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

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

COMPLAINT COUNSEL'S REPLY TO RESPONDENT'S POST TRIAL PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

Richard A. Feinstein
Director

Pete Levitas
Deputy Director

Melanie Sabo
Assistant Director

Geoffrey M. Green
Deputy Assistant Director

Bureau of Competition

Richard B. Dagen
William L. Lanning
Melissa Westman-Cherry
Laurel A. Price
Steven Osnowitz
Tejasvi Srimushnam
Michael J. Turner

601 New Jersey Ave, NW
Washington, D.C. 20001
(202) 326-2628
(202) 326-3496 Facsimile
rdagen@ftc.gov

Michael J. Bloom, Assistant Director
Erika Meyers
Office of Policy & Coordination

Counsel Supporting Complaint

Dated: May 5, 2011

RECORD REFERENCES

References to the record are made using the following citation forms and abbreviations:

CCPFF - Complaint Counsel's Proposed Findings of Fact

CCPCL - Complaint Counsel's Proposed Conclusions of Law

RPF - Respondent's Proposed Findings of Fact

JX - Joint Exhibit

CX - Complaint Counsel Exhibit

RX - Respondent Exhibit

Tr. - Citations to Trial Testimony

(CX0000 at 000 (XX, Dep. at xx)) - Citations to Deposition Testimony

(CX0000 at 000 (XX, IHT at xx)) - Citations to Investigational Hearing Testimony

Joint Stipulations of Law and Fact - Citation to Joint Stipulations of Law and Fact

State Action Opinion - Citation to the Opinion of the Commission issued February 3, 2011

Response to RFA - Citation to Respondent's Objections and Responses to Complaint Counsel's First Set of Requests for Admissions

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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).

Response to Finding No. 1

Every fact witness from the Board who appeared live or by deposition testified that the process of sending out the cease and desist orders involved at least these steps:

- The complaint comes into to the Board. (CCPFF ¶¶ 92-99).
- The Board, by agreement of its members, has its deputy operations officer receive the complaint on behalf of the Board. (CCPFF ¶ 99).
- The Board, by agreement of its members, has set up a procedure whereby an Investigative Panel is established with respect to each complaint. (CCPFF ¶¶ 103-105).
- The Board, by agreement of its members, has the Investigative Panel consist of Case Officer, the Deputy Operations Officer or Board designee, an investigator, and legal counsel as needed. (CCPFF ¶¶ 103-105).
- The Board, by agreement of its members, has one dentist serve as the Case Officer. (CCPFF ¶¶ 102, 104-105).

- The Board, by agreement of its members, has authorized the Case Officer to act on behalf of the Board with respect to the decision of whether or not to send a Cease and Desist Order to a non-dentist teeth whitener. (CCPFF ¶¶ 112-113).
- The Board, by agreement of its members, has authorized the Order to be sent on Board letterhead and signed by a full time Board Employee. (CCPFF ¶¶ 286, 290-291).
- The Board, by agreement of its members, decides when to close an investigation into non-dentist teeth whitening. (CCPFF ¶ 117, 119).
- The Board, by agreement of its members, authorized Mr. Bobby White, the Chief Operations Officer, to draft a policy with respect to non-dentist teeth whitening operations in March 2008. (CCPFF ¶ 388; White, Tr. 2312-2313).
- The Board, by agreement of its members, authorized Mr. Bobby White, the Chief Operations Officer, to draft a policy with respect to non-dentist teeth whitening operations in January 2010. (White, Tr. 2312-2315).
- The Board, by agreement of its members, authorized Ms. Carolin Bakewell, then Board counsel, to draft and send letters to eleven mall operators that operated malls in North Carolina, notifying them that teeth whitening by non-dentists without dentist supervision was illegal. (CCPFF ¶¶ 315-320).
- After discussion and consensus, the Board unanimously voted to send the letters to mall operators, the purpose of which was to deprive non-dentist teeth whiteners of access to the commercial facilities from which to offer teeth whitening services. (CCPFF ¶¶ 318-325; CX0565 at 054-055 (Hardesty, Dep. at 206-210)).

The Board campaign against mall kiosks is reflected in an e-mail from Mr. White to a complaining dentist where he states that the offending mall kiosk "is one of many such 'bleaching kiosks' with which we are currently going forth to do battle," and that the Board had sent out "numerous cease and desist orders throughout the state." (CX0404 at 001-002 (emphasis added)). It is axiomatic that you cannot have a battle without a common plan, tactic, or strategy.

Although three members of the Board testified live, there is no testimony that the Board, by agreement of its members, or otherwise, repudiated the actions of any Case Officer with respect to the sending of a Cease and Desist Order to a non-dentist teeth whitening operation. (CX0554 (Allen, Dep. (entire transcript)); CX0555 (Brown, Dep. (entire transcript)); CX0556 (Burnham, Dep. (entire transcript)); CX0557 (Dempsey, Dep. (entire transcript)); CX0558 (Dempsey, IHT (entire transcript)); CX0559 (Efird, Dep. (entire transcript)); CX0560 (Feingold, Dep. (entire transcript)); CX0561 (Friddle, Dep. (entire transcript)); CX0562 (Friddle, IHT (entire transcript)); CX0563 (Goode, IHT (entire transcript)); CX0564 (Hall, Dep. (entire transcript)); CX0565 (Hardesty, Dep. (entire transcript)); CX0566 (Hardesty, IHT (entire transcript)); CX0567 (Holland, Dep. (entire transcript)); CX0568 (Kurdys, Dep. (entire transcript)); CX0569 (Morgan, Dep. (entire transcript)); CX0570 (Owens, Dep. (entire transcript)); CX0571 (Owens, IHT (entire transcript)); CX0573 (White, Dep. (entire transcript)); CX0574 (White, IHT (entire transcript)); CX0581 (Bakewell, Dep. (entire transcript))).

Although three members of the Board testified live, there is no testimony that the Board, by agreement of its members, or otherwise, indicated to any Case Officer with respect to the sending of a non-dentist teeth whitening operation that his actions were *ultra vires*. (CX0554 (Allen, Dep. (entire transcript)); CX0555 (Brown, Dep. (entire transcript)); CX0556 (Burnham,

Dep. (entire transcript)); CX0557 (Dempsey, Dep. (entire transcript)); CX0558 (Dempsey, IHT (entire transcript)); CX0559 (Efird, Dep. (entire transcript)); CX0560 (Feingold, Dep. (entire transcript)); CX0561 (Friddle, Dep. (entire transcript)); CX0562 (Friddle, IHT (entire transcript)); CX0563 (Goode, IHT (entire transcript)); CX0564 (Hall, Dep. (entire transcript)); CX0565 (Hardesty, Dep. (entire transcript)); CX0566 (Hardesty, IHT (entire transcript)); CX0567 (Holland, Dep. (entire transcript)); CX0568 (Kurdys, Dep. (entire transcript)); CX0569 (Morgan, Dep. (entire transcript)); CX0570 (Owens, Dep. (entire transcript)); CX0571 (Owens, IHT (entire transcript)); CX0573 (White, Dep. (entire transcript)); CX0574 (White, IHT (entire transcript)); CX0581 (Bakewell, Dep. (entire transcript))).

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).

Response to Finding No. 2

Every fact witness from the Board who appeared live or by deposition testified that the process of sending out the cease and desist orders involved at least these steps:

- The complaint comes into to the Board. (CCPFF ¶¶ 92-99).
- The Board, by agreement of its members, has its deputy operations officer receive the complaint on behalf of the Board. (CCPFF ¶ 99).
- The Board, by agreement of its members, has set up a procedure whereby an Investigative Panel is established with respect to each complaint. (CCPFF ¶¶ 103-105).

- The Board, by agreement of its members, has the Investigative Panel consist of Case Officer, the Deputy Operations Officer or Board designee, an investigator, and legal counsel as needed. (CCPFF ¶¶ 103-105).
- The Board, by agreement of its members, has one dentist serve as the Case Officer. (CCPFF ¶¶ 102, 104-105).
- The Board, by agreement of its members, has authorized the Case Officer to act on behalf of the Board with respect to the decision of whether or not to send a Cease and Desist Order to a non-dentist teeth whitener. (CCPFF ¶¶ 112-113).
- The Board, by agreement of its members, has authorized the Order to be sent on Board letterhead and signed by a full time Board Employee. (CCPFF ¶¶ 286, 290-291).
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- The Board, by agreement of its members, authorized Ms. Carolin Bakewell, then Board counsel, to draft and send letters to eleven mall operators that operated

malls in North Carolina, notifying them that teeth whitening by non-dentists without dentist supervision was illegal. (CCPFF ¶¶ 315-320).

- After discussion and consensus, the Board unanimously voted to send the letters to mall operators, the purpose of which was to deprive non-dentist teeth whiteners of access to the commercial facilities from which to offer teeth whitening services. (CCPFF ¶¶ 318-325; CX0565 at 054-055 (Hardesty, Dep. at 206-210)).

Although nine members of the Board testified by deposition, there is no testimony that the Board, by agreement of its members, or otherwise, repudiated the actions of any Case Officer with respect to the sending of a Cease and Desist Order to a non-dentist teeth whitening operation. (CX0554 (Allen, Dep. (entire transcript)); CX0555 (Brown, Dep. (entire transcript)); CX0556 (Burnham, Dep. (entire transcript)); CX0557 (Dempsey, Dep. (entire transcript)); CX0558 (Dempsey, IHT (entire transcript)); CX0559 (Efird, Dep. (entire transcript)); CX0560 (Feingold, Dep. (entire transcript)); CX0561 (Friddle, Dep. (entire transcript)); CX0562 (Friddle, IHT (entire transcript)); CX0563 (Goode, IHT (entire transcript)); CX0564 (Hall, Dep. (entire transcript)); CX0565 (Hardesty, Dep. (entire transcript)); CX0566 (Hardesty, IHT (entire transcript)); CX0567 (Holland, Dep. (entire transcript)); CX0568 (Kurdys, Dep. (entire transcript)); CX0569 (Morgan, Dep. (entire transcript)); CX0570 (Owens, Dep. (entire transcript)); CX0571 (Owens, IHT (entire transcript)); CX0573 (White, Dep. (entire transcript)); CX0574 (White, IHT (entire transcript)); CX0581 (Bakewell, Dep. (entire transcript)).

Although nine members of the Board testified by deposition, there is no testimony that the Board, by agreement of its members, or otherwise, indicated to any Case Officer with respect to the sending of a Cease and Desist Order to a non-dentist teeth whitening operation that his actions

were *ultra vires*. (CX0554 (Allen, Dep. (entire transcript)); CX0555 (Brown, Dep. (entire transcript)); CX0556 (Burnham, Dep. (entire transcript)); CX0557 (Dempsey, Dep. (entire transcript)); CX0558 (Dempsey, IHT (entire transcript)); CX0559 (Efird, Dep. (entire transcript)); CX0560 (Feingold, Dep. (entire transcript)); CX0561 (Friddle, Dep. (entire transcript)); CX0562 (Friddle, IHT (entire transcript)); CX0563 (Goode, IHT (entire transcript)); CX0564 (Hall, Dep. (entire transcript)); CX0565 (Hardesty, Dep. (entire transcript)); CX0566 (Hardesty, IHT (entire transcript)); CX0567 (Holland, Dep. (entire transcript)); CX0568 (Kurdys, Dep. (entire transcript)); CX0569 (Morgan, Dep. (entire transcript)); CX0570 (Owens, Dep. (entire transcript)); CX0571 (Owens, IHT (entire transcript)); CX0573 (White, Dep. (entire transcript)); CX0574 (White, IHT (entire transcript)); CX0581 (Bakewell, Dep. (entire transcript))).

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).

Response to Finding No. 3

In light of the testimony and deposition testimony, each cease and desist letter, each policy statement, and each letter to manufacturers and mall operators is documentary evidence in the record indicating agreement on behalf of the Board in connection with non-dental teeth whitening operations.

In addition, the Board's pleadings continuously and unambiguously refer to the actions at issue in the matter as the actions of the Board.

- Non-dentist teeth whitening "was targeted by the State Board's regulation." (Respondent's Post-Trial Brief ("RPTB") at 15).

- Complaints regarding non-dentist teeth whitening are "received by the State Board." (RPTB at 21).
- The Secretary-Treasurer of the State Board evaluates each complaint for jurisdictional issues and assigns it to a Case Officer. (RPTB at 21).
- The Case Officer "was authorized to oversee the State Board's efforts to protect the public by enforcing" the Dental Act. (RPTB at 27 (emphasis added)).
- "The investigatory panel includes the Case Officer, a State Board's investigator, and sometimes the State Board attorney." (RPTB at 22).
- "[T]he State Board approached investigations into allegations of unlawful teeth whitening services in the same manner as it approached its other investigations into the unauthorized practice of dentistry . . . ." (RPTB at 23).
- "[C]ease and desist letters or orders [were] utilized by the State Board . . . [to enforce] prohibitions on unauthorized practice . . ." (RPTB at 27).
- "[C]ease and desist letters were sent by the State Board only when there was prima facie evidence" of a violation. (RPTB at 23).
- "Further, the State Board sends cease and desist letters when there is evidence that a person has engaged in the unauthorized practice of dentistry, not just teeth whitening." (RPTB at 28).
- "[T]he State Board sent cease and desist letters because there was credible evidence of a violation . . . ." (RPTB at 28).
- "[T]he State Board may be informed that [a cease and desist letter] had been sent out at the next Board meeting." (RPTB at 22).

- In the Edie's Salon Panache investigation the Case Officer elected to go forward with the case with the **approval of the Board**. (RPFF ¶ 149; *see also* CX0437; RX49 (Allen, Dep. at 119-120) (emphasis added)).
- In the Florida Smiles investigation, a cease and desist letter was sent to the company, and the Case Officer directed the case manager to consult with Board Counsel and the Chief Operating Officer as to the next step to take. (RPFF ¶ 154).
- The Board campaign against mall kiosks is reflected in an e-mail from Mr. White to a complaining dentist where he states that the offending mall kiosk "is one of many such 'bleaching kiosks' with which we are currently going forth to do battle," and that the Board had sent out "numerous cease and desist orders throughout the state." (CX0404 at 001-002 (emphasis added)). It is axiomatic that you cannot have a battle without a common plan, tactic, or strategy.

In addition, the Board – by the unanimous agreement of its members after discussion and consensus – authorized Ms. Carolin Bakewell, then Board counsel, to draft and send letters to eleven mall operators that operated malls in North Carolina, notifying them that teeth whitening by non-dentists without dentist supervision was illegal. (CCPFF ¶¶ 315-320; CX0565 at 054-055 (Hardesty, Dep. at 206-210)). The purpose of the mall letters was to deprive non-dentist teeth whiteners of access to the commercial facilities from which to offer teeth whitening services. (CCPFF ¶¶ 318-325).

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 nondentists 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)).

Response to Finding No. 4

The finding is inaccurate and misleading. The rote, self-serving testimony of Drs. Hardesty, Owens, and Wester in response to the leading questions of counsel at trial do not support the broad proposition of this finding. Drs. Wester, Hardesty, and Owens only testified that they personally did not have conversations with other dentists with regard to the listed topics. (Wester, Tr. 1306-1307; Owens, Tr. 1462-1463; Hardesty, Tr. 2785). Mr. White only testified that he had not heard conversations between dentists and Board members on the listed topics. (White, Tr. 2236-2237).

The rest of the cited testimony, (e.g. other Board members and the Executive Director of the North Carolina Dentist Society), certainly does not support a finding that there have been "no conversations between dentist Board members and other dentists" on each of the topics listed as noted in RPF 4. Dr. Parker's cited testimony does not even address the point of conversations between Board members and dentists, but addresses the issue of whether dentists in general sought regulation of teeth whitening because they were "so financially threatened from teeth whitening." (RX76 (Parker, Dep. at 249)). Ms. Efird's cited testimony does not support the proposition because she only testified about discussions among Board members, not Board members and dentists. (RX55 (Efird, Dep. at 42, 68-70, 75)). In addition, Ms. Efird only testified that she was not aware of "any discussions of the board about the prices being charged for teeth

whitening" and that she was not aware of "any discussions within the board about trends in income for dentists in North Carolina" which are not statements that support RPF 4. (RX55 (Efird, Dep. at 42). At page 75 of her deposition, Ms. Efird testified that she had not overheard or participated in "any discussions by any board members to the effect that, we really need to wipe out these teeth-whitening guys because they're cutting into our -- our business." (RX55 (Efird, Dep. at 75)). Similarly, Dr. Burnham's cited testimony does not support the proposition that there were "no conversations between dentist Board members and other dentists" as noted in this finding, but instead supports the proposition that the Board members themselves discussed competition between dentists and non-dentists. (RX52 (Burnham, Dep. at 151-153)).

Dr. Morgan's cited testimony was in response to the specific question that he had not heard during "meetings with professional colleagues," exclusive of his Board activities or attendance at continuing education classes, a dentist express a concern that competition from non-dentists resulted in that dentist having less revenue or profit. (RX65 (Morgan, Dep. at 24-26)). Dr. Feingold's deposition testimony only supports the propositions that he personally did not discuss with other dentists whether the practice of non-dentists performing cosmetic procedures exerted a downward pressure on prices dentists charge for similar services and whether such practices affected a dentist's ability to earn a living. (RX56 (Feingold, Dep. at 182-183)).

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)).

Response to Finding No. 5

This finding is misleading because the dentist Board members actually excluded the consumer and hygienist Board members from participating in discussions about teeth whitening and teeth whitening investigations. (CCPFF ¶ 108, 126). The actions of dentist Board members to exclude non-dentist board members from discussions about teeth-whitening and investigations of teeth-whitening should not be used to create the misleading impression that the Board's interest in teeth whitening was minimal especially when the exclusion of non-dentist Board members suggests that the dentist Board members reserved the discussions about teeth whitening and the investigation of teeth whitening complaints for themselves. In fact, Ms. Hall testified that at a general Board meeting where it was mentioned that the Board would be investigating complaints about teeth whitening that such discussion did not proceed further in Hall's presence. (CX0564 at 006 (Hall, Dep. at 15-16)).

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)).

Response to Finding No. 6

This finding is misleading because the dentist Board members excluded the consumer and hygienist Board members from participating in the investigation of teeth whitening complaints. (CCPFF ¶ 108).

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)).

Response to Finding No. 7

The finding is inaccurate. At least one Board member discussed with another Board member the amount of teeth whitening he did in his practice. RX55 (Efird, Dep. at 42, 68-70, 75).

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)).

Response to Finding No. 8

This finding is inaccurate and misleading because the conversations between Board members or Board staff with the North Carolina Dental Society about teeth whitening were not informal, random, or insignificant. For instance, the Board discussed a formal request from the North Carolina Dental Society to discuss teeth whitening clinics at the April 4, 2008 tripartite meeting between the Board, the University of North Carolina School of Dentistry, and the North Carolina Dental Society at the Board's March, 2008 Board Meeting. (CCPFF ¶ 222; CX0109 at 003; Hardesty Tr. 2867). Thereafter, at the April 4, 2008 tripartite meeting of the Board, the Dental Society, and the University of North Carolina Dental school, the Dental Society members attending complained about the proliferation of non-dentist teeth whitening kiosks and asked the Board what it was going to do about it. The Board assured the Dental Society that it was investigating complaints about non-dentist teeth whiteners. (CCPFF ¶ 223; CX0565 at 067 (Hardesty, Dep. at 259-261); Hardesty, Tr. at 2866-2867; CX0109 at 003).

At the February 2007 Board meeting at which the Board discussed the increasing number of complaints regarding non-dental teeth whitening being provided in spas, Dr. Hardesty emphasized the need to seek the assistance of the North Carolina Dental Society ("NCDS") to have the legislature change the statutory penalty for unlicensed practice of dentistry from a misdemeanor to a felony. (CCPFF ¶ 271; CX0056 at 005). Dr. Litaker, the North Carolina

Dental Society's liaison to the Board, attributed the NCDS's consideration of the Board's request to approach the legislature to make the penalty for the unlicensed practice of dentistry more severe to three issues: the provision of non-dental teeth whitening in the state; the creation of metal cosmetic prostheses covering the teeth, known as "grill[s]"; and a case involving the unlicensed practice of dentistry in Hickory, North Carolina. (CX0576 at 008-009 (Litaker, Dep. at 25-26)).

In addition, the Board's Chief Operating Officer White and Board Counsel Bakewell took steps to address the issue of non-dentist teeth whitening with other national dental associations. In October 2008, Mr. White gave a presentation at the American Association of Dental Administrators meeting in San Antonio entitled "Teeth Whitening in the Mall," which reviewed the legal efforts of some states against non-dentist teeth whitening and urged states to check their statutes for authority to combat non-dentist teeth whitening. (CX0519 at 001; CX0409 at 004). Further, both Mr. White and Ms. Bakewell were involved with communications with other dental boards and the American Dental Association ("ADA") that were intended to facilitate efforts against non-dentist teeth whitening. (CX0417 at 001-002 (one person exclaiming that all the boards should "savor the victory in Alabama" over teeth whitening kiosks); CX0052 at 001-004; CX0179 at 001-003; CX0254 at 001; CX0415 at 001; CX0416 at 001-003; CX0418 at 001; CX0420 at 001; CX0518 at 001; CX0519 at 001; CX0526 at 001-003).

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)).

Response to Finding No. 9

This finding is incorrect, inaccurate, and misleading. The March 2008 Board minutes specifically refer to a formal request from the NCDS to discuss teeth whitening at the April 4, 2008 Tripartite meeting that included representatives of the State Board, the N.C. State Dental Society, and University of North Carolina School of Dentistry. (CCPFF ¶ 222; CX0109 at 003; Hardesty Tr. 2867). Thereafter, at the April 4, 2008 tripartite meeting of the Board, the Dental Society, and the University of North Carolina Dental school, the Dental Society members attending complained about the proliferation of non-dentist teeth whitening kiosks and asked the Board what it was going to do about it. The Board assured the Dental Society that it was investigating complaints about non-dentist teeth whiteners. (CCPFF ¶ 223; CX0565 at 067 (Hardesty, Dep. at 259-261); Hardesty, Tr. at 2866-1867; CX0109 at 003).

10. Complaint Counsel has failed to meet its burden of proof. (Entire record).

Response to Finding No. 10

This finding calls for a conclusion of law rather than a factual finding and does not warrant a further response.

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)).

Response to Finding No. 11

Complaint Counsel has no specific response.

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)).

Response to Finding No. 12

Complaint Counsel has no specific response.

13. The North Carolina Dental Practice Act was enacted in 1879. (White, Tr. 2203-2204; CX19 at 1).

Response to Finding No. 13

Complaint Counsel has no specific response.

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. (CXI9 at 1; RX65 (Morgan, Dep. at 191-192)).

Response to Finding No. 14

Complaint Counsel have no specific response.

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).

Response to Finding No. 15

Complaint Counsel has no specific response.

16. The election of dentist and hygienist Board members is governed by N.C. Gen. Stat. §90-22(b), (c). (Joint Stipulations ¶ 5).

Response to Finding No. 16

Complaint Counsel has no specific response.

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).

Response to Finding No. 17

Complaint Counsel has no specific response.

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).

Response to Finding No. 18

Complaint Counsel has no specific response.

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).

Response to Finding No. 19

Complaint Counsel has no specific response.

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).

Response to Finding No. 20

Complaint Counsel has no specific response.

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).

Response to Finding No. 21

Complaint Counsel has no specific response.

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).

Response to Finding No. 22

Complaint Counsel has no specific response.

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.OI04).

Response to Finding No. 23

Complaint Counsel has no specific response.

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).

Response to Finding No. 24

Complaint Counsel has no specific response.

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. (CXI9 at 19-20).

Response to Finding No. 25

Complaint Counsel has no specific response.

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).

Response to Finding No. 26

Complaint Counsel has no specific response.

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).

Response to Finding No. 27

Complaint Counsel has no specific response.

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).

Response to Finding No. 28

Complaint Counsel has no specific response.

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).

Response to Finding No. 29

Complaint Counsel has no specific response.

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).

Response to Finding No. 30

Complaint Counsel has no specific response.

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).

Response to Finding No. 31

This finding is inaccurate. The statute only says that the Board may hire investigators "for the purpose of . . . inquiring into any practices committed in this state that . . . violate any of the provisions of this Article [Dentistry] or of Article 16 [Dental Hygiene]" or any of the Board's rules. (CX0019 at 022-023). The cited testimony only references the Board's ability to hire investigators, and the Board's ability "to take a civil action or a criminal action. (White, Tr. 2206). The cited portions of Mr. White's testimony in this finding does not address how investigators are actually utilized by the Board in practice. (White, Tr. 2205-2206).

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).

Response to Finding No. 32

Complaint Counsel has no specific response.

33. 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).

Response to Finding No. 33

Complaint Counsel has no specific response.

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).

Response to Finding No. 34

Complaint Counsel has no specific response.

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).

Response to Finding No. 35

This finding misstates both the applicable terms of the North Carolina Administrative Procedure Act and the Board's implementing rules. (CX0515 at 011 (N.C. Gen. Stat. § 150B-20 (a) (any person can petition for a rule) and (b) (a board must respond in 120 days–agencies other than boards or commissions must respond within 30 days)); (CX0514 at 040 (21 N.C.A.C. 16N.0101 (any person can petition for a rule)); (CX0514 at 040 (21 N.C.A.C. 16N.0103(b) (the

Board will act on petition at its next regularly schedule meeting or within 120 days after submission)).

36. The Administrative Procedure Act has a provision for emergency rulemaking, which still allows for public participation. (White, Tr. 2214; CX515 at 17-19).

Response to Finding No. 36

Complaint Counsel has no specific response.

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).

Response to Finding No. 37

This finding misstates the law in that the Board's obligation to entertain declaratory rulings only extends to a "person aggrieved," rather than as stated in RPF 37 to "any person;" and the limited subjects that may be addressed in a declaratory ruling are "as to the validity of a rule or as to the applicability to a given state of facts of a statute administered by the agency," rather than: "on any rule or subject," as stated in RPF 37; and, finally, even a person aggrieved's right to a declaratory ruling would have been importantly limited by the following clause in the statute: *"except when the agency for good cause finds issuance of a ruling undesirable*." (CX0515 at 008-09 (N.C. Gen. Stat. 150B-4(a) (emphasis supplied); CX0514at 043 (21 N.C.A.C. 16N.0403(c) ("Whenever the Board believes for good cause that the issuance of a declaratory ruling is undesirable, the Board may refuse to issue such ruling.")). The Board's answer within 60 days to a request from a non-dentist teeth whitener would, in all likelihood, have been that such a ruling was "undesirable," consistent with the Board's teeth whitening policy that expressly states: "The Board is unable to give legal advice regarding whether a particular type or method of

chemical bleaching is in violation of the statute." (CX0475 at 001 (Unauthorized Practice of Dentistry interpretive statement adopted by the Board pursuant to N.C. Gen. Stat. § 150B-2(8a)(c)); *see* White, Tr. 2313-2314). Accordingly, seeking a declaratory ruling from the Board regarding non-dentist teeth whitening would, in all likelihood, have been a nugatory gesture.

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)).

Response to Finding No. 38

Complaint Counsel has no specific response.

39. All rules of state agencies, including the Board, are published. (White, Tr. 2216; CX515 at 33-35).

Response to Finding No. 39

Complaint Counsel has no specific response.

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).

Response to Finding No. 40

This finding misstates the law. Articles 3 and 3A of the North Carolina Administrative Procedures Act apply to administrative hearings held by different types of agencies. *Compare* N.C. Gen. Stat. § 150B-23(a) (Article 3 applies to agencies "except as provided in Article 3A") *with* (CX0515 at 036) (N.C. Gen. Stat. § 150B-38(a)(1) (Article 3A applies to hearings held by, *inter alia*, occupational licensing agencies, like the Board)). Further, Article 3A hearings may be conducted by the agency, designated member(s) of the agency, (CX0515 at 038 (N.C. Gen. Stat. §

150B-40(b)), or in some cases, by an administrative law judge assigned by the Director of the Office of Administrative Hearings, (CX0515 at 039 (N.C. Gen. Stat. § 150B-40(c)). Additionally, the inapplicability of Article 3 hearings to the Board is demonstrated by the Board implementing regulations adopted in accordance with the provisions of N.C. Gen. Stat. § 150B-38(h) (CX0515 at 037); for instance, Board Rule 21 N.C.A.C. 16N.0501 (Right to Hearing) (CX0514 at 044) only cites G.S. 150B-38(h) as its authority to hold contested hearings, and the provisions of that statute only permit the adoption of regulations pertaining to Article 3A hearings. (CX0515 at 037 (N.C. Gen. Stat. § 150B-38(h) ("Every agency shall adopt rules governing the conduct of hearings that are consistent with the provisions of *this* Article [3A].") (emphasis supplied)). Finally, whether a non-licensee could get a contested case heard before the Board is wholly discretionary with the Board. (CX0514 (21 N.C.A.C. 16N.0503(a) ("The Board will decide whether to grant a request for a hearing.")). Unlike an Article 3 hearing that can be initiated by any person (and without the consent of the agency), Article 3A hearings can only be started by the Board. *Compare* N.C. Gen. Stat. § 150B-22 (an Article 3 hearing can be commenced by "either the agency or the [other] person") *with* (CX0514 at 044 (21 N.C.A.C. 16N.0503(c) ("Approval [by the Board] of a request for a hearing will be signified by issuing a notice as required by G.S. 150B-38(b) [Article 3A] and explained in Rule .0504 of this Section. [CX0514 at 044 (21 N.C.A.C. 16N.0504)]")).

The citations to the provisions of Article 3 of the North Carolina Administrative Procedure Act do not contain a citation to a litigation exhibit number because the copy of the North Carolina Administrative Procedure Act moved into evidence by Complaint Counsel as CX0515 was produced by the Board to the Commission in response to pre-complaint process

without four sections of Article 2A of that statute (N.C. Gen. Stat. §§ 150B-21.25-21.28) and all of the provisions of Article 3 (N.C. Gen. Stat. §§ 150B-22-37) of that statute. This can be confirmed by observing that the pages between which the omitted materials would have appeared, if they had been produced, (CX0515 at 035 and CX0515 at 036), are consecutively Bates numbered NCBOARD1485 and NCBOARD1486, respectively. Presumably, the Board recognized the inapplicability of Article 3 of that statute to the Board's activities, at least, before the Commission issued its Complaint herein.

Complaint Counsel request that the Court take official notice of the provisions of Article 3 of the North Carolina Administrative Procedure Act in accordance with Commission Rule 3.43(f), 16 C.F.R. § 3.43(f).

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).

Response to Finding No. 41

This finding is misleading and irrelevant. Mr. White's testimony about the Board's legal obligation to conduct its business in public view might correctly interpret the law of North Carolina, but it says nothing about whether the Board actually complies with the law. In particular, Board members Holland and Allen admitted that the votes taken to close investigations are conducted by e-mail and out of public view. (CX0554 at 021 (Allen, Dep. at 74); CX0567 at 40 (Holland Dep. at 158)(Respondent designated relevant portion of testimony at lines 01-17, but

did not provide copy of RX63 to Complaint Counsel); CCPFF ¶ 118). The act of voting, according to Mr. White, is not permitted during Closed Sessions of the Board and implies that votes are taken in the public view during Open Sessions of the Board. Certainly, votes of the Board members conducted by e-mail and outside of actual meetings of the Board were taken outside of public view.

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).

Response to Finding No. 42

Complaint Counsel has no specific response.

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)).

Response to Finding No. 43

Complaint Counsel has no specific response.

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).

Response to Finding No. 44

This finding is inaccurate and misleading because Respondent represents that the proposition applies to "all dentist Board members who testified in connection with this

proceeding." At a minimum, Board members Drs. Allen and Brown testified that they set forth positions on issues during their campaigns for the Board. (CCPFF ¶¶ 55, 56).

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).

Response to Finding No. 45

Complaint Counsel has no specific response.

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).

Response to Finding No. 46

Complaint Counsel has no specific response.

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).

Response to Finding No. 47

Complaint Counsel has no specific response.

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).

Response to Finding No. 48

This finding is incorrect, inaccurate, and misleading because the citations to the record do not remotely support the proposition stated that "the Board has sought criminal prosecution for the unauthorized practice of dentistry when public safety was an issue and the facts warranted such action." First, there is no trial testimony on this point from Dr. Owens at Tr. 1251 because

this portion of the transcript related to Dr. Kwoka. (Owens, Tr. 1251). Second, Mr. White's cited trial testimony does not relate to RPF 48. Instead, Mr. White's cited testimony only addresses the issue of whether the Board can pursue a criminal action under the statute by referring a matter to a District Attorney. (White, Tr. 2206). Finally, the citation to the statute does not address the issue of the rationale for the Board having sought a criminal prosecution. (CX0019 at 020).

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)).

Response to Finding No. 49

This finding is incorrect, inaccurate, and misleading because the citations to the record do not support the proposition stated that "the State Board sought injunctions for the unauthorized practice of dentistry whenever public safety was an issue." Mr. White's cited trial testimony, at best, relates to a single civil action relating to the maker of mouth jewelry where the Board had safety concerns, but does not contain any testimony that the Board sought civil actions whenever public safety was an issue. (White, Tr. 2332-2333). Similarly, Dr. Burnham's deposition testimony does not support the proposition that the State Board sought injunctions for the unauthorized practice of dentistry whenever public safety was an issue. In fact, Dr. Burnham did not testify concerning any instance where the Board brought a civil action. (RX52 (Burnham, Dep. at 103-105)). The citation to the statute certainly does not address the issue of whether the Board "sought injunctions" and for what purpose they "sought injunctions." (CX0019 at 020-021).

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).

Response to Finding No. 50

Complaint Counsel has no specific response.

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 corne 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).

Response to Finding No. 51

Complaint Counsel has no specific response.

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).

Response to Finding No. 52

Complaint Counsel has no specific response.

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).

Response to Finding No. 53

Complaint Counsel has no specific response.

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).

Response to Finding No. 54

Complaint Counsel has no specific response.

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).

Response to Finding No. 55

Complaint Counsel has no specific response.

56. The Board meets once a month, usually for about three days. (White, Tr. 2194).

Response to Finding No. 56

Complaint Counsel has no specific response.

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).

Response to Finding No. 57

Complaint Counsel has no specific response.

58. 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 (halfby 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).

Response to Finding No. 58

Complaint Counsel has no specific response.

59. The Board regularly receives commentary for proposed rules during its public hearings before the Rules Review Commission, including adverse commentary. (White, Tr. 2201).

Response to Finding No. 59

Complaint Counsel has no specific response.

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).

Response to Finding No. 60

Complaint Counsel has no specific response.

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).

Response to Finding No. 61

Complaint Counsel has no specific response.

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).

Response to Finding No. 62

This finding contains both a misstatement of law and a misunderstanding of Mr. White's cited testimony. The Board is an "occupational licensing board" within the meaning of N.C. Gen. Stat. § 93B-1 (CX0593 at 001), and, as such, is subject to the lobbying ban regarding "occupational licensing boards" created by N.C. Gen. Stat. § 93B-6 (CX0593 at 003). In addition, the finding is ambiguous because the statute does not clearly prohibit the Board from lobbying on its own behalf, but relates to the expenditure of funds to hire lobbyists. Neither the statutory provisions cited herein nor the above-cited testimony of Mr. White addresses the

question of whether any other state agencies in and of the State of North Carolina can engage in lobbying activities addressed to the North Carolina legislature. (White, Tr. 2202, 2212).

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).

Response to Finding No. 63

Complaint Counsel has no specific response.

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).

Response to Finding No. 64

The finding is misleading because it suggests that Board members have only discussed teeth whitening matters "out of the public view" once in a closed session. The evidence shows that the Board often discusses Board business out of public view through e-mail exchanges. For instance, Dr. Allen admitted that the votes taken to close investigations are conducted by e-mail and out of public view. (CX0554 at 021 (Allen, Dep. at 74); CX0567 at 040 (Holland, Dep. at 158) (Respondent designated relevant portion of testimony at lines 01-17, but did not provide copy of RX63 to Complaint Counsel); CCPFF ¶ 118). In addition, Board members have discussed teeth whitening investigations, the settlement of teeth whitening matters, potential teeth whitening investigations, news reports about teeth whitening, and teeth whitening policies in e-mails using their personal e-mail accounts. (CX0041 at 001-003) (discussion among Board members and staff of teeth whitening claims made in the Hollywood Smiles brochure, whether the Board had jurisdiction, and how to proceed); (CX0424 at 001) (discussion among Board

members and Board staff on teeth whitening and the unlicensed practice of dentistry); (CX0214 at 001) (discussion among Board members whether to accept the settlement offer from the proprietors of Signature Spas of Hickory); (CX0217 at 001)(Dr. Morgan's assessment of a media report about non-dentist teeth whitening that "could not be better for dentistry" shared with Board members); (CX0129 at 001)(e-mail between Dr. Holland and Dr. Morgan concerning teeth whitening televison report on WRAL).

65. Investigations are not subject to public view under the Open Meetings Act. (White, Tr. 2218-2219).

Response to Finding No. 65

Complaint Counsel has no specific response.

66. 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.

Response to Finding No. 66

This proposed finding is inaccurate. Mr. White did not testify that Complaint Counsel mischaracterized Mr. White's deposition testimony or anything else in the opening statement. Quite to the contrary, Mr. White reaffirmed the fundamental point underlying Complaint Counsel's statement in opening argument. After Respondent's counsel read verbatim Mr. White's deposition testimony, in response to a leading question from Respondent's counsel, Mr. White not surprisingly agreed that the verbatim transcript was more accurate than Complaint Counsel's paraphrasing of the deposition testimony. (White, Tr. 2240-2241). In fact, it would be literally impossible, short of quoting the deposition, for Complaint Counsel to have been more accurate than the deposition transcript. More importantly, when given an opportunity to retract his

deposition testimony relating to relief, Mr. White instead reaffirmed his agreement that the proposed relief would not impact the Board's ability to fulfill its statutory obligations. (White, Tr. 2240-2241). Mr. White testified that "Complaint Counsel had asked if we were more clear to make sure that anybody receiving that, the letter, knew that it was a notice rather than an order, would that impact the board's ability to do its job. I said no. We can change the letter." (White, Tr. 2240-2241). Thus, far from testifying as to any mischaracterization, Mr. White effectively and essentially agreed with Complaint Counsel.

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. (CX0019 at 7).

Response to Finding No. 67

This finding is inaccurate and misleading. Although the definition of the unlawful practice of dentistry has not changed since it was enacted in 1935, the statute does not contain the term "teeth whitening," does not contain a definition of the term "teeth whitening," and does not discuss the "unlawful practice of dentistry as it relates to teeth whitening." (CX0019 at 001-026).

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).

Response to Finding No. 68

Complaint Counsel have no specific response.

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).

Response to Finding No. 69

This finding is misleading and inaccurate. Although Drs. Hardesty, Owens, and Wester testified that it was their individual lay opinion that they considered teeth whitening to be the removal of stains, their testimony does not support the finding that "both current and former Board members who are dentists consider teeth whitening to be the removal of stains form 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)).

Response to Finding No. 70

This finding is incorrect, inaccurate, and misleading because none of the testimony stands for the proposition that the Board's interpretation of the statute "was based on the Board's public protection duties." Dr. Hardesty's cited testimony reflects his perception of his duty "to ensure that the dental profession received the confidence of the public and to protect the health, safety, and welfare of the public" as a Board member. (Hardesty, Tr. 2766). The remainder of Dr. Hardesty's cited testimony does not address the basis for the Board's interpretation of the statute either, but generally discusses case assignments and the issuance of Cease and Desist Orders. (Hardesty, Tr. 2772-2773). Similarly, Dr. Owens' cited testimony states his perception of his duty to "protect the health, safety and welfare of the public," but does not address how the Board interpreted the statute. In fact, the cited testimony focuses on the assignment of cases and the investigative practices of the Board. (Owens, Tr. 1440-1441). Dr. Holland's testimony does not support the proposition of the finding. CX0567 at 047-048 (Holland, Dep. at 181-182)). Ms.

Bakewell's testimony only supports the proposition that it was her legal opinion that the Board had the discretion to interpret the act to protect the public, but does not support the proposition that any of the Board's varied statutory interpretations were based upon their public protection duties. (RX50 (Bakewell, Dep. at 178)).

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)).

Response to Finding No. 71

This finding is inaccurate and misleading. Although Dr. Holland testified that the Board did not see a need for a rule on teeth whitening because the Board thought the statute was "pretty clear," his testimony is contradicted by many other members of the Board and staff, each of whom discussed numerous gray areas in the statute with respect to teeth whitening. (Hardesty, Tr. 2845-2846; CX0554 at 028, 039 (Allen, Dep. at 103, 146); CX0565 at 032-033, 069 (Hardesty, Dep. at 121-122, 268-269); CX0572 at 020, 023, 041 (Wester, Dep. at 70-72, 82, 155-156; *see also* CX0573 at 021 (White, Dep. at 77 (the application of the Dental Practice Act in any given teeth whitening case is a gray area))).

For example, Dr. Hardesty admitted that there are "gray areas" about what does and does not constitute the practice of dentistry with respect to teeth whitening services in North Carolina. Nevertheless, the Board did not seek to clarify the "gray area" through a rulemaking. (Hardesty, Tr. 2845-2846).

There is also contradictory testimony from Board member Dr. Feingold that suggests that one of the considerations for not pursuing rulemaking to clarify the provisions of the Dental Practice Act was related to the "risks" of submitting such rules to the legislature. (CX0560 at 022

(Feingold, Dep. at 79-81)). Dr. Feingold testified that Board Counsel, Ms. Bakewell, and the Board's chief operating officer, Mr. Bobby White, were cautious about promulgating rules because it would involve the legislature and the legislature might make other unrequested changes to the Dental Practice Act and could alter the scope of the Board's authority. (CX0560 at 022 (Feingold, Dep. at 79-81)).

The proposition that no administrative rule was needed "since the statute was clear" is also refuted by RPF 73. If the State Board did not believe it was necessary to pass an administrative rule subject to the scrutiny of the legislature "since the statute was clear," then why did the Board find it necessary to adopt "an interpretive statement incorporating its [the Board's] definition of the unauthorized practice of dentistry on January 9, 2010. (RPF 73).

The cites to the testimony of Drs. Brown and Dr. Morgan also do not support the finding. Dr. Brown only testified that the Board did not consider promulgating a rule with regard to the unlicensed practice of dentistry or with regard to teeth whitening and did not testify to any rationale for not doing so. Dr. Brown explicitly did not attribute the Board's inaction to the clarity of the statute. (RX51 (Brown, Dep. at 113-114). Dr. Morgan only testified that the Board had not considered a rule to clarify the meaning of "practice of dentistry" in the Dental Practice Act and did not even discuss the Board's rationale. (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)).

Response to Finding No. 72

This finding is incorrect, inaccurate, and misleading because the cited testimony does not support the finding and the finding is factually incorrect. First, there is no reference in the cited testimony to the Joint Legislative Administrative Oversight Committee. (RX50 (Bakewell, Dep. at 95, 178)).

Second, the cited testimony does not support the proposition that the Board will "use their knowledge and common sense" to presumably accomplish their "dictate." Ms. Bakewell testified that the Board "ought to use their common sense" when they enforce the statute. (RX50 (Bakewell, Dep. at 95, 178)).

Third, the Board points to no authority that North Carolina courts will intervene on their own to correct statutory misinterpretations of the law.

Fourth, the proposition that the North Carolina courts have not corrected the Board's interpretation of the Dental Practice Act is false and Ms. Bakewell's testimony is incorrect. (CCPFF ¶ ¶ 228-231, 240; RX50 at 025, 046 (Bakewell, Dep. at 95, 178)). The Board brought a civil suit wherein it alleged that Rodriguez Brunson, a maker of mouth jewelry, was fabricating dental devices in violation of N.C.G.S. 90-29(b)(8) which is a provision of the Dental Practice Act that addressed the unauthorized practice of dentistry. (CX0159 at 001-002) (Order and Judgment in North Carolina Board of Dental Examiners vs. Rodriguez Brunson ("*Brunson*") March 31, 2005). The Board sought a permanent injunction to prohibit the defendant from fabricating and selling metal devices or mouth jewelry. (CX0159 at 001-002) (Order and Judgment in North Carolina Board of Dental Examiners vs. Rodriguez Brunson ("*Brunson*") March 31, 2005). In *Brunson*, the North Carolina Court rejected the Board's interpretation that the making and selling of grills, fangs, or "mouth jewelry" violated the Dental Practice Act

prohibition of the fabrication of a dental device without a license. (CX0159 at 001; White Tr. 2331-2332). The Court stated, "[w]hile important public health concerns attend the marketing, fabrication and sale of any product or device that is inserted in a persons' mouth, and while N.C.G.S. 90-29(b)(8) should be liberally construed so as to serve the remedial purpose of the licensing statute, the fang device and similar devices offered and sold by Brunson are not oftlinesubstitutes for the wearer's natural teeth (or prosthetic teeth, if the wearer has a crown, bridge or plate) but temporary, removable adornments loosely referred to as 'jewelry.'" The judge also stated that "[t]he extension of the definition of 'practice of dentistry' to include such devices, or otherwise providing for regulation and control of the fabrication and sale thereof, is best left to the legislature." (CX0159 at 006).

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).

Response to Finding No. 73

Complaint Counsel has no specific response.

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)).

Response to Finding No. 74

Complaint Counsel has no specific response.

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).

Response to Finding No. 75

Complaint Counsel has no specific response.

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)).

Response to Finding No. 76

Complaint Counsel has no specific response.

77. The dentists on the Board, the hygienist, and the public member all receive the same ethics training. (White, Tr. 2194; CX594 at 15).

Response to Finding No. 77

Complaint Counsel has no specific response.

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).

Response to Finding No. 78

Complaint Counsel has no specific response.

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).

Response to Finding No.79

Complaint Counsel has no specific response.

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).

Response to Finding No. 80

Complaint Counsel has no specific response.

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).

Response to Finding No. 81

Complaint Counsel has no specific response.

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).

Response to Finding No. 82

Complaint Counsel has no specific response.

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).

Response to Finding No. 83

Complaint Counsel has no specific response.

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).

Response to Finding No. 84

Complaint Counsel has no specific response.

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).

Response to Finding No. 85

Complaint Counsel has no specific response.

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).

Response to Finding No. 86

This finding is inaccurate because the cited testimony and exhibits do not support the proposition that "all former Board members received written evaluations of their SEIs from the N.C. Ethics Commission." In addition, according to the Board, the N.C. Ethics Act was not effective prior to 2007 so that "former Board members" would not have received evaluation from the N.C. Ethics Commission prior to 2007. (RPF ¶ 78).

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).

Response to Finding No. 87

Complaint Counsel has no specific response.

88. Prior to the creation of the N.C. Ethics Commission, the Gubernatorial Ethics Board handled approval of SEIs. (White, Tr. 2196-2197).

Response to Finding No. 88

The finding is not supported by the cited testimony. (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).

Response to Finding No. 89

Complaint Counsel has no specific response.

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).

Response to Finding No. 90

Complaint Counsel has no specific response.

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)).

Response to Finding No. 91

Complaint Counsel has no specific response.

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)).

Response to Finding No. 92

This proposed finding is inaccurate, misleading, and not supported by the testimony cited. The evidence cited does not substantiate that Board members, either singly or collectively, took their ethical obligations "seriously," and recused themselves "when appropriate." Mr. White merely testified that ethical notices were given at the start of each Board meeting because that notice was mandated by law. He does not testify that any Board member took their ethical obligations seriously or cite any other evidence that they did. (White, Tr. 2208-09; 2197-2198).

The testimony of Dr. Hardesty at trial and at deposition contradicts the proposition that Board members took their ethical obligations seriously. Dr. Hardesty testified that he had held

several offices in the North Carolina Academy of General Dentistry including the presidency of that organization while he simultaneously was a Board member and held officer positions at the Board. (Hardesty, Tr. 2800). He admitted that the North Carolina Academy of General Dentistry was a component organization of the national Academy of General Dentistry and that he was also a delegate to the House of Delegates of the national organization simultaneously with his service on the Board. (Hardesty, Tr. 2798-2799). Dr. Hardesty also testified that both organizations had as a purpose the furthering of the financial interests of the dental profession. (Hardesty, Tr. 2798-2801).

At trial and at his deposition, Dr. Hardesty testified that all of the other Board members were aware that he held leadership positions in the North Carolina Academy of General Dentistry. (Hardesty, Tr. 2801; CX0565 at 015 (Hardesty, Dep. at 50-51)). According to Dr. Hardesty, no member of the Board "expressed concerns" or suggested that he consult with anyone about potential conflicts of interest related to his simultaneous service with the North Carolina Academy of General Dentistry and the Board. (CX0565 at 015 (Hardesty, Dep. at 52); Hardesty, Tr. 2801)). Dr Hardesty further testified that he did not consult with Board Counsel, the State Ethics Commission, or any other state agency to determine whether there were any conflicts that he needed to be aware of or to address as a result of his simultaneous service on the Board and the North Carolina Academy of General Dentistry. (CX0565 at 015 (Hardesty, Dep. at 51-52); Hardesty, Tr. 2801-2802)).

In addition, Dr. Hardesty never recused himself from a Board matter based on the fact that the Academy of General Dentistry had a policy or resolution on the subject matter of the Board action. (CX0565 at 015 (Hardesty, Dep. at 51)). Dr. Hardesty claimed to be unaware of the

official position of the Academy of General Dentistry relating to the fabrication of bleaching trays by non-dentist teeth whitening providers despite the fact that he was "generally familiar" with the policies of the Academy of General Dentistry after he became vice president of the North Carolina Academy of General Dentistry and was made a delegate to the house of delegates. (CX0377 at 014; CX0565 at 011-013 (Hardesty, Dep. at 35, 43-44)).

Nor does the cited testimony of the remaining witnesses stand for the proposition that Board dentists recused themselves when appropriate. Dr. Brown testified that he would only recuse himself in a matter where he had a competitive interest in the case, only if he "had prior knowledge of the case" and that it was a personal decision. (RX51(Brown, Dep. at 102,104)). Dr. Burnham testified that he recused himself twice when he possessed knowledge of the case that was potentially prejudicial to the respondent dentist. Additionally; he was not aware of any instance when a Board member was requested to recuse him or herself. Dr. Brown and he was only aware of one instance when a Board member recused himself because he was one of two dentists "practicing in a very small town together." (RX52 (Burnham, Dep. at 72-73)). Dr. Feingold testified that he had never recused himself from any matter pending before the Board. (RX56 (Feingold, Dep. at 61)). Dr. Holland testified that he took his ethical obligations "very seriously" and recused himself from matters where he knew the respondent well or practiced in close proximity to the respondent. (CX0567 at 011 (Holland, Dep. at 35-37)). Dr. Morgan appeared reluctant to discuss the reasons for any recusals he may have entered. (RX0065 (Morgan, Dep. at 127-28) ("Q. Have you ever recused yourself for reasons of conflict of interest at any Board meeting? A. Yes. Q. Tell me about that, please? A. What about it do you want to know? Q. What subject matters came up that led to you recusing yourself? A. Discipline of

another dentist. Q. Any other subject matters? A. Not that I recall.")). At best, the record as a linewhole indicates that Board members did not see the elimination of non-dentist teeth whiteners as a conflict of interest, applied no generally approved standard for recusals, and, in fact, each Board member applied his or her own personal standard for recusals. (RX51(Brown, Dep. at 102,104)).

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)).

Response to Finding No. 93

Complaint Counsel has no specific response.

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)).

Response to Finding No. 94

The finding is misleading. The cited testimony accurately cites Drs. Morgan, Wester, and Feingold concerning their loss of income due to their fulfillment of their Board duties, but it fails to account for the potential gain in day-to-day income that dentists, including financially interested Board members, have or will obtain as a result of Board's exclusionary conduct. The testimony of both Dr. Kwoka and Dr. Baumer is that dentists, including financially interested Board members, may benefit from the Board's exclusionary conduct because the price and demand for dentist provided teeth whitening will rise as non-dentist teeth whiteners are excluded from North Carolina. (CCPFF ¶¶ 557-562, 684, 687, 689).

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 anyone 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 anyone 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.

Response to Finding No. 95

Complaint Counsel has no specific response.

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)).

Response to Finding No. 96

Complaint Counsel has no specific response.

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).

Response to Finding No. 97

This finding is misleading because the exhibit cited only pertains to the eighteen open cases referenced on Dr. Owens' list of open teeth whitening cases as of August 12, 2010. (CX0462 at 003-005).

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)).

Response to Finding No. 98

Complaint Counsel has no specific response.

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)).

Response to Finding No. 99

This finding is misleading and inaccurate. Dr. Holland's testimony only supports the proposition that he believes that teeth whitening cases were a low priority for the Board, but Ms. Bakewell's and Ms. Goode's testimony do not support the proposition. (RX50 (Bakewell, Dep. at 306); RX59 (Goode, IHT at 90); CX0567 (Holland, Dep. at 118-119)). Ms. Goode did testify, however, that she considered that unsafe practitioners and defrauding the government were higher priorities for the Board than teeth whitening. (RX59 (Goode, IHT at 90). Ms. Bakewell merely testified that she would not describe teeth whitening at malls as a "hot issue in North Carolina," but made no representation concerning whether or not the Board considered teeth whitening a low priority. (RX50 (Bakewell, Dep. at 306).

Of course, the evidence of record concerning the Board's strategic efforts to deter teeth whiteners who operated at malls and in spas from offering their products suggests that teeth whitening was anything but a low priority for the Board. (CCPFF ¶¶ 318-319, 324-325, 351, 353-

355, 358-359). Mr. White's past statements do as well, such as when he used a "war" metaphor to describe the Board efforts against non-dentist teeth whitening in an e-mail to a complaining dentist (stating that the offending mall kiosk "is one of many such 'bleaching kiosks' with which we are currently going forth to do battle"). Mr. White also explained that the Board had sent out "numerous cease and desist orders throughout the state." (CX0404 at 001-002 (emphasis added)).

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)).

Response to Finding No. 100

This finding is inaccurate and misleading. Although the Board may pay lip service to investigating each matter on a case by case basis, in practice Case Officers often authorized the sending of cease and desist letters before sending, or in lieu of sending, an investigator to investigate. (CCPFF ¶¶ 261-266). For instance, on March 22, 2007, Ms. Friddle sent an e-mail to Dr. Holland asking about the necessity of sending an undercover investigator to a non-dental teeth whitening provider, to which the Board might send a Cease and Desist Order. (CCPFF ¶ 263). Ms. Friddle explained that the Board was too busy to send a private investigator to the "spa deals," and therefore, "Dr. Hardesty has pretty much taken the stance that we write them a Cease and Desist Order the first go round." (CX0070 at 001; *see also* CCPFF ¶ 263). On at least five occasions, Ms. Friddle followed Dr. Hardesty's direction to send a cease and desist order before

an investigation was conducted. (CX0070 at 001; CX0561 at 022-023 (Friddle, Dep. at 81-84)). Ms. Friddle testified that in 2007 and 2008, Cease and Desist Orders were sent "fairly quickly, like shortly after the case was set up" (CX0562 at 013 (Friddle, IHT at 47)), and that "if it is unclear as to whether or not, or if it appears that there's a violation, then we would send a cease and desist." (CX0562 at 012 (Friddle, IHT at 43-44)).

In addition, Dr. Wester's cited testimony does not support the proposition of this finding because he only testified that "one should treat these operations on a case-by-case basis, visit the operation and determine whether or not the sanitation and other type of concerns you have are addressed." (Wester, Tr. 1323).

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).

Response to Finding No. 101

This proposed finding is inaccurate. Exhibit RX1 does not indicate that the Board, or anyone else, conducted internet research. (RX1 at 1-3).

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).

Response to Finding No. 102

This proposed finding is inaccurate. The exhibit does not indicate how the esthetician, gathered information from the Cosmetology Board.

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).

Response to Finding No. 103

Complaint Counsel has no specific response.

104. The investigative panel recommended that the file be closed. (CX530 at 4).

Response to Finding No. 104

Complaint Counsel has no specific response.

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).

Response to Finding No. 105

This proposed finding is incomplete. The complaint came from a Greensboro, North Carolina dentist, reporting teeth whitening at the salon his wife visits. (CX0304 at 001).

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).

Response to Finding No. 106

Complaint counsel has no specific response except that Exhibit CX530 does not support this proposed finding.

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).

Response to Finding No. 107

Complaint Counsel has no specific response.

108. The investigative panel recommended that the case be closed. (CX658 at 6).

Response to Finding No. 108

Complaint Counsel has no specific response.

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).

Response to Finding No. 109

This proposed finding is misleading and incomplete. The complaints about Beach Bunz came from a Morehead City, North Carolina dentist, and another person. Both complaints were sent to the Board under the same fax cover sheet from Coastal Dentistry located at 405 N. 35th St., Morehead City, North Carolina. Both complainants listed their business addresses on their respective complaint forms as 405 N. 35th St., Morehead City, North Carolina, which is evidence that the second complainant is someone who works in the Moorehead City dentist's office. Both complaints identify Beach Bunz and Master Tanning (wholesale supplies) as the complained of entities. The dentist's complaint does not mention carbamide peroxide. The other complaint states, "[t]he product that they are using is twilight teeth platinum 25. On their website the bleaching solution is stated to be 25% carbamide peroxide. There is not a professional over looking the patient." (RX3 at 13- 22).

110. The Case Officer requested further information, and a Board investigator was sent to the salon. (RX3 at 6-12).

Response to Finding No. 110

Complaint Counsel has no specific response.

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).

Response to Finding No. 111

Complaint Counsel has no specific response.

112. Given the fact that the consumer applied the material themselves, the Board closed the file with no further action. (RX3 at 1-2).

Response to Finding No. 112

Complaint Counsel has no specific response.

{BleachBright}, Case 08-072

113 **{Brian Runsick was injured during a teeth whitening procedure and filed a complaint, which the Board received on April 29, 2008.}** (RX5 at 2-5, *subject to protective order*).

Response to Finding No. 113

This proposed finding is inaccurate. The record shows that Mr. Runsick's injuries were not likely the result of teeth whitening. On the complaint form he filed with the Board, Mr. Runsick stated he had his teeth whitened on February 17, 2008. Mr. Runsick stated his gums began to hurt on February 21, 2008. He stated he was in constant pain on February 23, 2008. Mr. Runsick stated that he got on a cruise ship on February 23, 2008 but did not visit the ship's doctor until February 26, 2008. Mr. Runsick stated his condition became 80% better within 24 hours of starting a course of antibiotics.

Dr. Giniger also assessed the complaint filed with the Board by Mr. Runsick, and concluded that Mr. Runsick's claimed injuries could not have been caused by a chemical burn from non-dentist teeth bleaching. (Giniger, Tr. 274-276, 337-338; CX0653 at 045; CCPFF ¶ 1149). Mr. Runsick reported that four days (elsewhere reported as five days (CX0117 at 1) elapsed between his non-dentist provided teeth bleaching and the first appearance of any adverse

symptoms. Dr. Giniger explained that there is no plausible mechanism by which a chemical burn from exposure to a bleaching agent could produce no discernible symptoms for more than three days, only becoming symptomatic on the fourth. (Giniger, Tr. 270-274; CCPFF ¶ 1150). Other explanations for Mr. Runsick's claimed symptoms are, however, plausible. For example, Dr. Tilley, who had been engaged by the Board some time later to examine and report on Mr. Runsick's condition, found his teeth and gum tissue to be stippled and in "generally good condition." However, Dr. Tilley observed that tartar build-up and that the tissue between two of Mr. Runsick's teeth "did not completely fill the interdental space (which is the triangular tissue that descends between two teeth)." (CX0327 at 001). Those findings are consistent with periodontal disease. (Giniger, Tr. 273-276; CX0653 at 045; CCPFF ¶ 1151). Further, Mr. Runsick's symptoms are consistent with other conditions such as a periodontal abscess that occurred within a few days of his teeth bleaching, which may have been worsened by constant teeth brushing and other attempted therapies, holding an aspirin against the cheek or gums and/or periodontal disease. (Giniger, Tr. 273-276; Tilley, Tr. 2084; 2093-2094; CX0653 at 045; CCPFF ¶¶ 1149-1154).

114. **{The Board sent Mr. Runsick to Dr. Larry Tilley for an evaluation.}** (CX440, *subject to protective order*). **{Dr. Tilley concluded that the gingival tissue would eventually return to 90% of its original condition.}** (RX5 at 1, *subject to protective order*).

Response to Finding No. 114

This proposed finding is misleading. Dr. Tilley found that Mr. Runsick's gums were within normal ranges, notwithstanding an incomplete filling of his interdental space, and Dr. Tilley had no baseline information about Mr. Runsick's gums and their height prior to his having his teeth bleached. (Tilley, Tr. 2078-2079; CCPFF ¶ 1137-38). Further, Dr. Tilley was not

concerned as the gum tissue height was within the limits of normal. (CX0580 at 023 (Tilley, Dep. at 82-85); CCPFF ¶ 1139). In addition, the lack of a complete filling of the interdental space between Runsick's number 23 and 24 teeth could be the result of a congenital condition, or the result of an infection either prior to or secondary to an abscess. (CX0580 at 035 (Tilley, Dep. at 130-131); CCPFF ¶ 1141).

115. **{This file remains open.}** (CX462 at 3, *subject to protective order*).

Response to Finding No. 115

Complaint Counsel has no specific response.

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).

Response to Finding No. 116

This proposed finding is incomplete. The complaint was from a licensed dentist located in Greensboro, North Carolina in the same shopping center as the salon. (RX6 at 1-2).

117. The investigative panel directed an investigator to visit the spa to find out what was going on. (RX6 at 2).

Response to Finding No. 117

Complaint Counsel has no specific response.

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).

Response to Finding No. 118

Complaint Counsel has no specific response.

119. Upon receipt of the investigative report, the Case Officer requested further information. (RX6 at 1).

Response to Finding No. 119

Complaint Counsel has no specific response.

120. Based upon the investigative report and advertising material, the Board sent a cease and desist letter on April 3, 2009. (CX272).

Response to Finding No. 120

This proposed finding is inaccurate. The exhibit identified does not state that the order was sent based upon the investigative report and advertising material. (CX272 at 001-002).

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).

Response to Finding No. 121

Complaint Counsel has no specific response.

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).

Response to Finding No. 122

This proposed finding is incomplete. The complaint came from a registered dental hygienist. (RX7 at 1).

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).

Response to Finding No. 123

This proposed finding is incomplete and inaccurate. CX0069 is the cease and desist order the Board sent to Body, Mind & Spirit Day Spa on March 29, 2007. It does not state the reasons why the cease and desist order was sent, and is contradicted by the other cited exhibit, CX0070. (CX0069 at 001-002). CX0070 is an e-mail from Ms. Friddle to Dr. Holland dated March 22, 2007, Ms. Friddle states, "[w]e are having a difficult time getting the time to send staff to perform these undercover spa deals. Dr. Hardesty has pretty much taken the stance that we write them a cease and desist letter the first go around. If we find out they are still doing it we move in with the big guns. What are your thoughts? Would you still like us to send someone undercover?" Dr. Hardesty replied, "I prefer the undercover first as this gives us some direct evidence rather than hearsay for the cease and desist letter. Ask Carolin regarding sending a cease and desist without first having any substantiated evidence that a law has been broken. I will not take a hard line on this point. I just want what we do to be legal and valid." (CX0069 at 001-002; CX0070 at 001).

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).

Response to Finding No. 124

Complaint Counsel has no specific response.

125. The investigative panel requested that the case be closed. (CX368 at 5).

Response to Finding No. 125

Complaint Counsel has no specific response.

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).

Response to Finding No. 126

This proposed finding is misleading. There is no evidence that the Carmel Day Spa was using Zoom! which is used by dentists. (CX0361).

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).

Response to Finding No. 127

This proposed finding is incomplete and misleading. Mr. Dempsey's Investigative memo states that the morning after his August 20, 2007 visit to Carmel Day Spa, "Ms. Goode stated that a gentleman called her and informed her that they did not think there was anything wrong. He had his attorneys review the case, and he did not think they were practicing dentistry." Mr. Dempsey's Investigative Memo states that during this phone call on the morning of August 21, 2007, Ms. Goode asked for a written response to the allegations. (RX8 at 010-011). Nothing in the record indicates that the caller stated he would provide a written response during the August 21, 2007 phone call. The Board's cease and desist to Carmel Day Spa is dated October 1, 2007. (CX0279 at 1). In an Addendum to Investigative Memo dated December 17, 2007, Mr. Dempsey wrote that a "Cease and Desist order was mailed to the (sic) Ms. Shohreh Rafie, and her attorney contacted Casie Goode. He intimated that he would be submitting a response. We never heard anything more. . . ." (RX8 at 9).

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).

Response to Finding No. 128

Subject to Complaint Counsel's Response to No. 127, Complaint Counsel has no additional response.

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).

Response to Finding No. 129

Complaint Counsel has no specific response.

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).

Response to Finding No. 130

This proposed finding is misleading. There is no evidence that the Carmel Day Spa was using Zoom! which is used by dentists, as could be implied by statement that the spa "was indeed" doing what was alleged. (CX0361).

131. The investigative panel decided to pursue a lawsuit. (RX8 at 9).

Response to Finding No. 131

Complaint Counsel has no specific response.

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).

Response to Finding No. 132

Complaint Counsel has no specific response.

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).

Response to Finding No. 133

This proposed finding is misleading. There have been no decisions on the merits in a North Carolina court relating to the Dental Board's enforcement of the Dental Practice Act with respect to non-dental teeth whitening. (Respondent's Response to RFA ¶ 22; CX0573 at 017 (White, Dep. at 58-59)). The Board settled the Carmel Day Spa litigation prior to a decision on the merits by entry of a consent order in July 2008. (RX00008 at 015-017).

{Celebrity Smiles}, Case 07-208

134. **{On November 19, 2007, the Board received a complaint from a noted teeth whitening expert about a mail [sic] kiosk teeth whitening operation. The complainant expressed concern about the percentage of carbamide peroxide used in the process.}** (RX9 at 2-6, *subject to protective order*).

Response to Finding No. 134

This proposed finding is incomplete. The e-mail stated "[m]y son Gavin first saw this and made me aware of it, so I went to take a look for myself. The lady with whom I spoke is named [Ms. H to protect personally identifiable information]. She said it was legal since it was a cosmetic procedure. She said they use 44% carbamide peroxide administered in a gel tray!! They charge $100!" (RX9 at 2-6). Therefore, to the extent that the e-mail expresses a concern about the percentage of peroxide, it also expresses a concern about the price charged for the teeth whitening service.

135. **{The Board conducted some online research and sent an investigator to visit the kiosk at the case officer's direction.}** (RX9 at 2, 7, *subject to protective order*).

Response to Finding No. 135

This proposed finding is inaccurate. Although the exhibit includes what appears to be a WowSmile web page immediately following Dr. Heymann's e-mail to Dr. Hardesty on November

19, 2007, the exhibit does not indicate who found the web page. Although Ms. Friddle asks Dr. Owens, if it is "o.k. if we go ahead and draft a cease and desist order to take with us when we go back over to check this out," (RX9 at 2), there is no specific reference that a Board investigator visited the kiosk before attempting to hand deliver the cease and desist order. (RX9).

136. **{Following an on-site investigation, the investigator hand delivered a cease and desist order on November 20, 2007.}** (CX350, *subject to protective order*; CX351, *subject to protective order*).

Response to Finding No. 136

Complaint Counsel has no specific response.

137. **{This case remains open, and at least one subsequent complaint has been received on March 17, 2008.}** (RX9 at 1, *subject to protective order*; CX462 at 3, *subject to protective order*).

Response to Finding No. 137

This proposed finding is incomplete. The second complaint came from a licensed Chapel Hill, North Carolina dentist in an e-mail dated March 17, 2008. (CX0245 at 001).

Champagne Taste/Lash Lady, Case 07-114

138. The Board began its investigation on January 7, 2007 after receiving an e-mail notifying the Board of an advertisement for in-office whitening at this facility using an LED light. (RX10 at 1; CX622 at 3).

Response to Finding No. 138

This proposed finding is incomplete. The complaint came from a licensed North Carolina dentist. (RX10 at 1).

139. Board staff researched this establishment by checking Champagne Taste's website, which advertised WhiteSpa professional teeth whitening. (RX10 at 2-3).

Response to Finding No. 139

Complaint Counsel has no specific response.

140. Based on this advertising information from the website, the Board sent a cease and desist letter on February 8, 2007. (CX77).

Response to Finding No. 140

This proposed finding is incomplete. On January 19, 2007, Ms. Friddle e-mailed Dr. Hardesty regarding the non-dental teeth whitening provider referred to as "Lashlady" at the Champagne Taste salon whose case she assigned the identification number 07-114. After indicating that the only investigation conducted was viewing Lashlady's website, Ms. Friddle asked Dr. Hardesty whether he wished the Board to proceed with sending Lashlady a cease and desist letter. (CX0281 at 001). On January 20, 2007, Dr. Hardesty replied to Ms. Friddle's question regarding the service of a cease and desist letter to the non-dental teeth whitening provider "Lashlady." Dr. Hardesty instructed Ms. Friddle to send a cease and desist letter without requesting any further investigation than the website viewing Ms. Friddle previously indicated. (CX0281 at 001).

141. The owner of Champagne Taste contacted the Board office by telephone on March 26, 2007 to confirm that she was no longer offering teeth whitening services. (CX75).

Response to Finding No. 141

This proposed finding is incomplete. After receiving a Cease and Desist Order from the Board dated February 8, 2007, the owner of Champagne Taste Salon, also known as "Lash Lady," wrote to the Board stating that "they have now stopped offering [teeth whitening] service[s]." (CX0622 at 003). On March 22, 2007, Ms. Bakewell sent a letter to Champagne Taste of Charlotte, North Carolina, reminding Champagne Taste of the Cease and Desist Order the Board sent it on February 8, 2007. Ms. Bakewell indicated that the Board had "not received any

response from [the salon] nor any acknowledgment that [the salon] intend[s] to abide by the Notice and Order." (CX0076 at 001). On March 27, from Carolin Bakewell to Champagne Taste with the salutation "Dear Madam," (CX0075 at 001) Ms. Bakewell states, "[t]hank you for your call of yesterday afternoon regarding my March 22 letter. I regret that the Dental Board staff has no record of having received your call about the Cease and Desist Order. So that we can properly document your cooperation, please complete and return the enclosed acknowledgment form in the self addressed stamped envelope provided. That will permit us to close our file and eliminate the need for further contacts with your business." (CX0075 at 001). The form asked the addressee to both acknowledge receipt of the cease and desist and state that she was no longer offering teeth whitening services. (CX0075 at 002). However, the letter does not memorialize the March 26th conversation between Ms. Bakewell and Champagne Taste. It also does not indicate whether Champagne Taste provided teeth whitening. The form referenced in the letter is not filled out and is unsigned.

142. Based on the owner's response, the investigative panel recommended that the file be closed. (CX622 at 3).

Response to Finding No. 142

Complaint Counsel has no specific response.

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).

Response to Finding No. 143

This proposed finding is incomplete. A licensed North Carolina dentist faxed this complaint to the Board. (CX0619).

144. Based on the advertisement, a cease and desist order was sent. (CX660 at 3).

Response to Finding No. 144

Complaint Counsel has no specific response.

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).

Response to Finding No. 145

Complaint Counsel has no specific response.

146. Based on the information provided, the investigative panel recommended that the file be closed. (CX660 at 3).

Response to Finding No. 146

Complaint Counsel has no specific response.

Edie's Salon Panache, Case 04-187

147. The Board received several faxes, e-mails, 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).

Response to Finding No. 147

This proposed finding is incomplete. Between August and September 2, 2004, four North Carolina dentists complained to the Board that Edie's Salon Panache advertised teeth whitening provided by non-dentist at prices lower than dentists. (CX0036 at 002-007). One of these dentists sent an e-mail dated September 2, 2004 to the Board providing information that Edie's

Salon Panache was advertising non-dentist teeth whitening in the Charlotte area for $149 dollars which she asserted was "[l]ess than dentists charge." (CX0036 at 002) (emphasis in original).

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)).

Response to Finding No. 148

This proposed finding is inaccurate and misleading. With respect to the poison ivy, Ms. Friddle wrote "[a]s I was leaving, however, Marcia told me, as she was scratching her head, that she thought she had Poison Ivy! All I could think of at that point was that I was going out of town in a couple of days and [the make up artist] had touched my face with her gloveless hands during the impression procedure." (RX11 at 6) (emphasis added). However, when Ms. Friddle described the impression procedure in her memo, including the make up artist's failure to wash her hands, Friddle did not mention a rash on the make up artist's hand. Ms. Friddle's description of the impression procedure does not specifically state that the make up artist touched Ms. Friddle.

149. The case officer elected to go forward with the case with the approval of the Board. (CX437; RX49 (Allen, Dep. at 119-120)).

Response to Finding No. 149

Complaint Counsel has no specific response.

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).

Response to Finding No. 150

Complaint Counsel has no specific response.

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)).

Response to Finding No. 151

This proposed finding is misleading. The criminal case was disposed of before a trial on the merits determined whether she may have been engaged in the unauthorized practice of dentistry. (CX0034 at 003).

{Florida White Smile/Sam's Club}, Case 08-083

152. **{The Board received a number of reports about Florida White Smile, which was operating at Sam's Clubs around the state.}** (RX14 at 1,2,20, *subject to protective order*).

Response to Finding No. 152

This proposed finding is misleading. The Board received three reports about Florida White Smile. The fax masthead one of the reports indicates that they came from Board member Dr. Owens' office. The advertisement Dr. Owens appears to have sent is for Florida White Smile in Asheville, North Carolina. (RX14 at 2). An e-mail from Casie Goode asked if Board investigators Sean Kurdys or Line Dempsey would be in the Southern Pines area because they need to check out a Sam's club. However, the exhibit does not state who, other than Dr. Owens, complained about the teeth whitening in Southern Pines. (RX14 at 3). Another e-mail forwarded from Dr. Parker of the North Carolina Dental Society indicates that someone complained about a Sam's club in Matthews, North Carolina.

153. **{Research on the company and its teeth whitening method was performed online.}** (RX14 at 4-19, *subject to protective order*). **{An investigator was instructed to visit the Sam's Club in Southern Pines, N.C.}** (RX14 at 3, *subject to protective order*).

Response to Finding No. 153

Complaint Counsel has no specific response.

154. **{A cease and desist letter was sent to the company, and the case officer directed the case manager to consult with Board counsel and the Chief Operating Officer as to the next step to take.}** (CX298 at 2, *subject to protective order*).

Response to Finding No. 154

Complaint Counsel has no specific response.

155. **{The case remains open.}** (CX462 at 3, *subject to protective order*).

Response to Finding No. 155

Complaint Counsel has no specific response.

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).

Response to Finding No. 156

This proposed finding is incomplete. The complaint came from a licensed North Carolina dentist. (RX33 at 2).

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).

Response to Finding No. 157

This proposed finding is incomplete. A Board employee attended the "Southern Women's Show" when it was in Raleigh, North Carolina to investigate the "possible illegal practice of dentistry," but the Great White teeth whiteners were not in attendance. After the Board learned that Great White employees had been told by a dentist that "they were breaking the law and eventually the Dental Board would find out," the dentist reported that Great White did not intend

to return to North Carolina. Dr. Brown then directed Ms. Friddle to close the investigation for "lack of evidence." (CX0032 at 001-005).

158. A Board staff member was sent to a trade show in Raleigh, but did not find Great White in attendance. (CX32 at 3).

Response to Finding No. 158

Subject to its response to No. 157, Complaint Counsel has no specific response.

159. The file was closed for lack of evidence. (CX33 at 1).

Response to Finding No. 159

The cited document does not support the proposed finding. (CX0033 at 001).

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).

Response to Finding No. 160

This proposed finding is misleading. Although Dr. Holland did state the brochure "was full of false claims," but he did not specify which claims he believed were false, nor is there any credible evidence that the claims were false. (RX15 at 11).

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 teeth whitening was done on the premises. (RX15 at 9-10).

Response to Finding No. 161

Complaint Counsel has no specific response.

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)}.

Response to Finding No. 162

This proposed finding is inaccurate and misleading. In January 2005, the District Attorney of Davidson County entered a voluntary dismissal of the criminal charges of unauthorized practice of dentistry against Brandi Temple. Assistant District Attorney Kinsey informed the Board that he had taken a voluntary dismissal based upon Ms. Temple's affidavit wherein Ms. Temple did not admit guilt and noted that the affidavit was "given in compromise of a doubtful and disputed criminal charge . . . and is not to be construed as an admission of guilt or liability on the part of [Ms. Temple] that she practiced or attempted to practice dentistry in the State of North Carolina" without a license. Ms. Temple denied any guilt with respect to the unauthorized practice of dentistry. In addition, Ms. Temple only agreed to stop taking impressions, and was not required to stop offering teeth whitening services without taking impressions. (CX0040 at 002-004).

{Lite Brite}, Case 08-132

163. **{The Board received two complaints dated June 3, 2008 and July 10, 2008, from persons who suffered severe reactions after undergoing teeth whitening at the same mall teeth whitening kiosk in Greenville, North Carolina.}** (RX17 at 1, 2, *subject to protective order*).

Response to Finding No. 163

This proposed finding is inaccurate and misleading. The evidence suggests that the two complaints received by the Board were in reference to a single teeth whitening experience; thus, there were not "persons" allegedly injured. In an August 12, 2010 memo written by Ms. Friddle

to Dr. Owens listing investigative files assigned to Dr. Owens, the entry for Lite Brite states in its entirety, "[c]omplaint received from [redacted in original]. Ms. [redacted in original] indicated that she had been injured as a result of getting a bleaching treatment at the Lite Brite kiosk in Colonial Mall in Greenville. The date of the opening of the investigation is listed as June 3, 2008. There are no additional entries for Lite Brite showing a second complaint from a consumer about this particular non-dentist teeth whitening business. A similar, earlier memo dated April 15, 2010 contains the exact same entry for Lite Brite, case number 08-132. (CX0462 at 003; CX0317 at 003). A spreadsheet appearing to list Dr. Owens' cases contains an entry for Lite Brite ("log number" 08-132). It lists the complainant as "Board" and does not contain a log date. (CX0447 at 001-002).

The Board received a complaint from a Ms. W (to protect sensitive health information) on June 3, 2008. Ms. W claimed she developed blisters on her upper and lower lips after receiving teeth whitening at the Lite Brite kiosk in Colonial Mall in Greenville. According to Ms. Bakewell's memorandum memorializing their telephone call, Ms. W stated that her teeth were only whitened one shade and that the kiosk owner refused to give a refund or pay for medical treatment. When Carolin Bakewell suggested that Ms. W see her regular dentist, Ms. W "seemed to think that she just had to wait out the blisters. . . ." (RX17 at 2).

The Board received an e-mail from Mr. Y (to protect sensitive health information) on July 10, 2008. The e-mail describes a similar complaint to that of Ms. W's, on behalf of his wife. Mr. Y indicated that his wife had experienced what "looked like a burn or reaction to the inner part of her lip not the gum line." In no portion of the e-mail did he give his wife's name. He stated that

his wife saw her dentist. He stated that "[t]he dentist would not give her a direct explanation of what caused the problem. . . ." It took a week for her lip to heal. (RX17 at 1).

The timing and similarity of these complaints, in addition to the single reference in the Board's files to a complaint against Lite Brite, suggests that these two complaints are regarding the same consumer- Ms. W, and that Mr. Y is her husband. (RX17 at 1-2; CX0462 at 003; CX0317 at 003). In addition, the record is devoid of evidence that this complainant actually experienced any dental issues. And even if this complainant did experience dental issues, the record is similarly devoid of any evidence that they were caused by non-dentist teeth whitening at Lite Brite or anywhere else. In fact, in Mr. Y's e-mail, it states that a dentist could not identify "what caused the problem." (RX17 at 1; entire record).

164. **{The first individual developed "a burn or reaction" on the inner part of her lip that took about a week to heal.}** (RX17 at 2, *subject to protective order*).

Response to Finding No. 164

This proposed finding is misleading, inaccurate, and incomplete. The Board received a second *complaint* from Mr. Y on July 10, 2008. The complaint indicated Mr. Y's unnamed wife had experienced what "looked like a burn or reaction to the inner part of her lip not the gum line." (RX17 at 1). In addition, insofar as the statement "the first individual" implies that there is more than one teeth whitening event complained about regarding Lite Brite, Complaint Counsel disputes this assertion as set forth in the response to RPF ¶¶ 163 and 513. (Complaint Counsel's Response to RPF ¶¶ 163, 513). Further, this proposed finding is misleading to the extent it suggests that this injury did in fact occur and was caused by non-dentist teeth whitening. The record is devoid of evidence that this injury actually occurred or that it was caused by non-dentist

teeth whitening. (RX17 at 1; entire record). In addition, the Board did not present any testimony from this witness, and therefore this evidence should be given little if any weight.

165. **{The other person developed blisters inside her upper and lower lips.}** (RX17 at 1).

Response to Finding No. 165

As described above, Complaint Counsel disputes that this is a second event. (Complaint Counsel's Response to RPF ¶¶ 163, 513). Complaint Counsel further disputes that there was in fact an injury or that any injury was caused by non-dentist teeth whitening. (RX17 at 1; entire record; Response to RFP ¶ 164).

166. **{In both cases, the Lite Brite kiosk personnel refused to make refunds or did not agree to compensate the consumer for any medical expenses associated with the injuries.}** (RX17 at 1-2, *subject to protective order*).

Response to Finding No. 166

This proposed finding is incomplete and misleading. As described above, Complaint Counsel disputes that there are two separate instances of teeth whitening services with respect to Lite Brite. (Complaint Counsel's Response to RPF ¶¶ 163, 513). In addition, according to Mr. Y's complaint, the company informed Mr. Y's wife that because a dentist could not offer a decisive explanation about the cause of the injury, Lite Brite would not refund the money. (RX17 at 1). According to the memorandum Ms. Bakewell wrote to memorialize Ms. W's telephonic complaint, Lite Brite refused to refund Ms. W's money but the memorandum does not state why. (RX17 at 2).

167. **{A cease and desist letter was sent to Lite Brite on July 17, 2008.}** (CX388, *subject to protective order*).

Response to Finding No. 167

This proposed finding is incomplete. In an e-mail written to Mr. Y on July 10, 2008, Ms. Bakewell stated "[t]he N.C. State Board of Dental Examiners does not license whitening salons or spas, as our authority is generally limited to the conduct of dentists and hygienists. . . . The Dental Board has filed two lawsuits against whitening salons in the past for engaging in the unauthorized practice of dentistry. Both of those matters are still pending in court." (CX0517 at 001). She added, "I cannot offer you an opinion regarding whether the business your wife dealt with is engaged in the unauthorized practice of dentistry." (CX0517 at 001). Notwithstanding this statement, the Board sent a cease and desist letter to Lite Brite dated July 17, 2008.

The Board has filed two civil suits against non-dentist teeth whiteners, one against Carmel Day Spa and one against Signature Spas of Hickory. (CX0073 at 004 (complaint for declaratory judgment and injunctive relief against Carmel Day Spa & Salon (filed January 17, 2008)); CX0103 at 003-016 (complaint for temporary restraining order and permanent injunction against Signature Spas of Hickory (filed November 21, 2006)). In the Board's suit against Carmel Day Spa, Ms. Bakewell signed the consent order on July 8, 2008. (RX8 at 17). The consent decree was filed with the court on July 9, 2008. (RX8 at 15; RPF ¶ 133). It was not pending when Ms. Bakewell wrote to Mr. Y.

168. **{This case remains open.}** (CX462 at 3, *subject to protective order*).

Response to Finding No. 168

Complaint Counsel has no specific response.

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).

Response to Finding No. 169

This proposed finding is misleading. The complaints about Beach Bunz and Master Tanning came from a Morehead City, North Carolina dentist, and another person. Both complaints were sent to the Board under the same fax cover sheet from Coastal Dentistry located at 405 N. 35th St., Morehead City, North Carolina. Both complainants listed their business addresses on their respective complaint forms as 405 N. 35th St., Morehead City, North Carolina, which is evidence that the second complainant is someone who works in the Moorehead City dentist's office. Both complaints identify Beach Bunz and Master Tanning (wholesale supplies) as the complained of entities.

Each complainant used a single complaint form to complain about both Beach Bunz and Master Tanning. The dentist's complaint form indicates that Master Tanning sells supplies. The other complaint form indicates Master Tanning as "Whole sales supplies." ((RX3 at 13- 22). Additionally a memo written by Line Dempsey, dated March 4, 2009, describing his investigation into Beach Bunz also states that Master Tanning is a distributor of tanning beds and supplies. (RX00003 at 4).

170. The case officer requested further information, and a Board investigator was sent to the salon. (RX 18 at 2-7).

Response to Finding No. 170

Complaint Counsel has no specific response.

171. The investigation revealed that the business was a teeth whitening kit supplier and clients would self-apply. (RX18 at 13).

Response to Finding No. 171

Complaint Counsel has no specific response.

172. The file was closed since the salon was not providing teeth whitening services. (RX18 at 1; RX58 (Friddle, IHT at 79)).

Response to Finding No. 172

Complaint Counsel has no specific response.

{Movie Star Smile}, Case 07-223

173. **{A dentist reported to the Board on December 17, 2007, that teeth whitening using LED lights was occurring at a kiosk in Hickory Mall.}** (RX19 at 1-2,6, *subject to protective order*).

Response to Finding No. 173

Complaint Counsel has no specific response.

174. **{The Board's investigator paid a visit to the mall. He took photos of the operation and obtained a question and answer sheet about the process.}** (RX19 at 3-4, 7, *subject to protective order*; CX548 at 1, *subject to protective order*).

Response to Finding No. 174

Complaint Counsel has no specific response, other than to note that RX19 at 5 states that a single photo is provided with his investigative memo. In addition, the photo is not included in the exhibit.

175. **{A cease and desist letter was sent to the business at the case officer's direction on January 17, 2008.}** (RX19 at 5, *subject to protective order;* CX 79, *subject to protective order*; CX201 at 1-3, *subject to protective order*).

Response to Finding No. 175

Complaint Counsel has no specific response.

176. **{Movie Star Smile responded that they had no contact with the customer and sold a self-administered bleaching kit that could be used at the retail space or taken home.}** (CX528 at 1, *subject to protective order*).

Response to Finding No. 176

Complaint Counsel has no specific response.

177. **{This file is still open.}** (CX624 at 4, *subject to protective order*).

Response to Finding No. 177

Complaint Counsel has no specific response.

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).

Response to Finding No. 178

Complaint Counsel has no specific response.

179. An investigator visited the salon and reported that they were simply selling the kits. (RX20 at 2-3).

Response to Finding No. 179

Complaint Counsel has no specific response.

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).

Response to Finding No. 180

This proposed finding is inaccurate. The letter is limited to the taking of impressions. The letter states that "G.S. § 90-29 defines the practice of dentistry as anyone who undertakes or attempts to do, or claims the ability to do any one or more of the following ..... (sic) '(7) takes or makes an impression of the human teeth, gums or jaws." (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).

Response to Finding No. 181

Complaint Counsel has no specific response.

{Port City Tanning}, Case 08-018

182. **{The Board received several complaints about this establishment.}** (RX21 at 1, 2, 8-10). **{There was also a practitioner complaint from Michael Lee Hasson, D.D.S., received February 19, 2008. Dr. Hasson submitted the complaint after treating a patient who had her teeth bleached at the salon.}** (RX21 at 4-7, *subject to protective order*).

Response to Finding No. 182

This proposed finding is incomplete. One of the complaints came from a licensed dentist from Wilmington, North Carolina. (RX21 at 2; CX0603-001, 003).

183. **{According to Dr. Hasson's complaint, the tanning booth operator used an unknown whitening chemical and light source to bleach the teeth. The patient developed very irritated gums, ulcers, and possible permanent nerve damage.}** (RX21 at 4-7, *subject to protective order*; RX71 (Hasson, Dep. at 60, 62-63)). **{His patient also had a swollen chin, which he attributed to the teeth bleaching.}** (RX71 (Hasson, Dep. at 69-70)).

Response to Finding No. 183

This proposed finding is incomplete, inaccurate and misleading. There is no record evidence to support the conclusion that Dr. Hasson's patient was harmed by non-dentist teeth whitening. Dr. Hasson's complaint form states that "[t]anning booth operators provided chemical and light source for patient to bleach teeth." It further states that the patient "sustained mucosal ulcers with possible permanent nerve damage." (RX21 at 5). However, Dr. Hasson's patient record merely states that patient's "gums [were] very irritated after having her teeth bleached." (RX21 at 7). Neither the patient record nor the complaint form reference a swollen chin. Moreover, Dr. Hasson's patient record indicates that the patient had infected upper and lower left wisdom teeth. (RX21 at 7).

Dr. Hasson also testified that during his examination of the patient, he determined that she had bone loss, including about 50% bone loss around her wisdom teeth, which is serious and

indicative of infection. (CX0575 at 015-016 (Hasson, Dep. at 53-54); CCPFF ¶ 1170). Dr. Hasson testified that he found she also had missing teeth, teeth out of position, teeth which had root canals, and teeth which had crowns. (CX0575 at 015-016 (Hasson, Dep. at 53-54); CCPFF ¶ 1171). Teeth out of position can make them "impossible to clean adequately" and can lead to contact fractures of the teeth. (CX0575 at 020 (Hasson, Dep. at 72-73); CCPFF ¶ 1171). Dr. Hasson testified that he found the patient had teeth that were moving more than they should, which is associated with bone loss, not teeth whitening. (CX0575 at 019 (Hasson, Dep. at 68); CCPFF ¶ 1172). Dr. Hasson testified that he found her gums presenting inflammation and bleeding when probed, indicative of chronic infection not caused by teeth whitening. (CX0575 at 019 (Hasson, Dep. at 66-69); CCPFF ¶ 1173). Inflammation can be caused by infection or blunt trauma. (CX0575 at 020 (Hasson, Dep. at 70); CCPFF ¶ 1173). Dr. Hasson stated that ulcers can be caused by autoimmune reactions, viruses, or chemical or thermal reactions. (CX0575 at 017 (Hasson, Dep. at 60); CCPFF ¶ 1174). Dr. Hasson's patient records indicate that the patient used tobacco, but Dr. Hasson does not know whether she smoked tobacco or chewed it. (CX0575 at 021 (Hasson, Dep. at 76); CCPFF ¶ 1174). Any tobacco use by the patient would increase the inflammatory state in her mouth, thereby retarding the healing of any oral injury. (CX0575 at 017 (Hasson, Dep. at 61); CCPFF ¶ 1174). At deposition, Dr. Hasson testified that he found the patient presenting the following dental conditions: bone loss, missing teeth, teeth moving more than ordinary, teeth out of position, inflammation, bleeding when probed, ulcers, soreness, and evidence of root canals and crowns. Many of these indicated infection, and the patient's noted tobacco use would only exacerbate her inflammation and ostensible infection. (CX0476 at 002, 004; CX0575 at 015-016, 018-021, 023 (Hasson, Dep. at 53-54, 62-63, 66-69, 72-73, 76, 85);

CCPFF ¶ 1175). Finally, as previously noted, Dr. Hasson is not a credible witness. (CCPFF ¶¶ 1177).

184. **{The case officer ordered an investigation.}** (RX21 at 3, *subject to protective order*). **{The Board's investigator paid a visit to the salon, spoke to the owner, and received the owner's business card and a brochure.}** (RX21 at 11-13, *subject to protective order*; RX64 (Kurdys, Dep. at 59)). **{The business card of the tanning spa's owner also advertised "Teeth Whitening - Whiter teeth in 30 mins. FDA approved."}** (RX21 at 11, *subject to protective order*). **{The Shine White brochure distributed by the salon also stated that it was FDA approved and pictured a dental-type chair with an activator light.}** (RX21 at 12-13, *subject to protective order*).

Response to Finding No. 184

Complaint Counsel has no specific response.

185. **{The investigator also spoke to Patient X, (to protect sensitive health information) the person whose teeth were whitened at the salon and who was the subject of Dr. Hasson's complaint.}** (RX64 (Kurdys, Dep. at 58-59)).

Response to Finding No. 185

Complaint Counsel has no specific response.

186. **{Based on his investigation and the advertising materials, the investigator hand delivered the cease and desist letter on October 7, 2008.}** (CX59, *subject to protective order*).

Response to Finding No. 186

This proposed finding is incomplete. The exhibit identified is the solely the cease and desist letter the Board sent to the salon on October 7, 2008. Standing alone, it provides no basis for which the letter was sent. (CX0059).

187. **{The salon owner responded that his business was only selling a self administered whitening kit.}** (CXI25, *subject to protective order*).

Response to Finding No. 187

The Board has stated that the sale of a self administered teeth whitening is not the unauthorized practice of dentistry. Therefore, any problems experienced in this case could not be caused by the unauthorized practice of dentistry and or non-dentist provided teeth whitening. (White, Tr. 2229-2230).

188. **{This case remains open.}** (CX462 at 3, *subject to protective order*).

Response to Finding No. 188

Complaint Counsel has no specific response.

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).

Response to Finding No. 189

This proposed finding is incomplete. On August 14, 2007, Dr. Owens stated, "[p]lease have the guys stop by and investigate. I called the number and got an answering machine. I smell a cease and desist order." In an e-mail to Terry Friddle sent later on August 14, 2007, Dr. Owens stated he was keeping the case as Case Officer. (RX22 at 20).

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).

Response to Finding No. 190

Complaint Counsel has no specific response.

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).

Response to Finding No. 191

Complaint Counsel has no specific response.

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).

Response to Finding No. 192

This proposed finding is incomplete and inaccurate. CX0095 does not make any statement about whether the Board first attempted to send a cease and desist letter using certified mail.

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).

Response to Finding No. 193

Complaint Counsel has no specific response.

194. A subsequent visit to the salon revealed that teeth whitening services were no longer being offered or provided. (CX623 at 4).

Response to Finding No. 194

Complaint Counsel has no specific response.

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).

Response to Finding No. 195

Complaint Counsel has no specific response

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).

Response to Finding No. 196

This proposed finding is incomplete. The report came from a Hendersonville, North Carolina dentist who has a practice near the spa. (CX0037 at 001).

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).

Response to Finding No. 197

This proposed finding is incomplete. The Board staff member contacted the spa to make an appointment and learned the spa was no longer offering teeth whitening service on January 10, 2006. (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).

Response to Finding No. 198

This proposed finding is incomplete. Despite Ms. Smythe's conclusion that the spa no longer offered teeth whitening services, on January 11, 2006 the Board sent Serenity Day Spa a cease and desist order to cease "taking dental impressions to fabricate bleaching trays for 'professional teeth whitening.'" The Board stated that practicing dentistry without a license was subject to civil and criminal penalties and that Serenity Day Spa was "hereby ordered to CEASE AND DESIST any and all activities constituting the practice of dentistry" as defined by the Dental Practices Act. (CX0038 at 001; CX0554 at 033 (Allen Dep. at 125)).

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).

Response to Finding No. 199

This proposed finding is incomplete. In a letter received by the Board on April 12, 2006, Gale Barnett – a part-time employee at Serenity Day Spa and a dental assistant – assured the Board in response to a cease and desist letter that Serenity Day Spa does not take impressions for bleaching trays and merely sells bleaching kits. Ms. Barnett also explained that the complainant dentist has a practice next to the spa and may be so desperate for business that he is trying to intimidate other businesses so that customers desiring teeth whitening services would have to come to him. (CX0037 at 001).

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).

Response to Finding No. 200

This proposed finding is incomplete. Mr. Dempsey's Investigative memo dated February 16, 2007, states "I received an anonymous telephone call from an individual who worked at a dental office. . . ." (RX24 at 1).

201. Based upon the spa's advertising, a cease and desist letter was sent on February 23, 2007. (CX96; Hughes, Tr. 943-944).

Response to Finding No. 201

This proposed finding is misleading. The exhibit consists solely of the Board's cease and desist letter and a copy of a SheSheStudio spa teeth whitening brochure. Although the exhibit contains a copy of the spa's brochure, the exhibit provides no basis to determine why the Board sent the cease and desist letter based on the advertising. (CX0096). Moreover, Ms. Hughes did not testify (and could not, without speculating) that the Board sent its cease and desist letter based

on the spa's advertising. She testified she received Exhibit CX0096, the cease and desist letter, dated February 23, 2007, sent by the Board. (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).

Response to Finding No. 202

Complaint Counsel has no specific response.

203. Board Counsel sent a follow-up letter about the taking of impressions, which was returned undelivered. (RX24 at 1-2; CX368 at 5).

Response to Finding No. 203

Complaint Counsel has no specific response.

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).

Response to Finding No. 204

Complaint Counsel has no specific response.

205. Based on the evidence, the investigative panel recommended that the file be closed. (CX368 at 6).

Response to Finding No. 205

Complaint Counsel has no specific response.

Signature Spas, Case 06-193

206. The Board received a formal complaint on September 8, 2006. (RX25 at 17-21).

Response to Finding No. 206

This proposed finding is incomplete. On September 8, 2006, a Claremone, North Carolina dentist filed a complaint with the Board that described Signature Spas of Hickory as providing teeth whitening without a dentist or dental hygienist and included an advertisement of teeth whitening services from Signature Spas of Hickory as an attachment. (CX0611 at 002, 004).

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).

Response to Finding No. 207

Complaint Counsel has no specific response.

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).

Response to Finding No. 208

This proposed finding is incomplete. Ms. Bakewell informed Mr. Tickle that Signature Spas could not continue to offer teeth whitening without the participation of a licensed dentist. (CX00366-001).

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).

Response to Finding No. 209

This proposed finding is inaccurate and misleading. Signature Spa and Jack Tickle stipulated to a temporary restraining order, and consented to a permanent injunction before there

was any trial on the merits to determine whether the spa was in fact engaged in the unauthorized practice of dentistry. (CX0057 at 001-003; RX25 at 25-28).

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).

Response to Finding No. 210

This proposed finding is incomplete. Signature Spa voluntarily entered into a consent order temporarily restraining it from offering teeth whitening services. (CX0057 at 001-003). The proprietors of Signature Spas of Hickory offered to settle the matter by agreeing to stop providing teeth whitening services. In fact, Signature Spas of Hickory had already stopped providing teeth whitening services. (CX0231 at 001; CX0215 at 001; CCPFF ¶ 248). The Board was unwilling to accept a consent order unless the proprietors of Signature Spas of Hickory admitted that they were engaged in the unlawful practice of dentistry. (CX0212 at 001; CX0556 at 035 (Burnham, Dep. at 130-131); CX0211 at 001; CCPFF ¶ 249). Dr. Hardesty wrote to Drs. Burnham, Owens & Feingold, Bobby White, and Ms. Carolin Bakewell, "I personally think that we need to play hardball and have them admit to the illegal practice as we are in other litigation. I also think that we should have them taxed for us having to take this to court." (CX0214 at 001; CCPFF ¶ 249). The Board wanted the Signature Spas defendants to admit to the unauthorized practice of dentistry because they wanted to use it as precedent against other teeth whitening businesses. (CX0216 at 001-002; CCPFF ¶ 250). In fact, on May 14, 2008, Ellie Bradshaw sent an e-mail to Carolin Bakewell stating that the owners of Signature Spa would agree to enter a consent decree permanently enjoining them from violating the dental practice act. (CX0215 at

002). On March 19, 2008, Ms. Bakewell responded, "[w]as it not possible to get one of the partners/investors to agree to the actual violation? As drafted, the order doesn't really get my folks where they want to go." (CX0215 at 001). Ms. Bradshaw replied, "I think this is a reasonable result. These folks immediately ceased the service when you contacted them and have cooperated fully. They were assured by the manufacturer and rep that this was a safe aesthetic procedure. They have had no complaints or injuries. In short, they are responsible citizens who are doing their best to comply with the act. They have stopped offering the service and have agreed to an injunction from violating the act." (CX0215 at 001).

Additionally, based upon a conversation with Dr. Brown, Dr. Litaker indicated that the Board was hoping to get statements from non-dentist teeth whitening providers admitting guilt in order to set a precedent for future cases and for other states. (CX0576 at 012-013, 023-024, 030-031 (Litaker, Dep. at 40-42, 85-87, 113- 115); CCPFF ¶ 250). The Board was concerned about its likelihood of success on the merits of the case against Signature Spas of Hickory. As Mr. White stated, "[l]itigation is a roll of the dice and there is no guarantee we will come away with the finding we want." (CX0211 at 001; CCPFF ¶ 251). Although the Board's counsel advised the Board that a settlement would not provide legal precedent in other teeth whitening cases, the Board settled the matter. (CX0581 at 063-065 (Bakewell, Dep. at 243-251); CCPFF ¶ 251).

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).

Response to Finding No. 211

Complaint Counsel has no specific response.

{Spa White/White Science}, Case 07-020

212. **{There were allegations that this spa was performing teeth whitening services.}** (CX624 at 6, *subject to protective order*).

Response to Finding No. 212

This proposed finding is inaccurate. Spa White/White Science involves a kiosk, not a spa. (RPF ¶ 213).

213. **{Board Counsel visited this mall kiosk and gathered information.}** (RX26 at 2, *subject to protective order*). **{Internet research was also performed about the White Science teeth whitening system.}** (RX26 at 4-10, *subject to protective order*).

Response to Finding No. 213

Complaint Counsel has no specific response.

214. **{A follow-up visit was conducted by a Board investigator}** (RX26 at 2-3, *subject to protective order*), **{who spoke with George Nelson of White Science on the phone. Mr. Nelson confirmed that he had received a cease and desist order.}** (RX26 at 2, *subject to protective order*). **{The kiosk owner was advised by the investigator to contact Board Counsel.}** (RX26 at 3, *subject to protective order*).

Response to Finding No. 214

This proposed finding is incomplete. On December 19, 2007, Board investigator Line Dempsey visited the Spa White kiosk in Concord Mills Mall in Charlotte, North Carolina. Board attorney Carolin Bakewell had previously visited the kiosk. Mr. Dempsey spoke to the kiosk owner David Cogan, who when asked, stated that his business had never received a Cease and Desist Order from the Board. Mr. Cogan called White Science– the company that manufactured the products used in his kiosk– and spoke to White Science President George Nelson. (CX0258 at 001). Mr. Dempsey spoke to White Science President George Nelson while at the Spa White kiosk in Concord Mills Mall in Charlotte, North Carolina. Mr. Nelson stated that he had received a Cease and Desist Order, and that White Science was "working it all out" with the Board.

(CX0258 at 001). After speaking to White Science President George Nelson while at the Spa White kiosk in Concord Mills Mall in Charlotte, North Carolina, Mr Dempsey explained verbally to Spa White kiosk owner David Cogan that "he was practicing dentistry without a license and that he should cease and desist" and that he "needed to cease and desist" offering teeth whitening services. (CX0258 at 001).

215. **{A cease and desist order was sent to Spa White on January 29, 2008; no further action has been taken.}** (CX624 at 6, *subject to protective order*).

Response to Finding No. 215

Complaint Counsel has no specific response.

Star-Bright/Cutting Crib, Case 06-114

216. The Board received two complaints about "professional lab made bleaching trays" being offered at this salon in 2006. (RX27 at 6-10).

Response to Finding No. 216

This proposed finding is incomplete. One complaint came from a Sanford, North Carolina dentist and is dated May11, 2006. (RX27 at 6-8). The other was faxed from a dental office in Apex, North Carolina and appears to be dated May 8, 2006. (RX27 at 9-10).

217. A Board investigator made an anonymous call to inquire about the bleaching trays. (RX27 at 4-5).

Response to Finding No. 217

This proposed finding is incomplete. Line Dempsey made the anonymous phone call on May 12, 2006. (CX0044 at 006).

218. An on-site visit was made later that week. The proprietor stated that she did not take the impressions and had the client sign a release to that effect. A cease and desist letter was hand delivered during the visit on May 13, 2006. (RX27 at 1-2; CX235 at 3).

Response to Finding No. 218

The proposed finding is misleading. The cease and desist letter dated May 13, 2006 was created after the Board investigator, Line Dempsey, made a single phone call to inquire about the recipients teeth whitening services on May 12, 2006. (CX0044 at 001-006). The Cease and Desist Order, dated May13, 2006, sent to Stephanie R. Keith stated that the Board was investigating a report that she was engaged in the unlicensed practice of dentistry in violation of North Carolina law, which was punishable by civil and criminal penalties. Specifically, Ms. Keith was informed that she was violating G.S. 90-29(b)(7) for taking or making "an impression of human teeth." The Board told Ms. Keith that she was "hereby ordered to CEASE AND DESIST the practice of dentistry. (CX0044-004). On May 15, 2006 Mr. Dempsey, an investigator for the Board, submitted his report of his investigation of Star-Bright Whitening Systems teeth whitening procedures. Upon visiting the Star-Bright location Mr. Dempsey, Stephanie Keith, the owner, assured him that she does not take the impression of the customers; the customers take their own impression and send it to a company in Florida for a bleaching tray to be fabricated. Mr. Dempsey then presented her with the cease and desist order and gained her assurance that she would not take impressions in the future, despite her statement that she had not taken any impressions. (CX0232 at 001-002). Dr. Burnham, the Case Officer, (CX0044 at 001-005) testified that he did not know why a cease and desist order was sent to Stephanie Keith, on May 13, 2006, before an investigation was conducted. (CX0556 at 053 (Burnham, Dep. at 202-203); CX0044 at 004).

219. This case was recommended for closure by the investigative panel. (CX235 at 3).

Response to Finding No. 219

Complaint Counsel has no specific response.

{Suave D's}, Case 09-272

220. **{The Board received a complaint and advertisement for BleachBright teeth whitening at this salon on December 15, 2009.}** (RX28 at 3-4, *subject to protective order*).

Response to Finding No. 220

This proposed finding is incomplete. The complaint came from a Thomasville, North Carolina dentist.

221. **{The case was assigned to Dr. Owens, who telephoned the business and was told that although they did not insert the tray, they did everything else and that it was "just like at the dentist." Dr. Owens instructed the case manager to send a cease and desist letter.}** (RX28 at 1-2, *subject to protective order*; CX156, *subject to protective order*).

Response to Finding No. 221

Complaint Counsel has no specific response.

222. **{This case remains open.}** (CX317 at 5, *subject to protective order*).

Response to Finding No. 222

Complaint Counsel has not specific response.

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).

Response to Finding No. 223

Complaint Counsel has no specific response.

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).

Response to Finding No. 224

This proposed finding is inaccurate. CX0098 is not a cease and desist letter. CX0098 is an April 18, 2008 letter from Carolin Bakewell to Algis Augustine who represented non-dentist teeth whitening business WhiteScience, informing him that the Board refused his request to meet with them to discuss non-dentist teeth whitening. (CX0098 at 001; CX0521 at 001).

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).

Response to Finding No. 225

Complaint Counsel has no specific response.

226. The investigative panel recommended that the file be closed. (CX659 at 3).

Response to Finding No. 226

Complaint Counsel has no specific response.

{Tom Jones Express Smile}, Case 09-049

227. **{The Board received information about teeth whitening occurring at this pharmacy.}** (CX316 at 4, *subject to protective order*).

Response to Finding No. 227

This proposed finding is incomplete and inaccurate. Dr. Hardesty filed a complaint with the Board on February 18, 2009 against Tom Jones Drug regarding a business offering non-dentist teeth whitening services. On the same day, Dr. Hardesty was assigned as the Case Officer of the Tom Jones investigation. (CX0128 at 001; CX0160 at 001-007; CX0567 at 057-059 (Holland, Dep. at 221-226)).

228. **{Advertising claimed this establishment used "FDA approved, teeth whitening technology along with dental grade carbamide peroxide for a safe and effective way**

to whiten your teeth in 30 minutes or less guaranteed!"} (RX30 at 8, *subject to protective order*).

Response to Finding No. 228

Complaint Counsel has no specific response.

229. **{To determine whether the information that it received was credible, the Board's investigator paid a visit to the store on February 18, 2009.}** (CX316 at 4, *subject to protective order*).

Response to Finding No. 229

The citation does not support this proposed finding. It does not mention any investigation of this business or any indication that the Board tried to determine whether "the information that it received was credible" and simply confirms that a cease and desist letter was sent to this business on the same day the Board received the complaint from Dr. Hardesty and Dr. Hardesty was named the Case Officer of the investigation. (CX0128 at 001; CX0160 at 001-007; CX0567 at 057-059 (Holland, Dep. at 221-226); CX0316 at 004).

230. **{Based on the results of his investigation and the advertising that he received, the investigator hand delivered the cease and desist letter that day, February 18,2009.}** (CX58, *subject to protective order*).

Response to Finding No. 230

This proposed finding is incomplete. February 18, 2009 is also the same day that Dr. Hardesty filed the complaint against Tom Jones Drug and was also assigned as the Case Officer of the Tom Jones investigation. (CX0128 at 001; CX0160 at 001-007; CX0567 at 057-059 (Holland, Dep. at 221-226). In addition, the exhibit identified is the cease and desist letter the Board sent to Tom Jones Drug on February 18, 2009. However, standing alone, it provides no basis upon which the letter was sent. (CX0058 at 001-002).

231. **{The Board received a letter from a sales representative of the drug store, stating that they discontinued all advertising related to the removal of stains from the teeth. He also stated that the product was self-administered.}** (CX39, *subject to protective order*).

Response to Finding No. 231

The citation does not support this proposed finding. CX0039 is a brochure for a day spa. (CX0039).

232. **{An undercover visit was made to the pharmacy just over a year later. The visit revealed that teeth whitening was still being offered and was performed by a pharmacy technician who directed clients through the steps, positioned the light, and required completion of a consent form.}** (RX30 at 1-2,4-6, *subject to protective order*).

Response to Finding No. 232

This proposed finding is misleading. Ms. Smythe's stated in a sworn affidavit that the pharmacy technician said she would not put her hands in a client's mouth. (RX30 at 1). The affidavit also states that the customer applied the bleaching agent to his or her teeth using a pre-filled mouthpiece. (RX30 at 1).

233. **{This case remains open.}** (CX462 at 5, *subject to protective order*).

Response to Finding No. 233

Complaint Counsel has no specific response.

{WOW! Whitening on Wheels,} Case 09-049

234. **{Several complaints were received by the Board about this company.}** (RX32 at 2-5, *subject to protective order*).

Response to Finding No. 234

This proposed finding is misleading. Two complaints were received by the Board from licensed dentists about this company, including one from Board member Dr. Owens. Dr. Owens contacted Bobby White in October of 2008 and sent a brochure to the Board from "the

WOW wagon teeth whitening mobile van." (CX0411 at 003).

235. **{The company advertised "cosmetic teeth whitening is an FDA approved treatment" and mentioned positioning a "patented light." A 15 minute treatment was claimed to last six months to two years.}** (RX32 at 4-5, *subject to protective order*).

Response to Finding No. 235

Complaint Counsel has no specific response.

236. **{A cease and desist letter was sent November 12, 2008.}** (CX390, *subject to protective order*).

Response to Finding No. 236

Complaint Counsel has no specific response.

237. **{This file remains open.}** (CX462 at 4, *subject to protective order*).

Response to Finding No. 237

Complaint Counsel has no specific response.

I. The Board's Investigatory Process Is Properly Authorized.

i. Receipt of Complaints

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)).

Response to Finding No. 238

This proposed finding is misleading and inaccurate. Although it is true that the Board is complaint driven for most types of investigations (CCPFF ¶ 93), Board members themselves are the source of complaints. The Board has on its own volition initiated investigations into non-dentist teeth whitening. For example, Board member Dr. Owens contacted Bobby White in October 2008 and sent a brochure to the Board from "the WOW wagon teeth whitening mobile

van." (CX0411 at 003). The Board sent a "Notice and Order to Cease and Desist"dated November 12, 2008, to Mr. Nathaniel Vinke of Whitening on Wheels in Cornelius, North Carolina. (CX0390 at 001-002). The Board on several occasions listed itself as the complainant in non-dentist teeth whitening investigations, some resulting in a cease and desist order being sent. (CX0443 at 001; CX0444 at 001; CX0451 at 001; CX0453 at 001; CX0456 at 001; CX0458 at 001).

In at least one instance a Board member complained about a non-dentist teeth whitener and then was assigned as Case Officer for the same case. On February 18, 2009, Dr. Hardesty filed a complaint with the Board against Tom Jones Drug regarding its offering of non-dentist teeth whitening services; on the same day, Dr. Hardesty was assigned as the Case Officer of the Tom Jones investigation. (CX0128 at 001; CX0160 at 006; CX0567 at 057-059 (Holland, Dep. at 221-226)). Soon afterward, the Board hand-delivered a "Notice and Order to Cease and Desist" dated February 18, 2009 to Tom Jones Drug. (CX0058 at 001-002).

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).

Response to Finding No. 239

This proposed finding is misleading because it seeks to give the impression that complaints about teeth whitening "come in the form of a written, signed, and notarized complaint" when Board members and Board staff have admitted that teeth whitening complaints are accepted if they are not notarized, signed or written. (CCPFF ¶¶ 94, 98). While it is true that complaints against dentists must be in writing, signed, and notarized (CX0558 at 19 (Dempsey,

IHT at 72); CX0560 at 024-025 (Feingold, Dep. at 88-90)), the Board did not require that complaints against non-dentist teeth whiteners be in writing, signed, and notarized, and indeed the Board accepted anonymous complaints of non-dentist teeth whitening. (CX0566 at 021 (Hardesty, IHT at 78-79); CX0560 at 050 (Feingold, Dep. at 192); CX0563 at 007 (Goode, IHT at 23-25); CX0198 at 001-002). Ms. Goode also testified that the use of complaint forms are less common for complaints pertaining to teeth whitening than for other complaints. (CX0563 at 007 (Goode, IHT at 23-25)).

Although the unlicensed practice of dentistry is not listed in the Board's Investigations Manual as an exception to the rule that requires all complaints be in written form (CX0527 at 014), the Board will consider a complaint that a non-dentist teeth whitener is engaging in the unlicensed practice of dentistry even when the Board's normal complaint filing requirements are not met – the requirement for a notarized form may be waived. (CX0566 at 021 (Hardesty, IHT at 78-79)). And many of the complaints against non-dentist teeth whiteners leading to investigations came in the form of dentist complaints submitted by fax, e-mail, or by phone without any specific allegations of special circumstances that would warrant waiving in the requirement of a written, signed, and notarized complaint. (CX0035 at 001-002; CX0036 at 001-002, 005-006, 007-018; CX0043 at 001-002, 003-008, 009-010, 011-013; CX0045 at 002-006; CX0092 at 001; CX0198 at 001-002; CX0411 at 001, 003; CX0465 at 001; CX0619 at 001-002; CX0620 at 001).

According to Dr. Feingold, a complaint to the Board consisting of an advertisement that shows a potential occurrence of the unlicensed practice of dentistry could lead to an investigation

even if it was not submitted with a formal complaint form. (CX0560 at 050 (Feingold, Dep. at 192); CX0198 at 001-002).

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).

Response to Finding No. 240

Complaint Counsel has no specific response.

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)).

Response to Finding No. 241

Complaint Counsel has no specific response.

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)).

Response to Finding No. 242

Complaint Counsel has no specific response.

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).

Response to Finding No. 243

This proposed finding is inaccurate, unfounded, and irrelevant. Mr. White's testimony that the Federal Trade Commission "investigated" people who filed complaints regarding purported unlicensed practice of dentistry is inaccurate. (White, Tr. 2234-2235). The Federal Trade Commission did not open an investigation into any person that filed a complaint with the

Board, but did conduct discovery in this matter. Mr. White's testimony is thus unfounded. (White, Tr. 2234-2235). In addition, Mr. White's mere "opinion" that the current action had a "chilling effect on the Board's complaint process" is a naked assertion unsupported by reference to any evidence. (White, Tr. 2234-2235). Further, Board's counsel admitted in court that he elicited the testimony that is the basis of this proposed finding to "lay a foundation" for a potential claim for attorney fees in a separate proceeding. (Statement of Mr. Nichols, Tr. at 2235-2236). As such, this proposed finding should be disregarded as irrelevant.

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)).

Response to Finding No. 244

This proposed finding is inaccurate. The Board has closed or "resolved" teeth whitening cases in some instances after it has sent a Cease and Desist Order when the proprietor informed the Board that it had capitulated to the Board's order to cease and desist. (RX58 (Friddle, IHT at 44)). For example, the Board received notice of the FTC's investigation in early 2008 (CX0046 at 002 (March 2008 e-mail from Dr. Feingold referencing "FTC whitening matter")), but in a Closed Investigational File dated August, 25, 2008, Ms. Friddle recommended the closure of an investigation into Bailey's Lightning Whitening. (CX0658 at 005-006). The Board had received the complaint in June 2008 and thereafter sent a Cease and Desist Order. (CX0658 at 005; CX0387 at 001-002 (July 17, 2008, Cease and Desist Order)). Upon receiving the Cease and Desist Order, the salon owner responded by informing the Board that she immediately disposed of the whitening product and "has no plans to carry whitening products in the future." (CX0658

at 005). After this information was confirmed by a Board investigator, Ms. Friddle recommending closing the case in August, 2008 – well after the Board received notice of the FTC's investigation. (CX0658 at 005-006). In another example, after receiving a Cease and Desist Order from the Board (CX0042 at 028-029 (February 29, 2009)), a non-dentist teeth whitener responded on February 9, 2009 by promising that she would "no longer perform this service as per your order to stop and will no longer perform teeth whitening services unless told otherwise by the North Carolina Board of Dental Examiners." (CX0162 at 001).

Indeed, the Board has attempted to "resolve" numerous teeth whitening investigations after receiving notice of the FTC's investigation by sending many other Cease and Desist Orders to non-dentist teeth whiteners ordering them to "CEASE AND DESIST any and all activity constituting the practice of dentistry." (CX0059 at 001-002; CX0120 at 001-002; CX0122 at 001-002; CX0123 at 001-002; CX0387 at 001-002; CX0388 at 001-002; CX0389 at 001-002; CX0390 at 001-002; CX0391 at 001-002; CX0042 at 001-002; CX0042 at 008-009; CX0042 at 010-011; CX0042 at 012-013; CX0042 at 014-015; CX0042 at 016-017; CX0042 at 018-019; CX0042 at 020-021; CX0042 at 022-023; CX0042 at 024-025; CX0042 at 026-027; CX0042 at 028-029; CX0042 at 030-031; CX0042 at 032-033; CX0042 at 034-035; CX0058 at 001-002; CX0112 at 001-002; CX0153 at 001-002; CX0155 at 001-002; CX0156 at 001-002; CX0272 at 001-002).

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)).

Response to Finding No. 245

Complaint Counsel has no specific response.

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)).

Response to Finding No. 246

Complaint Counsel has no specific response.

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).

Response to Finding No. 247

This proposed finding is incomplete, inaccurate, and misleading. As a matter of fact, in many instances Case Officers authorized the sending of cease and desist letters before sending, or in lieu of sending, an investigator to investigate. (CCPFF ¶¶ 261-266). For instance, on March 22, 2007, Ms. Friddle sent an e-mail to Dr. Holland regarding the necessity of sending an undercover investigator to a non-dental teeth whitening provider, whom the Board might send a Cease and Desist Order. (CCPFF ¶ 263). Ms. Friddle explained that the Board was too busy to send a private investigator to the "spa deals," and therefore, "Dr. Hardesty has pretty much taken the stance that we write them a Cease and Desist Order the first go round." (CX0070 at 001; *see also* CCPFF ¶ 263). On at least five occasions, Ms. Friddle followed Dr. Hardesty's direction to

send a cease and desist order before an investigation was conducted. (CX0070 at 001; CX0561 at 022-023 (Friddle, Dep. at 81-84)). Mr. Friddle testified that in 2007 and 2008, Cease and Desist Orders were sent "fairly quickly, like shortly after the case was set up" (CX0562 at 013 (Friddle, IHT at 47)), and that "if it is unclear as to whether or not, or if it appears that there's a violation, then we would send a cease and desist." (CX0562 at 012 (Friddle, IHT at 43-44)).

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).

Response to Finding No. 248

Complaint Counsel has no specific response.

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)).

Response to Finding No. 249

This proposed finding is inaccurate and incomplete. Mr. Dempsey did testify that he believes that the Board's investigations manual is followed and that teeth whitening cases are under, "as I understand it, practicing dentistry without a license," but he also testified that he doesn't "categorize" cases and that it had been "many years" since he had reviewed the investigations manual; therefore, Mr. Dempsey's testimony should not be credited. (RX54 (Dempsey, IHT at 38-39, 54)). As a matter of fact, the Board's investigations manual was not followed by Case Officers in many instances. For example, the Board's investigations manual requires that "[c]ases will be randomly assigned to a Board Member (Case Officer) on the basis of

current case load, as well as the location of the respondent" (CX0527 at 008), yet there is testimony that "they just started assigning all of the teeth whitening cases to [Dr. Owens]" (CX0561 at 26-27 (Friddle, Dep. at 97-98)) because Dr. Owens assigned many of them to himself when he was Secretary-Treasurer. (Owens, Tr. 1445-1446, 1605; CCPFF ¶ 1292).

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)).

Response to Finding No. 250

Complaint Counsel has no specific response.

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)).

Response to Finding No. 251

It is undisputed that witnesses testified to this effect, but as a practical matter this proposed finding is incorrect. Board members other than the Case Officer on the investigation have in fact had knowledge of the details of the case. For instance, in the Hollywood Smiles/The Temple investigation Bobby White e-mailed a number of Board members regarding the suspected conduct in the case and described the specific facts of the case. (CX0041 at 001-003; *see also* CCPFF ¶¶ 232-233). In another example, Dr. Hardesty, a board member who was not the Case Officer on the investigation, was able to discuss details of the investigation with the complaining dentist. (Owens, Tr. 2263-2266; CX0365 at 001-002; *see also* CCPFF ¶ 218).

Of course, a vote of the Board is required to close an investigation. When a recommendation by an Investigative Panel to close an investigation is made, the details of the

investigation are made available to each of the six-dentist members of the Board (CCPFF ¶¶ 118, 119, 120; CX0562 at 004- 005 (Friddle, IHT at 13-14); CX0530 at 004; CX0659 at 001; CX0623 at 001).

In addition, knowledge of a case is imputed to each member of the Board because they have fully authorized the Case Officer to act on its behalf. (CX0527).

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)).

Response to Finding No. 252

Complaint Counsel has no specific response.

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)).

Response to Finding No. 253

This proposed finding is incorrect and misleading. Case officers have had knowledge of cases handled by another Case Officer. For instance, in the Hollywood Smiles/The Temple investigation Bobby White e-mailed a number of Board members regarding the suspected conduct in the case and described the specific facts of the case. (CX0041 at 001-003; *see also* CCPFF ¶¶ 232-233). In another example, Dr. Hardesty, a board member who was not the Case Officer on the investigation, was able to discuss details of the investigation with the complaining dentist. (Owens, Tr. 2263-2266; CX0365 at 001-002; *see also* CCPFF ¶ 218). In addition, knowledge of a case is imputed to each member of the Board because they have fully authorized the Case Officer to act on its behalf. (CX0527).

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).

Response to Finding No. 254

This proposed finding is incorrect. On a number of occasions Board members and employees have discussed the details of an investigation with a member of the public. (CCPFF ¶¶ 219, 322, 323). Some examples include when Dr. Hardesty discussed the details of an investigation, including that the Board would potentially seek an injunction, with non-Board dentist Dr. Heymann. (CX0365 at 001-002; Owens, Tr. 2263-2266). In another example, Ms. Bakewell informed two dentists who had complained about a mall kiosk that the Board had sent a letter to the operator of the mall, and included a copy of the letter. (CCPFF ¶¶ 322-323; CX0102 at 001-003; CX0524 at 001-003). In yet another example, the Board's Executive Director responded to a complaint from Dr. Casey of Raleigh, North Carolina about a teeth whitening kiosk in Crabtree Valley Mall by stating that the Crabtree Valley whitening kiosk is "one of many such 'bleaching kiosks' with which we are currently going forth to do battle," and that the Board had sent out "numerous cease and desist orders throughout the state." (CX0404 at 001-002).

255. Board members do not discuss with each other anything pertaining to cease and desist letters. (Hardesty, Tr. 2773).

Response to Finding No. 255

This proposed finding is inaccurate, misleading, and incomplete. Although it is undisputed that Dr. Hardesty testified to this point, Dr. Hardesty is not omniscient and is unqualified to testify as to the behavior of all other Board members – for such a sweeping statement all Board members would need to testify to this effect. As a factual matter, Board

members have discussed cease and desist letters to some degree, or such information is passed by Board employees from Board member to Board member. (CCPFF ¶¶ 254-256, 263). For example, Board members discussed the efficacy of using cease and desist letters after Mr. Dempsey suggested their widespread use, and came to the conclusion that the Board should use such letters. (CX0080 at 001-002; *see also* CCPFF ¶¶ 254-256). In another instance, Ms. Friddle explained to Dr. Holland that the Board was too busy to send a private investigator to the "spa deals," and therefore, "Dr. Hardesty has pretty much taken the stance that we write them a cease and desist letter the first go round." (CX0070 at 001; *see also* CCPFF ¶ 263).

256. Board members do not discuss with members of the general public anything pertaining to cease and desist letters. (Hardesty, Tr. 2773).

Response to Finding No. 256

This proposed finding is inaccurate, misleading, and incomplete. Although it is undisputed that Dr. Hardesty testified to this point, Dr. Hardesty is not omniscient and is unqualified to testify as to the behavior of all other Board members – for such a sweeping statement all Board members would need to testify to this effect. As a factual matter, Mr. White, although not a Board member, is an employee of the Board and he discussed the use of cease and desist letters against non-dentist teeth whiteners with a reporter and even sent a copy of a cease and desist order. (CX0369 at 001). Board members were aware of this action, including Dr. Hardesty. (CX0369 at 001).

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).

Response to Finding No. 257

This proposed finding is misleading, inaccurate, and incomplete. First, although it is undisputed that Dr. Hardesty testified to this point, Dr. Hardesty is not omniscient and is unqualified to testify as to the behavior of all other Board members – for such a sweeping statement all Board members would need to testify to this effect. Second, this proposed finding is misleading because it implies that communications about cease and desist orders with non-board dentists who are also complainants is somehow less serious than communications with non-board dentists who are not complainants. All dentists who are licensed in North Carolina are the constituents of the Board, and the Board is in a position to enhance their incomes through exclusion of non-dentists. (Kwoka, Tr. 1111-1112, 1115-1116; (CX0581 (Bakewell, Dep. at 20-21); White, Tr. 2276). The Board responds to complainant dentists by giving information about investigations because it wants to be responsive to its constituents and "follow through" with the complaint. (White, Tr. 2275-2276). Here the Board clearly admits by implication that Board members or employees discuss cease and desist orders with complainant dentists, who are the most likely non-Board member dentists to be discussing the issue with Board members.

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).

Response to Finding No. 258

This finding is misleading because the Board has fully authorized the Case Officer to act on its behalf and this finding gives the impression that the Case Officer acts without Board approval. (CX0527-0061).

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)).

Response to Finding No. 259

This proposed finding is based on inaccurate and misleading testimony. First, only Dr. Wester of the five people cited in this proposed finding actually supports the citation; the other four witnesses state that the Board's only options in a non-licensed person case is to seek a civil injunction or refer the matter for criminal prosecution. In fact, the Dental Practice Act authorizes the Board to address suspected instances of the unlicensed practice of dentistry in either of two ways: the Board may petition a state court for an injunction, (CX0019 at 020-021, Dental Practice Act § 90-40.1), or it may request the district attorney to initiate a criminal prosecution. (CX0019 at 020, Dental Practice Act § 90-40; CX0581 at 021-022 (Bakewell, Dep. at 76-80)). The remainder of the record contradicts the notion that the Board has the authority to send a cease and desist order. The great weight of testimony from Board members and employees shows that this is the Board's understanding as well. (Owens, Tr. 1444; White, Tr. 2224; Hardesty, Tr. 2770; CX0554 at 034-035 (Allen, Dep. at 129-130); CX0581 at 021-022 (Bakewell, Dep. at 76-80). With respect to teeth whitening investigations, Mr. White, the Board's Chief Operating Officer and a licensed attorney (White, Tr. 2188-2189), testified that the Board does not have the legal

authority to order anyone to stop violating the Dental Practice Act. (White, Tr. 2284). (*See also* CCPFF ¶¶ 81-89).

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).

Response to Finding No. 260

This proposed finding is incorrect, misleading, and directly contradicted by Respondent's finding No. 262 as to the assertion that the Board does not vote to file an injunction in a case. There is testimony from a Board member and a Board employee that the Board does vote to file a civil injunction in a case. (CX0567 at 041 (Holland, Dep. at 157)(Respondent designated relevant portion of testimony at lines 08-25, but did not provide copy of RX63 to Complaint Counsel); CX0581 at 023 (Bakewell, Dep. at 83-84)). Further, the Board's investigations manual states that "[b]efore the Investigative Panel may proceed with an injunction or Civil action against an individual, it must obtain approval by a majority vote of the Hearing Panel. (CX0527 at 041).

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)).

Response to Finding No. 261

This proposed finding is incorrect, misleading, and directly contradicted by Respondent's Finding No. 262 as to the assertion that the Board would not know that an injunction had been issued until the recipient challenged it in court. In fact, two of the witnesses cited for this proposed finding expressly rebut this assertion, testifying that the Board would be informed of this injunction at the next Board meeting. (Owens, Tr. 1444; White, Tr. 2224; *see also* CX0556

at 064 (Burnham, Dep. at 248)). Additionally, there is testimony from a Board member and a Board employee that the Board votes on whether to bring a civil injunction, so it is not true that the first time the Board will learn about an injunction is when the recipient challenges it in court. (CX0567 at 041 (Holland, Dep. at 157) (Respondent designated relevant portion of testimony at lines 08-25, but did not provide copy of RX63 to Complaint Counsel); (CX0581 at 023 (Bakewell, Dep. at 84)). Further, the Board's investigations manual states that "[b]efore the Investigative Panel may proceed with an injunction or Civil action against an individual, it must obtain approval by a majority vote of the Hearing Panel." (CX0527 at 041).

262. The Board would discuss and vote on whether to file civil litigation. (RX50 (Bakewell, Dep. at 84); RX63 (Holland, Dep. at 157)).

Response to Finding No. 262

This proposed finding is directly contradicted by Respondent's Finding Nos. 260-261 and the testimony of other Board members and employees. There is testimony from two Board members that the Board does not vote to file a civil injunction in a case. (Wester, Tr. 1285; Owens, Tr. 1444). Further, there is testimony that the Case Officer can direct the Board attorney to take civil action or recommend criminal prosecution in an unlicensed practice of dentistry case; if that happens the Board would be informed at the next Board meeting. (White, Tr. 2224; CX0556 at 064 (Burnham, Dep. at 248)).

263. The entire Board would vote to go ahead with a civil or criminal action. (RX58 (Friddle, IHT at 57-58)).

Response to Finding No. 263

This proposed finding is incorrect and directly contradicted by Respondent's Finding Nos. 260-261. There is testimony from two Board members that the Case Officer decides on whether

to bring a criminal or civil action without a Board vote. (Wester, Tr. 1284-1285; Owens, Tr. 1444). Further, there is testimony that the Case Officer can direct the Board attorney to take civil action or recommend criminal prosecution in an unlicensed practice of dentistry case; if that happens the Board would be informed at the next Board meeting. (White, Tr. 2224; CX0556 at 064 (Burnham, Dep. at 248)).

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)).

Response to Finding No. 264

This proposed finding is incorrect, ambiguous, and directly contradicted by Respondent's Finding Nos. 260-261. There is no testimony explaining what the word "resolved" means in this context, and so the finding is fatally ambiguous. The word "resolved" could mean either a vote for the closure of a case or a vote on how to proceed with a case. There is testimony from two Board members and a Board employee that the Case Officer decides on whether to bring a criminal injunction without a Board vote. (Wester, Tr. 1284-1285; Owens, Tr. 1444; White, Tr. 2224). The testimony from Dr. Owens, Dr. Brown, and Mr. White states that the Board does not vote on anything but the decision to close a case. (Owens, Tr. 1444; White, Tr. 2223-2224; CX0555 at 042 (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)).

Response to Finding No. 265

Complaint Counsel has no specific response.

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).

Response to Finding No. 266

This proposed finding is inaccurate. The Board states that it sent at least 40 Cease and Desist letters, and 18 would not be more than half of 40. (Joint Stipulation of Fact ¶ 30).

267. Dr. Owens assigned himself teeth whitening cases when he served as Secretary-Treasurer. (Owens, Tr. 1445-1446).

Response to Finding No. 267

Complaint Counsel has no specific response.

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)).

Response to Finding No. 268

This proposed finding is incorrect, misleading, and not supported by the citation. Ms. Friddle actually said that she "[didn't] know if there was an official discussion, but because Dr. Owens had a number of teeth whitening cases . . . they just started assigning all of the teeth whitening cases to him." (CX0561 at 026-027 (Friddle, Dep. at 97-98). Dr. Owens had a number of teeth whitening cases because he assigned them to himself when he was Secretary-Treasurer. (Owens, Tr. 1445-1446, 1605; CCPFF ¶ 1292).

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)).

Response to Finding No. 269

Complaint Counsel has no specific response.

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).

Response to Finding No. 270

Complaint Counsel has no specific response.

271. Teeth whitening products and services constituted only about {1.5 percent} of Dr. Owens' practice revenues for {2005-2010}. (CX467 at 1, subject to protective order).

Response to Finding No. 271

Complaint Counsel has no specific response.

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).

Response to Finding No. 272

This proposed finding is misleading and incorrect. The unrebutted testimony is that the Cease and Desist Orders were intended to be official orders to stop non-dentist teeth whiteners from offering teeth whitening services, that non-dentist teeth whiteners viewed the Cease and Desist Orders as an order to stop teeth whitening backed by the full authority of the state of North Carolina, and that non-dentist teeth whiteners in fact did stop offering teeth whitening services after receiving a Cease and Desist Order. (CCPFF ¶¶ 294-314, 628-639). These Cease and Desist Orders, although effective, were sent by the Board without statutory authority. (CCPFF ¶¶ 81-89).

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)).

Response to Finding No. 273

Complaint Counsel has no specific response.

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)).

Response to Finding No. 274

The cited evidence does not support this proposed finding and is also a legal conclusion. Nevertheless, Ms. Bakewell testified that the Board does not have the authority to issue enforceable orders to cease and desist to a nonlicensee. (RX050 (Bakewell, Dep. at 215) ("Q. The Board does not have any authority to order in that sense [self-executing] a nonlicensee to do or refrain from doing anything at all. A. Right, and no – no other agency or court does either."); CCPFF ¶ 88. Bakewell's testimony does not reflect the fact that the Board has authority to issue self-executing subpoenas to nonlicensees, (CX019 at 006, N.C. Gen. Stat. § 90-27 ("Any person who shall reject or refuse to obey any subpoena [issued by the Board] . . . shall be guilty of a Class 1 misdemeanor.")). Likewise, Dr. Morgan testified that he was aware of no authority that permitted the Board to issue orders to nonlicensees. (RX65 (Morgan, Dep. at 247-248)). Other facts contradict this proposed finding as well. CCPFF ¶¶ 81 (Board has no authority over non-dentists and its only recourse is through the courts), 84 (unlicensed dental practice violations can only be enjoined by the Superior Court), 85 (unlicensed dental practice can only be addressed civilly or criminally through the courts), 86 (the Board cannot address unlicensed practice of

dentistry through an administrative hearing), 87 (Board has no authority to discipline non-licensees), and 89 (White testified the Board has no legal authority to order anyone to stop violating the Dental Practice Act).

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. (CXI9 at 20; RX50 (Bakewell, Dep. at 215)).

Response to Finding No. 275

This proposed finding is a conclusion of law, is not a finding of fact, and is a misstatement of law. The cited provisions of the Dental Practice Act do not "clearly" grant the Board any authority, or obligation, to provide any pre-trial notice to prospective defendants. In addition, Respondent's Counsel Mr. Nichols represented to the Court that the Respondent was not arguing that the Cease and Desist orders were litigation threat letters as this proposed finding or conclusion of law does. (Tr. 1612-1614). Further, nothing in the Dental Practice Act clearly grants the authority to the Board to notify prospective defendants in advance of initiating a judicial proceeding; indeed, the Dental Practice Act says nothing at all in this regard. (CX0019 at 20-21, Dental Practice Act §§ 90-40, 90-40.1).

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).

Response to Finding No. 276

This proposed finding is inaccurate, misleading, and an improper conclusion of law. Complaint Counsel has, in fact, demonstrated in multiple filings that the Board's actions are a violation of federal law (*see, e.g.*, Complaint Counsel's Post-Trial Brief at 70-106; Complaint

Counsel's Pre-Trial Brief at 5-18), but Respondent's attempt to masquerade a conclusion of law as a finding of fact is improper, particularly since Respondent cites to the entire record rather than specific findings.

277. Complaint Counsel has made no presentation of fact that any such cease and desist letter has restrained any lawful activity. (Entire record).

Response to Finding No. 277

This proposed finding is inaccurate and contains a conclusion of law. It is improper for Respondent to assert that non-dentist teeth whitening is lawful or unlawful. Further, there are numerous examples that non-dentist teeth whiteners have left the market or altered their business practices because of the Cease and Desist Orders. (CCPFF ¶¶ 312-313, 628-639). Respondent's economic expert acknowledged that the cease and desist letters "were effective and many kiosk and spa operated [*sic*] complied" by ceasing teeth whitening. (RX78 at 008). Contemporaneous evidence and trial testimony that non-dentists left the market after receiving a cease and desist order includes: (1) Amazing Grace Day Spa stopped offering teeth-whitening services after receiving a Cease and Desist Order from the Board (CX0347 at 001); (2) after receiving a Cease and Desist Order from the Board, the owner of Champagne Taste Salon, also known as "Lash Lady" wrote to the Board stating that "they have now stopped offering [teeth whitening] service[s]" (CX0622 at 003); (3) Modern Enhancement Salon owner Tonya Norwood notified that Board that her salon "no longer performs this service as per your order to stop and will no longer perform whitening services unless told otherwise by the NC Board of Dental Examiners" (CX0162 at 001); a Bleach Bright business in Carolina Place Mall was "forced out of business" after receiving a Cease and Desist Order from the Board (CX0815 at 001); (4) Margie Hughes of

SheShe Studio Spa testified that she stopped offering teeth whitening services immediately upon receiving the Board's Cease and Desist Order dated February 23, 2007 (Hughes, Tr. 946); (5) Details, Inc. notified the Board that it had sold its teeth whitening equipment and was no longer providing teeth whitening services (CX0660 at 003); (6) after receiving a Cease and Desist Order from the Board the owner of Bailey's Lightening Whitening wrote to the Board that "due to [the Cease and Desist Order she] had disposed of the [teeth whitening] product" and "would not be providing any teeth whitening services at her salon" (CX0658 at 005); and (7) two business reduced or eliminated advertising teeth whitening services after receiving a Cease and Desist Order. (Hughes, Tr. 946; CX0309 at 001).

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).

Response to Finding No. 278

This proposed finding is misleading and certainly not supported by the citations. Nothing within the citations supports the assertion that Cease and Desist letters or orders are "time-honored, customary, and widely-accepted" by boards either within or without North Carolina. (White, Tr. 2226-2227; RX37 at 2; RX38; RX39).

As to RX 38 or RX 39, Mr. White did not lay a foundation for either exhibit. The cited testimony does not explain whether the single letter from two other states were sent, are currently in use, or represent a single one-off letter sent by the state. A single exhibit that consists of a letter that may or may not have been utilized by another state is hardly evidence to support that

cease and desists letters sent by other states are "time-honored, customary, and widely-accepted."(White, Tr. 2226-2227; RX38; RX39). Similarly, the reference in a newsletter citing currently issued cease and desist orders does not support the proposition that cease and desist letters are a "time-honored, customary, and widely-accepted" because the article states that the dental board in that state began the practice in November of 2009. Even if the purported evidence was found to be reliable, it only stands for the proposition that three boards in other states may have used have used cease and desist letters at some time which certainly does not support that they are "widely accepted." (White, Tr. 2226-2227; RX37 at 2; RX38; RX39).

Nor does the testimony of Mr. White with regard to North Carolina support the finding. Mr. White merely testified that three out of nearly sixty other boards within North Carolina used cease and desist letters – hardly "widely accepted." (White, Tr. 2226-2227; RX37 at 2; RX38; RX39; CX0862). The assertion that cease and desist letters are "time honored" is further refuted by the fact that the Board itself only began using letters entitled "cease and desist" in 2006. (*See* CCPFF ¶¶ 254-257; White, Tr. 2338-2339). And previously, with respect to allegations of the unauthorized practice, the Board used other forms of letters. For example, in October 2000, a letter sent to Ortho Depot regarding alleged unauthorized practice of dentistry had no heading stating "Cease and Desist," nor did the body of the letter state "You are hereby ordered to cease and desist." Instead, the Board stated "This is to advise you that the North Carolina State Board of Dental Examiners is considering initiating a civil suit to enjoin you from the unlawful practice of dentistry." (CX0136 at 001 (October 3, 2000); CX0139 at 001 (December 10, 2001); CX0138 at 001 (February 12, 2002)).

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).

Response to Finding No. 279

This proposed finding is misleading, inaccurate, and not supported by evidence in the record. The North Carolina Board of Massage & Bodywork Therapy's ("Massage Board") statutory authority is not similar to that of the Dental Board's in that the Massage Board has the express authority to levy civil penalties of as much as $1,000 against licensees and nonlicensees for any violations of its Act. (N.C. Gen. Stat. § 90-634.1). Further, the selective newsletters of the Massage Board that Respondent has entered into evidence do not include any exemplars of such cease and desist orders entered by the Massage Board; accordingly, there is no evidence in the record that the Massage Board's cease and desist orders were in any way comparable to the cease and desist orders issued by the Dental Board. Finally, there is no evidence in the record that the Massage Board continued to issue its cease and desist orders after having received notice of the pendency of this matter against the Dental Board.

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).

Response to Finding No. 280

Complaint Counsel has no specific response.

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).

Response to Finding No. 281

This proposed finding is incomplete and misleading. Most (42) of the Cease and Desist Orders sent to non-dentist teeth whiteners also contain bold, capitalized headings that state: "NOTICE AND ORDER TO CEASE AND DESIST" or "NOTICE TO CEASE AND DESIST," or "CEASE AND DESIST NOTICE." (CCPFF ¶ 287). In addition to the headings and the text noted in the finding, the Cease and Desist Orders sent to 39 non-dentist teeth whitening service providers, stating: "The North Carolina State Board of Dental Examiners is investigating a report that you are engaged in the unlicensed practice of dentistry. Practicing dentistry without a license in North Carolina is a crime. See (NC General Statutes § 90-40 and § 90-40.1)." (*See* Cease and Desist Orders listed in CCPFF ¶ 288).

Further, three of the cease and desist orders included the language: "The Dental Board hereby demands that you CEASE AND DESIST any and all activity constituting the practice of dentistry as defined by North Carolina General Statutes § 90-29 and the Dental Board Rules promulgated thereunder." (CCPFF ¶ 289). Finally, the finding is misleading in that it implies that an order to cease and desist "any and all activity constituting the practice of dentistry or dental hygiene" was not sufficient to induce non-dentist teeth whiteners to exit the whitening market, but the substantial evidence shows that it was. (CCPFF ¶¶ 312-313, 628-639).

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)).

Response to Finding No. 282

This proposed finding is incomplete, misleading, and not supported by the citations. Dr. Wester, Mr. White, and Ms. Friddle did not testify as to who drafted the Cease and Desist Orders. (Wester, Tr. 1286; White, Tr. 2227; RX57 (Friddle, Dep. at 62-63)). In fact, Mr. White, the

Board's Chief Operations Officer, drafted the Cease and Desist Orders used in "grillz" cases (White, Tr. 2335), the letter that sparked the use of cease and desist letters for non-dentist teeth whitening. (CCPFF ¶ 254-257, White, Tr. 2334-2336).

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)).

Response to Finding No. 283

Complaint Counsel has no specific response.

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).

Response to Finding No. 284

Complaint Counsel has no specific response.

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)).

Response to Finding No. 285

Complaint Counsel has no specific response.

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)).

Response to Finding No. 286

Complaint Counsel has no specific response.

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)).

Response to Finding No. 287

This proposed finding is misleading and incorrect. First, the evidence shows that Case Officers authorized the sending of Cease and Desist Orders before any investigation – and without reference to "credible evidence" – because the Board was too busy to send a private investigator to the "spa deals," and that if the Cease and Desist Orders did not work the Board would "move in with the big guns." (CCPFF ¶ 263). In fact, when Dr. Hardesty directed Ms. Friddle to "write [non-dentist teeth whitening businesses] a cease and desist letter the first go round," Ms. Friddle understood that to mean to send a Cease and Desist Order when a complaint initially came in, and on at least five occasions she followed Dr. Hardesty's directions. (CX0070 at 001; CX0561 at 022-023 (Friddle, Dep. at 81-84)). Further, Ms. Friddle testified that in 2007 and 2008, Cease and Desist Orders were sent "fairly quickly, like shortly after the case was set up," and that cease and desist letters were sent in situations where "it is unclear as to whether or not" there was a violation. (CCPFF ¶ 265, 266; CX0562 at 012-013 (Friddle, IHT at 43-47)). This hardly seems like a "credible evidence" standard, and indeed the term "credible evidence" is never mentioned in the citations.

Second, even in situations where there was an advertisement or website attached to the complaint, Case Officers did not require anything approaching credible evidence to send a Cease and Desist Order. For instance, Dr. Hardesty authorized the sending of a Cease and Desist Order to a salon solely based on an e-mail from a dentist and his review of the website for the whitening product that the salon was considering using; not only did the salon not offer teeth whitening, but the complaining dentist never even claimed that it did. (CX0565 at 043-044 (Hardesty, Dep. at 163-168); CX0293 at 001). (*See also* CCPFF ¶¶ 206-266).

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) ({Celebrity Smiles, #07-208, eye witness report from a noted teeth bleaching expert, who was told by retail staff that a 44 % carbamide peroxide solution was being used; an internet search of the company's claims was also performed prior to the issuance of the cease and desist letter}); (RXI0 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)).

Response to Finding No. 288

This proposed finding is unfounded, misleading, and incorrect. First, Respondent only cites to four examples to support its broad assertion that "in every instance" the Board had *prima facie* evidence before sending a Cease and Desist Order. Further, none of the citations referenced in this proposed finding make the assertion that "in every instance" the Board had *prima facie* evidence from a credible source of a violation, and the citations referenced in this proposed finding are neither examples of *prima facie* evidence nor offer a representative sample that one could draw such a conclusion from. (RX7 at 3; RX9 at 2, 7; RX10 at 2; RX58 (Friddle, IHT at 53-54)). In fact, some of the citations in this proposed finding are mere advertisements, without more, and none of the citations in this proposed finding represent that an advertisement alone constitutes *prima facie* evidence from a credible source of a violation. (RX7 at 3; RX10 at 2).

Second, the evidence shows that Case Officers have authorized Cease and Desist Orders without credible evidence of a violation. Dr. Hardesty directed Ms. Friddle to "write [non-dentist teeth whitening businesses] a cease and desist letter the first go round"; Ms. Friddle understood that to mean to send a Cease and Desist Order when a complaint initially came in, and on at least five occasions she followed Dr. Hardesty's directions. (CX0070 at 001; CX0561 at 022-023 (Friddle, Dep. at 81-84)). Further, Ms. Friddle testified that in 2007 and 2008, Cease and Desist Orders were sent "fairly quickly, like shortly after the case was set up," and that cease and desist

letters were sent in situations where "it is unclear as to whether or not" there was a violation. (CCPFF ¶ 265, 266; CX0562 at 012-013 (Friddle, IHT at 43-47)). In another example, Dr. Hardesty authorized the sending of a Cease and Desist Order to a salon solely based on an e-mail from a dentist and his review of the website for the whitening product that the salon was considering using; not only did the salon not offer teeth whitening, but the complaining dentist never even claimed that it did. (CX0565 at 043-044 (Hardesty, Dep. at 163-168); CX0293 at 001). In fact, Dr. Brown testified that the point in an investigative process that a Cease and Desist Order would be issued would probably be if there wasn't clear evidence that a case against the target of the investigation could be won. (CX0555 at 060 (Brown, Dep. at 231)). This is hardly *prima facie* evidence from a credible source of a violation. (*See also* CCPFF ¶¶ 206-266).

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. (CXI53; CX155; CXI56).

Response to Finding No. 289

Complaint Counsel has no specific response.

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. *14S1, ISIS-ISI8;* White, Tr. 2229; RX49 (Allen, Dep. at 126-127); RXSO (Bakewell, Dep. at *21S);* RXS2 (Burnham, Dep. at 102-103); RX63 (Holland, Dep. at *12S-126);* RX64 (Kurdys, Dep. at 118)).

Response to Finding No. 290

This proposed finding is incorrect, not supported by the citations, and irrelevant. First, the Commission has already found that the Cease and Desist Orders were in fact orders. "The undisputed facts show that the Board on numerous occasions sent letters to non-dentist providers,

alleging that those recipients were engaging in the unauthorized practice of dentistry in violation of North Carolina laws, and ordering the recipients to cease and desist from providing teeth-whitening services in North Carolina." (State Action Opinion at 5).

Second, testimony from Board members and employees demonstrates that they viewed the cease and desist letters as orders to stop. (CCPFF ¶ 294). Dr. Wester testified that the Cease and Desist Order was a message that "they should stop" or "cease and desist" from engaging in teeth whitening activities. (CX0572 at 016 (Wester, Dep. at 57)). Dr. Allen testified that he agreed that with a Cease and Desist Order, the "board [is] saying that you not only are ordered but you have the responsibility to comply with this order[.]" (CX0554 at 034 (Allen, Dep. at 126-127)). Dr. Allen further testified that a Cease and Desist Order from the Board is "an order in the sense that the board as the State's designee to regulate the practice of dentistry and protect the public is – is telling you not to do this anymore . . . . I mean, the letter implies that if you continue to do it you'll be either fined or in prison if you continue." (CX0554 at 034 (Allen, Dep. at 127-128)). Dr. Burnham believes that the Board sending a Cease and Desist Order to a non-dentist teeth whitener is "the same thing as filing a lawsuit." (RX0052 at 31 (Burnham, Dep. at 117-118)). Dr. Wester testified that he treats a Cease and Desist Order sent by a Case Officer as essentially the same thing as an injunction or a court order, because the expected impact of a Cease and Desist Order is that the recipient will stop doing what the Board wants them to stop doing. (Wester, Tr. 1337-1338, 1352-1353). Mr. White testified that a Cease and Desist Order issued by the Board is "ordering [the recipient] either to stop whatever that activity is or to demonstrate why what they're doing is not a violation of the Act." (CX0573 at 007 (White, Dep. 19-20)). Mr.

White also testified that he understands that in common parlance, "an order is viewed as a command to stop." (CX0573 at 010 (White, Dep. at 31)).

Third, contemporaneous e-mails, letters, and reports drafted by Board members and Board staff confirm that the Cease and Desist Orders sent were intended to be orders. (CX0254 at 001; CX0258 at 001-002; CX0347 at 001). For example, On November 26, 2007, Board Investigator Line Dempsey wrote in an e-mail to Dr. Owens, Terry Friddle, Carolin Bakewell, Bobby White and Casie Goode, that he "was able to serve the Cease and Desist Order to Ms. Heather York" of Celebrity Smiles. (CX0350 at 001). The next day, on November 27, 2007, Ms. Carolin Bakewell wrote in an e-mail that the Board "has recently issued cease and desist orders to an out of state company that has been providing bleaching services in a number of malls in the state." (CX0254 at 001). Similarly, on February 20, 2008, Mr. Bobby White wrote in an e-mail in response to a dentist's complaint, "We've sent out numerous cease and desist orders throughout the state." (CX0404 at 001). (*See generally* CCPFF ¶¶ 302-311).

Fourth, recipients reasonably understood the letters to be orders to cease and desist. (*See generally* CCPFF ¶¶ 312-314).

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)).

Response to Finding No. 291

This proposed finding is incorrect and misleading. The Board could not have been seriously intending to educate non-dentist teeth whiteners about the law given that the letters ordered recipients to cease and desist the unlicensed practice of dentistry (not teeth whitening), and then quotes statutory language that does not reference teeth whitening. (*See, e.g.,* CX0042 at

001-002; CCPFF ¶¶ 287-289). Further, there appears to be no contemporaneous evidence to the sending of the Cease and Desist Orders that demonstrates the inclusion of the statutory language is anything other than what it appears to be – a club to frighten non-dentist teeth whiteners into stopping teeth whitening. The great weight of testimony and evidence from Board members and employees, as well as from non-dentists teeth whiteners, is that the letters were intended and interpreted to be orders to cease and desist, not as informational letters about North Carolina's laws. (CCPFF ¶¶ 294-314, 632). In fact, Dr. Brown testified that the point in an investigative process that a Cease and Desist Order would be issued would probably be if there wasn't clear evidence that a case against the target of the investigation could be won. (CX0555 at 060 (Brown, Dep. at 231)).

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)).

Response to Finding No. 292

This proposed finding is incorrect and misleading. Recipients of a cease and desist order are not "voluntarily" complying if they believe that the Cease and Desist Order is a mandatory order from a state agency. (CCPFF ¶¶ 312-314, 632). Further, it is clear from contemporaneous evidence and from testimony that the Cease and Desist Orders were actually intended be methods whereby the Board induced non-dentists to exit the teeth whitening market without having to launch an investigation or bring a court case (CCPFF ¶¶ 254-257; CX0562 at 012 (Friddle, Dep. at 44)), and that Board members and employees viewed the Cease and Desist Orders as orders to stop, not a common sense method by which persons were given an opportunity to voluntarily

comply. (CCPFF ¶¶ 294-311). In fact, Dr. Brown testified that the point in an investigative process that a Cease and Desist Order would be issued would probably be if there wasn't clear evidence that a case against the target of the investigation could be won. (CX0555 at 060 (Brown, Dep. at 231)). In addition, Respondent's Counsel Mr. Nichols represented to the Court that the Respondent was not arguing that the cease and desist orders were litigation threat letters as this proposed finding suggests. (Tr. 1612-1614).

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).

Response to Finding No. 293

Complaint Counsel has no specific response.

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)).

Response to Finding No. 294

This proposed finding is incorrect and misleading. Recipients of a cease and desist order are not "voluntarily" complying if they believe that the Cease and Desist Order is a mandatory order from a state agency, as it was intended to be viewed by the Board. (CCPFF ¶¶ 294-314, 632). In addition, nothing in the given citation states that non-dentist teeth whiteners are voluntarily stopping teeth whitening in response to Cease and Desist Orders. (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. § I50B-23(a)).

Response to Finding No. 295

This proposed finding is inaccurate and misleading. The only hearings authorized by the Dental Practice Act (CX0019 at 023, N.C. Gen. Stat. § 90-41.1) are hearings initiated by the Board through the service of a notice on a "licensee, provisional licensee, intern, or applicant for license;" the provisions of the statute do not extend to non-dentist providers or other non-licensees or non-applicants. (CX0019 at 023; CCPFF ¶ 86).

The only hearings authorized by the North Carolina Administrative Practice Act that may be conducted before the Board (N.C. Gen. Stat. § 150B-38) are hearings commenced by the issuance of a notice of hearing by the Board. Under the Board's rules, the Board does not have to grant a non-licensee a hearing. (CX0514 at 044 (21 N.C.A.C. 16N.0503(a) ("The Board will decide whether to grant a request for a hearing."). Even if requested, the Board has the ability and incentive to cherry-pick only claims that it is certain to win.

Cease and Desist Orders issued to non-dentist teeth whiteners and manufacturers of teeth whitening products did not provide the recipients notice of any right to a contested case before the Board to challenge the validity of the Board's interpretation of the Dental Practice Act. (*See*, *e.g.*, CX0042 at 001-002 (Cease and Desist Order of January 19, 2009, issued to James and Linda Holder); CX0100-001 (Cease and Desist Order of December 4, 2007, issued to White Science)).

The Board sent at least 40 Cease and Desist Orders to non-dentist teeth whiteners (Joint Stipulation of Fact ¶ 30) that did not include notice of an opportunity to file a contested case before the Board (*Compare* Board's Opening Stmt., Tr. 67 (". . . since we have the model Administrative Procedure Act in North Carolina, they could have filed . . . a contested case before the board. . . .") *with* CX0042 at 001-002 (January 19, 2009, Cease and Desist Order to James &

Linda Holder) *with* Board Rule 21 N.C.A.C. 16N.0501 (CX0514 at 044) ("When the Board acts . . . in a manner which will affect the rights . . . of a person, such person has a right to an administrative hearing. When the Board proposes to act in such a manner, *it shall give such person notice of his right to a hearing* by mailing by certified mail to him at his last known address a notice of the proposed action and a notice of a right to a hearing.") (emphasis supplied)).

The Board issued a Cease and Desist Order to a manufacturer of products used by non-dentist teeth whiteners (CX0100 at 001 (December 4, 2007, Cease and Desist Order from Carolina Bakewell to White Science, Roswell, Georgia) that did not include notice of an opportunity to file a contested case before the Board. (*Compare* Board's Opening Stmt., Tr. at 67 (". . . since we have the model Administrative Procedure Act in North Carolina, they could have filed . . . a contested case before the Board. . . .") *with* (CX0100 at 001 (December 4, 2007, Cease and Desist Order from Carolina Bakewell to White Science, Roswell, Georgia) *with* Board Rule 21 N.C.A.C. 16N.0501 (CX0514 at 044) ("When the Board acts . . . in a manner which will affect the rights . . . of a person, such person has a right to an administrative hearing. When the Board proposes to act in such a manner, *it shall give such person notice of his right to a hearing* by mailing by certified mail to him at his last known address a notice of the proposed action and a notice of a right to a hearing.") (emphasis added)).

Even if the Board were authorized to conduct contested cases where the respondent would be a non-licensee or a non-applicant, the cease and desist orders issued by the Board to non-dentist teeth whiteners and manufacturers of teeth whitening products did not comply with the notice requirements of the Board's rules governing contested cases. (CX0514 at 044 (21

N.C.A.C. 16N.0501) ("When the Board proposes to act in such [a manner which will affect the rights, duties, or privileges of a person], *it shall give such person notice of his right to a hearing* by mailing by certified mail to him at his last known address a notice of the proposed action and *a notice of a right to a hearing.*") (emphasis added)); (*See, e.g.,* CX0042 at 001-002 (Cease and Desist Order of January 19, 2009, issued to James and Linda Holder); CX0100 at 001 (Cease and Desist Order of December 4, 2007, issued to White Science)).

The refusal on a variety of pretexts of the Board's legal counsel, Carolin Bakewell, to meet with lawyers representing non-dentist teeth whitening interests to discuss the Board's position on non-dentist teeth whitening is inconsistent with the Board's contention at trial that recipients of Cease and Desist Orders and other negative communications regarding non-dentist teeth whitening could, or even should, have obtained hearings before the Board. (*Compare* CX0257 at 001 (letter from Carolin Bakewell to Chicago attorney Algis Augustine dated March 10, 2008) ("The Dental Board will be pleased to communicate with you about this matter if you obtain a written opinion from the North Carolina State Bar, indicating that your participation does not constitute the unauthorized practice [of] law, or, alternatively, if you retain North Carolina counsel.") *with* CX0098 at 001 (letter from Carolin Bakewell to Chicago attorney Algis Augustine dated April 18, 2008) ("Under the present circumstances, the Board does not believe that an in person meeting would be productive.").

Recipients of the mall letters (Joint Stipulations ¶ 31) issued by Carolin Bakewell on November 21, 2007, did not receive any notice of hearing rights before the Board regarding the Board's interpretation of the Dental Practice Act contained in such letters. (*See, e.g.,* CX0203 (Blue Ridge Mall); CX0204 (CBL & Associates Properties, Inc., Chatanooga, Tennesee);

CX0205 (Colonial Mayberry Mall Office); CX0259 (Cleveland Mall Office); CX0260 (General Growth Properties, Chicago, Illinois); CX0261 (Hendon Properties, Atlanta, Georgia) ; CX0262 (University Mall Office); CX0263 (Westfield Eastridge Mall Office); CX0323 (Boone Mall Management); CX0324 (Northgate Mall Office); CX0325 (Randolph Mall Management Office). On that same date, Carolin Bakewell also sent at least one e-mail to another mall that contained the identical information that was in the forgoing letters. (CX0326)(Crabtree Valley Mall)).

The Board sent at least 11 letters to third parties, including out-of-state property management companies, indicating that "North Carolina law specifically provides that the removal of stains from human teeth constitutes the practice of dentistry" (Joint Stipulation of Facts ¶ 31) that did not include notice of an opportunity to file a contested case before the Board. (*Compare* Board's Opening Stmt., Tr. 67 (". . . since we have the model Administrative Procedure Act in North Carolina, they could have filed . . . a contested case before the board. . . .") *with* CX0260 at 001-002 (November 21, 2007, letter from Carolin Bakewell to General Growth Properties, Chicago, Illinois) *with* Board Rule (CX0514 at 044 (21 N.C.A.C. 16N.0501 ("When the Board acts . . . in a manner which will affect the rights . . . of a person, such person has a right to an administrative hearing. When the Board proposes to act in such a manner, *it shall give such person notice of his right to a hearing* by mailing by certified mail to him at his last known address a notice of the proposed action and a notice of a right to a hearing.") (emphasis supplied)).

The Board sent a letter to a manufacturer of products used by non-dentist teeth whiteners advising that the users of the manufacturer's product are committing a misdemeanor under N.C. Gen. Stat. § 90-40 (CX0371 at 001 (February 13, 2007, letter from Carolin Bakewell to Enhanced

Light Technologies, Charlotte, North Carolina) that did not include notice of an opportunity to file a contested case before the Board. (*Compare* Board's Opening Stmt., Tr. 67 (". . . since we have the model Administrative Procedure Act in North Carolina, they could have filed . . . a contested case before the board. . . .") *with* (CX0371 at 001 (February 13, 2007, letter from Carolin Bakewell to Enhanced Light Technologies, Charlotte, North Carolina)) *with* Board Rule 21 N.C.A.C. 16N.501 ("When the Board acts . . . in a manner which will affect the rights . . . of a person, such person has a right to an administrative hearing); (CX0514 at 044)). When the Board proposes to act in such a manner, *it shall give such person notice of his right to a hearing* by mailing by certified mail to him at his last known address a notice of the proposed action and a notice of a right to a hearing.") (emphasis supplied)).

The Board's claim that non-dentist teeth whiteners or other interested parties could have instituted a contested case before the Board is a *post hoc* rationalization constructed by counsel that is neither supported by the contemporaneous records nor the practices of the Board.

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)).

Response to Finding No. 296

This finding is inaccurate, misleading and is negated by the Board's contemporaneous records and conduct, including:

a. The Board sent at least 40 cease and desist orders to non-dentist teeth whiteners (Joint Stipulations ¶ 30) that did not include any mention or notice of an opportunity to obtain a declaratory ruling from the Board. (*Compare* Board's

Opening Stmt., Tr. 67 (". . . since we have the model Administrative Procedure Act in North Carolina, they could have filed an action for a declaratory ruling . . . .") *with* CX0042 at 001-002 (January 19, 2009, Cease and Desist Order to James & Linda Holder)).

b. The Board sent a cease and desist order to a manufacturer of products used by non-dentist teeth whiteners (CX0100-001 (December 4, 2007, Cease and Desist Order from Carolin Bakewell to White Science, Roswell, Georgia) that did not include any mention or notice of an opportunity to obtain a declaratory ruling from the Board. (*Compare* Board's Opening Stmt., Tr. 67 (". . . since we have the model Administrative Procedure Act in North Carolina, they could have filed an action for a declaratory ruling . . . .") *with* CX0100 at 001 (December 4, 2007, Cease and Desist Order from Carolin Bakewell to White Science, Roswell, Georgia)).

c. The Board sent at least 11 letter to third parties, including out-of-state property management companies, indicating that "North Carolina law specifically provides that the removal of stains from human teeth constitutes the practice of dentistry" (Joint Stipulations ¶ 31) that did not include any mention or notice of an opportunity to obtain a declaratory ruling from the Board. (*Compare* Board's Opening Stmt., Tr. 67 (". . . since we have the model Administrative Procedure Act in North Carolina, they could have filed an action for a declaratory ruling . . . .") *with* CX0260 at 001-002 (November 21, 2007, letter from Carolin Bakewell to General Growth Properties, Chicago, Illinois)).

d. The Board sent a letter to a manufacturer of products used by non-dentist teeth whiteners advising that the users of the manufacturer's product are committing a misdemeanor under N.C. Gen. Stat. § 90-40 (CX0371at 001 (February 13, 2007, letter from Carolin Bakewell to Enhanced Light Technologies, Charlotte, North Carolina) that did not include any mention or notice of an opportunity to obtain a declaratory ruling from the Board. (*Compare* Board's Opening Stmt., Tr. 67 (". . . since we have the model Administrative Procedure Act in North Carolina, they could have filed an action for a declaratory ruling . . . .") *with* (CX0371 at 001 (February 13, 2007, letter from Carolin Bakewell to Enhanced Light Technologies, Charlotte, North Carolina)).

e. The Board's regulations grant the Board virtually unlimited discretion to decline to give a declaratory ruling, even if one is requested. (CX0514 at 043 (21 NCAC 16N.0403(a) and (c) ("When the Board deems it appropriate to issue a declaratory ruling it shall issue such declaratory ruling. . . . Whenever the Board believes for good cause that the issuance of a declaratory ruling is undesirable, the Board may refuse to issue such ruling.")).

f. The Board's teeth-whitening policy adopted January 9, 2010, expressly states that: "The Board is unable to give legal advice regarding whether a particular type or method of chemical bleaching is in violation of the statute." (CX0475 at 001 (Unauthorized Practice of Dentistry interpretive statement adopted by the Board pursuant to N.C. Gen. Stat. § 150B-2(8a)(c)); (White, Tr. 2313-2314).

g. The refusal on a variety of pretexts of the Board's legal counsel, Carolin Bakewell, to meet with lawyers representing non-dentist teeth whitening interests to discuss the Board's position on non-dentist teeth whitening is inconsistent with the Board's contention at trial that recipients of Cease and Desist Orders and other negative communications regarding non-dentist teeth whitening could, or even should, have sought a declaratory ruling from the Board. (*Compare* CX0257 at 001 (letter from Carolin Bakewell to Chicago attorney Algis Augustine dated March 10, 2008) ("The Dental Board will be pleased to communicate with you about this matter if you obtain a written opinion from the North Carolina State Bar, indicating that your participation does not constitute the unauthorized practice [of] law, or, alternatively, if you retain North Carolina counsel.") *with* CX0098 at 001 (letter from Carolin Bakewell to Chicago attorney Algis Augustine dated April 18, 2008) ("Under the present circumstances, the Board does not believe that an in person meeting would be productive.").

Accordingly, a declaratory ruling from the Board regarding the legality of particular forms of teeth whitening by non-dentists would not have been available to a recipient of one of the Board's Cease and desist orders. (CX0475 at 001 (Unauthorized Practice of Dentistry interpretive statement adopted by the Board on January 9, 2010, pursuant to N.C. Gen. Stat. § 150B-2(8a)(c)).

The Board's claim that non-dentist teeth whiteners or other interested parties could have sought a declaratory ruling from the Board is a *post hoc* rationalization constructed by counsel that is not supported by the contemporaneous records and practices of the Board. Ms. Bakewell's

testimony only supports that one recipient of a Cease and Desist letter did not request a declaratory ruling. (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)).

Response to Finding No. 297

This is a conclusion of law rather than a proposed finding of fact, is unsupported, and is also incorrect and misleading. The reality is that not all recipients of Cease and Desist Orders have the financial capability or legal sophistication to bring a case in court, even if they do have a right under North Carolina law. (Kwoka, Tr. 1133-1134; Nelson, Tr. 776). Further, there is nothing in the Cease and Desist Order that puts the recipient on notice that they have the right to contest the Board's actions in North Carolina court. (CCPFF ¶¶ 286-292). Finally, even if the recipient had both notice of the right and the possessed the ability to bring an action in court some might refuse, either because the expense would outweigh the benefit or because they would not want to be perceived as breaking the law. (*Cf.* Osborn, Tr. 672-674 (as a family business cannot take the reputational risk of receiving a Cease and Desist Order); Hughes, Tr. 946-950 (did not feel comfortable offering teeth whitening after receiving Cease and Desist Order even after Mr. Dempsey told her it was okay as long as she did not take impressions)).

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).

Response to Finding No. 298

Complaint Counsel has no specific response.

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)).

Response to Finding No. 299

Complaint Counsel has no specific response.

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).

Response to Finding No. 300

This proposed finding is inaccurate, misleading, a misstatement of law, and a mischaracterization of the cited testimony of Dr. Wester. Dr. Wester did not testify that any court could enforce a cease and desist order issued by the Board. (Wester, Tr. 1287-1288 ("Q. And what options does the Board have if the recipient does not comply with a cease and desist order. A. We can go to court."). The Board is authorized to seek an injunction (CX019at 020-21 (N.C. Gen. Stat. § 90-40.1)) or request the initiation of a criminal proceeding with regard to the unlicensed practice of dentistry (CX019 at 020 (N.C. Gen. Stat. § 90-40)); in no case does any statute provide any court with the authority to "enforce" the Board's Cease and desist orders.

Carolin Bakewell, the Board's legal counsel, testified that the Board does not have the authority to issue enforceable orders to cease and desist to a nonlicensee. (RX050 (Bakewell, Dep. at 215) ("Q. The Board does not have any authority to order in that sense [self-executing] a nonlicensee to do or refrain from doing anything at all. A. Right, and no – no other agency or court does either."); CCPFF ¶ 88). This finding also directly contradicts most of the Board's statements on this issue. Dr. Morgan testified that he was aware of no authority that permitted the Board to issue orders to nonlicensees. (RX0065, (Morgan, Dep. at 247-48)). Other facts

contradict this proposed finding as well. (CCPFF ¶¶ 81) (Board has no authority over non-dentists and its only recourse is through the courts), 84 (unlicensed dental practice violations can only be enjoined by the Superior Court of North Carolina), 85 (unlicensed dental practice can only be addressed civilly or criminally through the courts), 86 (the Board cannot address unlicensed practice of dentistry through an administrative hearing), 87 (Board has no authority to discipline non-licensees), and 89 (White testified the Board has no legal authority to order anyone to stop violating the Dental Practice Act)).

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).

Response to Finding No. 301

Complaint Counsel has no specific response.

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).

Response to Finding No. 302

This proposed finding misstates the testimony. Mr. Nelson actually testified that the local affiliates "don't have the time or finances to fight North Carolina," not just the Board. (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).

Response to Finding No. 303

Complaint Counsel has no specific response.

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).

Response to Finding No. 304

Complaint Counsel has no specific response.

305. Brian 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).

Response to Finding No. 305

Complaint Counsel has no specific response.

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).

Response to Finding No. 306

This proposed finding misrepresents Mr. Wyant's testimony. What he actually said was "I guess I would assume today that, yes, I would have that option [go to court] to do so" but that "I didn't [exercise the option] then." (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).

Response to Finding No. 307

This proposed finding is incorrect and internally inconsistent. The logical implication of the statement "[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" is that the Board is asking the mall operator to do the only thing within its power – to not lease space to non-dentists teeth whiteners. Indeed, there is testimony from Mr. Gibson, a mall operator, that he understood the letter to mean that the Board took the position that non-dentist teeth whitening would be a violation of North Carolina law. (Gibson, Tr. 629). After receiving the letter, Mr. Gibson's company would no longer lease space to non-dentist teeth whiteners. (CCPFF ¶¶ 336-343). Other mall operators refused to lease space to non-dentist teeth whiteners after receiving the letter from the Board as well. (CCPFF ¶¶ 344-347). The fact that three separate mall operators reacted to the mall letters by refusing to lease to non-dentist teeth whiteners naturally leads to the conclusion that the letters were interpreted as asking mall operators not to lease space to non-dentists.

Further, contemporaneous evidence and testimony from Board members and employees demonstrate that the purpose of the mall letters was indeed to induce mall operators to not lease space to non-dentist teeth whiteners. Ms. Bakewell suggested sending the letters to mall operators as a way of depriving non-dentist teeth whiteners of access to the commercial facilities from which to offer teeth whitening services. (CCPFF ¶ 321). In fact, soon after sending the mall letters Ms. Bakewell forwarded copies to two dentists that had complained of mall whitening

kiosks – at the locations she had sent mall letters to – as proof of the Board's response to their complaints. (CCPFF ¶¶ 322-323). Dr. Feingold confirmed that the purpose of the mall letters was to induce the malls to refuse to rent space to non-dental teeth whiteners, and Ms. Friddle testified that the Board sent the letters "in hopes of trying to prevent further expansion" with respect to non-dentist teeth whitening. (CCPFF ¶¶ 324-325). Given that both the purpose and effect of the letters was to induce mall operators to refuse to lease space to non-dentist teeth whiteners, any suggestion that the mendaciously ambiguous language of the letters prevents a finding of anticompetitive intent and effect is completely specious.

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).

Response to Finding No. 308

This proposed finding misleading and unfounded. This proposed finding implies that "multiple North Carolina licensing boards" have sent "similar" letters to malls, but the only evidence cited is a newsletter reference to an informational letter being sent by one licensing board. (RX36 at 3). As such, there is no support for the proposition that the letter is similar to the Board's letter. And there is no support for the proposition that more than one North Carolina licensing board sent an "informational letter" to any shopping mall or airport in the State of North Carolina.(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)).

Response to Finding No. 309

This proposed finding is incorrect and misleading. Testimony and contemporaneous documents show that the Board's purpose in sending the mall letters was to induce mall operators to refuse to lease space to non-dentist teeth whiteners. Ms. Bakewell suggested sending the letters to mall operators as a way of depriving non-dentist teeth whiteners of access to the commercial facilities from which to offer teeth whitening services. (CX00581 at 066-071 (Bakewell, Dep. at 259-264, 266-277)). Soon after sending the mall letters, Ms. Bakewell contacted two dentist who complained about mall kiosks, reported the actions that the Board was taking on their behalf against the mall kiosks, and attached copies of the letters to the malls. (CCPFF ¶¶ 322-323). Dr. Feingold confirms that the purpose of the letters sent by the Board to mall operators was to induce the malls to refuse to rent space to non-dental teeth whiteners. (CX0560 at 052 (Feingold, Dep. at 199-200)). Further, Ms. Friddle testified that the Board sent the letters to malls and mall property management groups "in hopes of trying to prevent further expansion" with respect to non-dentist teeth whitening. (CX0562 at 019-020 (Friddle, IHT at 72, 75-76 ("So not to have them there")).

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).

Response to Finding No. 310

Complaint Counsel has no specific response.

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)).

Response to Finding No. 311

This proposed finding is misleading and unfounded. There is testimony from Dr. Hardesty that the Board discussed and "unanimously voted" for Ms. Bakewell to send letters to mall operators warning them that all non-dentist teeth whitening was illegal, and that the Board had intended that "quite a number" of these letters be sent. (CCPFF ¶¶ 318-319). Ms. Bakewell suggested that the Board send the letters to mall operators as a way of depriving non-dentist teeth whiteners of access to the commercial facilities from which to offer teeth whitening services (CX00581 at 066-071 (Bakewell, Dep. at 259-264, 266-277)), a purpose that was confirmed by Dr. Feingold and Ms. Friddle. (CCPFF ¶¶ 324-325). It is hardly likely that there was a commonly understood purpose without some concurrent "strategy or tactic."

Further, in one of the tripartite meetings consisting of the Board, the Dental Society, and the University of North Carolina dental school, the Board assured anxious Dental Society members that the Board was taking action to deal with mall kiosks where possible. (CCPFF ¶¶ 222-223). This Board campaign against mall kiosks is reflected in an e-mail from Mr. White to a complaining dentist where he states that the offending mall kiosk "is one of many such 'bleaching kiosks' with which we are currently going forth to do battle," and that the Board had sent out "numerous cease and desist orders throughout the state." (CX0404 at 001-002 (emphasis added)). It is axiomatic that you cannot have a battle without a common plan, "tactic," or "strategy."

312. Board Counsel testified that the Board has no intention of taking any action against mall owners. (RX50 (Bakewell Dep. at 264)).

Response to Finding No. 312

Complaint Counsel has no specific response.

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 nondentist teeth whitening business. (Owens, Tr. 1451; Hardesty, Tr. 2774).

Response to Finding No. 313

Complaint Counsel has no specific response.

314. 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).

Response to Finding No. 314

Complaint Counsel has no specific response.

315. BleachBright of Carolina misrepresented to Mr. Gibson and his associate, Cathy Elkins (formerly Cathy Mosley) that the Board had approved BleachBright's nondentist 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).

Response to Finding No. 315

This proposed finding is misleading as to whether BleachBright of Carolina "misrepresented" the Board's approval of their whitening process. Nothing in the citations provided speak to the state of mind of the representative of BleachBright of Carolina such that a finding of "misrepresentation" is warranted or appropriate. (CX0525; Gibson, Tr. 629-632, 637-629). Ms. Elkins felt compelled to follow up with the Board because "[w]e received a letter from [the Board] back in November which stated that this process was illegal because this was not being supervised by licensed North Carolina dentists." (CX0525 at 001).

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)).

Response to Finding No. 316

This proposed finding misrepresents the testimony. What Ms. Friddle actually testified to is that "I referred all the calls that I got to Ms. Bakewell." (RX58 (Friddle, IHT at 77-78) (emphasis added)).

317. In responding to Ms. Elkins' e-mail 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).

Response to Finding No. 317

This finding is incomplete and incorrect. Although Ms. Bakewell did not write the word "illegal" in the referenced e-mail, from context the obvious implication she gave is that it is illegal for teeth whitening to be provided by non-dentists without a licensed dentist's supervision. Ms. Elkins wrote the e-mail in the first place because Hull Gibson had earlier received a letter from Ms. Bakewell stating: "It is our information that the teeth whitening services offered at these kiosks are not supervised by a licensed North Carolina dentist. Consequently, this activity is illegal." (CX0203 at 001-002; CX0259 at 001-002) (emphasis added). Ms. Elkins specifically mentions the letter from the Board in her e-mail regarding BleachBright of Carolina, stating "[w]e received a letter from you back in November which stated that this process was illegal because this was not being supervised by licensed North Carolina dentist." (CX0525 at 001). With this as context, Ms. Bakewell's response that the Board "has not issued any sort of blanket approval for the operation of teeth whitening kiosks by BleachBright" affirmed that it was still "illegal" for BleachBright/non-dentists to offer teeth whitening services in malls without a licensed dentist's supervision. (CX0525 at 001).

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)).

Response to Finding No. 318

Complaint Counsel has no specific response.

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).

Response to Finding No. 319

Complaint Counsel has no specific response.

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).

Response to Finding No. 320

Complaint Counsel has no specific response.

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).

Response to Finding No. 321

Complaint Counsel has no specific response.

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).

Response to Finding No. 322

Complaint Counsel has no specific response.

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).

Response to Finding No. 323

Complaint Counsel has no specific response.

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).

Response to Finding No. 324

Complaint Counsel has no specific response.

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)).

Response to Finding No. 325

Complaint Counsel has no specific response.

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).

Response to Finding No. 326

This finding is unfounded and mischaracterizes the evidence. Respondent cites to two examples of North Carolina boards "cooperating," which hardly proves that such interactions are more than uncommon. (CX0645 at 001; RX44 at 007). The first citation is not even an example of cooperation, but simply an instance where the Cosmetology Board notes that the issue of teeth whitening "delves into the scope of the NC Dental Board." (CX645 at 001). A real example of the Board and the Cosmetology Board cooperating is when the Board convinced the Cosmetology Board to post a statement on its website to the effect that it was illegal to perform teeth whitening

without dentist supervision, a posting that discouraged cosmetologists from offering teeth whitening services. (CCPFF ¶¶ 351-359, 650-655).

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)).

Response to Finding No. 327

This proposed finding misrepresents the testimony. Ms. Bakewell stated that "I think some of them had been told that the Board had approved these proposed activities." (RX50 (Bakewell, Dep. at 309-310)). There was no testimony that all the complaining spa and salon owners who contacted the Board stated that manufacturer/distributors had told them that there was no problem offering the whitening service, as this proposed finding implies. (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)).

Response to Finding No. 328

Complaint Counsel has no specific response.

329. The Cosmetology Board agreed to include an article in its newsletter citing the provisions ofN.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).

Response to Finding No. 329

Complaint Counsel has no specific response.

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).

Response to Finding No. 330

At trial, the court rejected precisely this tender, instead stating: "[t]o the extent any opinions offered by the doctor meet the proper legal standards, those opinions will be considered." (Haywood, Tr. 2391). Dr. Haywood's opinions are sorely compromised by his lack of objectivity: his personal identification with dentist provided Nightguard Vital Bleaching using 10% carbamide peroxide, which he co-developed, and his unremitting animus against products and services that non-dentists offer as alternatives to Nightguard Vital Bleaching, and against those non-dentist providers themselves. A thorough description of Dr. Haywood's positional bias is contained in CCPFF ¶¶ 800-906. This bias infects and distorts Dr. Haywood's opinions time and again, and they should be given little or no weight.

331. Dr. Van B. Haywood is an academician who performs independent research in his fields of expertise. (Haywood, Tr. 2392).

Response to Finding No. 331

Complaint Counsel has no specific response.

332. Dr. Haywood is not an industry expert. (Haywood, Tr. 2392).

Response to Finding No. 332

Dr. Haywood testified that he was not an "industry expert," (Haywood, Tr. 2392), but he has "been a consultant" to several commercial enterprises, and has "oftentimes [gotten] product support," "grant support," and "honoraria" from these companies. (Haywood, Tr. 2405-2406).

333. Dr. Haywood independently performs grant-sponsored research on teeth whitening products with no strings attached. (Haywood, Tr. 2392-2393).

Response to Finding No. 333

Dr. Haywood testified only that "most," not all, of his research was grant-sponsored and without strings attached. (Haywood, Tr. 2392). He also acknowledged, with respect to grant-sponsored research, that he and his employer have an ongoing interest in the continued receipt of research dollars from grantors. (Haywood, Tr. 2896-2897). Dr. Haywood said there was "no way to know" whether that ongoing interest affected the rigor of grant-sponsored research at some academic institutions, (Haywood, Tr. 2897), and acknowledged that some academic research is "poorly done." (Haywood, Tr. 2898). When asked if his own study of the application of Nightguard Vital Bleaching to the amelioration of tetracycline stains was an example of "poorly done" academic research, Dr. Haywood replied only: "I don't know if I can answer that." (Haywood, Tr. 2898). Dr. Haywood's use of his "academic research" to support the extension of Nightguard Vital Bleaching to long-term use, including by children, adolescents, and the elderly, has been roundly criticized. (CCPFF ¶¶ 836; *see also* CCPFF ¶¶ 833-834).

334. Dr. Haywood does not actively promote teeth whitening products. (Haywood, Tr. 2393).

Response to Finding No. 334

Dr. Haywood does not actively promote a specific brand teeth whitening product, but he often and aggressively promotes the use of Nightguard Vital Bleaching by dentists using 10% carbamide peroxide. (CCPFF ¶ 802; *see also* ¶¶ 804-810 (Dr. Haywood's professional success is bound up with success of the Nightguard Vital Bleaching by dentists), 816 (Dr. Haywood has sometimes promoted Nightguard Vital Bleaching with limited and inadequate evidence), 820-836 (Dr. Haywood has promoted Nightguard Vital Bleaching to vulnerable populations based on research that has been criticized by expert commentators and using claims that appear untrue).

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).

Response to Finding No. 335

Complaint Counsel has no specific response.

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).

Response to Finding No. 336

Complaint Counsel has no specific response.

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).

Response to Finding No. 337

Complaint Counsel has no specific response.

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).

Response to Finding No. 338

The FTC did not approach Dr. Haywood a second time. An FTC attorney called another employee of the Medical College of Georgia seeking to identify other potential experts with whom to consult, and that person "transferred her to [Dr. Haywood's] office." (Haywood, Tr. 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).

Response to Finding No. 339

Complaint Counsel has no specific response.

340. Dr. Giniger sent Dr. Haywood an e-mail in 2005 that complimented Dr. Haywood on the bleaching research he had done. In the e-mail, Dr. Giniger also asked if Dr. Haywood wanted to collaborate with him. Dr. Giniger provided Dr. Haywood with his contact information and signed the e-mail, zyour hero for the last eleven years." (Haywood, Tr. 2411-2412).

Response to Finding No. 340

Complaint Counsel has no specific response.

Dr. Giniger's Credibility

341. Dr. Giniger spent most of his professional career in the teeth whitening industry. (Giniger, Tr. 364).

Response to Finding No. 341

Complaint Counsel has no specific response.

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

Response to Finding No. 342

Complaint Counsel has no specific response.

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).

Response to Finding No. 343

In that consulting role, Dr. Giniger also helps companies refine their product formulations to increase their stability, effectiveness, and safety. (Giniger, Tr. 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).

Response to Finding No. 344

Complaint Counsel has no specific response.

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).

Response to Finding No. 345

GrinRX is the name of a defunct company, not a product. (Giniger, Tr. 101-103). Power Swabs has a wholly different formulation than the product that had been sold by GrinRX, but the same dispensing mechanism. (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).

Response to Finding No. 346

Respondent's citation does not support its proposed finding. Dr. Giniger's testimony taken in context is that he is paid by companies that retain his consulting services. (Giniger, Tr. 365-366). That is unrelated to Power Swabs. The "companies that use Power Swabs" are dental practices that simply pay for the purchase of that product, as they do for all other supplies they use in their practices. (Giniger, Tr. 103-104, 393).

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).

Response to Finding No. 347

Complaint Counsel has no specific response.

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).

Response to Finding No. 348

In the testimony cited by Respondent, Dr. Giniger also makes clear that he is testifying as to "what people could reasonably understand to be the circumstance of teeth bleaching and dental stain removal in the period of the 1930s." (Giniger, Tr. 370; *see also* CCPFF ¶¶ 161-164 (stain removal likely would have been understood to mean use of sharp and rotary instruments to scrape or abrade away stains, but not use of bleaching agents for cosmetic, whole mouth whitening/brightening)). Dr. Giniger additionally notes the objective fact–not requiring expertise in the law–that the Dental Practice Act refers to stain removal, but nowhere to teeth bleaching. (Giniger, Tr. 370-371). And finally, Dr. Giniger notes that in fact teeth bleaching lightens, but does not remove stains. (Giniger, Tr. 371).

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).

Response to Finding No. 349

In the testimony cited by Respondent, Dr. Giniger explained that his conclusion that the exclusion of non-dentist providers by the Board did not serve the public was based on his expertise with respect to teeth bleaching products/services and in oral medicine. (Giniger, Tr. 377-378). Dr. Giniger reviewed each of the Board's purported justifications for the exclusion of non-dentist providers and concluded that those purported justifications were not valid. (Giniger, Tr. 353-357). Non-dentist provided teeth bleaching, he concluded for example, is safe. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962

(little or no risk to enamel or pulp), 963-971 *and* 976-977 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked delaying diagnosis/treatment, little or no harm would result)). Dr. Giniger also opined that the availability of non-dentist provided teeth bleaching is advantageous to consumers. (CCPFF ¶¶ 468, 473). It may promote improved dental hygiene, for example. (Giniger, Tr. 124). Those opinions plainly are within the scope of Dr. Giniger's expertise. Given that the availability of non-dentist provided teeth bleaching is a benefit to consumers and none of the Board's purported justifications for its exclusion are valid, Dr. Giniger does not require any additional expertise to observe that the Board's exclusion of non-dentist- providers does not serve the public.

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).

Response to Finding No. 350

Complaint Counsel has no specific response.

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).

Response to Finding No. 351

Complaint Counsel has no specific response.

352. Dr. Giniger has also served as an expert witness in previous litigation for BriteSmile, Procter & Gamble, and Colgate-Palmolive. (Giniger, Tr. 393).

Response to Finding No. 352

Taken together, this and Respondent's immediately preceding proposed finding (351) suggest that Dr. Giniger was retained as an expert witness by Proctor & Gamble on two occasions. Although the record is not free from doubt, the better reading of the material cited by Respondent in support of the findings is that Dr. Giniger twice discusses the one instance in which he was so-retained. (Giniger, Tr. 380-381, 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).

Response to Finding No. 353

Complaint Counsel has no specific response.

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).

Response to Finding No. 354

Complaint Counsel has no specific response.

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).

Response to Finding No. 355

Dr. Giniger testified that his "position with GRINrx (sic) was chief scientific officer." (Giniger, Tr. 398). At trial, Counsel for Respondent showed Dr. Giniger what counsel represented to be a **GrinRX Securities and Exchange Commission (SEC) Form D**. That document, which is **not in evidence**, identified Dr. Giniger as a principal shareholder (beneficial

owner), executive officer, and director. (Giniger, Tr. 398-399). In response to questions posed by Respondent's counsel, Dr. Giniger explained that he was entirely unfamiliar with the Form and its purpose. (Giniger, Tr. 397-398). Dr. Giniger reaffirmed that, insofar as he was aware, he had held no offices in GrinRX, in which he was a principal shareholder, other than Chief Scientific Officer. (Giniger, Tr. 399). And Dr. Giniger observed that it was stated on the Form that it had been filed with the SEC on May 3, 2007, some time after Dr. Giniger had been told by the businessmen with whom he had founded GrinRX and on whom he was reliant for the conduct of all of GrinRX's business affairs (other than product research and development) to cease operations and that GrinRX had been closed. (Giniger, Tr. 400). The representations contained in the Form D are neither Dr. Giniger's nor representations made with his knowledge or consent. (Giniger, Tr. 408; *see also* Giniger, Tr. 101-103, 393-396 (describing the limited role of Dr. Giniger in GrinRX, and the fleecing he took at the hands of the businessmen to whom he had entrusted GrinRX's affairs)).

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).

Response to Finding No. 356

Whereas Respondent's proposed finding claims that Dr. Giniger "touted" the product Simply White, the cited testimony indicates only that Dr. Giniger had "been involved" with that Colgate product. (Haywood, Tr. 2414). According to Dr. Haywood's description of the **Journal of Esthetic and Restorative Dentistry article** to which he referred–the article **is not in**

evidence–it appears that the study showed only that, under whatever study conditions prevailed, Simply White reduced enamel microhardness relative to a second, unidentified, product, which was dentist-prescribed, and a control. (Haywood, Tr. 2428). This effect, according to Dr. Haywood's description of the article, was "possibly due to the phosphoric acid." (Haywood, Tr. 2428). Dr. Haywood did not claim that the difference in enamel microhardness among the materials tested was found clinically significant. (Haywood, Tr. 2428). Moreover, Dr. Haywood testified elsewhere that until recently dentists used phosphoric acid in conjunction with teeth bleaching to enhance the whitening effect. (CX0823 at 034 (Haywood, Dep. at 132-133); *see also* CX0402 at 003 (1991 article by Dr. Haywood stating, "[t]he most popular technique for the in-office bleaching of vital teeth involves 35% hydrogen peroxide, etching the teeth with phosphoric acid to facilitate bleaching, and either a heating element or a light source to enhance the action of the peroxide")).

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).

Response to Finding No. 357

To begin, all of the material at Haywood, Tr. 2416, cited repeatedly by Respondent as the basis for portions of its proposed finding, was found objectionable and was struck. (Haywood, Tr. 2417). As described by Dr. Haywood in his testimony, Dr. Kanka's 2005 Letter to the Editor–which is not in evidence–challenged Dr. Giniger's study design and statistical methodology.

Both Dr. Haywood's testimony and Respondent's proposed finding ignore inconvenient evidence known to Dr. Haywood and Respondent's counsel. The article was attributed to Dr. Giniger alone by Dr. Haywood and Respondent's counsel, but was co-authored by Dr. Giniger and several colleagues. (Giniger, Tr. 448). The Journal of the American Dental Association, in which, as Dr. Haywood acknowledged it was published, is a highly regarded peer-reviewed journal. (Giniger, Tr. 448; RX0077 at 020, 027, 048 (Dr. Haywood frequently cites, has authored articles published in, and has been a peer-reviewer for, JADA)). The article was subjected to that peer-review process; but Letters to the Editor, like Dr. Kanka's, go through no peer-review process whatsoever. (Giniger, Tr. 448). Both Dr. Haywood's testimony and Respondent's proposed finding state that Dr. Giniger never responded to Dr. Kanka's letter, (Haywood, Tr. 2454-2457), but there was no need for Dr. Giniger to do so because, as Dr. Haywood testified at his deposition, Dr. Giniger's co-authors at Discus dental replied to Dr. Kanka's criticisms, defending their collective work, in the same issue of JADA in which the Giniger *et al.* article was, itself, published. (CX0823 at 74-75 (Haywood, Dep. at 290, 296-297)).

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).

Response to Finding No. 358

Again without record support, Respondent's proposed fact claims that Dr. Giniger "touted" some product, this time light-emitting diode ("LED") lights used in conjunction with teeth bleaching. Dr. Giniger testified with complete candor and without hesitation that in his opinion LED lights used by dentists and non-dentist providers alike do not promote the cleaving

of carbon:carbon double bonds, which is the mechanism of action of bleaching agents; rather they cause the dentists' patients and the non-dentist providers' customers to keep their mouths open for a prolonged period of time, resulting in drying out of the teeth, which makes them temporarily appear whiter. (Giniger, Tr. 476-479). Dr. Giniger's research documented that this temporary whitening effect consistently is a one to two shade increase in whiteness. (Giniger, Tr. 479-480). Dr. Giniger acknowledges that someone might have developed, or might develop, a bleaching system in which an LED light functions as a true photoinitiator of chemical bleaching, although he is not aware of any such system. (Giniger, Tr. 477).

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).

Response to Finding No. 359

Power Swabs is not based on a theory and mechanism of bleaching at all. Dr. Haywood claimed, as to "Dr. Giniger[']s posited] theory of bleaching agents and mechanism of action" that "there's no scientific evidence that supports this particular theory [that bleaching decolorizes but does not remove stains]." (Haywood, Tr. 2525). Dr. Haywood at first claims, "that's the theory behind the Power Swabs . . ."; but then tacitly concedes that that is not true at all: "the Power Swabs being a detergent that claims to take out stains as opposed to bleaching materials which decolorize them." (Haywood, Tr. 2526; *see also* CX0632 at 023-024 (contrasting the different mechanisms of action of bleaching agents and detergents)). Nowhere in the record does anyone suggest that bleaching and detergency are or do the same thing. (Entire record). Moreover, Dr. Haywood's claim that Dr. Giniger's explanation of the mechanism of action of teeth bleaching lacks scientific support is itself incorrect. (Giniger, Tr. 154-155 (at molecular level, bleaching is

a simple and well-understood chemical reaction); Haywood, Tr. 2634-2638 (noting peer-reviewed articles agreeing in whole or in part with Dr. Giniger's explanation of the mechanism of action of teeth bleaching)).

360. 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).

Response to Finding No. 360

To begin, the RX142 was offered and admitted by the court for demonstrative purposes only. (Haywood, Tr. 2396-2397). There is no evidence that the document referred to in Respondent's proposed finding was "posted online for Dr. Giniger's GrinRX company," as Respondent asserts. The evidentiary record does not disclose precisely what the document is; why it was created, and by whom; the uses to which it was put, and by whom; and why it was posted and/or maintained on the web after GrinRX was closed. What is known – as Respondent's counsel knew at the time it put the demonstrative exhibit before Dr. Haywood – is that Dr. Giniger did not participate in or authorize its creation and, in fact, had no knowledge of it prior to being shown it by Complaint Counsel in the few days immediately before trial. (Giniger, Tr. 408-411). Dr. Giniger testified that if he had had knowledge of the document, he "would never have allowed" the use of Dr. Haywood's name, and that of others, without their consent. (Giniger, Tr. 409; *see also* Giniger, Tr. 101-103, 393-396 (describing the limited role of Dr. Giniger in GrinRX, and the fleecing he took at the hands of the businessmen to whom he had entrusted GrinRX's affairs)).

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).

Response to Finding No. 361

Complaint Counsel has no specific response.

362. Dr. Haywood testified that this was a fraudulent use of his name without his permission. (Haywood, Tr. 2557-2560).

Response to Finding No. 362

Dr. Giniger did not participate in or authorize the creation of the document that Dr. Haywood referred to as using his name, and, in fact, had no knowledge of it prior to being shown it by Complaint Counsel in the few days immediately before trial. (Giniger, Tr. 408-411). Dr. Giniger testified that if he had had knowledge of the document, he "would never have allowed" the use of Dr. Haywood's name, and that of others, without their consent. (Giniger, Tr. 409; *see also* Giniger, Tr. 101-103, 393-396 (describing the limited role of Dr. Giniger in GrinRX, and the fleecing he took at the hands of the businessmen to whom he had entrusted GrinRX's affairs)).

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).

Response to Finding No. 363

Complaint Counsel has no specific response.

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).

Response to Finding No. 364

Dr. Haywood purported to construe the North Carolina Dental Practice Act, "as a dentist." (Haywood, Tr. 2545; *see also* Haywood, Tr. 2573). Construction of statutes is outside of the expertise of a dentist. With respect to statutory construction, Dr. Haywood is a lay person, whose opinion is entitled to no weight. Unlike Dr. Giniger, who provided factual information as to the state of dentistry in the 1930s, from which the court could conclude that the Act was intended to preclude lay persons' removal of stains using sharp instruments and highly abrasive rotary instruments rather than chemical bleaching for whitening/brightening of the entire smile, Dr. Haywood provided nothing more than his say-so that the Act condemns lay teeth bleaching. Dr. Haywood's mere say-so, his opinion "as a dentist," is immaterial and irrelevant. Accordingly it should be disregarded.

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).

Response to Finding No. 365

Teeth bleaching is not "the practice of dentistry" in North Carolina, nor is it illegal. We separately consider each of the citations provided by Respondent for this proposed finding. First, whatever may be said of "the practice of dentistry" in other jurisdictions, in North Carolina it is defined by the North Carolina Dental Practice Act. Dr. Haywood's testimony at Haywood, Tr. 2459-2460, that teeth bleaching is the practice of dentistry (that is all he said there), was a generalized statement claiming broad scope for dentistry. It did not reckon at all with the North Carolina statute. Indeed, had Dr. Haywood testified as to the meaning of "the practice of dentistry" under North Carolina law, that testimony would have been unqualified opinion evidence of the sort repeatedly found objectionable by the court at trial. (For example, Haywood,

Tr. 2399-2400). Second, at Haywood, Tr. 2539, Dr. Haywood asserted, without foundation, that teeth bleaching by non-dentists is illegal. Dr. Haywood was indifferent as to either the scope of the teeth bleaching activity engaged in by the non-dentist, or the jurisdiction in which the conduct occurred. For Dr. Haywood, even the most trivial of assistance to a consumer bleaching his own teeth is "the practice of dentistry." (Haywood, Tr. 2640 (store clerk recommending one teeth bleaching product in preference to another is practicing dentistry)). And Dr. Haywood continued to insist, without limitation, that teeth bleaching by non-dentists is therefore illegal even after being repeatedly informed that in several jurisdictions teeth bleaching by non-dentists was plainly lawful. (Haywood, Tr. 2640). These are not the claims of an objective observer, analyst, or reporter. A thorough description of Dr. Haywood's positional bias, as a consequence of which his testimony should be given little if any weight, is contained in CCPFF ¶¶ 800-906. Last, at Haywood, Tr. 2573, Dr. Haywood, without more, and again without foundation, offered his summary/conclusion that teeth bleaching is the removal of stains. That is incorrect both in terms of the mechanism of action of bleaching and as a matter of interpretation of the North Carolina Dental Practice Act. (*See* CCPFF ¶¶ 161-167, 169-173).

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).

Response to Finding No. 366

The material cited by Respondent in support of this proposed finding does not support it. Dr. Haywood testified that the removal of stains is taught "as the practice of dentistry." (Haywood, Tr. 2573). Dr. Haywood then claimed that bleaching is the removal of stains, but he

never claimed in his testimony that the alleged fact that bleaching is the removal of stains is taught to dental students. (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).

Response to Finding No. 367

Complaint Counsel has no specific response.

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).

Response to Finding No. 368

Teeth bleaching does not remove stains from the teeth nor does it change their genetic color. The mechanism of the action of bleaching has long been understood. A bleaching agent generates "free radicals" that cleave the carbon:carbon double bonds that impart color to stains on or in the teeth. With the cleaving of those double bonds, the stains lighten, but they are not removed and the stains will "rebound" over time. (CCPFF ¶ 170). Teeth whitening includes, but it is not limited to, bleaching; the use of sharp instruments to scrape and rotary instruments to abrade away stains also is teeth whitening, as is the placement of dental restorations and the application of veneers to the teeth. (CCPFF ¶¶ 159, 162). Put a bit differently, teeth bleaching is a species of teeth whitening; but teeth whitening encompasses several species. They are not the same thing. Moreover, the fact that teeth bleaching is a form of teeth whitening is not relevant to this litigation. Indeed, even if it were true that teeth bleaching and teeth whitening were the same thing, that would not be relevant to this litigation. The North Carolina Dental Practice Act

provides that the removal of stains is the practice of dentistry. It does not speak to the whitening of teeth any more than it speaks to the bleaching of teeth. (Giniger, Tr. 370).

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).

Response to Finding No. 369

Teeth bleaching does not remove stains from the teeth nor does it change their genetic color. The mechanism of action of bleaching has long been understood. A bleaching agent generates "free radicals" that cleave the carbon:carbon double bonds that impart color to stains on or in the teeth. With the cleaving of those double bonds, the stains lighten, but they are not removed and the stains will "rebound" over time. (CCPFF ¶ 170). Teeth whitening includes, but it is not limited to, bleaching; the use of sharp instruments to scrape and rotary instruments to abrade away stains also is teeth whitening, as is the placement of dental restorations and the application of veneers to the teeth. (CCPFF ¶¶ 159, 162). Put a bit differently, teeth bleaching is a species of teeth whitening; but teeth whitening encompasses several species. They are not the same thing. Moreover, the fact that teeth bleaching is a form of teeth whitening is not relevant to this litigation. Indeed, even if it were true that teeth bleaching and teeth whitening were the same thing, that would not be relevant to this litigation. The North Carolina Dental Practice Act provides that the removal of stains is the practice of dentistry. It does not speak to the whitening of teeth any more than it speaks to the bleaching of teeth. (Giniger, Tr. 370).

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).

Response to Finding No. 370

Although stain removal techniques have been and are used for a variety of purposes, Respondent's proposed finding confuses stain removal and teeth bleaching, which does not remove stains. The mechanism of action of bleaching has long been understood. A bleaching agent generates "free radicals" that cleave the carbon:carbon double bonds that impart color to stains on or in the teeth. With the cleaving of those double bonds, the stains lighten, but they are not removed and the stains will "rebound" over time. (CCPFF ¶ 170). Teeth whitening includes, but it is not limited to, bleaching; the use of sharp instruments to scrape and rotary instruments to abrade away stains also is teeth whitening, as is the placement of dental restorations and the application of veneers to the teeth. (CCPFF ¶¶ 159, 162). The use of sharp and rotary instruments in stain removal has a long history. (CX0653 at 015). But prior to 1989, the use of bleaching agents to lighten (but not remove) stains was largely limited to teeth that were non-vital – or dead –, because of the limitations of the bleaching procedures then available. (CCPFF ¶ 161). The use of bleaching to enhance the whole smile did not take hold until after the advent of Nightguard Vital Bleaching in 1989. (CCPFF ¶ 167). The application of Nightguard Vital Bleaching to severe stains of the kind identified in Respondent's proposed finding was a still later development. (*See* CX0402 at 001-012 (1991 article by Dr. Haywood discussing use of Nightguard Vital Bleaching on, among others, tetracycline stains)).

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).

Response to Finding No. 371

People often refer to teeth bleaching colloquially as stain removal. But contemporary colloquial usage does not, and ought not be expected to, reflect an understanding of the molecular processes involved in teeth bleaching, nor the historical understanding of "the removal of stains" by 1930s North Carolina legislators. Teeth bleaching does not remove stains, (CCPFF ¶ 170), nor is it likely that the North Carolina legislature considered teeth bleaching, as contrasted with the use of scraping and rotary instruments, to be "the removal of stains" and hence the "practice of dentistry." (CCPFF ¶¶ 161-164).

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).

Response to Finding No. 372

Teeth bleaching providers located in malls assist consumers with teeth bleaching in a variety of helpful and valued ways. (CCPFF ¶ 461). The products, protocols, and procedures used are safe, and result in a high degree of consumer satisfaction. (CCPFF ¶¶ 711 (consumer satisfaction is high), 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 976-977 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked delaying diagnosis/treatment, little or no harm would result)). Teeth bleaching is not "the practice of dentistry" under North Carolina law. It is

neither mentioned explicitly nor is it included, by implication, under "the removal of stains," the operative phrase used in the Dental Practices Act. (Giniger, Tr. 370-371). Teeth bleaching does not remove stains, (CCPFF ¶ 170), nor is it likely that the North Carolina legislature considered teeth bleaching, as contrasted with the use of scraping and rotary instruments, to be "the removal of stains" and hence the "practice of dentistry." (CCPFF ¶¶ 161-164).

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).

Response to Finding No. 373

Dr. Haywood's opinion that non-dentist providers present themselves as dental professionals with the skill and training to diagnose and treat dental conditions is utterly unsupported by factual evidence. It reflects his lack of care and objectivity. Dr. Haywood acknowledges that he has "not studied the question" of whether consumers confuse non-dentist providers with dentists or other licensed professionals or are deceived by the look and feel of non-dentist teeth bleaching operations. (Haywood, Tr. 2745). Non-dentist providers testified and documents, such as operating protocols, showed, that non-dentist providers are at pains to ensure that consumers do not confuse them with dental professionals. (*See* CX0632 at 022-023; CX0630 at 001-013). The record is devoid of any evidence of any non-dental provider holding herself out as having the skill to diagnose and treat dental conditions; and it is devoid of any evidence that consumers believe that non-dentist providers have the training and skills to diagnose and treat dental conditions. Dr. Haywood believes that the mere offering of teeth bleaching is an implied representation of the training and skill to diagnose and treat dental conditions. He is untroubled

by the lack of evidence of consumer confusion; he is ignorant as to non-dentist provider practices and protocols that help to avoid any possible confusion, and content to remain so (CCPFF ¶ 848); and he is not in the least hobbled by his lack of qualification in interpreting implied claims and consumer behavior. (Haywood, Tr. 2579). Indeed, Dr. Haywood's position is that even were each non-dentist provider to explicitly inform each prospective customer that she is not a dental professional and is not qualified by training or skill to diagnose and treat dental conditions, still the mere fact of offering teeth bleaching would constitute an implied representation of the expressly disclaimed training and skill; no conceivable set of disclosures could remedy consumer confusion or deception regarding the qualifications/status of non-dentist providers. (Haywood, Tr. 2745; *see also* CCPFF ¶¶ 846-847). This is not the claim of an objective observer, analyst, or reporter. A thorough description of Dr. Haywood's positional bias, as a consequence of which his testimony should be given little if any weight, is contained in CCPFF ¶¶ 800-906.

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).

Response to Finding No. 374

Dr. Haywood's testimony notwithstanding, the Board is not charged with determining what activities require a dental license. The legislature has not vested it with any such authority; for example, with respect to what non-licensees may or may not do, the legislature has specified those acts which are "the practice of dentistry," and which therefore may not be engaged in by non-licensees. (*See* CX0020 at 001-023 (Dental Practice Act)). The Board does not have, and

has not claimed, the power to enlarge the set of acts prohibited to non-licensees. The Dental Practices Act entrusts to the Board the enforcement of the Act by bringing, or inducing other officials to bring, suit in the courts of North Carolina. That is the only grant of authority to the Board with respect to non-licensees. (CCPFF ¶ 81). The Board has claimed that, rather than going out to inform non-licensees as to what they can or cannot do as stated in Respondent's proposed finding, it is "complaint driven." (CCPFF ¶ 93). Moreover, non-licensees are not subject to training requirements under the Dental Practice Act, and they are, by definition, not subject to licensure exam. Accordingly Respondent's statement–Dr. Haywood's testimony–that "[T]he Board . . . informs non-dentists what they can or cannot do based on training and the licensure exam" is just wrong.

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).

Response to Finding No. 375

Complaint Counsel has no specific response.

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).

Response to Finding No. 376

Dr. Haywood's opinion that non-dentist providers convey the illusion of having dentist supervision by use of "dental chairs," LED lights, and other unnamed things is utterly unsupported by factual evidence. It reflects his lack of care and objectivity. Dr. Haywood acknowledges that he has "not studied the question" of whether consumers confuse non-dentist providers with dentists or other licensed professionals or are deceived by the look and feel of non-dentist teeth bleaching operations. (Haywood, Tr. 2745). Non-dentist providers testified and documents, such as operating protocols, showed, that non-dentist providers are at pains to ensure that consumers do not confuse them with dental professionals. (*See* CX0632 at 022-023; CX0630 at 001-013). The record is devoid of any evidence of any non-dental provider holding herself out as having dental supervision, and it is devoid of any evidence that consumers believe that non-dentist providers have that supervision. Dr. Haywood believes that the mere use of "dental chairs," LED lights, and the like is an implied representation of dental supervision. He is untroubled by the lack of evidence of consumer confusion; he is ignorant as to non-dentist provider practices and protocols that help to avoid any possible confusion, and content to remain so (CCPFF ¶ 848); and he is not in the least hobbled by his lack of qualification in interpreting implied claims and consumer behavior. (Haywood, Tr. 2579). Indeed, Dr. Haywood's position is that even were each non-dentist provider to explicitly inform each prospective customer that she is not a dental professional and is not supervised by a dental professional, still the mere fact of using "dental chairs" and LED lights would constitute an implied representation of the expressly disclaimed qualifications or supervision; "no conceivable set of disclosures [] could remedy consumer confusion or deception" regarding the qualifications/status of non-dentist providers. (Haywood, Tr. 2745). This is not the claim of an objective observer, analyst, or reporter. A

thorough description of Dr. Haywood's positional bias, as a consequence of which his testimony should be given little if any weight, is contained in CCPFF ¶¶ 800-906.

377. Because of the equipment used by non-dentist teeth whiteners, there is an illusion of people having dental training. (Haywood, Tr. 2459).

Response to Finding No. 377

Dr. Haywood's opinion that non-dentist providers convey the illusion of having dental training by use of unspecified equipment, presumably dental chairs, LED lights, and other unnamed things, is utterly unsupported by factual evidence. It reflects his lack of care and objectivity. Dr. Haywood acknowledges that he has "not studied the question" of whether consumers confuse non-dentist providers with dentists or other licensed professionals or are deceived by the look and feel of non-dentist teeth bleaching operations. (Haywood, Tr. 2745). Non-dentist providers testified and documents, such as operating protocols, showed, that non-dentist providers are at pains to ensure that consumers do not confuse them with dental professionals. (*See* CX0632 at 022-023; CX0630 at 001-013). The record is devoid of any evidence of any non-dental provider holding herself out as having the skill to diagnose and treat dental conditions; and it is devoid of any evidence that consumers believe that non-dentist providers have dental training. Dr. Haywood believes that the mere use of equipment like "dental chairs" and LED lights is an implied representation of dental training. He is untroubled by the lack of evidence of consumer confusion; he is ignorant as to non-dentist provider practices and protocols that help to avoid any possible confusion, and content to remain so (CCPFF ¶ 848); and he is not in the least hobbled by his lack of qualification in interpreting implied claims and consumer behavior. (Haywood, Tr. 2579). Indeed, Dr. Haywood's position is that even were

each non-dentist provider to explicitly inform each prospective customer that she has no dental training, still the mere fact of offering teeth bleaching would constitute an implied representation of the expressly disclaimed training; "no conceivable set of disclosures [] could remedy consumer confusion or deception" regarding the qualifications/status ofnon-dentist providers. (Haywood, Tr. 2745). This is not the claim of an objective observer, analyst, or reporter. A thorough description of Dr. Haywood's positional bias, as a consequence of which his testimony should be given little if any weight, is contained in CCPFF ¶¶ 800-906.

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).

Response to Finding No. 378

Dr. Haywood's opinion that non-dentist providers who encourage or direct customers during teeth bleaching convey an illusion that they possess the knowledge of a dental professional about teeth whitening is utterly unsupported by factual evidence. It reflects his lack of care and objectivity. Dr. Haywood acknowledges that he has "not studied the question" of whether consumers confuse non-dentist providers with dentists or other licensed professionals or are deceived by the look and feel of non-dentist teeth bleaching operations. (Haywood, Tr. 2745). Non-dentist providers testified and documents, such as operating protocols, showed, that non-dentist providers are at pains to ensure that consumers do not confuse them with dental professionals. (*See* CX0632 at 022-023; CX0630 at 001-013). The record is devoid of any evidence of any non-dental provider holding herself out as having knowledge of teeth bleaching beyond what would be expected of a lay teeth bleaching provider, and it is devoid of any evidence that consumers believe that non-dentist providers have knowledge beyond what would be

expected of a lay teeth bleaching provider. Dr. Haywood believes that the mere offering of teeth bleaching is an implied representation of the knowledge of a dental professional about teeth whitening. He is untroubled by the lack of evidence of consumer confusion; he is ignorant as to non-dentist provider practices and protocols that help to avoid any possible confusion, and content to remain so (CCPFF ¶ 848); and he is not in the least hobbled by his lack of qualification in interpreting implied claims and consumer behavior. (Haywood, Tr. 2579). Indeed, Dr. Haywood's position is that even were each non-dentist provider to explicitly inform each prospective customer that she is not a dental professional and has only the knowledge of a lay person regularly engaged in teeth bleaching, still the mere fact of offering teeth bleaching would constitute an implied representation of the expressly disclaimed knowledge; "no conceivable set of disclosures [] could remedy consumer confusion or deception" regarding the qualifications/status of non-dentist providers. (Haywood, Tr. 2745). This is not the claim of an objective observer, analyst, or reporter. A thorough description of Dr. Haywood's positional bias, as a consequence of which his testimony should be given little if any weight, is contained in CCPFF ¶¶ 800-906. We offer one final comment regarding this proposed finding, which refers somewhat glibly to "the knowledge of a dental professional about teeth whitening." Some dentists, including some Board members, have remarkably little knowledge and experience of teeth bleaching. (CCPFF ¶ 981). And the manufacturer-provided training and experience of teeth bleaching acquired by lay teeth bleaching providers may be substantial, and in some instances superior. (CCPFF ¶ 461).

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).

Response to Finding No. 379

Dr. Haywood's opinion that non-dentist providers present themselves as dental professionals with the skill and training to diagnose and treat dental conditions is utterly unsupported by factual evidence. It reflects his lack of care and objectivity. Dr. Haywood acknowledges that he has "not studied the question" of whether consumers confuse non-dentist providers with dentists or other licensed professionals or are deceived by the look and feel of non-dentist teeth bleaching operations. (Haywood, Tr. 2745). Non-dentist providers testified and documents, such as operating protocols, showed, that non-dentist providers are at pains to ensure that consumers do not confuse them with dental professionals. (*See* CX0632 at 022-023; CX0630 at 001-013). The record is devoid of any evidence of any non-dental provider holding herself out as having the skill to diagnose and treat dental conditions, and it is devoid of any evidence that consumers believe that non-dentist providers have the training and skills to diagnose and treat dental conditions. Dr. Haywood believes that the mere offering of teeth bleaching is an implied representation of the training and skill to diagnose and treat dental conditions. He is untroubled by the lack of evidence of consumer confusion; he is ignorant as to non-dentist provider practices and protocols that help to avoid any possible confusion, and content to remain so (CCPFF ¶ 848); and he is not in the least hobbled by his lack of qualification in interpreting implied claims and consumer behavior. (Haywood, Tr. 2579). Indeed, Dr. Haywood's position is that even were each non-dentist provider to explicitly inform each prospective customer that she is not a dental professional and is not qualified by training or skill to diagnose and treat dental conditions, still the mere fact of offering teeth bleaching would constitute an implied representation of the

expressly disclaimed training and skill; "no conceivable set of disclosures [] could remedy consumer confusion or deception" regarding the qualifications/status of non-dentist providers. (Haywood, Tr. 2745). This is not the claim of an objective observer, analyst, or reporter. A thorough description of Dr. Haywood's positional bias, as a consequence of which his testimony should be given little if any weight, is contained in CCPFF ¶¶ 800-906 .

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).

Response to Finding No. 380

Teeth bleaching is a cosmetic procedure, not a "treatment." (CCPFF ¶ 732; Giniger, Tr. 216 (Food and Drug Administration ("FDA") has classified hydrogen peroxide as a cosmetic)). Non-dentist provided teeth bleaching is itself safe and does not mask pathologies thereby inhibiting diagnosis and treatment resulting in harm. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 976-977 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked delaying diagnosis/treatment, little or no harm would result)). Despite millions upon millions of non-dentist provided teeth bleachings, there is no literature showing non-transient material injury from teeth bleaching, (CCPFF ¶ 734), nor is there so much as a single case report in which non-dentist provided teeth bleaching masked a pathology thereby harming a consumer. (CCPFF ¶ 994). Consumer satisfaction with non-dentist provided teeth bleaching is high, (CCPFF ¶ 711), and may

increase a consumer's interest in maintaining dental hygiene, including by seeking dental care he might otherwise have avoided. (Giniger, Tr. 124). If a given non-dentist provided teeth bleaching does not satisfy a consumer, that itself may lead the consumer to consult a dentist, whereas the consumer might otherwise not do so.

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).

Response to Finding No. 381

Complaint Counsel has no specific response.

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).

Response to Finding No. 382

Teeth bleaching is a cosmetic procedure, not a "treatment. (*See* CCPFF ¶ 732, Giniger, Tr. 216 (FDA has classified hydrogen peroxide as a cosmetic)). Non-dentist provided teeth bleaching is itself safe and does not mask pathologies thereby inhibiting diagnosis and treatment resulting in harm. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 976-977 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked delaying diagnosis/treatment, little or no harm would result)). Despite millions upon millions of non-dentist provided teeth bleachings, there is

no literature showing non-transient material injury from teeth bleaching, (CCPFF ¶ 734), nor is there so much as a single case report in which non-dentist provided teeth bleaching masked a pathology thereby harming a consumer. (CCPFF ¶ 994). Non-dentist providers routinely inform customers of the limitations of teeth bleaching, such as the fact that most existing restorations will not change color, that the product is not recommended for nursing mothers, and that consumers with dental problems should consult a dentist before using the product. (*See* CX0632 at 022-023). The bleaching agents used by non-dentists are the same as those used by dentists, in concentrations appropriate to lay provided bleaching and the specific delivery system used. (CCPFF ¶¶ 447, 456, 953-954). Consumer satisfaction with non-dentist provided teeth bleaching is high. (CCPFF ¶ 711).

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).

Response to Finding No. 383

Notwithstanding Dr. Haywood's expressed concern, non-dentist provided teeth bleaching is safe and does not mask pathologies thereby inhibiting diagnosis and treatment resulting in harm. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 976-977 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked delaying diagnosis/treatment, little or no harm would result)). Despite millions upon millions of non-dentist provided teeth bleachings, there is

no literature showing non-transient material injury from teeth bleaching, (CCPFF ¶ 734), nor is there so much as a single case report in which non-dentist provided teeth bleaching masked a pathology thereby harming a consumer. (CCPFF ¶ 994). Non-dentist providers routinely inform customers of the limitations of teeth bleaching, such as the fact that most existing restorations will not change color, that the product is not recommended for nursing mothers, and that consumers with dental problems should consult a dentist before using the product. (*See* CX0632 at 022-023). The bleaching agents used by non-dentists are the same as those used by dentists, in concentrations appropriate to lay provided bleaching and the specific delivery system used. (CCPFF ¶¶ 447, 457, 953-954). Consumer satisfaction with non-dentist provided teeth bleaching is high. (CCPFF ¶ 711). These kinds of concerns, whether expressed by Dr. Haywood or by the Board, are not reasons for excluding non-dentist providers from teeth bleaching; they are mere excuses for doing so based on bias or interest.

384. 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).

Response to Finding No. 384

Concern as to allergic materials is, at best, misguided. Hydrogen peroxide is naturally occurring in the human body, and so is not an allergen. (CCPFF ¶ 932). Non-dentist provided bleaching formulations often are similar to and made in the same facilities as dentists' formulations, and contain food-safe ingredients. (CCPFF ¶ 954). There is no evidence that non-dentist providers are more likely to use latex materials in their facilities than are dentists in their offices, and latex-allergic consumers are vigilant in their avoidance of latex. (Giniger, Tr. 229-230). Neither Dr. Haywood nor any other witness was aware of even one reported instance of a

customer ever suffering an anaphylactic reaction resulting from non-dentist provided teeth bleaching. (CCPFF ¶¶ 931, 939, 1050). Similarly, concern as to aspiration or gagging on impression material is, at best, misguided. As demonstrated at trial, non-dentist teeth bleachers use a variety of delivery systems that do not require the taking of impressions, such as self-customizing trays that the consumer simply bites on. (CCPFF ¶¶ 198, 449-451). And again, neither Dr. Haywood nor any other witness was aware of even one reported instance of a customer being injured as a result of aspiration or gagging on impression material while undergoing non-dentist provided teeth bleaching. (CCPFF ¶ 1050). These kinds of concerns, whether expressed by Dr. Haywood or by the Board, are not reasons for excluding non-dentist providers from teeth bleaching; they are mere excuses for doing so based on bias or interest.

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).

Response to Finding No. 385

Complaint Counsel has no specific response.

386. Infection control and sanitation are critical issues for the delivery of patient care, including teeth bleaching. (Haywood, Tr. 2530).

Response to Finding No. 386

Non-dentist provided teeth bleaching facilities follow infection control and sanitation procedures that are appropriate to their setting, and that often are the subject of written protocols. (CCPFF ¶ 1079; *see also* CX0630 at 001-013). And as to the many non-dentist providers who are

licensed cosmeticians, extensive, detailed sanitation regulations to which they must adhere are prescribed by another State Board. (CCPFF ¶ 1092). All non-dentist providers typically use pre-packaged, single use bleaching materials that are self-applied by consumers, regularly disinfect items of equipment like "dental chairs" and LED lights, and glove (and re-glove) up prior to interacting with each new consumer. (CCPFF ¶¶ 198, 453, 457, 1099 (describing typical protocol for lay-operated facility), 449-451, 1078 (discussing pre-packaged, single use products)). Neither Dr. Haywood nor any other witness was aware of even one reported instance of a customer being injured by the spread of a communicable disease or otherwise as a result of an infection control or sanitation failure at a non-dentist-operated teeth bleaching facility. (CCPFF ¶ 1077).

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).

Response to Finding No. 387

Dentists regularly use invasive procedures with their patients – dentists' fingers go into patients' mouths. Their use of gloves is, according to the Board's Dr. Hardesty, to "protect us [the dentists] from potentially [sic] contamination or contaminated material and saliva and blood." (Hardesty, Tr. 2782). The highest standards of infection control and sanitation therefore are incumbent on them, and yet many dentists have been found to be woefully ignorant of prescribed infection control and sanitation requirements for dental practices. (*See* Giniger, Tr. 264; *see also* CCPFF ¶¶ 1093 (Board has found licensed dentists that have engaged in unsanitary practices), 1100 (dental office equipment can harbor/transmit deadly microbes)).

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).

Response to Finding No. 388

Not all dentists are members of the Board Counsel and bound by its code of ethics. And membership or no, not all dentists govern themselves by high ethical standards. (Haywood, Tr. 2625-2626). Dr. Haywood himself noted that dentists sometimes subordinate patients' interests to their own financial interests when he wrote, "the biggest challenge in esthetic dentistry is to maintain the ethics of the dental profession and to place patient care ahead of financial gain." (Haywood, Tr. 2626).

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).

Response to Finding No. 389

Complaint Counsel has no specific response.

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).

Response to Finding No. 390

Complaint Counsel has no specific response.

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).

Response to Finding No. 391

Complaint Counsel has no specific response.

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 theconcentration maximums that might be appropriate. (Haywood, Tr. 2564).

Response to Finding No. 392

Despite the concerns expressed by the ADA House of Delegates and in the report it chartered, several prominent commentators reviewed a draft and rejected key elements of the report that challenged the safety of non-dentist provided teeth bleaching. (CCPFF ¶¶ 884-885). These included Dr. Haywood's co-developer of Nightguard Vital Bleaching, Dr. Heymann, who concluded that consumer use of OTC bleaching products such as Crest Whitestrips was safe, rejecting Dr. Haywood's theory that non-dentist provided teeth bleaching might mask pathology and impede diagnosis and treatment to the harm of consumers. (CCPFF ¶¶ 883-885, 1004-1005).

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).

Complaint Counsel has no specific response.

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).

Response to Finding No. 394

The ADA petition has been challenged as reflecting bad science as well as for failing to apprise the FDA of the numerous studies that tend to establish the safety of hydrogen peroxide when used as a cosmetic in teeth bleaching, contrary to its obligation to do so. (CX0496 at 001-008; *cf.* CCPFF ¶ 1124).

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) nondental 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 bee 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).

Response to Finding No. 395

Notwithstanding Dr. Haywood's expressed concern, non-dentist provided teeth bleaching is itself safe, and does not mask pathologies thereby inhibiting diagnosis and treatment resulting in harm. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 976-977 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked delaying diagnosis/treatment, little or no harm would result)). Dr. Haywood says there has been no research for concentrations of hydrogen peroxide above 15%, but dentists regularly use concentrations of hydrogen peroxide of 25% and more–the highest concentrations of all users, without apparent harm to patients (CCPFF ¶¶ 177-178, 427), and without Dr. Haywood, or the Board, calling for regulatory action. Despite millions upon millions of non-dentist provided teeth bleachings, there is no literature showing non-transient material injury from teeth bleaching, (CCPFF ¶ 734), nor is there so much as a single

case report in which non-dentist provided teeth bleaching masked a pathology thereby harming a consumer. (CCPFF ¶ 994). Non-dentist providers routinely inform customers of the limitations of teeth bleaching, such as the fact that most existing restorations will not change color, that the product is not recommended for nursing mothers, and that consumers with dental problems should consult a dentist before using the product. (*See* CX0632 at 022-023). The bleaching agents used by non-dentists are the same as those used by dentists, in concentrations appropriate to lay provided bleaching and the specific delivery system used. (CCPFF ¶¶ 447, 457, 953-954). Consumer satisfaction with non-dentist provided teeth bleaching is high. (CCPFF ¶ 711). These kinds of concerns, whether expressed by Dr. Haywood or by the Board, are not reasons for excluding non-dentist providers from teeth bleaching; they are mere excuses for doing so based on bias or interest. Dr. Haywood preferred to express concern about "unknown" non-dentist applied product composition – possible too low pH, possible use of ingredients posing risk of anaphylactic reaction to sufferers of Celiac Disease or latex allergy – than to make any inquiries that might eliminate those concerns. (*See, e.g.*, CCPFF ¶¶ 868 (no effort to learn about ingredients in non-dentist products despite expressing concerns about allergies), 869-873 (no effort to learn about the potential for harm to enamel despite expressing such concerns), 867 (no effort to learn about protocols of non-dentist operated facilities despite expressing concerns about sanitation)).

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).

Response to Finding No. 396

Complaint Counsel has no specific response.

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).

Response to Finding No. 397

Complaint Counsel has no specific response.

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).

Response to Finding No. 398

Non-dentist provided teeth bleaching is itself safe and does not mask pathologies thereby inhibiting diagnosis and treatment resulting in harm. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 976-977 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked delaying diagnosis/treatment, little or no harm would result)). It is a valued alternative to dentist provided teeth bleaching based on consumers' varied preferences, lifestyles, finances, and other considerations. (CCPFF ¶¶ 473, 494). Non-dentist providers routinely inform customers of the limitations and cautions appropriate to teeth bleaching, such as the fact that most existing restorations will not change color, that the product is not recommended for nursing mothers, and that consumers with dental problems should consult a dentist before using the product. (*See* CX0632 at 022-023). This operates to protect consumers much as informed consent does in those

dental practices that obtain it. Consumers make their own cost-benefit analyses, and customer satisfaction with non-dentist provided teeth bleaching is high. (CCPFF ¶ 711).

399. In Dr. Haywood's opinion, non-dentist teeth whitening does not have a good cost-benefit or risk-benefit ratio, and misleads the public as to safety and efficacy. (Haywood, Tr. 2573).

Response to Finding No. 399

Non-dentist provided teeth bleaching is itself safe and does not mask pathologies thereby inhibiting diagnosis and treatment resulting in harm. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 976-977 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked delaying diagnosis/treatment, little or no harm would result)). It is a valued alternative to dentist provided teeth bleaching, based on consumers' varied preferences, lifestyles, finances, and other considerations. (CCPFF ¶¶ 473, 494). Non-dentist providers routinely inform customers of the limitations and cautions appropriate to teeth bleaching, such as the fact that most existing restorations will not change color, that the product is not recommended for nursing mothers, and that consumers with dental problems should consult a dentist before using the product. (*See* CX0632 at 022-023). This operates to protect consumers much as informed consent does in those dental practices that obtain it. Consumers make their own cost-benefit analyses, and customer satisfaction with non-dentist provided teeth bleaching is high. (CCPFF ¶711). Dr. Haywood's opinion that non-dentist provided teeth whitening is a bad or unsafe bargain is a product of his

positional bias rather than objective evidence, which runs quite to the contrary. A thorough description of Dr. Haywood's positional bias is contained in CCPFF ¶¶ 800-906.

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).

Response to Finding No. 400

Teeth bleaching is not the removal of stains. The mechanism of action of bleaching has long been understood. A bleaching agent generates "free radicals" that cleave the carbon:carbon double bonds that impart color to stains on or in the teeth. With the cleaving of those double bonds, the stains lighten, but they are not removed and the stains will "rebound" over time. (CCPFF ¶ 170).

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).

Response to Finding No. 401

Complaint Counsel has no specific response.

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).

Response to Finding No. 402

Dr. Haywood claimed that "millions upon millions of consumers" is an aggregation of OTC product and non-dentist service provider sales. A precise aggregation of those sales, however, would be perhaps 100 million consumers, given that sales of Crest Whitestrips alone likely exceeds 50 million units. (CX0585 at 009; CCPFF ¶ 997). A precise estimate of consumers who had their teeth bleached by lay providers is not available, but, according to trial testimony, retail customers served by lay-operated bleaching facilities using the White Science and White Smile products alone numbered more than a million. (Nelson, Tr. 733; Valentine, Tr. 547). The decades-long collective experience of consumers whose teeth is bleached without prior dental consultation, whether by themselves or by a lay provider, establishes the safety of non-dentist provided teeth bleaching. Both OTC products and those applied by lay providers are hydrogen peroxide or carbamide peroxide at concentrations well-below those used by dentists in their offices. Apart from differences in concentration, the product applied in all three contexts is fundamentally the same. (*See, e.g.,* CCPFF ¶ 1126; *see also* CCPFF ¶¶ 447, 457, 953-954). No material non-transient harm has arisen in any context – which shows the safety of hydrogen peroxide and carbamide peroxide in teeth bleaching – period. (CCPFF ¶¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 976-977 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard)). Further, if non-dentist provided teeth bleaching could mask pathology, it would be at least as apt to do so in instances where consumers self-applied Crest Whitestrips and other OTC products nightly for weeks at a time as in instances where a bleaching agent is applied once by a lay provider. So the absence of any report of masking of pathology in the hundred million plus people who have used Whitestrips demonstrates that Dr. Haywood's

"masked pathology theory" has no basis in reality, period. (CCPFF ¶¶ 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked delaying diagnosis/treatment, little or no harm would result)).

There is a wealth of data demonstrating that non-dentist provided teeth bleaching does not harm consumers. (CCPFF ¶¶ 896-897; *see also* CCPFF ¶¶ 733-736). Dr. Haywood simply refuses to consider it. The reason, he says, is that it is impossible to construct a study that would be probative of the safety of non-dentist provided teeth whitening because all studies begin with a baseline dental examination and have inclusion/exclusion criteria. (CCPFF ¶ 898). This position is extreme and illogical, and has been refuted by Dr. Giniger, (CCPFF ¶¶ 899-904), who himself has conducted numerous studies of the safety of bleaching formulations used by dentists and non-dentist providers, (CCPFF ¶786), and by other commentators including Dr. Haywood's co-developer of Nightguard Vital Bleaching, Dr. Heymann, (CCPFF ¶¶ 905-906). Dr. Haywood acknowledges that under his analysis, even if it were plainly true that non-dentist provided teeth whitening is safe and does not harm consumers by masking pathology, there would be no way to establish those facts and he, therefore, would continue to oppose non-dentist provided teeth bleaching, whether by consumers themselves or by lay providers. (CCPFF ¶¶ 889-894) . Dr. Haywood's reluctance to in the least credit either collective experience with or sound research into non-dentist provided teeth bleaching reflects his positional bias rather than objective evidence, which runs quite to the contrary. A thorough description of Dr. Haywood's positional bias is contained in CCPFF ¶¶ 800-906.

403. There are a number of reasons that there is no "data" showing harm from nondentist 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).

Response to Finding No. 403

Non-dentist provided teeth bleaching is not "a new phenomenon" as claimed in Respondent's proposed finding; non-dentist provided teeth whitening has been in existence since at least 2004. (*See, e.g.*, CX0036 at 001-003 (2004 complaint against Edie's Salon Panache)). And numerous studies showing its safety have been conducted. (CCPFF ¶¶ 896-897). Dr. Haywood simply refuses to consider these studies. The reason, he says, is that it is impossible to construct a study that would be probative of the safety of non-dentist provided teeth whitening because all studies begin with a baseline dental examination and have inclusion/exclusion criteria. (CCPFF ¶ 898). This position is extreme and illogical, and has been refuted by Dr. Giniger, (CCPFF ¶¶ 899-904), who himself has conducted numerous studies of the safety of bleaching formulations used by dentists and non-dentist providers, (CCPFF ¶ 786), and by other commentators including Dr. Haywood's co-developer of Nightguard Vital Bleaching, Dr. Heymann, (CCPFF ¶¶ 905-906). Dr. Haywood acknowledges that under his analysis, even if it were plainly true that non-dentist provided teeth whitening is safe and does not harm consumers by masking pathology, there would be no way to establish those facts and he, therefore, would continue to oppose non-dentist provided teeth bleaching, whether by consumers themselves or by lay providers. (CCPFF ¶¶ 889-894). Dr. Haywood attempted to explain away the absence of even a single Case Report demonstrating that someone, somewhere suffered harm as the result of

a masked pathology by suggesting that dentists have neither the time nor the experience to write such reports. (Haywood, Tr. 2519). But they do write Case Reports, and Dr. Haywood was obliged to concede that there is an incentive for the writing of any Case Report that showed masking of pathology because such a Case Report would be important and well-received by the profession. (CCPFF ¶ 999). Dr. Haywood's excuses for the absence of studies showing harm and his unwillingness to consider the collective experience of consumers and the studies showing lack of harm reflect his positional bias, as a result of which his testimony should be given little or no weight. A thorough description of Dr. Haywood's positional bias is contained in CCPFF ¶¶ 800-906.

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).

Response to Finding No. 404

Dr. Haywood says it is impossible to construct a study that would be probative of the safety of non-dentist provided teeth whitening because all studies begin with a baseline dental examination and have inclusion/exclusion criteria. (CCPFF ¶ 898). This position is extreme and illogical, and has been refuted by Dr. Giniger, (CCPFF ¶¶ 899-904), who himself has conducted numerous studies of the safety of bleaching formulations used by dentists and non-dentist providers, (CCPFF ¶ 786), and by other commentators including Dr. Haywood's co-developer of Nightguard Vital Bleaching, Dr. Heymann, (CCPFF ¶¶ 905-906). Dr. Haywood acknowledges that under his analysis, even if it were plainly true that non-dentist provided teeth whitening is

safe and does not harm consumers by masking pathology, there would be no way to establish those facts and he, therefore, would continue to oppose non-dentist provided teeth bleaching, whether by consumers themselves or by lay providers. (CCPFF ¶¶ 889-894). Dr. Haywood's unwillingness to consider the many studies showing lack of harm reflect his positional bias, as a result of which his testimony should be given little or no weight. A thorough description of Dr. Haywood's positional bias is contained in CCPFF ¶¶ 800-906.

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).

Response to Finding No. 405

Respondent's proposed fact is based on yet another malformed excuse by Dr. Haywood for the lack of evidence in support of his position. It is based on the faulty premise that non-dentist provided teeth bleaching is everywhere illegal. It is not. It may be illegal in some jurisdictions, but, as Dr. Haywood knows, it is legal in others. (Haywood, Tr. 2640). Given the organized dental profession's keen interest in non-dentist provided teeth bleaching, as reflected in its efforts to produce a position paper attacking non-dentist provided teeth bleaching and its petition to the FDA seeking to have hydrogen peroxide declared and regulated as a drug, (CCPFF ¶ 1124), there seemingly would be plenty of interest in the conduction and publication of research on the safety of non-dentist provided teeth whitening showing that such teeth whitening actually harmed consumers. And still, there are no studies of teeth bleaching that show that consumers actually are harmed. (CCPFF ¶¶ 734-736). With respect to research evaluating Dr. Haywood's "masking pathology theory," Dr. Haywood acknowledged that publication of even a Case Report would be important and well-received by the profession. (CCPFF ¶ 999). But there are none.

(CCPFF ¶ 994). Finally, Dr. Haywood's "people don't study practices that are illegal" excuse could not in any event explain the absence of studies showing that consumers' use of plainly lawful OTC products like Crest Whitestrips actually harms consumers. All studies are to the contrary. (CCPFF ¶¶ 896-897).

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).

Response to Finding No. 406

Dr. Haywood is asked, at the portion of the transcript cited by Respondent, if he is aware of any "anecdotal instances of harm to members of the public as a result of kiosk whitening." In reply, he identifies a single instance of harm to a single consumer's enamel–a 1991 Case Report in which the author speculated that observed de-enamelization was attributable to the consumer's use of an OTC product (not to lay provided bleaching). (Haywood, Tr. 2520). That appeared to exhaust Dr. Haywood's list of inculpatory anecdotes. At Haywood, Tr. 2521-2522, Respondent's counsel prompted Dr. Haywood to include Mr. Runsick's story as an anecdotal instance of harm, but counsel could not lay an appropriate foundation and the prompting question was found leading and without foundation by the court, and withdrawn by counsel.

Looking at the infirmity of anecdotes such as these, Dr. Giniger explained that anecdotal claims are not a sound basis for making valid determinations, especially isolated claims where the alleged cause of harm is widely present. Application of the scientific method is required to properly identify and weigh effects and determine their causes. (Giniger, Tr. 268, 278-279).

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).

Response to Finding No. 407

Although Respondent's proposed finding suggests that its few bits of anecdotal "evidence" of consumer injury are "all that is available" to assess the safety of non-dentist provided teeth bleaching, that is wildly untrue. Research and experience alike indicate that non-dentist provided teeth bleaching is itself safe and does not mask pathologies thereby inhibiting diagnosis and treatment resulting in harm. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 976-977(no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked delaying diagnosis/treatment, little or no harm would result)). Despite millions upon millions of non-dentist provided teeth bleachings, there is no literature showing non-transient material injury from teeth bleaching, (CCPFF ¶ 734), nor is there so much as a single case report in which non-dentist provided teeth bleaching masked a pathology thereby harming a consumer. (CCPFF ¶ 994). There are, however, numerous studies showing the safety of non-dentist provided teeth bleaching, and in particular of at-home use of OTC products. (CCPFF ¶¶ 896-897). Dr. Haywood simply refuses to consider these studies. Instead, Respondent directs the court to its few bits of anecdotal "evidence." Dr. Giniger explained that anecdotal claims are not a sound basis for making valid determinations, especially isolated claims where the alleged cause of harm is widely present.

Application of the scientific method is required to properly identify and weigh effects and determine their causes. (Giniger, Tr. 268, 278-279).

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 - RXlDl; RXI03; RX114 - RX118; RX120 - RX124; RX126 - RX129; RX133 - RX135).

Response to Finding No. 408

Dr. Giniger did no such thing. All of the RXs cited by Respondent in support of the proposed finding were admitted for demonstrative purposes only. They are for the most part newspaper clippings. They were put before Dr. Giniger one by one, and he was asked whether he had heard of them, and nothing more.

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).

Response to Finding No. 409

Teeth bleaching does not remove stains from the teeth. The mechanism of action of bleaching has long been understood. A bleaching agent generates “free radicals” that cleave the carbon:carbon double bonds that impart color to stains on or in the teeth. With the cleaving of those double bonds, the stains lighten, but they are not removed and the stains will “rebound” over time. (CCPFF ¶170). Dr. Haywood’s claim that Dr. Giniger’s explanation of the mechanism of action of teeth bleaching lacks scientific support is itself incorrect. (Giniger, Tr. 154-155 (at molecular level, bleaching is a simple and well-understood chemical reaction);

Haywood Tr. 2634-2638 (noting peer-reviewed articles agreeing in whole or in part with Dr. Giniger's explanation of the mechanism of action of teeth bleaching)).

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).

Response to Finding No. 410

What Dr. Haywood actually said was, "there are some dentists that feel like it does harm the enamel . . . ," and "we've had reports of damage to enamel by inappropriate use of materials, so it's a very innocuous procedure, but it's not without risk." (Haywood, Tr. 2517). Dr. Haywood does not identify these reports. The one such report he elsewhere identified was a 1991 Case Report in which the author speculated that observed de-enamelization was attributable to the consumer's use of an OTC product (not to lay provided bleaching). (RX 77 at 9). Dr. Haywood now simply ignores *in vitro* studies demonstrating that hydrogen peroxide-induced enamel surface changes are smaller than normal variations in the enamel and smaller than those caused by orange juice and carbonated beverages, (CCPFF ¶ 948); *in vivo* studies showing that saliva dilutes hydrogen peroxide, buffers, and remineralizes the teeth preventing softening or etching of enamel, (CCPFF ¶¶ 947, 949-950); and the fact that millions upon millions of consumers have had non-dentist provided teeth bleaching without reported adverse effects to enamel (other than the one consumer reported on in the 1991 Case Report), (CCPFF ¶ 955).

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).

Response to Finding No. 411

Dr. Haywood did no such thing. Dr. Haywood demonstrated through his examples the unremarkable facts that dental trauma can result in abscess to the affected teeth, which may result in their discoloration, and that some such people may not associate the discoloration with the prior trauma. As Dr. Giniger explained, numerous other low-probability events all would have to occur for pathology to be masked, impeding diagnosis/treatment. (CCPFF ¶¶ 1010-1044). Among them, the teeth bleaching would have to be so effective as to substantially eradicate all traces of the trauma-induced stain. But Dr. Haywood concluded that non-dentist provided teeth bleaching was ineffective and unlikely to so-lighten severe staining as to make it unnoticeable by a dentist. (CCPFF ¶¶ 1029-1031). Although Dr. Giniger finds that non-dentist provided teeth bleaching lightens teeth to a degree that satisfies most consumers, (CCPFF ¶ 711), he too observes that non-dentist provided teeth bleaching will not so thoroughly lighten trauma-induced stains as to conceal them from a dentist. (CCPFF ¶ 1028; *see also* CCPFF ¶ 1006 (Board's Dr. Wester testifying teeth bleaching would not conceal pathology from him)). And if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result. (CCPFF ¶ 1045).

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).

Response to Finding No. 412

Dr. Giniger is not an opponent of regular dental check-ups. And the prompt detection of dental abscesses and other conditions that may cause discoloration would, Dr. Giniger agrees, obviate Dr. Haywood's concerns. But Dr. Giniger's testimony was unwavering: the likelihood of non-dentist provided teeth bleaching masking pathology and impeding diagnosis/treatment, and thereby injuring a consumer, is close to zero. (CCPFF ¶¶ 1001, 1043-1044). And if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result. (CCPFF ¶ 1045).

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).

Response to Finding No. 413

Respondent's proposed finding takes Dr. Giniger's testimony out of context. The question to which he was responding was: "Can you explain that to me, how he [Dr. Haywood] supplies or sells specialized trays." Dr. Giniger replied: "He has indicated in his report that he's able–one of the advantages of going to a dentist is that at least in his case he's been able to supply a specialized bleaching tray for persons who have a single darkened tooth." (Giniger, Tr. 468-469). Elsewhere in his testimony, Dr. Giniger explained that a specialized tray is not required in those circumstances. (Giniger, Tr. 324-325).

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).

Response to Finding No. 414

Respondent's proposed finding misstates Dr. Ginger's testimony. Dr. Giniger testified that Dr. Haywood's lack of a PhD "does not mean" that he "is not qualified to testify as an expert in this proceeding." Dr. Giniger rightly testified that the breadth and depth of his own expertise exceeded that of Dr. Haywood, especially insofar as Dr. Giniger, unlike Dr. Haywood, had earned a PhD in Oral Medicine and had undertaken other advanced training beyond the DDS, Dr. Haywood's terminal degree. (Giniger, Tr. 467; *see also* CCPFF ¶¶ 779-780).

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).

Response to Finding No. 415

To clarify the point, Dr. Giniger testified that he reviewed the deposition testimony of Dr. Tilley and Mr. Runsick. Their trial testimony was subsequent to Dr. Giniger's appearance.

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).

Response to Finding No. 416

Dr. Giniger testified that, based on other survey results he had seen as well as his own experience, consumers of non-dentist provided teeth bleaching had greater levels of satisfaction than patients who had undergone dentist provided teeth bleaching. He acknowledged that those

findings differed from those of the survey he had just been shown by Respondent's counsel, but rejected the characterization urged on him by counsel that he disagreed with that survey's "statistic," since he was not aware of the research methodology used in that survey. (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).

Response to Finding No. 417

Several prominent commentators reviewed a draft of the ADA report stating the ADA's position, of which Dr. Haywood was a co-author, and rejected key elements of the report that challenged the safety of non-dentist provided teeth bleaching. (CX585 at 001-012; *see also* CCPFF ¶ 884). These included Dr. Haywood's co-developer of Nightguard Vital Bleaching, Dr. Heymann, who concluded that consumer use of OTC bleaching products such as Crest Whitestrips was safe, rejecting Dr. Haywood's theory that non-dentist provided teeth bleaching might mask pathology and impede diagnosis and treatment to the harm of consumers. (CCPFF ¶¶ 883-885, 1004 ; *cf.* CCPFF ¶1005).

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).

Response to Finding No. 418

It is not necessary to have a dental examination prior to teeth bleaching. (*See* Giniger, Tr. 440-441). Teeth bleaching is a cosmetic procedure, not a "treatment." (CCPFF ¶ 732; Giniger, Tr. 216 (FDA has classified hydrogen peroxide as a cosmetic)). Non-dentist provided teeth

bleaching is itself safe, and does not mask pathologies, and therefore does not inhibit diagnosis and treatment, or result in harm. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 975-976 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked delaying diagnosis/treatment, little or no harm would result)). Despite millions upon millions of non-dentist provided teeth bleachings, there is no literature showing non-transient material injury from teeth bleaching (CCPFF ¶ 734), nor is there so much as a single case report in which non-dentist provided teeth bleaching masked a pathology, thereby harming a consumer. (CCPFF ¶ 994). Consumer satisfaction with non-dentist provided teeth bleaching is high. (CCPFF ¶ 711).

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).

Response to Finding No. 419

No one can determine with precision the required time for optimal bleaching of the teeth. The best counsel for someone seeking optimal whiteness is to continue bleaching until it is achieved. (*See* Giniger Tr. 324, 339-340). Optimal whiteness is unlikely to be achieved in any single chair-side bleaching, whether done by a dentist or a lay-operator. *(*CCPFF ¶ 1030). Non-dentist providers adhere to protocols that require the provision of information to consumers as to the limitations and cautions applicable to teeth bleaching. Customers of lay-operated teeth

bleaching facilities are purchasing a value-proposition that recognizes that, as attested to by their high level of satisfaction. (Kwoka, Tr. 994-995; Giniger, Tr. 322-323). If non-dentist provided teeth bleaching does not ameliorate a discoloration, the consumer may be more motivated than otherwise to consult a dentist. And if more aggressive bleaching or dental treatment of some kind is warranted, the consumer can obtain it at that time without complication. (*Cf.* CCPFF ¶ 1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result)).

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).

Response to Finding No. 420

No one can determine with precision the required time for optimal bleaching of the teeth. The best counsel for someone seeking optimal whiteness is to continue bleaching until it is achieved. (*See* Giniger Tr. 324, 339-340). Optimal whiteness is unlikely to be achieved in any single chair-side bleaching, whether done by a dentist or a lay-operator. (CCPFF ¶ 1030). Non-dentist providers adhere to protocols that require the provision of information to consumers as to the limitations and cautions applicable to teeth bleaching. Customers of lay-operated teeth bleaching facilities are purchasing a value-proposition that recognizes this, as attested to by their high level of satisfaction. (Kwoka, Tr. 994-995; Giniger, Tr. 322-323). If non-dentist provided teeth bleaching does not ameliorate a discoloration, the consumer may be more motivated than otherwise to consult a dentist. And if more aggressive bleaching or dental treatment of some kind

is warranted, the consumer can obtain it at that time without complication. (*Cf.* CCPFF ¶ 1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result)).

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).

Response to Finding No. 421

Notwithstanding Dr. Haywood's expressed concerns, non-dentist provided teeth bleaching is itself safe, and does not mask pathologies, and therefore does not inhibit diagnosis and treatment, or result in harm. (CCPFF ¶ 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result)). Despite millions upon millions of non-dentist provided teeth bleachings, there is no literature showing non-transient material injury from teeth bleaching, (CCPFF ¶ 734), nor is there so much as a single case report in which non-dentist provided teeth bleaching masked a pathology, thereby harming a consumer. (CCPFF ¶ 994). Consumer satisfaction with non-dentist provided teeth bleaching is high. (CCPFF ¶ 711). As Dr. Giniger explained, numerous low-probability events all would have to occur for pathology to be masked, impeding diagnosis/treatment. (CCPFF ¶¶ 1010-1044). Among them, the teeth bleaching would have to be so effective as to substantially eradicate all traces of the trauma-induced stain. But Dr. Haywood concluded that non-dentist provided teeth bleaching was ineffective, and unlikely to so-lighten severe staining as to make it unnoticeable by a dentist. (CCPFF ¶¶ 1029-1031). Although Dr. Giniger finds that non-dentist

provided teeth bleaching lightens teeth to a degree that satisfies most consumers, (CCPFF ¶ 711), he too observes that non-dentist provided teeth bleaching will not so thoroughly lighten trauma-induced stains as to conceal them from a dentist. (CCPFF ¶ 1028; *see also* CCPFF ¶ 1006 (Board's Dr. Wester testifying teeth bleaching would not conceal pathology from him)). And if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result. (CCPFF ¶ 1045). Despite millions upon millions of non-dentist provided teeth bleachings, there is not so much as a single case report in which non-dentist provided teeth bleaching masked a pathology, thereby harming a consumer. (CCPFF ¶ 994). Consumer satisfaction with non-dentist provided teeth bleaching is high (CCPFF ¶ 711), and may increase a consumer's interest in maintaining dental hygiene, including by seeking dental care he might otherwise have avoided. (CCPFF ¶ 738). If a given non-dentist provided teeth bleaching does not satisfy a consumer, that itself may lead the consumer to consult a dentist, whereas the consumer might not otherwise do so.

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).

Response to Finding No. 422

Non-dentist provided teeth bleaching is itself safe, and does not mask pathologies, and therefore does not inhibit diagnosis and treatment, or result in harm. (CCPFF ¶ 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no

harm would result)). As Dr. Giniger explained, numerous low-probability events all would have to occur for pathology to be masked impeding diagnosis/treatment. (CCPFF ¶¶ 1010-1044). Among them, the teeth bleaching would have to be so effective as to substantially eradicate all traces of the trauma-induced stain. But Dr. Haywood concluded that non-dentist provided teeth bleaching was ineffective, and unlikely to so-lighten severe staining as to make it unnoticeable by a dentist. (CCPFF ¶ 1029-1031). Although Dr. Giniger finds that non-dentist provided teeth bleaching lightens teeth to a degree that satisfies most consumers, (CCPFF ¶ 711), he too observes that non-dentist provided teeth bleaching will not so thoroughly lighten trauma-induced stains as to conceal them from a dentist. (CCPFF ¶ 1028; *see also* CCPFF ¶1006 (Board's Dr. Wester testifying teeth bleaching would not conceal pathology from him)). And if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result. (CCPFF ¶ 1045). Despite millions upon millions of non-dentist provided teeth bleachings, there is not so much as a single case report in which non-dentist provided teeth ftlinebleaching masked a pathology, thereby harming a consumer. (CCPFF ¶ 994).

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).

Response to Finding No. 423

Non-dentist provided teeth bleaching is itself safe, and does not mask pathologies, and therefore does not inhibit diagnosis and treatment, or result in harm. (CCPFF ¶ 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked delaying diagnosis/treatment, little or no harm

would result)). As Dr. Giniger explained, numerous low-probability events all would have to occur for pathology to be masked, impeding diagnosis/treatment. (CCPFF ¶¶ 1010-1044). Among them, the teeth bleaching would have to be so effective as to substantially eradicate all traces of the trauma-induced stain. But Dr. Haywood concluded that non-dentist provided teeth bleaching was ineffective, and unlikely to so-lighten severe staining as to make it unnoticeable by a dentist. (CCPFF ¶¶ 1029-1031). Although Dr. Giniger finds that non-dentist provided teeth bleaching lightens teeth to a degree that satisfies most consumers, (CCPFF ¶ 711), he too observes that non-dentist provided teeth bleaching will not so thoroughly lighten trauma-induced stains as to conceal them from a dentist. (CCPFF ¶ 1028; *see also* CCPFF ¶1006 (Board's Dr. Wester testifying teeth bleaching would not conceal pathology from him)). And if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result. (CCPFF ¶ 1045). Despite millions upon millions of non-dentist provided teeth bleachings, there is not so much as a single case report in which non-dentist provided teeth bleaching masked a pathology, thereby harming a consumer. (CCPFF ¶ 994). Consumer satisfaction with non-dentist provided teeth bleaching is high, (CCPFF ¶ 711), and may increase a consumer's interest in maintaining dental hygiene, including by seeking dental care he might otherwise have avoided. (CCPFF ¶ 738). If a given non-dentist provided teeth bleaching does not satisfy a consumer, that itself may lead the consumer to consult a dentist, whereas the consumer might not otherwise do so.

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).

Response to Finding No. 424

Non-dentist provided teeth bleaching is itself safe, and does not mask pathologies, and therefore does not inhibit diagnosis and treatment, or result in harm. (CCPFF ¶ 717 (does not mask pathology impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result)). As Dr. Giniger explained, numerous low-probability events all would have to occur for pathology to be masked, impeding diagnosis/treatment. (CCPFF ¶¶ 1010-1044). Among them, the teeth bleaching would have to be so effective as to substantially eradicate all traces of the trauma-induced stain. But Dr. Haywood concluded that non-dentist provided teeth bleaching was ineffective, and unlikely to so-lighten severe staining as to make it unnoticeable by a dentist. (CCPFF ¶¶ 1029-1031). Although Dr. Giniger finds that non-dentist provided teeth bleaching lightens teeth to a degree that satisfies most consumers, (CCPFF ¶ 711), he too observes that non-dentist provided teeth bleaching will not so thoroughly lighten trauma-induced stains as to conceal them from a dentist. (CCPFF ¶ 1028; *see also* CCPFF ¶1006 (Board's Dr. Wester testifying teeth bleaching would not conceal pathology from him)). And if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result. (CCPFF ¶ 1045). Despite millions upon millions of non-dentist provided teeth bleachings, there is not so much as a single case report in which non-dentist provided teeth bleaching masked a pathology, thereby harming a consumer. (CCPFF ¶ 994). Consumer satisfaction with non-dentist provided teeth bleaching is high, (CCPFF ¶ 711), and may increase a consumer's interest in maintaining dental hygiene, including by seeking dental care he might otherwise have avoided. (CCPFF ¶ 738). If a given non-dentist provided teeth bleaching does not satisfy a consumer, that

itself may lead the consumer to consult a dentist, whereas the consumer might not otherwise do so.

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).

Response to Finding No. 425

Complaint Counsel does not disagree with this statement, but notes that the cited material does not support the finding. CX0595 at 002 and CX0185 at 001 suggest that the safety of their patients is a concern of dentists, but not that dentists have an obligation to insure such safety. Dr. Baumer does not discuss whether or not dentists can evade personal liability for their own malpractice at Baumer, Tr. 1931. (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).

Response to Finding No. 426

Board members did testify that a parade of horribles attends non-dentist provided bleaching services to consumers. These ranged from aspiration/asphyxiation (Owens, Tr. 1457-1459), to the spread of diseases including hepatitis, tuberculosis, and AIDS (Wester, Tr. 1301; Hardesty, Tr. 2782, 2784), to triggering "severely painful" perio-endo lesions and irreversible pulpitis (Hardesty, Tr. 2780-2781), ulceration of corneas (Wester, Tr. 1303; Owens, Tr. 1460), and ripping consumers' lips, (Owens, Tr. 1453-1454). The problem with this testimony is that it is utterly unsupported by factual evidence. In fact, not a single witness at trial could identify any instance, anywhere, in which any of these horribles happened in connection with non-dentist

provided bleaching. They are figments of the imaginations of persons disposed to oppose any encroachment on the territory that the dental profession claims as its own. Unlike non-dentist providers, dentists performing teeth bleachings routinely put fingers and instruments in patients' mouths, paint high concentrations of hydrogen peroxide on patients' teeth, and take impressions with materials that often cause gagging and a risk of aspiration. These activities, not those of non-dentist providers, are attended by the risks identified by Board members. And not all dentists have appropriate knowledge or use appropriate care. (*See* Giniger, Tr. 264; *see also* CCPFF ¶¶ 1093 (Board has found licensed dentists that have engaged in unsanitary practices), 1100 (dental office equipment can harbor/transmit deadly microbes)). But these are outliers. The evidence shows that whether provided by dentists or non-dentist providers, or by consumers' self-applying OTC products, teeth bleaching is itself safe, and does not mask pathologies, and therefore does not inhibit diagnosis and treatment, or result in harm. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 975-976 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology, impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result)).

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).

Response to Finding No. 427

The ADA is organized, among other reasons, to promote the interests of dentists. (*See, e.g.,* CX0496 at 001 (according to Procter & Gamble, ADA's application to reclassify teeth whitening products as a drug is "motivated primarily by the commercial interests of ADA membership")). This often includes opposition to encroachment on the territory that the dental profession claims as its own, for that reason. (Haywood, Tr. 2630-2632 (Haywood's comment about draft document ADA answering "Frequently Asked Questions": "I believe this bleaching question will be what the definition of the profession hinges on for the future. If you cannot defend the position that it is best to see a dentist, then there is no need for a dentist for any other treatments.")). Even so, the final ADA FAQ notes that "whether tooth whitening is performed under the care and supervision of a dentist, self-applied at home or in non-dental settings, whitening materials are generally well-tolerated when used appropriately and according to directions." (CX0227 at 004). Non-dentist provided teeth bleaching is itself safe, and does not mask pathologies, and therefore does not inhibit diagnosis and treatment, or result in harm. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 975-976 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology, impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result)).

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).

Response to Finding No. 428

Complaint Counsel has no specific response.

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).

Response to Finding No. 429

Although it is undisputed that Mr. Valentine did testify that WhiteSmile USA did not encourage its customers to have a dental exam or dental cleaning before undergoing teeth whitening treatment, this proposed finding is incomplete and misleading. Mr. Valentine testified that a version of WhiteSmile USA's training manual did provide that operators should direct customers "to have a regular visit to the dentist." (Valentine, Tr. 583-584).

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)).

Response to Finding No. 430

Dr. Morgan testified at deposition that he was not sure whether the presence of cavities is a contraindication for teeth bleaching. (RX 65 (Morgan, Dep. at 50)). With respect to periodontal disease, Dr. Morgan appears similarly uncertain, first stating that his concern was not that periodontal disease is a contraindication for teeth bleaching, but rather that patients with periodontal disease ought to "spend their money more wisely on getting their teeth fixed and their gums fixed," (RX 65 (Morgan, Dep. at 33-34)), and later suggesting that advanced periodontal disease might be a contraindication for the taking of an impression, because the loosened tooth could be pulled out in the impression material. (RX 65 (Morgan, Dep. at 35)). This is relevant to dentist provided teeth bleaching, but less so, if at all, to non-dentist provided teeth bleaching.

There is little or no evidence that non-dentist providers currently take impressions. Some non-dentist providers of teeth bleaching some time ago appear to have taken impressions of consumers' teeth. There is little or no evidence that such practice continues. Three manufacturers of bleaching systems, together accounting for more than a million consumer applications, testified at trial, and each of them testified that their systems used some kind of pre-formed or self-adapted tray. (Valentine, Tr. 520-521 *and* CX0812 (WhiteSmile product); Osborne, Tr. 653-654 (BriteWhite product); Nelson, Tr. 750-751 (White Science product)). Dr. Giniger demonstrated other systems used by non-dentist providers, that also used pre-formed trays. (Giniger, Tr. 183-186 *and* CX0805 (Whiter Image product)). The use of pre-formed trays entirely obviates the need for the taking of impressions. (*See, e.g.,* Nelson, Tr. 750-751; CCPFF ¶ 457). Dr. Morgan's testimony with respect to "problems with dental work" relates either to increased risk of transient sensitivity or, again, to the taking of impressions rather than teeth bleaching as typically practiced by non-dentist-practitioners. (RX 65 (Morgan, Dep. at 50-51)). Non-dentist providers caution consumers to avoid teeth bleaching if they do not have healthy teeth and gums. (*See* CX0632 at 022-023). And ultimately, the most salient fact with respect to alleged contraindications is that despite millions upon millions of non-dentist provided teeth bleachings, there is no literature showing actual harm to consumers. (CCPFF ¶¶ 734-736).

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).

Response to Finding No. 431

CX0392 at 005, one of the two materials cited by Respondent for its proposed finding, describes an idealized "typical dental examination" including patient interview questions the authors believe relevant to teeth bleaching, such as identifying patient allergies and sensitivities. Dentists may or may not exercise the degree of knowledge and care suggested by the authors of CX0392, but at least some Board members who do sell teeth bleaching services to their patients, could not identify the bleaching formulations they use, the concentration of the bleaching agents in those formulations, or even whether the bleaching agent was hydrogen peroxide or carbamide peroxide. (CCPFF ¶ 981). Non-dentist providers do not provide dental examinations because they neither diagnose nor treat patients. What is more, the bleaching methods they use are less invasive and use lower concentrations of bleaching agents than dentist provided in-office bleaching methods. (*Compare* CCPFF ¶¶ 429-432, 435 (discussing dentist applied teeth bleaching agents and methods) *with* 447-459 (discussing non-dentist applied teeth bleaching agents and methods)). CX0392 does not discuss the information/cautions that non-dentist providers regularly provide to their customers or the other precautions that non-dentist providers take to ensure consumer safety and satisfaction. (CX0632 at 022-023). It provides no basis for the comparative claim made in the proposed finding. The other material cited by Respondent, CX0596 at 002, appears inapposite to the proposed finding.

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)).

Response to Finding No. 432

Complaint Counsel has no specific response.

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)).

Response to Finding No. 433

Complaint Counsel has no specific response.

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).

Response to Finding No. 434

As Respondent indicates, Complaint Counsel's description in its Statement of Material Facts is that of the "typical" procedure. It does not purport to be "universally" applicable.

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)).

Response to Finding No. 435

This proposed finding is inaccurate, misleading, and not entirely supported by the cited evidence. Complaint Counsel does not dispute that some non-dentist providers of teeth bleaching, some time ago, appear to have taken impressions of consumers teeth. There is little or no evidence that this practice continues. Three manufacturers of bleaching systems, together accounting for more than a million consumer applications, testified at trial, and each of them testified that their systems used some kind of a pre-formed or self-adapted tray. (Valentine, Tr.

520-521 *and* CX0812-B (WhiteSmile product); Osborne, Tr. 653-654 (BriteWhite system); Nelson, Tr. 750-751 (White Science product)). Dr. Giniger demonstrated other systems used by non-dentist providers, which also use pre-formed trays. (Giniger, Tr. 183-186 *and* CX0805 (Whiter Image product)). The use of pre-formed trays entirely obviates the need for the taking of impressions. (CCPFF ¶ 457).

Further, after the *Brunson* case decision, the Board believed that courts would be "making a very narrow interpretation of that Dental Practice Act" relating to the unlicensed practice of dentistry (CX0554 at 035, (Allen, Dep. at 133)), with respect to teeth whitening and mouth jewelry, and that there "is not much we can do about it" if customers were "taking their own impressions." (CX0243 at 001; *see also* CCPFF ¶¶ 229-230; CX0159 at 001-002 (Order and Judgment in North Carolina Board of Dental Examiners vs. Rodriguez Brunson ("*Brunson*") March 31, 2005)). In addition, Dr. Brown informed Dr. Litaker of his opinion that the judge had ruled the fabrication of "grills" to be no different than a child wearing a set of wax teeth. (CX0576 at 011, 023 (Litaker, Dep. at 40, 86-87). The Board has not proposed legislation and there has been no change in the Dental Practice Act relating to the fabrication of appliances such as mouth jewelry. (White, Tr. 2332).

In addition, during the NCDS consideration to request that the North Carolina legislature increase the severity of the penalty for unlicensed practice of dentistry, Lisa Piercey, lobbyist for the NCDS, requested an opinion from the North Carolina Attorney General, Roy Cooper, as to whether provision of non-dental teeth whitening or fabrication of "grills" constituted the unlicensed practice of dentistry. In Mr. Cooper's opinion, neither of these constituted the unlicensed practice of dentistry. (CX0576 at 007-008 (Litaker, Dep. at 25-28)).

Finally, the cited testimony suggests that two Board member dentists suggested that they had concerns about safety. Not only is this testimony self-serving, but it does not support the alleged fact that taking impressions actually creates any safety issues. Also, Board members testified that they are not aware of any transmission of infectious disease being attributed to a business providing non-dentist teeth whitening services. (CCPFF ¶¶ 1047).

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).

Response to Finding No. 436

Non-dentist provided teeth bleaching facilities follow infection control and sanitation procedures that are appropriate to their setting, and that often are the subject of written protocols. (CCPFF ¶ 1079; CX0630 at 001-013). And as to the many non-dentist providers who are licensed cosmeticians, the extensive, detailed sanitation regulations to which they must adhere are prescribed by another State Board. (CCPFF ¶ 1092). All non-dentist providers typically use pre-packaged, single-use bleaching materials that are self-applied by consumers, regularly disinfect items of equipment like "dental chairs" and LED lights, and glove (and re-glove) up prior to interacting with each new consumer. (CCPFF ¶¶ 198, 453, 457, 1099 (describing typical protocol for lay-operated facility), 449-451, 1078 (discussing pre-packaged, single-use products)). Neither Dr. Haywood nor any other witness was aware of even one reported instance of a customer being injured by the spread of a communicable disease or otherwise as a result of an infection control or sanitation failure at a non-dentist-operated teeth bleaching facility. (CCPFF ¶ 1077).

In addition, dentist office equipment with running water can carry deadly microbes. (CX0508 at 036-038; Wester, Tr. 1412 (Dr. Wester agrees that there could be "potential fatal issues in dentist's offices" associated with dental equipment using running water); Owens, Tr. 1671-1672; CCPFF ¶1100).

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).

Response to Finding No. 437

Non-dentist provided teeth bleaching facilities follow infection control and sanitation procedures that are appropriate to their setting, and that often are the subject of written protocols. (CCPFF ¶ 1079; CX0630 at 001-013). And as to the many non-dentist providers who are licensed cosmeticians, extensive, detailed sanitation regulations to which they must adhere are prescribed by another State Board. (CCPFF ¶ 1092). All non-dentist providers typically use pre-packaged, single-use bleaching materials that are self-applied by consumers, regularly disinfect items of equipment like "dental chairs" and LED lights, and glove (and re-glove) up prior to interacting with each new consumer. (CCPFF ¶¶ 198, 453, 457, 1099 (describing typical protocol for lay-operated facility), 449-451, 1078 (discussing pre-packaged, single-use products)). Neither Dr. Haywood nor any other witness was aware of even one reported instance of a customer being injured by the spread of a communicable disease or otherwise as a result of an infection control or sanitation failure at a non-dentist-operated teeth bleaching facility. (CCPFF ¶ 1077).

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).

Response to Finding No. 438

This proposed finding in incomplete and misleading. It is undisputed that Mr. Valentine testified that sanitation measures at WhiteSmile mall kiosks included wiping LED lights, chairs, and other surfaces with Lysol sanitary wipes; however, this ignores his testimony that states that the LED light never came in contact with the customer's mouth, and that Lysol kills germs on contact. (Valentine, Tr. 532).

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).

Response to Finding No. 439

This proposed finding is incomplete and misleading. Ms. Osborn is the President of the Council for Cosmetic Teeth Whitening, which advocates a best practices protocol, that includes, among other things, safety and sanitation practices such as making sure that the procedure is totally self-administered; providing protective eyewear where appropriate; insuring that employees wash their hands often; prohibiting employees from touching a customer's lips, mouth, gums or teeth; wearing clean smocks or coats; wearing disposable gloves while handling teeth whitening products; practicing sanitary disposal techniques including using sealed bio-hazard bags for all mouthpieces and other materials that come in contact with the customer; properly cleaning and disinfecting all non-disposable items that come in direct contact with customers using an EPA registered disinfectant; generally following OSHA standards; and encouraging customers with questions or concerns to consult a dentist. (CX0630 at 001-013; Osborn, Tr. 676-679).

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)).

Response to Finding No. 440

Complaint Counsel has no specific response.

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)).

Response to Finding No. 441

Running water is or can be provided to teeth bleaching kiosks in mall operations on request (CCPFF ¶ 1097), and is not only available in salons and other lay-operated teeth bleaching facilities, but required in salons and spas by the North Carolina State Board of Cosmetic Arts Examiners. (CX0827 at 2). But running water is not necessary for effective sanitation in non-dentist provided teeth bleaching. Dr. Owens links the need for running water to teeth bleaching operations in which the provider puts his or her hands in the consumer's mouth (Owens, Tr. 1457), whereas non-dentist providers fixedly adhere to customer self-application principles. (CCPFF ¶¶ 198, 453, 454, 457 (describing typical protocol for lay-operated facility)). And although Dr. Wester prefers soap and water, he acknowledges the possibility that gel and foam sanitizers might be adequate. (Wester, Tr. 1407). Non-dentist provided teeth bleaching facilities follow infection control and sanitation procedures that are appropriate to their setting, and are often the subject of written protocols. And as to the many non-dentist providers who are licensed cosmetologists or estheticians, extensive and detailed sanitation regulations to which they must adhere are prescribed by another State Board. (CCPFF ¶ 1092). All non-dentist

providers typically use pre-packaged, single use bleaching materials that are self-applied by consumers, regularly disinfect items such as "dental chairs" and LED lights, and glove (and re-glove) up prior to interacting with each new consumer. (CCPFF ¶¶ 198, 453, 457, 1099 (describing typical protocol for lay-operated facility), 449-451, 1078 (discussing pre-packaged, single-use products)). Neither Dr. Haywood nor any other witness was aware of even one reported instance of a customer being injured by the spread of a communicable disease or otherwise as a result of an infection control or sanitation failure at a non-dentist-operated teeth bleaching facility. (CCPFF ¶ 1077). Moreover, if there were a reason to require running a water, that would be a less restrictive alternative than a ban. Finally, the presence of running water can be an issue for dentists offices and presents its own potential problems. (CX0508 at 036; Wester, Tr. 1412 (Dr. Wester agrees that there could be "potential fatal issues in dentist's offices" associated with dental equipment using running water); Owens, Tr. 1671-1672; CCPFF ¶1100).

442. Jim Valentine testified that at WhiteSmile mall kiosks there was no running water available for employees to wash their hands. (Valentine, Tr. 598).

Response to Finding No. 442

Concerns related to running water are unsubstantiated; salons have running water. (Osborn, Tr. 954-955 (describing using water and washing hands in salon); Wester, Tr. 1322 ("I'm sure [salons] do" have running water); ¶ 1094). In addition running water is not generally needed. For example, Jim Valentine testified that WhiteSmile used Lysol sanitary wipes to clean its lights, cabinets, and chairs after each customer use because Lysol sanitary wipes kill germs on contact. (Valentine, Tr. 531-532). Also, George Nelson testified that WhiteScience's protocol is

to clean equipment with a disinfectant pad, and that doing so complies with sanitation rules at malls. (Nelson, Tr. 834-835).

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).

Response to Finding No. 443

Complaint Counsel has no specific response.

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)).

Response to Finding No. 444

The materials cited by Respondent do not support the proposed finding. Neither Dr. Oyster nor Dr. Holland discuss the effectiveness of disinfectant wipes in the passages to which Respondent directs the court. And Dr. Hardesty does, but relates the need for other disinfection procedures to the risks created when one person puts his or her hands in the mouth of another (Hardesty, Tr. 2782-2783), something that non-dentist providers studiously avoid doing. (CCPFF ¶ 454; CCPFF ¶¶ 198, 453, 457 (describing typical protocol of a lay provided whitening system)). Non-dentist provided teeth bleaching facilities follow infection control and sanitation procedures that are appropriate to their setting, and that often are the subject of written protocols. (CCPFF ¶ 1079; *see also* CX0630 at 001-013). And as to the many non-dentist providers who are licensed cosmeticians, extensive and detailed sanitation regulations to which they must adhere are prescribed by another State board. (CCPFF ¶ 1092). All non-dentist providers typically use pre-packaged, single-use bleaching materials that are self-applied by consumers, regularly disinfect

items of equipment like "dental chairs" and LED lights, and glove (and re-glove) up prior to interacting with each new consumer. (CCPFF ¶¶ 198, 453, 457, 1078, 1099). Neither Dr. Haywood nor any other witness was aware of even one reported instance of a customer being injured by the spread of a communicable disease or otherwise as a result of an infection control or sanitation failure at a non-dentist-operated teeth bleaching facility. (CCPFF ¶ 1077).

445. Board Counsel contacted the county or state health department about the sanitation issues in the mall kiosks. (RX50 (Bakewell, Dep. at 317-321)).

Response to Finding No. 445

This proposed finding is inaccurate. Ms. Bakewell thinks she contacted one county health department, but it was possibly the state health department instead.

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).

Response to Finding No. 446

This proposed finding is misleading in that it ignores the fact that Board members testified that they are not aware, either personally or through research, that any of these potential injuries ever occurred. (CX0554 at 026 (Allen, Dep. at 95-96) (little to no evidence of any serious harm or non-transient effects caused by non-dentist teeth whitening); CX0555 at 026 (Brown, Dep. at 97) (unaware of any evidence that the practice of teeth whitening by non-dentists, has caused any harm other than transient or temporary sensitivity or irritation); Wester, Tr. 1405-1406 (unaware of any evidence that the practice of teeth whitening by non-dentists has caused any harm other

than transient or temporary sensitivity or irritation); CX0560 at 066 (Feingold, Dep. at 254) (unaware of any empirical literature establishing that consumers have been subject to significant non-transient harm from teeth whitening provided by a non-dentist); CCPFF ¶¶ 907-915).

447. Teeth bleaching could mask the pathology of teeth, such as with the case of an abscess. (Wester, Tr. 1306).

Response to Finding No. 447

Dr. Wester almost expressed concern that teeth bleaching could mask pathology when prompted to do so by Respondent's counsel. But on cross examination Dr. Wester was again asked about the plausibility of non-dentist provided teeth bleaching masking pathology. In reply he indicated that, "[b]eing a trained dentist, I would pick up the pathology," and later adding, "I don't know that a bleaching would lighten it up enough that we couldn't tell that there was a shade difference . . . ." (Wester, Tr. 1397-1398). Non-dentist provided teeth bleaching is itself safe, and does not mask pathologies, and therefore does not inhibit diagnosis and treatment, or result in harm. (CCPFF ¶ 717). As Dr. Giniger explained, numerous low-probability events all would have to occur for pathology to be masked, impeding diagnosis and/or treatment. (CCPFF ¶¶1010-1044). Among them, the teeth bleaching would have to be so effective as to substantially eradicate all traces of the trauma-induced stain. But Dr. Haywood concluded that non-dentist provided teeth bleaching was ineffective, and unlikely to so-lighten severe staining as to make it unnoticeable by a dentist. (CCPFF ¶¶ 1029-1031). Although Dr. Giniger finds that non-dentist provided teeth bleaching lightens teeth to a degree that satisfies most consumers (CCPFF ¶ 711), he too observes that non-dentist provided teeth bleaching will not so thoroughly lighten trauma-induced stains as to conceal them from a dentist. (CCPFF ¶ 1028; *see also* CCPFF ¶1006

(Board's Dr. Wester testifying teeth bleaching would not conceal pathology from him)). And if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result. (CCPFF ¶ 1045). Despite millions upon millions of non-dentist provided teeth bleachings, there is not so much as a single case report in which non-dentist provided teeth bleaching masked a pathology, thereby harming a consumer. (CCPFF ¶ 994). Consumer satisfaction with non-dentist provided teeth bleaching is high, (CCPFF ¶ 711), and may increase a consumer's interest in maintaining dental hygiene, including by seeking dental care he might otherwise have avoided. (CCPFF ¶ 738). If a given non-dentist provided teeth bleaching does not satisfy a consumer, that itself may lead the consumer to consult a dentist, whereas the consumer might otherwise not do so.

448. Jim Valentine of WhiteSmile admitted under oath that "bleaching can potentially mask pathology." (Valentine, Tr. 599).

Response to Finding No. 448

This proposed finding is misleading. Mr. Valentine qualified his answer, stating that any claim from an expert witness on the potential causes of harm from teeth whitening are "wildly exaggerated." It also ignores the fact that Mr. Valentine was not tendered as an expert in dental pathology, and that Complaint Counsel's tendered expert testified that teeth whitening cannot mask pathology. (Valentine, Tr. 599-600; CCPFF ¶¶ 992-1045).

449. Patients with periodontal problems may not be good candidates for teething [*sic*] 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).

Response to Finding No. 449

This proposed finding is misleading. Teeth whitening side-effects are typically transient, and last only a matter of days. (CCPFF ¶¶ 920-923; CX0653 at 012). Reversible pulpitis is not a consequence of teeth bleaching, and there is no data demonstrating harm in this respect from non-dentist teeth whitening. (CCPFF ¶¶ 918, 735-736, 907-909). Any gum inflammation from teeth whitening is temporary and reversible. (CX0653 at 012). In addition there is substantial evidence that non-dentist providers of teeth bleaching products and services work carefully to avoid bleaching vulnerable populations. (CX0632 at 022-023; CX0637 at 002 ("if you have tooth decay, exposed roots, gum disease, braces, have had recent oral surgery or other dental problems, *consult your dentist before using this product*." (emphasis added))).

450. For certain consumers, teeth bleaching could cause damage or necrosis to the nerve of a tooth. (Owens, Tr. 1453-1454; [*sic*.]

Response to Finding No. 450

The sole evidence for Respondent's proposed finding is the testimony of Dr. Owens. The proposed finding is not supported by the testimony of Respondent's expert Dr. Haywood, nor by any credible evidence. Dr. Owens' testimony is so untethered from any actual knowledge, and so inconsistent with the evidence of extensive consumer experience with non-dentist provided teeth bleaching without reported harms, that it should be disregarded in its entirety. Dr. Owens provided a list of "harms" that went as follows: "You could – number one, you could cause – you can cause the nerve of the tooth to be affected, damaged, or necrosed. You could harm the gingival tissues. You could indeed damage the oral soft tissue. The patient's lips can be torn. Parts of the mouth can be torn. And I think that's–I think that's it." (Owens, Tr 1454). On cross

examination, Dr. Owens was asked whether he had "actual knowledge of a nerve of a tooth being necrosed" by non-dentist provided teeth bleaching. Dr. Owens repeatedly answered unresponsively, but after being admonished by the court, Dr. Owens finally admitted that he had no such knowledge. (Owens, Tr. 1648). He then was obliged to admit that he was aware of no literature showing that a nerve of a tooth had been necrosed as a result of non-dentist provided teeth bleaching; that he was unaware of any instance in which a patient's lips were torn as a result of non-dentist provided teeth bleaching; that he was unaware of any instance in which a patient's mouth had been torn as a result of non-dentist provided teeth bleaching; and that he was not aware of any literature showing any instance of any of these things. (Owens, Tr. 1649-1650). Dr. Owens' testimony is unreliable, unsupported by the testimony of Respondent's expert, and inconsistent with the experience of millions of satisfied consumers. The evidence shows that non-dentist provided teeth bleaching is safe. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 975-976 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology, impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result)).

451. For certain consumers, teeth bleaching could cause damage to the gingival tissues. (Owens, Tr. 1453-1454; RX52 (Burnham, Dep. at 114)).

Response to Finding No. 451

If a dentist doing in-office bleaching fails to properly isolate the teeth from the gingival and other soft tissues of the mouth or splatters bleaching material onto unprotected tissue, irritation, inflammation, and burning may occur. (CCPFF ¶ 178). The reason is that dentists doing in-office bleaching use very high concentrations of hydrogen peroxide. (CCPFF ¶¶ 177-178). Because non-dentist provided teeth bleaching does not use similarly high concentrations of hydrogen peroxide, no isolation of the teeth is required. (CCPFF ¶ 456). Further, because non-dentist providers require consumers to self-apply bleaching materials, the delivery systems used almost always involve the use of trays impregnated with peroxide or to which peroxide is applied, avoiding any risk to consumers from splatter. (CCPFF ¶¶ 198, 453-454, 457 (describing typical protocol for lay-operated facility), 449-451, 1078 (discussing pre-packaged, single use products)). If non-dentist providers were using materials/methods that were inappropriate, given the millions of consumers who have had their teeth bleached by lay providers one would expect the literature– or at least a substantial volume of consumer complaints, claims against insurance carriers, and even law suits to reflect that. They do not. There is no such literature; at trial Respondent was able to provide evidence of only three unverified consumer complaints, and, the non-dentist teeth whitening provider witnesses, who themselves account for over a million bleachings, testified that of all consumers served, only one consumer made any claim against their insurance carriers or brought suit. (CCPFF ¶¶ 1108-1109). The evidence shows that non-dentist provided teeth bleaching is safe. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 975-976 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology, impeding diagnosis/treatment), 993-995 (no studies or reports showing masking),

1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result)).

In addition, Dr. Owens' testimony is unreliable, unsupported by the testimony of Respondent's expert, and inconsistent with the experience of millions of satisfied consumers. (Response to RPF ¶ 453).

452. For certain consumers, teeth bleaching could cause damage to the soft tissues of the mouth. (Owens, Tr. 1453-1454).

Response to Finding No. 452

If a dentist doing in-office bleaching fails to properly isolate the teeth from the gingival and other soft tissues of the mouth or splatters bleaching material onto unprotected tissue, irritation, inflammation, and burning may occur. (CCPFF ¶ 178). The reason is that dentists doing in-office bleaching use very high concentrations of hydrogen peroxide. (CCPFF ¶¶ 177-178). Because non-dentist provided teeth bleaching does not use similarly high concentrations of hydrogen peroxide, no isolation of the teeth is required. (CCPFF ¶ 456). Further, because non-dentist providers require consumers to self-apply bleaching materials, the delivery systems used almost always involve the use of trays impregnated with peroxide or to which peroxide is applied, avoiding any risk to consumers from splatter. (CCPFF ¶¶ 198, 453-454, 457 (describing typical protocol for lay-operated facility), 449-451, 1078 (discussing pre-packaged, single use products)). If non-dentist providers were using materials/methods that were inappropriate, given the millions of consumers who have had their teeth bleached by lay providers one would expect the literature– or at least a substantial volume of consumer complaints, claims against insurance carriers, and

even law suits to reflect that. They do not. There is no such literature; at trial Respondent was able to provide evidence of only three unverified consumer complaints, and the non-dentist teeth whitening provider witnesses, who themselves account for over a million bleachings, testified that of all consumers served, only one consumers made any claim against their insurance carriers or brought suit. (CCPFF ¶¶ 1108-1109). The evidence shows that non-dentist provided teeth bleaching is safe. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 975-976 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology, impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result)).

In addition, Dr. Owens' testimony is unreliable, unsupported by the testimony of Respondent's expert, and inconsistent with the experience of millions of satisfied consumers. (Response to RPF ¶ 453).

453. For certain consumers, teeth bleaching could cause the lips or parts of the mouth to be torn. (Owens, Tr. 1453-1454).

Response to Finding No. 453

The sole evidence for Respondent's proposed finding is the testimony of Dr. Owens. The proposed finding is not supported by the testimony of Respondent's expert Dr. Haywood, nor by any credible evidence. Dr. Owens' testimony is so untethered from any actual knowledge, and so inconsistent with the evidence of extensive consumer experience with non-dentist provided teeth

bleaching without reported harms, that it should be disregarded in its entirety. Dr. Owens provided a list of "harms" that went as follows: "You could – number one, you could cause – you can cause the nerve of the tooth to be affected, damaged, or necrosed. You could harm the gingival tissues. You could indeed damage the oral soft tissue. The patient's lips can be torn. Parts of the mouth can be torn. And I think that's–I think that's it." (Owens, Tr 1454). On cross examination, Dr. Owens was asked whether he had "actual knowledge of a nerve of a tooth being necrosed" by non-dentist provided teeth bleaching. Dr. Owens repeatedly answered unresponsively, but after being admonished by the court Dr. Owens finally admitted that he had no such knowledge. (Owens, Tr. 1648). He then was obliged to admit that he was aware of no literature showing that a nerve of a tooth had been necrosed as a result of non-dentist provided teeth bleaching; and that he was unaware of any instance in which a patient's lips were torn as a result of non-dentist provided teeth bleaching; that he was unaware of any instance in which a patient's mouth had been torn as a result of non-dentist provided teeth bleaching; and that he was not aware of any literature showing any instance of any of these things. (Owens, Tr. 1649-1650). Dr. Owens' testimony is unreliable, unsupported by the testimony of Respondent's expert, and inconsistent with the experience of millions of satisfied consumers. The items on Dr. Owens list are not reasons for excluding non-dentist providers from teeth bleaching; they are mere excuses for doing so based on bias or interest. The evidence shows that non-dentist provided teeth bleaching is safe. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 975-976 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology, impeding diagnosis/treatment), 993-995 (no studies or reports showing masking),

1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result)).

454. There is a risk of aspirating a device placed in the mouth during any teeth whitening procedure. (RX52 (Burnham, Dep. at 114-155).

Response to Finding No. 454

Dr. Giniger and other witnesses showed the court the bleaching trays that consumers put in their mouths when bleaching their teeth, either at a lay-operated facility or in their homes using OTC products like Crest Whitestrips. (CCPFF ¶ 450 *and* CX0805 (non-dentist chair-side bleaching product), CCPFF ¶ 451 *and* CX0817 (non-dentist chair-side bleaching product), CCPFF ¶ 464 *and* CX0810 (non-dentist take-home product)). They are similar to the mouthpieces used by athletes to protect their teeth in contact sports, who appear to do so without choking on them. It is apparent from observation alone that bleaching trays are of a size and shape that makes choking on them a remote possibility, if that. Dr. Burnham, whose deposition is the only reference cited by Respondent for its proposed fact, acknowledged that he had never heard of a consumer being injured by aspirating a bleaching tray or any other device or substance during non-dentist provided teeth bleaching. (RX52 (Burnham, Dep. at 115)). Said Dr. Burnham, "we're talking hypothetical, okay?" (RX52 (Burnham, Dep. at 115)).

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).

Response to Finding No. 455

Dr. Hardesty did not testify that teeth bleaching posed a danger to severe gaggers. He simply indicated that they should not undergo teeth bleaching because "[t]hey can't tolerate the impressions." (Hardesty, Tr. 2779). As demonstrated at trial, non-dentist teeth bleachers use a variety of delivery systems that do not require the taking of impressions, such as self-customizing trays that the consumer simply bites on. ((CCPFF ¶ 450 *and* CX0805 (non-dentist chair-side bleaching product); CCPFF ¶ 451 *and* CX0817 (non-dentist chair-side bleaching product); CCPFF ¶ 464 *and* CX0810 (non-dentist take-home product)). Dr. Hardesty was asked on cross examination whether there were people who would gag if he tried to make an alginate impression of their teeth, but who would not gag on a "boil-and-bite" tray. (Hardesty, Tr. 2819). He claimed a lack of knowledge sufficient to reply (Hardesty, Tr. 2819), notwithstanding his acknowledgment that even the taking of an alginate impression only infrequently triggered a gag reflex, and that "absolutely" he has had "a number of patients" who will gag on alginate, but not during dental examination and prophylactic treatments. (Hardesty, Tr. 2820). And again, neither Dr. Hardesty nor any other witness was aware of even one reported instance of a customer being injured as a result of aspiration or gagging while undergoing non-dentist provided teeth bleaching. (CCPFF ¶ 1050). The evidence shows that non-dentist provided teeth bleaching is safe. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 975-978 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology, impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions),

1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result)).

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).

Response to Finding No. 456

The material cited by Respondent is plainly inapposite. At Hardesty, Tr. 2779-2780, Dr. Hardesty did not testify that non-dentist provided teeth bleaching posed a danger to people with severely limited range of jaw motion. He simply stated that "you can't force [their jaws] open for long periods of time that some of the in-office procedures require." (Hardesty, Tr. 2780). Dr. Hardesty's statement referred to dental procedures, not non-dentist provided teeth bleaching, but in any event addressed practicability, not risk.

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).

Response to Finding No. 457

Concern as to allergic reaction is, at best, misguided. Hydrogen peroxide is naturally occurring in the human body, and so is not an allergen. (CCPFF ¶932; Giniger, Tr. 224). Non-dentist provided bleaching formulations often are similar to and made in the same facilities as dentists' formulations, and contain food-safe ingredients. (CCPFF ¶954). There is no evidence that non-dentist providers are more likely to use latex materials in their facilities than are dentists in their offices, and latex-allergic consumers are vigilant in their avoidance of latex. (Giniger, Tr. 230). Not a single witness indicated awareness of, nor did any documentary evidence identify, even one reported instance of a customer ever suffering an anaphylactic reaction resulting from

non-dentist provided teeth bleaching. (CCPFF ¶¶ 939 (Dr. Haywood not aware), 1050 (Dr. Hardesty not aware); entire record).

458. Dentists have also expressed concerns about follow-up care and informed consent. (RX76 (Parker, Dep. at 84-85).

Response to Finding No. 458

Teeth bleaching is a cosmetic procedure, not a "treatment." (CCPFF ¶ 732; Giniger, Tr. 216 (FDA has classified hydrogen peroxide as a cosmetic)). Non-dentist providers routinely inform customers of the limitations and cautions appropriate to teeth bleaching, such as the fact that most existing restorations will not change color, that the product is not recommended for nursing mothers, and that consumers with dental problems should consult a dentist before using the product. (*See e.g.*, CX0632 at 022-023). This operates to protect consumers much as informed consent does in those dental practices that obtain it. Consumers make their own cost-benefit analyses, and customer satisfaction with non-dentist provided teeth bleaching is high. (CCPFF ¶ 711). Non-dentist provided teeth bleaching is safe. (CCPFF ¶ 716 (safe and effective); *see also* ¶¶ 931-944 (little or no risk of allergic reaction), 945-962 (little or no risk to enamel or pulp), 963-971 *and* 975-978 (no systemic toxicity), 1047 *and* 1077-1087 (no infection control/sanitary hazard), 717 (does not mask pathology, impeding diagnosis/treatment), 993-995 (no studies or reports showing masking), 1010-1044 (masking theory requires satisfaction of all of numerous low-likelihood conditions), 1045 (if in some instance a pathology were masked, delaying diagnosis/treatment, little or no harm would result)). If required, follow-up information relating to use of NSAIDs and other measures to relieve post-bleaching transient teeth pain or

gum sensitivity is readily available, and dentists are available in the unlikely event that follow-up care is required. (*Cf.* CX0632 at 015).

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).

Response to Finding No. 459

This proposed finding is inaccurate, misleading, and only partially supported by the evidence. The cited evidence only shows that on the date of these documents, complaints were filed with the Board by two consumers alleging they were harmed by non-dentist teeth whitening. The cited evidence does not support the contention that they were in fact harmed by non-dentist teeth whitening. In fact, the e-mail in RX17 states that a dentist could not attribute the consumer's dental problems to the whitening procedure she received. RX17 at 1.

In addition, insofar as "began receiving" suggests that additional complaints were received, the evidence only supports the fact that these two complaints were received and no others. (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).

Response to Finding No. 460

Complaint Counsel has no specific response.

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).

Response to Finding No. 461

Complaint Counsel has no specific response.

462. Mr. Runsick has used over-the-counter teeth whitening products. He used Crest Whitestrips in the mid- to late 1990s. (Runsick, Tr. 2103).

Response to Finding No. 462

Complaint Counsel has no specific response.

463. Mr. Runsick received very minimal results from his use of Crest Whitestrips. (Runsick, Tr. 2104).

Response to Finding No. 463

Complaint Counsel has no specific response.

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).

Response to Finding No. 464

Complaint Counsel has no specific response.

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).

Response to Finding No. 465

Complaint Counsel has no specific response.

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).

Response to Finding No. 466

Complaint Counsel has no specific response.

467. After agreeing to undergo a teeth whitening procedure, Mr. Runsick was given a cloth to wipe his teeth off with. (Runsick, Tr. 2106).

Response to Finding No. 467

Complaint Counsel has no specific response.

468. Mr. Runsick was not given a warning about the teeth whitening services before he underwent the procedure. (Runsick, Tr, 2107).

Response to Finding No. 468

The proposed finding is inconsistent with previous and subsequent testimony, and likely inaccurate. At trial, Mr. Runsick did testify to this fact, but other sworn testimony suggests that this statement is inaccurate. Mr. Runsick testified that prior to beginning his teeth whitening procedure he was asked to sign a release, which he twice admitted not reading, and he could not recall whether that document contained any information about a possible risk from the product. Typically a non-dentist provider will follow a protocol provided by a teeth whitening manufacturer or distributor. While each protocol is slightly different, all require the operator to provide the customer with literature, and some require the customer to answer questions before the procedure begins. Therefore it is quite likely that Mr. Runsick was given information about the potential side effects of teeth whitening, and did not bother to read it. (Runsick, Tr, 2107, 2140-2141; CX0579 at 016 (Runsick, Dep. at 55-57); CX0108 at 009; CX0049 at 056-067; Valentine, Tr. 545-546; Osborn, Tr. 653, 707; Nelson, Tr. 796-797; RPF ¶ 469).

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).

Response to Finding No. 469

This proposed finding is potentially inconsistent with RPF ¶ 468. (RPF ¶ 468).

470. Mr. Runsick paid about $99, plus tax, for his teeth whitening services at BleachBright. (Runsick, Tr. 2108).

Response to Finding No. 470

Complaint Counsel has no specific response.

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).

Response to Finding No. 471

Complaint Counsel has no specific response.

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).

Response to Finding No. 472

Complaint Counsel has no specific response.

473. Mr. Runsick did not observe any BleachBright employee sanitize the chair before he sat in it. (Runsick, Tr. 2108).

Response to Finding No. 473

Complaint Counsel has no specific response.

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).

Response to Finding No. 474

This proposed finding is misleading and contradicted by sworn testimony. Mr. Runsick clarified several times that the piece that was cleaned was not from inside another customer's mouth, but was a piece that attached to the light which could come in contact with the person's

mouth. In addition, Mr. Runsick testified that the tray that he placed in his own mouth was brand new. Further, upon cross-examination, Mr. Runsick testified that it was not a Handi-Wipe which you might see at KFC, but that it was a moist towelette in a package, and that he was "sure" it contained a disinfectant or possibly a bacteriocide. (Runsick, Tr. 2142-2145).

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).

Response to Finding No. 475

Complaint Counsel has no specific response.

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).

Response to Finding No. 476

Complaint Counsel has no specific response.

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).

Response to Finding No. 477

Complaint Counsel has no specific response.

478. The BleachBright employee who turned the light on for Mr. Runsick was a new hire, and she forgot to tum the timer on after he had started his teeth whitening procedure. (Runsick, Tr. 2110).

Response to Finding No. 478

Complaint Counsel has no specific response.

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. 211 O).

Response to Finding No. 479

Complaint Counsel has no specific response.

480. After the procedure, Mr. Runsick's teeth appeared whiter to him. (Runsick, Tr. 2110-2111).

Response to Finding No. 480

Complaint Counsel has no specific response.

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).

Response to Finding No. 481

This proposed finding is inaccurate, misleading, unreliable, unfounded and incorrect. In his notarized complaint to the Board on April 11, 2008, less than two months after his visit to the teeth whitening kiosk, Mr. Runsick states that his gums began to hurt on February 21, 2008 – four days after undergoing non-dental teeth whitening on February 17, 2008. (CCPFF ¶ 1134). At trial, Mr. Runsick admitted that his complaint to the Board in which he stated that he experienced no symptoms whatsoever until February 21, 2008 – four days after he underwent non-dental teeth whitening – was closest in time to the event, and given the fact that he made the earlier statements much closer in time to the alleged incident, is probably "the most accurate." (Runsick, Tr. 2171-2172; CX0055 at 003).

In addition, Mr. Runsick spoke with Channel 5 News on approximately May 21, 2008, at which time he reportedly said that after his teeth were bleached, "[e]verything was fine until about five days later when, while on a cruise, his gums became sore." This contemporaneous

evidence provides that Mr. Runsick's discomfort began at least four days after his teeth whitening treatment. (Runsick, Tr. 2166-2167, 2171-2172; CX0117 at 001).

Further, Dr. Giniger explained that there is no plausible mechanism by which a chemical burn from exposure to a bleaching agent could produce no discernible symptoms for more than three days, only becoming symptomatic on the fourth. Therefore the assertion that Mr. Runsick's discomfort was an after-effect of teeth whitening is incorrect. (Giniger, Tr. 270-274; CCPFF ¶¶ 1150-1154).

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).

Response to Finding No. 482

Complaint Counsel has no specific response.

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).

Response to Finding No. 483

Complaint Counsel has no specific response.

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).

Response to Finding No. 484

This proposed finding is contrary to the written report to the Board from Dr. Tilley, and Dr. Tilley's trial testimony. Dr. Tilley stated that his examination showed that gum tissue did not

completely fill the interdental space between teeth #23 and #24, which are to the left of the center bottom two teeth. (Tilley, Tr. 2078).

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).

Response to Finding No. 485

Complaint Counsel has no specific response.

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).

Response to Finding No. 486

Complaint Counsel has no specific response.

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).

Response to Finding No. 487

Complaint Counsel has no specific response.

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).

Response to Finding No. 488

Complaint Counsel has no specific response.

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).

Response to Finding No. 489

The cited testimony does not support the assertion that Mr. Willett 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).

Response to Finding No. 490

Complaint Counsel has no specific response.

491. Mr. Runsick at that point decided to contact C. W. Baudot, one of the co-founders of Bleach Bright 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).

Response to Finding No. 491

The statements in this proposed finding were not offered for the truth of the matter asserted, and instead are merely foundational. This proposed finding should be disregarded. (Nichols, 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).

Response to Finding No. 492

The statements in this proposed finding were not offered for the truth of the matter asserted, and instead are merely foundational. This proposed finding should be disregarded. (Nichols, Tr. 2117-2119).

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).

Response to Finding No. 493

This proposed finding is inaccurate in that in 2008, non-dentist provided teeth whitening had been in existence for at least four years. (CX0036 at 001-003).

494. Mr. Runsick filed a formal complaint with the Board about his teeth whitening experience on April 11, 2008. (Runsick, Tr. 2120-2122; CX55).

Response to Finding No. 494

Complaint Counsel has no specific response.

495. At the Board's request, Dr. Larry Tilley evaluated Mr. Runsick on April 16, 2008. (Tilley, Tr. 2009-2011,2075-2076; CXl18 at 2; CX327; Runsick, Tr. 2132)).

Response to Finding No. 495

Complaint Counsel has no specific response.

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).

Response to Finding No. 496

Complaint Counsel has no specific response.

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).

Response to Finding No. 497

Complaint Counsel has no specific response.

498. Dr. Tilley has not served as a member ofthe Board. (Tilley, Tr. 2004).

Response to Finding No. 498

Complaint Counsel has no specific response.

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).

Response to Finding No. 499

Complaint Counsel has no specific response.

500. Dr. Tilley has experience and training in teeth whitening procedures. (Tilley, Tr. 1999, 2001-2004).

Response to Finding No. 500

This proposed finding is misleading in that Dr. Tilley's experience with teeth whitening is minimal. (Tilley, Tr. 1999).

501. Dr. Tilley recommends take-home over-the-counter teeth whitening products to his patients, such as Crest Whitestrips. (Tilley, Tr. 2003-2004).

Response to Finding No. 501

Complaint Counsel has no specific response.

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).

Response to Finding No. 502

Complaint Counsel has no specific response.

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).

Response to Finding No. 503

Complaint Counsel has no specific response.

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).

Response to Finding No. 504

This proposed finding should be disregarded because it directly contradicts RPF ¶ 512 which states that Mr. Runsick specifically asked Dr. Tilley whether his gum loss would be permanent and. Dr. Tilley told him that some of it could be. (RPF ¶ 512).

505. Dr. Tilley's evaluation of Mr. Runsick did not reveal any evidence of periodontal disease or a periodontal abscess (an infection ofthe gum tissue relating to gum tissue's response to bacteria in the mouth). (Tilley, Tr. 2021-2022, 2040-2041).

Response to Finding No. 505

This proposed finding is inaccurate. Dr. Tilley noted a build-up of tartar on Mr. Runsick's teeth. Tartar on a person's teeth makes that person susceptible to periodontal disease, and an evaluation that revealed pain and tartar build-up can indicate that the person had a periodontal abscess, or other problems relating to tartar build-up. (CX0327 at 001; Giniger, Tr. 273-275).

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).

Response to Finding No. 506

Complaint Counsel has no specific response.

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).

Response to Finding No. 507

Complaint Counsel has no specific response.

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).

Response to Finding No. 508

To the extent that this proposed finding purports that Mr. Runsick's complaint regarding pain, swelling and bleeding were consistent with a chemical burn caused by his teeth whitening session, it is inaccurate. Mr. Runsick's symptoms are not consistent with chemical burns. After reviewing the complaint filed by Mr. Runsick, Dr. Giniger testified that that Mr. Runsick's claimed injuries could not have been caused by chemical burn from non-dentist teeth bleaching. (Giniger, Tr. 274-276, 337-338; CX0653 at 045). Mr. Runsick reported that four days elapsed between his non-dentist provided teeth bleaching and the first appearance of any adverse symptoms. Dr. Giniger explained that there is no plausible mechanism by which a chemical burn from exposure to a bleaching agent could produce no discernible symptoms for more than three days, only becoming symptomatic on the fourth. (Giniger, Tr. 270-274; CCPFF ¶¶ 1149-1150).

Further, Mr. Runsick's symptoms are consistent with other conditions such as a periodontal abscess that occurred within a few days of his teeth bleaching, which may have been worsened by constant teeth brushing and other attempted therapies, holding an aspirin against the cheek or gums and/or periodontal disease. (Giniger, Tr. 273-276; Tilley, Tr. 2084, 2093-2094; CX0653 at 045; CCPFF ¶¶ 1149-1154).

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).

Response to Finding No. 509

This proposed finding restates the same proposition as RPF ¶ 508, and is inaccurate for the same reasons. To the extent that this proposed finding purports that Mr. Runsick's complaint regarding pain, swelling and bleeding were consistent with a chemical burn caused by his teeth whitening session, it is inaccurate. Mr. Runsick's symptoms are not consistent with chemical burns. After reviewing the complaint filed by Mr. Runsick, Dr. Giniger testified that that Mr. Runsick's claimed injuries could not have been caused by chemical burn from non-dentist teeth bleaching. (Giniger, Tr. 274-276, 337-338; CX0653 at 045). Mr. Runsick reported that four days elapsed between his non-dentist provided teeth bleaching and the first appearance of any adverse symptoms. Dr. Giniger explained that there is no plausible mechanism by which a chemical burn from exposure to a bleaching agent could produce no discernible symptoms for more than three days, only becoming symptomatic on the fourth. (Giniger, Tr. 270-274; CCPFF ¶¶ 1149-1150).

Further, Mr. Runsick's symptoms are consistent with other conditions such as a periodontal abscess that occurred within a few days of his teeth bleaching, which may have been worsened by constant teeth brushing and other attempted therapies, holding an aspirin against the cheek or gums and/or periodontal disease. (Giniger, Tr. 273-276; Tilley, Tr. 2084, 2093-2094; CX0653 at 045; CCPFF ¶¶ 1149-1154).

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).

Response to Finding No. 510

This proposed finding is inaccurate and misleading. Dr. Tilley reported that Mr. Runsick's teeth and gums were in good condition. And Dr. Tilley testified that despite noting

that the gum tissue between teeth #23 and #24 did not fully fill the inter-dental space, he had no baseline documentation of what that inter-dental space looked like prior to Mr. Runsick's teeth whitening experience, that his gums were healthy and within a normal range, and that gum tissue like Mr. Runsick's could be a congenital matter. Also, there is an inconsistency between Mr. Runsick's complaint and Dr. Tilley's report. Mr. Runsick claims that he experienced loss of the gum tissue from the space between his two center bottom teeth after his teeth whitening treatment. (Runsick, Tr. 2112-2113). The written report to the Board from Dr. Tilley, and Dr. Tilley's trial testimony state that his examination showed that gum tissue did not completely fill the interdental space between teeth #23 and #24, which are actually to the left of the center bottom two teeth. (Tilley, Tr. 2078).

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).

Response to Finding No. 511

This proposed finding is misleading. Dr. Tilley testified that he had no baseline examination of Mr. Runsick to compare to with his examination of Mr. Runsick, and that the missing gum tissue was healthy and within a normal range. Therefore, Dr. Tilley had no way to know if Mr. Runsick's gums were in any different condition than they were in prior to Mr. Runsick's bleaching experience, and therefore cannot speak to whether or not there was even an original condition to which the gums could return. (Tilley, Tr 2078-2079).

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).

Response to Finding No. 512

This proposed finding directly contradicts RPF ¶ 504 which states that Dr. Tilley "did not discuss his findings with Mr. Runsick" and should be disregarded. (Tilley, Tr 2012-2013; RPF ¶ 504).

b. Other Consumers' Injuries

{Lite Brite}, Case 08-132

513. **{The Board received two complaints from persons who suffered severe reactions after undergoing teeth whitening at the same mall teeth whitening kiosk in Greenville, North Carolina.}** (RX17 at 1, 2, *subject to protective order*).

Response to Finding No. 513

This proposed finding is misleading. The evidence suggests that the two complaints received by the Board were in reference to a single teeth whitening experience. In an August 12, 2010 memo written by Ms. Friddle to Dr. Owens listing investigative files assigned to Dr. Owens on the date, the entry for Lite Brite states in its entirety, "[c]omplaint received from [redacted in original]. Ms. [redacted in original] indicated that she had been injured as a result of getting a bleaching treatment at the Lite Brite kiosk in Colonial Mall in Greenville." The date of the opening of the investigation is listed as June 3, 2008. There are no additional entries for Lite Brite showing a second complaint from a consumer about this particular non-dentist teeth whitening business. A similar, earlier memo dated April 15, 2010 contains the exact same entry for Lite Brite, case number 08-132. (CX0462 at 003; CX0317 at 003). A spreadsheet appearing to list Dr. Owens' cases contains an entry for Lite Brite ("log number" 08-132). It lists the complainant as "Board" and does not contain a log date. (CX0447 at 001-002).

The Board received a complaint from a Ms. W (to protect sensitive health information) on June 3, 2008. Ms. W claimed she developed blisters on her upper and lower lips after receiving

teeth whitening at the Lite Brite kiosk in Colonial Mall in Greenville. According to Ms. Bakewell's memorandum memorializing their telephone call, Ms. W stated that her teeth were only whitened one shade and that the kiosk owner refused to give a refund or pay for medical treatment. When Carolin Bakewell suggested that Ms. W see her regular dentist, Ms. W "seemed to think that she just had to wait out the blisters. . . ." (RX17 at 2).

The Board received an e-mail Mr. Y (to protect health information) on July 10, 2008. The e-mail describes a similar complaint to that of Ms. W's, on behalf of his wife. Mr. Y indicated that his wife had experienced what "looked like a burn or reaction to the inner part of her lip not the gum line." In no portion of the e-mail did he give his wife's name. He stated that his wife saw her dentist. He stated that "[t]he dentist would not give her a direct explanation of what caused the problem. . . ." It took a week for her lip to heal. (RX17 at 1).

The timing and similarity of these complaints, in addition to the single reference in the Board's files to a complaint against Lite Brite, suggests that these two complaints are regarding the same consumer- Ms. W, and that Mr. Y is her husband. (RX17 at 1-2; CX0462 at 003; CX0317 at 003).

514. **{The first customer, [Ms. W], signed a consent form that said the procedure was generally safe, but no one explained the risks to her.}** (RX17 at 2, *subject to protective order*).

Response to Finding No. 514

This proposed finding is inaccurate and misleading. Contrary to the assertion that no one explained the risks of teeth whitening to Ms. W, according to the cited evidence, Ms. W's complaint stated that Ms. W **signed a consent form** that said that the procedure was generally safe "**although there were risks.**" (RX17 at 2) (emphasis added).

In addition, insofar as the statement "the first customer" implies that there is more than one teeth whitening event complained about regarding Lite Brite, Complaint Counsel disputes this assertion as set forth in the response to RPF ¶ 513. (Response to RPF ¶ 513). Finally, the Board did not present any testimony from this witness, and therefore this evidence should be given little if any weight.

515. **{During the procedure, the kiosk employee put the bleaching solution in the whitening tray and placed the tray in [Ms. W's] mouth. The employee also shone a blue light at her mouth.}** (RX17 at 2, *subject to protective order*).

Response to Finding No. 515

This proposed finding is incomplete and misleading. The evidence shows that according to Ms. W, the Lite Brite kiosk had running water, and the operator wore gloves during the whitening session. (RX00017 at 002).

516. **{[Ms. W] quickly developed blisters inside her upper and lower lips following the procedure.}** (RX17 at 2, *subject to protective order*).

Response to Finding No. 516

The Board did not present any testimony from this witness, and therefore this evidence should be given little if any weight.

517. **{When [Ms. W] asked the kiosk owner for a refund or payment of any medical expenses, the kiosk owner was rude and declined to offer any refund or compensation.}** (RX17 at 2, *subject to protective order*).

Response to Finding No. 517

The Board did not present any testimony from this witness. In addition, this is unreliable hearsay without any indicia of reliability. Therefore this evidence should be given little if any weight.

518. **{A kiosk employee also told [Ms. W] that there had been one other complaint in the past that she was aware of.}** (RX17 at 2, *subject to protective order*).

Response to Finding No. 518

This is unreliable hearsay without any indicia of reliability and should be accorded little if any weight. This complaint could have been related to cost, effectiveness, or a host of other consumer concerns.

519. **{The second individual, [Ms. L] (to protect personal and sensitive health information), had a reaction that appeared to be "a burn or reaction to the inner part of [the] lip not the gum line."}** (RX17 at 1, *subject to protective order*).

Response to Finding No. 519

This proposed finding is inaccurate and misleading. Nowhere in RX 17 does it state that the individual who had a reaction is named Ms. L. It only states that a complaint was e-mailed (without following the formal complaint procedures) by a Mr. Y (to protect personal and sensitive health information). As described above, the evidence suggests that the Mr. Y complaint and the Ms. W complaint are regarding the same kiosk visit. (Response to RPF ¶¶ 163, 513). In addition, the Board did not present any testimony from this person, and therefore the evidence should be given little if any weight.

520. **{[Mr. Y], who reported the incident on his wife's behalf, stated that the kiosk owner would not provide a refund.}** (RX17 at 1, *subject to protective order*).

Response to Finding No. 520

Complaint Counsel has no specific response.

{Port City Tanning}, Case 08-018

521. **{Dr. Michael Hasson filed a practitioner complaint with the State Board on behalf of his patient, who presented to him after having her teeth whitened at a tanning salon.}** (RX21 at 4-7, *subject to protective order*).

Response to Finding No. 521

Complaint Counsel has no specific response.

522. **{He filed the complaint on behalf of the patient because he was more familiar with the process.}** (RX71, (Hasson, Dep. at 93-94, *subject to protective order*)).

Response to Finding No. 522

Complaint Counsel has no specific response.

523. **{Dr. Hasson saw the patient two days after her tanning salon experience.}** (RX71 (Hasson, Dep. at 60, *subject to protective order*)).

Response to Finding No. 523

Complaint Counsel has no specific response.

524. **{According to Dr. Hasson's complaint, the tanning booth operator used a whitening chemical and light source to bleach the teeth.}** (RX21 at 5, *subject to protective order*).

Response to Finding No. 524

Complaint Counsel has no specific response.

525. **{The patient developed very irritated gums, ulcers, and possible permanent nerve damage.}** (RX21 at 5, 7, *subject to protective order;* RX71 (Hasson, Dep. at 60,62-63, *subject to protective order*)).

Response to Finding No. 525

This proposed finding is incomplete and misleading. Dr. Hasson's complaint form states that "[t]anning booth operators provided chemical and light source for patient to bleach teeth." (RX21 at 5). It further states that the patient "sustained mucosal ulcers with possible permanent nerve damage." (RX21 at 5). However, Dr. Hasson's patient record merely states that patient's "gums [were] very irritated after having her teeth bleached." (RX21 at 7). Neither the patient record nor the complaint form reference a swollen chin. Moreover, Dr. Hasson's patient record indicates that the patient had infected upper and lower left wisdom teeth. (RX21 at 7).

At deposition, Dr. Hasson testified that he presumed the patient's chin swelling was due to the teeth bleaching. He added, "[b]ecause there is no reason that she should have a puffy chin unless she has some infection underneath it. She didn't have an infection under her chin muscle or chin tissue. What she did have was ulcers in the vestibule which is the space in between the teeth and the cheeks or the lips, and an area -- in the chin area, especially in a small person, and this was a small female, where there's not a lot of tissue, if you have mucosal damage, then the fluid infiltrate that accompanies mucosal damage will show up as puffiness in the chin. It probably wouldn't show up in the four of us. It would show up in our stenographer here, because she's thin enough." (RX71 (Hasson, Dep. at 69-70)). However, he also testified that during his examination of the patient, Dr. Hasson determined that she had bone loss, including about 50% bone loss around her wisdom teeth, which is serious and indicative of infection. (CX0575 at 015-016 (Hasson, Dep. at 53-54); CCPFF ¶ 1170). Dr. Hasson testified that he found that she also had missing teeth, teeth out of position, teeth which had root canals, and teeth which had crowns. (CX0575 at 015-016 (Hasson, Dep. at 53-54); CCPFF ¶ 1171). Teeth out of position can make them "impossible to clean adequately" and can lead to contact fractures of the teeth. (CX0575 at 020 (Hasson, Dep. at 72-73); CCPFF ¶ 1171). Dr. Hasson testified that he found the patient had teeth that were moving more than they should, which is associated with bone loss, not teeth whitening. (CX0575 at 019 (Hasson, Dep. at 68); CCPFF ¶ 1172). Dr. Hasson testified that he found her gums presenting inflammation and bleeding when probed, indicative of chronic infection not caused by teeth whitening. (CX0575 at 019 (Hasson, Dep. at 66-69); CCPFF ¶ 1173). Inflammation can be caused by infection or blunt trauma. (CX0575 at 020 (Hasson, Dep. at 70); CCPFF ¶ 1173). Dr. Hasson stated that ulcers can be caused by autoimmune reactions,

viruses, or chemical or thermal reactions. (CX0575 at 017 (Hasson, Dep. at 60); CCPFF ¶ 1174). Dr. Hasson's patient records indicate that the patient used tobacco, but Dr. Hasson does not know whether she smoked tobacco or chewed it. (CX0575 at 021 (Hasson, Dep. at 76); CCPFF ¶ 1174.). Any tobacco use by the patient would increase the inflammatory state in her mouth, thereby retarding the healing of any oral injury. (CX0575 at 017 (Hasson, Dep. at 61); CCPFF ¶ 1174). At deposition, Dr. Hasson testified that he found the patient presenting the following dental conditions: bone loss, missing teeth, teeth moving more than ordinary, teeth out of position, inflammation, bleeding when probed, ulcers, soreness, and evidence of root canals and crowns. Many of these indicated infection, and the patient's noted tobacco use would only exacerbate her inflammation and ostensible infection. (CX0476 at 002, 004; CX0575 at 015-016, 018-021, 023 (Hasson, Dep. at 53-54, 62-63, 66-69, 72-73, 76, 85); CCPFF ¶ 1175).

526. **{His patient also had a swollen chin, which Dr. Hasson attributed to the teeth bleaching.}** (RX71 (Hasson, Dep. at 69-70, *subject to protective order*)).

Response to Finding No. 526

This proposed finding is misleading and inaccurate. Dr. Hasson's patient record merely states that patient's "gums [were] very irritated after having her teeth bleached." (RX21 at 7). Neither the patient record nor the complaint form reference a swollen chin. Moreover, Dr. Hasson's patient record indicates that the patient had infected upper and lower left wisdom teeth. (RX21 at 7).

At deposition, Dr. Hasson testified that he presumed the patient's chin swelling was due to the teeth bleaching. He added, "[b]ecause there is no reason that she should have a puffy chin unless she has some infection underneath it. She didn't have an infection under her chin muscle

or chin tissue. What she did have was ulcers in the vestibule which is the space in between the teeth and the cheeks or the lips, and an area -- in the chin area, especially in a small person, and this was a small female, where there's not a lot of tissue, if you have mucosal damage, then the fluid infiltrate that accompanies mucosal damage will show up as puffiness in the chin. It probably wouldn't show up in the four of us. It would show up in our stenographer here, because she's thin enough." (RX71 (Hasson, Dep. at 69-70)). However, he also testified that during his examination of the patient, Dr. Hasson determined that she had bone loss, including about 50% bone loss around her wisdom teeth, which is serious and indicative of infection. (CX0575 at 015-016 (Hasson, Dep. at 53-54); CCPFF ¶ 1170). Dr. Hasson testified that he found that she also had missing teeth, teeth out of position, teeth which had root canals, and teeth which had crowns. (CX0575 at 015-016 (Hasson, Dep. at 53-54); CCPFF ¶ 1171). Teeth out of position can make them "impossible to clean adequately" and can lead to contact fractures of the teeth. (CX0575 at 020 (Hasson, Dep. at 72-73); CCPFF ¶ 1171). Dr. Hasson testified that he found the patient had teeth that were moving more than they should, which is associated with bone loss, not teeth whitening. (CX0575 at 019 (Hasson, Dep. at 68); CCPFF ¶ 1172). Dr. Hasson testified that he found her gums presenting inflammation and bleeding when probed, indicative of chronic infection not caused by teeth whitening. (CX0575 at 019 (Hasson, Dep. at 66-69); CCPFF ¶ 1173). Inflammation can be caused by infection or blunt trauma. (CX0575 at 020 (Hasson, Dep. at 70); CCPFF ¶ 1173). Dr. Hasson stated that ulcers can be caused by autoimmune reactions, viruses, or chemical or thermal reactions. (CX0575 at 017 (Hasson, Dep. at 60); CCPFF ¶ 1174). Dr. Hasson's patient records indicate that the patient used tobacco, but Dr. Hasson does not know whether she smoked tobacco or chewed it. (CX0575 at 021 (Hasson, Dep. at 76); CCPFF ¶ 1174.

). Any tobacco use by the patient would increase the inflammatory state in her mouth, thereby retarding the healing of any oral injury. (CX0575 at 017 (Hasson, Dep. at 61); CCPFF ¶ 1174). At deposition, Dr. Hasson testified that he found the patient presenting the following dental conditions: bone loss, missing teeth, teeth moving more than ordinary, teeth out of position, inflammation, bleeding when probed, ulcers, soreness, and evidence of root canals and crowns. Many of these indicated infection, and the patient's noted tobacco use would only exacerbate her inflammation and ostensible infection. (CX0476 at 002, 004; CX0575 at 015-016, 018-021, 023 (Hasson, Dep. at 53-54, 62-63, 66-69, 72-73, 76, 85); CCPFF ¶ 1175).

527. **{Dr. Hasson spoke with the salon manager and confirmed the teeth whitening technique, but he did not visit the tanning salon.}** (RX21 at 5; RX71 (Hasson, Dep. at 63, *subject to protective order*)).

Response to Finding No. 527

Complaint Counsel has no specific response.

528. **{Dr. Hasson prescribed a topical antibiotic and analgesic.}** (RX71 (Hasson, Dep. at 75, *subject to protective order*)).

Response to Finding No. 528

Complaint Counsel has no specific response.

529. **{Dr. Hasson deduced that "something that occurred with the bleaching process caused the ulcers."}** (RX71 (Hasson, Dep. at 86-87, *subject to protective order*)}.

Response to Finding No. 529

Complaint Counsel has no specific response.

530. **{Dr. Hasson's patient described the teeth whitening procedure as an application of the chemical by salon personnel to her teeth. The salon manager also stated that the teeth whitening chemical was applied by salon personnel.}** (RX71 (Hasson, Dep. at 96-98, *subject to protective order*).

Response to Finding No. 530

Complaint Counsel has no specific response.

531. **{Dr. Hasson informed the salon manager that the process as described was a violation ofthe Dental Practice Act.}** (RX71 (Hasson, Dep. at 99, *subject to protective order*).

Response to Finding No. 531

Complaint Counsel has no specific response.

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).

Response to Finding No. 532

RX 47 is not in evidence. (See Runsick, Tr. 2123-2124). With respect to the evidentiary status of Runsick, Tr. 2123-2134, the testimony reported there was found relevant only for the limited purpose of Respondent's laying foundation for a cost-recovery action under Commission Rule 3.81(d), as described in the immediately following paragraph, and it should not be relied on as support for findings of fact in this Hearing. Therefore, Respondent has cited no admissible evidence in support of proposed findings 532-539, and those proposed findings should be rejected in their entirety. Alternatively, because Complaint Counsel has not had any opportunity to respond to this testimony of Mr. Runsick, with which counsel for Respondent surprised Complaint Counsel at trial, again as described in the immediately following paragraph, Complaint Counsel respectfully requests that the court accept the attached Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 20011, and Declaration of Tejasvi Srimushnam in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011, which addresses

only matters covered by Mr. Runsick in the testimony found relevant only for the limited purpose described above.

Prior to Mr. Runsick's taking the witness stand at trial, Complaint Counsel had no notice that Respondent intended to adduce at trial testimony of no relevance to the substantive issues raised by the Federal Trade Commission's Complaint against the North Carolina State Board of Dental Examiners, but instead relating solely to non-substantive aspects of Commission attorneys' contacts with Mr. Runsick. (Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011). Nevertheless, Respondent sought to do so at trial, and Complaint Counsel objected to this line of questioning as irrelevant. (Runsick, Tr. 2126). The court ruled that Complaint Counsel's objection was premature. (Runsick, Tr. 2126). At the first reasonable opportunity Complaint Counsel renewed its objection, again urging that the entire line of questioning was irrelevant. (Runsick, Tr. 2127). The court asked Respondent's counsel to reply, and Respondent's counsel stated that Respondent was laying the foundation for recovery of costs under Commission Rule 3.81(d). (Runsick, Tr. 2127). The court determined that the line of questioning was relevant to that purpose.

RX 47 is not in evidence. (See Runsick, Tr. 2123-2124). Mr. Runsick is incorrect. Mr. Bloom did not participate in the initial contact between FTC staff and Mr. Runsick. (Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011; Declaration of Tejasvi Srimushnam in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011). Mr. Tejasvi Srimushnam alone participated in that contact, which occurred in September of 2010.

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).

Response to Finding No. 533

RX 47 is not in evidence. (See Runsick, Tr. 2123-2124). With respect to the evidentiary status of Runsick, Tr. 2123-2134, the testimony reported there was found relevant only for the limited purpose of Respondent's laying foundation for a cost-recovery action under Commission Rule 3.81(d), as described in the immediately following paragraph, and it should not be relied on as support for findings of fact in this Hearing. Therefore, Respondent has cited no admissible evidence in support of proposed findings 532-539, and those proposed findings should be rejected in their entirety. Alternatively, because Complaint Counsel has not had any opportunity to respond to this testimony of Mr. Runsick, with which counsel for Respondent surprised Complaint Counsel at trial, again as described in the immediately following paragraph, Complaint Counsel respectfully requests that the court accept the attached Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011 and Declaration of Tejasvi Srimushnam in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011, which addresses only matters covered by Mr. Runsick in the testimony found relevant only for the limited purpose described above.

RX 47 is not in evidence. (See Runsick, Tr. 2123-2124). Mr. Runsick is incorrect. Mr. Bloom did not participate in the initial contact between FTC staff and Mr. Runsick. (Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011; Declaration of Tejasvi Srimushnam in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011). Mr. Tejasvi Srimushnam alone participated in that contact, which occurred in September of 2010. Mr. Srimushnam informed Mr. Runsick that the Federal Trade Commission had issued a

Complaint against the North Carolina State Board of Dental Examiners relating to its exclusion of non-dentist teeth whiteners from the market; that he understood that Mr. Runsick had filed a complaint with the Board based on his experience with a non-dentist teeth bleaching facility; and that Commission staff would like to set up time to learn more from Mr. Runsick if he were open to participating in a further telephone conversation with Commission attorneys. Mr. Runsick said that he was open to that. (Declaration of Tejasvi Srimushnam in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011; Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011).

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).

Response to Finding No. 534

RX 47 is not in evidence. (See Runsick, Tr. 2123-2124). With respect to the evidentiary status of Runsick, Tr. 2123-2134, the testimony reported there was found relevant only for the limited purpose of Respondent's laying foundation for a cost-recovery action under Commission Rule 3.81(d), as described in the immediately following paragraph, and it should not be relied on as support for findings of fact in this Hearing. Therefore, Respondent has cited no admissible evidence in support of proposed findings 532-539, and those proposed findings should be rejected in their entirety. Alternatively, because Complaint Counsel has not had any opportunity to respond to this testimony of Mr. Runsick, with which counsel for Respondent surprised Complaint Counsel at trial, again as described in the immediately following paragraph, Complaint Counsel respectfully requests that the court accept the attached Declaration of Michael Bloom in

Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011 and Declaration of Tejasvi Srimushnam in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011, which addresses only matters covered by Mr. Runsick in the testimony found relevant only for the limited purpose described above.

RX 47 is not in evidence. (See Runsick, Tr. 2123-2124). At the beginning of this telephone contact, which also occurred in September 2010, the FTC attorneys again informed Mr. Runsick that the purpose of the call was to obtain information relevant to a Complaint that the Federal Trade Commission had issued against the North Carolina State Board of Dental Examiners relating to its exclusion of non-dentist teeth whiteners from the market. (Declaration of Tejasvi Srimushnam in Reply to Testimony of Mr. Brian Runsick, dated []; on information and belief, Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011). Near the close of that conversation FTC attorneys informed Mr. Runsick that they might need to depose him if it later appeared that he was going to testify at the Hearing in the North Carolina State Board of Dental Examiners litigation. (Declaration of Tejasvi Srimushnam in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011; Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011).

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).

Response to Finding No. 535

RX 47 is not in evidence. (See Runsick, Tr. 2123-2124). With respect to the evidentiary status of Runsick, Tr. 2123-2134, the testimony reported there was found relevant only for the

limited purpose of Respondent's laying foundation for a cost-recovery action under Commission Rule 3.81(d), as described in the immediately following paragraph, and it should not be relied on as support for findings of fact in this Hearing. Therefore, Respondent has cited no admissible evidence in support of proposed findings 532-539, and those proposed findings should be rejected in their entirety. Alternatively, because Complaint Counsel has not had any opportunity to respond to this testimony of Mr. Runsick, with which counsel for Respondent surprised Complaint Counsel at trial, again as described in the immediately following paragraph, Complaint Counsel respectfully requests that the court accept the attached Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011 and Declaration of Tejasvi Srimushnam in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011, which addresses only matters covered by Mr. Runsick in the testimony found relevant only for the limited purpose described above.

RX 47 is not in evidence. (See Runsick, Tr. 2123-2124). On information and belief, Ms. Westman-Cherry told Mr. Runsick that he would be receiving a subpoena to testify at a deposition by FTC attorneys, and that the reason FTC attorneys planned to depose him was that he had been listed by the Board on its final witness list in the North Carolina State Board of Dental Examiners litigation. (Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011).

536. Mr. Runsick first asked about 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).

Response to Finding No. 536

RX 47 is not in evidence. (See Runsick, Tr. 2123-2124). With respect to the evidentiary status of Runsick, Tr. 2123-2134, the testimony reported there was found relevant only for the limited purpose of Respondent's laying foundation for a cost-recovery action under Commission Rule 3.81(d), as described in the immediately following paragraph, and it should not be relied on as support for findings of fact in this Hearing. Therefore, Respondent has cited no admissible evidence in support of proposed findings 532-539, and those proposed findings should be rejected in their entirety. Alternatively, because Complaint Counsel has not had any opportunity to respond to this testimony of Mr. Runsick, with which counsel for Respondent surprised Complaint Counsel at trial, again as described in the immediately following paragraph, Complaint Counsel respectfully requests that the court accept the attached Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011 and Declaration of Tejasvi Srimushnam in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011, which addresses only matters covered by Mr. Runsick in the testimony found relevant only for the limited purpose described above.

RX 47 is not in evidence. (Runsick, Tr. 2123-2124). Prior to his deposition, Mr. Runsick was informed by FTC attorneys on at least two occasions that the purpose of the FTC attorneys' contacts with him was to obtain information relevant to a Complaint that the Federal Trade Commission had issued against the North Carolina State Board of Dental Examiners relating to its exclusion of non-dentist teeth whiteners from the market. (Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011; Declaration of Tejasvi Srimushnam in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011).

537. Mr. Runsick expressed that he would like for his deposition and testimony to be entered into the public record. (Runsick, Tr. 2131-2132).

Response to Finding No. 537

Complaint Counsel has no specific response.

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).

Response to Finding No. 538

Complaint Counsel has no specific response.

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).

Response to Finding No. 539

RX 47 is not in evidence. (See Runsick, Tr. 2123-2124). With respect to the evidentiary status of Runsick, Tr. 2123-2134, the testimony reported there was found relevant only for the limited purpose of Respondent's laying foundation for a cost-recovery action under Commission Rule 3.81(d), as described in the immediately following paragraph, and it should not be relied on as support for findings of fact in this Hearing. Therefore, Respondent has cited no admissible evidence in support of proposed findings 532-539, and those proposed findings should be rejected in their entirety. Alternatively, because Complaint Counsel has not had any opportunity to respond to this testimony of Mr. Runsick, with which counsel for Respondent surprised Complaint Counsel at trial, again as described in the immediately following paragraph, Complaint Counsel respectfully requests that the court accept the attached Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011 and Declaration of Tejasvi

Srimushnam in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011, which addresses only matters covered by Mr. Runsick in the testimony found relevant only for the limited purpose described above.

Mr. Runsick was asked whether he would consent to release and use as necessary in connection with the litigation all records and materials, including for example dentist notes, x-rays, and models, relating to his evaluation by Dr. Tilley. (Declaration of Michael Bloom in Reply to Testimony of Mr. Brian Runsick, dated May 3, 2011). Mr. Runsick did so consent.

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).

Response to Finding No. 540

This proposed finding is incorrect, misleading, and not supported by the citation. The Court did not accept Dr. Baumer as an economic expert, but instead will consider "any opinions offered by [Dr. Baumer]" if they "meet the proper legal standards." (Baumer, Tr. 1695). The only basis for the assertion that Dr. Baumer is an expert in the "professional markets specifically" comes from Respondent's counsel, and nothing within Dr. Baumer's testimony, report and attachments, or deposition demonstrate that Dr. Baumer has a specific expertise in professional markets. (Baumer, Tr. 1684-1900; CX0826 at 004-006 (Baumer, Dep. at 7-14); RX0078 at 4-5, 26-41). Further, Dr. Baumer has admitted that he has not published an article in what he would consider a "top" economics journal (CX0826 at 012 (Baumer, Dep. at 41); that the last time Dr. Baumer wrote on the issue of antitrust was in 2004, for a textbook; and the last time Dr. Baumer

published an article in the area of antitrust was in the mid 1980s. (CX0826 at 004 (Baumer, Dep. at 7-9).

By contrast, Professor Kwoka has published extensively in the area of professional markets (CX0654 at 024-025), which was acknowledged by Dr. Baumer (Baumer, Tr. 1897); Professor Kwoka has published in what Dr. Baumer would consider a "top" economic journal (CX0654 at 023; CX0826 at 012 (Baumer, Dep. at 41); and Professor Kwoka has recently published in the area of economics and antitrust. (CX0654 at 020; *see also* CCPFF ¶¶ 1324-1330).

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).

Response to Finding No. 541

Complaint Counsel has no specific response.

542. Dr. Baumer has an active consulting practice related to economics. (Baumer, Tr. 1693).

Response to Finding No. 542

Complaint Counsel has no specific response.

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).

Response to Finding No. 543

Complaint Counsel has no specific response.

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).

Response to Finding No. 544

This proposed finding is incorrect and misleading. Dr. Baumer has admitted that he did not read the reports of the dental industry experts and that he only scanned the titles and abstracts of articles relating to the health effects of teeth whitening. (Baumer, Tr. 1827-1829, 1830; CX0826 at 022-023 (Baumer, Dep. at 79-82)). Dr. Baumer admits that this does not constitute "due diligence" (Baumer, Tr. 1835-1836; CX0826 at 023 (Baumer, Dep. at 82)); thus the Court should find that Dr. Baumer did not "rely" on these reports or other materials related to teeth whitening referenced in his report. (CCPFF ¶ 1334).

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).

Response to Finding No. 545

Complaint Counsel has no specific response.

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).

Response to Finding No. 546

This proposed finding is misleading. Professor Kwoka did not address or resolve any disputed medical or scientific or technical issues concerning teeth whitening. Professor Kwoka did testify, on the basis of his review of the record, that the Board had adduced essentially no empirical evidence to support its health and safety claims. Professor Kwoka acknowledged that he was not a medical expert (Kwoka, Tr. 1166). Economists routinely examine whether restrictions have justifications, including health and safety justifications. (Kwoka, Tr. 1056-1057, 1108). And

in this case, Dr. Baumer also examined the potential for consumer harm due to non-dentist teeth whitening. (Baumer, Tr. 1769).

547. Dr. Kwoka is not a dentist, but purported to testify as to the existence (or nonexistence) of reliable evidence of serious and systematic harm (from teeth whitening). (Kwoka, Tr. 1223).

Response to Finding No. 547

The citation does not support Respondent's proposed finding. Further, economists may rely on evidence or lack of evidence of systematic harm to come to an economic conclusion (Kwoka, Tr. 1056-1057, 1108; CCPFF ¶ 1198), just as Dr. Baumer relied upon Dr. Haywood's unsupported assertion that non-dentist teeth whitening could cause consumer harm. (Baumer, Tr. 1769).

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).

Response to Finding No. 548

This citation does not support Respondent's finding. Professor Kwoka actually stated that the Board sent letters to non-dentists, "instructing them to cease and desist in the provision of non -- cease and desist in the provision of teeth whitening since it was in contravention to 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).

Response to Finding No. 549

Professor Kwoka actually testified that his analysis considered a number of economic models and applied the one model – the exclusion model – that fit the Board's conduct, and the one to which Dr. Baumer subscribed. (Kwoka, Tr. 1104; CCPFF ¶¶ 545-546).

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. (K woka, Tr. 981-984; CX654 at 3-4).

Response to Finding No. 550

The citations do not support this proposed finding. Dr. Baumer in fact wholly "accepted" Dr. Kwoka's definition of the teeth whitening market. (Baumer, Tr. 1844-1845).

551. Dr. Baumer acknowledged the four methods' characteristics, and cross-elasticity of demand as proof of the competition between each. (Baumer, Tr. 1842).

Response to Finding No. 551

Complaint Counsel has no specific response.

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).

Response to Finding No. 552

The citations do not support this proposed finding. Dr. Baumer does not discuss the "fairness" of comparing legal to illegal teeth whitening products, and admits that exclusion of safe products from a market will result in a price increase. (Baumer, Tr. 1726-1727). In fact, Dr. Baumer admits that whether or not a product is illegal does not change the economic analysis, stating: "I read Dr. Kwoka's testimony and I tend to agree with it, that the fact that it's illegal

doesn't mean there isn't a cross-price elasticity. . . . [E]conomics doesn't change if it's [a] unauthorized or illegal product." (Baumer, Tr. 1711).

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).

Response to Finding No. 553

This proposed finding is irrelevant, unfounded, incorrect, and misleading. Professor Kwoka made it clear that he considered non-price economic elements in his analysis, such as innovation (Kwoka, Tr. 1011, 1184-1185), potential consumer harm (Kwoka, Tr. 1056-1057, 1108), and consumer choice (Kwoka, Tr. 1004-1005, 1016, 1033). (CCPFF ¶¶ 560-566). Far from being fixated on one market alternative, Professor Kwoka testified that he considered a number of models in relation to the Board's conduct and chose the one that fit the facts of the case (Kwoka, Tr. 1104); Dr. Baumer agrees that the exclusion model is the appropriate model to apply. (Baumer, Tr. 1839-1840). Further, Professor Kwoka did not "fixate" on licensing; instead, he examined on the ban of non-dentist teeth whitening, its effects, and the reasonable alternatives to a ban if there were valid concerns with non-dentist teeth whitening. (CCPFF ¶¶ 551-554, 560-566, 677-693, 709-710, 1197-1201, 1203-1211).

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).

Response to Finding No. 554

Complaint Counsel has no specific response.

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).

Response to Finding No. 555

Although it is undisputed that Dr. Baumer testified to the opinions in this proposed finding, Dr. Baumer's testimony is incorrect, unfounded, and misleading. First, as an economic expert, Dr. Baumer cannot "find" anything. Second, Dr. Baumer has admitted that any empirical data related to the price effects would require "Herculean assumptions that would be virtually unverifiable." (CX0826 at 043 (Baumer, Dep. at 165)). Far from simply asking dentists what they have charged patients for the past five years, Dr. Baumer has stated that "the actual study would be subject to a lot of caveats." (CX0826 at 043 (Baumer, Dep. at 164-165)). Dr. Baumer has neither attempted such a study nor knows of any source of data that would enable such a study. (Baumer, Tr. 1731, 1980; CX0826 at 043 (Baumer, Dep. at 162); CCPFF ¶¶ 694-696). Finally, Dr. Baumer admitted that he does not believe that the absence of data allowing such an economic study requires antitrust law to ignore potentially anticompetitive conduct. (Baumer, Tr. 1980).

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 anti competitive act, nor does it reveal bias. (Baumer, Tr. 1698-1699).

Response to Finding No. 556

This proposed finding calls for a legal conclusion; the Court allowed Dr. Baumer to testify "based on the [economics] field rather than law." (Baumer, Tr. 1710). Thus, this proposed finding should not be considered.

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).

Response to Finding No. 557

This proposed finding calls for a legal conclusion; the Court allowed Dr. Baumer to testify "based on the [economics] field rather than law." (Baumer, Tr. 1710). Thus, this proposed finding should not be considered. Even though a substantive reply is not required, it bears mentioning that Complaint Counsel does not advocate a *per se* standard in this case; indeed, under all three legal standards proffered by Complaint Counsel the Board has the opportunity to present procompetitive justifications for the anticompetitive restraint. (Complaint Counsel's Post Trial Brief at 75).

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).

Response to Finding No. 558

Complaint Counsel has no specific response.

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).

Response to Finding No. 559

Although it is undisputed that Dr. Baumer disagrees with Dr. Kwoka with respect to whether exclusion is justified, Dr. Baumer's testimony is unreliable and unfounded; specifically, Dr. Baumer does not point to any fact that supports this assertion of "value." In fact, Dr. Baumer admits that in order to demonstrate that exclusion of non-dentists is justified he performed a "thought analysis" (Baumer, Tr. 1708, 1776, 1819-1820) that assumed without evidence that non-

dentist teeth whitening could be so "seriously dangerous" that one in ten consumers suffered from oral cancer after ten years. (Baumer, Tr. 1708, 1820). In fact, Dr. Baumer admits that at the time he wrote his report he had no basis for his conclusions or assumptions relating to the health effects of non-dentist teeth whitening other than from conversations with Respondent's counsel and from reading titles and abstracts of articles cited in Respondent's statement of facts. (Baumer, Tr. 1830; CX0826 at 022-023 (Baumer, Dep. at 79-82)). Therefore, the only source of Dr. Baumer's justifications for exclusion of non-dentist teeth whiteners was Respondent's counsel, and accordingly Dr. Baumer's opinion on this issue should be disregarded as unfounded and self-serving.

Professor Kwoka testified that although there are situations where complete exclusion of a product is appropriate economic policy, such as where the product is "irremediably dangerous" (Kwoka, Tr. 1056; CX0631 at 008), "[e]xclusion is not justified by any economic argument set forth by the Board." (CX0822 at 002). Indeed, exclusion is the last possible resort even where a product has inherent health or safety problems and there are no significantly less restrictive alternatives to exclusion; many products have potential harms and are tolerated in a world full of risk (Kwoka, Tr. 1061-1062). Even Dr. Baumer is not in favor of banning all products or services that pose a risk to customers. (CX0826 at 029 (Baumer, Dep. at 108)). In this case, there is no evidence of risk to life or any other significant harm from non-dentist teeth whitening services (Kwoka, Tr. 1062-1064), and "[s]peculation about what 'can' happen and what can be 'imagined' are not substitutes for evidence." (CX0631 at 010). In sum, the record does not disclose convincing evidence of health and safety concerns from non-dentist teeth whitening that justify banning the service (Kwoka, Tr. 1066-1067, 1212), and Dr. Baumer concedes that he is

not aware of any empirical data indicating a systemic public health problem with non-dentist teeth whitening. (Baumer, Tr. 1962, 1967-1968; CX0826 at 043 (Baumer, Dep. at 162)). (*See also* CCPFF ¶¶ 1197-1224).

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).

Response to Finding No. 560

Although it is undisputed that Dr. Baumer disagrees with Professor Kwoka on the exclusionary impact of cease and desist letters, Dr. Baumer's testimony is unreliable and incorrect. It is illogical to argue that the cease and desist order are "consistent with exclusion" and yet are "not exclusion." (Baumer, Tr. 1712). The actual intent and effect of the cease and desist orders were to induce non-dentist teeth whiteners to exit the market, and that the non-dentist teeth whiteners – perceiving that the Board was ordering them to cease teeth whitening – did in fact exit the market for this reason. (Kwoka, Tr. 1008, 1100-1101, 1129-1131; CCPFF ¶¶ 294-314, 628-639, 657-680).

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).

Response to Finding No. 561

This proposed finding is unreliable and incorrect. Dr. Baumer admits that it is a standard assumption in economics that people "promote their own self-interests" (CX0826 at 011 (Baumer, Dep. at 34)); that the Board has an interest in exclusion of non-dentist teeth whiteners because it would "help dentists in terms of their bottom line" (Baumer, Tr. 1781); that because of human nature, board members might be influenced by the impact of their decisions on the

financial bottom line of dentists (Baumer, Tr. 1871); that members of professional boards have in the past acted in ways calculated to enhance their own income and the income of the constituents of the boards, to the detriment of patients and the general public (Baumer, Tr. 1848-1850, 1855, 1912-1913); and that it is well recognized that medical professional board members engaged in conduct that harmed consumers despite their oaths to protect the public health. (Baumer, Tr. 1915). Dr. Baumer's own statements show that Professor Kwoka's belief – that just because Board members swear an oath does not change the fact that they represent their own financial interests and the interests of their constituent North Carolina dentists – is correct. (Kwoka, Tr. 1111-1112; *see also* CCPFF ¶¶ 606-615).

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).

Response to Finding No. 562

This proposed finding is unreliable and incorrect. In fact, the citation blatantly misrepresents the record on this point: on the cited page Dr. Baumer testifies "I did agree that I could eliminate that word, that I should eliminate that word 'solely.'" (Baumer, Tr. 1765). No testimony could be clearer on this point. Professor Kwoka testified that dentists practice in honest and ethical ways, but nonetheless clearly understand their financial interest in various restrictions that may be put in place. (Kwoka, Tr. 1053; CX0631 at 003, 009). Further, Dr. Baumer admitted that if it were true that the Board sent a mall letter to a mall operator that was only two miles from the location of a Board member's dental practice, it would influence Dr. Baumer's opinion of whether the Board had tried to eliminate financial conflicts of interest.

(Baumer, Tr. 1870-1871). The predicate has been demonstrated (*see* CCPFF ¶ 153) and therefore Dr. Baumer would be more likely to opine that the Board had not eliminated financial conflicts of interest.

563. Dr. Baumer found that self-interest does not define the actions of the Board.(Baumer, Tr. 1780-1781).

Response to Finding No. 563

Although it is undisputed that Dr. Baumer claims that self-interest does not define the actions of the Board, Dr. Baumer's testimony is unfounded, unreliable, and incorrect. First, as an economic expert Dr. Baumer cannot "find" anything. Second, he does not cite to any facts or evidence as the basis for that opinion; instead, Dr. Baumer makes a generalized claim that "when people serve on professional boards they put on another hat" – a claim that flies in the face of his own assertions that it is a standard assumption in economics that people "promote their own self-interests" (CX0826 at 011 (Baumer, Dep. at 34) and that the Board has an interest in exclusion of non-dentist teeth whiteners because it would "help dentists in terms of their bottom line." (Baumer, Tr. 1781).

Lastly, Dr. Baumer has admitted that the professions studies have shown that consumers were harmed by restrictions imposed by medical boards through higher prices and less choices (Baumer, Tr. 1852), and agreed that the licensing board restrictions examined in the professions studies were unwarranted and harmful to consumers. (Baumer, Tr. 1764; CX0631 at 006-007; *see also* CCPFF ¶¶ 576, 591-594). Dr. Baumer agreed that not all of the anticompetitive conduct undertaken by the healthcare professional boards in the 1970s and 1980s has been eliminated, and that there is "absolutely" "continuing potential for abuse by state boards," and that "it certainly

does occur." (CCPFF ¶ 604). Dr. Baumer himself relied upon the professions studies in a study where he noted his concern that pharmacy boards could be engaging in anticompetitive activity that resulted in consumer harm, and that the actions of the pharmacy boards could simply be disguising "economic protectionism." (CCPFF ¶¶ 577-578).

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).

Response to Finding No. 564

This proposed finding is incorrect. Dr. Baumer himself agreed that "one innovation that [he recognizes] is the ability for a consumer to get quick teeth whitening in a convenient mall location on the same day with same-day results." (Baumer, Tr. 1973). Further, he agreed the ability of non-dentists to offer same-day whitening procedures fills a niche in the market. (Baumer, Tr. 1974-1975).

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).

Response to Finding No. 565

Although it is undisputed that Dr. Baumer testified to this point, Dr. Baumer's testimony is unfounded and incorrect. Professor Kwoka actually stated that the professions studies empirically showed that there were "no systematic benefits in quality of safety" from the licensing restrictions that they examined. (Kwoka, Tr. 1046-1047). Dr. Baumer apparently takes exception to this statement despite his own admissions that the professions studies generally showed that consumers were harmed by restrictions imposed by medical boards through higher prices and less choices (Baumer, Tr. 1852); that the licensing board restrictions examined in the

professions studies were unwarranted and harmful to consumers (Baumer, Tr. 1764; CX0631 at 006-007); and that the professions studies showed that in many cases the health and safety justifications proffered by the boards turned out to be false. (Baumer, Tr. 1852-1853; *see also* CCPFF ¶¶ 590-594).

566. Dr. Kwoka's assertions 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).

Response to Finding No. 566

Neither economic expert claimed to be a dental expert (Kwoka, Tr. 1166; Baumer, Tr. 1818-1819), and both economic experts relied upon dental experts for the opinion that teeth whitening either did or did not cause consumer harm. (Baumer, Tr. 1769; Kwoka, Tr. 1166-1167, 1082-1083). It is inconsistent at best for Dr. Baumer to rely on Dr. Haywood's expert testimony and then assert that Professor Kwoka is not entitled to rely on Dr. Giniger's testimony. Further, even though Professor Kwoka did not establish the fact that non-dentist teeth whitening is not harmful to consumers, once that opinion was expressed by Dr. Giniger (CCPFF ¶¶ 716-738) and industry participants (CCPFF ¶ 907), and admitted by Board members and employees ((CCPFF ¶¶ 908-909, 913-915), and demonstrated by substantial evidence, Professor Kwoka was entitled to rely upon it to assert that – as an economic matter – the Board's exclusion of non-dentists was not justified. (Kwoka, Tr. 1082-1083, 1166-1167). (*See* CCPFF ¶¶ 716-738, 907-1054, 1077-1102, 1124-1129, 1197-1237).

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).

Response to Finding No. 567

This proposed finding is unfounded and incorrect. Dr. Baumer provides no evidence and references no evidence for his assertion that the Board's regulation of dentistry is "precisely constituted" to exclude unlicensed people from practicing dentistry. (Baumer, Tr. 1700). As a matter of fact, the Board does not have any statutory authority over the unlicensed practice of dentistry, and its only authorized recourse against non-dentists engaged in the practice of dentistry is to go through the courts. (CX0554 at 034 (Allen, Dep. at 129); CX0019 at 006, 007, 020-021, Dental Practice Act § 90-27, 29, 40, 40.1). Further, on the one hand, the Board has many other duties if "precisely" means the only thing it does, and on the other hand, both the general public as well as other local district attorneys can enlist the courts to stop the unlicensed practice of dentistry. (CX0019 at 020-021, Dental Practice Act § 90-40, 40.1).

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).

Response to Finding No. 568

There is no evidence that there are bona fide health concerns regarding non-dentist teeth whitening that justify exclusion (Kwoka, Tr. 1082-1083, 1166-1167; CCPFF ¶¶ 716-738, 907-1054, 1077-1102, 1124-1129), there has been testimony that over the last 20 years, millions of consumer have safely bleached their teeth without dental involvement, and there is not a single study demonstrating substantial, non-transient harm from non-dentist teeth bleaching. (Giniger, Tr. 121-123, 430-431, 453-455; Haywood, Tr. 2713-2714 (acknowledging no systematic documentation of harm in twenty-year history of non-dentist teeth whitening), 2729; CX0653 at 007; CCPFF ¶¶ 907-909, 913-915). The Board has admitted that dentists have harmed their patients through the provision of teeth whitening services, and yet the Board has not attempted to

exclude dentists from providing teeth whitening. (Respondent's Response to Complaint Counsel's Request For Admissions ¶ 30; Respondent's Response to Interrogatory ¶ 4; Kwoka, Tr. 1059-1061).

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).

Response to Finding No. 569

This proposed finding appears to be directed at the supervision element of the state action requirement, and as such it is both irrelevant and wrong given the Commission's State Action Decision. The Commission ruled that as a matter of law that the Board was not supervised by the state legislature, holding that "[t]his sort of generic oversight . . . does not substitute for the required review and approval of the 'particular anticompetitive acts' that the complaint challenges." (State Action Opinion at 14-17). In addition, this proposed finding is a legal opinion and is not within the scope of Dr. Baumer's expertise. (Baumer, Tr. 1710)

Further, Dr. Baumer has no foundation for his assertion; he makes it purely based on the facts that the North Carolina legislature enacted the Dental Practices Act and that the Board was created by the Dental Practices Act and is supposed to enforce it. (Baumer, Tr. 1811). Dr. Baumer does not point to a single instance where the legislature directly supervised any action by Board, much less an action related to teeth whitening. (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).

Response to Finding No. 570

This proposed finding is unfounded, irrelevant, and incorrect. First, both Dr. Baumer and Professor Kwoka agreed that the cartel model did not apply to the conduct in this case (Baumer, Tr. 1839, 1896; Kwoka, Tr. 1025), and so this proposed finding is irrelevant. Second, this proposed finding misrepresents Dr. Baumer's testimony regarding a "government-sponsored" cartel in the citations provided; Dr. Baumer never claimed that attributes of a cartel include "creat[ing] barriers to entry that are not tied to health and public safety." (Baumer, Tr. 1696-1697, 1886). Lastly, the Board has made decisions in private, for instance in its "Closed Sessions," in its executive sessions, or in Case Officers' non-public decisions to send cease and desist letters. (CX0056 at 002, 005-007; CX0106 at 002, 004, 007, 009-010; CX0109 at 001, 006-011; CX0107 at 002-006; CX0581 at 029-030 (Bakewell, Dep. at 109-110); CX0561 at 012 (Friddle, Dep. at 41); (CX0028 at 005; CX0449 at 005; CX0219 at 005; CX0242 at 005; CX0581 at 030 (Bakewell, Dep. at 110-113); Response to RFA ¶ 44; *see also* CCPFF ¶¶ 120-130).

571. There is a rational basis for the Board's existence, including the promotion of health and safety in dentistry. (Baumer, Tr. 1810-1811).

Response to Finding No. 571

Complaint Counsel has no specific response.

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).

Response to Finding No. 572

The citations do not support this proposed finding. Further, whether practicing dentists are the most knowledgeable about the practice of dentistry is outside of Dr. Baumer's expertise, and he apparently does not take into account that other people may be more knowledgeable than

practicing dentists, such as retired dentists, dental academics and professors, research dentists, and government dentists. (Baumer, Tr. 1809-1810).

573. Allowing the practice of dentistry by unlicensed persons would threaten public health and safety. (Baumer, Tr. 1810-1811).

Response to Finding No. 573

This proposed finding is based on unreliable testimony and testimony that is outside the expertise of Dr. Baumer. First, Dr. Baumer cites no evidence showing that the practice of dentistry by unlicensed persons would threaten public safety, and his unsupported opinion regarding dental licensing should be disregarded given his demonstrated, abject lack of knowledge in this area. (Baumer, Tr. 1923-1924 (admitting that he does not know how states other than North Carolina treat non-dentist teeth whitening), 1944 (admitting that he did not know that North Carolina Health Department had an oral hygiene section), 1969 (admitting that he did not know that licensed hygienists were not permitted to whiten teeth without dental supervision in North Carolina)).

Second, this proposed finding implies that teeth whitening is the practice of dentistry and thus threatens the public's health and safety – otherwise the finding would be completely irrelevant. The weight of credible evidence shows that teeth whitening should not be considered "stain removal" under the Dental Practice Act and therefore is not the practice of dentistry. (Giniger, Tr. 76, 111-112, 116-118, 132-133, 142; CX0653 at 006). Further, there is no evidence that non-dentist teeth whitening is harmful to consumers, and indeed the overwhelming evidence shows that non-dentist teeth whitening is safe and effective. (Giniger, Tr. 120-123, 430-431, 453-455; Haywood Tr. 2713-2714 (acknowledging no systematic documentation of harm in twenty-

year history of non-dentist teeth whitening), 2729). (CCPFF ¶¶ 716-738, 907-1054, 1077-1102, 1124-1129).

574. The Board's organizational structure is indistinguishable from other licensing boards across the country, and it is not anticompetitive. (Baumer, Tr. 1815).

Response to Finding No. 574

Dr. Baumer's testimony on this point should be disregarded given his demonstrated lack of knowledge of licensing board models; Dr. Baumer admitted that he was not aware of other state regulatory models where a Department of Health oversees the state licensing boards. (CX0826 at 038 (Baumer, Dep. at 142, 144); CX0488 at 020-021; White, Tr. 2255). Dr. Baumer admitted that such an arrangement could make licensing boards less anticompetitive, remarking "that's an interesting variation" and "removing conflicts of interest . . . other things being equal is a good thing." (CX0826 at 038 (Baumer, Dep. at 142, 144)). Further, Dr. Baumer admitted that he did not complete "due diligence" in writing his report and that he relied upon Respondent's counsel as the source for all of his information, other than some desultory searches in an internet browser. (Baumer, Tr. 1821-1822, 1827-1830, 1835-1838, 1868, 1932-1936, 1951-1952, 1955-1956; CX0826 at 003, 006, 022-023 (Baumer, Dep. at 5, 17, 79-82)).

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).

Response to Finding No. 575

This proposed finding is unreliable, unfounded, and incorrect. First, Dr. Baumer has admitted that there is "no difference" between the "limited exclusion" and absolute, horizontal exclusion, which means that any implication in this proposed finding that exclusion of non-dentist

teeth whitening is somehow "limited" is incorrect (Baumer, Tr. 1778). Second, Dr. Baumer admitted that he formed his opinions about the "benefits" of exclusion based solely on representations of Respondent's counsel and some desultory internet searches, and that this is not his normal practice when giving his opinion. (Baumer, Tr. 1821-1822, 1827-1830, 1835-1838, 1868, 1932-1936, 1951-1952, 1955-1956; CX0826 at 003, 006, 022-023 (Baumer, Dep. at 5, 17, 79-82)). Any "cost-benefit" analysis based on such an insubstantial foundation of knowledge is entitled to no weight.

Third, Dr. Baumer's "cost-benefit analysis" appears to require only that the benefits of exclusion exceed the costs (Baumer, Tr. 1815-1816), but this is not the correct economic standard. Professor Kwoka testified that total exclusion of a product or service is not appropriate except in some very limited circumstances, such as when the product or service is "irremediably dangerous." Exclusion of non-dentist teeth whitening might be appropriate where (1) there is convincing evidence of significant health or safety problems, (2) the health and safety problems are inherent in the excluded service, not ancillary, and (3) there are no less restrictive alternatives to outright exclusion of the product; non-dentist teeth whitening does not meet this standard. (Kwoka, Tr. 1056-1057). In fact, exclusion is the last possible resort even where a product has inherent health or safety problems and there are no significantly less restrictive alternatives to exclusion, because in a world full of risk many products with a potential for harm are tolerated. (Kwoka, Tr. 1061-1062). Contrary to his "cost-benefit analysis," Dr. Baumer agrees that not all products with potential for risk should be banned and that, in general, where intervention is appropriate less restrictive alternatives should be used. (Baumer, Tr. 1771, CX0826 at 029

(Baumer, Dep. at 108)). Less restrictive alternatives were available to the Board but Board members did not take advantage of them. (Kwoka, Tr. 1149-1150, 1057-1059, 1223-1225, 1238).

Fourth, the overwhelming evidence shows that not only is there no credible evidence that non-dentist teeth whitening is harmful – thereby justifying exclusion – but in fact non-dentist teeth whitening is safe and effective, as demonstrated by millions of whitening procedures performed without any appreciable consumer harm. (Giniger, Tr. 120-123, 430-431, 453-455; Haywood, Tr. 2713-2714 (acknowledging no systematic documentation of harm in twenty-year history of non-dentist teeth whitening), 2729).

Lastly, it is incorrect as an economic matter to imply that consumers suffer little harm from higher prices and "inconvenience." As Professor Kwoka testified, the discipline of economics promotes allowing customers to choose freely among the products unless there is a compelling justification for exclusion. Even if it were true that there is only a minor inconvenience to switching from non-dentist whitening to an alternative method, good economics does not deny consumer choice based on inadequate justifications. (Kwoka, Tr. 1100-1101, 1225-1226).

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).

Response to Finding No. 576

Complaint Counsel incorporates its response to Finding No. 575. Further, Respondent's implied argument that there is no economic harm due to exclusion of non-dentist teeth whitening because OTC strips provide a cheaper alternative and dentists provide a higher quality alternative is contrary to modern economics. (Kwoka, Tr. 1100; CX0631 at 015). Consumers make choices

based on their own revealed preference for a given alternative. (Kwoka, Tr. 1002-1003). To ask consumers to simply be satisfied with the alternatives is akin to Henry Ford's declaration that "you can have your car in any color you want as long as its black." (Kwoka, Tr. 1225).

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).

Response to Finding No. 577

Complaint Counsel incorporates its response to Finding No. 569. This proposed finding is irrelevant, unfounded, and incorrect. This proposed finding appears to be directed at the supervision element of the state action requirement, and as such it is irrelevant given the Commission's State Action Decision.

As an economic matter, Professor Kwoka testified that the anticompetitive effects of a licensing board's restrictions are the same regardless of whether the board adopts the restriction through a rule or is mandated to enforce the restriction through statute; economic analysis of a restriction is unaffected by the origins and locus of the power to restrict competition. (Kwoka, Tr. 1149, 1173-1174, 1228-1229). The consumer harm that occurs from the elimination of a product that consumers desire is the same regardless of whether the market is regulated or unregulated. (Kwoka, Tr. 1196). Therefore, Dr. Baumer's implication that there exclusion is okay simply because there is a statute involved is incorrect. (Baumer, Tr. 1815-1816).

Additionally, the statement within the finding "in the form of procedures that allow appeals of the actions of the Board" is entirely unsupported by the citation. (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).

Response to Finding No. 578

This proposed finding is incorrect. Professor Kwoka testified that he was not familiar with the limited exclusion model – as defined by the Respondent's counsel or in any other way – within the economics literature. (Kwoka, Tr. 1150-1152). Dr. Baumer agreed that in his view the "limited exclusion model" was the same thing as absolute horizontal exclusion (Baumer, Tr. 1778), and both economic experts testified that horizontal exclusion was the appropriate model to apply to the Board's actions. (Kwoka, Tr. 1004-1005, 1154; Baumer, Tr. 1839-1840; CX0826 at 027 (Baumer, Dep. at 100)). In addition, the citation does not support the finding to the extent that Professor Kwoka did not reject the application of a model but simply stated that the efficiency justifications asserted by the Board had no economic basis. (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).

Response to Finding No. 579

Although it is undisputed that Dr. Baumer testified that he did not believe that exclusion of non-licensed people can be compared to exclusion of licensed people, Dr. Baumer's testimony is unfounded and incorrect. (Baumer, Tr. 1764). One of the studies cited by Professor Kwoka did in fact examine the harm caused by the exclusion of non-licensed chair assistants. (Kwoka, Tr. 1050-1051; CX0631 at 013). Professor Kwoka further testified that from an economic perspective the important fact is that there has been exclusion – consumer harm follows from exclusion regardless of whether the excluded group is licensed or unlicensed. (Kwoka, Tr. 1050-

1051; CX0631 at 013; CCPFF ¶ 597). In fact, many of the boards studied based their exclusionary conduct on the fact that using the "other" licensed occupation (e.g., dental assistant) was unsafe. (Kwoka, Tr. 1041, 1043-1044; CX0631 at 009). Indeed, Dr. Baumer admitted that economists can learn from other types of exclusionary conduct to make inferences about new exclusionary conduct. (Baumer, Tr. 1982).

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).

Response to Finding No. 580

Although it is undisputed that Dr. Baumer testified to this point, this proposed finding is inaccurate and unfounded. Professor Kwoka clearly stated that "I'm not claiming that [the Board's financial interest] dominates their interest. I'm saying that it represents a significant factor in how they proceed." (Kwoka, Tr. 1115).

Further Dr. Baumer does not have a foundation for his belief that the Board would not allow financial interests to impact their judgment because it would be unprofessional other than the fact that he served on bar association sections. (Baumer, Tr. 1781-1782). In addition, this assertion is directly rebutted by Dr. Baumer's own statements that it is a standard assumption in economics that people "promote their own self-interests" (CX0826 at 011 (Baumer, Dep. at 34)); that the Board has an interest in exclusion of non-dentist teeth whiteners because it would "help dentists in terms of their bottom line" (Baumer, Tr. 1781); that because of human nature, board members might be influenced by the impact of their decisions on the financial bottom line of dentists (Baumer, Tr. 1871); that members of professional boards have in the past acted in ways calculated to enhance their own income and the income of the constituents of the boards, to the

detriment of patients and the general public (Baumer, Tr. 1848-1850, 1855, 1912-1913); and that it is well recognized that medical professional board members engaged in conduct that harmed consumers despite their oaths to protect the public health. (Baumer, Tr. 1915; *see also* CCPFF ¶¶ 609, 613-615).

581. Dr. Kwoka conceded that Board members acted based in part on their sworn duty as public officials. (Kwoka, Tr. 1111-1113).

Response to Finding No. 581

Complaint Counsel has no specific response.

582. Dr. Kwoka conceded that Board members are also motivated by ethical and professional standards of behavior. (Kwoka, Tr. 1111-1113).

Response to Finding No. 582

Complaint Counsel has no specific response.

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).

Response to Finding No. 583

This proposed finding is incorrect and misleading. Neither on pages 1246-1248 nor anywhere else was Professor Kwoka asked to define "how material the Board members' alleged financial interest was." (Kwoka, Tr. 1246-1248). Instead, Professor Kwoka was asked to define the exact number where an interest becomes material, and he responded that as an economic principle a material interest was defined as a "nontrivial amount." (Kwoka, Tr. 1247). Dr. Baumer agreed that the Board has "a financial interest in prohibiting teeth whitening by non-dentists" (Baumer, Tr. 1875). Indeed the record shows that Board dentists have earned a nontrivial amount of money from teeth whitening over the past six years. (CX0467 at 001 (Dr.

Owens – $77,333); CX0606 at 005 (Dr. Morgan – $15,753); CX0378 at 005 (Dr. Hardesty – $29,537); CX0614 at 001 (Dr. Wester – $28,287); CX0340 at 002 (Dr. Morgan – $11,536)).

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).

Response to Finding No. 584

This proposed finding is irrelevant, incorrect, and misleading. First, Professor Kwoka's quote in the first sentence of this proposed finding is related to the Akerlof "lemons problem," which is concerned with situations where a lack of information leads consumers to choose lower quality goods over higher quality goods, and thereby drive out the higher quality producers. But both Professor Kwoka and Dr. Baumer agree that there is no lemons problem in the teeth whitening market. (Kwoka, Tr. 1090-1091; Baumer Tr. 1772-1773). Dr. Baumer was actually responding to Professor Kwoka's claim that "some evidence indicates that simpler and more routine services are well provided by nonprofessionals or less traditional practitioners," but Dr. Baumer provides no foundation for his opinion. (Baumer, Tr. 1786-1787). In addition, Professor Kwoka did not state that non-dentists provide higher quality service than dentists, but simply that certain simpler services can be well provided by nonprofessionals; Dr. Baumer did not attempt to rebut this statement. (Baumer, Tr. 1786-1786; *see also* CCPFF ¶ 571).

585. Dr. Kwoka failed to account for significant health considerations in his discussion. (Baumer, Tr. 1817).

Response to Finding No. 585

This proposed finding is incorrect, misleading, and unfounded. First, Dr. Baumer actually claimed that Professor Kwoka "refuses to acknowledge that there is a significant health dimension" not that he "failed to account for significant health considereations." (Baumer, Tr. 1817). This first sentence needs explanation or should be dropped. Second, Professor Kwoka did in fact investigate, as an "integral part" of his analysis, whether there was a justification for exclusion based on health considerations (Kwoka, Tr. 1137-1138); he concluded that the "record of complaints, the testimony of experts in the field, and the experience with non-dentist teeth whitening" demonstrated that there was no economic or efficiency justification based on health and safety benefits that would require exclusion of non-dentist teeth whitening. (Kwoka, Tr. 1166-1167). Lastly, Professor Giniger testified that there is no significant health issue with non-dentist teeth whitening, as demonstrated by the millions of teeth whitening procedures without appreciable consumer harm, and Dr. Haywood acknowledged that there had been no systematic documentation of harm in the twenty-year history of non-dentist teeth whitening. (Giniger, Tr. 120-123, 430-431, 453-455; Haywood Tr. 2713-2714, 2729).

586. Dr. Kwoka conceded that if he assumed evidence of health and safety issues was [sic] present, either in the form of expert testimony or literature, he would weigh that evidence in his analysis. (Kwoka, Tr. 1139-1140, 1141-1143).

Response to Finding No. 586

This proposed finding is misleading and incorrect. Professor Kwoka actually stated that if there had been evidence of health and safety issues that he would have weighed such evidence in his analysis and that it might have changed his conclusions. (Kwoka, Tr. 1139-1143). Professor Kwoka did in fact weigh all of the applicable evidence regarding health and safety issues and

concluded from an economic viewpoint that they did not justify exclusion of non-dentist teeth whitening. (Kwoka, Tr. 1166-1167; CCPFF ¶¶ 1197-1204).

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).

Response to Finding No. 587

The citations do not support this proposed finding. Professor Kwoka actually said that he did not perform a consumer protection analysis, but that a consumer protection analysis would be similar to his exclusion analysis in that less restrictive alternatives are always preferred to exclusion. (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).

Response to Finding No. 588

This proposed finding is incorrect, misleading, and not supported by the citations. In his testimony, Professor Kwoka did consider whether the exclusion of non-dentist teeth whitening could have a zero effect on the prices that dentists charge and rejected that possibility as a matter of economic theory. (Kwoka, Tr. 1028-1029). Because the cross-elasticity of demand between non-dentist teeth whitening and dentist teeth whitening is high, economic theory predicts that there will be a substantial price effect as a result of the exclusion of non-dentist teeth whitening. (Kwoka, Tr. 1028-1031; CCPFF ¶¶ 687, 693-694). Dr. Baumer agrees that non-dentist and dentist teeth whitening have a high cross-elasticity of demand (Baumer, Tr. 1842; CX0826 at 029 (Baumer, Dep. at 106)), and Dr. Baumer agrees that the exclusion of non-dentist teeth whitening will in fact result in a higher price for teeth whitening services, all things being equal. (Baumer, Tr. 1700). Further, Dr. Baumer admits that if non-dentist teeth whiteners were just gaining a

foothold in the market, and therefore did not have a substantial restraining effect on price, that their exclusion from the market would not necessarily result in a price change (Baumer, Tr. 1857). This exclusion would still result in consumer harm due to a reduction in consumer choice, and each year that non-dentists are excluded represents another iteration of loss of consumer surplus. (Kwoka, Tr. 1017-1018, 1031-1032; *see also* CCPFF ¶¶ 691-692, 702-703).

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).

Response to Finding No. 589

This proposed finding is incorrect and unfounded. In his testimony, Professor Kwoka stated that because the cross-elasticity of demand between non-dentist teeth whitening and dentist teeth whitening is high, economic theory predicts that there will be a substantial price effect as a result of the exclusion of non-dentist teeth whitening. (Kwoka, Tr. 1028-1031). Dr. Baumer agreed that non-dentist and dentist teeth whitening have a high cross-elasticity of demand (Baumer, Tr. 1842; CX0826 at 029 (Baumer, Dep. at 106)), and Dr. Baumer agrees that the exclusion of non-dentist teeth whitening will in fact result in a higher price for teeth whitening services, all things being equal. (Baumer, Tr. 1700). Further, Dr. Baumer admits that if non-dentist teeth whiteners were just gaining a foothold in the market, and therefore did not have a substantial restraining effect on price, that their exclusion from the market would not necessarily result in a price change (Baumer, Tr. 1857), but this exclusion would still result in consumer harm due to a reduction in consumer choice. (Kwoka, Tr. 1031-1032).

Dr. Baumer's assertion that dentists may base their fees on the time expended to perform the service and therefore will not respond with a price increase to the exclusion of non-dentists is incompatible with his admissions that: (1) dentist and non-dentist teeth whitening have a high cross-elasticity between them (Baumer, Tr. 1842, 1844; RX0078 at 009); (2) all other things being equal, exclusion of non-dentist teeth whitening will result in a price increase (Baumer, Tr. 1700); and (3) there could be an increase in volume if they are under capacity with no price increase. (RX0078 at 008; Baumer, Tr. 1856; CX0826 at 028 (Baumer, Dep. at 105)). Dr. Baumer's hypothesis that dentists may charge fees based on time expended is self-serving, unsupported by the record, and should be accorded no weight.

This testimony also focuses only on the price that dentists charge, and does not account for the increase in price paid by the consumers who switch. This substitution would raise the average price paid by consumers, even if the dentists did not change their prices. (CCPFF ¶¶ 682, 684).

590. Dr. Kwoka relied on outdated literature in the form of studies from the 1970s and 1980s. (Baumer, Tr. 1733, 1743-1744).

Response to Finding No. 590

This proposed finding is incorrect, misleading, and not supported by the citation. Dr. Baumer's testimony regarding the "outdatedness" of the studies relied upon by Professor Kwoka has been shown to be unreliable. First, Dr. Baumer admits that at the time these studies were published they were valid as to both their methodologies and their conclusions. (Baumer, Tr. 1896-1897 ("top notch economists with blind refereed acceptances in top journals")). Dr. Baumer agrees that the type of analysis used in the studies would still be a valid type of analysis

if used today because nothing has changed in terms of economic theory or empirical study. (Baumer, Tr. 1897-1898; CX0826 at 032 (Baumer, Dep. at 120); *See also*, CCPFF ¶¶ 575-578, 590-594, 601; Complaint Counsel's Post Trial Brief at 30-34).

Second, Dr. Baumer admits that one study, the Kleiner and Kudrle article, is not subject to the same criticism he levels against the other professions studies — that they are too old to be relevant. (Baumer, Tr. 1971-1972). Indeed, Dr. Baumer agrees that he does not have any reason to criticize the Kleiner and Kudrle study. (Baumer, Tr. 1971-1972). Dr. Baumer admits that the study found that individuals from states with more restrictive dental practice provisions had greater untreated dental problems than individuals from states with less restrictive provisions. (Baumer, Tr. 1971-1972). This study confirms the conclusions drawn by the earlier studies also relied upon by Professor Kwoka. (Kwoka, Tr. 1045-1046; *see also*, CCPFF ¶¶ 585-586).

Third, contradicting any claim that the studies are outdated, Dr. Baumer himself relied on some of the healthcare professions studies for an article he published in 2007 on an organization composed of state pharmacist licensing boards. (Baumer, Tr. 1901, 1903). Dr. Baumer based his opinions partially on the professions studies from the 1970s and 1980s. (Baumer, Tr. 1903). At the time he wrote his 2007 article, Dr. Baumer believed the professions studies had continued relevance. (Baumer, Tr. 1903). Dr. Baumer only came to his opinion that these healthcare professions studies are too old to be valid during the process of writing his paid expert report for the Board. (Baumer, Tr. 1908-1909). Despite relying on studies he now believes are outdated, Dr. Baumer stands by his 2007 study and has no intention of retracting or correcting the article. (Baumer, Tr. 1910; *see also*, CCPFF ¶¶ 577-578). This inconsistency demonstrates that the opinions expressed post-engagement are not credible.

Fourth, Dr. Baumer admitted that he may have exaggerated in describing the professions studies as outdated. (Baumer, Tr. 1766). Indeed, Professor Kwoka testified that just because most of the professions studies were conducted 25 years ago does not mean that the studies are outdated; the recent lack of interest in publishing on the subject results from the fact that all of the studies came to similar conclusions (higher prices due to restrictions without a corresponding increase in quality), and there have been no studies in recent years that challenge this conventional and consensus view. (Kwoka, Tr. 1054-1055, 1120-1121; CX0631 at 012-013). (*See* Complaint Counsel's Post Trial Brief at 33-34).

Lastly, it must also be noted that in the citation given in Respondent's finding Dr. Baumer only describes one study as being outdated. (Baumer, Tr. 1733, 1743-1744).

591. Dr. Kwoka admitted that the model of licensing boards on [sic] a whole does not resemble the widespread model of 20 years ago because licensing practices have changed. (Kwoka, Tr. 1121).

Response to Finding No. 591

This proposed finding is incorrect, misleading, and blatantly misrepresents the testimony. When asked the question "on the whole, wouldn't you say that the model we're faced with today on state occupational licensing is not anywhere -- it does not closely resemble the model we had 25 years ago?" Professor Kwoka answered: "No. I don't believe that's a fair statement". (Kwoka, Tr. 1122).

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).

Response to Finding No. 592

This finding is incorrect and misleading. Although Professor Kwoka did not consider some policy aspects that fall outside economic analysis (Kwoka, Tr. 1108-1109 (Q: Are there other aspects of it beyond economics that might justify the exclusion . . . . Other policy, for example? A: Of course. My role here is as an economist. I evaluated the justification from an economic perspective.) (emphasis added)), he did consider economic public policy justifications, such as the health and safety of consumers. (CCPFF ¶ 1199). In fact, Professor Kwoka expressly referred to public policy in describing his analysis, stating: "I would weigh the [consumer harm] evidence that seemed reliable . . . and represented the sort of evidence that we're familiar with in evaluating public policy . . . [I]t is certainly part of a public policy analysis. It reflects economic content. It reflects justifications." (Kwoka, Tr. 1141-1142; *see also* Kwoka, Tr. 1167-1168). And indeed, Professor Kwoka evaluated the consumer harm justifications of the Board and concluded that they did not justify exclusion of non-dentist teeth whitening providers, particularly given the less restrictive alternatives available to the Board. (CCPFF ¶¶ 1197-1208, 1210-1212, 1215, 1217-1220, 1222, 1226).

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).

Response to Finding No. 593

The citation misrepresents the testimony multiple times and does not support this proposed finding. The Board is in fact a creature of state law, but rather than simply state that as a proposed finding, this proposed finding unaccountably misrepresents the testimony of Professor Kwoka by stating he "conceded" rather than "assumed" the Board was a "creature of state law."

Further, in the absence of anything in the record indicating "the Board's enforcement role involves issuing cease and desist letters," this proposed finding misrepresents that Professor Kwoka offered a legal opinion on this subject (Kwoka, Tr. 1146-1148), rather than the correct testimony:

> Q. Might issuing a cease and desist letter be one
> 4 of those powers and discretion?
> 5 A. Again, I have no legal judgment about the cease
> 6 and desist letters." (Kwoka, Tr. 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).

Response to Finding No. 594

The finding is inaccurate, unfounded, and not supported by the citation, and parts are a complete fabrication. Professor Kwoka did state that the mechanics of exclusion do not change the economic analysis of the effect of the exclusion on consumer welfare; however, Professor Kwoka did not testify to whether the "mechanics of exclusion in this case are discretionary," and he did not testify to whether "the Board is required by law to enforce the statute." (Kwoka, Tr. 1173-1174). Those statements are complete fabrications by Respondent.

595. Dr. Kwoka's general assessment of licensing lists no positives and recognizes no efficacies for the licensing construct. (Kwoka, Tr. 1126-1128).

Response to Finding No. 595

The citation does not support this proposed finding. Professor Kwoka stated that he "found no economic justification for [the Board's] restriction" but did not state that licensing generally has no positives or efficacies. (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. (K woka, Tr. 1186-1187).

Response to Finding No. 596

Complaint Counsel has no specific response.

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).

Response to Finding No. 597

This finding blatantly misrepresents the testimony found at 1131-1135 and is not supported by the citation. Professor Kwoka did not testify that he "assumed that the cease and desist letters automatically had an exclusory effect," or anything approaching that statement. Most of those pages are filled with assumptions by Respondent's counsel. The answers by Professor Kwoka were opposite of the proposed finding and in fact stated that the letters, as an "empirical proposition," actually had an exclusionary effect. (Kwoka, Tr. 1131-1135). Professor Kwoka made this point explicitly several times. Further, Professor Kwoka never testified that the letters had 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).

Response to Finding No. 598

Complaint Counsel has no specific response.

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).

Response to Finding No. 599

Complaint Counsel has no specific response.

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).

Response to Finding No. 600

The material cited by Respondent for the proposed finding is entirely inapposite.

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).

Response to Finding No. 601

Complaint Counsel has no specific response.

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)).

Response to Finding No. 602

Complaint Counsel has no specific response.

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)).

Response to Finding No. 603

Complaint Counsel has no specific response.

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).

Response to Finding No. 604

This proposed finding ignores the fact that despite the assertion that dentist earnings from teeth whitening are not a substantial portion of their dental practice revenue, some dentists earn appreciable amounts of revenue from teeth whitening. Some dentists in North Carolina have averaged tens of thousands of dollars annually in revenue from the provision of teeth whitening procedures for the period from 2005 until August of 2010. (CX0599 at 003) (Charlotte, North Carolina dentist had revenue of $120,490); (CX0605 at 003) (Chapel Hill, North Carolina dentist had revenue of $77,302); (CX0616 at 021) (Raleigh, North Carolina dentist had revenues of $74,710); (CX0601 at 008) (Cary, North Carolina dentist had revenues of $88,713); (CX0608 at 002) (Huntersville, North Carolina dentist had revenues of $66,545); (CX0602 at 002) Another Huntersville, North Carolina dentist had revenues of $149,806); (CX0600 at 003) (Greensboro, North Carolina dentist had revenues of $197,970); (CX0603 at 003) (Wilmington, North Carolina dentist had revenues of $118,298).

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).

Response to Finding No. 605

Complaint Counsel has no specific response.

606. 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).

Response to Finding No. 606

Complaint Counsel has no specific response.

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).

Response to Finding No. 607

Complaint Counsel has no specific response.

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)).

Response to Finding No. 608

Complaint Counsel has no specific response.

609. Dentists' teeth whitening fees are tied to "office overhead," which can be substantial. (RX65 (Morgan, Dep. at 139); RX75 (Oyster, Dep. at 65)).

Response to Finding No. 609

The cited testimony does not support this proposed finding. Dr. Morgan testified that his teeth whitening fees are tied to overhead but not that the amount is substantial or otherwise. Dr. Oyster testified that he couldn't even assess the value of his "chair time" with respect to teeth whitening. (RX65 at 35 (Morgan, Dep. at 139); RX75 at 17 (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)).

Response to Finding No. 610

The cited testimony does not support this proposed finding. Although there are certain strengths of peroxide that dental product manufacturers will not sell to non-dentists, without limitation the FDA treats hydrogen peroxide as a cosmetic, not a drug. No prescription is required for its purchase irrespective of concentration. (Giniger, Tr. 213, 216, 256; CX0653 at

024, 035-036). This is likely what Dr. Holland was referring to as "prescription-*type*" materials. In addition, Dr. Holland merely testified that the cost to him to buy teeth bleaching materials has increased over time, the same as the cost of "everything has gone up." He stated that the last time he bought these materials, they cost him $60. He charges $175 to whiten a single arch, which more than covers his costs for materials. (CX0567 at 017 (Holland, Dep. at 60-61)).

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).

Response to Finding No. 611

This proposed finding contradicts itself, by stating that dentists "typically have brochures or posters" that market teeth whitening in their offices. It is inapposite whether the information that the office provides regarding teeth whitening services is conveyed in visibly displayed writing or verbally. (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).

Response to Finding No. 612

Complaint Counsel has no specific response.

613. Zoom! and Bright Smile are two products used by dentists for in-office teeth whitening procedures. (Joint Stipulations ¶ 25).

Response to Finding No. 613

Complaint Counsel has no specific response.

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).

Response to Finding No. 614

Complaint Counsel has no specific response.

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)).

Response to Finding No. 615

Complaint Counsel has no specific response.

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).

Response to Finding No. 616

Complaint Counsel has no specific response.

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).

Response to Finding No. 617

Complaint Counsel has no specific response.

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).

Response to Finding No. 618

Complaint Counsel has no specific response.

619. No evidence was presented at trial demonstrating that all non-dentist teeth whiteners use FDA-approved teeth whitening products. (Entire record).

Response to Finding No. 619

This finding is misleading. The record is equally devoid of evidence that all dentists use products that are approved by the FDA, or anyone else. (Entire record). In addition, there is no evidence that any non-dentist teeth whiteners did not use FDA-approved teeth whitening products. To the contrary, the witnesses who manufacture and sell non-dentist teeth whitening products who appeared at trial all testified that their products are manufactured in FDA-approved facilities. (Valentine, Tr. 531; Osborn, Tr. 652-653; Nelson, Tr. 737-738).

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).

Response to Finding No. 620

This finding is misleading. The record is equally devoid of evidence that any state or federal regulatory entity, including the Board, ensures that FDA-approved teeth whitening products are used by 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).

Response to Finding No. 621

Complaint Counsel has no specific response.

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).

Response to Finding No. 622

This proposed finding is inaccurate. Mr. Valentine never testified that WhiteSmile USA sought to avoid regulation. Mr. Valentine testified that his business was being scrutinized in certain states as to whether his business was the practice of dentistry. WhiteSmile USA sought to avoid its operators being accused of practicing dentistry without a license by avoiding any activities that could be construed as practicing dentistry. (Valentine, Tr. 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).

Response to Finding No. 623

This proposed finding is inaccurate and misleading. That court determined that the WhiteSmile teeth whitening process was the practice of dentistry under the specific language of the Alabama dental statute, and has no bearing on the legality of non-dentist teeth whitening in North Carolina. (Valentine, Tr. 559-560, 600).

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).

Response to Finding No. 624

Complaint Counsel has no specific response.

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).

Response to Finding No. 625

WhiteSmile's pre-2009 lost sales, which indicate lost purchase opportunities for North Carolina consumers, are relevant because WhiteSmile delayed its expansion throughout North Carolina solely because of Respondent's actions, including the use of Cease and Desist orders. In Spring 2007, WhiteSmile USA entered the North Carolina market, operating a few trade shows in two metropolitan areas. (Valentine, Tr. 561). WhiteSmile was pleased with its sales at those trade shows. (Valentine, Tr. 561). In late 2007, WhiteSmile expanded its business in many areas of the U.S. to Sam's Clubs. It would have liked to do so in North Carolina, in which Sam's Clubs had numerous stores. (Valentine, Tr. 562). Mr. Valentine and his Sam's Club buyer discussed WhiteSmile's serving North Carolina consumers through non-dentist-operated teeth whitening facilities rotating through North Carolina Sam's Club's. (Valentine, Tr. 562). WhiteSmile and Sam's Clubs did not take that step at that time, or at any other time prior to 2009, "based on the knowledge of the actions that the Dental Board was taking in that State. (Valentine, Tr. 562). Those actions included Respondent's sending out of Cease and Desist letters to various other non-dentist providers, of which they knew. (Valentine, Tr. 561-562). But for that, WhiteSmile would have expanded throughout North Carolina via Sam's Clubs in January 2008. (Valentine, Tr. 568). However, it did not do so until 2009, following media reports that Respondent had changed its disposition toward non-dentist teeth bleaching operations. (Valentine, Tr. 567).

626. Mr. Valentine admitted that since 2009, WhiteSmile USA's sales had "dropped off significantly due to the economy." (Valentine, Tr. 575).

Response to Finding No. 626

This proposed finding is incomplete, inaccurate and misleading. In addition to the economy, Mr. Valentine testified that his sales were down because potential customers heard that

non-dentist teeth whitening was illegal. Mr. Valentine believed that those customers heard that in the media. There were several reports in various North Carolina news outlets that the Board had determined that non-dentist teeth whitening was illegal. (Valentine, Tr. 575; CX0117 at 001-002; CX0170 at 002-003; CX0158 at 001-002; CX0163 at 001-002).

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).

Response to Finding No. 627

This proposed finding is inaccurate. Mr. Valentine testified that he is "not sure" whether or not online sales are being placed by residents of North Carolina. (Valentine, Tr. 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).

Response to Finding No. 628

Complaint Counsel has no specific response.

629. WhiteSmile USA has not made a determination as to how it would comply with HIPAA or CDC requirements. (Valentine, Tr. 593).

Response to Finding No. 629

This proposed finding is misleading. There is no evidence that any HIPAA or CDC "requirements" have any application to WhiteSmile operations. (Entire record).

630. WhiteSmile USA does not take the medical history of its customers prior to providing teeth whitening services. (Valentine, Tr. 594).

Response to Finding No. 630

Complaint Counsel has no specific response.

631. WhiteSmile USA requires that its customers sign a consent form containing a waiver of liability. (Valentine, Tr. 597).

Response to Finding No. 631

Complaint Counsel has no specific response.

632. WhiteSmile USA did not require salons or kiosks carrying its products to maintain general liability insurance. (Valentine, Tr. 606-607).

Response to Finding No. 632

Complaint Counsel has no specific response.

633. Mr. Valentine contacted the FTC in 2008 to file a complaint. (Valentine, Tr. 597-598).

Response to Finding No. 633

Complaint Counsel has no specific response.

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).

Response to Finding No. 634

Complaint Counsel has no specific response.

635. People using Ms. Osborn's BriteWhite Teeth Whitening System receive no training other than a training manual to read. (Osborn, Tr. 655-656).

Response to Finding No. 635

This proposed finding is incomplete and misleading. Ms. Osborn testified that there is "hardly any training" with the Brite White system because it is such a user-friendly device. (Osborn, Tr. 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).

Response to Finding No. 636

This proposed finding is inaccurate, misleading and not supported by the cited evidence. Ms. Osborn testified that she stopped using the word "stain" in connection with her non-dentist teeth whitening system because she changed anything associated with her system that could potentially be construed 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).

Response to Finding No. 637

This proposed finding is irrelevant. There is no evidentiary significance to this out-of-court statement.

638. Ms. Osborn never received a cease and desist letter from North Carolina. (Osborn, Tr. 672-673).

Response to Finding No. 638

Complaint Counsel has no specific response.

639. Ms. Osborn testified that she was not aware of any certification program for people that provide non-dentist teeth whitening. (Osborn, Tr. 705).

Response to Finding No. 639

Complaint Counsel has no specific response.

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).

Response to Finding No. 640

Complaint Counsel has no specific response.

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).

Response to Finding No. 641

This proposed finding is inaccurate and misrepresents the cited evidence. Ms. Osborn was not given the opportunity to respond to any question about HIPAA. (Osborn, Tr. 706 ("Q. Do you know whether or not you or your affiliates are required to comply with HIPAA? A. Comply for what? Q. Never mind.")).

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).

Response to Finding No. 642

Complaint Counsel has no specific response.

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).

Response to Finding No. 643

Complaint Counsel has no specific response.

644. There is no testimony that Ms. Osborn was prevented from selling teeth whitening products to dentists in North Carolina. (Entire record).

Response to Finding No. 644

Complaint Counsel has no specific response.

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).

Response to Finding No. 645

This proposed finding is inaccurate, misleading and mischaracterizes the evidence. There is no evidence that this statement refers to Ms. Osborn's light. Instead it refers to a light that requires the use of catalysts, activators, photosensitizing agents or heat, discussed in Ms. Osborn's application to distinguish it from her system. There is no evidence that any of these things are used in the Brite White system. (Osborn, Tr. 683-686). With respect to Ms. Osborn's patented system, it is "simple enough to be used for administration - - without administration by a dental professional." (Osborn, Tr. 684-685).

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).

Response to Finding No. 646

Complaint Counsel has no specific response.

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).

Response to Finding No. 647

Complaint Counsel has no specific response.

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).

Response to Finding No. 648

Complaint Counsel has no specific response.

649. 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).

Response to Finding No. 649

This proposed finding is inaccurate. Ms. Osborn never testified that affiliates were "required" to provide either form to customers. (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 current information form, which simply provides information to the customer. (Osborn, Tr. 708-709).

Response to Finding No. 650

Complaint Counsel has no specific response.

651. 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).

Response to Finding No. 651

Complaint Counsel has no specific response.

652. Ms. Osborn testified that the Council for Cosmetic Teeth Whitening has a significant interest in the outcome of this matter. (Osborn, Tr. 715).

Response to Finding No. 652

Complaint Counsel has no specific response.

653. While under oath, Ms. Osborn denied having any personal contact with anyone at the FTC. (Osborn, Tr. 716).

Response to Finding No. 653

This proposed finding is inaccurate, irrelevant and misrepresents the testimony. Ms. Osborn was asked "when did you first contact the FTC with your concerns about teeth whitening?" Ms. Osborn testified that "I personally did not contact the FTC, sir. It was our

attorney that we had for the [Council for Cosmetic Teeth Whitening] that made the contact."

(Osborn, Tr. 715).

654. Ms. Osborn admitted to sending an e-mail on September 13, 2009 to Melissa Westman-Cherry transmitting the restraining order for Signature Spas in Hickory, N.C. She also admitted sending an e-mail to Ms. Westman-Cherry thanking her for bringing this proceeding. (Osborn, Tr. 716).

Response to Finding No. 654

Complaint Counsel has no specific response.

c. WhiteScience

655. George Nelson is the President of White Science, a teeth whitening manufacturing and marketing business. (Nelson, Tr. 721-722).

Response to Finding No. 655

Complaint Counsel has no specific response.

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).

Response to Finding No. 656

Complaint Counsel has no specific response.

657. WhiteScience has a product that it markets and sells to dentists called Artiste. (Nelson, Tr. 729).

Response to Finding No. 657

Complaint Counsel has no specific response.

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).

Response to Finding No. 658

Complaint Counsel has no specific response.

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).

Response to Finding No. 659

This proposed finding is not fully supported by the cited material. Mr. Nelson does not testify about whether or not he considered having a dentist supervise or recommend that their local affiliates have a dentist supervise teeth whitening services that they provided to customers at Nelson, Tr. 817. (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).

Response to Finding No. 660

Complaint Counsel has no specific response.

661. 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).

Response to Finding No. 661

Complaint Counsel has no specific response.

662. WhiteScience does not require local affiliates selling its product to maintain any sort of documentation of its business or customers. (Nelson, Tr. 796).

Response to Finding No. 662

This proposed finding is inaccurate. Mr. Nelson testified that his business affiliates are required to maintain a business license. (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).

Response to Finding No. 663

This proposed finding is inaccurate. Mr. Nelson testified that WhiteScience's protocol for its "local affiliates" is to provide information to their customers, and in fact part of the WhiteScience training is to role play with the operator in interacting with the customer in providing this information. (Nelson, Tr. 797-798).

664. 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).

Response to Finding No. 664

Complaint Counsel has no specific response.

665. WhiteScience operations in 40 states in the United States, and still currently operates in North Carolina. (Nelson, Tr. 800, 809-811).

Response to Finding No. 665

Complaint Counsel has no specific response.

666. Mr. Nelson is on the board of the Council for Cosmetic Teeth Whitening, and is one of the founding partners. (Nelson, Tr. 801).

Response to Finding No. 666

Complaint Counsel has no specific response.

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).

Response to Finding No. 667

Complaint Counsel has no specific response.

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 ofthe 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).

Response to Finding No. 668

Complaint Counsel has no specific response.

669. WhiteScience's marketing literature states that its product will "deliver real teeth whitening and stain removal." (Nelson, Tr. 817-819).

Response to Finding No. 669

This proposed finding is misleading. Mr. Nelson testified that he recognized the ad, but was unsure whether WhiteScience created the ad, or a retailer of WhiteScience's product created it. (Nelson, Tr. 818).

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).

Response to Finding No. 670

Complaint Counsel has no specific response.

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).

Response to Finding No. 671

Complaint Counsel has no specific response.

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).

Response to Finding No. 672

This proposed finding is misleading. There is no evidence that HIPAA or CDC has any application to WhiteScience operations. (Entire record).

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).

Response to Finding No. 673

Complaint Counsel has no specific response.

674. Employees and local affiliates of WhiteScience do not keep any documentation of the teeth whitening procedures that they conduct on behalf oftheir customers, unless it is information for marketing purposes. (Nelson, Tr. 824).

Response to Finding No. 674

Complaint Counsel has no specific response.

675. Mr. Nelson recalls contacting Ms. Westman-Cherry in February 2008, and informing her about the Wyants, teeth whitening affiliates of White Science whose kiosk lease was cancelled by the North Carolina mall where they were operating. (Nelson, Tr. 824-825).

Response to Finding No. 675

Complaint Counsel has no specific response.

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).

Response to Finding No. 676

Complaint Counsel notes that CX0139 is a letter from Terry Friddle to Barry Hughie at the Dowd Central YMCA and does not provide any support for this proposed finding. (CX0139).

677. Mr. Nelson admitted that Mr. Baudot is his competitor in the teeth whitening industry. (Nelson, Tr. 828-829).

Response to Finding No. 677

Complaint Counsel has no specific response.

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).

Response to Finding No. 678

This proposed finding is inaccurate and wholly unsupported by the evidence. CX0139 is a letter from Terry Friddle to Barry Hughie at the Dowd Central YMCA and does not provide any support for this proposed finding. (CX0139). In addition, Counsel for Respondent Mr. Nichols asks if Mr. Nelson is aware that someone named Lisa Tarry sent an e-mail on Mr. Nelson's behalf to Mr. Osnowitz at the FTC. Mr. Nelson testified that he does not know Mr. Osnowitz and does not recall sending a letter with the quoted information in this proposed finding to Mr. Baudot. (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).

Response to Finding No. 679

Complaint Counsel has no specific response.

680. WhiteScience did not require its local affiliates operating teeth whitening kiosks at malls to have running water. (Nelson, Tr. 834).

Response to Finding No. 680

Complaint Counsel has no specific response.

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).

Response to Finding No. 681

Complaint Counsel has no specific response.

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).

Response to Finding No. 682

Complaint Counsel has no specific response.

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).

Response to Finding No. 683

Complaint Counsel has no specific response.

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).

Response to Finding No. 684

Complaint Counsel has no specific response.

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).

Response to Finding No. 685

This proposed finding is inaccurate and misleading. Ms. Osborn testified that the purpose of the Council for Cosmetic Teeth Whitening's "best practices" protocol is to help non-dentist providers understand what it is legal for them to do when performing teeth whitening services. (Osborn, Tr. 676).

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; RXll at 6; RX15 at 9; RX17 at 2, *subject to protective order*; RX22 at 18; RX25 at 15; RX27 at 1).

Response to Finding No. 686

This proposed finding ignores the fact that dentists and hygienists often do not follow their required protocols. (Giniger, Tr. 422-423).

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).

Response to Finding No. 687

This proposed finding is inaccurate and misleading. The Council for Cosmetic Teeth Whitening's "best practices" protocol advocates safety and sanitation practices including making sure that the procedure is totally self-administered; providing protective eyewear where appropriate; employees washing their hands often; employees never touching a customer's lips, mouth, gums or teeth; wearing clean smocks or coats; wearing disposable gloves while handling teeth whitening products; using sanitary disposal techniques including using sealed bio-hazard bags for all mouthpieces and other materials that come in contact with the customer; properly cleaning and disinfecting all non-disposable items that come in direct contact with customers using an EPA registered disinfectant; generally following OSHA standards; and encouraging

customers with questions or concerns to consult a dentist. (CX0630 at 001-013; Osborn, Tr. 676-679).

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).

Response to Finding No. 688

This proposed finding is misleading. The citation to Mr. Runsick's testimony does not support this proposed finding. Mr. Runsick could not recall whether kiosk employees sanitized their hands and wore gloves, or not, when he had his teeth whitened. In addition, it ignores the fact that the Board itself has determined, through its investigations, that licensed dentists have engaged in unsanitary practices. (Runsick, Tr. 2108; Response to RFA ¶ 32-33; CCPFF ¶ 1093).

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).

Response to Finding No. 689

This proposed finding is inaccurate. CCTW President Joyce Osborn testified that she has no knowledge of ever advising stores that use her Brite White system not to hire a dentist. (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).

Response to Finding No. 690

Complaint Counsel has no specific response.

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).

Response to Finding No. 691

Complaint Counsel has no specific response.

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).

Response to Finding No. 692

Complaint Counsel has no specific response.

iv. Testimony of Kiosk/Spa Teeth Whiteners

a. Brian Wyant

693. Brian 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).

Response to Finding No. 693

This proposed finding is incomplete and possibly misleading. Brian Wyant's wife Angela Wyant signed a lease agreement for kiosk space with General Growth Properties, Inc., owner and operator of Carolina Place Mall, in Pineville, North Carolina on December 7, 2007. Brian Wyant operated a teeth whitening kiosk there as One Bright Smile, using WhiteScience products. (CCPFF ¶¶ 344-345; CX0665 at 001-011; Wyant, Tr. 862-865, 871-873).

694. 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).

Response to Finding No. 694

Complaint Counsel has no specific response.

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).

Response to Finding No. 695

This proposed finding is irrelevant. There is no evidence that any of the topics listed in this proposed finding is even necessary in order to provide non-dentist teeth whitening services. (Entire record).

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).

Response to Finding No. 696

Complaint Counsel has no specific response.

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).

Response to Finding No. 697

Complaint Counsel has no specific response.

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).

Response to Finding No. 698

Complaint Counsel has no specific response.

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).

Response to Finding No. 699

Complaint Counsel has no specific response.

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).

Response to Finding No. 700

This proposed finding is inaccurate regarding the products Mr. Wyant sold. The bleaching product Mr. Wyant used in his mall kiosk was from WhiteScience and known as "SpaWhite." Mr. Wyant also sold "a to-go pen called WhiteICE" from WhiteScience which he referred to as a "lipstick-type" product, intended to be used as "a maintenance-type product." Of these two WhiteScience products, about 90% of Mr. Wyant's customers bought SpaWhite and 3% bought WhiteIce. (Wyant, Tr. 865, 869, 889-891).

Mr. Wyant also sold a third product, a take-home product called iWhite that sold for $99 (Wyant, Tr. 869). Mr. Wyant testified that in addition to choosing WhiteScience products for sale and use in his kiosk, "I also selected an iWhite product, which was a take-home kit." (Wyant, Tr. 863).

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).

Response to Finding No. 701

This proposed finding is incomplete and misleading. Mr. Wyant trained the people he worked with to use the same protocols he had been trained to use, including safety measures, cleanliness, how to wipe down chairs and lights with disinfectants, use of the consent form, questions customers asked, and the answers to those questions. (Wyant, Tr. 865-866, 869-870, 919-920).

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).

Response to Finding No. 702

Complaint Counsel has no specific response.

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).

Response to Finding No. 703

This proposed finding is in part misleading and incomplete. In late January 2008, the mall's leasing agent informed Mr. Wyant that the licensing agreement would not be renewed and that his teeth whitening business would have to leave Carolina Place Mall by February 1, 2008. Mr. Wyant was told that the North Carolina State Board of Dental Examiners had sent a letter stating that the business was the illegal practice of dentistry. In a subsequent meeting with Carolina Place Mall General Manager Michael Payton, Mr. Wyant was shown the Board's letter to General Growth Properties and was told that it meant Mr. Wyant would have to close his business in Carolina Place Mall. (Wyant, Tr. 876-879, 884; CCPFF ¶ 346; CX0629).

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).

Response to Finding No. 704

This proposed finding is inaccurate, misleading, and incomplete. Carolina Place Mall, owned and operated by General Growth Properties (GGP), was very pleased with the performance of One Bright Smile, extended its lease for January, 2008, and arranged for an even better location for One Bright Smile within Carolina Place Mall, to begin on February 1, 2008. (Wyant, Tr. 874-876, 882-883). Mr. Wyant was understandably "absolutely shocked" and "upset" when he was then told by the leasing agent that the Dental Board was accusing him of practicing dentistry and One Bright Smile would have to leave the mall. (Wyant, Tr. 876, 879). Mr. Wyant had invested $10,000 to $15,000, as well as his time and energy, and had received overwhelmingly favorable responses from his customers. (Wyant, Tr. 870-871, 880). Mr. Wyant did argue to save his business from being closed in just a few days, and did obtain a meeting with the General Manager of Carolina Place Mall, Michael Payton. (Wyant, Tr. 876-879). Mr. Wyant was shown the Board's letter to General Growth Properties (CX0260) and was told that it meant Mr. Wyant would have to close his business in Carolina Place Mall. (Wyant, Tr. 876 ; CCPFF ¶ 346).

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).

Response to Finding No. 705

Complaint Counsel has no specific response.

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 White Science. 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).

Response to Finding No. 706

This proposed finding is inaccurate, misleading, and incomplete. Mr. Wyant conducted extensive research before starting his business, including extensive research on the product and discussions with different product suppliers. Mr. Wyant developed a business plan and made financial projections, as well as researching possible locations. Mr. Wyant testified he did not rely solely on the representations and information given by WhiteScience. (Wyant, Tr. 860-862, 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).

Response to Finding No. 707

The cited evidence does not support this proposed finding. (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).

Response to Finding No. 708

Complaint Counsel has no specific response.

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).

Response to Finding No. 709

Complaint Counsel has no specific response.

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).

Response to Finding No. 710

Complaint Counsel has no specific response.

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).

Response to Finding No. 711

Complaint Counsel has no specific response.

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).

Response to Finding No. 712

Complaint Counsel has no specific response.

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).

Response to Finding No. 713

Complaint Counsel has no other specific response beyond CCPFF ¶ 208.

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).

Response to Finding No. 714

This proposed finding is inaccurate and misleading. Ms. Hughes testified that she took an impression of her own mouth in order to fashion a whitening tray for her own personal use in order to try the product she intended to offer her customers before actually offering the service in her salon. With her customers, Ms. Hughes would prepare the putty and hand the tray to her customer who would take their own impression. Ms. Hughes did not take impressions of her client's teeth herself. (Hughes, Tr. 935-936, 954-955; CX0353-002).

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).

Response to Finding No. 715

Complaint Counsel has no specific response.

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).

Response to Finding No. 716

Complaint Counsel has no specific response.

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).

Response to Finding No. 717

This proposed finding is not fully supported by the cited material. Mrs. Hughes testified that she does not recall information in the training materials about having clean teeth prior to

teeth whitening, or situations that might be dangerous to a customer. "It may have been in the material, but I do not remember seeing that." (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).

Response to Finding No. 718

Complaint Counsel has no specific response.

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).

Response to Finding No. 719

This proposed finding is irrelevant. There is no evidence that any of the topics listed in this proposed finding is even necessary in order to provide non-dentist teeth whitening services. (Entire record).

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).

Response to Finding No. 720

Complaint Counsel has no specific response.

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).

Response to Finding No. 721

Complaint Counsel has no specific response.

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).

Response to Finding No. 722

The citation to Respondent's exhibit does not support this proposed finding, as it is a brochure and not a newspaper advertisement. Mrs. Hughes testified that she created "a brochure" to explain "in detail what the teeth whitening kit was all about, and then I also took an ad out in our local newspaper . . ." Mrs. Hughes identified the brochure as CX0096 at 003-004 (identical to RX24 at 4-5) she created to advertise her services. (Hughes, Tr. 937-938; CX0096 at 003-004).

723. Ms. Hughes charged $139 per person for her teeth whitening services. (Hughes, Tr.938).

Response to Finding No. 723

The $139 per person charge included the custom-made trays, the gel, the carrying case, the consultation, and detailed instructions. (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).

Response to Finding No. 724

Complaint Counsel has no specific response.

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).

Response to Finding No. 725

Complaint Counsel has no specific response.

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).

Response to Finding No. 726

This proposed finding is misleading and mischaracterizes the evidence cited. The citation given refers to the concerns raised by Mrs. Hughes after viewing the bulletin on the website of the North Carolina Board of Cosmetic Arts Examiners. After viewing the website, Mrs. Hughes "was shocked and very concerned" that teeth whitening had been labeled a misdemeanor and that "I could lose my license." Mrs. Hughes "was scared enough not to do anything. I didn't want to bring any attention to myself." (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).

Response to Finding No. 727

Complaint Counsel has no specific response.

728. After speaking with two different attorneys, Ms. Hughes decided to stop advertising her teeth whitening services. (Hughes, Tr. 963-964).

Response to Finding No. 728

This proposed finding is inaccurate and misleading. After viewing the bulletin on the website of the North Carolina Board of Cosmetic Arts Examiners, Mrs. Hughes stopped advertising and offering any services related to teeth whitening. "I just was very afraid and I stopped. I stopped advertising. I stopped offering it. And if people would call, I would tell them no, that the service was no longer available." (Hughes, Tr. 946). Mrs. Hughes believed the

Dental Board had ordered her to stop offering this teeth whitening process. (Hughes, Tr. 947; CCPFF ¶ 635, ¶ 638).

Mrs. Hughes testified that among the people she spoke with were two attorneys, and she indicated that they gave different opinions without testifying as to the specific advice or opinions or whether she followed the advice of either attorney. (Hughes, Tr. 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).

Response to Finding No. 729

Complaint Counsel has no specific response.

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).

Response to Finding No. 730

Complaint Counsel has no specific response.

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 anyone 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 anyone 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.

Response to Proposed Conclusion of Law No. 1:

Complaint Counsel has no specific response to this quotation of the statute.

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.

Response to Proposed Conclusion of Law No. 2:

Complaint Counsel has no specific response to this quotation of the statute; however, a Joint Stipulation of Fact does not a constitute supporting legal authority.

3. The State Board is an agency of the State of North Carolina pursuant to N.C. Gen. Stat. § 90-22(b).

Response to Proposed Conclusion of Law No. 3:

Complaint Counsel has no specific response to this conclusion of law.

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).

Response to Proposed Conclusion of Law No. 4:

Complaint Counsel has no specific response to this conclusion of law.

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."

Response to Proposed Conclusion of Law No. 5:

There is no other legal authority cited here as required by the Order on Post Trial Briefs at 2 (Mar. 30, 2011) ("PTB Order"), and the enforcement means utilized by the Board, e.g., cease and desist orders are inconsistent with the court-supervised enforcement regime specified by the Dental Practice Act (CX0019 at020-021 (N.C. Gen. Stat. §§ 90-40, 90-40.1)). Regardless, the state action defense is not available to the Board because the Commission held in its state action opinion that the Board could not satisfy the active supervision prong of the *Midcal* test. (Complaint Counsel's Proposed Conclusions of Law and Fact ("CCPCL") ¶ 11).

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.

Response to Proposed Conclusion of Law No. 6:

The cited statutes authorize the Board limited civil and criminal enforcement through the North Carolina courts with respect to the unlicensed practice of dentistry; however, no provision of the cited statutes authorizes the Board either to make or communicate determinations regarding possible violations of the Dental Practice Act by third persons. The Board has cited no other authority to support its assertion of such rights as required by PTB at 2.

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.

Response to Proposed Conclusion of Law No. 7:

The cited statutes authorize the Board limited civil and criminal enforcement through the North Carolina courts with respect to the unlicensed practice of dentistry; however, no provision of the cited statutes authorizes the Board to order any person to cease and desist violating any provision of Dental Practice Act. The Board has cited no other authority to support its assertion of such a right as required by PTB at 2.

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.

Response to Proposed Conclusion of Law No. 8:

Complaint Counsel has no specific response to this proposed conclusion of law.

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.

Response to Proposed Conclusion of Law No. 9:

The Board may seek to enjoin a suspected violation of the cited statute; however, no provision of the Dental Practice Act authorizes the Board to issue, or the courts to enforce, cease and desist orders issued by the Board. The Board has cited no other legal authority supporting this conclusion as required by PTB at 2.

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.

Response to Proposed Conclusion of Law No. 10:

This proposed conclusion is redundant with No. 6. And like 6, the cited statutes authorize the Board limited civil and criminal enforcement through the North Carolina courts with respect to the unlicensed practice of dentistry. However, no provision of the cited statutes authorizes the Board either to make or communicate determinations regarding possible violations of the Dental Practice Act. The Board has cited no authority to support its assertion of such rights as required by PTB at 2.

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.

Response to Proposed Conclusion of Law No. 11:

This proposed conclusion is redundant with No. 7. And like 7, the cited statutes authorize the Board limited civil and criminal enforcement through the North Carolina courts with respect to the unlicensed practice of dentistry. However, no provision of the cited statutes authorizes the Board to order any person to cease and desist violating any provision of Dental Practice Act. The Board has cited no other authority to support its assertion of such right as required by PTB at 2.

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.

Response to Proposed Conclusion of Law No. 12:

Complaint Counsel has no specific response to this proposed conclusion of law.

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.

Response to Proposed Conclusion of Law No. 13:

This proposed conclusion of law is substantially redundant with Nos. 6 and 10, and like Nos. 6 and 10, the cited statutes authorize the Board limited civil and criminal enforcement through the North Carolina courts with respect to the unlicensed practice of dentistry; however, no provision of the cited statutes authorizes the Board to either make or communicate determinations regarding possible violations of the Dental Practice Act. The Board has cited no other authority to support its assertion of such rights as required by PTB at 2.

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).

Response to Proposed Conclusion of Law No. 14:

Complaint Counsel has no specific response to this proposed conclusion of law in that it paraphrases the provision of law cited; however, a joint stipulation of fact does not constitute citation of legal authority.

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 [sic] to accrue to all members of that profession, occupation, or general class."

Response to Proposed Conclusion of Law No. 15:

This statute prohibits a member to act for the benefit of other licensed dentists in North Carolina, or for the member's own benefit, if he benefits more from the anticompetitive conduct than other dentists in North Carolina.

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.

Response to Proposed Conclusion of Law No. 16:

While this proposed conclusion of law is theoretically correct, the almost unlimited discretion retained by the Board to deny a request for a declaratory ruling (CX0514 at 043 (21 N.C.A.C. 16N.0403(c) ("Whenever the Board believes for good cause that the issuance of a declaratory ruling is undesirable, the Board may refuse to issue such ruling.")), operating in conjunction with the Board's interpretative statement on non-dentist teeth whitening (CX0475 at 001 ("The Board is unable to give legal advice regarding whether a particular type or method of chemical bleaching is in violation of the statute."); CX0098 at 001 (April 18, 2008, letter from Carolin Bakewell to the attorney for White Science refusing a meeting to discuss the Board's non-dentist teeth whitening policy because the Board "does not believe that would be productive")), renders such a course of action largely moot.

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.

Response to Proposed Conclusion of Law No. 17:

The cited provisions of North Carolina law do not address the rights, if any, of a recipient of a Board issued cease and desist letter to pursue relief in the courts of North Carolina. The

Board has cited no other legal authority as required by PTB Order at 2 confirming its interpretation of such provisions to provide such rights to the recipients of its cease and desist letters.

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).

Response to Proposed Conclusion of Law No. 18:

This is a misstatement of law. Article 3 administrative hearings, as cited above, have to be conducted before the Office of Administrative Hearings, wherein the Board would be the respondent, if Article 3 hearings applied to the Board, which they do not. By its express terms, N.C. Gen. Stat § 150B-23(a), does not apply to the Board. That statute provides with respect to administrative hearings under Article 3 of the N.C. Administrative Procedure Act that: "A contested case shall be commenced by paying a fee in an amount established in G.S. 150B-23.2 and by filing a petition with the Office of Administrative Hearings and, *except as provided in Article 3A of this Chapter*, shall be conducted by that Office." N.C. Gen. Stat. § 150B-23(a) (emphasis supplied). Article 3A of this Chapter provides only for contested cases before the Board when the Board initiates a contested case. (CX0515 at 036 (N.C. Gen. Stat. § 150B-38(a) and (b)). The Dental Practice Act only provides the Board with authority to conduct contested cases with respect to the Board's licensees or applicants for such licenses. (CX0019 at 023 (N.C. Gen. Stat. § 90-41.1(a) (". . . every licensee, provisional licensee, intern, or applicant for licenses, shall be afforded notice and opportunity to be heard before the [Board] shall take any action")). The Board's implementing regulations for hearings under Article 3A purport to afford non-

licensees an opportunity to request a hearing before the Board, (CX0514 at 044 (21 N.C.A.D. 16N.0503)(a) ("The Board will decide whether to grant a request for a hearing.")).

Even if the Board were authorized to conduct contested cases where the respondent would be a non-licensee or a non-applicant, the C&D Orders issued by the Board to non-dentist teeth whiteners and manufacturers of teeth whitening products did not comply with the notice requirements of the Board's rules governing contested cases (CX0514 at 044 (21 N.C.A.C. 16N.0501) ("When the Board proposes to act in [a manner which will affect the rights, duties, or privileges of a person], *it shall give such person notice of his right to a hearing* by mailing by certified mail to him at his last known address a notice of the proposed action and *a notice of a right to a hearing.*") (emphasis added)); (*see, e.g.,* CX0042 at 001-002 (C&D Order of Jan. 19, 2010, issued to James and Linda Holder); CX0100 at 001 (C&D Order of Dec. 4, 2007, issued to White Science)).

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.

Response to Proposed Conclusion of Law No. 19:

This proposed conclusion of law is substantially redundant with No. 17; and like No. 17, the cited provisions of North Carolina law do not address the rights, if any, of a recipient of a Board issued cease and desist letter, or other aggrieved person, to pursue relief in the courts of North Carolina. The Board has cited no legal authority as required by PTB at 2 confirming its

interpretation of such provisions to provide such rights to the recipients of its cease and desist letters.

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).

Response to Proposed Conclusion of Law No. 20:

Complaint Counsel has no specific response to this proposed conclusion of law.

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]

Response to Proposed Conclusion of Law No. 21:

Even if true, such deference would not satisfy prong two of the *Midcal* test. (CCPCL ¶ 11).

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. Hamer, No. 5:09-CT-3027H, 2011 U.S. Dist. LEXIS 29499, at *29 (E.D.N.C. Mar. 22,2011).[2]

[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* Camenter v. N.C. Dep't of Human Res., 107 N.C. App. 278, 279, 419 S.E.2d 582, 584 (1992).

[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.").

Response to Proposed Conclusion of Law No. 22:

Even if true, economic theory and economic studies effectively rebut any presumption that the Board acted fairly where competition with non-dentist teeth whiteners was in issue.

(Complaint Counsel's Proposed Findings of Fact ("CCPFF") ¶¶ 545-627).

23. The administrative proceeding before the Commission is *ultra vires* and violates the 10th Amendment to the U.S. Constitution.

Response to Proposed Conclusion of Law No. 23:

The Board has cited no other authority in support of this argument as required by PBT Order at 2. (CCPCL ¶ 12).

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.

Response to Proposed Conclusion of Law No. 24:

The Board has cited no other authority in support of this argument as required by PBT Order at 2.

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.

Response to Proposed Conclusion of Law No. 25:

The Board has cited no other authority in support of this argument as required by PTB Order at 2.

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.

Response to Proposed Conclusion of Law No. 26:

The Board has cited no other authority in support of this argument as required by PTB Order at 2, and this conclusion of law is inconsistent with Judge Flanagan's May 3, 2011, Order dismissing the Board's district court action seeking to enjoin this matter. *North Carolina State Bd. of Dental Examiners v. FTC*, Docket No. 5:11-CV-49 (E.D. N.C. May 3, 2011).

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.

Response to Proposed Conclusion of Law No. 27:

The Board has cited no other authority in support of this argument as required by PTB Order at 2, and the Commission's state action decision found expressly to the contrary. (CCPCL ¶11).

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.

Response to Proposed Conclusion of Law No. 28:

The Board has cited no other authority as required by PTB at 2 in support of this argument, and the Commission's state action decision found expressly to the contrary. (CCPCL ¶ 11).

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).

Response to Proposed Conclusion of Law No. 29:

The Board has cited no other authority in support of this argument as required by PTB Order at 2, and the Commission's state action decision found expressly to the contrary. (CCPCL ¶ 11).

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.*

Response to Proposed Conclusion of Law No. 30:

The Board has cited no other authority in support of this argument as required by PTB Order at 2.

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.

Response to Proposed Conclusion of Law No. 31:

The Board is a state agency, and the Commission held in its state action opinion that it has to meet both prongs of the *Midcal* test. (CCPCL ¶ 11).

32. The Commission's assertion of Sherman Act violations hinges upon *per se* illegality of majority licensees boards.

Response to Proposed Conclusion of Law No. 32:

First, this is not an intelligible statement. Second, the Board has cited no authority in support of its argument as required by PTB at 2. Third, to the extent that it claims that Complaint Counsel are relying on the doctrine of *per se* illegality under Section 1 of the Sherman Act, it is an erroneous description of Complaint Counsel's position. Complaint Counsel have consistently maintained that the Board's conduct is unlawful under the Sherman Act under any version of the rule of reason. (CCPCL ¶¶ 9-10). Finally, nothing in the record suggests *per se* illegality for the Board's conduct in this matter.

33. The State Board is a state agency not a private actor.

Response to Proposed Conclusion of Law No. 33:

The Commission has already decided that the Board's actions have to be independently supervised by the state. (CCPCL ¶ 11). Accordingly, the Board is a private actor, for the purposes of this matter.

34. The State Board acted pursuant to a clearly articulated state policy and was subject to active supervision.

Response to Proposed Conclusion of Law No. 34:

The Commission's state action decision expressly found that the Board was not entitled to state action protection for its conduct. (CCPCL ¶ 11).

35. Under the appropriate rule of reason analysis, the State Board has not committed an antitrust violation.

Response to Proposed Conclusion of Law No. 35:

The Board's conduct is unlawful under three versions of the rule of reason. (CCPCL ¶¶ 9-10).

36. Complaint Counsel did not meet its burden of showing that the State Board's challenged conduct had an unreasonable anti competitive effect.

Response to Proposed Conclusion of Law No. 36:

The Board's elimination of non-dentist teeth whitening services from North Carolina adversely affected competition. (CCPCL ¶¶ 9-10).

37. The State Board did not commit a *per se* violation of the Sherman Act.

Response to Proposed Conclusion of Law No. 37:

Complaint Counsel has no specific response to this conclusion of law.

38. The State Board's actions should be judged according to the traditional rule of reason test.

Response to Proposed Conclusion of Law No. 38:

Correct. The Board's conduct should be judged un the traditional rule of reason, as well as more abbreviated versions (e.g., inherently suspect). (CCPCL ¶¶ 9-10).

39. The State Board's actions are lawful under the rule of reason.

Response to Proposed Conclusion of Law No. 39:

Incorrect. The Board's conduct is unlawful under three versions of the rule of reasons. (CCPCL ¶¶ 9-10).

40. The nexus of the State Board's challenged conduct was not in and did not affect interstate commerce.

Response to Proposed Conclusion of Law No. 40:

The provision of teeth whitening goods and services in North Carolina by dentists and non-dentists is in or affecting commerce as "commerce" is defined in the FTC Act. (CCPCL ¶ 7).

41. Complaint Counsel did not establish liability because it has not properly defined the relevant market.

Response to Proposed Conclusion of Law No. 41:

The Board has not provided any legal or factual support for its argument as required by PTB Order at 2. Contrary to the Board's assertion there is substantial evidence, attested to by both economic experts, that there is substantial cross-elasticity of demand, hence substitutability, among all four methods of teeth whitening, supporting at least one antitrust market composed of all four methods of teeth whitening. (CCPFF ¶¶ 513-530; CCPCL ¶¶ 7-10). Further, the experts also concluded that dentist and non-dentist teeth whitening are the closest substitutes which, in turn, supports finding a market composed of dentist and non-dentist teeth whiteners within which to measure the competitive effects of the Board's conduct. Finally, it is not necessary to define a market to establish antitrust liability

42. Complaint Counsel failed to prove collusion among State Board members in violation of the antitrust laws.

Response to Proposed Conclusion of Law No. 42:

Incorrect. (*see* CCPCL ¶ 8 (The Board is a combination of competitors with respect to its challenged conduct.)).

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.

Response to Proposed Conclusion of Law No. 43:

Incorrect. (*see* CCPCL ¶ 8 (The Board is a combination of competitors with respect to its challenged conduct.)).

44. Complaint Counsel could not establish collusion among State Board members based solely on the State Board's composition.

Response to Proposed Conclusion of Law No. 44:

Complaint Counsel has no specific response to this conclusion of law.

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.

Response to Proposed Conclusion of Law No. 45:

This proposed conclusion fails either as a conclusion of law that is unsupported by any legal authority or as a statement of fact that is not supported by the citation of record evidence as required by PTB at 2, in either case. (CCPCL ¶ 10 (Respondent has not shown a plausible or cognizable efficiency justification for the Board's elimination of non-dentist teeth whitening from North Carolina.)).

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.

Response to Proposed Conclusion of Law No. 46:

The Board has cited no other authority to support this argument as required by PTB Order at 2. (*see* CCPCL ¶ 12).

47. The relief sought by Complaint Counsel violates the U.S. Constitution's Commerce Clause.

Response to Proposed Conclusion of Law No. 47:

The Board has cited no other authority to support this argument as required by PTB at 2. (CCPCL ¶ 13 (The Proposed Order is necessary and appropriate.)).

48. Complaint Counsel has failed to meet its burden of proof.

Response to Proposed Conclusion of Law No. 48:

The Board has cited no authority to support this argument as required by PTB at 2. (*see* CCPCL ¶¶ 9-10).

Respectfully submitted,

s/ Richard B. Dagen
Richard B. Dagen
Counsel Supporting the Complaint
Federal Trade Commission
Bureau of Competition
Washington, DC 20580
Telephone: (202) 326-2628
Facsimile: (202) 326-3496

Dated: May 5, 2011

DECLARATION OF MICHAEL J. BLOOM

IN REPLY TO TESTIMONY OF MR. BRIAN RUNSICK

Declaration of Michael J. Bloom in Reply to Testimony of Mr. Brian Runsick

Pursuant to 28 U.S.C. § 1746, I hereby make the following statement:

1. My name is Michael J. Bloom. I am making this statement in the Matter of The North Carolina Board of Dental Examiners, FTC Docket No. 9343. Except as otherwise indicated, all statements in this Declaration are based upon my personal knowledge as a Federal Trade Commission ("FTC") attorney participating in that litigation. Insofar as I indicate in this Declaration that certain matters are "upon information and belief," I have made reasonable search and inquiry that supports those statements of information and belief.

2. Prior to Mr. Runsick's taking the witness stand at trial, Complaint Counsel had no notice that Respondent intended to adduce at trial testimony of no relevance to the substantive issues raised by the FTC's Complaint against the North Carolina State Board of Dental Examiners, but instead relating solely to non-substantive aspects of FTC attorneys' contacts with Mr. Runsick.

3. I did not participate in the initial contact between FTC staff and Mr. Runsick.

4. Upon information and belief, Mr. Tejasvi Srimushnam alone participated in that contact, which occurred in September of 2010.

5. Upon information and belief, Mr. Srimushnam informed Mr. Runsick that the FTC had issued a Complaint against the North Carolina State Board of Dental Examiners ("the Board") relating to its exclusion of non-dentist teeth whiteners from the market; that he understood that Mr. Runsick had filed a complaint with the Board based on his experience with a non-dentist teeth bleaching facility; and that FTC attorneys would like to set up time to learn more from Mr. Runsick if he were open to participating in a further telephone conversation with FTC attorneys. Mr. Runsick said that he was open to that.

6. I participated in a subsequent phone contact between Brian Runsick and Complaint Counsel in September 2010. Upon information and belief, FTC attorneys Richard B. Dagen, Melissa Westman-Cherry, and Tejasvi Srimushnam also participated on behalf of Complaint Counsel.

7. At the beginning of this telephone contact, the FTC attorneys again informed Mr. Runsick that the purpose of the call was to obtain information relevant to a Complaint that the Federal Trade Commission had issued against the North Carolina State Board of Dental Examiners relating to its exclusion of non-dentist teeth whiteners from the market.

8. Near the close of that conversation, FTC attorneys informed Mr. Runsick that they might need to depose him if it later appeared that he was going to testify at the Hearing in the North Carolina State Board of Dental Examiners litigation.

9. During post-complaint discovery in this matter I deposed Dr. Larry F. Tilley, who had examined Mr. Runsick in the capacity of consultant to the Board. During that deposition Mr. Runsick was contacted by telephone and asked whether he would consent to release and use as necessary in connection with this litigation all records and materials, including for example dentist notes, x-rays, and models, relating to his evaluation by Dr. Tilley. Mr. Runsick so-consented.

10. Pursuant to 28 U.S.C. § 1746, I declare, under penalty of perjury, that the foregoing is true and correct.

Executed on May 3, 2011

Michael J. Bloom

DECLARATION OF TEJASVI SRIMUSHNAM

IN REPLY TO TESTIMONY OF MR. BRIAN RUNSICK

Declaration of Tejasvi Srimushnam in Reply to Testimony of Mr. Brian Runsick

Pursuant to 28 U.S.C. § 1746, I hereby make the following statement:

1. My name is Tejasvi Srimushnam. I am making this statement in the Matter of The North Carolina Board of Dental Examiners, FTC Docket No. 9343. Except as otherwise noted, all statements in this Declaration are based upon my personal knowledge as Counsel in Support of the Complaint and as Staff Attorney at the Federal Trade Commission, Bureau of Competition. Insofar as I indicate in this Declaration that certain matters are "upon information and belief," I have made reasonable search and inquiry that supports those statements of information and belief.
2. Mr. Michael J. Bloom did not participate in the initial contact between FTC staff and Mr. Runsick.
3. I alone participated in that contact, which occurred in September of 2010.
4. During that telephone contact, I informed Mr. Runsick that the Federal Trade Commission ("FTC") had issued a Complaint against the North Carolina State Board of Dental Examiners ("the Board") relating to its exclusion of non-dentist teeth whiteners from the market. I told Mr. Runsick that I understood that he had filed a complaint with the Board based on his experience with a non-dentist teeth bleaching facility; and that FTC attorneys would like to set up time to learn more from Mr. Runsick if he were open to participating in a further telephone conversation with FTC attorneys. Mr. Runsick said that he was open to that.
5. I also participated in a subsequent phone contact between Brian Runsick and Complaint Counsel in September 2010. Upon information and belief, FTC attorneys Richard B.

Dagen, Melissa Westman-Cherry, and Michael J. Bloom also participated on behalf of Complaint Counsel.

6. At the beginning of this telephone contact, the FTC attorneys again informed Mr. Runsick that the purpose of the call was to obtain information relevant to a Complaint that the Federal Trade Commission had issued against the North Carolina State Board of Dental Examiners relating to its exclusion of non-dentist teeth whiteners from the market.

7. Near the close of that conversation, FTC attorneys informed Mr. Runsick that they might need to depose him if it later appeared that he was going to testify at the Hearing in the North Carolina State Board of Dental Examiners litigation.

8. Pursuant to 28 U.S.C. § 1746, I declare, under penalty of perjury, that the foregoing is true and correct.

Executed on May 3, 2011

Tejasvi Srimushnam

CERTIFICATE OF SERVICE

I hereby certify that on May 5, 2011, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

Donald S. Clark
Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580

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

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

I further certify that I delivered via electronic mail a copy of the foregoing document to:

Noel Allen
Allen & Pinnix, P.A.
333 Fayetteville Street
Suite 1200
Raleigh, NC 27602
nla@Allen-Pinnix.com

Counsel for Respondent
North Carolina State Board of Dental Examiners

CERTIFICATE FOR ELECTRONIC FILING

I 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 the adjudicator.

May 5, 2011 By: s/ Richard B. Dagen
Richard B. Dagen