CI – 015M C.P. – P.L. 29 Code des professions VERSION RÉVISÉE

Mémoire présenté dans le cadre des consultations et auditions publiques sur le projet de loi 29, loi modifiant le code des professions et d'autres dispositions notamment dans le domaine bucco-dentaire et celui des sciences appliquées.

Présentation de l'auteur

L'auteur de ce mémoire est Marc Amram président de la société PURE IMAGE CANADA dont les bureaux sont situés au 3767 boulevard Thimens suite 269 à Ville Saint-Laurent, Québec .

Pure image existe depuis 10 ans et se spécialise dans les fournitures et produits cosmétiques de blanchiment des dents vendus à travers le Québec, le Canada, les États-Unis et en Europe. Pure Image compte parmi ses clients des dentistes, mais surtout les salons d'esthétique, coiffure, spas et des centres de blanchiment dentaire indépendants. Pure Image opère aussi un centre de blanchiment dentaire à ville Saint-Laurent

Résumé du mémoire

Ce mémoire vise à s'opposer formellement à certains passages du projet de loi 29, plus particulièrement, les modifications apportées aux titres réservés et à la description du champ d'exercice de certaines professions à titre réservé, ainsi que celles prévoyant que les activités esthétiques à risque de préjudice dans le domaine de la santé bucco-dentaire soient désormais réservés aux dentistes. À deux occasions l'auteur s'est adressé à la ministre de la Justice pour manifester son opposition la proposition de l'Office des professions soumise en 2014 et réclamer le statut-quo.

La première fois le 18 mai 2016 auprès de la ministre Stéphanie Vallée et la seconde fois auprès de la ministre Sonia Lebel le 17 décembre 2018.

À chaque fois les raisons évoquées étaient identiques et certaines seront développées dans ce mémoire :

A: Le blanchiment des dents n'est pas actuellement considéré comme une activité réservée au dentiste et le statut quo devrait prévaloir

B: Le blanchiment des dents n'est pas considéré comme un traitement invasif mais plutôt comme un traitement cosmétiques simple, avec des produits de blanchiment qui ne causent pas d'atteinte à la structure des dents ou à la solidité de l'émail selon la publicité des dentistes eux même (P2)

C: Ces produits sont disponibles en vente libre en pharmacie et les personnes qui le désirent peuvent se les appliquer elles-mêmes.

<u>D: Les techniques d'application de ces produits ne justifient d'aucune manière le monopole recherché</u> par les dentistes.

E: Les propos alarmistes véhiculés depuis plusieurs mois par l'Ordre des dentistes et des hygiénistes dentaire avec force d'exemples montés en épingle, ne visent qu'à contrôler un marché en plein développement, les coûts de ces traitements et a priver le consommateur québécois du choix qui lui est offert présentement.

F: Accorder l'exclusivité de l'application du blanchiment dentaire aux dentistes et aux hygiénistes dentaire, causerait un préjudice irréparable à mon entreprise ainsi qu'à tous mes clients et aux centaines de commerçants offrant le blanchiment dentaire au Québec

Pure Image, qui n'a reçu aucune plainte ou déploré quelque incident que ce soit depuis dix ans ,offre à ses clients dans son centre de blanchiment, l'application de produits cosmétiques surs, avec méthode et dans des conditions optimales de confort et de sécurité offrant ainsi une alternative à l'auto application achetée en pharmacie et à la visite en cabinet de dentiste.

L'auteur de ce mémoire n'a pas la prétention ou le mandat de défendre ou de représenter les autres centres de blanchiment des dents et leur personnel et, de ce fait, ne s'exprime qu'en son nom personnel.

C'est à ce titre qu'il s'interroge sur la pertinence des modifications au Code des professions, notamment celles touchant le domaine bucco-dentaire. L'auteur conteste l'affirmation de l'Office des professions, à l'origine du projet de loi 29, à l'effet que les activités de blanchiment des dents soit à risque pour la population.

L'auteur voit aussi une incohérence dans le fait que le projet de loi 29 veuille réserver aux seuls dentistes et hygiénistes dentaires l'application de produits de blanchiment à « risque » et, dans un même souffle n'entend pas empêcher la vente pour l'auto application de ces produits de blanchiment dans les pharmacies.

De plus, les centres offrant le blanchiment dentaire peuvent se prévaloir d'une assurance spécifique pour l'application du blanchiment dentaire auprès de sociétés d'assurances dans le domaine esthétique, telle que la compagnie d'assurances Asserpro. Pure Image y est assurée, ainsi que d'autres centres de blanchiment. Pourquoi il y aurait une assurance ainsi disponible pour appliquer le blanchiment dentaire, si celui-ci est hors norme?

L'auteur entends démontrer, non seulement que les produits de blanchiment sont sûrs et efficaces, mais que leur application simple, ne nécessite aucune expertise particulière. À l'appui de ces affirmations l'auteur s'inspire du rapport d'expert du docteur Martin Giniger DMD, MsD, PhD, FICD qui a permis à la Cour Suprême des États-Unis, en 2015, de renverser la décision de l'État de la Caroline du Nord, de réserver au seuls dentistes et hygiénistes dentaires, l'application de produits de blanchiment. Ce rapport d'expert et en annexe du présent mémoire. (P1)

Exposé général

Mise à part un lobby intense et une campagne médiatique soutenue depuis plusieurs années, visant à réserver le blanchiment dentaire aux seuls dentistes et hygiénistes dentaires, rien ne justifie une telle restriction.

Les arguments du Dr Martin Giniger le prouvent amplement.

Un acte réservé injustifié

D'emblée, le docteur Giniger souligne que le blanchiment dentaire qui est devenu extrêmement populaire est un procédé sécuritaire et efficace qu'il soit dispensé par un dentiste, par le consommateur lui-même ou par un centre de blanchiment des dents.

Il existe en effet trois manières de procéder au blanchiment des dents.

- 1:Chez le dentiste, alors que les dents sont enduites d'une forte concentration de 20 à 35 % de peroxyde d'hydrogène activé ou non par une source de lumière : coût Environ \$600-800 \$ par session. Autre méthode proposée, la fabrication de gouttières de plastique à partir des empreintes des dents du patient. Ce dernier rentre chez lui avec une solution de peroxyde à injecter dans les gouttières qu'il porte à la maison pour des séances qui s'échelonnent quelques semaines.
- 2 : En pharmacie, sous forme de bandelettes ou de gels à placer dans des gouttières fournies avec le produit ou à appliquer soi-même avec un pinceau. Ces produits, en vente libre sont aussi à base de peroxyde d'hydrogène mais en plus faible concentration que ceux utilisés chez le dentiste. Coût : entre 6 et 60 \$
- 3: Dans des centres de blanchiment dentaire, spas, des salons d'esthétique, des gels sont appliqués au pinceau et activé par une source de lumière LED. Ces gels sont aussi à base de peroxyde d'hydrogène

en plus faible concentration que chez les dentistes, soit entre 11 à 16 % ce qui les rend plus sécuritaires. Coût entre 80 et 120 \$. Il est à remarquer que c'est chez le dentiste que les risques d'irritation des gencives est le plus élevé selon la tolérance du patient a des fortes doses de peroxyde, selon le docteur Giniger qui souligne que la concentration de 11 % à 16 % de peroxyde est efficace et sécuritaire pour blanchir les dents sans l'intervention d'un dentiste.

Selon lui, il n'existe aucune preuve documentaire démontrant que le risque d'irritation des gencives ou de sensibilité des dents et plus élevé selon que le blanchiment est effectuée par un dentiste, un centre de blanchiment ou par la personne elle-même.

En fait, si le détartrage ou l'enlèvement des taches relèvent du dentiste et nécessite l'utilisation d'instruments pointue, des produits abrasifs pour le polissage, ce qui affecte les dents, il en va autrement pour le blanchiment des dents qui peut être réalisé par la personne elle-même en achetant les produits à la pharmacie, ou dans un centre de blanchiment dentaire par un personnel formé ou dans un tout autre endroit au choix du consommateur, autre que chez le dentiste.

Ce, au même titre qu'une personne qui décide de faire elle-même sa teinture sans passer par un coiffeur, ou qui se pose elle-même des faux cils sans demander la bénédiction d'un ophtalmologue ou encore celui ou celle qui se fait appliquer un tatouage sans l'intervention d'un dermatologue. En ce sens, réserver l'application du blanchiment dentaire au seuls dentistes et hygiénistes dentaires, est totalement injustifié et abusif.

Un traitement non invasif:

Il importe de différencier l'enlèvement des taches sur les dents, du blanchiment dentaire. L'utilisation d'instruments dentaires et de produits abrasifs de polissage permets d'enlever les taches sur les dents, alors qu'il est reconnu scientifiquement que les produits de blanchiment des dents n'enlèvent pas les taches, tout au plus les éclaircissent temporairement, mais n'endommagent pas pour autant l'émail des dents.

En ce sens, le blanchiment dentaire n'est pas un procédé invasif.

Les produits de blanchiment dentaire peuvent causer de la sensibilité chez certaines personnes et même de l'irritation des gencives, <u>mais il importe de souligner que ces effets sont temporaires et cliniquement insignifiants, selon le Dr Giniger.</u>

Il en est de même pour les dentifrices qui contiennent jusqu'à 40 % de silice (sable) et particulièrement les dentifrices blanchissant qui contiennent encore plus de silice en plus fines particules qui lustrent les dents et mais contiennent aucun gel blanchissant.

Le peroxyde d'hydrogène:

Découvert en 1818, le peroxyde d'hydrogène et aujourd'hui répandu au niveau industriel dans l'agriculture et dans les produits de consommation. <u>Sa sécurité a été reconnue notamment par la FDA Federal Food and Drug Administration et par Santé Canada.</u>

Les produits de blanchiment à base de peroxyde d'hydrogène sont identifiés et vendus comme produits cosmétiques et ce, depuis 1991. Santé Canada a décrété que les produits contenant du peroxyde d'hydrogène visant le blanchiment des dents qui ne contiennent aucun fluor, sont dans les faits des produits cosmétiques.

<u>Pure Image, en tant que distributeur et utilisateur de ces produits de blanchiment, est détenteur de numéros d'identifications cosmétique délivrés par Santé Canada.</u>

Les effets secondaires:

Selon le docteur Giniger, s'Il est vrai que les produits de blanchiment sont sûrs et efficaces, il est faux de prétendre qu'ils ne provoquent aucun effet secondaire. Il en existe, même si ils **sont mineurs et temporaire** (sensibilité des dents)

Le docteur Giniger souligne que ses effets sont plus fréquents et prononcés lorsque le blanchiment est effectué chez le dentiste qui utilise une plus forte concentration de peroxyde et une lumière à chaleur plus intense. Le docteur Giniger soumet qu'une moins faible concentration de peroxyde d'hydrogène entraine moins de sensibilité et il souligne qu'il n'existe aucune preuve documenté à l'effet que le blanchiment dentaire entraîne plus de sensibilité des dents, selon qu'il est dispensée par un dentiste, un centre de blanchiment, ou appliquée par la personne elle-même.

Selon lui, le peroxyde contenu dans les produits de blanchiment sont sécuritaires à basse concentration et les irritations des gencives augmentent lorsque la concentration de peroxyde est plus élevé.

À souligner enfin, que le peroxyde d'hydrogène est un puissant agent antimicrobien et qu'il peut contribuer à contrer une contamination accidentelle dans une situation particulière.

Pour le reste, toute prétention à l'effet que le blanchiment des dents et un traitement invasif comportant un risque de préjudice pour le patient-client est une affirmation erronée et alarmiste qui est loin de la réalité.

Affirmant comme l'a fait au départ l'Office des professions du Québec que les activités de blanchiment des dents sont à risque de préjudice pour la population est farfelu, surtout si ces mêmes activités, avec les mêmes produits sont permis en vente libre en pharmacie.

Des propos alarmistes:

En 2012, le docteur Barry Dolman, président de l'Ordre des dentistes donnait le ton en affirmant

« C'est ridicule n'importe qui peut ouvrir une clinique de blanchiment des dents mais le blanchiment reste un traitement invasif qui peut avoir des conséquences sur la santé bucco-dentaire. La plupart des produits offerts dans les commerces contiennent du peroxyde, une substance qui peut rendre les dents sensibles et causer des irritations, des brûlures »

Comme il a été démontré précédemment le blanchiment des dents n'est pas un traitement invasif, un terme délibérément alarmiste qui ne décrit pas du tout la réalité.

Tel que décrit plutôt le peroxyde d'hydrogène peut causer de la sensibilité et des irritations temporaires et sans conséquences physiologiques, <u>surtout en forte concentration, chez le dentiste</u>.

Autre exemple de matraquage médiatique, le journal de Montréal dans son édition du 16 juin 2019 et sous la plume d'Étienne Paré, titre « blanchiment des dents: la population appelée à être prudente— et poursuit « en attendant que le blanchiment des dents soit un acte réservé aux dentistes et délégué aux hygiénistes, les professionnels de la santé dentaire tiennent à prévenir la population de possible danger des blanchiments offerts dans les cliniques d'esthétique »

Une hygiéniste dentaire en rajoute » le blanchiment des dents est peut-être un traitement esthétique, ça reste quand même du peroxyde qu'on met sur les dents, il faut un suivi médical, sinon il peut y avoir des complications pour les gencives notamment »

À noter que lorsqu'un dentiste donne des gouttières à un patient pour faire son blanchiment à la maison, le peroxyde touche inévitablement les gencives et il ne semble pas y avoir plus d'inquiétude que cela.

Sans rire, le président de l'Ordre des dentistes affirme que « la position de son organisme n'est pas motivée par les profits, que les dentistes pourraient tirer de la loi 29 », tout en reconnaissant que le coût d'un blanchiment coûte beaucoup plus cher chez un dentiste, que dans une clinique de blanchiment.

Et, l'hygiéniste cité dans le même article, Fannie Leblanc de rajouter cette « perle »: c'est sûr que c'est plus cher, mais c'est le prix à payer pour ne pas avoir de problème!"

Digne du film « Le Parrain »!

Toujours selon le docteur Barry Dolman, le président de l'Ordre des dentistes du Québec :

« Il y a bel et bien des risques à mettre des produits de blanchiment dans la bouche, si celle-ci n'est pas en santé: il peut y avoir des problèmes de gencive, des lésions dans la bouche, un cancer, des caries, des obturations fissurées.... les patients peuvent avoir de graves problèmes si on applique des produits de blanchiment dans ces situations »

Le Dr Dolman présume qu'un patient ayant des problèmes de gencive, des lésions ou un cancer de la bouche se préoccupe de l'aspect esthétique de ses dents! Sans compter que ce même patient pourrait s'acheter des produits en vente libre en pharmacie et les appliquer lui-même.

Il présume aussi que les clients des centres de blanchiment des dents ou autre endroits, ne signalent pas, qu'ils ont des caries, des couronnes ou autre situations problématiques.

Le docteur Dolman présume aussi de l'incompétence et de l'irresponsabilité des personnes susceptibles d'appliquer des produits de blanchiment, y compris les clients eux-mêmes, ce qui est profondément méprisant.

<u>Ce faisant, il tente surtout de détourner l'attention des cas documentés d'erreurs médicales et traitements bâclés réalisés par des membres de son Ordre professionnel.</u>

En suivant sa logique, il faut s'étonner qu'il ne demande pas que le brossage des dents avec du dentifrice contenant du produit abrasif (silice) soit un acte réservé au dentiste!

Une autre affirmation entendue dans ces pseudos témoignages serait un problème de formation pour l'application de produits de blanchiment.

La réalité est que l'application de produits cosmétiques de blanchiment et d'une simplicité désarmante et qu'il suffit de lire les directives livrées avec le produit pour l'appliquer soi-même ou aller se le faire appliquer dans un centre de manière plus confortable et sécuritaire.

Les avancées technologiques des dernières années permettent d'offrir sur le marché, en pharmacie, des produits de blanchiment sûrs, de qualité et sécuritaires, qu'ils soient pour auto application ou par application par une personne autre qu'un dentiste ou une hygiéniste et ce, par application sur les dents ou en gouttières.

<u>La concentration de peroxyde contenue dans les produits appliqués hors du bureau du dentiste est différente, moins irritante et plus sécuritaire, tel que démontré précédemment.</u>

La frustration des dentistes et des hygiénistes dentaires vient du fait que c'est un procédé, simple d'application et que la multiplication des endroits où ils sont offerts est si importante, qu'ils y ont vu une menace et un marché à investir, quitte à imaginer d'hypothétiques dangers pour santé bucco-dentaire de la population.

L'Orthodontie aussi:

Le développement technologique permet aussi depuis quelque temps la vente libre de trousses permettant de procéder soi-même au redressement des dents (orthodontie). Ils sont disponibles sur le marché (Smile Direct Club) qui compte plusieurs succursales au Québec.

Les dentistes et orthodontistes vont-ils faire interdire la vente de ces trousses qui sont par ailleurs vendues par leur propres fournisseurs (Invisalign et d'autres).

Nous pensons que l'Ordre des dentistes, au lieu de s'opposer aux avancées technologiques, recherchent plutôt le monopole des soins cosmétiques ne nécessitant aucune expertise particulière. Il devrait plutôt concentrer ses efforts sur la mission première de ses membres, celle d'assurer de s'acquitter avec professionnalisme les soins bucco-dentaire complexes pour lesquels ils ont été formés.

Un préjudice irréparable:

Il est paradoxal de constater que le projet de loi 29 veuille faire du blanchiment dentaire, une activité réservée aux dentistes et aux hygiénistes dentaires, mais ne vise pas à empêcher la vente libre des produits de blanchiment en pharmacie.

En suivant le raisonnement de l'office des professions du Québec et les arguments de l'Ordre des dentistes à l'effet qu'il « faut protéger le public, diagnostiquer, développer un plan de traitement, s'assurer qu'il n'y a pas de problème de gencive, des lésions dans la bouche, des caries ou des obturations fissurées avant d'appliquer les produits de blanchiment », la vente libre de ces produits en pharmacie devrait être interdite.

Comment expliquer que le produit qui devrait selon l'Ordre des dentistes, et les recommandations de l'Office des professions, nécessite autant de précaution, demeure en vente libre à la portée de n'importe qui, avec l'aval de Santé Canada, si ce n'est qu'il est inoffensif?

Pourquoi s'en prendre aux centres de blanchiment et autres endroits susceptibles de faire du blanchiment?

Pourquoi le peroxyde d'hydrogène à forte concentration deviendrait subitement moins dommageable parce qu'il est appliqué par un dentiste ou une hygiéniste, mais dangereux à doses moins concentrés si il est appliqué par une autre personne qu'un dentiste ou hygiéniste?

Et pour ce qu'il y est des produits, de blanchiment vendus librement en pharmacie, faudra-t-il aller les faire appliquer chez un dentiste ou un hygiéniste a l'avenir?

Tel que nous l'avons mentionnée, depuis 10 ans, Pure Image, en plus de distribuer des produits de blanchiment, opère un centre de blanchiment des dents.

Jamais en 10 ans il y a eu de plaintes ou d'incidents et la clientèle satisfaite reviens et recommande notre centre de blanchiment à ses connaissances ainsi que nos produits utilisés par la majorité des centres de blanchiment au Québec .

Si la loi est adoptée telle quelle, le gouvernement provoquera la fermeture pure et simple de mon entreprise et se rendra aux arguments fallacieux et alarmistes de l'Ordre des dentistes.

L'objectif de ce dernier, loin de protéger le public, vise plutôt à s'accaparer un marché et a en contrôler les prix et priver la population québécoise de choix et d'une alternative à une visite chez le dentiste pour un blanchiment dentaire.

J'ose espérer que les députés membres de la commission sauront faire la part des choses et refuseront de reconnaître aux seuls dentistes et hygiénistes dentaires le droit exclusif de procéder au blanchiment dentaire en en faisant une activité réservée.

Ce droit exclusif est non seulement injustifié et abusif, mais il met en péril l'emploi de centaines de personnes et l'existence d'une multitude d'entreprises québécoises.

Il nous apparait que le statu-quo devait prévaloir à cet égard

Conclusion:

Nous espérons avoir fait la démonstration des principales raisons qui motivent notre opposition a l'adoption du projet de loi 29 touchant notamment les titres réservés et, les activités esthétiques dans le domaine bucco-dentaire.

Nous espérons que la décision de la Cour Suprême des États-Unis en 2015 de renverser celle de l'État de la Caroline du Nord qui avait choisi de réserver le blanchiment dentaire exclusivement aux dentistes et hygiénistes dentaires, saura influencer positivement le législateur.

Le rapport d'expert du docteur Giniger, présenté à la Cour Suprême et qui a influencé sa décision à servit d'inspiration dans ce mémoire.

Il démontre clairement que le blanchiment dentaire est un traitement non- invasif, efficace, qui utilise des produits sécuritaires qui sont à base de peroxyde d'hydrogène, qui sont approuvés par Santé Canada comme produits cosmétiques.

À cet égard, nous voyons une incohérence dans le fait que le projet de loi 29 veuille réserver au seuls dentistes et hygiénistes l'application des produits de blanchiment « à risque de préjudice » et en même temps, n'entend pas empêcher la vente libre en pharmacie de ces mêmes produits pour auto application!

Nous soumettons que la situation qui prévaut présentement, devrait être maintenue et que le statu-quo (P3) en ce qui trait à l'application de produits de blanchiment cosmétiques sécuritaires, prévaudra au terme de cette consultation publique.

Nous considérons que toute solution accordant aux seuls dentistes et hygiénistes, l'application de produits de blanchiment, causerait un préjudice irréparable à mon entreprise.

Pure image, dont le centre de blanchiment et de distribution des produits a une réputation irréprochable depuis 10 ans, ce verrait dans l'obligation de mettre fin à ses activités et serait victime d'une décision injuste et abusive basée sur une volonté d'accorder un monopole aux dentistes et hygiénistes, au détriment du choix offert aux consommateurs actuellement.

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

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

I. BACKGROUND AND QUALIFICATIONS

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

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

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

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

including, among others, Colgate Whitening Toothpastes and Systems, Discus Dental NiteWhite with ACP, a take-home teeth whitening product, and the Discus Dental Zoom2 in-office whitening system, have had aggregate sales of more than \$10 billion dollars.

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

II. MATERIALS CONSIDERED IN FORMULATING OPINIONS

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

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

to do.

III. SCOPE OF WORK AND COMPENSATION

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

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

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

IV. SUMMARY OF OPINIONS

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

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

Beyond this, my opinions may be summarized as follows:

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

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

- occur within a few days of his teeth bleaching. The questionable nature of Mr. Runsick's claim, and the extraordinary lack of similar complaints, demonstrates, among other things, that a few anecdotal reports are not a substitute for reliable clinical or empirical evidence of product/service safety and efficacy. 48,49
- In addition to unwarranted concerns about the teeth bleaching itself, representatives of the NC-SBODE have expressed concerns about sanitary conditions in non-dentist-operated teeth whitening establishments, such as kiosks in malls. I have reviewed the operating protocols^{1,2,3,4,5} used by many such establishments. Based thereon I see no reason why appropriate sanitary conditions cannot be maintained in non-dentist-operated teeth whitening establishments, including kiosks without running water. If regulation were warranted, regulatory regimes such as are applicable to numerous other endeavors-food-handling, for example, seem practicable and would be far less draconian and anti-consumer than the wholesale exclusion of non-dentist-provided teeth whitening services. Moreover, I find it telling that, as I have been informed, the NC-BODSE never has complained about sanitary conditions at a kiosk or like establishment to any public health agency in or outside of North Carolina.
- Based on my searches of the literature and my experience, there is no evidence that nondentist-provided teeth whitening poses any greater risk than dentist-provided teeth
 whitening. Indeed, as I have said, I am aware of no credible evidence that non-dentistprovided teeth whitening poses any public safety risk at all.
- Indeed, the availability of retail teeth whitening establishments may actually contribute to dental health by encouraging consciousness of teeth appearance and, consequently, dental

- health. This may help people overcome fear of dentists and seek dental care for dental conditions.⁶
- Given differing consumer wants and willingness to pay, a variety of safe alternatives has to be seen as a good thing. For example, some consumers appreciate the quick results that can be had only with chairside teeth whitening, want more or less support and advice, and are more or less sensitive to costs; therefore it seems self-evident that the availability of chairside teeth whitening from dentists and non-dentists, with differing service and support, and at different prices, would be good for consumers if those alternatives are equally safe—and they are equally safe, subjecting consumers only to comparable risks of minor side effects, principally transient tooth sensitivity or gingival irritation.
- Accordingly I conclude that actions of the NC-SBODE in excluding non-dentists from the market have injured consumers needlessly.

V. STATEMENT OF OPINIONS TO BE EXPRESSED AND REASONS THEREFORE

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

materials in a variety of settings.

A. Who Can Perform "Teeth Whitening" Procedures

Dentists and hygienists commonly perform both dental stain removal and teeth bleaching procedures. Consumers also can perform these procedures on themselves in their homes, for example, through teeth picking or brushing and use of OTC teeth bleaching products. According to the NC Dental Practices Act, N.C. Gen. Stat. 90-29⁷, no person other than a licensed dentist or a hygienist acting under his or her supervision can remove another person's dental stains. The NC-SBODE presumes that in-home self-application of these procedures and products is lawful; but interprets the Act such that an unlicensed person may not so much as assist another person to remove teeth stains—even by simply offering information or advice. *See* Ref. 44, No. 9-10 (NC-SBODE asserts that it is unlawful to read instructions or provide "services and or advice attendant to the sale of a teeth whitening product"). The NC-SBODE also takes the position, contrary to fact, that teeth bleaching is stain removal.

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

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

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

The state dental practice statutes pertaining to the regulation of dental stain removal pre-dated the invention of modern vital teeth bleaching products and procedures by more than 50 years. The first report of modern teeth bleaching technique was published in 1989²⁰, while the part of the NC Dental Practices Act that designates stain removal as the practice of dentistry was written in the mid 1930s. It is interesting to note that the adoption of the stain removal provision coincides with the wide-spread adoption of mechanical dental stain removal devices created for use in dental offices. The use of these devices in dental stain removal, like the use of picks and abrasives, was—and is—known to pose significant safety risks, and it is reasonable to conclude that the Act's limitation of dental stain removal was a reasonable reaction to legislators' concerns about the risks attending dental scraping and polishing procedures and had no relation to chemical bleaching.

C. Dental Stain Removal versus Teeth Bleaching

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

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

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

1. Understanding Dental Stains and Dental Stain Removal

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

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

Extrinsic stains are defined as stains located on the outer surface of the tooth structure.

Extrinsic stains are categorized under the Nathoo classification system as follows:

- Nathoo type 1 (N1): N1-type colored material (chromagen) binds to the tooth surface.
 The color of the chromagen is similar to that of dental stains caused by tea, coffee, wine, chromogenic bacteria, and metals;
- Nathoo type 2 (N2): N2-type colored material changes color after binding to the tooth.

 The stains actually are N1-type food stains that darken with time; and
- Nathoo type 3 (N3): N3-type colorless material or prechromogen binds to the tooth and undergoes a chemical reaction to cause a stain. N3-type stains are caused by carbohydrate-rich foods (e.g., apples, potatoes), stannous fluoride, and chlorhexidine.

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

2. Consumer Stain Removal

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

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

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

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

3. Professional Stain Removal

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

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

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

commercial toothpastes.¹⁶ Because of this, some authorities recommend the use of toothpaste alone to polish teeth.¹⁶ Nevertheless, many dental professionals choose polishing agents based on how efficiently they remove extrinsic dental stains. Rather than take the additional time and effort needed to remove the same stains using a less destructive, fine prophy paste, they opt for coarser, more "efficient," pastes¹⁶, which have the greatest potential for causing excessive abrasion, scratching the enamel, and contributing to an increased rate of exogenous stain reformation and bacterial plaque retention.

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

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

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

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

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

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

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

Licensed dental professionals and lay-operated bleaching facilities may offer two methods of teeth bleaching. The most popular teeth bleaching method offered by dental professionals requires consumers to wear a dental tray containing bleach for up to an hour daily for a number of days. Tray-based bleaching products and systems also are available to consumers through brick-and-mortar retail outlets such as pharmacies as well as through the Internet. The other alternative offered by licensed dental professionals and lay-operated bleaching facilities is chairside, same day treatment, which offers patients/customers more immediate results and gratification—usually in less than 2 hours.

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

1. Tray-Based Systems

As I have indicated, tray-based teeth bleaching products and services are offered by dentists and lay-person bleaching centers and can also be purchased by consumers over-the-counter. They typically utilize carbamide peroxide or hydrogen peroxide as the bleaching agent. Carbamide Peroxide has the advantage of being very stable in anhydrous formulations and breaks down into hydrogen peroxide (3 parts carbamide peroxide yielding approximately 1 part hydrogen peroxide) and urea only by exposure to water and salivary enzymes. Hydrogen peroxide systems are much less stable and require a more acidic pH to prevent unwanted oxygen release. Other stabilizers also are used to promote stability at a variety of ambient temperatures. When carbamide peroxide is exposed to saliva, it breaks down to release hydrogen peroxide and urea. A bleaching gel consisting of 10% carbamide peroxide, for example, would yield roughly 3% hydrogen peroxide and 7% urea. The urea is thought to further assist in the whitening process, because it is itself a mild bleaching agent. Higher concentrations of carbamide peroxide may result in faster whitening of teeth. However, the literature suggests²⁴ that there is no difference in whitening effect after six weeks of use irrespective of whether a 10% carbamide peroxide formulation or a more concentrated formulation is used. A variety of concentrations of hydrogen peroxide and carbamide peroxide are available for use in tray-based bleaching systems. 40

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

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

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

2. Chairside Systems

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

recommended to prevent gingival irritation; however, use of a barrier may not be necessary if the bleaching gel does not grossly overflow treatments onto the soft tissue and the bleaching session is kept brief. Lay-operated teeth bleaching facilities use chairside bleaching products at somewhat lower hydrogen peroxide/carbamide peroxide concentrations, typically equivalent to 16% or less of hydrogen peroxide⁴⁰, obviating any need for a gingival barrier. In these facilities too, a light may be used as a secondary photo-initiator to speed whitening.

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

3. Comparing Teeth Bleaching Products and Services

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

SheShe studio spa) ("Teeth whitening has also always been offered in dental offices . . . and delivers the same results that we offer at a fraction of the cost."); Ref. 47 (Bleach Bright advertisement - \$99 - side-by-side with "Dentists \$350-\$500").

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

E. A Brief History of Vital Teeth Bleaching

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

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

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

1. Hydrogen Peroxide and the Domestic Regulatory Environment Hydrogen peroxide was discovered by Louis Jacques Thenard in 1818.²⁴ Today it finds widespread use industrial, agricultural, and consumer product applications. Its safety in numerous such applications has been reviewed by domestic scientific bodies and regulatory agencies, including the United States Food and Drug Administration (FDA), and its use in those

applications has been approved.

A solution of 30 percent hydrogen peroxide has been continuously sold in the United States, since long before 1938²², principally as an anti-bacterial agent and antiseptic. As a result of its early entry into the market, it has not been subject to the requirement that FDA approve its sale through the new drug application (NDA) process, nor has its sale been reviewed under the FDA Drug Efficacy Study Implementation (DESI) program or the FDA OTC Drug Review. However, in lower concentrations hydrogen peroxide has been the subject of scientific evaluation under the OTC Drug Review and found by expert evaluators and FDA to be safe for diverse oral and dermatological medical uses including: (1) in a 3 percent aqueous solution as an oral wound cleanser; (2) in a 3 percent aqueous solution as an oral debriding agent/wound cleanser; (3) in a 3 percent aqueous solution as a general dental first aid antiseptic; and (4) in a 3 percent alcohol-based aqueous solution in a mouthwash.²⁴

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

Vital teeth bleaching products have been and are labeled and sold as cosmetics as that term is used in the FDA Act. And in May 1991 the Canadian Health Protection Branch concluded that

products containing hydrogen peroxide labeled to whiten or brighten teeth were, indeed, cosmetic goods. In September 1991, however, the U.S. FDA sent warning letters to manufacturers stating that FDA considered teeth whiteners to be "drugs" under the FDA Act. The manufacturers disagreed, submitted citizen petitions to FDA asking FDA to change its position and affirm that teeth bleaching products are cosmetics, and began a declaratory judgment action seeking a determination that bleaching products were cosmetics rather than drugs.²⁴

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

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

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

F. Possible Side-Effects of Vital Teeth Bleaching Treatment

Vital teeth bleaching has become a mainstream treatment in the U.S. and is generally regarded as safe and effective. That is not to say that there are no side effects—there are, but they are minor and nonpermanent, the most common being transient dentinal hypersensitivity (*i.e.*, temporary tooth sensitivity). Moreover, these transient adverse side effects are not specific to any class of provider—indeed, they may be most frequent and pronounced with dentist-provided chairside bleaching owing to the greater concentration of hydrogen peroxide and more intense light/heat activation often used in dental offices. For example, Dr. Owens, a member of the NC-SBODE testified at his deposition that he cannot always tell whether a patient will react adversely to teeth bleaching, and that he has had patients on whom he has done chairside whitening who have, as a result, suffered dentinal sensitivity "for several months to close to a year." Reference 41, p. 85. Based on the literature and my own research and observations, Dr. Owens' experience is not at all extraordinary among dentists.

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

The transient sensitivity experienced is believed to be due to an unfavorable osmotic gradient (see Brannstrom's hypersensitivity theory). Dehydration of the teeth and tissues is caused by the acidified and thickened bleaching gels which, when held against the teeth, create a negative osmotic pressure drawing odontoblastic processes into the dentinal tubules. The use of intense lights and heat during the bleaching process may contribute to this dehydration and the resulting sensitivity. Again, these effects typically are mild and invariably transient. Moreover, there are no reports in the literature to suggest that non-dentist-provided teeth bleaching causes a greater or more severe incidence of transient dentinal sensitivity than dentist-provided bleaching or bleaching through self-application of over-the-counter products.²⁵

Rebound: I've previously referred to color rebound following teeth bleaching. Stain color returns over time because the stain was never removed in the first instance; it was only temporarily lightened. Studies report varied times between bleaching and rebound, from a few days or weeks to as much as 47 months. One study found a rebound in 40% of patients at 6 months with use of concentrations ranging from 16% to 18% carbamide peroxide. An additional cause of rebound is the reversal of the enamel etching and dehydration that occur during teeth whitening, and which imparted an appearance of greater whiteness. There are no reports in the literature to suggest that the incidence or extent of rebound is greater in instances of non-dentist-provided bleaching than in instances of dentist-provided bleaching or bleaching through self-application of over-the-counter products.²⁵

Surface Changes: Use of hydrogen peroxide and carbamide peroxide has been found in vitro testing to result in minor reversible surface changes in. However, other studies have found that

the normal morphological variation in enamel exceeds surface changes induced by use of up to 35% hydrogen peroxide. One study testing varying concentrations of carbamide peroxide found no differences in the decreased surface microhardness between 10% and 35% concentrations. Another study found changes in the absence of saliva, but not in the presence of saliva. Other studies point out the surface changes are no different from those that occur after drinking a glass of orange juice, and any decalcification is quickly reversed when teeth are exposed to saliva. And in any event, there are no literature reports that suggest that bleaching in lay-operated bleaching facilities results in any more "surface changes" than are found with dentist-provide bleaching or bleaching through self-application of over-the-counter products. ²⁵

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

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

The potential for systemic adverse effects from exposure to a chemical is dependent on several variables. One of these is the extent of systemic exposure. Systemic exposure to hydrogen peroxide or carbamide peroxide through vital teeth bleaching is quite low. ^{30, 51} For example a recent independent review²⁴ of the safety profile of Crest WhiteStrips® concluded that the maximum daily exposure to hydrogen peroxide from use of its retail product is 42 mg, and from use of its professional product—often sold through dental offices—, 49 mg.²⁴ This exposure is well below any known risk level for humans.^{24,30} In chairside bleaching, whether performed at a dentist's office or a lay-operated teeth bleaching facility, one would expect the total exposure to hydrogen peroxide to be substantially less than that found benign in the WhiteStrips® review. For example, the most popular professional chair-side bleaching preparation would expose a person to three 3mL (15mg) applications of 25% hydrogen peroxide. 40,52 Potential exposure, therefore, would be 11.25mg (3 x 15mg x .25) of hydrogen peroxide per bleaching treatment.⁵² Alternatively, the most popular non-dentist-provided chair-side bleaching preparation would expose a person to one application of 10mL (50mg) of 30% carbamide peroxide. 40,53 Potential exposure would be only 5.00mg (1 x 50mg x .10) of hydrogen peroxide per bleaching. 53 From these calculations, it is easy to see that chair-side exposure is much less than what a consumer would be exposed to with an OTC bleaching product.

Another factor affecting the potential for systemic effects from exposure to a chemical is conditions of use. The conditions of use of hydrogen peroxide or carbamide peroxide in teeth bleaching work against any material systemic exposure. The independent review of the safety profile of Crest WhiteStrips® noted in the prior paragraph found that under typical conditions

the peroxide in saliva of test subjects was less than 0.01 percent. While systemic exposure to hydrogen peroxide as a result of swallowing of saliva during teeth bleaching would be difficult to quantify, it is considered to be quite small. Among other reasons, the abundance of peroxidases in the saliva and oral cavity would be expected to break down hydrogen peroxide, allowing little systemic absorption through the gingiva or other structures in the buccal cavity.²⁴

Hydrogen peroxide has been extensively studied for systemic toxicity in experimental animals. Numerous drinking water and gastric gavage studies using rats and mice as test subjects indicate that, although adverse effects are observed at repeated high exposures (100 mg/kg), no adverse effects occur at doses of less than 36 mg/kg. Very conservatively—that is to say, ignoring the very consequential differences between the methods of administration in these animal studies and the exposure of consumers to hydrogen peroxide having their teeth bleached—, these studies would suggest that for a 70 kg person (one weighing 154 lbs), no adverse affects are plausible unless systemic exposure exceeds 2 grams. As I noted previously, potential exposure from chairside bleaching using the most popular preparations would be a small fraction of that—11.25 mg for dentist-provided bleaching and 5 mg for non-dentist-provided bleaching. Based on these findings, it would be expected that use of peroxide-based teeth bleaching systems could not result in any systemic toxicity under normal conditions. ^{24,30}

In addition to hydrogen peroxide or carbamide peroxide, teeth bleaching preparations contain such ingredients as water, glycerine, carbopol, sodium hydroxide, sodium acid pyrophosphate, sodium saccharin, flavorings, and the like. All of these ingredients are considered safe inactive ingredients for various OTC drug and cosmetic products. They all have been rigorously

evaluated for toxicity, and as present in bleaching gels present no safety concern, even if accidentally ingested.²⁴

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

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

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

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

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

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

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

1. Mice drinking 0.15% hydrogen peroxide (about 150 mg/kg/day) *ad libitum* grew normally and developed no visible abnormalities during a 35-week test period (FDA,

- 1983). Necropsy results show changes in the liver, kidney and stomach and small intestine. Hydrogen peroxide solutions at >1% (> 1 g/kg/day) caused pronounced weight loss and death of mice within 2 weeks. [DR. GINNIGER PLEASE CONFIRM THAT THE FIRST CITE IS 32 OR 36] 326,38
- 2. When Wistar rats were administered 5% hydrogen peroxide by oral gastric tube 6 days weekly for 90 days with a dose range 56.2 to 506 mg/kg bw/day, the dose of 506 mg/kg suppressed bodyweight gain, decreased food consumption, and caused changes in haematology, blood chemistry, and organ weights. Principal organ affected was gastric mucosa, and the effect was local. The no-observed-effect-level (NOEL) of hydrogen peroxide was 56.2 mg/kg/day.^{26,39}

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

- There is an absence of good clinical data and long-term epidemiological studies that assess the possible adverse effects within the oral cavity.
- Several in vivo studies on peroxide containing tooth whiteners detected absolutely no
 genotoxicity. No increased frequency of micronuclei was observed in bone marrow cells
 of mice that were gavage-fed with two solutions containing 10% carbamide peroxide.

- Three tooth whiteners containing 10% carbamide peroxide did not have any mutagenic effects to the bone marrow cells of Chinese hamsters and mice after the animals received doses up to 10 g/kg.²⁶ A tooth whitener paste containing 10% carbamide peroxide was found to be non-genotoxic when administered to rats at doses ranging from 0.1 to 1.0 g/kg for 5 days.^{26, 30} Munro et al.^{26, 30} are of the opinion that the available genetic toxicity and animal toxicology data do not indicate that hydrogen peroxide poses a carcinogenic risk to the human oral mucosa.
- According to industry, market experience indicates that hydrogen peroxide tooth whitening products are well tolerated by consumers, with an adverse event incidence rate of 0.1%. The top five complaints received by consumers have been mouth irritation, oral miscellaneous, tooth hypersensitivity, gastrointestinal, and stained teeth. Oral cavity related effects represent the majority of health effects reported, with 58% of symptoms reported being tooth sensitivity and 56% of symptoms reported being oral soft tissue irritation. Whitening products that contain peroxide are known to have the potential to produce oral irritation and tooth hypersensitivity. These effects have usually been transient in nature and resolved shortly after cessation of product use.²⁶

In addition, I note that in teeth bleaching using hydrogen peroxide or carbamide peroxide, consumers are exposed to concentrations far below the determined toxic limit²⁴, and as I previously have explained, systemic exposure is further mitigated by salivary dilution and the action of the many peroxidases present in saliva. *See, e.g.*, Munro et al. ^{26, 30}, who, in response to the SCCP report, undertook a review of available safety data and "intended and exaggerated" hydrogen peroxide exposure, including a large number of published and unpublished studies and

clinical trials on teeth whitening procedures, and concluded that they do not indicate a genotoxic or carcinogenic risk³⁰ Munro et al. ^{26, 30} also concluded, in another article, that "dosimetric exposure analyses from tooth whitening product users show[ed] margins of safety on the order of 100- to 1,000-fold or more between no effect levels in animal studies and transient peak hydrogen peroxide concentrations in saliva at the floor of the mouth."³⁰ And, again, the U.S. FDA, with access to the SCCP report and all of the data and studies on which it was based, has concluded that the action and safety of hydrogen peroxide and carbamide peroxide when used in vital teeth bleaching is such that it is properly classified not as a drug subject to FDA approval requirements, but rather as a readily saleable cosmetic.

A similar critique can be made of the journal article written by Goldberg, Grootveld and Lynch³⁵ cited by NC-SBODE in its legal papers in support of its exclusion of non-dentists from the vital teeth bleaching market. Moreover, neither the SCCP/EU nor Goldberg et al. purport to find that teeth bleaching by non-dentists or consumer use of over-the-counter products poses safety risk different in kind or degree from those they believe are posed by dentist-provided teeth bleaching. If their position were to be accepted, the proper response would not be to exclude certain practitioners from the market, but rather to limit teeth bleaching entirely, as the EU has done and the U.S. FDA purposefully has declined to do.

H. Considerations of Sanitation and Infection Control

The NC-SBODE has suggested that the practice of vital teeth bleaching by non-dentists and in environments like mall kiosks poses sanitation and infection control risks. As I have noted in a previous section of this Report, at lay-operated bleaching facilities consumers typically are

directed to self-apply their purchased tooth bleaching products using the information and advice supplied by the product manufacturer and bleaching center personnel. Even so, it appears that typically bleaching facility personnel freshly glove up for each customer (likely using the same non-sterile latex gloves used in dental offices throughout the country). Moreover, hydrogen peroxide is itself a potent antimicrobial agent and likely helps prevent any possible cross contamination. Accordingly, there seems to be little opportunity for cross contamination between bleaching center personnel and the consumer.

One might properly be concerned about sanitation and infection control if, for example, a kiosk operator used unsanitized re-usable trays; or (2) unsanitized re-usable lip and cheek retractors to aid in the delivery of the teeth bleaching gel; or (3) bleaching gel dispensed from a multi-use container that is used by multiple consumers. However, it appears to me that the vast majority of kiosk operators do none of these things. ^{1,2} There may be periodic breaches of proper sanitation and infection control in lay-operated bleaching facilities, but that will be true in dental offices as well. The findings of a study reported ³² in the May 2009 Journal of Dental Education "indicate a lack of understanding of the basics of infection control and the prevention of transmission of communicable infectious diseases not only in large percentages of dental and dental hygiene students, but also in graduate students and among the dentists and dental hygienists who responded to this survey." Any breach of proper sanitation and infection control practices might warrant action against the specific dentist or non-dentist teeth bleaching facility involved. It hardly seems to warrant exclusion of all non-dentist providers from the market. Indeed, it appears that although bent on excluding non-dentist providers from the market, the NC-SBODE

has never complained of unsanitary practices at a non-dentist operated teeth bleaching facility to a state or local health department or to any other responsible official.

I. Consumer Options for Vital Teeth Bleaching

At the present time there are three basic options available to the consumer for vital teeth bleaching. The first option is bleaching that is performed by a dentist in a dental office, or by a hygienist or dental assistant at the dentist's office under his or her direct supervision. There are a few variations as to how the dental office does the actual treatment, and those options will be discussed in detail below.

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

The third alternative involves teeth bleaching using some the same techniques and materials that the dentist would use, but without the bother and expense of having to go to the dental office.

Instead this option is typically made available in convenient shopping mall and other locations, or even in day spas and on cruise ships. These consumer-friendly cosmetic bleaching centers use lay personnel who have particular knowledge about the products that they sell to the public and

offer advice to the consumer on how to self-apply a professional style teeth bleaching gel to their own teeth to maximize performance and minimize any potential temporary side effects.

1. The Dentist Option

Some twenty-one years ago²⁰, VB Haywood and HO Heymann described in Quintessence International, a popular dental journal of the time, what they called "Nightguard Vital Bleaching." It used dentist-fabricated custom bleaching trays, made in a manner similar to nightguards used for people who ground their teeth, as a delivery system for carbamide peroxide. The trays and bleaching agents were given to the patients for use at home while they slept.

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

The results were usually very good, with shade changes reported of 5 to 8 shades whiter as measured by a dental shade guide. The system was so effective that, with some updating (for example, most dentists now fabricate the trays using a thinner, silicone material), it still is used by the majority of dentists despite the availability of alternatives. It is sold by many dental

offices to patients for \$200-\$600 or more. Over the years, professional products companies have modified the original 10% carbamide peroxide formula, changing its strength and the "wear instructions." This technique, done almost exclusively by dentists, is commonly known as the "Custom Take-Home Tray" method of bleaching. The safety and efficacy of this tooth-whitening method has been well documented in clinical studies.

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

The most popular systems use a high concentration of hydrogen peroxide, usually in the 20%-35% concentration range. During a lengthy prep time of up to a half hour, the patient's teeth are exposed using cheek retractors and the gums are isolated using a brushed-on plastic polymer that is hardened by light curing so as to prevent the gums from being exposed to the high peroxide concentration of the whitening gel. The gel is painted on the front surface of the teeth and left to work, usually for a 20-minute period. At this point an accelerator light, such as the ones in the SapphireTM, BriteSmileTM, LumaArchTM, or Zoom 2TM (the most popular among dentists) systems, may be employed to hasten the chemical reaction of the bleaching process.

After 20 minutes, the gel is usually suctioned off the teeth using a dental vacuum. The gel is reapplied, the light, if used, is set again, and the treatment is repeated up to two more times for a total of 60 minutes of actual bleaching time. Again, the results are usually very good with a 6 shades whiter or more change occurring.

One common undesirable side effect of Power Bleaching is post-procedure teeth sensitivity that can last two weeks or more. Patients using the popular Zoom 2TM system often experience quick, sharp, electrical-type, short duration pains that gradually subside with time. Use of a professional product known as Power SwabsTM, in conjunction with Power Bleaching can help minimize these transient discomforts and pains. The literature, including my own research, suggests that this transient dentinal hypersensitivity is due to the fact that while the isolated teeth are being bleached in the open air for a prolonged time using very high bleach concentrations, they become desiccated, or dried out, and that, coupled with the oft-times high heat output of the accelerator light, causes a temporary inflammation of the inner tooth nerve, known as a pulpitis. This pulpitis manifests itself in the form of the painful transient teeth sensitivity.

2. The Over-The-Counter Option

As I stated above, there are many teeth bleaching products available as over-the-counter preparations and kits. These products generally use a lower concentration of hydrogen peroxide or carbamide peroxide. They often use relatively unsophisticated formulations, but employ a variety of novel delivery systems that make the system easy to self-apply. In recent years, manufacturers have developed unique tray-less methods for OTC at-home bleaching. Crest Whitestrips® from Proctor and Gamble was one of the first OTC teeth bleaching products on the

market, and it remains the number one selling product today. When first made available to consumers in the year 2001, Whitestrips® contained approximately 5% hydrogen peroxide. Now, almost 10 years later, the most popular Whitestrips® contain almost three times that amount of bleaching agent. Other manufacturers have also developed generic whitening strips as well, and the concentration of hydrogen peroxide in these strips have also increased significantly over the years. In all cases strips are relatively inexpensive, usually costing between \$25 and \$80 per box of strips, depending on the amount of strips supplied in the kit and the concentration of the bleach. The whitening results with these strips are highly variable because user compliance is variable; a great many consumers will not complete the whitening regimen, which may require as much as 30 days of daily use.

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

3. Retail Non-Dentist Teeth Bleaching Center Option

In many ways, lay-operated teeth bleaching centers offer the best of all options to the cosmetic beauty-conscious public. These facilities typically are highly accessible, located most often in large shopping malls. No appointment is required. Many offer both light-activated, single session chairside systems and over-the-counter take home products for the consumer to choose from. The key difference between this option and the OTC option is that in lay-operated teeth bleaching centers consumers are offered professional or near-professional strength products that

can be self-applied in ways similar to those used by dental professionals. In this way consumers can achieve the white teeth they desire at much less cost than dentist-provided chairside bleaching, with much less time and hassle than is involved in achieving comparable results with OTC products.

Most often these consumer-friendly cosmetic lay-owned bleaching centers use lay personnel who have particular knowledge about the products and services they sell to the public and who offer advice to the consumer on how best to self-apply the products. Their insights and advice may very important, because the higher concentration products are more technique sensitive. Also because higher concentration products carry greater risk of transient side-effects, it is very helpful to have a live person review proper usage. The cost of a complete chairside teeth bleaching session in a lay-operated bleaching center is typically about \$100.

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

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

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

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

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

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

The available evidence—especially the elapse of four days between his teeth bleaching and the onset of Mr. Runsick's self-reported symptoms—is inconsistent with any claim that the bleaching caused Mr. Runsick's problems. A consulting physician for the NC-SBODE later examined Mr. Runsick and found that the tissue between two of Mr. Runsick's teeth "did not completely fill the interdental space," but that his teeth and gums were healthy. He also noted a build-up of tartar between Mr. Runsick's mandibular incisors "with no evidence of any recent attempts to remove the tartar," which is suggestive of inadequate prior dental care and possible prior periodontal disease. Having never seen or documented Mr. Runsick's "original condition" or his condition while he was symptomatic, Dr. Tilley "[felt] that all the gingival tissue will return to 90% of the original condition." Dr. Tilley sought to explain how it might be that Mr. Runsick's pain—his very first symptom of injury—took four days to develop, but his attempted explanation is contrary to science and experience. I know of no possible mechanism, aside from a delayed hypersensitivity reaction (which this could not have been, among other reasons, because our immune systems could not mistake hydrogen peroxide for a foreign pathogen given

that it is found abundantly in our bodies as a normal by-product of cellular metabolism), in which someone can be exposed to a chemical erosive agent on one day and then experience the harmful effects 4 days later with none appearing in the interval. The more likely explanation given available evidence is that Mr. Runsick suffered from a periodontal abscess that just happened to occur within a few days of his teeth bleaching. Indeed, Mr. Runsick may have worsened his condition in his effort to remedy it with constant teeth brushing and other attempted therapies. The questionable nature of Mr. Runsick's claim, and the extraordinary lack of similar complaints, demonstrates, among other things, that isolated anecdotal reports are not a substitute for reliable clinical or empirical evidence of product/service safety and efficacy. ^{48,49} The available clinical and empirical evidence is that vital teeth bleaching is safe and effective, and no less so when performed at bleaching centers or using OTC products than when performed by dentists.

VI. Conclusion

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

The NC-SBODE's efforts to exclude alternative practitioners of vital teeth bleaching from the market is neither authorized by the North Carolina Dental Practices Act's condemnation of stain removal by unlicensed persons nor warranted by public health considerations. Teeth bleaching is not the removal of stains. Plainly, vital teeth bleaching can produce transient adverse side

effects, but those are not specific to any class of provider—indeed, they may be most frequent and pronounced with dentist-provided chairside bleaching owing to the greater concentration of hydrogen peroxide often used in dental offices. But both the experience of millions upon millions of consumers and the relevant literature indicate that vital teeth bleaching is safe and effective, irrespective of how and by whom done.

Respectfully submitted,

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

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EXHIBIT 1: CURRICULUM VITAE

CURRICULUM VITAE MARTIN STEVEN GINIGER

PERSONAL INFORMATION

Citizenship: USA

Home Address: 101 Briny Avenue, Apt 2206

Pompano Beach, Florida 33062

Office Telephone: (561) 865-5499 Mobile Telephone: (954) 501-9005

Office Address: Power Swabs Corporation

100 East Linton Blvd, Suite 105-B

Delray Beach, FL 33483

EDUCATION

Pre-doctoral Degree: Rutgers College, Rutgers University

New Brunswick, New Jersey

BA in Biology, With Honors, 1980 Minor in Economics and Marketing

Doctoral Degree: Fairleigh Dickinson University

School of Dental Medicine Hackensack, New Jersey

DMD with Basic Science Award, 1984

Postdoctoral Degree: University of Connecticut

School of Dental Medicine Farmington, Connecticut

PhD in Biomedical Science (Oral Biology), 1993

3.99 GPA

Postdoctoral Certificate: University of Connecticut

School of Dental Medicine Farmington, Connecticut MsD in Oral Medicine, 1993

EMPLOYMENT HISTORY

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

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

PROFESSIONAL LICENSURE (DENTISTRY)

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

PRIVATE PRACTICE

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

HOSPITAL APPOINTMENTS

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

OTHER TRAINING & CLINICAL ROTATIONS

UConn John Dempsey Hospital

Hematology/Laboratory Medicine
Dermatology/Dermatopathology
Bone Marrow Transplant Unit
Head and Neck Cancer Clinic
Infectious Diseases

Saint Francis Medical Center Physical Diagnosis/Internal Medicine

LSU Charity Hospital Outpatient/Inpatient Leukemia Unit

Bone Marrow Transplant Unit

Armed Forces Institute of Pathology Oral Pathology

TEACHING RESPONSIBILITIES

UMDNJ – School of Dentistry	Course Director: Treatment Planning Clinic I
	Course Director: Treatment Planning Clinic II
	Course Director: Diagnostic Sciences Seminars I
	Course Director: Diagnostic Sciences Seminars II

Course Director: Diagnostic Sciences Seminars II Director, Prevention Section, GPR program

Intro to Oral Epidemiology

Diagnostic Sciences I, II, III and IV Sophomore Operative Dentistry

LSU – School of Dentistry Course Director: Internal Medicine

Course Director: Oral Diagnosis Screening Clinic

Course Director: Oral Diagnosis I Clinical Preceptor: Oral Diagnosis III

Mini-Clinic Faculty Advisor

UConn – School of Dentistry Lectures Given: Oral, Physical & Lab Evaluation

Lectures Given: General Pathology – Lecture Clinic: Oral Diagnosis Screening Clinic – Clinical Lecture Given: Nutrition in Public Health Policy

GRANTS

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

Other Grants

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

SPECIAL AWARDS

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

PROFESSIONAL MEMBERSHIPS

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

UNITED STATES PATENTS & PENDING PATENTS

1		20090004629	AESTHETIC DENTAL ARCH LAMINATES AND ADHESIVE
2	2	20080213719	Temperature Modified Oral Cleaning Device
3	}	20070122363	CORPOREAL DELIVERY OF CAROTENOIDS
4	ļ	20070122362	HYDROGEL SHEETS AND SHAPES FOR ORAL CARE
5	5	20060239757	Application and/or carrying devices for oral care compositions
6)	20060229226	Foaming compositions and methods
7	7	20060216256	Foaming oral care compositions of baking soda and vinegar
8	}	20060204455	Compositions for enhancing effects of other oral care compositions
9)	20060204453	Oral care cleaning compositions and methods
1	.0	20060198803	Whitening system capable of delivering effective whitening action
1	.1	20060198799	Tooth glossing or finishing compositions for oral care
1	2	20060198797	Stand-alone or enhancer composition for oral care
1	.3	20060198796	Whitening compositions and methods involving nitrogen oxide radicals
1	4	20060198795	Multi-component oral care compositions

PUBLICATIONS

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

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

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

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

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

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EXHIBIT 2: LIST OF REVIEWED MATERIALS

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

- Document Number CX0211: E-mail from Clifford Feingold to Bobby White et al., dated July 14, 2008
- Document Number CX0212: E-mail from Carolin Bakewell to Ronald Owens et al., dated May 27, 2008
- Document Number CX0213: E-mail from Clifford Feingold to Carolin Bakewell et al., dated May 28, 2008
- Document Number CX0214: E-mail from Stan Hardesty to Carolin Bakewell et al., dated May 27, 2008
- Document Number CX0215: Emails from Clifford Feingold to Carolin Bakewell et al., dated May 19, 2008
- Document Number CX0200: Emails from Clifford Feingold to Line Dempsey et al., dated January 16, 2008
- Document Number CX0218: The Dental Forum Newsletter, North Carolina State Dental Board of Examiners, dated Spring 2007
- Document Number CX0220: Petition signatures supporting the Candidacy of Clifford O. Feingold for the North Carolina State Board of Dental Examiners, dated January 5, 2005
- Document Number CX0124: E-mail from Cassie Goode to Wayne Holland, dated November 14, 2008
- Document Number CX0198: Advertisement for Movie Star Smile, undated
- Document Number CX0106: Closed Session Minutes of the NC State Board of Dental Examiners Board Meeting, dated August 10-11, 2007
- Document Number CX0067: E-mail from Carolin Bakewell to Mr. Van Essen, with attached Board of Cosmetology Notice, dated February 7, 2007
- Document Number CX0056: Minutes of the North Carolina State Board of Dental Examiners Board Meeting, dated February 9, 2007
- Document Number CX0054: Fax from Terry Friddle to Stan Hardesty, with attached Complaint Form, dated September 11, 2006
- Document Number CX0055: Brian Runsick's North Carolina State Board of Dental Examiners Complaint Form, dated April 11, 2008

- Document Number CX0327: Letter from Larry Tilley to North Carolina State Board of Dental Examiners, dated April 24, 2008
- Document Number CX0401: Vital Bleaching With A Thin Peroxide Gel, Journal of the American Dental Association, Vol. 135, dated January 2004
- Document Number CX0100: Cease and Desist letter sent to White Science from the North Carolina State Board of Dental Examiners, dated December 4, 2007
- Document Number CX0068: Cease and Desist letter sent to Joe Willet (BleachBright) from the North Carolina State Board of Dental Examiners, dated February 20, 2008
- Document Number CX0199: E-mail Terry Friddle to Casie Goode, dated January 17, 2008
- Document Number CX0103: Email from Bobby White to Christine Bennett et al., dated April 24, 2008
- Council for Cosmetic Teeth Whitening, available at http://www.cctwonline.org/
- Document Number 004428-004430: ADA Meeting Agenda, CSA Report on Whitening/Bleaching (73H-2008) – Subcommittee Recommendations, dated November 8-10, 2010.
- Van B. Haywood, A Comparison of At-Home and In-Office Bleaching, Dentistry Today, Vol. 19, No. 4, dated 2000
- 510K Permission to Market, BEKS, Inc., dated February 2007
- 510K Permission to Market, BEKS, Inc., dated April 2004
- 510K Permission to Market, BioLase Technology Inc., dated October 2003
- 510K Permission to Market, Cosmetic Dental Materials, Inc. dated October 2005
- 510K Permission to Market, Dentovations, Inc., dated November 2004
- 510K Permission to Market, Hoya ConBio, Inc., dated March 2007
- 510K Permission to Market, Hoya ConBio, Inc., dated April 2005
- 510K Permission to Market, Hoya ConBio, Inc., dated June 2007
- 510K Permission to Market, Hoya ConBio, Inc., dated October 2003

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

L'ARDRE VOUS INFORME

ASSEMBLÉE GÉNÉRALE ANNUELLE

Nous vous rappelons que l'assemblée générale annuelle de l'Ordre des dentistes du Québec aura lieu le lundi 31 mai à 16 h 30, à la salle 516-A du Palais des congrès de Montréal. Tout membre qui veut faire inscrire une question à l'ordre du jour de cette assemblée générale doit l'adresser par écrit au secrétaire de l'Ordre avant le 30 avril prochain.

MOIS DE LA SANTÉ **BUCCODENTAIRE 2010**

BLANCHIMENT DES DENTS

Avant de choisir, demandez conseil à votre dentiste



Le thème de la campagne du Mois de la santé buccodentaire 2010 portera sur le blanchiment des dents. Tout comme vous, l'Ordre constate que les offres liées à ce type de traitement se multiplient sur le marché. Il est important de noter qu'en vertu de la loi, le blanchiment des dents est un acte qui n'est pas strictement réservé au dentiste.

Préoccupé par la question, l'Ordre des dentistes souhaite, par cette campagne d'information, rappeler à la population l'importance d'obtenir un diagnostic et les conseils d'un dentiste avant d'entreprendre un traitement de blanchiment des dents.

Une campagne de relations publiques aura lieu au cours du mois d'avril; elle comprendra des placements publicitaires dans certains médias écrits. De plus, vous trouverez dans ce numéro du Journal une affichette que nous vous invitons à placer bien en vue dans votre salle d'attente.

PROTÉGEZ L'ENVIRONNEMENT: **RÉGLEZ VOTRE COTISATION** 2010-2011 EN LIGNE!

L'année dernière, l'Ordre des dentistes du Québec vous a offert la possibilité de faire votre déclaration annuelle par l'entremise du site Internet de l'Ordre, au www.odq.qc.ca, et de régler vos frais de cotisation en ligne au moyen d'une carte de crédit.

Vous avez été plus de 25 % à opter pour le mode électronique, ce qui démontre votre engagement à appuyer le virage vert entrepris par l'Ordre.

Les membres qui souhaitent faire leur déclaration annuelle et payer leur cotisation en ligne doivent remplir, avant le 23 avril 2010, le formulaire prévu à cet effet. Ce formulaire est disponible à l'adresse www.odq.qc.ca/envoi.

En optant pour le mode électronique, vous ne recevrez pas la documentation relative à la déclaration annuelle et à la cotisation 2010-2011 par la poste, mais plutôt par courriel. Voilà une façon simple, écologique et sécuritaire de mettre à jour votre situation professionnelle au tableau de l'Ordre!

Merci à l'avance à tous ceux et celles qui auront choisi de faire un bon geste pour l'environnement!

POUR PLUS DE RENSEIGNEMENTS

Michelle Giusti 514 875-8511, poste 2266

GUIDE DE SOINS DENTAIRES AVEC LES ÉDITIONS PROTÉGEZ-VOUS

Nous vous informions récemment que l'Ordre avait conclu une entente de partenariat avec les Éditions Protégez-Vous en vue de produire et de publier un guide pratique sur les soins dentaires. Cette publication sera officiellement lancée lors d'une conférence de presse tenue le 31 mai au Palais des congrès, pendar les Journées dentaires internationales du Québec.

Sachez que chaque membre de l'Ordre recevra un exemplaire de cette édition spéciale qui sera en vente dans les kiosques à journaux.