or appointed to serve more than two consecutive terms on said Board." (Joint Stipulations ¶ 7; CX19 at 1-2).
- 22. N.C. Gen. Stat. § 90-22(b) & (c) provide that elections can be contested. (CX19 at 1-2). Elections are "contested" when there are more candidates running for election than there are available Board positions. (Joint Stipulations ¶ 8).
- 23. If an election is contested, candidates may engage in solicitation for votes, such as distributing letters and making speeches discussing the reasons they want to serve on the Board, including their positions on issues that may come before the Board. (Joint Stipulations ¶ 9; CX514 at 38, 21 N.C. Admin. Code 16L.0104).
- 24. N.C. Gen. Stat. § 90-39 provides that the operating budget for the Board comes from license fees paid by North Carolina licensees (both dentists and dental hygienists). (Joint Stipulations ¶ 11; CX19 at 19-20).
- 25. N.C. Gen. Stat. § 90-39 provides that the mandatory fees paid by licensees can only be spent for public purposes, i.e., "carrying out and enforcing the provisions of" the Dental Practice Act. (CX19 at 19-20).

- 26. Pursuant to N.C. Gen. Stat. §§ 90-40 and 90-40.1, the Board and its members have the authority to enforce the provisions of the Dental Practice Act by seeking recourse to the courts of North Carolina. (Joint Stipulations ¶ 14; CX19 at 20-21).
- 27. Under N.C. Gen. Stat. §§ 90-29 through 90-38, 90-41, 90-40.1, and 90-41.1, the Board has the authority to license and take disciplinary actions against dentists practicing in North Carolina. (CX19 at 7-19, 23).
- 28. Pursuant to N.C. Gen. Stat. §§ 90-40 and 90-40.1, the State Board is authorized to seek criminal prosecution for the unauthorized practice of dentistry. (CX19 at 20-21).
- 29. Pursuant to N.C. Gen. Stat. § 90-40.1(a), the State Board is authorized to seek injunctions for the unauthorized practice of dentistry. (CX19 at 20-21).
- 30. Pursuant to N.C. Gen. Stat. §§ 90-40 and 90-40.1, the North Carolina General Assembly has given the State Board the authority to petition a North Carolina court, either on its own or with the assistance of a District Attorney, to stop violations of the Dental Practice Act. (CX19 at 20-21; White, Tr. 2206).
- 31. Pursuant to N.C. Gen. Stat. § 90-41(d), the Board is authorized to hire investigators to help fulfill its disciplinary and enforcement duties and to conduct investigations before it files any civil or criminal action. (White, Tr. 2205-2206; CX19 at 22-23).

ii. Other Statutory Authority

- 32. N.C. General Statute § 93B provides that all occupational licensing boards in North Carolina, including the Board, are state agencies, and that board employees are state employees. (White, Tr. 2212; CX593 at 1).
- N.C. General Statute § 93B provides that all occupational licensing boards in North Carolina, including the Board, must undergo an annual audit that is reviewed by the state auditor. These reports also must be submitted annually to the Secretary of State, the N.C. Attorney General, and the Administrative Procedures Oversight Committee, which is part of the N.C. General Assembly. (White, Tr. 2212-2213; CX593 at 1-2).
- 34. The Board is governed by N.C. General Statute § 150B, the Administrative Procedure Act. (Joint Stipulations ¶ 18). The Administrative Procedure Act sets forth rule-making and public participation requirements that apply to the Board. (White, Tr. 2213-2214; CX515 at 8-35).

- 35. Under the Administrative Procedure Act, any person who wishes to suggest a rule may do so to any occupational licensing board. The board then has 30 days to decide whether or not they will make that rule and respond to the person. The rule can then be implemented through the usual rulemaking procedures. (White, Tr. 2214; CX515 at 11).
- 36. The Administrative Procedure Act has a provision for emergency rulemaking, which still allows for public participation. (White, Tr. 2214; CX515 at 17-19).
- 37. Under the Administrative Procedure Act process for making a declaratory ruling, any person who wishes to request of the board a declaratory ruling on any rule or subject may do so, and the board has to respond within 60 days. (White, Tr. 2215; CX515 at 8-9).
- 38. Pursuant to the Administrative Procedure Act, administrative hearings are open to the public. (White, Tr. 2216; CX515 at 36, N.C. Gen. Stat. § 150B-38(e)).
- 39. All rules of state agencies, including the Board, are published. (White, Tr. 2216; CX515 at 33-35).
- 40. The Administrative Procedure Act has two articles applicable to administrative hearings: Article 3, which applies to hearings conducted by an administrative law judge, and Article 3A, which is conducted by a board itself. The Act allows the board to use an administrative law judge rather than conduct hearings itself. This is typically done when a majority of board members are presented with a conflict of interest. (White, Tr. 2216-2217; CX515 at 39).
- 41. N.C. General Statute § 143-318, the Open Meetings Act, which applies to the Board, governs whether state agencies must conduct their business in public view. It provides that meetings of North Carolina agencies must be open to the public. Certain activities are exempted from this requirement and may be discussed during sessions closed to the public, including receiving advice from legal counsel, offering an honorary degree, reviewing investigative matters with regard to a specific licensee, and review of proprietary testing material. The Board is not allowed to vote during closed sessions. (White, Tr. 2217-2218).
 - C. The Board Operates in Accordance With Its Statutory Authority.
 - i. Testimony of Current and Former Board Members
- 42. Consistent with North Carolina law, the Board consists of six practicing dentists, a hygienist, and a consumer representative. (Joint Stipulations ¶ 2).

- 43. Consistent with North Carolina law, the dentist Board members who testified in connection with these proceedings stated that they distributed letters discussing who they were and their desire to serve North Carolina dentists and protect the public. (Hardesty, Tr. 2796-2797; Wester, Tr. 1318; Owens, Tr. 1473-1474; RX52 (Burnham, Dep. at 62)).
- 44. All dentist Board members who testified in connection with this proceeding did not campaign for a position on the Board by announcing any position on certain issues. (RX51 (Brown, Dep. at 148, 153); RX52 (Burnham, Dep. at 62); RX56 (Feingold, Dep. at 36); RX63 (Holland, Dep. at 29-30); RX65 (Morgan, Dep. at 163).
- 45. All dentist Board members who testified in connection with this proceeding stated that they were elected in accordance with N.C. Gen. Stat. § 90-22. (Wester, Tr. 1277-1278; Owens, Tr.1435-1436; Hardesty, Tr. 2761-2762).
- 46. The Board has sought civil and criminal relief in North Carolina courts under the Dental Practice Act. (Joint Stipulations ¶ 13; RX8 at 1-8; RX11 at 1-4; RX15 at 1-8; RX25 at 1-14).
- 47. The civil and criminal relief the Board has sought in North Carolina courts against non-dentist teeth whitening operations has been in accordance with the Dental Practice Act. (Owens, Tr. 1448-1449; White, Tr. 2331, 2363; RX8 at 1-2, 8, 15-16; RX11 at 4; RX15 at 7; RX25 at 1-2, 9-10, 25-26).
- 48. In accordance with N.C. Gen. Stat. § 90-40, the Board has sought criminal prosecution for the unauthorized practice of dentistry when public safety was an issue and the facts warranted such action. (Owens, Tr. 1251; White, Tr. 2206; CX19 at 20).
- 49. In accordance with N.C. Gen. Stat. § 90-40.1(a), the State Board sought injunctions for the unauthorized practice of dentistry whenever public safety was an issue. (White, Tr. 2332-2333; CX19 at 20-21; RX52 (Burnham, Dep. at 103-105)).

ii. Testimony of the Board's Chief Operating Officer

50. Bobby White has been the Board's Chief Operating Officer since February 2004. He has a Master's of Divinity Degree from Duke University Divinity School and a law degree. He is licensed to practice in North Carolina, and is also an ordained minister. As Chief Operating Officer, he is responsible for the daily operations of the organization, including payroll, insurance, and contract negotiation. He also advises the Board on legal issues with regard to disciplinary matters. (White, Tr. 2188-2190).

- 51. As Chief Operating Officer, Mr. White works regularly with his counterparts in other occupational licensing boards in North Carolina. They discuss similar issues that come up, such as the joint 401(k) retirement plan that North Carolina occupational licensing boards share, and also matters that may be pending before the North Carolina legislature that would impact licensing boards. (White, Tr. 2190-2191).
- 52. In meeting with other North Carolina occupational licensing boards, Mr. White has become familiar with how they are structured. Each board is established pursuant to a separate statute by the North Carolina legislature. (White, Tr. 2191).
- 53. The Board's annual revenues are \$1.8 million. Most of its revenue comes from licensing and renewal fees from dentists and dental hygienists licensed in North Carolina. The Board does not receive any appropriations from the North Carolina General Assembly. (White, Tr. 2192).
- 54. The Board has nine employees. They include a licensing coordinator, who is responsible for all of the procedures with regard to issuing licenses for dentists and dental hygienists; a sedation/anesthesia coordinator, who is responsible for making sure that all dentists' sedation/anesthesia permits are up to date; two investigators, who follow up on complaints, interview witnesses, and meet with dentists and complainants; an assistant director and director of investigations who oversee the investigative process; and an administrative assistant who handles general administrative support for the office. (White, Tr. 2192-2193).
- 55. The Board had a legal counsel who was hired in-house in 2006 or 2007, but now is retained as an independent contractor and is no longer an employee of the Board. (White, Tr. 2193-2194).
- 56. The Board meets once a month, usually for about three days. (White, Tr. 2194).
- 57. Board member duties include conducting investigations and hearings, approving programs for certification or continuing education, responding to inquiries from the public regarding interpretations of the Dental Practice Act, managing the overall budget of the organization, and rulemaking. (White, Tr. 2198-2199).

- In North Carolina, all rules promulgated by administrative agencies must flow from a statute. The proposed wording of a new rule is published for the public to review, and then a public hearing is held where the Board receives commentary about the rule. Then the Board develops final language for the rule and submits it to the Rules Review Commission, a body appointed by the North Carolina legislature (half by the state House of Representatives and half by the Senate). If the rule passes the Rules Review Commission, it becomes codified in the North Carolina rules (unless there are ten or more objections to the rule by the Rules Review Commission, at which point the legislature must approve or disapprove it). All rules of North Carolina state agencies are subject to this process. (White, Tr. 2199-2200).
- 59. The Board regularly receives commentary for proposed rules during its public hearings before the Rules Review Commission, including adverse commentary. (White, Tr. 2201).
- 60. The Board is required to have statutory authority for fee increases. Generally, the statutory authority is a cap on the maximum amount that the fee can be. If the current fee is already below that cap, then it can be raised up to that cap by going through the general rule-making process. This is true for other state agencies as well. (White, Tr. 2200-2201).
- 61. As Chief Operating Officer, Mr. White responds to legislators when they contact the Board with questions. He also appears before legislative committees, such as the administrative procedure oversight committee. (White, Tr. 2201-2202).
- 62. As a state agency, the Board is not permitted to lobby the General Assembly for passage of any type of statute. (White, Tr. 2202, 2212; CX593 at 3).
- 63. The Board's officers, the President and the Secretary-Treasurer, are elected from the Board itself, a nominations committee, and are voted on by the Board members, including the hygienist and public member. (White, Tr. 2202).
- 64. The Board has discussed teeth whitening during a closed session only once, when it received legal advice from counsel regarding development of a policy to hand out to individuals who ask about teeth whitening. That policy was voted on in open session. (White, Tr. 2218).
- 65. Investigations are not subject to public view under the Open Meetings Act. (White, Tr. 2218-2219).
- Mr. White testified that Richard Dagen mischaracterized Mr. White's deposition testimony when he claimed in Complaint Counsel's Opening Statement that Mr. White had testified that Complaint Counsel's "proposed relief" in this matter would not severely impair the Board's ability to fulfill its statutory obligation. (White, Tr. 2238-2241; RX69 (White, Dep. at 30); Dagen, Tr. 43).

- D. Dentist Board Members Properly Utilized Their Knowledge and Expertise to Interpret and Enforce the Unauthorized Practice Statute.
- 67. The definition of the unlawful practice of dentistry as it relates to teeth whitening has remained the same as enacted by the N.C. Legislature in N.C. Gen. Stat. § 90-29 in 1935. (CX19 at 7).
- 68. Some Board members are knowledgeable about teeth whitening because they took courses in dental schools; other Board members were knowledgeable about teeth whitening because they had received training either through continuing education courses or by manufacturers as part of their practice. (Wester, Tr. 1277, 1288-1292, 1296-1297; Owens, Tr. 1451-1454; Hardesty, Tr. 2760-2761, 2774-2782).
- 69. Based on this background and their actual experience with teeth whitening, both current and former Board members who are dentists consider teeth whitening to be the removal of stains from teeth. (Wester, Tr. 1297-1298; Owens, Tr. 1454; Hardesty, Tr. 2781).
- 70. The State Board's interpretation of the statute was based on the Board's public protection duties as they relate to the unauthorized practice of dentistry. (Hardesty, Tr. 2766, 2772-2773; Owens, Tr. 1440-1441; RX50 (Bakewell, Dep. at 178); RX63 (Holland, Dep. at 181-182)).
- 71. The State Board did not see any necessity to promulgate a rule on the unauthorized practice of teeth whitening since the statute was clear. (RX51 (Brown, Dep. at 113-114); RX63 (Holland, Dep. at 237); RX65 (Morgan, Dep. at 269)).
- 72. The Joint Legislative Administrative Oversight Committee does not have the authority to interpret laws. The Board's dictate is to enforce the unauthorized practice statute. To accomplish this, they will use their knowledge and common sense. The Board relies on North Carolina's courts to correct its statutory interpretations, but the courts have not done so to date. (RX50 (Bakewell, Dep. at 95, 178)).
- 73. The State Board formally adopted an interpretive statement incorporating its definition of the unauthorized practice of dentistry on January 9, 2010. (White, Tr. 2229-2230; CX475).
- 74. The Board's interpretation is that the unauthorized practice dentistry does not include the sale of over-the-counter teeth whitening products that consumers apply themselves; rather, it is the offering of a service. (Wester, Tr. 1298-1299; Owens, Tr. 1455; White, Tr. 2229-2230; RX50 (Bakewell, Dep. at 283 285, 292-93); RX55 (Efird, Dep. at 46-47); RX58 (Friddle, IHT at 32-33); RX59 (Goode, IHT at 87-88); RX63 (Holland, Dep. at 140-41)).

- E. Board Members Are Required to Act Ethically, and There Is No Evidence of Bias.
- 75. All Board members are required to take an oath that they will uphold the laws of North Carolina and protect the health, safety and welfare of the public. (Wester, Tr. 1280; Owens, Tr. 1440, 1474-1475; White, Tr. 2197; Hardesty, Tr. 2763-2766; CX25 at 1; CX28 at 1; CX219 at 1; CX242 at 1; CX449 at 1; CX450 at 1).
- 76. Board members undergo ethics training once every two years pursuant to the North Carolina State Government Ethics Act ("Ethics Act"). They are required to take an ethics course within six months of being elected to the Board pursuant to N.C. Gen. Stat. § 138A-14(b). (Wester, Tr. 1278; Owens, Tr. 1436-1437; White, Tr. 2194, 2208; CX594 at 15; Hardesty, Tr. 2762; RX52 (Burnham, Dep. at 70); RX63 (Holland, Dep. at 32-33)).
- 77. The dentists on the Board, the hygienist, and the public member all receive the same ethics training. (White, Tr. 2194; CX594 at 15).
- 78. The Ethics Act became effective in 2007. Prior to the Ethics Act, the Board had training in ethics and conflict of interest policies, which was conducted by legal counsel. (White, Tr. 2194-2195).
- 79. Board members also must receive specialized training in the North Carolina Open Meetings Law, the Public Records Act, and state tort coverage. (CX593 at 2-3; White, Tr. 2194).
- 80. The North Carolina State Ethics Commission ("N.C. Ethics Commission") "regulates the Dental Board's conduct as it pertains to compliance with the Ethics Act and Lobbying Law." (CX594 at 7-8, N.C. Gen. Stat. § 138A-10; RX46 at 3).
- 81. N.C. Gen. Stat. § 138A-39(a) provides that "[w]ithin 30 days of notice of the Commission's determination that a public servant has a disqualifying conflict of interest, the public servant shall eliminate the interest that constitutes the disqualifying conflict of interest or resign from the public position." (CX594 at 31).
- 82. Board members file statements of economics interest ("SEIs") with the N.C. Ethics Commission. (Joint Stipulations ¶ 10). This includes the hygienist and the public member, in addition to the dentist Board members. The N.C. Ethics Commission reviews the SEIs and then provides notice to the Board members letting them know whether or not they have qualified to serve on the Board. (Wester, Tr. 1279; Owens, Tr. 1437; White, Tr. 2195-2196; Hardesty, Tr. 2762; CX594 at 18-23).

- 83. The SEIs filed with the N.C. Ethics Commission become public records once the Board member is sworn into office. (White, Tr. 2209; CX594 at 19).
- 84. The SEIs filed with the N.C. Ethics Commission require disclosure of financial and income information pertaining to the Board member, their spouse, and any individuals they live with. (White, Tr. 2209; CX594 at 19-23).
- 85. The N.C. Ethics Commission is required to prepare a written evaluation of SEIs submitted by prospective Board members. These evaluations are sent to the Board member who submitted the SEI, the head of the agency in which they serve, the governor for gubernatorial appointees and employees in agencies under the governor's authority, the appointing or hiring authority of agencies not under the governor's authority, and the Board of Dental Elections for Board members who are elected. (White, Tr. 2210-2211; CX594 at 22-23).
- 86. All current and former Board members received written evaluations of their SEIs from the N.C. Ethics Commission. (White, Tr. 2211; Wester, Tr. 1279; Owens, Tr. 1437-1438; Hardesty, Tr. 2762-2763; CX594 at 22, N.C. Gen. Stat. § 138A-24(e); see, e.g., CX134, CX334, CX375, CX592).
- 87. Board members who fail to comply with the relevant provisions of the N.C. Ethics Act with regard to SEIs can be assessed fines or criminally charged with the commission of offenses ranging from a class 1 misdemeanor to a class H felony. (White, Tr. 2211; CX594 at 23, N.C. Gen. Stat. § 138A-25).
- 88. Prior to the creation of the N.C. Ethics Commission, the Gubernatorial Ethics Board handled approval of SEIs. (White, Tr. 2196-2197).
- 89. Under N.C. Gen. Stat. § 138A-12(o), the N.C. Ethics Commission may remove a member of the Board from their officer status. (CX594 at 12-13; White, Tr. 2207).
- 90. Under N.C. Gen. Stat. § 138A-13, Board members may request guidance from the N.C. Ethics Commission. A written opinion provided under this provision provides safe harbor with respect to such a request. (CX594 at 13-15; White, Tr. 2207-2208).
- 91. Board members are under a continuing obligation to identify any conflicts or potential conflicts of interest, and to recuse themselves if a conflict exists. Board members are reminded of this at every Board meeting. (Wester, Tr. 1280; Owens, Tr. 1438; White, Tr. 2197, 2208-2209; Hardesty, Tr. 2763-2764; CX594 at 16, N.C. Gen. Stat. § 138A-15(d); RX51 (Brown, Dep. at 101-102); RX56 (Feingold, Dep. at 49); RX63 (Holland, Dep. at 35); RX65 (Morgan, Dep. at 127)).

- 92. Board members take this obligation seriously, and in the past have recused themselves when appropriate. (White, Tr. 2197-2198; Hardesty, Tr. 2764; RX51 (Brown, Dep. at 102, 104); RX52 (Burnham, Dep. at 72); RX55 (Efird, Dep. at 41); RX56 (Feingold, Dep. at 49); RX63 (Holland, Dep. at 35-38); RX65 (Morgan, Dep. at 127-128)).
- 93. Pursuant to the Ethics Act, Board members are not permitted to advertise their service as a Board member. (Wester, Tr. 1280; Owens, Tr. 1439; White, Tr. 2198; Hardesty, Tr. 2764; CX594 at 24, N.C. Gen. Stat. § 138A-31(b)).
- 94. Board members testified that they do not derive benefits to their day-to-day income from serving on the Board. In fact, serving on the Board takes away from their income because it forces them to be out of the office to attend to Board matters. (Wester, Tr. 1319, 1413-1414; RX65 (Morgan, Dep. at 157); RX56 (Feingold, Dep. at 28)).

F. Teeth Whitening Is the Unauthorized Practice of Dentistry in North Carolina

- 95. N.C. Gen. Stat. § 90-29 defines the unlawful practice of dentistry (in pertinent part) as follows:
 - (a) No person shall engage in the practice of dentistry in this State, or offer or attempt to do so, unless such person is the holder of a valid license or certificate of renewal of license duly issued by the North Carolina State Board of Dental Examiners.
 - (b) A person shall be deemed to be practicing dentistry in this State who does, undertakes or attempts to do, or claims the ability to do any one or more of the following acts or things which, for the purposes of this Article, constitute the practice of dentistry:
 - (2) Removes stains, accretions or deposits from the human teeth;
 - (7) Takes or makes an impression of the human teeth, gums or jaws;
 - (11) Owns, manages, supervises, controls or conducts, either himself or by and through another person or other persons, any enterprise wherein any one or more of the acts or practices set forth in subdivisions (1) through (10) above are done, attempted to be done, or represented to be done;
 - (13) Represents to the public, by any advertisement or announcement, by or through any media, the ability or qualification to do or perform any of the acts or practices set forth in subdivisions (1) through (10) above.

- G. The Investigation of Complaints of Teeth Whitening Is an Insignificant Part of the Board's Regulatory Activities.
- 96. The Board receives about 250-300 complaints per year. The substantial majority of these cases do not involve teeth whitening investigations. (White, Tr. 2219-2220; RX51 (Brown, Dep. at 224-225); RX64 (Kurdys, Dep. at 17); RX65 (Morgan, Dep. at 288)).
- 97. There were only about eighteen pending teeth whitening cases in August 2010 from complaints made over a number of years. (CX462 at 3-5).
- 98. Teeth whitening cases account for about 1% to 2% of the Board's investigations. (Wester, Tr. 1285-1286; Owens, Tr. 1445; Hardesty, Tr. 2771-2772; RX64 (Kurdys, Dep. at 37-38)).
- 99. Teeth whitening cases are a low priority for the Board. Other issues such as unsafe practitioners and defrauding government funds are higher priorities. (RX50 (Bakewell, Dep. at 306); RX59 (Goode, IHT at 90); RX63 (Holland, Dep. at 119)).

H. Teeth Whitening Cases Are Decided on a Case by Case Basis

100. The State Board decides cases involving investigations of the unauthorized practice of dentistry, including teeth whitening by non-dentists, on a case by case basis; that is, by examining the facts and evidence relevant to that particular case, and deciding whether or not to send out a cease and desist letter or take other action. (Wester, Tr. 1323; Owens, Tr. 1445, 1449; White, Tr. 2220, 2225; Hardesty, Tr. 2772; RX50 (Bakewell, Dep. at 83-84, 177, 323-324); RX51 (Brown, Dep. at 95); RX52 (Burnham, Dep. at 158-159); RX56 (Feingold, Dep. at 240); RX57 (Friddle, Dep. at 100-101); RX63 (Holland, Dep. at 195-196)).

Amazing Grace Spa, Case 07-021

- 101. The Board received a phone call from a complaining dentist on January 3, 2007. He reported that he telephoned the spa and was told they were bleaching teeth by placing a gel directly on the teeth and using an LED light. (RX1 at 3). Based on internet research and the dentist's information, a cease and desist letter was sent on March 21, 2007. (RX1 at 1).
- 102. On March 27, 2007, an esthetician who rented space at the spa responded to the Board's letter, stating that prior to receiving the Board's letter she had received a letter from the cosmetology board informing her that the BriteWhite machine she was using was illegal. She had "removed it from the salon where I rent and have not used it since." (RX1 at 1, 2).
- 103. At the direction of the investigative panel, the Board's investigator confirmed that the salon was no longer offering teeth whitening services. (RX1 at 1; CX530 at 4).
- 104. The investigative panel recommended that the file be closed. (CX530 at 4).

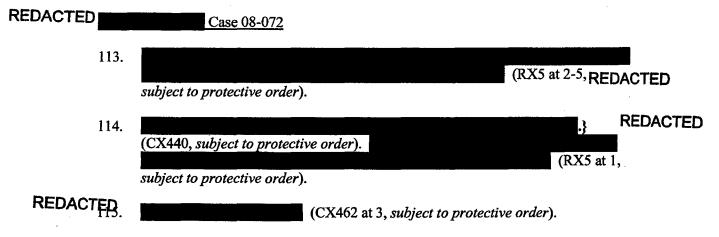
Bailey's Lightning Whitening, Case 08-133

- 105. The Board received a complaint from a dentist on June 17, 2008, about impressions taken for teeth whitening at a local salon; the complaint included an advertising brochure. (RX2 at 1-4).
- 106. Based on the advertising, a cease and desist letter was sent to the salon on July 17, 2008. (CX387). The salon owner responded, saying that she had never actually used the product and had disposed of it after receipt of the Board's letter. (RX2 at 5; CX530 at 4).
- 107. At the case officer's direction, a Board investigator visited the salon and verified that the service was no longer being offered. (RX2 at 6-7).
- 108. The investigative panel recommended that the case be closed. (CX658 at 6).

Beach Bunz Tanning Salon, Case 09-047

- 109. The Board received complaints from a practitioner and another individual on February 16, 2009, about a tanning salon offering teeth whitening services. The complainants expressed concern about the advertised use of 25% carbamide peroxide. (RX3 at 13-22).
- 110. The case officer requested further information, and a Board investigator was sent to the salon. (RX3 at 6-12).

- 111. The investigation revealed that the salon was simply selling the teeth whitening product and not assisting customers in the application of the product. (RX3 at 3-5).
- 112. Given the fact that the consumer applied the material themselves, the Board closed the file with no further action. (RX3 at 1-2).



BleachBright/Inspire Skin & Body, Case 08-214

- 116. The Board received a complaint in October 2008, including advertising, about teeth whitening sessions being offered at the spa. (RX6 at 2; CX478 at 3).
- 117. The investigative panel directed an investigator to visit the spa to find out what was going on. (RX6 at 2).
- 118. The investigator met with the spa's owner and BleachBright sales representatives who had stopped by. The sales representative informed the investigator that the company owners were in contact with the Board to ensure that what they were doing was legal. (RX6 at 2-3).
- 119. Upon receipt of the investigative report, the case officer requested further information. (RX6 at 1).
- 120. Based upon the investigative report and advertising material, the Board sent a cease and desist letter on April 3, 2009. (CX272).
- 121. The Board was subsequently informed by the spa's owner that her business had closed, and that she was no longer offering teeth whitening services at that location or any other. (CX661 at 1).

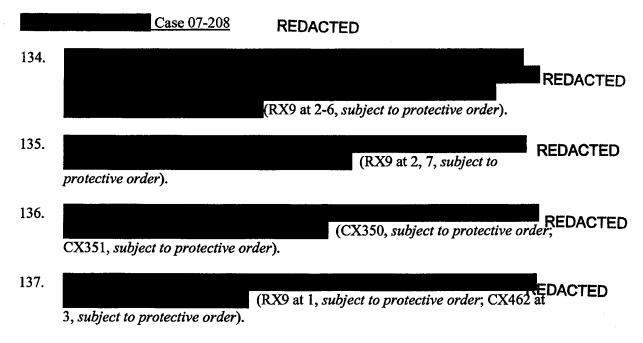
Body, Mind & Spirit Day Spa, Case 06-217

- 122. On October 10, 2006, the Board received a complaint and some advertising material mentioning laser teeth whitening taking place at a spa. (RX7 at 1; CX368 at 5).
- 123. Based upon the advertising material and at the case officer's direction, the Board sent a cease and desist letter to the spa via certified mail on March 29, 2007. (CX70; CX69).
- 124. The letter was returned to Board undelivered on two occasions. (CX368 at 5). An investigator tried to follow up, but could not locate the spa at the address in the advertising. (RX7 at 3).
- 125. The investigative panel requested that the case be closed. (CX368 at 5).

Carmel Day Spa & Salon, Case 07-146

- 126. The Board received a complaint of Zoom whitening at a spa on August 13, 2007 and commenced an investigation. (RX8 at 10, 12).
- 127. When the Board's investigator first visited this salon, the owner advised him that a licensed dentist performed the teeth whitening procedures. (RX at 6, 10). A salon representative contacted the Board the next day and stated that they would discontinue the practice and a letter would be sent in response to the allegations. (RX8 at 6, 10).
- 128. After receiving no further communication, the case officer directed that a cease and desist order be sent to the spa and a follow-up visit be made if no response was received. (RX8 at 4-5, CX349).
- 129. The cease and desist letter was sent on October 1, 2007 (CX279), and the spa's attorney contacted the Board, intimating that he would be sending a response. No response to the cease and desist letter was received. (RX8 at 6, 9).
- 130. During a follow-up visit to the spa on December 6, 2007, the Board's investigator was told that the spa did indeed provide teeth whitening services, in the form of a whitening substance being painted on the customer's teeth and activated by a light. (RX8 at 6-7).
- 131. The investigative panel decided to pursue a lawsuit. (RX8 at 9).
- 132. The Board filed a lawsuit seeking declaratory judgment and injunctive relief in Mecklenburg County Superior Court on January 22, 2008. (RX8 at 1-8).

133. A consent order of permanent injunction was filed on July 9, 2008. Conclusion of Law number 4 in the consent order stated that the defendants "have engaged in the unlicensed practice of dentistry by removing stains, accretions and deposits from human teeth and by circulating brochures and otherwise representing that ... they are capable of removing stains, accretions and deposits from human teeth at a time when no employee of Carmel Day Spa was licensed to practice dentistry in North Carolina." (RX8 at 15-17).



Champagne Taste/Lash Lady, Case 07-114

- 138. The Board began its investigation on January 7, 2007 after receiving an email notifying the Board of an advertisement for in-office whitening at this facility using an LED light. (RX10 at 1; CX622 at 3).
- 139. Board staff researched this establishment by checking Champagne Taste's website, which advertised WhiteSpa professional teeth whitening. (RX10 at 2-3).
- 140. Based on this advertising information from the website, the Board sent a cease and desist letter on February 8, 2007. (CX77).
- 141. The owner of Champagne Taste contacted the Board office by telephone on March 26, 2007 to confirm that she was no longer offering tooth whitening services. (CX75).
- 142. Based on the owner's response, the investigative panel recommended that the file be closed. (CX622 at 3).

Details, Inc., Case 06-198

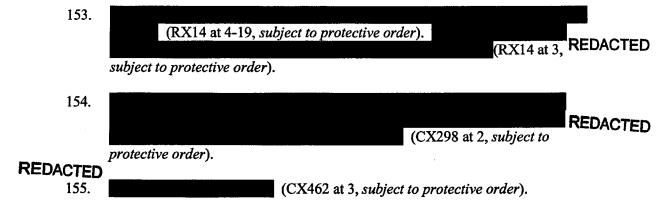
- 143. The Board received a complaint that included advertising for the spa. The advertisement implied that the spa was providing teeth whitening using LED light technology. (CX660 at 3).
- 144. Based on the advertisement, a cease and desist order was sent. (CX660 at 3).
- 145. In their response to the Board, the owner of the BriteWhite Teeth Whitening machine maintained that she sold her equipment to a medical spa in Washington, DC and no longer provided teeth whitening services. (CX660 at 3).
- 146. Based on the information provided, the investigative panel recommended that the file be closed. (CX660 at 3).

Edie's Salon Panache, Case 04-187

- 147. The Board received several faxes, emails, and mailings in late August/early September 2004 about this salon. Each communication made reference to a flyer advertising teeth whitening at the salon. (RX11 at 7-13).
- 148. An undercover investigation revealed that a makeup artist at the salon was making custom impressions as part of her teeth whitening services. She was not wearing gloves or following any sterilization procedures, and she had a poison ivy rash on her hands. (RX11 at 5-6; RX58 (Friddle, IHT at 96)).
- 149. The case officer elected to go forward with the case with the approval of the Board. (CX437; RX49 (Allen, Dep. at 119-120)).
- 150. An arrest warrant was issued to the makeup artist on October 27, 2004, on the charge of practicing dentistry without a license. (RX11 at 4).
- 151. She pled not guilty, but was found guilty of the charge. On January 5, 2005, the Cabarrus County District Court granted a prayer for judgment continued on the condition the makeup artist not engage in the unauthorized practice of dentistry. (RX11 at 1; RX57 (Friddle, Dep. at 128-129)).

Case 08-083 REDACTED

152. (RX14 at 1, 2, 20, subject to protective order).

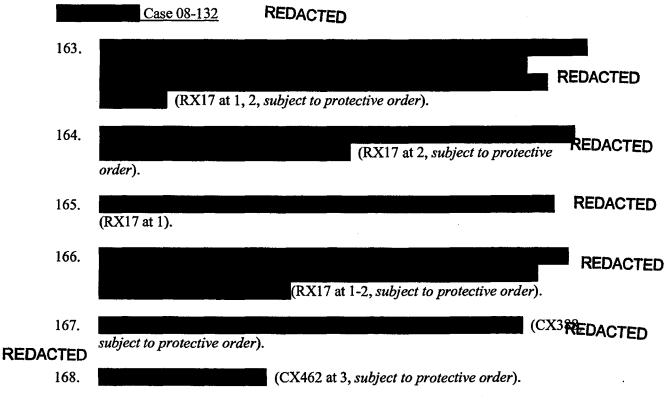


Great White, Case 03-184

- 156. The Board received a complaint on September 23, 2003 about impressions being taken at a trade show. (RX33 at 2-4).
- 157. The Board was subsequently informed that Great White had discontinued doing business in North Carolina, but may be planning to return. (CX32 at 4, 5, 6, 7).
- 158. A Board staff member was sent to a trade show in Raleigh, but did not find Great White in attendance. (CX32 at 3).
- 159. The file was closed for lack of evidence. (CX33 at 1).

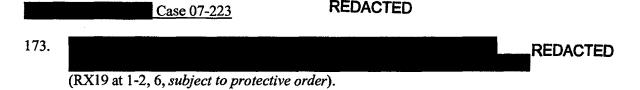
Hollywood Smiles, Case No. 04-188

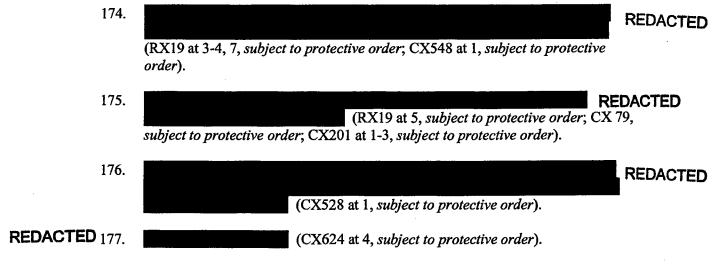
- 160. The Board received an advertising brochure for teeth whitening services at this spa. The brochure was full of false claims about the effectiveness of the teeth whitening gel and its ability to penetrate to the interior of the teeth. It also claimed that the stains "will not reappear." (RX15 at 13-14).
- 161. Board staff paid an undercover visit to the spa, where the proprietor took impressions of her teeth and created a custom teeth whitening tray on the premises. She also received a teeth whitening kit containing a 22% carbamide peroxide solution. No tooth whitening was done on the premises. (RX15 at 9-10).
- 162. An arrest warrant was issued by a Davidson County magistrate for the offense of engaging in the practice of dentistry without a license on November 23, 2004 (RX15 at 7-8). The district attorney then undertook the prosecution of the case. (RX15 at 1). The District Attorney voluntarily dismissed the criminal charges against the spa owner after she signed an affidavit stating she would no longer take teeth impressions in connection with the sale of teeth whitening kits. (RX15 at 1-4; RX57 (Friddle, Dep. at 129-130)).



Master Tanning Salon, Case 09-048

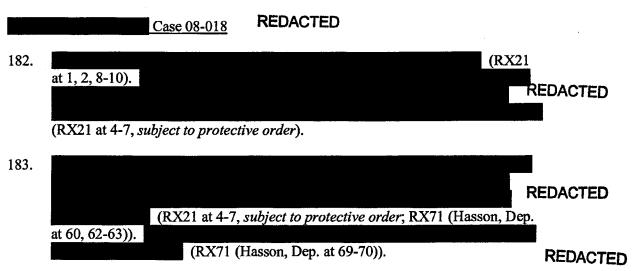
- 169. The same complainants as in the Beach Bunz Tanning Salon case alerted the Board to possible teeth whitening occurring at this establishment on February 16, 2009. (RX18 at 8-12).
- 170. The case officer requested further information, and a Board investigator was sent to the salon. (RX18 at 2-7).
- 171. The investigation revealed that the business was a teeth whitening kit supplier and clients would self-apply. (RX18 at 13).
- 172. The file was closed since the salon was not providing teeth whitening services. (RX18 at 1; RX58 (Friddle, IHT at 79)).

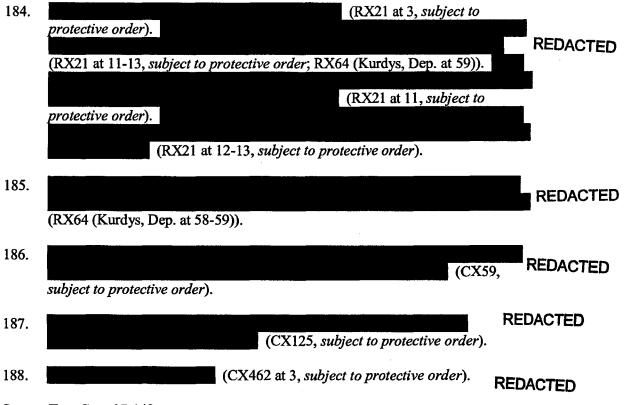




One West Salon & Day Spa, Case 06-008

- 178. The Board received a fax from a dental hygienist on January 5, 2006, with an advertisement from One West Salon, "introducing teeth whitening only \$169 for top & bottom." (RX20 at 4-5).
- 179. An investigator visited the salon and reported that they were simply selling the kits. (RX20 at 2-3).
- 180. A follow-up letter was sent to the spa on June 23, 2006, reiterating the provisions of the unauthorized practice of dentistry in the Dental Practice Act. (RX20 at 1).
- 181. The case officer found no violation of the Dental Practice Act, and the investigative panel recommended that the case be closed. (CX229 at 1, CX234 at 9).





Savage Tan, Case 07-148

- 189. The Board received a complaint on August 8, 2007 about an advertisement for teeth whitening services, and the case officer requested an investigation. (RX22 at 20-23).
- 190. A Board investigator visited the salon and was informed that the teeth whitening procedure was performed by brushing a gel on the client's teeth and using a curing light. (RX22 at 18-19; CX623 at 3).
- 191. Board staff contacted the individual who performed the teeth whitening by telephone and informed him that it was unlawful to offer teeth whitening services of this nature; however, he indicated that he did not intend to stop offering the services. (CX623 at 4).
- 192. A cease and desist order was sent by certified mail, but was not accepted. After the first cease and desist order was returned undelivered, the Board attempted to serve another cease and desist order through the Guilford County Sheriff on October 18, 2007. This attempt was not successful. (CX95).

- 193. The Board issued a third cease and desist order on November 26, 2007 and attempted service through a private investigator. (CX94). The private investigator was unable to personally serve the cease and desist order but left a copy with the individuals spouse at her place of employment. (RX22 at 1-17).
- 194. A subsequent visit to the salon revealed that teeth whitening services were no longer being offered or provided. (CX623 at 4).
- 195. The investigative panel recommended that the file be closed unless it was discovered that the individual was performing teeth whitening at another location. (CX623 at 4).

Serenity Day Spa, Case 05-210

- 196. On November 3, 2005, the Board received a report from a licensed dentist that a spa was taking impressions to create bleaching trays. A brochure for the spa also advertised "professional teeth whitening." (RX23 at 2-3).
- 197. The case was assigned, and the case officer directed that a staff member should visit the spa to have impressions done. (CX38 at 2, 4-5). A Board staff member contacted the spa to make an appointment for "professional teeth whitening." She was informed that the spa no longer offered the service due to difficulties with a supplier. (RX23 at 1).
- 198. On January 11, 2006, the Board sent a cease and desist letter to the spa about reports that they may be taking impressions, which constitutes the unlicensed practice of dentistry. (CX38).
- 199. A response was received from a dental assistant who was working at the spa. She assured the Board that they were merely selling kits. (CX37).

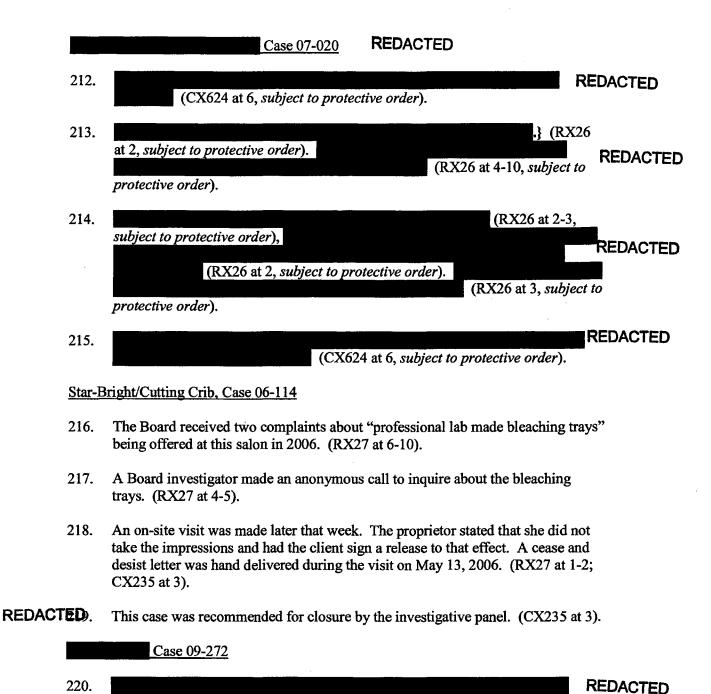
SheShe Studio Spa, Case 07-026

- 200. The Board received a complaint based upon advertising of teeth whitening services by this spa on February 15, 2007. (RX24 at 3). The spa's brochure advertised the taking of impressions in an identical procedure to that used by dentists. (RX24 at 4-5).
- 201. Based upon the spa's advertising, a cease and desist letter was sent on February 23, 2007. (CX96; Hughes, Tr. 943-944).
- 202. The Board received a response to the cease and desist letter from Margie Hughes on March 7, 2007. The letter, written in conjunction with Peggy Grater of Grater Whiter Smiles, stated that the customer took the impressions. (CX655; Hughes, Tr. 946-947).

- 203. Board Counsel sent a follow-up letter about the taking of impressions, which was returned undelivered. (RX24 at 1-2; CX368 at 5).
- 204. A Board investigator contacted Ms. Hughes several months later to determine whether she was in compliance with the law. (RX24 at 1-2). Ms. Hughes assured the investigator that she was not taking impressions. She also had a consent form on which her clients state that they will take their own impressions. (RX24 at 2; CX368 at 5).
- 205. Based on the evidence, the investigative panel recommended that the file be closed. (CX368 at 6).

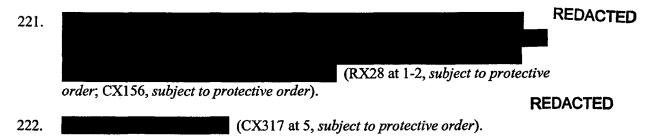
Signature Spas, Case 06-193

- 206. The Board received a formal complaint on September 8, 2006. (RX25 at 17-21).
- 207. A Board staff member posing as a potential customer made an undercover visit to the spa. The investigation revealed that a spa employee who formerly worked as a dental assistant was performing teeth whitening services. The whitening process involved the direct application of a hydrogen peroxide gel by the spa's employees and the shining of an LED light on the teeth. In some instances, the teeth were also polished to loosen stains or bacteria prior to the whitening procedure. (RX25 at 15-16).
- 208. There was some communication between Board Counsel and one of the spa principals about resolving the matter. (RX50 (Bakewell, Dep. at 223)). In a follow up letter to the conversation, Board Counsel sent a copy of the relevant statute and a proposed consent order for consideration. (CX366 at 1-2).
- 209. The Board filed a lawsuit seeking injunctive relief and a motion for a temporary restraining order in Catawba County Superior Court on November 21, 2006. (RX25 at 1-14). The court entered a temporary restraining order on November 22, 2006. (CX57).
- 210. Signature Spas voluntarily ceased offering teeth whitening services. However, the signing of a consent order remained an issue. (CX230; CX231). There were some back and forth negotiations about the contents of the consent order, particularly in regards to the admission of a violation of the Dental Practice Act. (CX212 at 1; CX215 at 1-2; CX126 at 1; CX127 at 1-3; CX216 at 1-3).
- 211. A consent order of permanent injunction was entered on October 28, 2008, which perpetually enjoined "Signature Spas and its employees from removing stains, accretions and deposits from human teeth and from representing to the public that it or they are capable of removing stains, accretions and deposits from human teeth, unless appropriately licensed as required by N.C. Gen. Stat. § 90-29." (RX25 at 25-27).



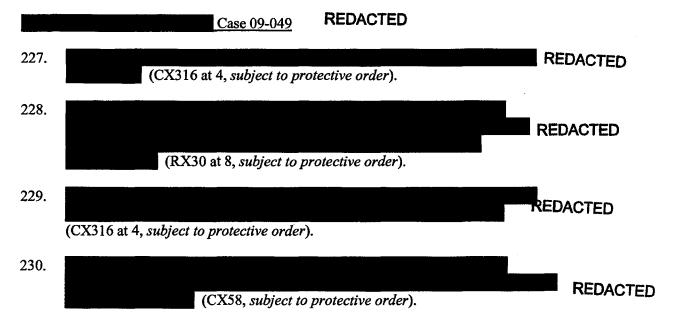
protective order).

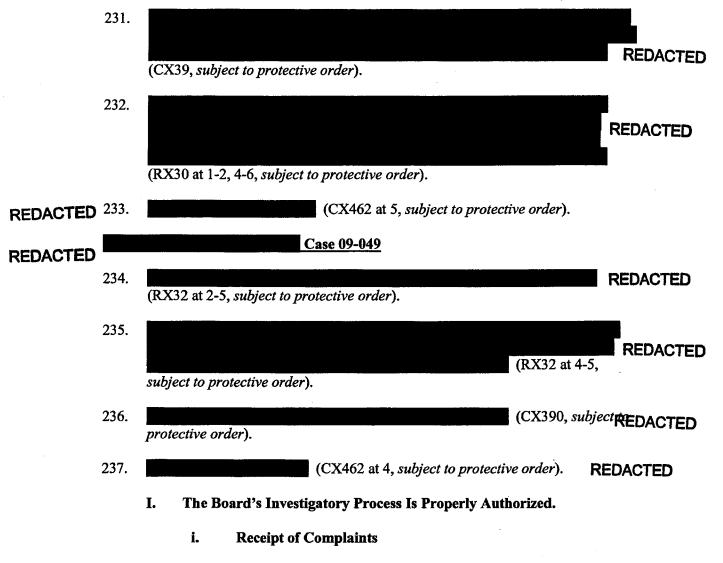
(RX28 at 3-4, subject to



Sunsational Tan, Case 07-120

- 223. The Board was informed on June 28, 2007, that a tanning salon was performing teeth whitening. The anonymous informant reported calling the salon and being told that "a device like a retractor is put in the mouth, then gel & it interacted w/uv light." (RX29 at 2). The complainant also forwarded a newspaper ad indicating "UV teeth whitening [was] available." (RX29 at 1-2).
- 224. Based upon this information, the Board sent a cease and desist letter to the salon on July 3, 2007. (CX65). An additional cease and desist letter was sent on September 4, 2007. (CX98 at 1-2).
- 225. An investigator was sent to the salon to determine if teeth whitening activity was still being performed. He was told that the salon was only selling the kits and the clients put the whitening material on their own teeth. No impressions were taken, and the staff did not apply gel or otherwise interact with the clients. (RX29 at 1; CX659 at 3).
- 226. The investigative panel recommended that the file be closed. (CX659 at 3).





- 238. The Board is complaint driven and will not open a case upon its own volition. (RX49 (Allen, Dep. at 34); RX51 (Brown, Dep. at 77-79); RX52 (Burnham, Dep. at 171-174); RX57 (Friddle, Dep. at 59); RX63 (Holland, Dep. at 154-156, 248); RX64 (Kurdys, Dep. at 53, 81-82); RX65 (Morgan, Dep. at 258-259, 287-288)).
- 239. Most of the complaints come in the form of a written, signed, and notarized complaint. There are a few instances where written complaints are not necessary, such as cases involving drug/alcohol abuse, prescription violations, infection, and sterilization problems at a dentist's office. (Wester, Tr. 1285).

- 240. The majority of the complaints that the Board receives come from the public. This can include other dentists and dental hygienists, but could also be from insurance companies who believe that they have discovered fraud. (Owens, Tr. 1444; White, Tr. 2219; Hardesty, Tr. 2771).
- 241. Teeth whitening complaints were made by consumers, dentists, dental hygienists, and dental assistants. (RX59 (Goode, IHT at 24-26); RX64 (Kurdys, Dep. at 57)).
- 242. Generally, persons who complained about non-dentist teeth whitening were asked to provide documentation to the Board if they had not already done so. (RX57 (Friddle, Dep. at 60-61; RX57 (Friddle, IHT at 19)).
- 243. The FTC's action against the Board has had a chilling effect on the Board's complaint process. A number of people who reported complaints to the Board were investigated by the FTC, which would tend to discourage people from filing complaints with the Board. (White, Tr. 2234-2235).
- 244. Although the Board has continued to investigate teeth whitening cases after receiving notice of the FTC's investigation, it has taken no action to resolve these cases. (Owens, Tr. 1447-1448; White, Tr. 2234; RX57 (Friddle, Dep. at 139-140); RX58 (Friddle, IHT at 58-60); RX59 (Goode, IHT at 99-101); RX63 (Holland, Dep. at 153-154, 157)).

ii. The Secretary-Treasurer Appoints the Case Officer.

- 245. When a complaint comes in, it is assigned a number by the director of investigations and sent to the Secretary-Treasurer, who evaluates it for jurisdictional issues and assigns it to a case officer. The Secretary-Treasurer will not assign a case to a Board member if the dentist complained of is in the same geographic area of the state in which the Board member practices. (Wester, Tr. 1281; Owens, Tr. 1440, 1464; White, Tr. 2202-2203, 2219-2220; Hardesty, Tr. 2765-2766; RX49 (Allen, Dep. at 38); RX58 (Friddle, IHT at 39); RX65 (Morgan, Dep. at 80-83)).
- 246. Once a case is assigned by the Secretary-Treasurer to a case officer, the case becomes that case officer's responsibility. The case officer has discretion in running the case, including sending out letters to collect more information, ordering further investigation, having the patient evaluated, and sending out a cease and desist letter. (Wester, Tr. 1281; Owens, Tr. 1440-1441, 1441-1442; White, Tr. 2202-2203; Hardesty, Tr. 2765-2767; RX50 (Bakewell, Dep. at 236); RX56 (Feingold, Dep. at 151); RX57 (Friddle, Dep. at 66); RX58 (Friddle, IHT at 45, 81-82); RX59 (Goode, IHT at 57-58); RX64 (Kurdys, Dep. at 14, 55-56); RX65 (Morgan, Dep. at 122-123)).

- 247. If a case officer finds out that a non-dentist is providing dental services, the case officer would send an investigator to investigate and gather more information. (Wester, Tr. 1286).
- 248. If the case officer finds evidence of a violation, they can instruct the Board attorney or staff to send a cease and desist letter or file an injunction. (Wester, Tr. 1286; Hardesty, Tr. 2772-2773).

iii. The Case Officer, Staff, and Legal Counsel Form the Investigative Panel.

- 249. The Board has an investigations manual, which is followed and accurately reflects the Board's investigative procedures. Teeth whitening cases are encompassed under the heading "practicing dentistry without a license" in the investigations manual. (RX54 (Dempsey, IHT at 38-39, 54)).
- 250. The investigative panel includes the case officer, the Board's staff assistant assigned to the case, a Board investigator, and sometimes the Board attorney. (Owens, Tr. 1441; RX58 (Friddle, IHT at 81-82)).
- 251. Other members of the Board do not have knowledge of a case assigned to a case officer; only that case officer and the investigative panel know the details of the case. (Wester, Tr. 1282; Owens, Tr. 1442; Hardesty, Tr. 2767-2768; RX49 (Allen, Dep. at 39); RX51 (Brown, Dep. at 116, 160-161); RX58 (Friddle, IHT at 35-36); RX60 (Hall, Dep. at 61); RX63 (Holland, Dep. at 199); RX65 (Morgan, Dep. at 122-123)).
- 252. When the first non-dentist teeth whitening complaints were received by the Board, the investigative panel consulted with counsel as to their authority to pursue the cases. (RX58 (Friddle, IHT at 101-102)).
 - iv. No One Outside the Investigative Panel Knows the Details of a Case, With the Possible Exception of the Complainant.
- 253. A case officer does not have knowledge of other cases handled by a separate case officer. (Wester, Tr. 1281, 1287; White, Tr. 2221; RX65 (Morgan, Dep. at 242)).
- 254. The details of an investigation remain confidential until the investigation is concluded. Investigations are not discussed with the public, including other dentists. (Wester, Tr. 1281, 1282-1283, 1286-1287; Owens, Tr. 1442-1443, 1450; White, Tr. 2221-2223; Hardesty, Tr. 2767-2769).
- 255. Board members do not discuss with each other anything pertaining to cease and desist letters. (Hardesty, Tr. 2773).

- 256. Board members do not discuss with members of the general public anything pertaining to cease and desist letters. (Hardesty, Tr. 2773).
- 257. Board members do not discuss with non-Board member dentists anything pertaining to cease and desist letters, other than dentists who are complainants. (Hardesty, Tr. 2773).

v. The Case Officer Decides a Course of Action Without Consulting with Other Board Members.

- 258. Once an investigation is completed, the case officer decides whether or not there is a violation of the Dental Practice Act. In cases involving licensees, the case officer can send it to the Board for a vote to dismiss the case, have a prehearing conference, a settlement conference, or a formal hearing. (Wester, Tr. 1283; Owens, Tr. 1443; White, Tr. 2223-2224; Hardesty, Tr. 2769-2770).
- 259. When dealing with non-licensed persons who are violating the Dental Practice Act, the only options the case officer has are to send a cease and desist letter, seek a civil injunction, or refer the matter to a local district attorney for criminal prosecution. The case officer can direct the Board attorney to do so without Board approval. (Wester, Tr. 1284; Owens, Tr. 1443-1444; White, Tr. 2224; Hardesty, Tr. 2770; (RX58 (Friddle, IHT at 63)).
- 260. The Board as a whole does not vote to file an injunction in a case or to open an investigation. (Wester, Tr. 1285; Owens, Tr. 1444; White, Tr. 2224-2225; Hardesty, Tr. 2771).
- 261. The Board would not know that a cease and desist letter had been sent or an injunction issued unless the recipient challenged it in court. However, the Board may be informed that such a letter had been sent out at the next Board meeting. (Wester, Tr. 1284, 1286; Owens, Tr. 1444, 1450; White; Tr. 2224; Hardesty, Tr. 2773; RX56 (Feingold, Dep. at 132)).
- 262. The Board would discuss and vote on whether to file civil litigation. (RX50 (Bakewell, Dep. at 84); RX63 (Holland, Dep. at 157)).
- 263. The entire Board would vote to go ahead with a civil or criminal action. (RX58 (Friddle, IHT at 57-58)).
- 264. The case officer's decision is eventually sent to the Board for a vote for the case to be resolved. (Wester, Tr. 1283; Owens, Tr. 1444; White, Tr. 2223-2224; RX51 (Brown, Dep. at 160-161)).
- 265. The Board votes as a body to close a case or investigation. (Wester, Tr. 1285; Owens, Tr. 1444; White, Tr. 2225; Hardesty, Tr. 2771; RX54 (Dempsey, IHT at 81); RX58 (Friddle, IHT at 82)).

- vi. Dr. Owens Is the Case Officer for Most of the Teeth Whitening Cases.
- 266. Dr. Owens served as case officer for at minimum eighteen of the Board's teeth whitening cases, which constitutes the majority of the Board's teeth whitening cases. (Owens, Tr. 1441, 1444; White, Tr. 2224; CX462 at 3-5).
- 267. Dr. Owens assigned himself teeth whitening cases when he served as Secretary-Treasurer. (Owens, Tr. 1445-1446).
- 268. There was no official discussion within the Board or involving Board staff about specifically assigning all teeth whitening cases to Dr. Owens. (RX57 (Friddle, Dep. at 97-99)).
- 269. Cases of a certain type will often be assigned to a particular Board member/case officer to maintain consistency. (RX57 (Friddle, Dep. at 98, 101); RX65 (Morgan, Dep. at 82)).
- 270. None of the recipients of cease and desist letters in the teeth whitening cases assigned to Dr. Owens ever filed a legal challenge to the Board's cease and desist letters, nor did they have legal counsel file any action against the Board challenging its authority. (Owens, Tr. 1448; White, Tr. 2232).
- 271. Teeth whitening products and services constituted only about of Dr. Owens' practice revenues for (CX467 at 1, subject to protective order).
 - J. Cease and Desist Letters Are Authorized Enforcement Techniques and Are Appropriately Utilized by the Board.
 - i. The Board's Enforcement Authority Regarding Cease and Desist Letters
- 272. No kiosk, spa, or other provider of teeth whitening services by a non-dentist could actually be forced to stop operations unless the Board obtained either a court order or the cooperation of a district attorney in a criminal conviction and a court judgment. (Owens, Tr. 1450-1451; Hardesty, Tr. 2774; RX53 (Dempsey, Dep. at 41); CX19 at 20-21).
- 273. The State Board does not have the statutory authority to independently enforce an order to any person or entity that they cease or desist violating the provisions of the Dental Practice Act. (White, Tr. 2228; RX48 (Allen, Dep. at 126); RX50 (Bakewell, Dep. at 216)).

- 274. The State Board is not prohibited or proscribed by any statute, rule or regulation, or by any other authority, from ordering that any person or entity cease and desist from violating provisions of the Dental Practice Act. (RX50 (Bakewell, Dep. at 214-215); RX65 (Morgan, Dep. at 247-248)).
- 275. Under the operation of N.C. Gen. Stat. §§ 90-40 (making the unauthorized practice of dentistry a misdemeanor) and 90-40.1 (enjoining unlawful acts), the Board has clearly been granted the authority to notify prospective defendants in advance of initiating a judicial proceeding. (CX19 at 20; RX50 (Bakewell, Dep. at 215)).
- 276. Complaint Counsel has cited no legal authority that a cease and desist letter that orders people to stop violating the Dental Practice Act is an *ultra vires* act of the State Board, a violation of any antitrust statute or, for that matter, a violation of any state or federal law. (Entire record).
- 277. Complaint Counsel has made no presentation of fact that any such cease and desist letter has restrained any lawful activity. (Entire record).

ii. Cease and Desist Letters in General

- 278. The general form of "cease and desist" letters or orders utilized by the State Board is a time honored, customary, and widely accepted method of enforcing prohibitions on unauthorized practice across a broad variety of professions in North Carolina and in a large number of states. (White, Tr. 2226-2227; see also (RX37 at 2; RX38; RX39).
- 279. The North Carolina Board of Massage & Bodywork, which has a similar enforcement statute, N.C. Gen. Stat. § 90-634, to that of the Respondent, has made it a practice of sending cease and desist orders to unauthorized practitioners of that licensed profession. (RX34 at 3; RX35 at 3; RX36 at 5).
- 280. Other North Carolina state boards that use cease and desist letters to enforce prohibitions on the unauthorized practice of a licensed profession include the North Carolina State Bar, the North Carolina Medical Board, and the North Carolina Board of Pharmacy. (White, Tr. 2226-2227).
- 281. Many of the cease and desist letters sent by the State Board state only that the recipient is to cease and desist "any and all activity constituting the practice of dentistry or dental hygiene," provides the verbatim part of the statute, and requests the recipient's cooperation. (CX42; CX58; CX59; CX68; CX69; CX74; CX96; CX97; CX112; CX279; CX351; CX386; CX387; CX388; CX389; CX390; CX391).

- 282. Board legal counsel, not Board members, drafts the Board's cease and desist letters. (Wester, Tr. 1286; Owens, Tr. 1449-1450; White, Tr. 2227; RX57 (Friddle, Dep. at 62-63)).
- 283. Board members and Board staff have referred to these cease and desist letters alternately as both "letters" and "orders." (Wester, Tr. 1349; Owens, Tr. 1506-1509; CX462 at 3-5; RX19 at 5; RX28 at 1; RX57 (Friddle, Dep. at 63)).
- 284. Cease and desist letters are sent by the Board where there is evidence that a person is engaged in the unauthorized practice of dentistry, not just teeth whitening. (RX59 (Goode, IHT at 56-57); RX63 (Holland, Dep. at 173)). (For example, see CX62, CX63, and CX306).
- 285. The cease and desist letters sent to non-dentists engaged in teeth whitening were based on cease and desist letters sent to individuals engaged in other types of unlawful practice of dentistry. (RX57 (Friddle, Dep. at 62-63); RX53 (Dempsey, Dep. at 135)).
- 286. The Dental Practice Act does not require a showing of harm for a violation of the Act to occur. (RX51 (Brown, Dep. at 222); RX50 (Bakewell, Dep. at 181)).
- 287. In the absence of an in-person investigation, cease and desist letters were sent because there was credible evidence of a violation, usually advertising, or on the face of the complaint. (RX56 (Feingold, Dep. at 267-277); RX58 (Friddle, IHT at 51-52, 53-54)).
- 288. In every instance, cease and desist letters were sent by the State Board only when there was *prima facie* evidence from a credible source of a violation. (RX7 at 3) (Body, Mind & Spirit Day Spa, #06-217, spa advertisement offering "laser teeth whitening"); (RX9 at 2, 7)

REDACTED

(RX10 at 2, *subject to protective order*) (Champagne Taste/Lash Lady, #07-114, spa's internet advertising was accessed prior to the sending of the cease and desist letter); RX58 (Friddle, IHT at 53-54)).

289. The Board has sent at least 40 cease and desist letters to non-dentist teeth whiteners. (Joint Stipulations ¶ 30). Some, but not all, of the letters were styled as cease and desist orders. Others were styled as a notice of apparent violation and demand to cease and desist. (CX153; CX155; CX156).

- 290. The cease and desist letters were intended to warn the recipient that what they were doing was potentially illegal and requested that they stop. (Owens, Tr. 1451, 1515-1518; White, Tr. 2229; RX49 (Allen, Dep. at 126-127); RX50 (Bakewell, Dep. at 215); RX52 (Burnham, Dep. at 102-103); RX63 (Holland, Dep. at 125-126); RX64 (Kurdys, Dep. at 118)).
- 291. The Board also intended to inform cease and desist letter recipients about the status of North Carolina's law. (White, Tr. 2230; RX49 (Allen, Dep. at 41-42)).
- 292. Cease and desist letters were a reasonable, common sense method by which persons were given an opportunity to voluntarily comply without the Board resorting to litigation or criminal prosecution. (RX50 (Bakewell, Dep. at 211-212, 215); RX56 (Feingold, Dep. at 104)).

iii. Options Available to Recipients of Cease and Desist Letters

- 293. Pursuant to N.C. Const. art. 1, § 18, every person has the right to access the courts of North Carolina to address an alleged injury. (Joint Stipulations ¶ 15).
- 294. Some recipients of cease and desist letters voluntarily stopped offering teeth whitening services, and the Board closed its investigation. (RX58 (Friddle, IHT at 44)).
- 295. The recipients of the cease and desist letters, as persons aggrieved in the teeth whitening cases, could have requested an administrative hearing proceeding under the Administrative Procedure Act, but did not do so. (White, Tr. 2232, N.C. Gen. Stat. § 150B-23(a)).
- 296. The recipients of the cease and desist letters in the teeth whitening cases could have filed a request for a declaratory judgment under the Administrative Procedure Act, but did not do so. (White, Tr. 2232-2233; CX515 at 8, N.C. Gen. Stat. § 150B-4; RX50 (Bakewell, Dep. at 87-88)).
- 297. Any person or entity receiving a cease and desist letter has the ability to pursue relief in the courts of the State of North Carolina if they feel they have been aggrieved. (Wester, Tr. 1284; Hardesty, Tr. 2774; White, Tr. 2234; RX50 (Bakewell, Dep. at 214-215)).
- 298. In certain instances, recipients of cease and desist letters made an informal showing that what they were doing was not barred by statute (notwithstanding their marketing material or what a witness reported), and the Board closed their file with no further action. (RX20 at 2; RX29 at 1).
- 299. Any person or entity ordered by the Board to cease and desist any activity may disregard such an order. (Owens, Tr. 1451; Hardesty, Tr. 2774; RX53 (Dempsey, Dep. at 41)).

300. Pursuant to N.C. Gen. Stat. § 90-40.1, in the event that a person or entity disregards an order to cease and desist any activity issued by the State Board, the Board is authorized by the Dental Practice Act to seek enforcement of that order in the courts of North Carolina by injunctive relief. (Wester, Tr. 1287-1288; CX19 at 20).

iv. No Member of the Teeth Whitening Industry Sought to Challenge the Board's Letters

- 301. James Valentine admitted under oath that WhiteSmile USA chose not to file anything against the Board, such as a declaratory ruling or requesting an administrative hearing, to challenge whether his business constituted the unlicensed practice of dentistry. (Valentine, Tr. 585-586).
- 302. George Nelson admitted under oath that WhiteSciences's local affiliates that received cease and desist letters from the Board discussed those letters with him and were aware that they could take legal action against the Board to challenge the cease and desist letters, but chose not to. (Nelson, Tr. 776).
- 303. Joyce Osborn admitted under oath that despite being advised that she could challenge the stance of state dental licensing boards on non-dental teeth whitening by filing a declaratory judgment action, she has not considered filing a declaratory judgment action against the Board in North Carolina. (Osborn, Tr. 694).
- 304. The Council for Cosmetic Teeth Whitening has been advised by an attorney that it could file a declaratory judgment action to challenge a dental board that had raised concerns about not having a dentist supervising teeth whitening operations, but has not pursued that course of action. (Osborn, Tr. 693-694).
- 305. Bryan Wyant admitted under oath that he did not consult an attorney about challenging the actions of the Board. He also did not contact the Board about whether or not he could sell take-home or over-the-counter teeth whitening kits. (Wyant, Tr. 920).
- 306. Mr. Wyant testified that he understands that he could go to court to challenge the Board with respect to providing teeth whitening services, but he never exercised his right to do so. (Wyant, Tr. 921).

K. The Board's Contact with Third Parties Was Undertaken in Furtherance of Its Public Protection Role.

i. Letters Sent to Mall Management

- 307. The Board sent letters to mall operators correctly stating that the unauthorized practice of dentistry was a misdemeanor pursuant to N.C. Gen. Stat. § 90-40. The letters did not ask the mall operators not to lease space to teeth whitening businesses operated by non-dentists. Further, the letters stated that "[t]he Dental Board would be most grateful if your company would assist us in ensuring that property owned or managed by your company is not being used for improper activity that could create a risk to the public health and safety." (CX203 CX205; CX259 CX263; CX323 CX325).
- 308. Similar letters have been sent by other North Carolina licensing boards. For example, the North Carolina Board of Massage & Bodywork Therapy sent "informational letters" to all major shopping malls and all major airports in the state apprizing them of the requirement that persons providing massage and bodywork therapy in those locations be licensed. (RX35 at 1; RX36 at 3).
- 309. The purpose of the letters sent to mall operators by the State Board was informational and to prevent harm to the public. (RX50 (Bakewell, Dep. at 259, 262-264, 286-87); RX52 (Burnham, Dep. at 178-179); RX56 (Feingold, Dep. at 203); RX58 (Friddle, IHT at 72-73, 75-76)).
- 310. The Board did not believe that commercial property owners would be violating the law by leasing space to non-dentist teeth whiteners. (Joint Stipulation ¶ 32).
- 311. There were no discussions within the Board or with Board staff about strategies or tactics to reduce or eliminate mall teeth whitening kiosks. (RX56 (Feingold, Dep. at 204)).
- Board Counsel testified that the Board has no intention of taking any action against mall owners. (RX50 (Bakewell Dep. at 264)).
- 313. Board members testified that they are aware that the Board has no authority to force the mall operators to stop leasing a kiosk or other retail space to a non-dentist teeth whitening business. (Owens, Tr. 1451; Hardesty, Tr. 2774).
- John Gibson testified that he would have been willing to lease a kiosk at his malls to a teeth whitening operation if he was assured that it could be done legally, but when he heard that the Board considered it the unlicensed practice of dentistry without a licensed dentist supervising, he was not willing to allow it. (Gibson, Tr. 630-631).

- 315. BleachBright of Carolina misrepresented to Mr. Gibson and his associate, Cathy Elkins (formerly Cathy Mosley) that the Board had approved BleachBright's non-dentist supervised provision of teeth whitening services. This prompted Ms. Elkins to follow up with the Board on this issue. (CX525; Gibson, Tr. 629-632, 637-638).
- 316. All inquiries from property management companies asking about the legality of teeth whitening kiosks were referred to Board Counsel. (RX58 (Friddle, IHT at 77-78)).
- 317. In responding to Ms. Elkins' email asking whether the Board had approved BleachBright's non-dentist supervised teeth whitening activities, Carolin Bakewell did not say that such activity was illegal, but that it was not approved by the Board and that BleachBright's representatives should contact the Board to clear up any confusion. (CX525; Gibson, Tr. 641-643).
- 318. Ms. Friddle testified that she did not receive any calls from persons who were having problems leasing retail space for teeth whitening operations. (RX58 (Friddle, IHT at 78)).
- 319. Mr. Gibson would not decline a tenant that wanted to lease a kiosk at his mall to provide over-the-counter teeth whitening products. (Gibson, Tr. 633-634).
- 320. Mr. Gibson testified that the decision to not lease to a teeth whitening kiosk would not adversely affect his company's profitability. (Gibson, Tr. 636).
- 321. A standard provision included in leases with Mr. Gibson's management company, Hill Story Gibson Companies ("HSG"), is that his tenants be in compliance with the law and carry liability insurance. (Gibson, Tr. 636).
- 322. Food kiosks at HSG are required to have both a health department inspection and permit, because they are required to obtain all necessary licenses under the local ordinances or laws of the state. The same is true for all businesses. For instance, a kiosk selling eyeglasses would also be required to obtain a license and a permit. (Gibson, Tr. 638).
- 323. If a business trying to lease a kiosk did not have such permits, Mr. Gibson would not allow it to operate in his malls. (Gibson, Tr. 638-639).
- 324. Mr. Gibson's malls do have the capability to run water to a kiosk, and have done so before for a TCBY frozen yogurt stand. (Gibson, Tr. 639).

ii. Communication with the North Carolina Board of Cosmetic Art Examiners

325. The Board contacted the North Carolina Board of Cosmetic Art Examiners (the "Cosmetology Board") about the subject of non-dentist teeth whitening services and provided the Cosmetology Board with a notice in February 2007 that stated:

"Cosmetologists should be aware that any device or process that 'removes stains, accretions or deposits from the human teeth' constitutes the practice of dentistry as defined by North Carolina General Statutes 90-29(b)(7).

Only a licensed dentist or dental hygienist acting under the supervision of a licensed dentist may provide these services. The unlicensed practice of dentistry in our state is a misdemeanor." (Joint Stipulations ¶ 33; Hardesty, Tr. 2861-2862; CX67; RX50 (Bakewell, Dep. at 309-310)).

- 326. Co-operation between licensing boards in the same state where there might be an overlap of enforcement authority is not uncommon. (CX645 at 1; also see, e.g., RX44 at 7).
- 327. Spa and salon owners who contacted the Board after receiving cease and desist letters indicated that the manufacturer/distributor told them that there was no problem with offering the service or that the Board had approved these activities. (RX50 (Bakewell, Dep. at 309-310); RX57 (Friddle, Dep. at 120)).
- 328. Counsel for the Board cited several distressed telephone calls that the Board received from cosmetologists as a motivating factor behind the communication with the Cosmetology Board. Some of the callers were angry about the way they had been treated by the distributors. (RX50 (Bakewell, Dep. at 307-308)).
- 329. The Cosmetology Board agreed to include an article in its newsletter citing the provisions of N.C. Gen. Stat. § 90-29 as the reason why "[o]nly a licensed dentist or dental hygienist acting under the supervision of a licensed dentist may provide these services." (CX67 at 1, 3).

L. The Board Tendered and the Court Accepted Dr. Van B. Haywood as an Expert.

- 330. Dr. Haywood is an expert in the fields of practical and clinical esthetic and restorative dentistry. (Haywood, Tr. 2391).
- 331. Dr. Van B. Haywood is an academician who performs independent research in his fields of expertise. (Haywood, Tr. 2392).
- 332. Dr. Haywood is not an industry expert. (Haywood, Tr. 2392).

- 333. Dr. Haywood independently performs grant-sponsored research on teeth whitening products with no strings attached. (Haywood, Tr. 2392-2393).
- 334. Dr. Haywood does not actively promote teeth whitening products. (Haywood, Tr. 2393).
- 335. Dr. Haywood has never been granted a financial stake or interest in any of the products about which he has consulted or published. (Haywood, Tr. 2407).
- 336. Dr. Haywood has never been a salaried employee, owner, stockholder, or member of management of any of the firms that have retained him as a consultant. (Haywood, Tr. 2408).
- 337. Dr. Haywood was contacted by the FTC almost three years ago to be an expert in this matter, and he refused because of his belief that teeth whitening constitutes the practice of dentistry and that he could not support that. (Haywood, Tr. 2459-2460).
- 338. The FTC approached Dr. Haywood a second time, about two years ago to discuss the case with him. This conversation was terminated when he voiced his opinion that there was a difference between over-the-counter teeth whitening methods and non-dental teeth whitening methods. (Haywood, Tr. 2459-2460).
 - M. Complaint Counsel Tendered and the Court Accepted Dr. Martin R. Giniger as an Expert.
- 339. Dr. Giniger is an expert in the field of "prevention, diagnosis and management of diseases and conditions that affect the oral cavity and history, practice, product formulation, efficacy and safety of teeth-bleaching products and other oral care products." (Giniger, Tr. 104).
- 340. Dr. Giniger sent Dr. Haywood an email in 2005 that complimented Dr. Haywood on the bleaching research he had done. In the email, Dr. Giniger also asked if Dr. Haywood wanted to collaborate with him. Dr. Giniger provided Dr. Haywood with his contact information and signed the email, "your hero for the last eleven years." (Haywood, Tr. 2411-2412).

Dr. Giniger's Credibility

- 341. Dr. Giniger spent most of his professional career in the teeth whitening industry. (Giniger, Tr. 364).
- 342. The teeth whitening industry has financed most of the research conducted by Dr. Giniger, as mentioned in his testimony. (Giniger, Tr. 364).

- 343. Dr. Giniger currently serves as a consultant to the teeth whitening industry. He frequently conducts clinical trials for companies that are interested in marketing a new product, or for an existing product on which they want to make further claims. Dr. Giniger conducts clinical trials in order for these oral care companies to make such claims. (Giniger, Tr. 364-365).
- 344. Dr. Giniger also sells a pre-whitening product to dentists called Power Swabs. It is a detergent that dentists apply to teeth, and which Dr. Giniger claims helps the bleaching results by working faster and reducing sensitivity. (Giniger, Tr. 365).
- 345. The Power Swabs use the same dispensing mechanism as Dr. Giniger's other product, GrinRX, though it uses a different formula. (Giniger, Tr. 365-366).
- 346. Dr. Giniger is paid by the companies that use Power Swabs for his work in connection with that product. (Giniger, Tr. 366).
- 347. The last time Dr. Giniger saw patients as a practicing dentist was in 2005. Since then, his only contact with patients has been through clinical trials. (Giniger, Tr. 367-368).
- 348. Dr. Giniger testified that he is not a lawyer. Despite his lack of legal expertise, he said that the Board has misinterpreted the term "stain removal" in the Dental Practice Act, and that it does not include teeth whitening because a tooth bleaching merely "lightens the stain." Dr. Giniger admitted that he has no expertise in statutory interpretation. (Giniger, Tr. 370-372).
- 349. Dr. Giniger also testified that he is not a professional economist. Despite his lack of economics expertise, he said in his report that he did not find sufficient evidence to conclude that the public is best served by the Board's exclusion of non-dentist teeth-bleaching operators and procedures. (Giniger, Tr. 377-378).
- 350. Dr. Giniger is being compensated in this matter at the rate of \$225 per hour. To date, the total value of his services has been approximately \$100,000. (Giniger, Tr. 380-381).
- 351. Dr. Giniger previously served as an expert witness for Proctor & Gamble in connection with litigation involving teeth whitening matters. In that litigation, Procter & Gamble challenged the advertising claims of Colgate-Palmolive. (Giniger, Tr. 380-381).
- 352. Dr. Giniger has also served as an expert witness in previous litigation for BriteSmile, Procter & Gamble, and Colgate-Palmolive. (Giniger, Tr. 393).

- 353. After spending a considerable amount of time working for various oral care companies, Dr. Giniger decided he wanted to get his own "cut" of the money he was helping companies make, and started a company called GrinRX with Roland Hanson. (Giniger, Tr. 393-396).
- 354. GrinRX was formed in February 2006 and raised \$7 million of capital through private offerings and sales of securities, registered with the U.S. Securities and Exchange Commission as "Reg D offerings". Dr. Giniger only was able to receive a small portion of the money raised for operating costs for his laboratory in New York. He later found out that other directors and officers of the company had engaged in "self-dealing", depleting the company of funds and leaving nothing for Dr. Giniger. (Giniger, Tr. 393-396).
- 355. Dr. Giniger's testified that his only position with GrinRX was as its chief scientific officer. However, according to a Form D filed with the Securities and Exchange Commission, he is also a beneficial owner, executive officer, and director. (Giniger, Tr. 398-399).
- 356. One of the products touted by Dr. Giniger is Simply White, which is a paint-on whitener made by Colgate. (Haywood, Tr. 2414). While reviewing literature on teeth bleaching, Dr. Haywood read an article in the Journal of Esthetic and Restorative Dentistry that evaluated this product. The article stated that Simply White contained phosphoric acid, which can be detrimental to enamel because it reduces enamel microhardness. The product is now no longer on the market. (Haywood, Tr. 2427-2428).
- 357. Another product touted by Dr. Giniger is the Discus Dental product, which is designed to reduce sensitivity during bleaching. (Haywood, Tr. 2416). Dr. Giniger published an article in the Journal of the American Dental Association about the product's effectiveness, but Dr. Giniger's findings were later refuted by a letter to the editor of the Journal written by Dr. John Kanca. In his letter, Dr. Kanca cited Dr. Giniger's invalid scientific method and statistical analyses. (Haywood, Tr. 2416, 2454-2457; Haywood, Dep. 289-290; Giniger, Tr. 447-449). Dr. Giniger never responded to Dr. Kanka's letter refuting all of Dr. Giniger's claims about the Discus Dental product. (Haywood, Tr. 2457).
- 358. Another product touted by Dr. Giniger is the LED lights that are used in teeth whitening procedures. In response to a question from the bench as to whether or not the lights work, Dr. Giniger testified that the only proven effect of these lights is to provide a "motivation for consumers to keep their mouth open during the teeth whitening process." (Giniger, Tr. 474-479).
- 359. Yet another product touted by Dr. Giniger, Power Swabs, is based on a theory of bleaching agents and a mechanism of bleaching that is not supported by any scientific evidence whatsoever. (Haywood, Tr. 2525-2526).

- A business overview posted online for Dr. Giniger's GrinRX company lists Dr. Haywood as a "pending" member of the company's "Advisory Board," along with several of Dr. Haywood's research colleagues. (RX142 at 22; Haywood, Tr. 2557-2560; Giniger, Tr. 408-410).
- 361. Dr. Haywood testified that he spoke with some of his colleagues about this, and they had no record of being contacted to be on the GrinRX advisory board. (Haywood, Tr. 2557-2560).
- 362. Dr. Haywood testified that this was a fraudulent use of his name without his permission. (Haywood, Tr. 2557-2560).
 - N. The Board's Actions Were Taken Pursuant to a Legitimate State Law Enforcement Objective.
 - i. Teeth Whitening Is the Practice of Dentistry.
- 363. Dr. Haywood testified that he has read and is familiar with the North Carolina Dental Practice Act, including the provision on stain removal. (Haywood, Tr. 2545).
- 364. Dr. Haywood's reading of the Act, based on his experience as a dentist and dental instructor, is that the Act does not permit stain removal by unlicensed persons. (Haywood, Tr. 2545, 2573).
- 365. Dr. Haywood testified that a non-dentist providing dental treatment such as teeth whitening is stain removal and is the illegal practice of dentistry. (Haywood, Tr. 2459-2460, 2539, 2573).

ii. Teeth Bleaching Is Teeth Whitening.

- 366. According to Dr. Haywood, dental school students are taught that bleaching is the removal of stains. (Haywood, Tr. 2573).
- 367. In Dr. Haywood's opinion, all three methods of teeth whitening (i.e., over-the-counter, non-dental, and dentist-supervised) involve bleaching techniques. (Haywood, Tr. 2403-2404).
- 368. The bleaching mechanism both removes stains from teeth and changes the genetic color of the tooth, and so bleaching and teeth whitening are the same thing. (Haywood, Tr. 2404).

iii. The Removal of Stains from Human Teeth Is Teeth Whitening.

- 369. Because the bleaching mechanism involves the removal of stains from teeth and changes the genetic color of the tooth, the removal of stains is teeth whitening. (Haywood, Tr. 2404).
- 370. Stain removal techniques have been used by dentists since the 1800s. Currently, various stain removal techniques are used for stains caused by exposure of the teeth to fluoride, tetracycline, iron and metals, and nicotine. (Haywood, Tr. 2418, 2437-2448; RX141 at 15-32).
- 371. Members of the teeth whitening industry testified that the use of their teeth whitening products was stain removal. (Wyant, Tr. 906; Nelson, Tr. 817-819).
 - iv. The Removal of Stains from Human Teeth by a Non-Dentist Is a Violation of the North Carolina Dental Practice Act.
- 372. With mall bleaching, there is someone assisting, guiding, directing, or influencing the customer to do something, which is unwise and constitutes the practice of dentistry. (Haywood, Tr. 2459).
- 373. In over-the-counter tooth whitening, products are applied by the consumer to themselves; in non-dentist tooth whitening, the service is provided by someone who, in Dr. Haywood's opinion, is presenting themselves as a health professional with the requisite training and skill to diagnose and treat dental conditions. (Haywood, Tr. 2403).
- 374. The Board is charged with enforcing North Carolina's Dental Practice Act, which states what is legal and illegal and what activities require a license within the confines of that state. In order for the Board to enforce the statutes or laws and define the practice of dentistry, it informs dentists what they can or cannot do and informs non-dentists what they can or cannot do based on training and the licensure exam. (Haywood, Tr. 2541-2542).
 - O. The Board's Actions Were Taken Pursuant to Legitimate Public Safety Concerns.
 - i. Dr. Haywood's Concerns
 - a. Difference Between OTC Products and Kiosk/Spa Teeth Whitening
- 375. Dr. Haywood provided the analogy that the difference between over-the-counter products and mall bleaching is analogous to the difference between suicide and assisted suicide. (Haywood, Tr. 2458-2459).

b. Problems With Kiosk/Spa Teeth Whitening

- 376. Non-dentists who provide teeth bleaching treatments convey the illusion of having dentist supervision by the use of chairs and lights similar to what might be found in a dentist office. (Haywood, Tr. 2458).
- 377. Because of the equipment used by non-dentist teeth whiteners, there is an illusion of people having dental training. (Haywood, Tr. 2459).
- 378. Non-dentists who encourage or direct a customer during the bleaching process may give the illusion that they are a dentist who possesses the knowledge of a dental professional about teeth whitening. (Haywood, Tr. 2473-2474).
- 379. In Dr. Haywood's opinion, non-dentists who perform teeth whitening are presenting themselves as a health professional such as a dentist, with the attendant training and skill to be able to diagnose and treat patients for dental conditions such as tooth discoloration and stains. (Haywood, Tr. 2403).
- 380. The correct diagnosis is important to avoid inappropriate treatment and ensure that appropriate treatment is not delayed. This often requires a radiograph or an x-ray to determine the cause of discoloration. (Haywood, Tr. 2567).
- 381. Kiosk personnel cannot examine a customer for cancer, decay, restorations, or temporomandibular joint problems. They cannot take radiographs or perform an esthetic evaluation as dentists can prior to teeth whitening. (Haywood, Tr. 2459).
- 382. In order to properly perform teeth whitening, one has to know the side effects of other conditions or other problems that may be intertwined with treatment. One must identify the existing restorations, which will not change color, and use the appropriate materials both in composition and in concentration and, if using tray bleaching, use the custom-fitted tray for the least amount of material used. (Haywood, Tr. 2568).
- 383. Dr. Haywood's main concern regarding non-dental teeth bleaching is the safety issues that may result from the lack of diagnosis for proper treatment, as well as the potential for a less esthetic outcome. (Haywood, Tr. 2571).
- Non-dentists do not have training to deal with allergic reactions to teeth whitening agents or if someone was to aspirate or gag on the impression material. (Haywood, Tr. 2459).

- c. Dentist Teeth Whitening Is Safer Because of Superior Training and Professional Obligations.
- 385. Dentists are able to prescribe custom-fitted trays, whose design is based on the patient, the material, and the situation. It can be a full arch tray or cover all the teeth, or it could only cover one tooth. The dentist may decide to take the tray off of the tissue to avoid tissue irritation with a certain patient. (Haywood, Tr. 2570).
- 386. Infection control and sanitation are critical issues for the delivery of patient care, including teeth bleaching. (Haywood, Tr. 2530).
- 387. Proper gloving, proper masking, and proper disinfectants are all part of what a dentist does to ensure the health and safety of their patients. (Haywood, Tr. 2530).
- 388. Dentists are governed by the American Dental Association's code of ethics, "which is to do no harm to patients, to take care of them, do the right thing and be truthful about what we do." (Haywood, Tr. 2462).

d. ADA Concerns about Teeth Whitening by Non-Dentists.

- 389. The House of Delegates of the American Dental Association ("ADA") adopted a policy position that directed the ADA staff to prepare an ADA position paper to explain the safety issues and concerns about teeth bleaching. (Haywood, Tr. 2561-2562).
- 390. Pursuant to the ADA's policy position, the ADA management tasked the ADA Council on Scientific Affairs with drafting a report about that concern. (Haywood, Tr. 2561-2562).
- 391. The purpose of the ADA teeth whitening report was to publicly explain the ADA's official position to dentists and patients all the ramifications of bleaching, including safety issues, examination issues and other concerns. (Haywood, Tr. 2561-2562).
- 392. The ADA House of Delegates' adopted policy stated, as the ADA's official position, the ADA's concerns about the public safety of non-dentist bleaching. It requested that Dr. Haywood and the others draft the report to list and enumerate all the components of a proper dental exam and the issues about a lack of discovery of those things by non-dentist application of bleaching materials. Dr. Haywood and others were also asked to deal with the safety issues and the concentration maximums that might be appropriate. (Haywood, Tr. 2564).

e. ADA Report to FDA Asking FDA to Classify Bleaching Products as a Medical Device.

- 393. The ADA House of Delegates also adopted a policy stating that the ADA's official position was to request that the Food and Drug Administration reevaluate bleaching and classify it as a medical procedure to more appropriately reflect what it is. (Haywood, Tr. 2510, 2561).
- 394. The ADA House of Delegates also adopted a policy stating that the ADA's official position was to request that the Food and Drug Administration classify teeth whitening and bleaching agents so that they could not be available for use by non-dentists. (Haywood, Tr. 2561-2563).

f. Dr. Haywood's Conclusions.

- 395. Dr. Haywood had the following concerns regarding the safety of non-dental teeth bleaching: (1) non-dental teeth bleaching does not involve a diagnosis for proper treatment and can mask the pathology for such treatment in the future; (2) non-dental teeth bleaching carries the potential for a less esthetic outcome (e.g., restorations are not identified, root canals are not known); (3) the safety of higher concentrations of teeth whitening solutions is unknown (e.g., there has been no research for concentrations of hydrogen peroxide above 15%); (4) the quality of some products is unknown, especially with respect to issues involving pH, allergic ingredients, or other ingredients; and (5) the patient may not receive any or the maximum benefit available for whitening, and may waste money on ineffective products. (Haywood, Tr. 2571-2572).
- 396. In Dr. Haywood's opinion, 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 the service. (Haywood, Tr. 2572).
- 397. In Dr. Haywood's opinion, low concentrations of carbamide peroxide in a custom-fitted tray are the safest, most cost-effective, and best-researched bleaching treatments available. (Haywood, Tr. 2572).
- 398. In Dr. Haywood's opinion, other bleaching treatments such as in-office dental treatments may be appropriate based on patient preference, lifestyle, finances, or other limitations, but only after informed consent that presents a cost-benefit and risk-benefit ratio. (Haywood, Tr. 2572).
- 399. In Dr. Haywood's opinion, non-dentist teeth whitening does not have a good costbenefit or risk-benefit ratio, and misleads the public as to safety and efficacy. (Haywood, Tr. 2573).

400. Finally, Dr. Haywood noted that the removal of stains has always been taught in dental school as the practice of dentistry and bleaching is the removal of stains. (Haywood, Tr. 2573).

ii. Dr. Giniger's Denials as to Dentistry

- 401. Dr. Giniger admitted that over-the-counter teeth whitening products purchased by individuals and kiosk teeth whitening are different. Non-dentist teeth whitening at kiosks usually involves a light and a tray containing bleaching gel, whereas an over-the-counter teeth bleaching product can be purchased in several different formats, such as strips or rinses. (Giniger, Tr. 383-385).
- 402. Dr. Giniger claims that "[r]elevant literature and experience of millions upon millions of consumers indicate that cosmetic teeth bleaching is safe and effective, whether performed by dentists, non-dentists or consumers." This claim actually aggregates the statistics from the over-the-counter teeth whitening products with non-dentist teeth whitening offered at spas and kiosks to arrive at his "millions upon millions" figure. There is no data on non-dentist teeth whitening that would show harm. (Haywood, Tr. 2547-2548).
- 403. There are a number of reasons that there is no "data" showing harm from non-dentist teeth whitening. One reason is that non-dentist bleaching is a new phenomenon in the marketplace, and there has not been time to conduct a formal scientific study of the potential harms. Such studies can take a while to conduct, including the review of relevant literature which can take about two years, and dentists in private practice often do not have the time to do this because it is a very involved procedure. (Haywood, Tr. 2518-2519).
- 404. Another problem with doing this research is that companies cannot ethically do a proper double-blind scientific study, where one group is treated one way and another group is treated another way. For the study to be ethical, both groups must have a dental exam. (Haywood, Tr. 2517-2518, 2528). When companies such as Procter & Gamble do such studies, they must provide a dental exam initially, which would not properly simulate non-dental teeth whitening. (Haywood, Tr. 2526-2527).
- 405. Yet another problem with doing a study of non-dental teeth whitening is that scientific journals normally do not conduct studies of illegal practices such as the provision of teeth whitening by non-dentists. (Haywood, Tr. 2538-2539).
- 406. Despite this lack of scientific data regarding the dangers of teeth whitening, there is anecdotal evidence of harm from teeth whitening. (Haywood, Tr. 2520-2521).

- 407. While anecdotal evidence may not be as reliable as a scientific article, sometimes that is all that is available. In fact, some estimates indicate that 80 percent of the practice of dentistry is non-evidence-based because it is what people have learned from doing it through the years, so it is very difficult to come up with evidence for every aspect of dentistry. (Haywood, Tr. 2519-2520).
- 408. Dr. Giniger acknowledged that numerous television news reports and newspaper articles have reported on and provided anecdotal evidence of the risks and dangers of non-dentist supervised teeth whitening. (Giniger, Tr. 461-466; RX82 RX91; RX94 RX96; RX98 RX101; RX103; RX114 RX118; RX120 RX124; RX126 RX129; RX133 RX135).
- 409. Dr. Haywood testified that Dr. Giniger's theory on the mechanism for stain removal (stains are not removed but "discolorized") is not universally accepted. To Dr. Haywood's knowledge, it is not accepted at all. Bleaching actually takes both the external stains off the teeth and takes the internal stains out of teeth. (Haywood, Tr. 2516-2517). Dr. Haywood is not aware of any support for Dr. Giniger's theory. (Haywood, Tr. 2516-2517, 2633).
- 410. Dr. Giniger claims that use of teeth bleaching products does not readily or permanently damage enamel or gingival tissue. Dr. Haywood pointed out that this is a hotly contested point in the profession. There are many dental experts who believe it does cause damage. There are also reports of damage to enamel by inappropriate use of bleaching materials. (Haywood, Tr. 2517).
- 411. Dr. Haywood refuted Dr. Giniger's claim that a remarkable set of circumstances must occur for a hypothetical Mr. X to have his tooth pathology masked by teeth bleaching. Dr. Haywood provided one example of a cheerleader who fell and injured her teeth. Her teeth darkened over time, but the two crowns that she received after the fall did not. Dr. Haywood has found that such circumstances are more common than not, but a patient often does not make the connection other than perceiving that they have a dark tooth. (Haywood, Tr. 2467, 2533).
- 412. Dr. Giniger admitted that having a dental examination prior to undergoing nondentist bleaching could resolve the issue cited by Dr. Haywood of bleaching masking a tooth's pathology. (Giniger, Tr. 437-440).
- 413. Dr. Giniger admitted that one of the advantages of going to licensed dentists for a bleaching procedure is that they sell specialized bleaching trays in case the person has a single darkened tooth. (Giniger, Tr. 468-469).
- 414. Although Dr. Giniger suggested earlier in his testimony that Dr. Haywood was less qualified because he did not have a Ph.D like Dr. Giniger, Dr. Giniger later admitted that not having a Ph.D did not make Dr. Haywood less qualified to render an opinion in this matter. (Giniger, Tr. 466-468).

- 415. Dr. Giniger said that he reviewed the testimony of Dr. Tilley and Mr. Runsick. He also reviewed Mr. Runsick's complaint about his injuries caused by teeth whitening. Based on this review, he reached the conclusion that Mr. Runsick did not suffer any damage from his teeth whitening procedure. (Giniger, Tr. 480-481, 484-485). Dr. Giniger admitted that he never examined Mr. Runsick himself. (Giniger, Tr. 481).
- 416. Complaint Counsel presented a market survey in their opening statement indicating that of the 55 percent of the general population engaged in teeth whitening, 14 percent used professional dentist teeth whitening and 86 percent used over-the-counter products. (CX489 at 22). The survey also indicated that 71 percent of the dental patients who used custom-made trays from dentists were either satisfied or very satisfied with the results, whereas only 34 percent of those using over-the-counter products were satisfied or very satisfied with the results. (CX489 at 30). Dr. Giniger disagreed with this statistic, suggesting instead that patients of dentists were more dissatisfied with their teeth whitening results than consumers purchasing over-the-counter products based on his experience conducting clinical trials for teeth whitening companies. (Giniger, Tr. 417-418).

iii. Public Safety Concerns Demand that a Proper Dental Examination Precede Teeth Whitening

- 417. In the opinion of the American Dental Association ("ADA"), a person who gets teeth whitening without a dental exam is at risk. (Haywood, Tr. 2472).
- 418. A person undergoing teeth whitening needs a proper examination to determine the cause of discoloration in order to diagnose the situation and prescribe the correct treatment. (Haywood, Tr. 2449).
- 419. Once a determination is made that a person is a good candidate for bleaching, diagnosing the cause of the discoloration or the stains that are on the teeth is an important factor in the determination of the time frame and the type of treatment that is prescribed. (Haywood, Tr. 2464).
- 420. Prior to teeth bleaching, a diagnosis should be made of the cause of the discoloration. Depending on the cause, there are other treatments that might be necessary for discolored or stained teeth, such as nonvital teeth or teeth with decay or with internal resorption, external resorption or if they have fillings on the lingual or tongue side of the tooth. The bleaching time prescribed would also vary based on the type of stain, whether it was inherited, aging, external, nicotine staining or tetracycline staining. (Haywood, Tr. 2464, 2567).
- 421. Dr. Haywood is concerned that if you do not have a proper examination and diagnosis prior to teeth whitening, which may include radiographs, that you may mask pathology or have an unesthetic outcome. (Haywood, Tr. 2449).

- 422. The bleaching process masks pathology. It is analogous to putting a cosmetic over skin cancer. "The cancer is still there, but you covered up the only symptom that the patient has of that, which can allow it to spread worse and have much more either detrimental effects or costly effects out of that." (Haywood, Tr. 2472).
- 423. Dr. Haywood is of the opinion that everyone needs to have an exam by the dentist prior to teeth whitening because non-dentists may be masking pathology or may be doing improper treatment. (Haywood, Tr. 2473).
- 424. Dr. Haywood testified that the Board's concern about non-dentist teeth whitening was warranted because it masks the pathology or treats the wrong condition in certain instances with one treatment when another is needed. (Haywood, Tr. 2545).

iv. Dentist's Concerns as to Sanitation and Other Safety Issues

- 425. Dentists have a professional obligation to ensure the safety of their patients. (CX595 at 2; CX185 at 1). Dentists cannot evade personal liability for their own malpractice. (Baumer, Tr. 1931).
- 426. The evidence shows that teeth whitening services provided in-office by a licensed dentist or under his/her supervision are safer than teeth whitening provided at a mall kiosk. (Wester, Tr. 1300-1302; Hardesty, Tr. 2781-2785; Owens, Tr. 1457-1459).
- 427. A Frequently Asked Questions informational document available on the website of the American Dental Association ("ADA") states that "[t]ooth whitening materials may affect tooth structure, fillings and the gums if abused or not used properly. . . . Importantly, proceeding with tooth whitening without consulting a dental professional may miss untreated dental disease; patients with some conditions may not be suitable candidates for tooth whitening." (CX0227 at 5).
- 428. Dentists provide a dental exam prior to making a recommendation that a patient undergo teeth whitening. (Wester, Tr. 1290-1291; Owens, Tr. 1451-1452; Hardesty, Tr. 2775-2776; RX63 (Holland, Dep. at 145-146); CX392 at 5).
- 429. James Valentine testified that WhiteSmile USA did not encourage its customers to have a dental exam or dental cleaning before undergoing teeth whitening treatment. (Valentine, Tr. 584).
- 430. A dental exam prior to a teeth-whitening procedure can reveal conditions that would be a contraindication for that patient to undergo teeth whitening. Periodontal disease, recession, oral-antral fistulas, cavities, and problems with dental work are some examples of such contraindications. (RX65 (Morgan, Dep. at 31-36, 40-44, 50-53, 145)).

- 431. Dentists take far greater precautions when performing teeth whitening procedures on patients than those provided by unauthorized teeth whiteners in examining and interviewing the patient, as well as the actual preparations for the procedure. (CX392 at 5; CX596 at 2).
- 432. By North Carolina law and in practice, hygienists must have dentist supervision to perform teeth whitening procedures. (CX19 at 9; RX52 (Burnham, Dep. at 223)).
- 433. The take-home tray teeth whitening process offered by dentists involves at least two visits to the dentist one for the exam and taking impressions for the custom tray, the other for delivery of the tray and instructions to the patient for use of the tray and whitening materials at home. (RX63 (Holland, Dep. at 49-53)).
- 434. Non-dentists offering teeth whitening services in salons, retail stores, and mall kiosks do not universally follow the typical procedure as described in Complaint Counsel's Rule 3.24 Statement of Material Facts. Specifically, those service providers do not universally: (1) place a bib around the client's neck; (2) don protective gloves; (3) take a tray from a sealed package, which is either pre-filled with peroxide solution or which the operator fills with the peroxide solution, and hand it to the customer, who places the tray into his or her mouth; (4) have the client sit in a "comfortable chair"; (5) adjust the whitening light; (6) start the timer; and (7) the customer will remove the tray and hand to the provider, who disposes it. (RX11 at 5, 6; RX15 at 9; RX27 at 1; RX25 at 15; RX22 at 18, 19; RX8 at 9; Runsick, Tr. 2108-2109).
- 435. Non-dentists offering teeth whitening services in salons, retail stores, and mall kiosks may take impressions of consumers' teeth, which also violates the Dental Practice Act and creates safety issues. (Wester, Tr. 1300-1301; RX11 at 5=6; RX15 at 9; RX27 at 1; RX51 (Brown, Dep. at 40-41, 43-44)).
- 436. Infection control and lack of sterilization is a concern at non-dentist teeth whitening establishments that do not meet the standards of a dental office pursuant to 20 N.C. Admin. Code 16J.0101, which adopts by reference the current ADA guidelines. (RX63 (Holland, Dep. at 84-85, 138-139); CX514 at 36).
- 437. Non-dentists offering teeth whitening services in salons, retail stores, and mall kiosks have numerous potential sanitation issues, including using only sanitary wipes and sprays (which are not sufficient sanitation measures) and cross-contamination from unsterilized surfaces (e.g., LED lights or other objects that may come in contact with consumers' mouths). (Wester, Tr. 1300-1302; Owens, Tr. 1457-1459; Hardesty, Tr. 2782-2785).
- 438. Jim Valentine testified that sanitation measures at WhiteSmile mall kiosks consisted of wiping LED lights, chairs, and other surfaces with Lysol sanitary wipes. (Valentine, Tr. 531-532, 599).

- 439. Joyce Osborn testified that the sanitation measures of employees and local affiliates selling her teeth whitening products consisted of wiping LED lights and other surfaces with sanitary wipes. (Osborn, Tr. 716-718).
- 440. The Board has received reports about non-dentist teeth whiteners operating at mall kiosks where there was no running water, and no use of gloves or masks. (RX50 (Bakewell, Dep. at 318)).
- 441. The lack of running water at mall kiosks can pose a health or sanitation risk to consumers, because sanitation is best accomplished through washing hands with soap and water. (Wester, Tr. 1321, 1323-1324, 1406-1407; Owens, Tr. 1457-1459; RX63 (Holland, Dep. at 139); RX65 (Morgan, Dep. at 146)).
- 442. Jim Valentine testified that at WhiteSmile mall kiosks there was no running water available for employees to wash their hands. (Valentine, Tr. 598).
- 443. Joyce Osborn testified that customers using her product do not wash their hands with soap, but are given antibacterial gels to sanitize their hands. (Osborn, Tr. 718-719).
- 444. Lysol wipes and other disinfectant wipes used by non-dentist teeth whiteners at malls are not sufficient methods for ensuring proper sanitation when interacting with consumers receiving teeth whitening treatments. Proper methods require adequate training in sanitation control measures, such as avoiding cross-contamination and knowing how to use OSHA-approved products such as ProSpray. (Hardesty, Tr. 2782-2785; RX63 (Holland, Dep. at 138-139); RX75 (Oyster, Dep. at 32)).
- 445. Board Counsel contacted the county or state health department about the sanitation issues in the mall kiosks. (RX50 (Bakewell, Dep. at 317-321)).
- 446. Teeth whitening products contain potentially harmful chemicals such as carbamide peroxide and hydrogen peroxide, which could cause injury to a consumer's eyes (e.g., ulceration of the cornea), skin (e.g., overexposure by contact could cause mild to severe irritation and/or burns of the skin and mucous membrane), and ingestions (e.g., ingestion of large amounts could cause irritation of the gastrointestinal tract with pain, nausea, constipation, diarrhea, distention of the stomach and/or esophagus, and potential suffocation). (CX108 at 4-5, Material Safety Data Sheet; Wester, Tr. 1302-1305; Owens, Tr. 1459-1462; Nelson, Tr. 807-809).
- 447. Teeth bleaching could mask the pathology of teeth, such as with the case of an abscess. (Wester, Tr. 1306).

- 448. Jim Valentine of WhiteSmile admitted under oath that "bleaching can potentially mask pathology." (Valentine, Tr. 599).
- 449. Patients with periodontal problems may not be good candidates for teething whitening because, if they have recently undergone periodontal surgery, the bleaching could interfere with the healing process. Bleaching in such patients could cause reversible pulpitis, or inflammation of the nerve inside the tooth. It could also cause irreversible pulpitis, or a severe toothache, which would bother the patient to the point that a root canal or removal of the tooth is necessary. Bleaching in such patients could also damage the actual tissue, and if the gel is too strong it could burn the tissue. If a patient had a severe bone loss, bleaching could set off a periodontal endodontic lesion, which would cause severe pain. (Hardesty, Tr. 2780-2781).
- 450. For certain consumers, teeth bleaching could cause damage or necrosis to the nerve of a tooth. (Owens, Tr. 1453-1454;
- 451. For certain consumers, teeth bleaching could cause damage to the gingival tissues. (Owens, Tr. 1453-1454; RX52 (Burnham, Dep. at 114)).
- 452. For certain consumers, teeth bleaching could cause damage to the soft tissues of the mouth. (Owens, Tr. 1453-1454).
- 453. For certain consumers, teeth bleaching could cause the lips or parts of the mouth to be torn. (Owens, Tr. 1453-1454).
- 454. There is a risk of aspirating a device placed in the mouth during any teeth whitening procedure. (RX52 (Burnham, Dep. at 114-155).
- 455. Non-dentist supervised teeth whitening may be dangerous for people who are severe gaggers, as they may have trouble tolerating having impressions taken. (Hardesty, Tr. 2779).
- 456. Non-dentist supervised teeth whitening may also be dangerous for people who have severe problems with the range of motion of their jaw because they cannot have their jaw forced open for long periods of time. (Hardesty, Tr. 2779).
- 457. Persons undergoing teeth whitening procedures might be subject to allergic reactions, which licensed dentists and their staff are trained to handle. (CX392 at 8).
- 458. Dentists have also expressed concerns about follow-up care and informed consent. (RX76 (Parker, Dep. at 84-85).

v. North Carolina Consumers Have Been Injured by Non-Dentist Teeth Whitening.

459. Beginning in or around 2008, the Board began receiving complaints about unauthorized teeth whitening providers from injured consumers of those services. (RX5 at 2; RX17 at 1).

a. Brian Runsick's Injuries

- 460. Brian Runsick was one of the individuals who submitted a written complaint to the Board about his experience with a non-dentist teeth whitening operation. (CX118 at 3).
- 461. Mr. Runsick testified that he brushes and flosses one to two times per day, and has gone to the dentist at least twice a year for the past two years. (Runsick, Tr. 2102-2103).
- 462. Mr. Runsick has used over-the-counter teeth whitening products. He used Crest Whitestrips in the mid- to late 1990s. (Runsick, Tr. 2103).
- 463. Mr. Runsick received very minimal results from his use of Crest Whitestrips. (Runsick, Tr. 2104).
- 464. Mr. Runsick first encountered a non-dentist teeth whitening operation, BleachBright, when he was at Crabtree Valley Mall in Raleigh on February 17, 2008. He made a spontaneous decision to try it. (Runsick, Tr. 2104-2106).
- 465. Mr. Runsick testified that the BleachBright non-dentist teeth whitening operation at Crabtree Valley Mall appeared to be a "dentist environment" because of the medical clothing worn by its employees and the types of chairs that they used. (Runsick, Tr. 2105).
- 466. The name of the customer service representative that Mr. Runsick interacted with at the Bleach Bright non-dentist teeth whitening facility was Joe Willett. Mr. Willett was dressed in what appeared to be a doctor's white jacket. Mr. Runsick described it as "definitely... what you would expect a dentist or dental people or a doctor to be wearing." (Runsick, Tr. 2106).
- 467. After agreeing to undergo a teeth whitening procedure, Mr. Runsick was given a cloth to wipe his teeth off with. (Runsick, Tr. 2106).
- 468. Mr. Runsick was not given a warning about the teeth whitening services before he underwent the procedure. (Runsick, Tr, 2107).

- 469. Mr. Runsick was given a form to sign that contained "legal mumbo jumbo that we all sometimes sign just to sign a release." He does not recall whether he read all or part of the document, and does not recall whether it said anything about a possible risk from using the teeth whitening product. (Runsick, Tr. 2107-2108).
- 470. Mr. Runsick paid about \$99, plus tax, for his teeth whitening services at BleachBright. (Runsick, Tr. 2108).
- 471. Before he sat in a chair to receive teeth whitening services, no BleachBright employee asked Mr. Runsick to wash or sanitize his hands. There was no sink or running water at the kiosk. There was a jug of sanitizing cream, but Mr. Runsick was not offered any of it. (Runsick, Tr. 2108).
- 472. Mr. Runsick did not observe any BleachBright employee washing their hands. He does not recall if any of the employees sanitized their hands. He does not recall whether any BleachBright employees wore gloves. (Runsick, Tr. 2108).
- 473. Mr. Runsick did not observe any BleachBright employee sanitize the chair before he sat in it. (Runsick, Tr. 2108).
- 474. Mr. Runsick saw BleachBright employees take a mouth piece out of another customer's mouth, detach it from the teeth whitening light, wipe it down with "a Handi-Wipe which you might see at KFC", and place it in Mr. Runsick's mouth for him. (Runsick, Tr. 2109).
- 475. Mr. Runsick himself put another mouthpiece with a chemical in it into his mouth. The BleachBright employees did not tell Mr. Runsick what chemical was in the mouthpiece he put in his mouth, nor was he told the percentage of hydrogen peroxide it contained, or given any instructions other than to put it in his mouth. (Runsick, Tr. 2109).
- 476. The BleachBright employees told Mr. Runsick that the light "intensifies" the effect "so that you don't have to come over so many procedures." (Runsick, Tr. 2109-2110).
- 477. A BleachBright employee told Mr. Runsick that the procedure normally takes 20 minutes. Mr. Runsick said that he wanted to get his teeth "as bright as I can", and the employee told him "no problem, we can do 30 minutes." (Runsick, Tr. 2110).
- 478. The BleachBright employee who turned the light on for Mr. Runsick was a new hire, and she forgot to turn the timer on after he had started his teeth whitening procedure. (Runsick, Tr. 2110).

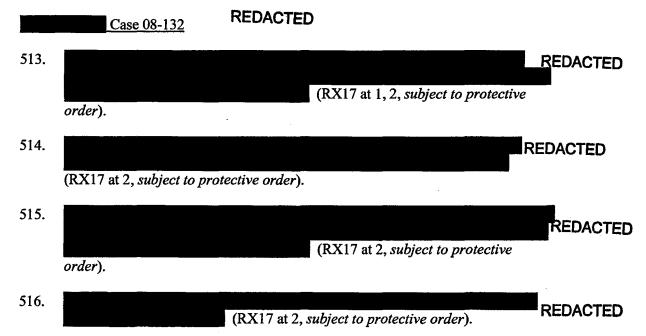
- 479. Ten minutes into his procedure, Mr. Runsick noticed that he was the only customer without protective glasses on. He asked for protective glasses, and protective glasses were provided for him. At that point, the BleachBright employees turned the timer on, and Mr. Runsick ended up having the chemical on his teeth for 40 minutes. (Runsick, Tr. 2110).
- 480. After the procedure, Mr. Runsick's teeth appeared whiter to him. (Runsick, Tr. 2110-2111).
- 481. Mr. Runsick began to feel after-effects from his teeth whitening within two to three days. Two days before he left for a vacation cruise, he began to experience pain at about a 5 on a 10-point pain threshold scale. (Runsick, Tr. 2111).
- 482. On his way to his cruise departure, Mr. Runsick went to a pharmacy and attempted to get mouthwash that might clear up his pain symptoms. He thinks that he purchased a Betadine mouth rinse. (Runsick, Tr. 2111).
- 483. Mr. Runsick gargled several times a day with the Betadine rinse and brushed his teeth three or four times a day. His pain did not go away, and within two days his gums "puffed out at least double, and blood oozed out of my teeth without even brushing my teeth." (Runsick, Tr. 2112).
- 484. On the third or fourth day of the cruise, Mr. Runsick was brushing his teeth and gargling. When he spit out his rinse, he saw the gums ("meat") from the space between his two center bottom teeth come out in the sink. (Runsick, Tr. 2112-2113).
- 485. The pain was so bad at this point that Mr. Runsick had to take 800 milligrams of Motrin and could not eat any solid food. (Runsick, Tr. 2114).
- 486. After losing some of his gum tissue, Mr. Runsick went to see the cruise ship doctor, who made an appointment for him with a certified dentist in Puerto Vallarta. The dentist put a protective coating on Mr. Runsick's gums, which took about an hour and a half. He told Mr. Runsick not to eat or drink anything for six hours, and that hopefully the protective coating would prevent any bacteria from getting into the gums. (Runsick, Tr. 2114).
- 487. By the time Mr. Runsick had reached the next port after seeing the dentist in Puerto Vallarta, the pain was worse. He went to a pharmacy and purchased some antibiotics that he knew he was not allergic to (Zithromax). Within 24 hours, on about the sixth day of the cruise, the pain was reduced by about 70 to 80 percent. (Runsick, Tr. 2114-2115).

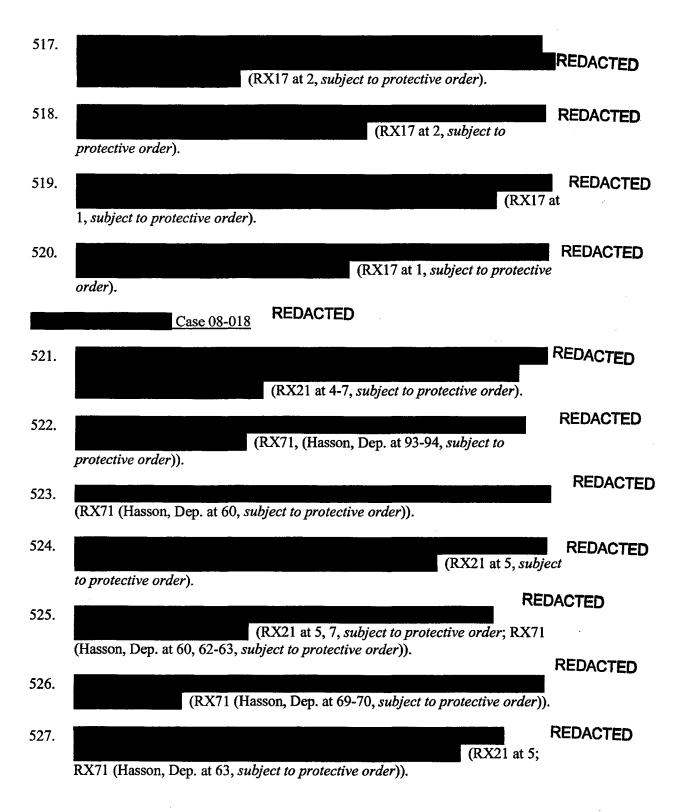
- 488. Mr. Runsick took the full 5-day course of Zithromax, but he felt the pain come back about three to four days after it was completed while he was at a trade show in Myrtle Beach. He went to an Urgent Care there, and was given another round of the antibiotic. This seemed to clear up his symptoms. (Runsick, Tr. 2115-2116).
- 489. When Mr. Runsick returned to Raleigh, he went to the mall within a week and spoke with Mr. Willett at the BleachBright kiosk about his problem. Mr. Willett insisted that BleachBright's product was FDA approved and there was nothing wrong with it. He told Mr. Runsick to leave. (Runsick, Tr. 2116).
- 490. Mr. Runsick returned to Bleach Bright about a week later to speak with Mr. Willett again, and Mr. Willett told Mr. Runsick to leave or he would throw him off the premises. Mr. Runsick left. (Runsick, Tr. 2116-2117).
- 491. Mr. Runsick at that point decided to contact C.W. Baudot, one of the co-founders of BleachBright about his experience. Mr. Runsick said Mr. Baudot was very nice at first. Mr. Baudot said that he had caught some dealers not using his chemical, just his equipment, and maybe this is what happened. He asked Mr. Runsick to fax him his receipts, and that he would get back to Mr. Runsick within 24 hours because he took these issues very seriously. (Runsick, Tr. 2117-2118).
- 492. Mr. Baudot never called Mr. Runsick back. After two or three days, Mr. Runsick called him several times, but he never answered. Mr. Runsick suspected Mr. Baudot was avoiding his calls. He was eventually able to get in touch with Mr. Baudot when he called using a friend's phone. Mr. Baudot picked up immediately. They had a brief conversation, but Mr. Runsick was not satisfied that Mr. Baudot had resolved his problem. (Runsick, Tr. 2118-2119).
- 493. After his second telephone call with Mr. Baudot, Mr. Runsick felt "very betrayed and very frustrated." He began to investigate teeth whitening on the internet and did not find a lot of information because it was a new industry. He made several calls to different organizations to learn more about whether or how it was regulated, and eventually made contact with the Board. (Runsick, Tr. 2120-2121).
- 494. Mr. Runsick filed a formal complaint with the Board about his teeth whitening experience on April 11, 2008. (Runsick, Tr. 2120-2122; CX55).
- 495. At the Board's request, Dr. Larry Tilley evaluated Mr. Runsick on April 16, 2008. (Tilley, Tr. 2009-2011, 2075-2076; CX118 at 2; CX327; Runsick, Tr. 2132)).
- 496. Dr. Tilley was asked by the Board to serve as a consultant on previous occasions during the past 20 years, generally about two to three times per year. (Tilley, Tr. 1997, 2004-2007).

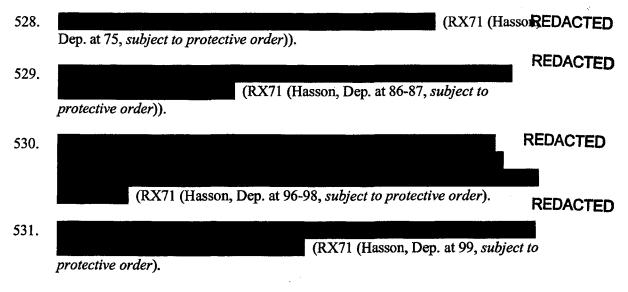
- 497. Mr. Runsick's case was the first time Dr. Tilley was asked by the Board to be a consultant in a teeth whitening case. (Tilley, Tr. 2006).
- 498. Dr. Tilley has not served as a member of the Board. (Tilley, Tr. 2004).
- 499. Dr. Tilley is licensed to practice dentistry in North Carolina and has a D.D.S. degree from the University of North Carolina School of Dentistry. He has practiced dentistry for 31 years. (Tilley, Tr. 1998).
- 500. Dr. Tilley has experience and training in teeth whitening procedures. (Tilley, Tr. 1999, 2001-2004).
- 501. Dr. Tilley recommends take-home over-the-counter teeth whitening products to his patients, such as Crest Whitestrips. (Tilley, Tr. 2003-2004).
- 502. When providing teeth whitening services, Dr. Tilley and his staff take such sanitation control measures as wearing gloves, gowns, and protective eyewear. (Tilley, Tr. 2003).
- 503. Dr. Tilley's evaluation of Mr. Runsick consisted of a general exam of the mouth and teeth structure, the mucosal of the oral tissue, and whether there were any fillings, decay, or unusual anatomy. He also conducted a head and neck exam to look for any cancers or growths. He also took a patient medical history of Mr. Runsick. (Tilley, Tr. 2011-2012; Runsick, Tr. 2133).
- 504. Dr. Tilley took notes based on his evaluation of Mr. Runsick. He also sent the Board a letter summarizing his findings. Sending this letter was standard Board policy. Dr. Tilley did not discuss his findings with Mr. Runsick. (Tilley, Tr. 2012-2013, 2024).
- 505. Dr. Tilley's evaluation of Mr. Runsick did not reveal any evidence of periodontal disease or a periodontal abscess (an infection of the gum tissue relating to gum tissue's response to bacteria in the mouth). (Tilley, Tr. 2021-2022, 2040-2041).
- 506. Dr. Tilley testified that Mr. Runsick reported taking of two courses of Zithromax would not have eliminated evidence of periodontal disease, if Mr. Runsick had originally had a periodontal disease. (Tilley, Tr. 2091-2093).
- 507. As part of his evaluation of Mr. Runsick, Dr. Tilley asked him about the nature of his problem and received from Mr. Runsick a summary of what occurred. He also reviewed Mr. Runsick's written complaint to the Board describing his experience with the teeth whitening service at Crabtree Valley Mall. (Tilley, Tr. 2022-2023; CX118).

- 508. The injuries Mr. Runsick claimed he suffered to his mouth as a result of the teeth whitening, including pain and bleeding in his gums, were consistent with Dr. Tilley's evaluation. (Tilley, Tr. 2024-2025; CX327).
- 509. Dr. Tilley observed that the injuries Mr. Runsick claimed he suffered to his mouth as a result of the teeth whitening were consistent with a chemical burn from whitening the teeth. (Tilley, Tr. 2035-2036; CX327).
- 510. Dr. Tilley observed that Mr. Runsick's mouth was healthy except for where he had a loss of gum tissue that possibly resulted from the teeth whitening procedure described by Mr. Runsick. This loss of gum tissue consisted of a gap in Mr. Runsick's interdental tissue, or area between his teeth, that had not fully healed and the gums failed to fill in the space, creating a dark area. (Tilley, Tr. 2036-2037; CX327).
- 511. Dr. Tilley observed that as a result of Mr. Runsick's injury, his gum tissue would only return to 90% of its original condition, and thus may not fully fill in the interdental space. Dr. Tilley has observed this condition before in other patients. (Tilley, Tr. 2037; CX327).
- 512. Mr. Runsick specifically asked Dr. Tilley whether his gum loss would be permanent. Dr. Tilley told him that some of it could be. (Runsick, Tr. 2135-2136).

b. Other Consumers' Injuries







P. Equal Access to Justice Act

- 532. Mr. Runsick remembers first being contacted by the Federal Trade Commission ("FTC") in August or September of 2010. He was contacted by Michael Bloom. (Runsick, Tr. 2124; RX47 at 1).
- 533. Mr. Bloom told Mr. Runsick that the FTC was conducting an investigation of BleachBright and other non-dental teeth whitening companies, and that they might have more questions for him. Mr. Bloom asked him if he would be available for a telephone conversation at a later date. (Runsick, Tr. 2124-2125; RX47 at 1).
- 534. Attorneys from the FTC later contacted Mr. Runsick by telephone. He thinks there were about three or four people on the call with him. The conversation lasted about 15 minutes, and they asked him about the details of his teeth whitening experience, including when he filed his complaint and what was in the complaint. (Runsick, Tr. 2126-2127; RX47 at 1).
- 535. The FTC's third contact with Mr. Runsick was initiated by the FTC by Melissa Westman-Cherry. She told him that he was going to be subpoenaed to testify, and that he would have to testify in Washington, D.C. He was never told by the FTC that he could testify somewhere other than Washington, D.C. or that he could have his deposition taken by telephone. (Runsick, Tr. 2127-2131; RX47 at 1-2).
- 536. Mr. Runsick first asked bout the nature of the FTC's proceeding at his deposition in Washington, D.C. on November 4, 2010. He suddenly realized that the investigation was not how it had initially been indicated to him as an FTC investigation of teeth whitening in cooperation with the Board in order to protect the public. He realized that the FTC had filed a complaint against the Board in support of the teeth whitening companies. (Runsick, Tr. 2129-2130; RX47 at 2).

- 537. Mr. Runsick expressed that he would like for his deposition and testimony to be entered into the public record. (Runsick, Tr. 2131-2132).
- 538. Mr. Runsick testified in this proceeding because he thinks that teeth whitening needs to be regulated by a government agency, especially for hygiene policies and adequate training. (Runsick, Tr. 2131-2132).
- 539. Mr. Runsick recalls receiving a telephone call contemporaneous with Mr. Tilley's deposition. He was asked whether he would consent to the extension of the period in which his medical records could be released. (Runsick, Tr. 2133-2134).
 - Q. The Board Tendered and the Court Accepted Dr. David L. Baumer as an Expert.
- 540. Dr. Baumer is an expert in the fields of the industrial organization and economics of regulated markets generally and professional markets specifically. (Baumer, Tr. 1695).
- 541. Dr. Baumer has been recruited several times, at least twice by the FTC. to serve as an economist. He has also been offered a position with the International Trade Commission. (Baumer, Tr. 1692-1693).
- 542. Dr. Baumer has an active consulting practice related to economics. (Baumer, Tr. 1693).
- 543. Dr. Baumer has conducted original research in the field of economics, including research regarding federal regulation of the dairy industry and legal restraints. (Baumer, Tr. 1693; RX78 at 26-37).
- 544. In conducting his analysis of this case, Dr. Baumer relied upon economic articles that examine professional associations and licensing, articles that describe teeth whitening services, statements and studies of medical and dental experts, and legal motions and pleadings in the matter. (RX78 at 6, 43-44).
 - R. Complaint Counsel Tendered and the Court Accepted Dr. John E. Kwoka as an Expert.
- 545. Dr. Kwoka is an expert in the fields of "industrial economics and the economics of professional regulation." (Kwoka, Tr. 976).
- 546. Dr. Kwoka does not hold himself out as a medical expert, although he purported to evaluate the weight of the evidence regarding health and safety benefits of Board intervention in the marketplace and concluded that it was not justified. (Kwoka, Tr. 1166-1167).

- 547. Dr. Kwoka is not a dentist, but purported to testify as to the existence (or non-existence) of reliable evidence of serious and systematic harm (from teeth whitening). (Kwoka, Tr. 1223).
- 548. Dr. Kwoka was not tendered as an expert in law, yet concluded that cease and desist letters issued by the Board were "in contravention of North Carolina state law." (Kwoka, Tr. 1216-1217).
- 549. Although Dr. Kwoka was tendered and accepted as an expert in "industrial economics and the economics of professional regulation", he insisted on limiting his economic analysis to an alternative analysis of one market model. (Kwoka, Tr. 1104).

S. The Teeth Whitening Markets

- 550. Dr. Baumer includes in his list of competing methods of teeth whitening (1) legal dentist-supervised teeth whitening services; (2) legal dental-provided take-home kits; (3) illegal non-dentist-supervised teeth whitening services; and (4) over-the-counter products. (Baumer, Tr. 1844). Dr. Kwoka defined the teeth whitening market in North Carolina to include over-the counter products, dental in-office procedures, dental take-home kits, and non-dentist teeth whitening. (Kwoka, Tr. -981-984; CX654 at 3-4).
- 551. Dr. Baumer acknowledged the four methods' characteristics, and cross-elasticity of demand as proof of the competition between each. (Baumer, Tr. 1842).
- 552. However, in Dr. Baumer's opinion, it is not fair to compare all of these methods as being on equal footing when one group of products is illegal. (Baumer, Tr. 1726-1727).
- 553. Dr. Kwoka is a one-handed economist, and his report fixates on one market alternative (licensing) and price. As a two-handed economist, Dr. Baumer's analysis looked at more than just the price aspect of this case. It also examined several market alternatives and non-price economic aspects including health and public policy. (Baumer, Tr. 1695-1696).
- 554. Restrictions on competition generally result in higher prices and loss of consumer welfare. Dr. Kwoka does not provide any statistical data on the effect on prices in his analysis with respect to exclusion. (Baumer, Tr. 1724-1725).
- 555. Dr. Baumer found that the credibility of Dr. Kwoka's claims is undermined by not including any empirical data that is potentially available and by analyzing more than one market structure and more than price. This could be rectified simply by asking dentists what they have charged patients for the past five years. (Baumer, Tr. 1731).

- 556. Dr. Baumer did not find that a rule of reason analysis applies in this case because the Board was simply enforcing a state statute that it was charged to enforce, and that is not a bad or anticompetitive act, nor does it reveal bias. (Baumer, Tr. 1698-1699).
- 557. Dr. Baumer found Dr. Kwoka's analysis to be consistent with a *per se* analysis, and not a rule of reason analysis. (Baumer, Tr. 1699).

T. Board Enforcement of a State Statute to Exclude Market Participants on a Limited Basis Is a Justifiable Activity

i. Dr. Baumer's Testimony

- 558. Dr. Baumer agrees with Dr. Kwoka that the exclusionary model applies in this case, that there is a downward sloping demand curve, and that there is no Akerlof problem. (Baumer, Tr. 1696-1697, 1700, 1772-1773).
- 559. Dr. Baumer disagrees with Dr. Kwoka with respect to whether the exclusion here of non-dentist teeth whiteners is justified there is value here in the Board's exclusion. (Baumer, Tr. 1708).
- 560. Without drawing a legal conclusion, Dr. Baumer also disagrees with Dr. Kwoka regarding the cease and desist letters. The letters are not exclusionary, although they may in some ways be consistent with exclusion. (Baumer, Tr. 1712).
- 561. Dr. Kwoka erroneously assumes that Board members represent themselves despite the fact that they swear an oath to protect the public interest. (Baumer, Tr. 1780-1781).
- 562. Dr. Kwoka also erroneously assumes that dentists are motivated solely by profit maximization. The Board takes several procedures on a routine basis to avoid conflicts of interest, such as not assigning Board members to cases in the geographical area where they practice. (Baumer, Tr. 1765-1766).
- 563. Dr. Baumer found that self-interest does not define the actions of the Board. (Baumer, Tr. 1780-1781).
- 564. Dr. Kwoka erroneously asserts that non-dentist provided teeth whitening is an innovative product/service. It is not innovative; arguably, non-dentists merely charge a lower price. (Baumer, Tr. 1723-1724).
- 565. Dr. Baumer disagrees with Dr. Kwoka's claim that there are "no systematic benefits in quality or safety" associated with licensing. (Baumer, Tr. 1734-1735).

- 566. Dr. Kwoka's assertion s that non-dentist teeth whitening falls "far short" of the standard for having significant health risks flies in the face of reality because dental experts disagree on whether or not it poses significant health risks. (Baumer, Tr. 1767-1768).
- 567. The Board's regulation of dentistry is precisely constituted to exclude unlicensed people from practicing dentistry. (Baumer, Tr. 1700). Teeth whitening has not been banned in North Carolina; it is simply not permitted to be done by unlicensed people. (Baumer, Tr. 1733-1734, 1764).
- 568. The only people being excluded are people for whom there are health concerns about their provision of teeth whitening services. (Baumer, Tr. 1784-1785, 1813).
- 569. The Board's regulation of dentistry takes place through the N.C. Dental Practice Act, not State Board administrative rules. This means that the State Board is supervised by the state legislature. (Baumer, Tr. 1811).
- 570. The Board is not a government-sponsored cartel; the Board does not: (1) set minimum prices, (2) punish price cutters, (3) create barriers to entry that are not tied to health and public safety, or (4) make its decisions in secret. (Baumer, Tr. 1696-1697, 1886).
- 571. There is a rational basis for the Board's existence, including the promotion of health and safety in dentistry. (Baumer, Tr. 1810-1811).
- 572. The people most knowledgeable about the practice of dentistry are practicing dentists, thus the requirement by North Carolina state law that a majority of Board members be dentists has a rational basis. (Baumer, Tr. 1809-1810).
- 573. Allowing the practice of dentistry by unlicensed persons would threaten public health and safety. (Baumer, Tr. 1810-1811).
- 574. The Board's organizational structure is indistinguishable from other licensing boards across the country, and it is not anticompetitive. (Baumer, Tr. 1815).
- 575. The exclusion of non-dentist teeth whitening services is a justifiable limited exclusion, and this exclusion could pass a cost-benefit test where the benefits to consumers exceed the cost, which is slightly higher prices and more inconvenience. (Baumer, Tr. 1815-1816).
- 576. The benefits to consumer welfare of the exclusion exceed the costs in terms of slightly higher prices and the "inconvenience" of going to a dentists' office or an over-the-counter site. (Baumer, Tr. 1815-1816).

577. The foundation for the exclusion lays with the voters of North Carolina, who elected the legislators to the North Carolina General Assembly, which created the Board to enforce the Dental Practice Act, and provide oversight and supervision in the form of procedures that allow appeals of the actions of the Board. (Baumer, Tr. 1815-1816).

ii. Rebuttal of Dr. Kwoka's Testimony

- 578. Dr. Kwoka admitted that you can have a justifiable limited exclusionary model, but denied that such a model applied with respect to the Board. (Kwoka, Tr. 1108).
- 579. Dr. Kwoka cited literature that addresses different restrictions by licensing boards; Dr. Baumer does not believe that excluding a class of providers with no training can be grouped in the same category. (Baumer, Tr. 1764).
- 580. Dr. Kwoka is really saying that the Board's financial interest overwhelms any other interest. Dr. Baumer did not consider this a fair assumption because it would be unprofessional for the Board to behave that way. (Baumer, Tr. 1781-1782).
- 581. Dr. Kwoka conceded that Board members acted based in part on their sworn duty as public officials. (Kwoka, Tr. 1111-1113).
- 582. Dr. Kwoka conceded that Board members are also motivated by ethical and professional standards of behavior. (Kwoka, Tr. 1111-1113).
- 583. When asked how material the Board members' alleged financial interest was, Dr Kwoka said it was impossible to quantify, and that he could not provide a precise number. (Kwoka, Tr. 1246-1248).
- 584. Dr. Kwoka's claim that there was "no tendency for lower-quality service to drive higher-quality service from markets for professional services" is far-fetched. It is improper and absurd to assert that the performance of a dentist with years of education and plenty of training is comparable to someone with little to no training and not subject to licensing standards. (Baumer, Tr. 1786-1787).
- 585. Dr. Kwoka failed to account for significant health considerations in his discussion. (Baumer, Tr. 1817).
- 586. Dr. Kwoka conceded that if he assumed evidence of health and safety issues was present, either in the form of expert testimony or literature, he would weigh that evidence in his analysis. (Kwoka, Tr. 1139-1140, 1141-1143).

- 587. Dr. Kwoka indicated that the assumption that the Board was working in the interest of consumer protection would not affect his analysis. (Kwoka, Tr. 1143-1146).
- 588. Dr. Kwoka did not consider that banning non-dentist teeth whitening might not have any effect at all on the prices that dentists charge. (Baumer, Tr. 1729-1730).
- 589. It is possible that there may be no effect on prices if consumers have to obtain teeth whitening serves from dentists instead of non-dentists. Dentists may base their fees for teeth whitening based on the time expended to perform those services. (Baumer, Tr. 1729-1730).
- 590. Dr. Kwoka relied on outdated literature in the form of studies from the 1970s and 1980s. (Baumer, Tr. 1733, 1743-1744).
- 591. Dr. Kwoka admitted that the model of licensing boards on a whole does not resemble the widespread model of 20 years ago because licensing practices have changed. (Kwoka, Tr. 1121).
- 592. Dr. Kwoka's economic model did not consider other aspects beyond economics, such as policy; he said he was not asked to evaluate such justifications (Kwoka, Tr. 1108-1109).
- 593. Dr. Kwoka conceded the Board was a creature of state law, and the state legislature makes the decisions and allocates responsibility for enforcing those judgments. Further, the Board's enforcement role involves issuing cease and desist letters. (Kwoka, Tr. 1146-1148).
- 594. Dr. Kwoka's analysis assumes that the mechanics of the exclusion are discretionary, when in fact the Board is required by law to enforce the statute; he denied that this affected his analysis because the effects are exclusionary. (Kwoka, Tr. 1173-1174).
- 595. Dr. Kwoka's general assessment of licensing lists no positives and recognizes no efficacies for the licensing construct. (Kwoka, Tr. 1126-1128).
- 596. Neither Dr. Kwoka's report nor his testimony produced any statistical evidence of the alleged effect of the loss of non-dentist teeth whitening in North Carolina; he stated that the data is not available. (Kwoka, Tr. 1186-1187).
- 597. Dr. Kwoka assumed that the cease and desist letters automatically had an exclusory effect, even though the letters did not have a self-enforcement capability. (Kwoka, Tr. 1131-1135).

U. The Teeth Whitening Industry

- 598. Hydrogen or carbamide peroxide is the primary whitening agent used in the whitening of teeth. In a water based solution, carbamide peroxide breaks down into hydrogen peroxide and urea, with hydrogen peroxide being the active bleaching agent. Carbamide peroxide contains 35% hydrogen peroxide. (Joint Stipulations ¶ 20).
- 599. Available OTC products include gels, rinses, chewing gums, trays, and strips. In a 2006 report, NBC's Today show correspondent Janice Lieberman reported that in 2005, the U.S. market for OTC products was \$41.4 billion. (Joint Stipulations ¶22).
- 600. There is "conflicting evidence" as to the dehydrating effects of bleaching lights in the teeth whitening process and whether any whitening obtained will last. (CX392 at 5).
- 601. A Frequently Asked Questions informational document available on the website of the ADA states that "[the] FDA has not classified tooth whitening products and as a result a formal submission of research results to [the] FDA is not required before products are marketed", and that some companies "may conduct only limited testing or almost no scientific evaluation of the safety of their whitening products." (CX227 at 4).

i. Dental Teeth Whitening

- 602. Teeth whitening comprised only one or two percent of the total practice revenues of most of the current or former dentist Board members, and one did not perform any teeth whitening at all. (Wester, Tr. 1289-1290; Owens, Tr. 1452; Hardesty, Tr. 2777; RX49 (Allen, Dep. at 18); RX52 (Burnham, Dep. at 148); RX56 (Feingold, Dep. at 10); RX63 (Holland, Dep. at 56-57); RX65 (Morgan, Dep. at 289-290); CX555 (Brown, Dep. at 8)).
- 603. Some current or former dentist Board members testified that their revenues from teeth whitening had decreased during the past five years. (Wester, Tr. 1290; Owens, Tr. 1452; Hardesty, Tr. 2777; RX52 (Burnham, Dep. at 149-150)).
- 604. Other dentists also reported that teeth whitening did not represent a substantial portion of their dental practice revenue. (CX600 at 3; CX602 at 2; CX599 at 3; CX603 at 3).
- 605. An American Academy of Cosmetic Dentistry ("AACD") press release dated June 22, 2006 and cited by Complaint Counsel states that whitening treatments provided by dentists "have increased more than 300% since 1996" a ten year time span. (CX397 at 1).

- Another press release issued by the AACD contains survey results indicating that teeth whitening is still a small percentage of the practices of those who specialize as cosmetic dentists. The survey found that although these cosmetic dentists did report performing an average of 70 teeth whitening procedures in 2006, which earned them \$25,000 in revenue, the majority of their revenues came from other procedures. (CX383 at 2).
- 607. An AACD report on cosmetic dentistry indicated that cosmetic dentists reported an average of 1,325 other procedures performed in 2006, for \$483,000, and that the percentage of their revenue generated from teeth whitening in the year 2006 was roughly 4.8%. (CX383 at 2).
- 608. Dentists who offer take-home products for teeth whitening may charge less than the \$300 cited by Complaint Counsel. (Hardesty, Tr. 2777; RX49 (Allen, Dep. at 19-20); RX56 (Feingold, Dep. at 10); RX60 (Hall, Dep. at 34); RX76 (Parker, Dep. at 13)).
- 609. Dentists' teeth whitening fees are tied to "office overhead," which can be substantial. (RX65 (Morgan, Dep. at 139); RX75 (Oyster, Dep. at 65)).
- 610. The prescription strength teeth whitening materials are a considerable up-front expense for dentists. (RX63 (Holland, Dep. at 61-62)).
- 611. The testifying dentists stated that they did not actively market their teeth whitening services. They would typically have brochures or posters visible in their office and would only discuss the possibility of teeth whitening if asked about it by a patient or in relation to dental work such as crowns. (Wester, Tr. 1290; Owens, Tr. 1452-1453; Tilley, Tr. 1999-2000; Hardesty, Tr. 2777).
- 612. The teeth whitening products used by dentists for in-office teeth whitening generally have a higher concentration of the active ingredients hydrogen or carbamide peroxide, than that typically available in non-dentist teeth whitening. When using a high concentration, dentists usually first apply an isolation dam to the gums to prevent burning. (Joint Stipulations ¶ 24).
- 613. Zoom and Bright Smile are two products used by dentists for in-office teeth whitening procedures. (Joint Stipulations ¶ 25).
- 614. Take home kits provided by dentists can either be used as a follow-up to in-office treatment or as the sole teeth whitening service. (Joint Stipulations ¶ 26).
- 615. Dentists, including some current or former dentist Board members, have recommended over-the-counter teeth whitening products to their patients. (Wester, Tr. 1290; Owens, Tr. 1453; Hardesty, Tr. 2778; RX63 (Holland, Dep. at 40-41, 45-47); RX76 (Parker, Dep. at 177-178)).

ii. Non-Dentist Teeth Whitening

- 616. Products sold by non-dentists fall under many brand names, including White Smile USA, Brite White, Beyond White Spa, Beyond Dental & Health, and SpaWhite. (Joint Stipulations ¶ 21).
- 617. Consumers of some non-dentist teeth whitening services may spend more money to have an over-the-counter strength teeth whitening product applied to their teeth than they would have if they had purchased and self-administered an over-the-counter kit. (CX595 at 3).
- 618. Non-dentist teeth whitening procedures do not universally provide the same degree of whitening as dental teeth whitening because they do not use as strong a percentage of hydrogen peroxide. (Nelson, Tr. 730-731; Osborn, Tr. 657-658, 686).
- 619. No evidence was presented at trial demonstrating that all non-dentist teeth whiteners use FDA-approved teeth whitening products. (Entire record).
- 620. No evidence was presented at trial that there is a state or federal regulatory entity that ensures that FDA-approved teeth whitening products are used by non-dentists selling the product to consumers. (Entire record).

iii. Testimony of Teeth Whitening Industry Representatives

a. WhiteSmile USA

- 621. James Valentine is a co-founder of WhiteSmile USA, a company that provides teeth whitening products and services. (Valentine, Tr. 514-515).
- 622. Mr. Valentine testified that WhiteSmile USA sought to avoid regulation by the State Board and other states by telling its employees to have customers self-administer bleaching products. Customers were instructed to brush their own teeth before undergoing teeth whitening treatment, dry their teeth off with a paper towel, place the teeth whitening chemical solution into the bleaching tray on their own, and place the bleaching tray and mouthpiece for the LED light into their own mouths. WhiteSmileUSA also told its employees to avoid putting their fingers in customers' mouths because this would be viewed as practicing dentistry. (Valentine, Tr. 536-541).
- 623. WhiteSmile USA challenged whether its non-dentist teeth whitening services fell within the scope of the Alabama Dental Practice Act. The Alabama Supreme Court held that the procedures constituted the practice of dentistry. (Valentine, Tr. 559-560, 585-586, 600-601).

- 624. WhiteSmile USA never received a cease and desist letter from the Board related to its operations in North Carolina. (Valentine, Tr. 562-563, 589).
- 625. WhiteSmile USA did not enter the North Carolina market until 2009; any damages Mr. Valentine may have quoted prior to that date are irrelevant. (Valentine, Tr. 567, 578).
- 626. Mr. Valentine admitted that since 2009, WhiteSmile USA's sales had "dropped off significantly due to the economy." (Valentine, Tr. 575).
- 627. WhiteSmile USA still has a market presence in North Carolina through its direct online sales of over-the-counter products. Sales of these products have not been restricted by the Board or any North Carolina agency. (Valentine, Tr. 580, 609).
- 628. WhiteSmile USA's education and training of its employees does not include training regarding dental anatomy, the general use of chemicals (other than hydrogen peroxide or carbamide peroxide), or the impact of drugs on a patient's body or mouth. (Valentine, Tr. 592-593).
- 629. WhiteSmile USA has not made a determination as to how it would comply with HIPAA or CDC requirements. (Valentine, Tr. 593).
- 630. WhiteSmile USA does not take the medical history of its customers prior to providing teeth whitening services. (Valentine, Tr. 594).
- 631. WhiteSmile USA requires that its customers sign a consent form containing a waiver of liability. (Valentine, Tr. 597).
- 632. WhiteSmile USA did not require salons or kiosks carrying its products to maintain general liability insurance. (Valentine, Tr. 606-607).
- 633. Mr. Valentine contacted the FTC in 2008 to file a complaint. (Valentine, Tr. 597-598).

b. BEKS Incorporated

- 634. Joyce Osborn operates a teeth whitening business called BriteWhite Teeth Whitening System, which operates under the corporate name BEKS Incorporated. (Osborn, Tr. 646).
- 635. People using Ms. Osborn's BriteWhite Teeth Whitening System receive no training other than a training manual to read. (Osborn, Tr. 655-656).

- 636. Ms. Osborn has revised her training, informational and marketing literature to no longer use the word "stains" to describe the teeth whitening process she helped develop. She did this in an attempt to avoid state regulations that would view her system as the practice of dentistry. (Osborn, Tr. 666-667).
- 637. Ms. Osborn admitted that the dentist she consulted with to develop her teeth whitening process used the word "stains" to describe the conditions of teeth that are removed by the teeth whitening process they developed. (Osborn, Tr. 666).
- 638. Ms. Osborn never received a cease and desist letter from North Carolina. (Osborn, Tr. 672-673).
- 639. Ms. Osborn testified that she was not aware of any certification program for people that provide non-dentist teeth whitening. (Osborn, Tr. 705).
- 640. Ms. Osborn was not aware whether teeth whitening employees or employees of her local affiliates are ever provided any training regarding dental anatomy, normal versus abnormal teeth, the use of chemicals (other than hydrogen peroxide), or the impact of drugs on a customer's body or mouth. Ms. Osborn testified that "[w]e're not in any way licensed or qualified to do any of that." (Osborn, Tr. 705-706).
- 641. Ms. Osborn does not know whether teeth whitening employees or employees of her local affiliates are required to comply with HIPAA or CDC requirements. (Osborn, Tr. 706).
- 642. Ms. Osborn does not know whether teeth whitening employees or employees of her local affiliates are trained to take the medical history of a customer. (Osborn, Tr. 706).
- 643. Ms. Osborn also sells teeth whitening products to dentists, and would gladly sell such products to dentists in North Carolina, but has not received any calls from North Carolina dentists. (Osborn, Tr. 680).
- 644. There is no testimony that Ms. Osborn was prevented from selling teeth whitening products to dentists in North Carolina. (Entire record).
- 645. Ms. Osborn has a patent pending for BriteWhite, an LED light to be used as part of a teeth whitening system. The patent application filed with the U.S. Patent and Trademark Office states that the method "is not suitable for use without administration by a dental professional." (Osborn, Tr. 683-686).
- 646. Ms. Osborn's sales of teeth whitening products to her local affiliates requires the signing of distributor agreements that only permit the affiliate to sell BriteWhite teeth whitening products. (Osborn, Tr. 695).

- 647. Neither Ms. Osborn's distributor agreements, nor any other materials she provides to her local affiliates, require the affiliate to comply with safety, sanitation, and other self-administration protocols. (Osborn, Tr. 700-701).
- 648. Ms. Osborn has discontinued selling products to local affiliates selling her teeth whitening systems for violating her exclusivity agreement, but she has not ever discontinued selling products to a local affiliate for not following her training or best practices protocols. (Osborn, Tr. 701-702).
- Ms. Osborn used to require that her local affiliates provide a consent form to customers purchasing teeth whitening services, but she has reconfigured the form as an "information form" about her teeth whitening products. The information form requests personally identifying information regarding her customers. This information is kept on file in an unlocked cabinet at her office in Alabama. (Osborn, Tr. 665, 702-703, 708-709).
- 650. The previous consent form that Ms. Osborn required her local affiliates to use asked customers whether or not they understood the risks of teeth whitening. That question has been removed from the currentinformation form, which simply provides information to the customer. (Osborn, Tr. 708-709).
- Ms. Osborn's claim on her website that her products have FDA approval only applies to her BriteWhite LED light, and not to any of her other products. (Osborn, Tr. 714-715).
- 652. Ms. Osborn testified that the Council for Cosmetic Teeth Whitening has a significant interest in the outcome of this matter. (Osborn, Tr. 715).
- 653. While under oath, Ms. Osborn denied having any personal contact with anyone at the FTC. (Osborn, Tr. 716).
- 654. Ms. Osborn admitted to sending an email on September 13, 2009 to Melissa Westman-Cherry transmitting the restraining order for Signature Spas in Hickory, N.C. She also admitted sending an email to Ms. Westman-Cherry thanking her for bringing this proceeding. (Osborn, Tr. 716).

c. WhiteScience

- 655. George Nelson is the President of WhiteScience, a teeth whitening manufacturing and marketing business. (Nelson, Tr. 721-722).
- 656. WhiteScience manufactures teeth whitening products, including its own dental light, and creates distributorships to market and sell its product to clients. (Nelson, Tr.725).

- 657. WhiteScience has a product that it markets and sells to dentists called Artiste. (Nelson, Tr. 729).
- 658. In a letter dated December 4, 2007, Board Counsel wrote to WhiteScience and informed the company that it or its affiliates could not provide teeth whitening services in North Carolina under North Carolina law unless such activities "are performed or supervised by a properly licensed North Carolina dentist." (CX100; Nelson, Tr. 814-816).
- 659. Mr. Nelson and representatives of WhiteScience did not consider having a dentist supervise or recommend that their local affiliates have a dentist supervise teeth whitening services that they provided to customers. He said that the major advantage of not having a dentist supervise the provision of teeth whitening services is that it would be cheaper without dentist involvement. (Nelson, Tr. 817).
- 660. Over-the-counter teeth whitening products are the cheapest and most convenient products in the teeth whitening market, compared to kiosk/spa and dentist-provided teeth whitening. (Nelson, Tr. 792).
- WhiteScience's distributor agreement with its local affiliates requires that they only sell WhiteScience teeth whitening products, and not the teeth whitening products of any competitor. (Nelson, Tr. 794-795).
- WhiteScience does not require local affiliates selling its product to maintain any sort of documentation of its business or customers. (Nelson, Tr. 796).
- 663. WhiteScience does not require its local affiliates to have customers sign a consent form or go over a checklist of information establishing that they understand the teeth whitening process and its health risks. (Nelson, Tr. 796-798).
- When Mr. Nelson first started up his company, he did not look into whether he would need to have a dentist involved in providing teeth whitening services. (Nelson, Tr. 800).
- WhiteScience operations in 40 states in the United States, and still currently operates in North Carolina. (Nelson, Tr. 800, 809-811).
- Mr. Nelson is on the board of the Council for Cosmetic Teeth Whitening, and is one of the founding partners. (Nelson, Tr. 801).
- 667. A Material Safety Data Sheet outlines potential risks and health effects of WhiteScience teeth whitening products. It is provided to WhiteScience employees for training. (Nelson, Tr. 806-807; CX0108 at 3-17).

- 668. The WhiteScience Material Safety Data Sheet states that potential risks of the chemical in WhiteScience's teeth whitening product include injury to a consumers' eyes (e.g., ulceration of the cornea), skin (e.g., overexposure by contact could cause mild to severe irritation and/or burns of the skin and mucous membrane), and ingestions (e.g., ingestion of large amounts could cause irritation of the gastrointestinal tract with pain, nausea, constipation, diarrhea, distention of the stomach and/or esophagus, and potential suffocation). These risks could apply to both the customer and the employee, though the customer's exposure likely would be more limited. (Nelson, Tr. 807-809; CX108 at 4-5).
- 669. WhiteScience's marketing literature states that its product will "deliver real teeth whitening and stain removal." (Nelson, Tr. 817-819).
- 670. Mr. Nelson testified that he believes that teeth whitening is really the removal of stains from the teeth. The only way for a person to have their teeth whitened permanently is "with a veneer or a crown." (Nelson, Tr. 818-819).
- 671. WhiteScience does not provide training to its employees or local affiliates regarding dental anatomy, recognizing normal versus abnormal teeth, the use of chemicals (other than hydrogen or carbamide peroxide), or the impact of drugs on a customer's body or mouth. (Nelson, Tr. 822-823).
- 672. Mr. Nelson has never been advised that his WhiteScience employees or their local affiliates should comply with HIPAA or CDC regulations. (Nelson, Tr. 823).
- 673. WhiteScience does not provide training to its employees or local affiliates regarding how to take a patient's medical history. (Nelson, Tr. 823-824).
- 674. Employees and local affiliates of WhiteScience do not keep any documentation of the teeth whitening procedures that they conduct on behalf of their customers, unless it is information for marketing purposes. (Nelson, Tr. 824).
- 675. Mr. Nelson recalls contacting Ms. Westman-Cherry in February 2008, and informing her about the Wyants, teeth whitening affiliates of WhiteScience whose kiosk lease was cancelled by the North Carolina mall where they were operating. (Nelson, Tr. 824-825).
- 676. Mr. Nelson wrote a letter to Mr. Baudot on April 28, 2010 about a restraint of trade lawsuit. He said he did this because "we were all in the same boat. We were all losing business and we all had to work together to protect the industry, so that's why I'd be talking to a competitor about it." By "industry", Mr. Nelson meant non-dentist teeth whitening businesses like WhiteScience. (CX139; Nelson, Tr. 828-831).

- 677. Mr. Nelson admitted that Mr. Baudot is his competitor in the teeth whitening industry. (Nelson, Tr. 828-829).
- 678. On April 28, 2010, Mr. Nelson forwarded to Steven Osnowitz and Ms. Westman-Cherry at the FTC an e-mail exchange between him and Mr. Baudot in which he said: "BleachBright and their industry is working with the FTC to file restraint of trade issues as well as law firms that will be litigating for violation of the individuals' CONSTITUTIONAL (sic) right to earn an honest living offering a safe, affordable competitive product." (CX139 at 1-2; Nelson, Tr. 826-827).
- 679. As part of his efforts to work with the FTC regarding restraint of trade issues, Mr. Nelson provided the FTC with names of about a half dozen potential witnesses. (Nelson, Tr. 832-834).
- 680. WhiteScience did not require its local affiliates operating teeth whitening kiosks at malls to have running water. (Nelson, Tr. 834).

d. The Council for Cosmetic Teeth Whitening

- 681. The Council for Cosmetic Teeth Whitening is a trade association devoted to the professional development of the cosmetic teeth-whitening industry in the United States. It is composed of members of the teeth whitening industry, and works to represent its members' best interests, including contacts with state and national regulatory agencies. (Osborn, Tr. 687-688).
- 682. Ms. Osborn and Mr. Nelson are on the board of the Council for Cosmetic Teeth Whitening, and are both founding partners. Ms. Osborn is the President of the organization. (Osborn, Tr. 668, 675; Nelson, Tr. 801).
- 683. The Council for Cosmetic Teeth Whitening has written to the State Board, the North Carolina State Attorney General, and elected North Carolina officials in the course of representing its members' interests. (Osborn, Tr. 688-689).
- 684. The Council for Cosmetic Teeth Whitening has written to other dental licensing boards, state attorneys general, and elected legislators in states across the country, including Pennsylvania, Nevada, and Florida, in the course of representing its members' interests. (Osborn, Tr. 691-692).
- 685. The Council for Cosmetic Teeth Whitening has developed "best practices" protocols for how to avoid state regulations that could potentially regard teeth whitening as the practice of dentistry, including not touching customers or their mouths and making sure that customers self-administer the teeth whitening products. (Osborn, Tr. 675-678).

- 686. These self-administration practices are not always followed by non-dental teeth whitening service providers at spas and mall kiosks. (Runsick, Tr. 2109; RX71 (Hasson (Dep. at 96-98); RX8 at 9; RX11 at 6; RX15 at 9; RX17 at 2, subject to protective order; RX22 at 18; RX25 at 15; RX27 at 1).
- 687. The only sanitation practices advocated by the Council for Cosmetic Teeth Whitening in its "best practices" protocols is to wipe surfaces down with disinfectant wipes, wear gloves, and properly dispose of the materials. (Nelson, Tr. 834-835).
- 688. These sanitation practices are not always followed by non-dental teeth whitening service providers at spas and mall kiosks. (Runsick, Tr. 2108; RX11 at 6; RX15 at 9).
- 689. Where states have raised the issue of having a dentist to supervise teeth whitening activities, the Council for Cosmetic Teeth Whitening has never advised its members to hire a dentist to ensure compliance with teeth whitening regulations. (Osborn, Tr. 692-693).
- 690. The Council for Cosmetic Teeth Whitening considered litigation in a number of states to challenge state dental board enforcement in connection with non-dentist teeth whitening. (Nelson, Tr. 805).
- 691. In a letter to George Nelson dated January 25, 2008, Algis Augustine, an attorney for the Council for Cosmetic Teeth Whitening, made the following recommendation regarding where to file a lawsuit challenging state dental board regulation of non-dentist teeth whitening: "we suggest we take action after a close analysis in a state where we feel we have the best chance of succeeding, but also one which is convenient for all of the parties and the attorneys." (CX99 at 2; Nelson Tr. 802-805, 842).
- 692. The members of the Council for Cosmetic Teeth Whitening decided not to litigate against the Board in North Carolina because the FTC became involved and was able to litigate these issues in lieu of the Council for Cosmetic Teeth Whitening. (Nelson, Tr. 805).

iv. Testimony of Kiosk/Spa Teeth Whiteners

a. Bryan Wyant

693. Bryan Wyant leased a kiosk under a short-term lease at Carolina Place Mall in Pineville, North Carolina, where he provided teeth whitening services using WhiteScience teeth whitening products. His business was called One Bright Smile. (Wyant, Tr. 863-865, 873).

- Mr. Wyant underwent a WhiteScience training program in Atlanta. His training lasted less than a full day and consisted of role-playing how to interact with customers, learning how to handle the teeth whitening products, learning what a consent form was, and learning WhiteScience's sanitation measures of wiping down chairs and whitening lamps with disinfectant wipes. (Wyant, Tr. 865-866, 911-912).
- 695. The WhiteScience training that Mr. Wyant attended was conducted by Mr. Nelson and Ron Topper. It did not include training in dental anatomy. Mr. Wyant was not certain whether it included recognizing normal versus abnormal teeth, or the use of chemicals other than hydrogen or carbamide peroxide. The training also did not include compliance with HIPAA or CDC regulations, how to take a medical history of a customer, whether it was important to conduct a dental exam prior to teeth whitening, or the proper maintenance of records that Mr. Wyant would keep. (Wyant, Tr. 912-914).
- 696. Mr. Wyant did not recall whether his training with WhiteScience in Atlanta reviewed the three categories of people listed on the WhiteScience website who should not undergo teeth whitening, namely (1) anyone in their third trimester of pregnancy, (2) anyone considering dental restorations, or (3) anyone undergoing periodontal or endodontal procedures. He also does not recall whether this information was provided on the consent form given to his customers. (Wyant, Tr. 916-917).
- 697. All of Mr. Wyant's customers who bought his teeth whitening product were given a consent form to sign that described the product and its ingredients. Customers had to sign the consent form in order to undergo the teeth whitening procedure. (Wyant, Tr. 866, 914-916).
- 698. Mr. Wyant did not recall ever seeing the Material Safety Data Sheet for WhiteScience teeth whitening products outlining the potential health risks of using such products. He also did not recall discussing this sheet with his employees. (Wyant, Tr. 917-920).
- 699. Mr. Wyant charged \$129 for a 15-minute teeth whitening session and \$199 for two 15-minute teeth whitening sessions at his kiosk. He used a WhiteScience product called SpaWhite. (Wyant, Tr. 868-869).
- 700. Mr. Wyant also sold a take-home WhiteScience product called iWhite, which he sold for \$99. iWhite is a "lipstick-type" product that contained a very small percentage of carbamide peroxide. It is "[n]ot a stand-alone [product]... It was intended more for a maintenance-type product." Customers would not see any results from using this product without using another more concentrated teeth whitening product. (Wyant, Tr. 869).

- 701. Mr. Wyant had other employees who would assist him in providing teeth whitening services. They were independent contractors who principally worked with him on the weekends for between 5 and 20 hours. Mr. Wyant trained these employees by giving them copies of the WhiteScience protocols, reviewing the protocols, and role-playing how to interact with a customer. (Wyant, Tr. 869-870, 894-895).
- 702. Mr. Wyant operated his teeth whitening business at Carolina Place Mall for approximately 50 days between December 7, 2007 and January 31, 2008. (Wyant, Tr. 872-873).
- 703. Around late January 2008, Mr. Wyant was informed that Carolina Place Mall would not be renewing his lease because of concerns that his provision of teeth whitening services was considered by the State Board to be the unlicensed practice of dentistry. (Wyant, Tr. 876).
- 704. Mr. Wyant testified that he became angry (specifically, he "went absolutely berserk on" one of the mall managers and "was going totally crazy") and upset when he learned that Carolina Place Mall would not renew the lease for his kiosk, and argued about whether his business was illegal with the mall's managers. (Wyant, Tr. 876-879).
- 705. Mr. Wyant spoke with other malls in the area, but they also would not lease to him because of their management's concerns that the State Board had said provision of teeth whitening services constituted the unlicensed practice of dentistry. (Wyant, Tr. 880-884).
- 706. While conducting research before starting his business, Mr. Wyant did not consult an attorney about the licenses and permits that would be required, nor did he consult the State Board. In agreeing to do business with WhiteScience, Mr. Wyant relied on the representations of WhiteScience. Mr. Wyant did not recall anyone from WhiteScience telling him that the Board had raised questions about whether such a business was the practice of dentistry. (Wyant, Tr. 896-897).
- 707. While Mr. Wyant was considering going into business with WhiteScience, representatives of WhiteScience never told Mr. Wyant about any concerns of the State Board regarding the provision of non-dental teeth whitening services using WhiteScience products and protocols as constituting the unlicensed practice of dentistry. (Wyant, Tr. 910).
- 708. The month-to-month lease that Mr. Wyant signed with Carolina Place Mall said that the mall could cancel the lease for any reason with or without cause. It also required him to maintain liability insurance. (Wyant, Tr. 897, 900-901).

- 709. Mr. Wyant knew about the FTC's investigation into the alleged restraint of trade by dental boards in January 2008 prior to the initial contact by the FTC with the Board because he was told about it by George Nelson with WhiteScience. (Wyant, Tr. 903, 910).
- 710. Mr. Wyant presented a number of other arguments regarding the legality of his business to the management at Carolina Place Mall based on information that had been given to him by Mr. Nelson and WhiteScience. (Wyant, Tr. 903-910).
- 711. Mr. Wyant testified that he understood that the WhiteScience teeth whitening products that he sold were designed to remove stains from teeth. (Wyant, Tr. 906).

b. Margie Hughes

- 712. Margie Hughes is a licensed esthetician whose business provides a range of facial and skin care treatments. She has a license from the Cosmetology Board and operates a business called SheShe Skin, Incorporated. She used to operate a small studio in Dunn, North Carolina, but now operates out of a room at a business called The Hair Republic. (Hughes, Tr. 928-933).
- 713. Ms. Hughes used to offer teeth whitening services as part of her business. She purchased teeth whitening kits from Peggy Grater, who operates the business Grater Whiter Smiles. (Hughes, Tr. 933-934).
- 714. Ms. Hughes would buy powder and trays from Ms. Grater to take impressions of people's teeth. She would mix the powder with water, take an impression of teeth on her own, and then mail that impression back to Ms. Grater. Ms. Grater would then mail back a custom-fitted tray fashioned from the impression. These trays were designed to be worn overnight while sleeping. Ms. Hughes or Ms. Grater would provide the customers with the teeth whitening gel for use with the tray. (Hughes, Tr. 935-936, 954-955).
- 715. Ms. Hughes relied on Ms. Grater's knowledge in beginning to offer her teeth whitening services. In her initial conversations with Ms. Grater, Ms. Hughes was never informed by Ms. Grater that she needed to be approved by the Board to offer teeth whitening services, nor did Ms. Grater inform Ms. Hughes that the Board had looked at other spas and kiosks offering teeth whitening services, nor that the Board had raised questions with other operators about whether or not such businesses were the unlicensed practice of dentistry. (Hughes, Tr. 951-953).
- 716. Ms. Grater provided a training DVD to Ms. Hughes that was not more than five or ten minutes in length. Ms. Hughes also received written materials. (Hughes, Tr. 953-954).

- 717. The training materials that Ms. Hughes received did not discuss the importance of cleaning one's teeth before undergoing teeth whitening, nor did they discuss the types of situations that might be dangerous to a customer where they should not undergo teeth whitening. (Hughes, Tr. 957).
- 718. The web site for Grater Whiter Smiles says "[w]hitening cannot be performed on those with decayed, broken or loose teeth or on someone with gum disease (periodontal disease). Whitening is not effective on crowns (caps), tooth-colored fillings, bridges or dentures." Ms. Hughes does not recall whether the training video that she received from Ms. Grater discussed these conditions. (Hughes, Tr. 959-960).
- 719. The training materials that Ms. Hughes received from Ms. Grater did not include training on dental anatomy, recognizing normal versus abnormal teeth, the use of chemicals, the impact of drugs on the customer's mouth or body, compliance with HIPAA or CDC regulations, the necessity of taking a medical history of a customer, the importance of a dentist performing a dental exam before whitening, or discussion of the risk, options and benefits of teeth bleaching with customers. (Hughes, Tr. 961-962).
- 720. Ms. Hughes did not know the ingredients that were in the teeth whitening gel or the powder that she would mix into a putty. She did not recall seeing any precautions about the use of the gel, nor did she recall a written warning on any of the documentation or packaging that she received. (Hughes, Tr. 955, 959).
- 721. Ms. Hughes did not require that customers wash their hands before handling any products, nor were they advised to wear gloves. (Hughes, Tr. 959).
- 722. Ms. Hughes put out advertisements in the local newspaper indicating that she was offering teeth whitening services. (Hughes, Tr. 937-938; RX24 at 4-5).
- 723. Ms. Hughes charged \$139 per person for her teeth whitening services. (Hughes, Tr. 938).
- 724. Ms. Hughes was informed by a fellow esthetician that a bulletin had been posted on the Cosmetology Board's website warning against offering teeth whitening services because it constituted the practice of dentistry and is a misdemeanor. (Hughes, Tr. 940-942; CX67at 3).
- 725. Ms. Hughes received a letter dated February 23, 2007 from the Board stating that the Board was investigating a report that Ms. Hughes was engaged in the practice of dentistry. She received this about a week after seeing the warning on the Cosmetology Board's website. (Hughes, Tr. 943-944; CX96 at 1-2).

- 726. When Ms. Hughes told Ms. Grater her concerns about her teeth whitening services constituting the illegal practice of dentistry, Ms. Grater assured her that was not the case. But Ms. Hughes was still concerned that it was illegal. (Hughes, Tr. 942-943).
- 727. Ms. Grater helped Ms. Hughes write a letter to the Board dated March 3, 2007. The letter explained the process they were engaged in and argued that it did not constitute the practice of dentistry. Ms. Grater wrote the majority of the letter. (Hughes, Tr. 946-947; CX655 at 1-3).
- 728. After speaking with two different attorneys, Ms. Hughes decided to stop advertising her teeth whitening services. (Hughes, Tr. 963-964).
- 729. Ms. Hughes said she spoke with Ms. Friddle from the State Board by telephone. Ms. Friddle explained to Ms. Hughes that taking impressions of others was the practice of dentistry in North Carolina and required a dental license. But if she was merely selling a teeth whitening kit and the customer was taking their own impression, then that was not practicing dentistry. (Hughes, Tr. 948).
- 730. In or about July 2007, Ms. Hughes received a phone call from Line Dempsey, a Board investigator. Mr. Dempsey said he was calling to make sure that Ms. Hughes was no longer taking impressions of other people's teeth. Ms. Hughes said she understood the requirements of the law and assured Mr. Dempsey that she was no longer taking impressions for others. (Hughes, Tr. 949-950; RX24 at 2).

II. PROPOSED CONCLUSIONS OF LAW

- 1. N.C. Gen. Stat. § 90-29 defines the unlawful practice of dentistry (in pertinent part) as follows:
 - (a) No person shall engage in the practice of dentistry in this State, or offer or attempt to do so, unless such person is the holder of a valid license or certificate of renewal of license duly issued by the North Carolina State Board of Dental Examiners.
 - (b) A person shall be deemed to be practicing dentistry in this State who does, undertakes or attempts to do, or claims the ability to do any one or more of the following acts or things which, for the purposes of this Article, constitute the practice of dentistry:
 - (2) Removes stains, accretions or deposits from the human teeth;
 - (7) Takes or makes an impression of the human teeth, gums or jaws;
 - (11) Owns, manages, supervises, controls or conducts, either himself or by and through another person or other persons, any enterprise wherein any one or more of the acts or practices set forth in subdivisions (1) through (10) above are done, attempted to be done, or represented to be done;
 - (13) Represents to the public, by any advertisement or announcement, by or through any media, the ability or qualification to do or perform any of the acts or practices set forth in subdivisions (1) through (10) above.
- 2. "The practice of dentistry in the State of North Carolina is hereby declared to affect the public health, safety and welfare and to be subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the dental profession merit and receive the confidence of the public and that only qualified persons be permitted to practice dentistry in the State of North Carolina. This Article shall be liberally construed to carry out these objects and purposes." N.C. Gen. Stat. § 90-22(a); Joint Stipulations ¶ 35.
- 3. The State Board is an agency of the State of North Carolina pursuant to N.C. Gen. Stat. § 90-22(b).
- 4. The State Board is authorized and empowered by the General Assembly of North Carolina to enforce the provisions of the Dental Practice Act. N.C. Gen. Stat. § 90-22(b).
- 5. The State of North Carolina has evidenced a clear intent to displace competition in the field of teeth whitening services by the enactment of N.C. Gen. Stat. § 90-29, which prohibits unlicensed persons from practicing dentistry, including the removal of "stains, accretions or deposits from the human teeth."

- 6. The State Board is authorized by the Dental Practice Act and North Carolina law to communicate its determination that any person or entity may be violating the provisions of the Dental Practice Act to that person or entity. N.C. Gen. Stat. §§ 90-22(a), 90-40, and 90-40.1.
- 7. The State Board is authorized by the Dental Practice Act and North Carolina law to order any person or entity suspected of violating the provisions of the Dental Practice Act to cease and desist violating the provisions of the Act. N.C. Gen. Stat. §§ 90-22(a), 90-40, and 90-40.1.
- 8. The State Board and its members have the authority to enforce the provisions of the Dental Practice Act with respect to the unauthorized and unlawful practice of dentistry by seeking recourse to the courts of North Carolina pursuant to N.C. Gen. Stat. §§ 90-40 and 90-40.1.
- 9. In the event a person or entity disregards an order to cease and desist any activity issued by the State Board, the Board is authorized by the Dental Practice Act to seek enforcement of that order in the courts of North Carolina by injunctive relief under N.C. Gen. Stat. § 90-40.1.
- 10. Pursuant to N.C. Gen. Stat. §§ 90-22(a), 90-40 & 90-40.1, the State Board is authorized by the Dental Practice Act and North Carolina law to communicate its determination that any person or entity may be violating the provisions of the Dental Practice Act to that person or entity.
- 11. Pursuant to N.C. Gen. Stat. §§ 90-22(a), 90-40 & 90-40.1, the State Board is authorized by the Dental Practice Act and North Carolina law to order any person or entity suspected of violating the provisions of the Dental Practice Act to cease and desist violating the provisions of the Act.
- 12. Pursuant to N.C. Gen. Stat. § 90-40.1(a), the State Board is authorized to seek injunctions for the unauthorized practice of dentistry, and pursuant to N.C. Gen. Stat. § 90-40 is authorized to seek criminal prosecution for the unauthorized practice of dentistry.
- 13. Under the operation of N.C. Gen. Stat. §§ 90-40 (making the unauthorized practice of dentistry a misdemeanor) and 90-40.1 (enjoining unlawful acts), the Board has clearly been granted the authority to notify prospective defendants in advance of initiating a judicial proceeding.
- 14. Pursuant to N.C. Gen. Stat. § 90-233(a), a dental hygienist must practice only under the supervision of one or more licensed dentists. (Joint Stipulation ¶ 36).

- 15. Pursuant to N.C. Gen. Stat. § 138A-38(a)(1), a member of a state occupational licensing board may participate in an official action if "the only interest or reasonably foreseeable benefit or detriment that accrues to the covered person ... is no greater than that which could reasonably be forseen to accrue to all members of that profession, occupation, or general class."
- 16. Any person or entity receiving a cease and desist letter could initiate a declaratory ruling proceeding pursuant to N.C. Gen. Stat. § 150B-4.
- 17. Any person or entity receiving a cease and desist letter has the right to pursue relief in the courts of the State of North Carolina if they feel they have been aggrieved pursuant to the N.C. Constitution (Article I, § 19, Law of the land, equal protection of the laws; and Article IV, § 13, Forms of action, rules of procedure) and N.C. Gen. Stat. § 7A-3.
- 18. Any person or entity receiving a cease and desist letter has the right to pursue an administrative hearing pursuant to N.C. Gen. Stat. § 150B-23(a).
- 19. The North Carolina Constitution guarantees, and the North Carolina General Assembly has provided the means for any aggrieved person to independently access the state's courts, though not necessarily pursuant to the provisions of the Dental Practice Act. N.C. Constitution (Article I, § 18, Courts shall be open; Article I, § 19, Law of the land, equal protection of the laws; and Article IV, § 13, Forms of action, rules of procedure) and N.C. Gen. Stat. § 7A-3.
- 20. Legislation enacted by North Carolina's General Assembly is presumed to have a purpose. *State v. White*, 101 N.C. App. 593, 605, 401 S.E.2d 106, 113 (1991).
- 21. A reviewing court is not free to set aside [agency] regulations simply because it would have interpreted the statute in a different manner." Batterton v. Francis, 432 U.S. 416, 425-26 (1977) (holding that regulation at issue was therefore "entitled to more than mere deference or weight. It can be set aside only if the Secretary exceeded his statutory authority or if the regulation is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.""); see also Am. Tel. & Tel. Co. v. United States, 299 U.S. 232, 236 (1936) ("This court is not at liberty to substitute its own discretion for that of administrative officers who have kept within the bounds of their administrative powers. To show that these have been exceeded in the field of action here involved, it is not enough that the prescribed system . . . shall appear to be unwise or burdensome or inferior to another.").

¹ North Carolina law gives great weight to an agency's interpretation of a law it administers. Frye Reg'l Med. Ctr. v. Hunt, 350 N.C. 39, 45, 510 S.E.2d 159, 163 (1999); see also Carpenter v. N.C. Dep't of Human Res., 107 N.C. App. 278, 279, 419 S.E.2d 582, 584 (1992).

- 22. "It is presumed that a public official in the performance of his official duties acts fairly, impartially, and in good faith and in the exercise of sound judgment or discretion, for the purpose of promoting the public good and protecting the public interest." Russ v. Causey, 732 F. Supp. 2d 589, 613 (E.D.N.C. 2010) (citing In re Annexation Ordinance, No. 300-X, 304 N.C. 549, 551, 284 S.E.2d 470 (1981); Oliver v. Harper, No. 5:09-CT-3027H, 2011 U.S. Dist. LEXIS 29499, at *29 (E.D.N.C. Mar. 22, 2011).
- 23. The administrative proceeding before the Commission is *ultra vires* and violates the 10th Amendment to the U.S. Constitution.
- 24. The administrative proceeding before the Commission is fundamentally flawed under the Due Process clause of the 5th amendment to the U.S. Constitution, based on the Commission's prejudgments and biases.
- 25. The administrative proceeding before the Commission is an *ultra vires* expansion of jurisdiction and violates Article 1, Section 8 of the U.S. Constitution.
- 26. The administrative proceeding before the Commission is an *ultra vires* expansion of jurisdiction and is fundamentally flawed, causing the State Board to suffer immediate and irreparable harm to its constitutional rights to Due Process.
- 27. The administrative proceeding before the Commission is an *ultra vires* exercise of jurisdiction and a violation of Section 4 of the Federal Trade Commission Act.
- 28. The administrative proceeding before the Commission is an *ultra vires* exercise of jurisdiction and a violation of Section 5 of the Federal Trade Commission Act.
- 29. The administrative proceeding before the Commission is an *ultra vires* exercise of jurisdiction violating the State Board's state action immunity pursuant to *Parker v. Brown*, 317 U.S. 341 (1943).
- 30. The administrative proceeding before the Commission is an *ultra vires* exercise of jurisdiction and violates the Administrative Procedures Act's prohibition of arbitrary and capricious conduct. 5 U.S.C. § 500 et seq.
- 31. The State Board is not a private party; it is a state agency. Therefore, it need only satisfy the first prong of the *Midcal* test.
- 32. The Commission's assertion of Sherman Act violations hinges upon per se illegality of majority licensees boards.
- 33. The State Board is a state agency not a private actor.

² See also Painter v. Wake County Bd. of Educ., 288 N.C. 165, 178, 217 S.E.2d 650, 658 (1975) (Absent evidence to the contrary, it will always be presumed that "public officials will discharge their duties in good faith and exercise their powers in accord with the spirit and purpose of the law. Every reasonable intendment will be made in support of the presumption.").

- 34. The State Board acted pursuant to a clearly articulated state policy and was subject to active supervision.
- 35. Under the appropriate rule of reason analysis, the State Board has not committed an antitrust violation.
- 36. Complaint Counsel did not meet its burden of showing that the State Board's challenged conduct had an unreasonable anticompetitive effect.
- 37. The State Board did not commit a per se violation of the Sherman Act.
- 38. The State Board's actions should be judged according to the traditional rule of reason test.
- 39. The State Board's actions are lawful under the rule of reason.
- 40. The nexus of the State Board's challenged conduct was not in and did not affect interstate commerce.
- 41. Complaint Counsel did not establish liability because it has not properly defined the relevant market.
- 42. Complaint Counsel failed to prove collusion among State Board members in violation of the antitrust laws.
- 43. There was no credible evidence of a conspiracy between State Board members, or between State Board members and North Carolina dentists, to engage in the challenged conduct.
- 44. Complaint Counsel could not establish collusion among State Board members based solely on the State Board's composition.
- 45. The State Board's challenged actions were not taken to suppress competition and were a legitimate law enforcement activity taken in response to a *prima facie* violation of the North Carolina Dental Practice Act.
- 46. The relief sought by Complaint Counsel exceeds the FTC's authority under the FTC Act and violates the Tenth Amendment to the U.S. Constitution.
- 47. The relief sought by Complaint Counsel violates the U.S. Constitution's Commerce Clause.
- 48. Complaint Counsel has failed to meet its burden of proof.

III. PROPOSED ORDER

PROPOSED ORDER DISMISSING COMPLAINT

The hearing in the administrative action In the Matter of The North Carolina [State] Board of Dental Examiners, Docket 9343, having concluded, the record being closed, counsel for both parties having briefed the relevant issues, and the Court being fully advised,

THE ADMINISTRATIVE LAW JUDGE FINDS:

- Complaint Counsel has failed to meet its burden of proof in establishing a
 conspiracy or collusion in restraint of trade in violation of the antitrust
 laws;
- Complaint Counsel has not demonstrated that the restraint was unreasonable;
- Complaint Counsel has not demonstrated that the nexus of the alleged restraint was in or affected interstate commerce;
- Complaint Counsel has not used a viable or consistent definition of the relevant market;
- 5. Complaint Counsel has failed to meet its burden of proof in establishing that the Respondent State Board's efforts to regulate non-dental teeth whitening were beyond the rule of reason;
- 6. The Respondent State Board acted to enforce North Carolina law and to protect the health, safety, and welfare of North Carolina citizens;
- 7. The Commission's proposed remedies are in violation of the Tenth Amendment of the U.S. Constitution;

8. The Commission's proposed remedies exceed Congressional authorization and are in violation of the Eleventh Amendment as well as the Commerce Clause of the U.S. Constitution.

THEREFORE, IT IS ORDERED that the administrative action *In the Matter of*The North Carolina [State] Board of Dental Examiners, Docket 9343, be, and is hereby

DISMISSED WITH PREJUDICE, AND THAT JUDGMENT IS ENTERED IN FAVOR

OF THE RESPONDENT.

Dated this day of	, 2011.
	D. Michael Chappell
	Administrative I aw Indae

This the 5th day of May, 2011.

Respectfully submitted,

ALLEN AND PINNIX, P.A.

/s/ M. Jackson Nichols

Noel L. Allen Alfred P. Carlton, Jr. M. Jackson Nichols Catherine E. Lee Brenner A. Allen, of counsel Jackson S. Nichols, of counsel Attorneys for Respondent Post Office Drawer 1270 Raleigh, North Carolina 27602 Telephone: 919-755-0505 Facsimile: 919-829-8098 -Email: nallen@allen-pinnix.com mjn@allen-pinnix.com acarlton@allen-pinnix.com clee@allen-pinnix.com ballen@allen-pinnix.com jsn@allen-pinnix.com

CERTIFICATE OF SERVICE

I hereby certify that on May 5, 2011, I electronically filed the foregoing with the Federal Trade Commission using the FTC E-file system, which will send notification of such filing to the following:

Donald S. Clark, Secretary Federal Trade Commission 600 Pennsylvania Avenue, N.W. Room H-113 Washington, D.C. 20580

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:

William L. Lanning
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room NJ-6264
Washington, D.C. 20580
wlanning@ftc.gov

Melissa Westman-Cherry
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room NJ-6264
Washington, D.C. 20580
mwestman@ftc.gov

Michael J. Bloom
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room NJ-7122
Washington, D.C. 20580
mjbloom@ftc.gov

Steven L. Osnowitz
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room NJ-6264
Washington, D.C. 20580
sosnowitz@ftc.gov

Tejasvi Srimushnam
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room NJ-6264
Washington, D.C. 20580
tsrimushnam@ftc.gov

Richard B. Dagen
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room NJ-6264
Washington, D.C. 20580
rdagen@ftc.gov

Michael D. Bergman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room H-582
Washington, D.C. 20580
mbergman@ftc.gov

Laurel Price
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room NJ-6264
Washington, DC 20580
lprice@ftc.gov

Geoffrey Green Federal Trade Commission 601 New Jersey Avenue, N.W. Washington, DC 20001 ggreen@ftc.gov

Michael Turner
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room NJ-6264
Washington, DC 20580
mturner@ftc.gov

I also certify that I have sent courtesy copies of the document via Federal Express and electronic mail to:

The Honorable D. Michael Chappell Administrative Law Judge Federal Trade Commission 600 Pennsylvania Avenue N.W. Room H-110 Washington, D.C. 20580 oali@ftc.gov

This the 5th day of May, 2011.

/s/ M. Jackson Nichols

M. Jackson Nichols

CERTIFICATION FOR ELECTRONIC FILING

I further certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and by the adjudicator.

/s/ M. Jackson Nichols

M. Jackson Nichols



UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION OFFICE OF ADMINISTRATIVE LAW JUDGES

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

RESPONDENT'S EXHIBIT LIST PURSUANT TO RULE 3.46(b)

RESPONDENT'S EXHIBIT LIST PURSUANT TO RULE 3.46(b)

Exhibit	Exhibit Title/Description	Transcript Page	Transcript Page	Exhibit	Confidential
Number		Where Exhibit	Where Exhibit	Cross-	Treatment
		Admitted	Discussed	Reference	
	Selected documents from Amazing Grace	PC Tr. 2, 56		CX0050-001	
R X00001	Spa Investigative File, Case 07-021	[JX1, Att. B]		CX0347	
	Selected documents from Bailey's	PC Tr. 2, 56		CX0249	
	Lightning Whitening Investigative File,	[JX1, Att. B]		CX0304	
RX00002	Case 08-133				
		PC Tr. 2, 56		CX0111-002	
		[JX1, Att. B]		to 007	
	Selected documents from Beach Bunz			CX0294	
	Tanning Salon Investigative File, Case 09-			CX0356	
RX00003	047			CX0362	
		PC Tr. 2, 56		CX0043-001	6/18/2010
		[JX1, Att. B]		to 010, 012 to	Protective
				013	Order
		•		CX0278	
	Selected documents from {Bleach Bright}			CX0369	
RX00004	Investigative File, Case 08-029		·	CX0404	
		PC Tr. 2, 56	2169:6 - 2169:24	CX0055	6/18/2010
	Selected documents from {BleachBright}	[JX1, Att. B]	2170:14	CX0327	Protective
RX00005	Investigative File, Case 08-072		2172:11		Order
	Selected documents from	PC Tr. 2, 56		CX0250	
	BleachBright/Inspire Skin & Body	[JX1, Att. B]		CX0251	
RX00006	Investigative File, Case 08-214				

Exhibit	Exhibit Title/Description	Transcript Page	Transcript Page	Exhibit	Confidential
Number		Where Exhibit	Where Exhibit	Cross-	Treatment
		Admitted	Discussed	Reference	
	Selected documents from Body, Mind &	PC Tr. 2, 56		CX0348	
RX00007	Spirit Day Spa Investigative File, Case 06-217	[JX1, Att. B]			
- 111	Selected documents from Carmel Day Spa	PC Tr. 2, 56		CX0192	
RX00008	& Salon Investigative File, Case 07-146	[JX1, Att. B]	·	CX0361	
		PC Tr. 2, 56		CX0245	6/18/2010
	Selected documents from {Celebrity	[JX1, Att. B]		CX0280	Protective
RX00009	Smiles} Investigative File, Case 07-208			CX0365	Order
	Selected documents from Champagne	PC Tr. 2, 56		CX0078	
٠	Taste/Lash Lady Investigative File, Case	[JX1, Att. B]		CX0282	
RX00010	07-114				
		PC Tr. 2, 56		CX0034-003,	
		[JX1, Att. B]		005 to 007	
				CX0036-002	
	Selected documents from Edie's Salon			to 013	
RX00011	Panache Investigative File, Case 07-146	<u> </u>		CX0284	
	{Fax from Larry Cook to Dental Board,	PC Tr. 2, 56			6/18/2010
	from The Extra Smile, Inc.}	[JX1, Att. B]			Protective
RX00012	Investigative File, Case 07-146				Order
	Fax from {Stuart Whiddon to Carolin	PC Tr. 2, 56			6/18/2010
	Bakewell, from Fantasticians, Inc.}	[JX1, Att. B]			Protective
RX00013	Investigative File, Case 08-206				Order
	Selected documents from {Florida White	PC Tr. 2, 56		CX0252	6/18/2010
	Smile/Sam's Club} Investigative File,	[JX1, Att. B]		CX0406	Protective
RX00014	Case 08-083			<u></u>	Order

Exhibit Number	Exhibit Title/Description	Transcript Page Where Exhibit Admitted	Transcript Page Where Exhibit Discussed	Exhibit Cross- Reference	Confidential Treatment
		PC Tr. 2, 56	Discussed	CX0040-002	
		[JX1, Att. B]		to 009	
	Selected documents from Hollywood			CX0041-001	
	Smiles/Brandi Temple Investigative File,			to 002, 006 to	
RX00015	Case 04-188			007	
	Selected documents from	PC Tr. 2, 56			6/18/2010
	{iBriteExpress/Joe Willett} Investigative	[JX1, Att. B]			Protective
RX00016	File, Case 08-199				Order
•		PC Tr. 2, 56			6/18/2010
	Selected documents from {Lite Brite}	[JX1, Att. B]			Protective
RX00017	Investigative File, Case 08-132				Order
	Selected documents from Master Tanning	PC Tr. 2, 56		CX0300	
RX00018	Salon Investigative File, Case 08-132	[JX1, Att. B]			
		PC Tr. 2, 56		CX0198	6/18/2010
	Selected documents from {Movie Star	[JX1, Att. B]		CX0538	Protective
RX00019	Smile} Investigative File, Case 07-223			CX0546	Order
		PC Tr. 2, 56		CX0029	
		[JX1, Att. B]		CX0030-006	
	Selected documents from One West			to.007	
RX00020	Investigative File, Case 06-008			CX0228	
		PC Tr. 2, 56		CX0093	6/18/2010
	Selected documents from {Port City	[JX1, Att. B]		CX0477	Protective
RX00021	Tanning Investigative File, Case 08-018				Order
	Selected documents from Sean	PC Tr. 2, 56	,	CX0094	
	Powers/Savage Tan Investigative File,	[JX1, Att. B]		CX0247	
RX00022	Case 07-148				

Exhibit	Exhibit Title/Description	Transcript Page	Transcript Page	Exhibit	Confidential
Number		Where Exhibit	Where Exhibit	Cross-	Treatment
		Admitted	Discussed	Reference	
		PC Tr. 2, 56		CX0039	
	Selected documents from Serenity Day	[JX1, Att. B]		CX0286	
RX00023	Spa Investigative File, Case 05-210			CX0620	
	Selected documents from SheShe Studio	PC Tr. 2, 56		CX0353	
RX00024	Spa Investigative File, Case 07-026	[JX1, Att. B]			
		PC Tr. 2, 56		CX0054-002	
	Selected documents from Signature Spas	[JX1, Att. B]		to 006	
RX00025	Investigative File, Case 06-193			CX0287	
	Selected documents from {Spa White/	PC Tr. 2, 56		CX0258	6/18/2010
	White Science Investigative File, Case	[JX1, Att. B]			Protective
RX00026	07-020				Order
		PC Tr. 2, 56		CX0044-001	
	Selected documents from Star	[JX1, Att. B]		CX0045-002	
	Bright/Cutting Crib Investigative File,			to 006	
RX00027	Case 06-114			CX0233	1
		PC Tr. 2, 56			6/18/2010
	Selected documents from {Suave D's}	[JX1, Att. B]			Protective
RX00028	Investigative File, Case 09-272				Order
	Selected documents from Sunsational Tan	PC Tr. 2, 56		CX0248	
RX00029	Investigative File, Case 07-120	[JX1, Att. B]		CX0621	
		PC Tr. 2, 56		CX0307-001	6/18/2010
	Selected documents from {Tom Jones	[JX1, Att. B]		CX0308-001	Protective
	Express Smile} Investigative File, Case			to 003, 007-	Order
RX00030	09-049		,	008	

Exhibit	Exhibit Title/Description	Transcript Page	Transcript Page	Exhibit	Confidential
Number		Where Exhibit Admitted	Where Exhibit Discussed	Cross- Reference	Treatment
	Fax from {Mike Doyle to Carolin	PC Tr. 2, 56	Discussed	Reference	6/18/2010
	Bakewell w/advertisement from Triad	[JX1, Att. B]			Protective
	Body Secrets } Investigative File, Case 08-				Order
RX00031	195				
	Selected documents from {WOW	PC Tr. 2, 56			6/18/2010
	Whitening on Wheels} Investigative File,	[JX1, Att. B]			Protective
RX00032	Case 09-049				Order
•		PC Tr. 2, 56		CX0032-003	
	Selected documents from Great White	[JX1, Att. B]		CX0033-003	
RX00033	Investigative File, Case 03-184			to 005	
	Newsletter of North Carolina Board of	PC Tr. 2, 56			
RX00034	Massage & Bodywork Therapy	[JX1, Att. B]			
	Newsletter of North Carolina Board of	PC Tr. 2, 56			
~~~~	Massage & Bodywork Therapy, Winter	[JX1, Att. B]			
RX00035	2007			ļ	
	Newsletter of North Carolina Board of	PC Tr. 2, 56			
2770000	Massage & Bodywork Therapy, Winter	[JX1, Att. B]			
RX00036	2008	DOM: 0.56			
DYGGGG	Tr. D. (1D. 1M.	PC Tr. 2, 56			
RX00037	Kansas Dental Board Newsletter	[JX1, Att. B]			
DÝZOGOGO	Letter from Brian K. Bishop to Paradise	PC Tr. 2, 56			
RX00038	Tanning Salon w/ affidavit	[JX1, Att. B]			
D3700020	Letter from Leah Diane Howell to White	PC Tr. 2, 56			
RX00039	Smile USA	[JX1, Att. B]			
D3700040	Letter from James F. Nagle to Joshua	PC Tr. 2, 56			
RX00040	Granson	[JX1, Att. B]		<u> </u>	

Exhibit Number	Exhibit Title/Description	Transcript Page Where Exhibit Admitted	Transcript Page Where Exhibit Discussed	Exhibit Cross- Reference	Confidential Treatment
	Letter from Tracy W. Wertz to Joshua	PC Tr. 2, 56	Discussed	Reference	
RX00041	Granson	[JX1, Att. B]			
	Letter from Lindsey L. Deere to Joshua	PC Tr. 2, 56			<del> </del>
RX00042	Granson	[JX1, Att. B]			
		PC Tr. 2, 56		CX0067-003	
RX00043	Newsletter article text	[JX1, Att. B]			
	Open session minutes of the North	PC Tr. 2, 56			
	Carolina Board of Massage & Bodywork	[JX1, Att. B]			
RX00044	Therapy			·	
	Supplemental Declaration of Perry W.	PC Tr. 2, 56			
RX00046	Newson	[JX1, Att. B]			
	Letter from Grayson G. Kelley to	PC Tr. 2, 56			
RX00048	Respondent Counsel	[JX1, Att. B]			
	Designated Deposition Transcript of	ALJ Order of			
RX00049	Stanley L. Allen, Jr., DDS	3/31/11			
	Designated Deposition Transcript of	ALJ Order of			
RX00050	Carolin Bakewell	3/31/11			
	Designated Deposition Transcript of	ALJ Order of			
RX00051	Benjamin W. Brown, DDS	3/31/11	: 		
	Designated Deposition Transcript of	ALJ Order of			
RX00052	Joseph S. Burnham, Jr., DDS	3/31/11			
	Designated Deposition Transcript of	ALJ Order of			
RX00053	William Linebaugh Dempsey, IV	3/31/11			
	Designated Investigational Hearing	ALJ Order of			
RX00054	Transcript of W. Line Dempsey, IV	3/31/11			
	Designated Deposition Transcript of	ALJ Order of			
RX00055	Zannie Poplin Efird	3/31/11			

Exhibit Number	Exhibit Title/Description	Transcript Page Where Exhibit	Transcript Page Where Exhibit	Exhibit Cross-	Confidential Treatment
· · · · · · · · · · · · · · · · · · ·		Admitted	Discussed	Reference	
	Designated Deposition Transcript of	ALJ Order of			
RX00056	Clifford O. Feingold, DDS	3/31/11			
	Designated Deposition Transcript of	ALJ Order of			
RX00057	Teresa W. Friddle	3/31/11			
-	Designated Investigational Hearing	ALJ Order of			
RX00058	Transcript of Terry W. Friddle	3/31/11			
	Designated Investigational Hearing	ALJ Order of			
RX00059	Transcript of Casie S. Goode	3/31/11			
	Designated Deposition Transcript of	ALJ Order of			
RX00060	Neplus S. Hall	3/31/11			
	Designated Deposition Transcript of	ALJ Order of			
RX00063	Charles Wayne Holland, DDS	3/31/11			
	Designated Deposition Transcript of Sean	ALJ Order of			
RX00064	Kurdys	3/31/11			
	Designated Deposition Transcript of	ALJ Order of			
RX00065	Bradley [Brad] C. Morgan, DDS	3/31/11			
	Designated Deposition Transcript of	ALJ Order of			
RX00071	Michael L. Hasson, DDS	3/31/11			
	Designated Deposition Transcript of	ALJ Order of			
RX00074	William M. Litaker, Jr., DDS	3/31/11			
	Designated Deposition Transcript of Gary	ALJ Order of			
RX00075	D. Oyster, DDS	3/31/11			
	Designated Deposition Transcript of M.	ALJ Order of			
RX00076	Alec Parker, DDS	3/31/11			

Exhibit Number	Exhibit Title/Description	Transcript Page Where Exhibit Admitted	Transcript Page Where Exhibit Discussed	Exhibit Cross- Reference	Confidential Treatment
		PC Tr. 2, 56	320:18 – 321:16		
		[JX1, Att. B]	2391:11 –	<u> </u>	
	Expert Witness Report of Van B.		2391:17		
RX00077	Haywood, D.M.D.		2451:4 – 2451:6		
		PC Tr. 2, 56	1697:16 –		
		[JX1, Att. B]	1697:18		
	Expert Witness Report of Dr. David L.		1694:24 –		
	Baumer (Reply to Expert Report of		1695:10		
RX00078	Professor John Kwoka)		1844:2 – 1845:6		
	Amendment to Expert Witness Report of	PC Tr. 2, 56			
	Dr. David L. Baumer: Additional	[JX1, Att. B]			
RX00079	Documents Relied Upon				
	Enforcement Actions in Industry/Sector:	PC Tr. 2, 56			
RX00081	Health Care -Professional Services (FY1996-2010) from FTC's website	[JX1, Att. B]			
		PC Tr. 2, 56			
RX00138	Open letter from Joyce Osborn	[JX1, Att. B]			
· <del>-</del> ·	Email string from George Nelson to P.	845-46	826:25 - 830:17	CX821	
RX00139	Sherman		842:11 - 842:21		
		1816	1807:10-1816:23		
RX00140	Dr. Baumer slideshow		1853:6 – 1853:19		

Exhibit Number	Exhibit Title/Description	Transcript Page Where Exhibit	Transcript Page Where Exhibit	Exhibit Cross-	Confidential Treatment
·		Admitted	Discussed	Reference	
		2397 [except for	2392:14 - 2397:4		
		page 010]	2404:25 - 2407:16		
			2417:17 - 2421:17		
			2428:4 - 2432:4		
			2432:21 –		
			2435:12		
			2436:10 - 2449:19		
			2458:5 - 2459:15		
			2460:14 - 2472:16		
			2474:24 - 2477:17		
			2480:17 - 2512:12		
			2505:4 – 2506:10		
			2750:13 –		
			2751:16		
			2927:16 –		
			2928:14		
			2980:5 – 2986:5		
			3001:16 - 3002:4		
RX00141	Giniger Comments by Haywood		3025:24 - 3026:6		

Exhibit Number	Exhibit Title/Description	Transcript Page Where Exhibit Admitted	Transcript Page Where Exhibit Discussed	Exhibit Cross- Reference	Confidential Treatment
		2397	404:24 - 405:21 408:25 - 411:10	***	
			2548:24 - 2549:7		
	·		2550:15 - 2511:19		
			2552:14 –		
			2553:13		
			2553:25 –		
			2555:18		
			2556:2 - 2560:2		
			2573:25 –		
RX00142	GrinRX Business Overview		2576:10		
RX00143	ADA House of Delegates	2397	2560:24 - 2561:15		
RX00144	2009 ADA Current Policies excerpt	2397	2563:23 – 2564:5		
RX00145	Giniger Power Swab Testimony	2397			
	Summary Conclusions for FTC NC	2397	2566:25 - 2573:9		
RX00146	Haywood		2692:5 – 2694:14		

### DEMONSTRATIVE EXHIBITS OFFERED BY RESPONDENT

# NOTE: None of Respondent's demonstrative exhibits have been accorded confidential treatment.

Exhibit Number	Exhibit Title/Description	Transcript Page Where Exhibit Admitted	Transcript Page Where Exhibit Discussed	Exhibit Cross- Reference
	Thompson Insurance Enterprises webpage re:	PC Tr. 2, 56		
	Independent Contractors Insurance for Teeth	[JX2, Att. C]		
	Whitening and Beauty & Health Professionals			
RX00080	Insurance Application			
	Article: When It Comes to Tooth Whitening,	PC Tr. 2, 56	462:3 - 462:11	
RX00082	Shoppers Beware	[JX2, Att. C]		
	News Report: Mall Teeth Whitening: Is It Safe?;	PC Tr. 2, 56	462:12 - 462:16	
RX00083	New Trend in Billion Dollar Industry	[JX2, Att. C]		
	Article: Sarah Albrecht, What Are the Dangers of	PC Tr. 2, 56	462:19 - 462:22	
RX00084	Teeth Whitening?, ehow.com	[JX2, Att. C]		
	Article: David Chandler, Dangers of Tooth	PC Tr. 2, 56	462:23 - 462:25	
RX00085	Whitening Chemicals and Treatments	[JX2, Att. C]		
		PC Tr. 2, 56	463:1 - 463:2	
RX00086	Article: Julia Temple, Dangers of Tooth Whitening	[JX2, Att. C]		
	Article: Special Report: Hidden Dangers of Teeth	PC Tr. 2, 56	463:3 - 463:5	
RX00087	Whitening	[JX2, Att. C]		
	Article: Teeth Whitening Dangers?,	PC Tr. 2, 56	463:6 - 463:7	
RX00088	teethvvhiteningreviews.com	[JX2, Att. C]		
	Article: Laurel Naversen Geraghty, The Dangers of	PC Tr. 2, 56	463:8 - 463:10	
RX00089	Teeth Whitening, Prevention	[JX2, Att. C]		
		PC Tr. 2, 56	463:11 - 463:12	
RX00090	Article: The Dangers of Teeth Whitening	[JX2, Att. C]		

Exhibit	Exhibit Title/Description	Transcript Page	Transcript Page	Exhibit Cross-
Number		Where Exhibit	Where Exhibit	Reference
		Admitted	Discussed	
	Press release: How Safe Is a Bright Smile?, Green	PC Tr. 2, 56	463:13 - 463:23	
RX00091	Facts	[JX2, Att. C]		
-	Article: C.D.N. Morris, Tooth Whiteners-The Legal	PC Tr. 2, 56	463:25 - 464:3	
RX00092	Position, British Dental Journal	[JX2, Att. C]	505:24 - 506:14	
	American Academy of Pediatric Dentistry, Policy	PC Tr. 2, 56	464:4 - 464:8	CX0589
	on the Use of Dental Bleaching for Child and	[JX2, Att. C]		
RX00093	Adolescent Patients			
	Article: Barney Calman, It Seemed as if My Teeth	PC Tr. 2, 56	464:9 - 464:12	
	Had Been Dipped in Acid; Now I Drink Coffee	[JX2, Att. C]		
RX00094	Through a Straw, The Mail			
	Better Business Bureau, Teeth Whitening Products	PC Tr. 2, 56	464:15 - 464:18	
RX00095	Sold Online Wipe Smile Off Consumers' Faces	[JX2, Att. C]		
	Article: Harvard Health Letters, A Guide to Pearly	PC Tr. 2, 56		
RX00096	Whites, Chicago Daily Herald	[JX2, Att. C]		
	Editorial: Dan Jenkins, Defining Dentistry, TCDS	PC Tr. 2, 56		
RX00097	Bulletin	[JX2, Att. C]		
	Article: Eliot Van Buskirk, Whiter Teeth Products	PC Tr. 2, 56	464:19 - 464:22	
	Stained by Dismal Advertising Practices,	[JX2, Att. C]		
RX00098	wired.com			
	Article: Matt, Will the Real Dazzle Smile Please	PC Tr. 2, 56	464:23 - 465:1	
RX00099	Stand Up?, scamtimes.com	[JX2, Att. C]		
	Article: Dental Boards Look to Stop Teeth-	PC Tr. 2, 56		
RX00100	Whitening at Salons, Redorbit.com	[JX2, Att. C]		
· · · · · · · · · · · · · · · · · · ·	Article: Anna Velasco, Teeth Whitening in State	PC Tr. 2, 56		
	Needs a Dentist; Desist Letters Sent to Spas,	[JX2, Att. C]		
RX00101	Beauty Parlors, Mall Booths, Birmingham News			

Exhibit	Exhibit Title/Description	Transcript Page	Transcript Page	Exhibit Cross-
Number	·	Where Exhibit	Where Exhibit	Reference
		Admitted	Discussed	
RX00102	Cassais David of Davidson Minutes 2/6/2000	PC Tr. 2, 56		
KX00102	Georgia Board of Dentistry Minutes – 3/6/2009	[JX2, Att. C]		
	Article: Andy Miller, Licensing at Issue; Dental	PC Tr. 2, 56		
DX00102	Group Frowns on Kiosk Whitening, Atlanta	[JX2, Att. C]		
RX00103	Journal-Constitution	DO T. 0. 66		
	Position Statement of Iowa Dental Board on Tooth	PC Tr. 2, 56		
D3200104	Whitening/Bleaching Services by Non-Licensed	[JX2, Att. C]		
RX00104	Persons	DOT 0.56		
D3700105	T D 117 117 1 10010	PC Tr. 2, 56		
RX00105	Kansas Dental Board Minutes – Jan. 2010	[JX2, Att. C]		
Dirontos	77 7 17 17 7 2000	PC Tr. 2, 56		
RX00106	Kansas Dental Board Minutes – Jan. 2009	[JX2, Att. C]		
D370010F	Kentucky Board of Dentistry Newsletter Spring	PC Tr. 2, 56		
RX00107	2008	[JX2, Att. C]		
~~~~	Kentucky Board of Dentistry Newsletter - Fall	PC Tr. 2, 56		
RX00108	2008	[JX2, Att. C]		
	Kentucky Board of Dentistry Newsletter - Fall	PC Tr. 2, 56		
RX00109	2009	[JX2, Att. C]		
	Article: Anish Gupta, Louisiana Debates Mobile	PC Tr. 2, 56		
RX00110	Dentistry, ASDA News	[JX2, Att. C]		
	BORID Policy on Tooth Whitening Services	PC Tr. 2, 56		
RX00111	(Massachusetts)	[JX2, Att. C]		
	Proposed Findings of Fact; Conclusions of Law;	PC Tr. 2, 56		
	and Recommended Order in In re Proposed	[JX2, Att. C]		
	Disciplinary Treatment of the Salon License of			
	Burtello Salon, Montana Board of Barbers and			
RX00112	Cosmetologists			

Exhibit Number	Exhibit Title/Description	Transcript Page Where Exhibit Admitted	Transcript Page Where Exhibit Discussed	Exhibit Cross- Reference
	Notice of Amendment re: rule of Montana Board of	PC Tr. 2, 56		
	Barbers and Cosmetologists, Montana	[JX2, Att. C]		
RX00113	Administrative Register			
	Article: Erin Nicholes, Teeth-Whiteners Abound,	PC Tr. 2, 56	465:2 - 465:9	
	but Which Is Better - the Dentist's or the Store's,	[JX2, Att. C]		•
RX000114	Montana Standard	_		
	Article: Salon, State in Pearly White Fight, Billings	PC Tr. 2, 56	465:10 - 465:12	
RX00115	Gazette	[JX2, Att. C]		
	New Report: Sue Manteris, Should You Trust Your	PC Tr. 2, 56	465-13 - 465:16	
RX00116	Teeth Whitening at the Mall?	[JX2, Att. C]		
		PC Tr. 2, 56	465:17 - 465:19	
RX00117	Article: Teeth Whitening May Be Health Concern	[JX2, Att. C]		·
	N.D. Issues Cease-and-Desist Order Against XM	PC Tr. 2, 56		
RX00118	Brands, Inc. and Kenneth Jacobi, Jamestown Sun	[JX2, Att. C]		
	Policy Regarding Bleaching Services Offered in	PC Tr. 2, 56		
	Mall Kiosks and Salons By Non-Licensed Dental	[JX2, Att. C]		
RX00119	Personnel (Ohio)			
	News Report: Teeth-Brightening Business Shut	PC Tr. 2, 56	465:20 - 465:23	
RX00120	Down	[JX2, Att. C]		
		PC Tr. 2, 56		
RX00121	Article: In S.C., The State	[JX2, Att. C]		
	News Report: Lindsay Patterson, Teeth Whitening	PC Tr. 2, 56		
RX00122	Kiosks Close in Oklahoma	[JX2, Att. C]		
	News Report: State Dental Board Bans Teeth	PC Tr. 2, 56		
RX00123	Whitening at Mall Kiosks	[JX2, Att. C]		
	Article: Dentists Angry About Non-Dental Teeth	PC Tr. 2, 56		
RX00124	Whitening Clinics, watchdognation.com	[JX2, Att. C]		

Exhibit	Exhibit Title/Description	Transcript Page	Transcript Page	Exhibit Cross-
Number		Where Exhibit	Where Exhibit	Reference
		Admitted	Discussed	
		PC Tr. 2, 56		
RX00125	Policy Statement: Teeth Whitening (Wisconsin)	[JX2, Att. C]		
	Article: Tom Morton, Dental Board Opposes	PC Tr. 2, 56		
	Salon's Teeth-Whitening Service, Casper Star-	[JX2, Att. C]		
RX00126	Tribune	<u> </u>		
	Article: Tom Morton, Salon Ends Teeth-Whitening	PC Tr. 2, 56		
RX00127	Service, Casper Star-Tribune	[JX2, Att. C]		
	Media Release: Magistrate Rules Against Tooth	PC Tr. 2, 56		
RX00128	Whitening, Australian Associated Press	[JX2, Att. C]		
	Article: Magistrate Rules Against Therapist	PC Tr. 2, 56	465:24 - 466:6	
RX00129	Whitening Teeth, Australian Associated Press	[JX2, Att. C]		
	Article: Randy Lang, Cosmetic Cowboys, Oral	PC Tr. 2, 56		
RX00130	Health Journal	[JX2, Att. C]		
	Webpage: Bartletts Solicitors, Claiming	PC Tr. 2, 56		
RX00131	Compensation for Tooth Whitening Accidents	[JX2, Att. C]		
	Press Release: Massachusetts Dental Society,	PC Tr. 2, 56		
RX00132	Shopping for Tooth Whitening at the Mall?	[JX2, Att. C]		
	News Report: David Wade, Curious if Teeth	PC Tr. 2, 56	466:7 - 466:9	
RX00133	Whitening at Mall Kiosks Is Safe	[JX2, Att. C]		
	Article: Leslie Kwoh, N.J. Dental Group Files Suit	PC Tr. 2, 56		
	Against Tanning Salon Chain Offering Teeth	[JX2, Att. C]		
RX00134	Whitening			
	Article: Donna Domino, NJDA Sues Tanning	PC Tr. 2, 56		
RX00135	Salons Over Whitening	[JX2, Att. C]		
	Page two of letter from Algis Augustine to George	PC Tr. 2, 56		
RX00136	Nelson	[JX2, Att. C]		

Exhibit Number	Exhibit Title/Description	Transcript Page Where Exhibit Admitted	Transcript Page Where Exhibit Discussed	Exhibit Cross- Reference
	Press Release: BleachBright America! Laser Teeth	PC Tr. 2, 56		
RX00137	Whitening! FDA Approved! Safe & Affordable	[JX2, Att. C]		

JOINT EXHIBITS

Exhibit Number	Exhibit Title/Description	Transcript Page Where Exhibit Admitted	Transcript Page Where Exhibit Discussed	Exhibit Cross- Reference
JX0001	Stipulations on Admissibility of Party Exhibits	PC Tr. 2, 56	1697:19 – 1697:20	
JX0002	Second Stipulation of Admissibility of party Exhibits	PC Tr. 2, 56	459:3 - 466:22 502:18 - 503:14 504:10 - 505:6 505:24 - 506:15 506:23 - 507:2	
JX0003	Third Stipulation of Admissibility of Party Exhibits	ALJ Order of 3/31/11		

UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION OFFICE OF ADMINISTRATIVE LAW JUDGES

GAL.	EXHIBIT	7
ALL-STATE LEGAL	B	
8-TTV		J

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

RESPONDENT'S WITNESS LIST PURSUANT TO RULE 3.46(c)

RESPONDENT'S WITNESS LIST PURSUANT TO RULE 3.46(c)

WITNESS NAME	IDENTIFICATION	TRANSCRIPT	IN CAMERA
		PAGES	TREATMENT
Dr. David L.	Head, Department of	1684-1687	
Baumer	Business	1690-1702	
	Management, N. C.	1705-1709	
	State University;	1711-1712	
,	Respondent's expert	1714-1736	
	economics witness	1742-1744	
		1761-1794	
		1796-1801	
		1803-1805	
		1807-1824	
		1826-1857	
		1859-1865	
		1870-1872	
		1874-1878	
		1880-1881	
		1884-1888	
		1892-1905	
		1907-1945	li .
		1948-1987	
Dr. W. Stan	Licensed NC dentist;	2759-2785	
Hardesty	former State Board	2787-2823	
	President	2828-2879	
Dr. Van B.	Professor,	2383-2392	
Haywood	Department of Oral	2397-2398	
	Rehabilitation,	2400-2413	
	School of Dentistry,	2414-2422	
	Medical College of	2427-2431	
	Georgia;	2433-2434	
	Respondent's expert	2436-2449	
	teeth whitening	2451-2454	
	expert	2458-2478	
		2480-2501	
		2504-2512	
		2515-2522	
		2525-2542	
		2544-2550	
		2552-2555	
		2557-2627	
		2629-2684	
		2692-2751	
		2895-2901	

WITNESS NAME	IDENTIFICATION	TRANSCRIPT	IN CAMERA
		PAGES	TREATMENT
Dr. Van B.		2903-2960	
Haywood (cont.)		2962-3012	
		3014-3023	
		3025-3028	
		3030-3035	
Dr. Ronald K.	Licensed NC dentist;	1434-1463	
Owens	current State Board	1466-1467	
	President; former	1469-1518	
	State Board	1520	
	Secretary-Treasurer	1535-1594	
		1596	
	 	1601-1611	
		1616-1644	
		1646-1679	
		1682	
Brian K. Runsick	National Distribution	2100	
	Sales Manager for	2102-2146	
	Jones-Frank Corp.;	2148-2155	
	complained to the	2157-2178	
	State Board about a		
	teeth whitening		
	injury		
Dr. Larry F. Tilley	Licensed NC dentist	1996-2007	
	who evaluated Mr.	2009-2017	
	Runsick at the State	2019-2025	
	Board's request	2027	
		2030	
		2035-2041	
		2043-2044	
		2047-2048	
		2050-2061	
		2063-2056	
		2058-2061	
		2063-2071	
		2072-2085]
		2087-2098	
Dr. Millard W.	Licensed NC dentist;	1276-1294	
"Buddy" Wester, III	Board Secretary-	1296-1307	
	Treasurer	1311-1392	
		1394-1417	

WITNESS NAME	IDENTIFICATION	TRANSCRIPT PAGES	IN CAMERA TREATMENT
Bobby White	Chief Operations Officer for the State Board	2188-2233 2234-2235 2236-2247 2254-2277 2279-2289 2291-2299 2302-2352 2354-2360	
		2362-2376	

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION OFFICE OF ADMINISTRATIVE LAW JUDGES



In the Matter of)	EXHIBIT E
The North Carolina Board of Dental Examiners, Respondent.) DOCKET NO. 9343	ALL-STATE L

PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL

Commission Rule 3.31(d) states: "In order to protect the parties and third parties against improper use and disclosure of confidential information, the Administrative Law Judge shall issue a protective order as set forth in the appendix to this section." 16 C.F.R. § 3.31(d). Pursuant to Commission Rule 3.31(d), the protective order set forth in the appendix to that section is attached verbatim as Attachment A and is hereby issued.

ORDERED:

D. Michael Chappell

Chief Administrative Law Judge

Date: June 18, 2010

ATTACHMENT A

For the purpose of protecting the interests of the parties and third parties in the above-captioned matter against improper use and disclosure of confidential information submitted or produced in connection with this matter:

IT IS HEREBY ORDERED THAT this Protective Order Governing Confidential Material ("Protective Order") shall govern the handling of all Discovery Material, as hereafter defined.

- 1. As used in this Order, "confidential material" shall refer to any document or portion thereof that contains privileged, competitively sensitive information, or sensitive personal information. "Sensitive personal information" shall refer to, but shall not be limited to, an individual's Social Security number, taxpayer identification number, financial account number, credit card or debit card number, driver's license number, state-issued identification number, passport number, date of birth (other than year), and any sensitive health information identifiable by individual, such as an individual's medical records. "Document" shall refer to any discoverable writing, recording, transcript of oral testimony, or electronically stored information in the possession of a party or a third party. "Commission" shall refer to the Federal Trade Commission ("FTC"), or any of its employees, agents, attorneys, and all other persons acting on its behalf, excluding persons retained as consultants or experts for purposes of this proceeding.
- 2. Any document or portion thereof submitted by a respondent or a third party during a Federal Trade Commission investigation or during the course of this proceeding that is entitled to confidentiality under the Federal Trade Commission Act, or any regulation, interpretation, or precedent concerning documents in the possession of the Commission, as well as any information taken from any portion of such document, shall be treated as confidential material for purposes of this Order. The identity of a third party submitting such confidential material shall also be treated as confidential material for the purposes of this Order where the submitter has requested such confidential treatment.
- 3. The parties and any third parties, in complying with informal discovery requests, disclosure requirements, or discovery demands in this proceeding may designate any responsive document or portion thereof as confidential material, including documents obtained by them from third parties pursuant to discovery or as otherwise obtained.
- 4. The parties, in conducting discovery from third parties, shall provide to each third party a copy of this Order so as to inform each such third party of his, her, or its rights herein.
- 5. A designation of confidentiality shall constitute a representation in good faith and after careful determination that the material is not reasonably believed to be already in the public domain and that counsel believes the material so designated constitutes confidential material as defined in Paragraph 1 of this Order.

- 6. Material may be designated as confidential by placing on or affixing to the document containing such material (in such manner as will not interfere with the legibility thereof), or if an entire folder or box of documents is confidential by placing or affixing to that folder or box, the designation "CONFIDENTIAL—FTC Docket No. 9343" or any other appropriate notice that identifies this proceeding, together with an indication of the portion or portions of the document considered to be confidential material. Confidential information contained in electronic documents may also be designated as confidential by placing the designation "CONFIDENTIAL—FTC Docket No. 9343" or any other appropriate notice that identifies this proceeding, on the face of the CD or DVD or other medium on which the document is produced. Masked or otherwise redacted copies of documents may be produced where the portions deleted contain privileged matter, provided that the copy produced shall indicate at the appropriate point that portions have been deleted and the reasons therefor.
- 7. Confidential material shall be disclosed only to: (a) the Administrative Law Judge presiding over this proceeding, personnel assisting the Administrative Law Judge, the Commission and its employees, and personnel retained by the Commission as experts or consultants for this proceeding; (b) judges and other court personnel of any court having jurisdiction over any appellate proceedings involving this matter; (c) outside counsel of record for any respondent, their associated attorneys and other employees of their law firm(s), provided they are not employees of a respondent; (d) anyone retained to assist outside counsel in the preparation or hearing of this proceeding including consultants, provided they are not affiliated in any way with a respondent and have signed an agreement to abide by the terms of the protective order; and (e) any witness or deponent who may have authored or received the information in question.
- 8. Disclosure of confidential material to any person described in Paragraph 7 of this Order shall be only for the purposes of the preparation and hearing of this proceeding, or any appeal therefrom, and for no other purpose whatsoever, provided, however, that the Commission may, subject to taking appropriate steps to preserve the confidentiality of such material, use or disclose confidential material as provided by its Rules of Practice; sections 6(f) and 21 of the Federal Trade Commission Act; or any other legal obligation imposed upon the Commission.
- 9. In the event that any confidential material is contained in any pleading, motion, exhibit or other paper filed or to be filed with the Secretary of the Commission, the Secretary shall be so informed by the Party filing such papers, and such papers shall be filed in camera. To the extent that such material was originally submitted by a third party, the party including the materials in its papers shall immediately notify the submitter of such inclusion. Confidential material contained in the papers shall continue to have in camera treatment until further order of the Administrative Law Judge, provided, however, that such papers may be furnished to persons or entities who may receive confidential material pursuant to Paragraphs 7 or 8. Upon or after filing any paper containing confidential material, the filing party shall file on the public record a duplicate copy of the paper that does not reveal confidential material. Further, if the protection for any such material expires, a party may file on the public record a duplicate copy which also contains the formerly protected material.

- 10. If counsel plans to introduce into evidence at the hearing any document or transcript containing confidential material produced by another party or by a third party, they shall provide advance notice to the other party or third party for purposes of allowing that party to seek an order that the document or transcript be granted *in camera* treatment. If that party wishes *in camera* treatment for the document or transcript, the party shall file an appropriate motion with the Administrative Law Judge within 5 days after it receives such notice. Except where such an order is granted, all documents and transcripts shall be part of the public record. Where *in camera* treatment is granted, a duplicate copy of such document or transcript with the confidential material deleted therefrom may be placed on the public record.
- 11. If any party receives a discovery request in any investigation or in any other proceeding or matter that may require the disclosure of confidential material submitted by another party or third party, the recipient of the discovery request shall promptly notify the submitter of receipt of such request. Unless a shorter time is mandated by an order of a court, such notification shall be in writing and be received by the submitter at least 10 business days before production, and shall include a copy of this Protective Order and a cover letter that will apprise the submitter of its rights hereunder. Nothing herein shall be construed as requiring the recipient of the discovery request or anyone else covered by this Order to challenge or appeal any order requiring production of confidential material, to subject itself to any penalties for non-compliance with any such order, or to seek any relief from the Administrative Law Judge or the Commission. The recipient shall not oppose the submitter's efforts to challenge the disclosure of confidential material. In addition, nothing herein shall limit the applicability of Rule 4.11(e) of the Commission's Rules of Practice, 16 CFR 4.11(e), to discovery requests in another proceeding that are directed to the Commission.
- 12. At the time that any consultant or other person retained to assist counsel in the preparation of this action concludes participation in the action, such person shall return to counsel all copies of documents or portions thereof designated confidential that are in the possession of such person, together with all notes, memoranda or other papers containing confidential information. At the conclusion of this proceeding, including the exhaustion of judicial review, the parties shall return documents obtained in this action to their submitters, provided, however, that the Commission's obligation to return documents shall be governed by the provisions of Rule 4.12 of the Rules of Practice, 16 CFR 4.12.
- 13. The provisions of this Protective Order, insofar as they restrict the communication and use of confidential discovery material, shall, without written permission of the submitter or further order of the Commission, continue to be binding after the conclusion of this proceeding.