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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

COMPLAINT COUNSEL'S MEMORANDUM IN REPLY TO RESPONDENT'S CORRECTED MEMORANDUM IN OPPOSITION TO COMPLAINT COUNSEL'S MOTION FOR PARTIAL SUMMARY DECISION

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Dated: December 28, 2010

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TABLE OF AUTHORITIES

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OTHER AUTHORITIES

I. INTRODUCTION

This case is indeed a tale of two agencies. On the one hand, we have the Dental Board that the North Carolina Legislature intended, with very limited authority over the activities of non-dentists. Under state law, if the Board is concerned that an individual is practicing dentistry without a license, it may bring this complaint to a state court. Nothing more. And on the other hand, we have the Dental Board in action: pursuing an anticompetitive campaign – unauthorized by the Legislature and independent of the courts – to exclude non-dentists from competing with dentists to provide teeth whitening services.

The Board claims that this ultra vires campaign is driven by safety concerns, but these concerns are difficult to credit. Over the years, and on literally tens of millions of occasions, carbamide peroxide and hydrogen peroxide have been used safely to whiten teeth. An extensive scientific literature shows that over-the-counter strength peroxide provides for a safe procedure, the principal negative side-effect being the potential for a transient discomfort. The Board has unearthed three individuals that it alleges have been more seriously harmed by a teeth whitening procedure; the evidence at trial will show that these claims are very likely to be inaccurate. Moreover, whatever the merits of those claims, they are not the genesis of the Board's efforts to eliminate non-dentist competitors, as the Board's campaign was initiated well before these incidents.

When a dentist complains to the Board that there is a non-dentist kiosk or salon in the vicinity, the Boards springs to action – but not with a lawsuit, and often without any investigation. Instead, the Board, presenting the imprimatur of the State, orders the non-dentist to cease and desist from providing teeth whitening services. In so doing, the Board is acting outside its authority, as the decision whether to prohibit non-dentist teeth whitening has <u>not</u> been

entrusted by the State to the Board.

The Board avers that this lawsuit undermines North Carolina's sovereign authority to regulate dentistry, and would require North Carolina to re-structure the Board, or to cease relying on experts, or to appoint two boards of dentistry. This is nonsense. What is required is for this Board to comply with the Dental Act as enacted by the North Carolina Legislature; specifically, if and when the Board has concerns regarding non-dentist providers, the Board may not itself order anyone to leave the market, but instead must rely on the North Carolina courts to do so. Of course, the Legislature may also address the antitrust violations detailed in the lawsuit by amending the statute so as (i) to authorize the Board to issue cease and desist orders, and (ii) to provide for supervision by a state agent that is not financially interested (*e.g.*, the Department of Health). But a statutory amendment is unnecessary, provided that the Board complies with the current law.

Finally, the Board makes a series of baseless allegations of misconduct directed at Complaint Counsel, all of which are false. Complaint Counsel categorically denies that it has abused deponents, deceived anyone, or otherwise acted unethically.

* * * *

The Board's discussion of state action obscures the key precepts. To begin, the state action defense requires the defendant to establish that the challenged restraint: (1) conforms with a "clearly articulated" state policy to displace the antitrust laws with regulation, and (2) is "actively supervised" by the state. Together, these requirements ensure that the state action defense shelters only the particular anticompetitive acts of private parties that, in the judgment of the State, promote state regulatory policies, as opposed to the interests of private parties.

The Board answers that, for a state agency such as the Board, the clear articulation

requirement should be lax, and the active supervision requirement should be abandoned. Why? Because the close scrutiny required by the Supreme Court would (the Board claims) undercut the policies of the state of North Carolina and impede the state's efforts to protect health and safety. The Supreme Court addressed – and rejected – this precise argument in *Ticor*. A demanding application of the *Midcal* requirements, the Court explained, actually protects the prerogatives of the State. *FTC v. Ticor Title Ins. Co.*, 504 U.S. 621, 635-36 (1992). The state legislature is undermined when a deliberately narrow delegation of authority is transmuted into a broad exemption from the antitrust laws. *Id.*

A second reason why the state is required both to authorize and to supervise the anticompetitive conduct of market participants, as a condition of displacing antitrust enforcement, is to assure political responsibility.

> States must accept political responsibility for actions they intend to undertake . . . . For States which do choose to displace the free market with regulation, our insistence on real compliance with both parts of the *Midcal* test will serve to make clear that the State is responsible for the price fixing it has sanctioned and undertaken to control.

Id. at 636. Thus, even if North Carolina were inclined to hand over to dentists unsupervised discretion to determine whether, when, and how to restrain competition, this would be prohibited by antitrust law. By approving each anticompetitive restraint, the State demonstrates and affirms its "ownership" of the restraints, and thus satisfies prong 2.

Because state action is an affirmative defense, the analysis starts with the presumption that North Carolina favors competition in the field of teeth whitening (low prices, convenience, and choice), and requires that the Board prove the opposite – that North Carolina has authorized and actively supervises the Board's anticompetitive campaign. The Board has failed to carry its burden, and hence the state action defense should be dismissed.

II. LEGAL STANDARD FOR PARTIAL SUMMARY DECISION

Commission Rule of Practice 3.24, like Federal Rule of Civil Procedure 56, authorizes partial summary judgment to dismiss an affirmative defense.[1] Summary judgment is appropriate where there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

The party seeking summary judgment has the initial burden of identifying evidence that establishes the absence of any genuine issue of material fact. *Id.* at 323. The opposing party must then "come forward with 'specific facts showing that there is a genuine issue of fact for trial.'" *Matsushita Elec. Indus. Corp. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); 16 C.F.R. § 3.24(a)(3).

The mere existence of any factual dispute will not defeat a properly supported motion for summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). There is no genuine issue, and summary judgment should be granted, unless there is evidence sufficient to lead a rational trier of fact to find for the non-moving party. *Id.* at 247, 249-50.

For example, where the moving party relies upon a document to support a finding, the opposing party does not create a material dispute by advancing an unreasonable interpretation of that document. Summary judgment may be based on the court's reading of a document that is clear on its face.[2]

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[1] *County of Hennepin v. Aetna Cas. & Sur. Co.*, 587 F.2d 945, 946 (8th Cir. 1978).

[2] *Bay State Milling Co. v. Martin*, 916 F.2d 1221, 1225-26 (7th Cir. 1990) ("no need to go outside the four corners of the document to determine . . . what was clear on the face of the document"); *Royal Neighbors of Am. v. Bank of the Commonwealth*, No. 77-1226, 1979 U.S. App. LEXIS 16940, at *1-*2 (6th Cir. Feb. 14, 1979); *Toscano v. Embree*, No. 05-4113, 2007 U.S. Dist. LEXIS 69327, at *16 (N.D. Cal. Sept. 19, 2007) ("[Plaintiff] cannot create a triable issue of fact by simply misrepresenting the contents of a document . . . .") *see also Scott v.*

Finally, a respondent does not avoid dismissal of an affirmative defense by showing a material dispute as to the underlying violation.[3] Thus, the issue before the Commission is whether, assuming the Board is otherwise liable, the state action defense will be available.

III. THE TWO-PRONG *MIDCAL* STANDARD IS APPLICABLE TO A FINANCIALLY-INTERESTED STATE BOARD

The anticompetitive conduct of private parties is exempt from the antitrust laws only if both prongs of the *Midcal* test – clear articulation and active supervision – are satisfied. Complaint Counsel's Summary Decision Memorandum explains that the Supreme Court distinguishes public actors from private actors based upon the decision-making incentives of the actor. A party that has, or represents those who have, a financial interest in the challenged conduct is deemed to be a private actor. Applying this test, a financially interested state board is properly considered to be a private actor, and the two-prong *Midcal* standard governs the analysis.

In lieu of this test, the Board offers the simple assertion that a state agency is always a public actor, and that the second prong of the *Midcal* test (active supervision) is not applicable. The Board's position is based upon a footnote from the *Hallie* decision, reading: "In cases in which the actor is a state agency, it is likely that active state supervision would also not be required, although we do not here decide that issue." *Town of Hallie v. City of Eau Claire*, 471 U.S. 34, at 46 n.10 (1985). Complaint Counsel's Summary Decision Memorandum explains at length that the Board misreads Footnote 10. As further developed below, the Board's

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Harris, 550 U.S. 372, 380-81 (2007) (Supreme Court interpreting a video for purposes of summary judgment).

[3] *Cmty. Communications Co. v. Boulder*, 455 U.S. 40, 58 (1982); *Cantor v. Detroit Edison Co.*, 428 U.S. 579, 582 (1976).

interpretation of *Hallie*, Footnote 10, and the corpus of Supreme Court decisions analyzing the state action doctrine is wholly inadequate.

We may start with the trilogy of Supreme Court antitrust cases assessing whether competing attorneys, acting through the vehicle of a state agency (the state bar), may successfully invoke the state action defense. Where the state supreme court articulates a policy to displace competition and supervises the implementation of this policy by the state bar, the challenged restraint is exempt from antitrust liability. *Hoover v. Ronwin*, 466 U.S. 558, 568-69 (1984); *Bates v. State Bar of Arizona*, 433 U.S. 350, 362 (1977) ("[W]e deem it significant that the state policy is so clearly and affirmatively expressed and the State's supervision is so active."). In contrast, where the state bar is not supervised by the state supreme court or another financially-disinterested state actor, the state action defense fails. *Goldfarb v. Virginia State Bar*, 421 U.S. 773 (1975).

For present purposes, *Goldfarb* is particularly important because antitrust liability was assessed against a state agency that, like the Board, is financially interested – attorneys empowered to regulate attorneys. For state action purposes, the Court treated the State Bar as a private actor and not as a public actor. Significantly, the Court supported its conclusion that state agency status does not shield the State Bar from antitrust review by citing *Gibson v. Berryhill*, 411 U.S. 564, 578-79 (1973), which held that a state board composed of self-employed optometrists violates due process by conducting hearings on whether to revoke the licenses of competitors. *See Goldfarb*, 421 U.S. at 791. This reliance is instructive. *Gibson* explicitly based its holding on the pecuniary interest of the board's members in excluding competitors. This indicates that the *Goldfarb* Court was also focusing on financial interest and

viewed it as the factor that rendered the state agency "private" for antitrust purposes.[4]

The Board denies that the absence of active and independent supervision was relevant to the Court's state action analysis in *Goldfarb*. This is plainly wrong. The Court indicated that the State Bar's anticompetitive conduct would have been exempt if it had been compelled or perhaps even approved by the Virginia Supreme Court.

> Although the State Bar apparently has been granted the power to issue ethical opinions, there is no indication in this record that the Virginia State Court approves the opinions. Respondents' arguments, at most, constitute the contention that their activities complemented the objective of the ethical codes. In our view that is not state action for Sherman Act purposes. It is not enough that, as the County Bar puts it, anticompetitive conduct is "prompted" by state action; rather, anticompetitive activities must be compelled by direction of the State acting as sovereign.

Goldfarb, 421 U.S. at 791.

Next, the Board suggests that active supervision is required only for really pernicious conduct like price fixing agreements. Nothing in the *Goldfarb* opinion supports this conclusion. The mechanics of required state oversight may depend upon the underlying conduct, but the need for active supervision of private anticompetitive restraints is a constant. In any event, the conduct at issue here, the naked exclusion of a class of low-cost competitors, is inherently suspect and almost always harmful, much like price fixing. *See In re Realcomp II, Ltd.*, No. 9320, 2009 F.T.C. LEXIS 206, at *28 (Oct. 30, 2009), *appeal docketed*, No. 09-4596 (6th Cir. Dec. 31, 2009). The Board seeks special dispensation because it is the designated regulator of an industry that affects public health. But the State Bar in *Goldfarb* was likewise responsible for

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[4] *See* Einer Elhauge, *The Scope of Antitrust Process,* 104 Harv. L. Rev. 668, 688 n.107 (1991). It does not matter whether the financial interest at issue is that of the agency's members, as in *Gibson v. Berryhill*, or instead involves the interest of those who elect the members. *See Goldfarb,* 421 U.S. at 791.

regulating a critical industry, and it did not escape liability.

The Board correctly points out that the state action test applicable to private parties has evolved since *Goldfarb*; however, that evolution does not effect the private/public dichotomy. In *Goldfarb*, the Supreme Court held that a state bar stands in the position of a private party when it regulates attorney conduct. That is, the Court treated a financially-interested state agency as a private actor, and applied the most searching level of scrutiny to that agency's state action defense.

The Board misreads *Continental Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690 (1962), which also addresses the scope of immunity afforded a financially-interested governmental agent. The Canadian government appointed a private company as administrator of a wartime rationing program (to purchase and to allocate vanadium products to Canadian industries). The firm was later accused of using its discretionary power to exclude a competing processor of vanadium ore. The Supreme Court found *Parker* immunity inapplicable because the restraint had not been approved by any "official within the structure of the Canadian government." *Id.* at 706-07.

The Board argues that *Continental Ore* should be disregarded because the defendant was the agent of the Canadian government, as opposed to an agent of a U.S. state. But this is not what determined the outcome. What was relevant to the Court's analysis was that the governmental agent was a private company that had a financial stake in the vanadium market, and that no independent Canadian official approved of its efforts to monopolize the sale of vanadium. *See also United Mine Workers v. Pennington*, 381 U.S. 657, 672 n.4 (1965) (explaining that the administrator in *Continental Ore* "was not a public official"). Professor Elhauge synthesizes *Continental Ore* and the Supreme Court decisions this way: "[W]hy some

official state agents are treated as private actors [becomes] readily explicable once one understands antitrust as embracing the proposition that those with financial interests in restraining competition cannot be trusted to determine which restraints are in the public interest."[5]

With this as background, we reach *Town of Hallie* and Footnote 10. The decision distinguishes between public and private actors by evaluating the financial incentives faced by the actor – the methodology advocated by Complaint Counsel here. The Court holds that active supervision by the state is generally not required where the actor is a municipality, for the reason that a municipality lacks a financial incentive to further its own interests "rather than the governmental interests of the State." *Town of Hallie*, 471 U.S. at 47. The Court does not overrule *Goldfarb*. Instead, the Court distinguishes *Goldfarb* on the basis that, unlike the municipality in *Hallie*, the state agency at issue there (the State Bar) was a "private party," and as such "may be presumed to be acting primarily on his or its own behalf." *Id.* at 45. Active supervision is required for the private, financially-interested party (the State Bar) that asserts the state action defense, but not for the public actor (a municipality).

Thus, when the Court indicates on the following page of its opinion (in Footnote 10) that a state agency is likely to be treated like a municipality (active supervision not required), the Court logically cannot have in mind a financially-interested regulatory board of the type at issue in *Goldfarb*.[6] The Board does not rebut this analysis, offering instead the unhelpful response that "the exact meaning of the *Hallie* quote in regards to *Goldfarb* is unclear." Resp. Mem. at 13-14.

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[5] Elhauge, *Antitrust Process*, *supra*, at 683.

[6] This is analyzed in greater detail in Complaint Counsel's Summary Decision Memorandum at 20-22.

The Supreme Court precedent establishes then that *Midcal* is the presumptive rule when a market participant invokes the state action defense, even when the market participant is simultaneously a government agent. Yet, the Board insists that a less demanding standard (the *Hallie* standard) should apply to the Board. Although financially interested, the Board contends that it should be trusted without supervision, and for the following reason: "[T]he state has proactively assured that licensees put aside their private interests and enforce the dental practice act for public purposes." Resp. Mem. at 29. The claim is that, during the few hours each month that these members leave their dental offices and attend to Board business, they are indifferent to their personal financial well-being; they care not for the interests of the dentists that have elected them; they pursue only the common good. According to the Board, the state has turned market-competitors into disinterested regulators with these few simple steps:

> The state has done so by requiring an oath of each Board member, requiring initial and annual detailed financial disclosures to a state Ethics Commission, limiting expenditures, prohibiting the use of funds for lobbying, and subjecting the State Board as a state agency to all of the requirements that any other state agency has, including the open meetings law, the Public Records Act, and the Administrative Procedures Act. The State also requires that each state Board member receive regular Ethics Act training.

Id.

Transparency, training, and admonitions are useful safeguards against corruption, but there is no allegation here that the Board or its members are corrupt. State action analysis of industry self-regulation is concerned with a different and more subtle set of dangers. "Good government" constraints will not, and cannot, consistently convert market participants into the neutral and unbiased regulators required under Supreme Court precedent. As Professors Areeda and Hovenkamp conclude: "Without reasonable assurance that the [decision-making] body is far more broadly based than the very persons who are to be regulated, outside supervision seems

required."[7]

The Board cites *Withrow v. Larkin*, 421 U.S. 35 (1975), for the proposition that Board members, like judges, should be presumed to act with honesty and integrity. The Board fails to point out that this presumption is overcome where, as here, the decisionmaker has a financial interest in the controversy: "[V]arious situations have been identified in which experience teaches that the probability of actual bias on the part of the judge or decisionmaker is too high to be constitutionally tolerable. Among those cases are those in which the adjudicator has a pecuniary interest in the outcome . . . ." *Id.* at 47. Significantly, there is no suggestion in *Withrow* that the danger of bias is erased where the decisionmaker takes an oath of office or receives regular ethics training.

Moreover, the Board does not address the issue of political responsibility highlighted in *Ticor*. In the absence of actual supervision of particular anticompetitive conduct by a disinterested state actor, the State's responsibility for anticompetitive outcomes is obscured. The dentists have determined to eliminate non-dentist competitors; but the State has not been actively involved. In this context, an oath of office and ethics training amount to no more than "casting . . . a gauzy cloak of state involvement over what is essentially a private" arrangement. *California Retail Liquor Dealers Ass'n* v. *Midcal Aluminum, Inc.*, 445 U.S. 97, 106 (1980).

In sum, for antitrust purposes, not all governmental actors are equivalent. A state court is not the same as the state bar. A department of public health is not the same as a dental board whose members consist of and are selected by practicing dentists. Put simply, financial incentives matter. *See Withrow*, 421 U.S. at 47; *Hallie*, 471 U.S. at 45. This critical distinction

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[7] Areeda & Hovenkamp, *Antitrust Law*, ¶ 227 at 208 (3d ed. 2006).

between a financially-interested state board and a true public entity comports with common sense, human experience, core antitrust principles, and Supreme Court precedent.

IV. THE BOARD IS A PRIVATE ACTOR BECAUSE ITS MEMBERS AND ITS CONSTITUENTS HAVE A FINANCIAL INTEREST IN EXCLUDING NON-DENTISTS AND RESTRAINING COMPETITION

Consistent with *Goldfarb*, the Commission should consider whether Respondent and/or its constituents have a financial interest in restraining competition from non-dentist teeth whitening. 421 U.S. at 791 ("The fact that the State Bar is a state agency for some limited purposes does not create an antitrust shield that allows it to foster anticompetitive practices for the benefit of its members."). Dentists elect the Board and dominate the Board. The evidence shows that over percent of dentists provide teeth whitening services.[8] It further shows that dentists can and do earn significant revenues by providing teeth whitening services. Respondent quibbles with this evidence but does not establish a true factual dispute.[9]

Respondent asserts that much of the evidence regarding moneys earned by dentists applies to dentists nationwide and is not specific to North Carolina – but offers no rationale or evidence to suggest that, in this regard, North Carolina dentists differ from their peers nationwide. There is no dispute that several dentists who complained to Respondent about teeth whitening in North Carolina have earned revenues from teeth whitening in excess of REDACTED during the relevant period. And there is no dispute that non-dentist teeth whitening services are popular in North Carolina. Eliminate these non-dentist establishments (as Respondent seeks to

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[8] Tab 1 (CX0513-007, 030) REDACTED

[9] *See* Resp. Material Facts ¶¶ 37, 39-41 (discussing existence of and potential for dentists to earn significant income from teeth whitening).

do), and these customers and fees are potentially available to the dentists of North Carolina.[10] Even dentists who do not provide teeth whitening today may start to do so; they are potential competitors. Elementary economics – and common sense – tell the Commission that the exclusion of non-dentists may result in Board members and the Board's constituents obtaining higher prices for teeth whitening and a greater volume of teeth whitening procedures.

What is Respondent's evidence that North Carolina dentists do not have a financial interest in teeth whitening services? No probative evidence is cited in Respondent's Memorandum, and no probative evidence is cited in Respondent's Statement of Material Facts. Consider for example this testimony highlighted by Respondent: "I don't know of any dentist that gets rich off of tooth whitening. General dentists don't derive the majority of their income from whitening." That North Carolina dentists have many alternative revenue sources is not probative. The significant and undisputed fact is that dentists in North Carolina, including numerous Board members, earn money from teeth whitening. This evidence could lead a rational fact-finder only to conclude that North Carolina dentists have a financial interest in the challenged restraints.

It is not Complaint Counsel's contention that any Board member is corrupt. And we are not obliged to show that any Board member is hostile to non-dentist teeth whitening because of

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[10] Even Respondent's own industry expert acknowledges that dentists may be tempted to act for their own benefit rather than the patient with respect to teeth whitening. Tab 2 (CX0627) ("The biggest challenge in aesthetic dentistry is to maintain the ethics of the dental profession, and to place patient care ahead of financial gain."); Tab 3 (CX0492-002 ("removal of products that are available to the dentist could limit competitive marketing by removing adequate but less costly materials. A market restricted to the dentist could result in increased patient costs."). Even P&G, which typically is in a symbiotic relationship with dentists, explained to the FDA that in light of the large body of literature demonstrating the safety of hydrogen peroxide use, an ADA petition to require dentist supervision of teeth whitening must be "motivated primarily by the commercial interests of ADA membership . . . ." Tab 4 (CX0496-002).

his financial stake. The issue is whether the anticompetitive actions of Respondent are likely to confer a financial benefit on Board members and/or its constituents. Given the fees actually and potentially available to North Carolina dentists, these dentists, and ergo Respondent, have a financial interest in the exclusion of non-dentists.

V. THE BOARD'S STATE ACTION DEFENSE IS WITHOUT MERIT AND SHOULD BE DISMISSED

A. The State of North Carolina Has Not Clearly Articulated A Policy of Permitting The Board To Exclude Non-Dentists

In applying the clear articulation prong of the *Midcal* test, courts ask whether the specific restraint that is challenged by the plaintiff has been clearly articulated and affirmatively authorized as state policy.[11]

North Carolina law is clear. Respondent is authorized to file suit in North Carolina courts to enjoin the unauthorized practice of dentistry. Only the courts are empowered actually to exclude persons engaged in unauthorized practice. Respondent does not dispute this. Resp. Mem. at 28-29 ("[B]efore anyone is restrained or enjoined from the illegal practice of dentistry, they must have their day in court in the country in which they reside.").

Nevertheless, on at least 40 separate occasions, Respondent has issued to a non-dentist teeth whitener a letter ordering the recipient to cease and desist. Most such orders carry a bold, all capitalized heading: **"NOTICE AND ORDER TO CEASE AND DESIST"** or **"NOTICE TO CEASE AND DESIST."** These letters are in the record, and may be interpreted and relied upon by the Commission. (*See* footnote 2, *supra.*) In any event, Respondent does not dispute

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[11] *Patrick v. Burget*, 486 U.S. 94, 101 (1988) ("[T]he state-action doctrine will shelter only the particular anticompetitive acts of private parties that, in the judgment of the State, actually further state regulatory policies."); *Cantor*, 428 U.S. at 594-95 n.31.

that these documents are cease and desist orders issued by Respondent.[12]

Respondent purports to find the required authority to issue cease and desist orders in the Dental Act itself. Respondent argues that because (in its view) non-dentist teeth whitening contravenes the Dental Act, and because Respondent is authorized "to enforce that statute," this means that Respondent may order non-dentists to cease and desist. This is plainly wrong. Respondent is not handed plenary or unlimited authority by the Dental Act. With regard to the alleged unauthorized practice of dentistry, Respondent's authority is limited, definite, and specific: Respondent may file lawsuits. The Legislature could not have intended or foreseen that Respondent would issue cease and desist orders – as this entails Respondent ignoring the clear language of the Dental Act, usurping the authority expressly granted to the judiciary, and taking the law into its own hands.

Respondent's Memorandum lists, without explanation, several other provisions of the Dental Act (Resp. Mem. at 36 & nn.27-30). These provisions do not remotely relate to cease and desist powers, or to the exclusion by Respondent of unauthorized practitioners.

B. The State of North Carolina Does Not Actively Supervise The Exclusionary Conduct Engaged In By The Board

In applying the active supervision prong of the *Midcal* test, courts ask whether the specific restraint that is challenged by the plaintiff (*e.g.*, the issuance of cease and desist orders) is supervised by the state. State officials must "have and exercise power to review particular

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[12] Resp. Mem. at 36 (Board documents "merely orders people to stop violating the law"); Resp. Material Facts ¶ 55 (Respondent does not dispute that "The Board has sent at least 40 cease and desist orders to non-dentist teeth whiteners."); Resp. Material Facts ¶ 60 (Respondent does not dispute that "[c]ontemporaneous emails, letters, and reports drafted by Board members and Board staff confirm that the documents sent were cease and desist orders.").

anticompetitive acts of private parties and disapprove those that fail to accord with state policy." *Patrick*, 486 U.S. at 101. Respondent makes no serious effort to demonstrate its compliance therewith.

Again, the Legislature intended that the state courts supervise efforts by Respondent to exclude non-dentist providers. But Respondent's cease and desist orders circumvent this procedure. Thus, Respondent, by its own action, ensures that there is no supervision by the State.

One finds in Respondent's Memorandum references to instances of state review of Board conduct, after the fact, by state entities separate from the courts. A committee of the Legislature monitors state boards generally.[13] A state Ethics Commission reviews financial disclosures. A Board member that violates (unspecified) ethics obligations may be removed from office or prosecuted criminally.[14] But no state entity supervises the issuance of cease and desist letters or the other exclusionary conduct of Respondent that is at issue in this litigation. Post hoc review is insufficient, and post hoc review of conduct unrelated to the Complaint is meaningless.

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[13] Resp. Mem at 29.

[14] Resp. Mem. at 29.

VI. CONCLUSION

The Commission should enter an order dismissing Respondent's state action defense.

Respectfully submitted,

s/ Richard B. Dagen
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Counsel Supporting Complaint

December 28, 2010

CERTIFICATE OF SERVICE

I hereby certify that on December 28, 2010, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

Donald S. Clark
Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580

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

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

I further certify that I delivered via electronic mail a copy of the foregoing document to:

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Counsel for Respondent
North Carolina State Board of Dental Examiners

CERTIFICATE FOR ELECTRONIC FILING

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

December 28, 2010

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

FEDERAL TRADE COMMISSION
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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

DECLARATION OF RICHARD B. DAGEN

1. I have personal knowledge of the facts set forth in this declaration, and if called as a witness I could and would testify competently under oath to such facts.

2. I am an attorney at the Federal Trade Commission and counsel supporting the Complaint in these proceedings. Attached to this declaration are the exhibits submitted in support of Complaint Counsel's Response to Respondent's Motion to Dismiss.

3. Tab 1 is a true and correct copy of excerpts from CX0513, REDACTED REDACTED dated September 2008, pages 1 to 7, 30.

4. Tab 2 is a true and correct copy of an article from the Dental Tribune titled "Interview with Prof. Van B. Haywood, USA, about bleaching sensitivity" dated December 17, 2010.

5. Tab 3 is a true and correct copy of an article by Dr. Van Haywood titled "The Food and Drug Administration and its influence on home bleaching."

6. Tab 4 is a true and correct copy of CX0652, the public version of a letter to Margaret Hamburg, M.D., Commissioner, U.S. Food and Drug Administration from W. Greg Collier, Ph.D. of The Proctor & Gamble Company dated April 28, 2010.

I declare under the penalty of perjury that foregoing is true and correct. Executed this 28th day of December, 2010, at Washington, D.C.

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TAB 1 IS A CONFIDENTIAL DOCUMENT AND HAS BEEN REDACTED IN ITS ENTIRETY

TAB 1

TAB 2

DENTAL TRIBUNE
The World's Dental Newspaper

Prof. Van B. Haywood

May 28, 2009 | USA

Interview with Prof. Van B. Haywood, USA, about bleaching sensitivity

by Claudia Salwiczek, DTI

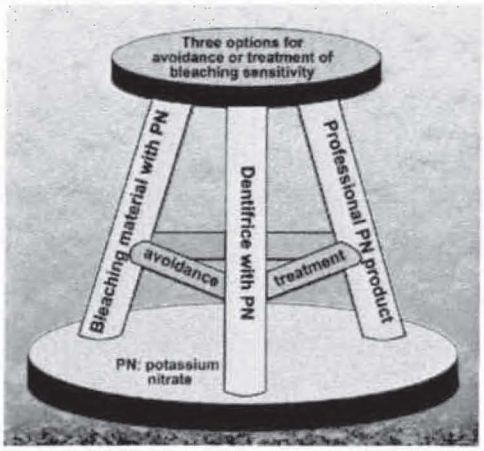
Dr Van B. Haywood is a Professor in the Department of Oral Rehabilitation in the School of Dentistry at the Medical College of Georgia. In 1989, Dr Haywood and Prof. Harald Heymann co-authored the first article in the world on nightguard vital bleaching (NGVB). He has completed over 90 publications on the NGVB technique and the topic of bleaching and aesthetics, including the first papers on treatment of bleaching sensitivity with potassium nitrate, direct thermoplastic tray fabrication, extended treatment of tetracycline stained teeth, and primary teeth bleaching. *Dental Tribune* Editor Claudia Salwiczek spoke with Dr Haywood about bleaching sensitivity.

Claudia Salwiczek: Tooth sensitivity is the single most significant deterrent to the very popular dental bleaching. How well do we understand this condition?

Prof. Haywood: Tooth sensitivity is the most common side effect of bleaching. Whereas all of the typical causes of dentine hypersensitivity generally involve the hydrodynamic theory of fluid flow, the sensitivity associated with bleaching seems to have a different origin. In bleaching situations, the teeth may be in an excellent condition, with no cracks, exposed dentine, or deep restorations, but following a few days of bleaching, the tooth may experience severe sensitivity. This seems to be related to the easy passage of hydrogen peroxide and urea through the intact enamel and dentine in the interstitial spaces into the pulp within 5 to 15 minutes. The tooth is a semi-permeable membrane that is quite open to molecules of a certain size. Once it is understood how easily the peroxide penetrates the tooth, the resultant pulpal response of sensitivity may be considered a reversible pulpitis.

RELATED ARTICLES

The basics of dentine hypersensitivity



Sensitivity avoidance and treatment involves potassium nitrate in a variety of delivery vehicles and techniques.

Can bleaching sensitivity cause damage in the long term?
Although penetration of peroxide through the tooth to the pulp can produce sensitivity, the pulp remains healthy and the sensitivity is completely reversible when treatment is terminated. No long-term sequelae remain after the sensitivity has abated.

Research has shown that patients have tooth sensitivity even when using non-bleaching agent in a tray, or just wearing a tray alone. Hence, it is not possible to have all patients be sensitivity free because of the mechanical forces of the materials and occlusion, and some plans must be made to address potential problems.

How can bleaching sensitivity be prevented?
Reliable methods for complete prevention have not yet been established. However, a history of sensitive teeth and the patient's response during examination can be reasonable predictors. The tooth's response to bleaching is individualistic and can only be determined by starting treatment. Most reports of sensitivity occur within the first two weeks. Often, these report a single day of sensitivity, followed by no problems the next day.

Because tooth sensitivity mainly depends on inherent patient sensitivity, frequency of application and concentration of the material, a history of sensitivity should be determined during examination. Existing sensitivity can be determined from the preoperative exam by simple methods of explorer contact with areas on the teeth or air blown on the teeth.

Patients must be counselled on the frequency of application and the appropriate concentration of bleaching agent. They need to be aware that applications more than once a day or higher concentrations of bleaching agent can increase the likelihood of sensitivity. Patients with pre-existing tooth sensitivity must be cautioned that increased sensitivity, albeit transitory, may occur and that management of the sensitivity may require a longer time span for bleaching as a result of the additional time to treat the sensitivity.

What treatment objectives are available?
No bleaching treatment should be initiated without a proper dental examination, which generally includes radiographs and determines a diagnosis for the cause of the discolouration. The examination should include an explanation to the patient of all their treatment options, considering existing restorations—which will not bleach—and other aesthetic needs. It should be noted that there are several causes of discolouration (abscessed teeth, caries, internal or external resorption) for which bleaching will mask the indication of pathology but not resolve the problem. Other treatments will be required before or instead of bleaching.

Sensitivity may be treated actively or passively, but at-home treatment is most favourable. Passive treatment involves reducing the frequency of application or the duration of treatment, or interrupting continuous application. Active treatment involves using a material with potassium nitrate in the product, applying potassium nitrate instead of bleaching material in the tray for 10 to 30 minutes when needed, and pre-brushing with potassium nitrate toothpaste for two weeks before bleaching initiation. Wearing the tray alone or with potassium nitrate before bleaching can also minimise patients' perceived pain responses.

How effective are the desensitising toothpastes available on the market, and how do they work?
The most common, professionally endorsed, self-applied approach to treating sensitive teeth is the use of desensitising toothpastes, which contain potassium salts (nitrate or chloride). Potassium ions pass easily through the enamel and dentine to the pulp in a matter of minutes. Potassium is believed to act by interfering with the transmission of the stimuli, by depolarising the nerve surrounding the odontoblast process. Most potassium-base desensitising toothpastes also contain fluoride for cavity protection, and some offer an array of flavours and the whitening, tartar-control, and baking soda benefits found in most regular toothpastes.

In clinical trials, the desensitising effect of brushing with anti-sensitivity toothpaste generally takes about two weeks of application twice per day to show reduction in sensitivity, and greater effect develops with continued use. The patient should be advised in accordance with the manufacturer's instructions, typically to be applied by brushing twice daily as a part of the regular oral hygiene regime.

What is your recommendation to dentists performing bleaching procedures?
The biggest challenge in aesthetic dentistry is to maintain the ethics of the dental profession, and to place patient care ahead of financial gain. Patients should be presented with all options for treatment, including the cost/benefit ratio and the risk/benefit ratio, based on research where possible. Conservative treatment that preserves enamel and tooth structure is always preferred. My credo, which has worked well for me AND my patients in the past, is: "Do unto others as you would have them do unto you."

Thank you very much for the interview.

Editorial note: For more information on sensitivity please read Pashley DH, Tay FR, Haywood VB, Collins MA, Drisko CL: Dentin Hypersensitivity: Consensus-Based Recommendations for the Diagnosis & Management of Dentin Hypersensitivity. Inside Dentistry, October 2008, Volume 4, Number 9 (Special Issue).

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Abbrechen

TAB 3

The Food and Drug Administration and its influence on home bleaching

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The era of bleaching vital teeth has captured the attention of the dental profession, the public, the media, and the government. This method, using a custom-fitted mouthguard and a carbamide peroxide solution, is known as home bleaching, matrix bleaching, nightguard vital bleaching, passive bleaching, and dentist-prescribed-home-applied bleaching. Recent action of the US Food and Drug Administration and continued research and clinical experience in the area have provided favorable and unfavorable information about the variations of the technique. This article discusses these variations, with the general conclusion that the technique of vital tooth bleaching, when administered by a dentist using a custom-fitted mouthguard, is as safe as many other routinely performed dental procedures.

Current Opinion in Cosmetic Dentistry 1993:12–18

This article reviews the past year's literature concerning vital teeth bleaching using the technique of a custom-fitted mouthguard and a carbamide peroxide solution. The article also comments on the actions taken by the US Food and Drug Administration (FDA) regarding vital teeth bleaching.

Many terms have been used to describe this bleaching technique, *eg*, mouthguard vital bleaching, matrix bleaching, home bleaching, passive bleaching, and dentist-prescribed–home-applied bleaching. These terms describe a treatment supervised by the dentist whereby a 10% carbamide peroxide solution is placed into a custom-fitted mouthguard and is worn home by the patient. However, many variations and improvements on the original technique have been made. Some of the variations include techniques not meant to be prescribed or administered by the dentist, but which should rather be performed entirely by the consumer. These consumer techniques are referred to as over-the-counter systems, but sometimes are called home bleaching systems. These over-the-counter products are sold directly to the consumer in retail stores and through advertisements. The availability of these over-the-counter products, which are sold directly to the public, has recently involved the FDA, whose role is to protect the consumer. The FDA has no connection with each state's dental practice act; thus its actions do not restrict dentists from providing this bleaching service to their patients. However, FDA actions will be reflected in the patients's perceptions of available treatment options in dental practice [1•].

History of home bleaching

The mouthguard vital-bleaching technique was formally introduced to the dental profession in 1989 [2–4]. The popularity and variations of this technique progressed so rapidly that product claims often exceeded the proof of research or clinical experience. In addition to the treatment offered by the dentist, many product variations were marketed directly to the consumer. The American Dental Association (ADA) was deluged with questions of safety and efficacy, approval of products, and long-term outcomes. Product advertisements appeared not only in dental journals but also in magazines, retail stores, and on television. The ADA deferred some of the questions to the FDA [5]. The FDA ruled in November 1991 that the use of carbamide peroxide in the form advocated for home bleaching constituted a new drug use, and hence was subject to the new drug approval process [6]. In its ruling, the FDA included all vital bleaching products except for the in-office, 35% hydrogen peroxide bleaching technique. The FDA did not make a distinction between the 10% carbamide or hydrogen peroxide materials prescribed by a dentist or those materials that were available directly to the consumer [7]. The in-office, 35% hydrogen peroxide technique has never been approved by the FDA; this is true for many treatments used by dentists. The FDA considered 35% hydrogen peroxide to be "grandfathered" from its long use in the dental office and was not aware that any manufacturer sold this chemical with claims for teeth bleaching (FDA, Per-

Abbreviations

ADA—American Dental Association; FDA—Food and Drug Administration.

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sonal communication). Recent literature has shown the history of the mouthguard vital-bleaching technique to date to the late 1960s; the knowledge of its effects dates to the late 1800s. Hence, the mouthguard vital-bleaching technique also has some history of successful use earlier than its formal introduction in 1989 [8••].

The FDA ruled that within 15 days from the receipt of the FDA notice, any manufacturer selling a material with claims to bleach teeth must submit information or evidence demonstrating the safety and efficacy of the material [9]. This action forced many small manufacturers to face closure because they lacked the resources to demonstrate safety and efficacy. In some instances, the removal of a product could be beneficial, based on the inferior quality of the product, the lack of efficacy, or the questionable safety. There have been many concerns about the efficacy of the over-the-counter kits, and the potential for harm from overuse of an acidic product with no efficacy [8••]. In other instances, removal of products that are available to the dentist could limit competitive marketing by removing adequate but less costly materials. A restricted market to the dentist could result in increased patient costs. In all instances the FDA action raised public concern about the dentist-prescribed method of tooth bleaching, and forced manufacturers to examine whether their products could meet the new drug standards. The new drug approval process is lengthy and costly, but certainly important when necessary. However, whether that process is necessary for 10% carbamide peroxide as used in the custom-fitted mouthguard is not clear.

Table 1. Product options for home bleaching

Only dentist can directly obtain a material from the manufacturer.
Dentist or patient can obtain a material over the counter that can be used for bleaching using the proper application technique (the manufacturer makes no claim that product will bleach teeth).
Patient can obtain a material over the counter that is also sold directly to the dentist.
Patient can obtain a bleaching kit over the counter.

The FDA's decision that home-bleaching agents should be classified as new drugs is based on the contention that the bleaching process causes a structural change in the tooth (a part of the body), and hence, the material should be classified as a drug. The manufacturers contend that there is no change in structure, only in color, and hence, the material is a cosmetic. At this time, no explicit research demonstrates which portion of the tooth changes color, and whether this change is structural [10•] or merely a change in a "color-center" that does not alter the structural properties of the tooth [11]. There has been some controversy about whether dentin is bleached [12]. Hence, a clear ruling in this area cannot be made.

Table 2. Delivery techniques for home bleaching

The dentist fabricates a custom, vacuum-formed tray from a stone cast of the patient's mouth.
The dentist fabricates a boil and form tray in the patient's mouth or on a stone cast.
The patient fabricates a boil and form tray in his or her mouth at home.
The patient uses a three-step kit technique, whereby the active agent is applied with a cotton swab at home.

A preliminary injunction against the FDA ruling that is pending by one of the manufacturers of a bleaching product, as well as safety and efficacy data that have been presented to the FDA by several companies, have prompted the FDA to reconsider its initial position. According to one company, "the FDA is presently reviewing its position on the proper classification of these products, and it has notified the manufacturer that it will do nothing to interfere with the continued manufacture and sale of bleaching products, or their use by patients under the dentist's supervision" [13]. This new position taken by the FDA seems to apply to all related bleaching materials at this time. In addition to the action taken by the FDA, several manufacturing companies own patents on various aspects of the bleaching process. The validity of these patents is also in contention among companies. It is unknown what effect these patents will have on future care delivery for dental patients.

In the dentist's interaction with the ADA, the FDA, and the public, the determination of the proper name for the material and procedure is still a source of confusion. The first article on the technique described the use of a custom-fitted mouthguard fabricated by the dentist who prescribed a material (Proxigel; Reed & Carnrick, Piscataway, NJ) that was available over the counter [8••]. However, the technique in the article is a dentist-prescribed–home-applied technique. Although the material cited in the original article had been available over the counter for intraoral use for almost 20 years, the dentist-prescribed–home-applied bleaching technique has not been equated with the over-the-counter kits now being sold in stores and on television. This question of correct terminology is further confused because some dental manufacturing companies sell their products directly to the dentist and market the products directly to the consumer. The various product purchase options for home bleaching materials are shown in Table 1. Additionally, various application techniques are available to the dentist and the patient (Table 2). The various combinations of materials and application methods create much confusion about which technique is meant by the term "home bleaching." This understanding is crucial to any discussion because certain materials and techniques are well researched, whereas others are merely conjecture. There are many reasons why the best treatment option still seems to be the use of dentist-prescribed materials in

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a custom-fitted mouthguard (Tables 3 and 4). The only disadvantage of the dentist-prescribed method using a custom-fitted mouthguard is the increased cost to the patient because of the number of appointments and the time involved for each visit. However, the advantages shown seem to far outweigh the disadvantages when the fee for the service is appropriate.

Table 3. Reasons for dentist-supervised bleaching

Correct diagnosis of discoloration must be made before treatment.
Inappropriate treatment is not initiated on conditions that require different treatment, such as caries, abscessed teeth, and internal resorption.
Appropriate treatment is not delayed for actual conditions while inappropriate bleaching is being performed.
Baseline status of oral conditions is recorded by a professional for future reference.
Radiographs can be taken to determine pulpal status and potential for poor outcome due to pulp chamber size discrepancy.
Professional determination of any lesion is made during treatment. Lesions could be a result of treatment, or could be a sign of a different problem occurring during the treatment time but unrelated to treatment.
The dentist can manage side effects as they occur, and recognize their relation to the treatment regimen or the need for a new mouthguard style.
More potent or highly viscous materials are available to the dentist. This material is retained in the mouthguard more efficiently, especially when tissue contact is a concern.
The dentist is familiar with the potential for success, and the determination of unsuccessful outcomes.
The dentist can easily identify existing restorative materials, and the possible need for replacement, should the technique be successful. Often the cost involved with the replacement of composites or crowns is a contraindication for bleaching, even though the teeth would respond quite well. The fee for the service must be weighed against other services that would be required after treatment.

Effects of the Food and Drug Administration action

Although the initial action taken by the FDA appeared to be negative for patients and dentists, there have been some positive effects. The questions raised by the FDA on bleaching have involved the private dentist in a new and exciting way. In seeking answers to these questions, more dentists are reading published laboratory and clinical research materials. In doing so, those dentist have been reminded that all laboratory research does not easily translate directly to the clinical environment. Dentists also have had to distinguish between the products with good research reports, and the products whose claims may be a good-sounding but unproved application of the material or technique [14]. This learning process also has demonstrated the importance of differentiating between the different materials and techniques when used together, rather than considering only the material without the appropriate application technique. The emergence of the controversy with this technique has reinforced the need for good research to support private practice, and the need for the general dentist to be the continual learner.

The controversy about bleaching has occurred in what is a new era for the ADA. Along with the tremendous public interest and controversy involving amalgam and fluoride, bleaching also has brought the ADA leaders into a fast-paced public arena. The public's questions have demonstrated to all dentists the importance of having a professional organization, and making that organization available to speak to the press and the public about dentistry. The questions that have been raised demonstrate the need for individuals in a profession to be members of a common organization, and for the professional organization to use a forum to discuss policy and to make decisions other than through the local newspapers and press releases. The continuing challenge for the ADA is to be ready to speak dynamically for the profession from a defensible position, and to become accustomed to being even more in the public eye in a pro-active way.

Table 4. Reasons for a dentist-inserted vacuum-formed mouthguard

An appropriate fit of the mouthguard can be determined to minimize side effects due to tissue or tooth irritation from an ill-fitting mouthguard.
A thinner, more comfortable mouthguard may be constructed to ensure the necessary duration of wear required for success of treatment.
The patient is not subjected to the dangers of self-fabrication of mouthguard using boiling water.
The dentist can fabricate a custom-fitted mouthguard that does not cover tissue, should the tissue warrant it.
Adaptation of a custom-fitted mouthguard minimizes the amount of material used, and ensures the position of the material in desirable locations.
The dentist can adjust the occlusion on the mouthguard to minimize any potential temporomandibular joint. problems.

In the research community, the FDA requirement that manufacturers submit safety and efficacy information has highlighted a new area for research, and has increased the motivation for funding from industrial sources. The questions raised by the FDA and the public have shown the importance of good laboratory and clinical research, and the responsibility of the average dentist to relate to those areas. The need and opportunity for research funding from industrial sources at a time when National Institutes of Health funding is difficult to receive has been emphasized. Manufacturers must alter past actions and act as independent funding sources in the future to be credible among the

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research community and practicing dentists. The resultant data then must be published in peer-reviewed journals, rather than in advertisements. The need for rapid information in an ever-changing dental world demonstrates the importance of timely research meetings to share scientific knowledge. These meetings include the American Association for Dental Research, the International Association for Dental Research, and various ADA symposia. Also, the practicing dentist as well as the manufacturer need to be aware of each scientific forum and its strengths and weaknesses. For example, abstracts are not refereed to the extent of a published paper, so they should not be given the same weight of credibility. However, abstracts can indicate the future knowledge that may be available in 1 to 2 years, pose questions, and share research protocols.

Literature review

Clinical studies

In a well-done double-blind clinical study, 37 patients were studied for 6 weeks. The study determined that 10% carbamide peroxide, applied under professional supervision in a custom-fabricated tray for 24 hours (in 1- to 2-hour intervals per day) was an effective agent for whitening vital teeth [15••]. Adverse effects to teeth and soft tissue were minimal and reversible in the study. An extensive survey of 7617 dentists in the United States, Canada, and Scandinavia showed that more than 90% used carbamide peroxide formulations, and more than 50% of those used a brand sold to dentists only [16••]. Of the respondents, 90% perceived patient satisfaction as good to excellent and 34% of the respondents reported seeing no postuse problems. When problems were present, gingival irritation and tooth sensitivity were the most common. In the more than 2 years since the concept was introduced, most treated teeth have not required rebleaching. Eighty-nine percent of the patients considered home bleaching a successful technique, preferable to in-office tooth bleaching procedures, and more than 90% indicated a desire to continue using the method as a routine procedure. This report continues to recommend the purchase of products from established dental companies and the administration and supervision of home tooth-bleaching products by dentists. This report also questions the unsubstantiated overstatement of dangers by some authors who compare the reported possible effects of 10% carbamide peroxide with research published on the effects of 30% hydrogen peroxide on the teeth. According to this paper, the current need is for clinically relevant biocompatibility studies and measures that stipulate dentist supervision and administration of products. Other clinical studies demonstrate the effectiveness of this type of bleaching [17,18]. Longevity is still undefined [19,20]. No detrimental effects on the gingiva were noted with daily application times of up to 2 hours for 6 weeks [21]. This finding may be related to the increase in salivary pH on insertion of the mouthguard [22].

Laboratory studies demonstrated that there is an immediate reduction in the bond strength of composite-to-etched enamel if the enamel is bleached before insertion [23•]. This reduction is transient, and can be resolved by either waiting more than a day before etching and bonding, or by roughening the surface of the enamel before etching and bonding [24•]. The reduction is attributed to residual peroxide at the surface, which inhibits the set of the composite. Several abstracts also demonstrated this fact [25–27].

Laboratory studies on composite showed some softening with certain brands of carbamide peroxide, but proposed that this softening may be no worse than that caused by food [28•]. However, it may be prudent to inform patients of the potential for the aging of their composites. Another abstract suggested that bleaching with peroxide increased the strength of the composite owing to continuing surface polymerization from the peroxide decomposition [29]. In a class V study on composites, it was determined that although there was no leakage in the enamel-composite junction, there was more leakage at the cementum-composite junction in the bleached teeth than demonstrated in control subjects for some composite materials (Prisma A.P.H; Caulk Dentsply, Milford, DE) but not for other materials (Silux Plus; 3M Dental Products, St. Paul, MN) [30•]. It was unclear whether the effect was in the tooth structure, the dentin bonding agent, the smear layer, or the resin.

One laboratory study evaluated the effects of different types of bleaching agents on enamel, including some of the true over-the-counter products [31]. The results varied between teeth, but showed some surface alterations. The effects of the various acidic prerinses for some of the materials was not distinguished from the bleaching effects. Further study is requested by the author. Another laboratory study demonstrated the cytotoxicity of 10% carbamide peroxide, and postulated why this finding may not be significant clinically [32]. The article also discusses the many other cytotoxic dental materials that are routinely used.

Application techniques

Some articles presented unique application techniques, such as bleaching a single tooth using a polycarbonate crown former as the matrix [33], or combining bleaching with microabrasion [34]. Another article demonstrated the techniques for single-tooth bleaching, both when the color of the adjacent teeth is to be maintained and when the adjacent teeth are to be lightened [8••]. This article also enumerated the many applications for the restorative dentist, including extending the life of the existing prosthesis when the adjacent teeth have discolored, improving the preoperative shade of natural teeth before placement of the prosthesis, harmonizing the postoperative shade between the prosthesis and the natural dentition, and bleaching nonvital teeth

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that have previously been internally bleached but are now restored.

Table 5. Systems for in-office bleaching*

Type of system	Manufacturer and location
Conventional 35% bleaching liquid for use with rubber dam and heat or light activation	Superoxol, Union Broach, York, PA
Regular 35% hydrogen peroxide bleaching gel for use with rubber dam	Starbrite Labs, Murray, UT
Fast 35% hydrogen peroxide bleaching gel for use with rubber dam and composite curing light activation	Hi Lite, Shofu, Dental Corp., Menlo Park, CA
Thirty-five percent carbamide (approximately 10% hydrogen peroxide) for use with paint-on rubber dam	Quick-Start, Den-Mat Corp., Santa Monica, CA

*None of these systems have been affected by the Food and Drug Administration action, nor are they approved by the Food and Drug Administration

Opinions and overviews

Most of the articles published during this time frame were opinions of the process, or overviews of the materials and techniques available for use. Opinions ranged from not believing that vital teeth bleaching was effective [35] to endorsing it for the profession [36•,37•,38••]. Good data have now been collected from many dentists, and the consensus of the data is that the bleaching is effective in 90% of the situations, with minimal side effects, and is an accepted dental treatment when supervised by a dentist [8••,36•,39]. The ADA demonstrated such a technique in a television program about tooth whiteners (Tooth Whiteners and Public Health Dentistry and Prevention, Dentistry Update, August 16, 1992, Lifetime Medical Television). Some of the best summaries of current research and knowledge in the area of bleaching may be found in some of these position articles or replies to concerns [40•,41,42•,43–45]. Information concerning patient instructions and appointment scheduling is also included [46].

In-office bleaching advances

Action taken by the FDA has also driven manufacturers to develop more materials that would be suitable for in-office bleaching techniques (Table 5). These materials also satisfy the patient who is not interested or inclined to wear the mouthguard for an extended period of time, and also benefit certain single-tooth situations.

There are also instances when the combination of the in-office and home bleaching is more beneficial than either of the two alone [8••,47]. Etching with phosphoric acid before bleaching the teeth does not seem to be necessary for in-office bleaching effectiveness, although some of the manufacturers still include this in their instructions [48].

The interest in bleaching has inspired manufacturers to introduce systems with more conventional methods of activation (composite curing light), or systems that do not require heat or light activation. Research has not been done at this time on whether a particular system is better, faster, or more effective in these areas. However, the system activated by a composite curing light (Hi Lite; Shofu Dental Corp, Menlo Park, CA) is very promising [49•]. This system requires the use of a rubber dam, but the time needed for the peroxide to oxidize with the light is relatively short (3 minutes). Use of this system is indicated when there may be a single dark tooth from excess secondary dentin, canine teeth that are darker than the remaining dentition, and in some cases of tetracycline banding. When multiple teeth are bleached, the use of the light has little advantage. Because the material will chemically oxidize in 8 minutes, it may be used in the same manner as other gel materials (Starbrite; Stardent Laboratories, Murray, UT). Hi Lite may be especially useful on nonvital teeth. The root portion of the tooth is sealed from the pulp chamber as in the walking bleach technique. Then the material may be placed on the internal and external aspects of the tooth and may be activated with the composite curing light for several applications at one appointment. With this system, and with conventional composite materials, the dentist must ensure that the composite curing light is operating at sufficient strength. Many testing devices are available to the private practitioner for this evaluation. The light tip must not contact the solution during the bleaching.

Conclusions

The hallmark of a profession is that it regulates itself. The action of the FDA was a way to regulate the manufacturer, because the FDA is concerned with claims by manufacturers about products sold directly to the consumer. The FDA is not involved with the Dental Practice Act, but its actions have an indirect effect on the practicing dentist who offers the home-bleaching service to patients.

The action and impact of the FDA highlights the need for better communication among the research community and the private practitioner, the academic institutions and the ADA, the ADA and its constituents, the profession and the public, and the manufacturers and the materials researchers. Although laboratory results are an important first step, clinical trials ultimately tell the tale.

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In spite of the concerns raised by the FDA, the technique of bleaching vital teeth using 10% carbamide peroxide in a custom-fitted mouthguard supervised by a dentist still seems to be a reasonable treatment option for the dentist. However, this treatment should remain as a professionally administered service, rather than being performed unsupervised. Dentists and manufacturers should strive to keep the fee for the service as cost-effective as possible, while still maintaining the proper examination and best management for the patient. Manufacturers should maintain the proper amount of unbiased research to support their claims. The ADA should continue to seek ways to effectively communicate among the different components of the manufacturer, dentist, patient, public, and government relationship.

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Van B. Haywood, DMD, Associate Professor, Department of Operative Dentistry, School of Dentistry, CB 7450, University of North Carolina, Chapel Hill, NC 27599–7450, USA.

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TAB 4

Procter&Gamble

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April 28, 2010

Margret Hamburg, MD
Commissioner US Food and Drug Administration
Division of Documents Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: Procter & Gamble's Comments on the November 20th, 2009 American Dental Association's Citizen Petition, Regulatory Treatment of Tooth Whitening Preparations

Dear Commissioner Hamburg,

In accordance with 21 CFR §10.30(d), The Procter & Gamble Company (P&G) respectfully submits the following comments for your consideration regarding the American Dental Association (ADA) Citizen's Petition (ADA Petition) filed on November 20th, 2009 which requested that the FDA review and establish appropriate regulatory classification of tooth whitening preparations.

P&G disagrees with the assertions in the ADA Petition that all direct-to-consumer tooth whitening products that act by chemical means to lighten tooth color are easily over-used and abused, and that the manufacturers of such products must conduct new studies to ensure their safety. Crest Whitestrips was introduced in 2000. Since that time, over 50 million Crest Whitestrips products have been used representing more than one billion potential exposures. Additionally, the products have been tested extensively. The wealth of published data referenced below and summarized in Attachment I support the safety of Crest Whitestrips. Further, we believe that Crest Whitestrips are correctly classified as cosmetic products.

The ADA Petition contains the certification required by 21 CFR §10.30(b) that to the best of the petitioner's knowledge, the petition contains all relevant information and views *including representative data and information known to the petitioner that are unfavorable to the petition* (emphasis added). **Despite this certification, we believe that the Petition does not reflect information known by the ADA to be unfavorable to its position.** The Petition relies heavily on an attached report prepared under the direction of the ADA Council on Scientific Affairs and entitled "Tooth Whitening/Bleaching Treatment Considerations for Dentists and Their Patients. This report cites a number of safety and usage concerns regarding certain consumer-use whitening products. There is published and easily accessible scientific literature that addresses most of these concerns, but these are not referenced in the Petition or report. Furthermore, over the last several years, P&G has shared these published data with the ADA on multiple occasions.

FDA-2009-P-0566

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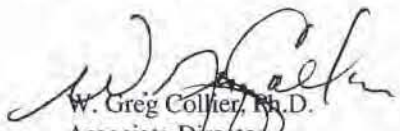
A summary of this large body of literature and the corresponding references are provided in Attachment I to this correspondence.

P&G has separately asked the ADA to update their Petition to reflect this published data and thus conform to the certification requirements, but to our knowledge this has not happened. P&G believes this is evidence that the ADA Petition is motivated primarily by the commercial interests of ADA membership and that their desired outcome is to restrict direct-to-consumer access to tooth-whiteners that offer results comparable to in-office and dentist-dispensed products.

For the reasons stated above, P&G respectfully requests that FDA deny the Petition.

Sincerely
THE PROCTER & GAMBLE COMPANY



W. Greg Collier, Ph.D.
Associate Director
Oral Care Product Safety and Regulatory Affairs and Safety Surveillance

Attachment I
Published Literature on Crest Whitestrips 2000 to 2010

Tooth whitening with peroxides began more than 25 years ago and gained significant popularity in the late 1980's via tray application of the peroxide gels (both OTC and dentist distributed products). In 2000, the introduction of Whitestrips represented a significant innovation on the delivery system of tooth whiteners (strip) eliminating the need for a tray device. Additionally, strip delivery introduced the added features of controlled application amount and the ability to treat specific dentition through size and shape of the strip. Since the Whitestrips introduction, over 50 million Whitestrips products have been sold representing more than one billion potential exposures to the strip products.

The safety and efficacy of Whitestrips is supported by a thorough and comprehensive battery of clinical trials. Our test populations comprise two general categories, adults (18+) and teens (12-18), across a wide rage of product designs and product usage regimens. For example, Kugel et al. (Comp. Cont. Ed., 2002) report on the safety and efficacy resulting from 2 months of continuous daily usage of 6.5% hydrogen peroxide Whitestrips to eliminate discolorations resulting from tetracycline. In yet another example, Bizhang et al. (Am J Dent, 2007) report on the safety and efficacy of two weeks of Whitestrips product use followed by 18 month follow-up on initial color change retention and safety profile. Our clinical trials database even goes beyond Whitestrips and often includes dentist distributed tray products when used as comparative test legs in the research.

Additionally, a scientifically advanced and thorough pre-clinical program parallels our vast clinical program. This pre-clinical program includes leading edge research on hard tissue (enamel and dentin), restorative materials used in dentistry, and toxicological assessments.

An exemplary list of 42 published clinical trials is attached for reference. The conclusions of the entire body of research are clear:

- ***Strip and peroxide based tooth whitening products are safe and effective when used as directed***. *(1-27, 29, 30, 34, 36-38, 41, 42)*

- ***Hydrogen peroxide based strip products do not alter the microstructure of the tooth surface, the enamel, the dentin or the dentin enamel junction.*** *(40)*

- ***ADA recommended testing shows hydrogen peroxide based strip products do not alter the micro hardness of the restorative materials.*** *(7, 28, 39)*

- ***The whitening effect is a function of concentration and contact time*** where higher concentration products whiten faster and longer contact time yields a better endpoint. *(8, 12, 13-16, 19, 21, 25, 36-38)*

- Transient temporary tooth sensitivity does occur and is more common with higher concentration products within any given formulation and delivery device. ***However, not a single case of unresolved tooth sensitivity was observed upon cessation of product usage.*** Product usage instructions include appropriate information and direction for consumers who experience tooth sensitivity. *(1-6, 8-27, 28-30, 34, 35-38, 41, 42)*

- Transient gingival irritation does occur and is more common with higher concentration products in which the amount of hydrogen peroxide applied per unit area of tissue is also greater. ***Like tooth sensitivity, not a single case of unresolved gingival irritation was observed upon cessation of product usage.*** Product usage instructions include appropriate information and direction for consumers who experience gingival irritation. *(1-6, 8-27, 28-30, 34, 35-38, 41, 42)*

  Note: In contrast to professionally distributed trays, the strip form is the only delivery device which controls the amount of peroxide composition applied per unit area. *Dentist distributed trays use general dosing guidelines for the entire tray. Upon application to the teeth, excess peroxide composition is forced to the gingival margin often resulting in high amounts of hydrogen peroxide applied per unit area. This can lead to a decrease in the tolerability of the product on soft tissue.*

- ***Hydrogen peroxide has been previously reviewed by the FDA Carcinogenicity Assessment Committee and approved by the FDA for use as an indirect food additive (46 FR 2341; January 9, 1981).***

- ***Peroxide based tooth whitening products do not pose a carcinogenic risk and the dosimetric exposure data show margins of safety of greater than 200 fold.*** *(31-33)*

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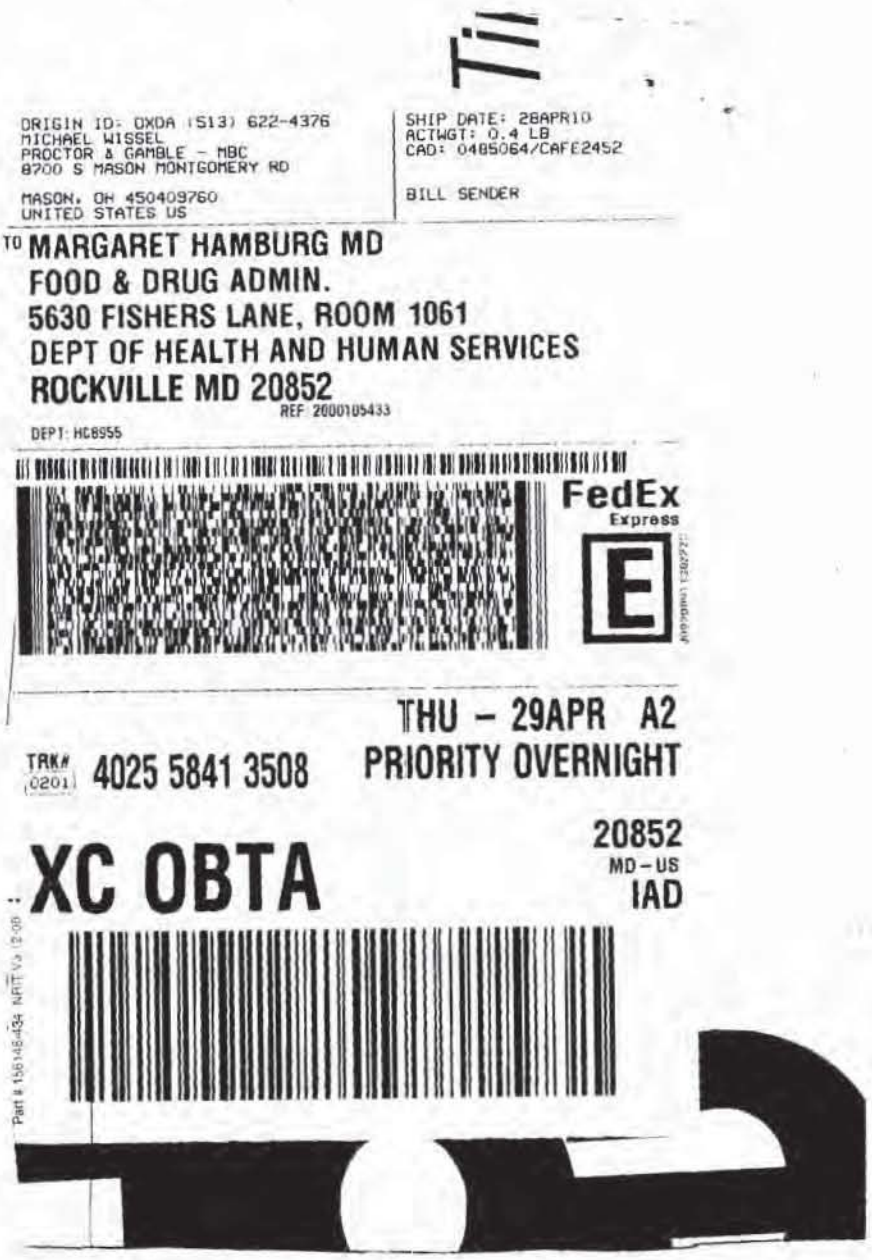
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Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

I further certify that I delivered via electronic mail a copy of the foregoing document to:

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December 28, 2010

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