Appeal: 12-1172 Doc: 36-4 Fileide 00 50 56 120 2021 2 Pg. 92: 01 fo 4848

No. 12-1172

IN THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

THE NORTH CAROLINA STATE BOARD OF DENTAL EXAMINERS,

Petitioner,

V.

FEDERAL TRADE COMMISSION,

Respondent.

Petition for Review From the Federal Trade Commission Docket Number 9343

AMICI CURIAE BRIEF OF AMERICAN DENTAL ASSOCIATION,
AMERICAN OSTEOPATHIC ASSOCIATION, AMERICAN VETERINARY
MEDICAL ASSOCIATION, AMERICAN ACADEMY OF PEDIATRIC
DENTISTRY, AMERICAN ACADEMY OF PERIODONTOLOGY,
AMERICAN ASSOCIATION OF ORTHODONTISTS, AMERICAN
ASSOCIATION OF DENTAL BOARDS, AND FEDERATION OF STATE
MEDICAL BOARDS IN SUPPORT OF THE NORTH CAROLINA
BOARD OF DENTAL EXAMINERS SEEKING REVERSAL

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May 16, 2012

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT DISCLOSURE OF CORPORATE AFFILIATIONS AND OTHER INTERESTS

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No. <u>12</u>	<u>2-1172</u> Caption: <u>The</u>	e North Carolina State Board of Dental Examir	ners v. FTC
Pursua	ant to FRAP 26.1 and Local Rule	26.1,	
Ameri Ass'n Board	ican Academy of Pediatric Den of Orthodontists, American As	steopathic Ass'n, American Veterinary Medic tistry, American Academy of Periodontology ss'n of Dental Boards, and Federation of State	y, American
	s <u>Amici</u> , make lant/appellee/amicus)	es the following disclosure:	
1.	Is party/amicus a publicly held	corporation or other publicly held entity?	□YES ⊠NO
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4.	, ,	I corporation or other publicly held entity est in the outcome of the litigation (Local re of interest:	□YES ⊠NO
5.	If yes, identify any publicly hel could be affected substantially	mici curiae do not complete this question) ld member whose stock or equity value by the outcome of the proceeding or whose pursuing in a representative capacity, or state	□YES □NO
6.	Does this case arise out of a ba	ankruptcy proceeding? rustee and the members of any creditors' comr	□YES ⊠NO nittee:

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INTEREST OF THE AMICI CURIAE

Amici Curiae American Dental Association, American Osteopathic Association, American Veterinary Medical Association, American Academy of Pediatric Dentistry, American Academy of Periodontology, and American Association of Orthodontists are comprised of doctors whose practices are regulated by duly constituted State Boards in all fifty States, the District of Columbia, and U.S. territories. Amici Curiae American Association of Dental Boards and Federation of State Medical Boards are, respectively, the national associations of such Boards in the fields of dentistry and medicine. Each amicus supports the determination by the States that the health professions should be regulated by knowledgeable health care professionals who have practical experience in the profession that they are regulating. Each has a direct interest in assuring that State Regulatory Boards are able to discharge their statutory responsibilities with accountability to the State legislatures that created them -without intervention and second guessing by the Federal Trade Commission ("FTC" or "Commission"), a federal agency that lacks jurisdiction over these Boards, that has no particular expertise in the professions regulated by these Boards, and that, by misapplying the federal antitrust laws, seeks to substitute its concept of the public interest for the position taken by the Board charged by the

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State legislature with determining what is in the public interest in the area of its regulatory authority.¹

Amici, therefore, offer this brief to discuss the jurisdiction of the FTC over State Regulatory Boards and the proper application of the federal antitrust laws to actions of such Boards. These are important issues for amici because the FTC has repeatedly sought to interject itself into the decision-making process of duly constituted State Regulatory Boards in medicine and dentistry. Amici urge this Court to rule that the FTC is without jurisdiction over such Boards and that, even if the FTC has jurisdiction, the federal antitrust laws do not extend to actions of a State Board exercising its authority conferred by the State legislature. Such a ruling is necessary to prevent the FTC from interfering with efforts by such Boards

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¹ This brief is submitted with the consent of both parties. The letters of consent are reproduced as Attachments 1 and 2 to Amici's Motion For Leave To File, filed concurrently herewith. Pursuant to Fourth Circuit Rule 29(c)(5), *Amici Curiae* certify that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; and no person – other than *amici curiae* – contributed money that was intended to fund preparing or submitting this brief.

² See, e.g., November 3, 2010 letter from FTC staff to Patricia E. Shaver, General Counsel of the Alabama State Board of Medical Examiners regarding a proposed rule on interventional pain management (Attachment 1). The FTC also has sued State Boards over actions which the Commission sees as suppressing competition, such as the case here on appeal. See, e.g., Va. Bd. Of Funeral Dirs. & Embalmers, 138 F.T.C. 645 (2004); S.C. State Bd. Of Dentistry, 138 F.T.C. 229 (2004); Mass. Bd. Of Registration in Optometry, 110 F.T.C. 549 (1988); and In re Okla. State Bd. of Veterinary Medical Examiners, 1990 WL 10012617 (1990).

³ *Amici* take no position on the merits of the actions of the North Carolina State Board of Dental Examiners with respect to tooth whitening clinics. Rather, this brief addresses the issues of whether the FTC has jurisdiction over the Board and, if so, how the federal antitrust laws apply to actions by a State Regulatory Board addressing an issue within its legislative grant of authority.

to protect the public health and to help assure that health care practitioners have the education, training, and experience to deliver quality care for patients.

ARGUMENT

I. The FTC Lacks Jurisdiction Over The North Carolina State Board of Dental Examiners.

Under § 5(a)(2) of the Federal Trade Commission Act ("the FTC Act" or "the Act"), the FTC is empowered to prevent the use of "unfair methods of competition in or affecting commerce by persons, partnerships, or corporations."

15 U.S.C. § 45(a)(2). A threshold question, therefore, is whether the North Carolina State Board of Dental Examiners ("the Dental Board" or "Board") comes within the phrase "persons, partnerships, or corporations" as used in § 5(a)(2). The answer is no.

Initially, the Dental Board is not alleged to be a "partnership." Nor is it alleged to be a "corporation." The term "corporation" is defined in § 44 of the FTC Act, 15 U.S.C. § 44, "to include any company . . . or association, incorporated or unincorporated, which is organized to carry on business for its own profit or that of its members." The Dental Board is not a "company" or an "association" – it is a state agency. It is not "organized to carry on business" at all. Instead, it is organized to regulate the practice of dentistry in North Carolina. N.C. Gen. Stat. § 90-22(b). Indeed, the FTC conceded that the Dental Board is not a "corporation" under § 5(a)(2) when, in its Opinion of February 3, 2011, the FTC asserted that the

holding of the Supreme Court in *California Dental Ass'n v. F.T.C.*, 526 U.S. 756 (1999), is "inapposite in this case where jurisdiction is asserted over a 'person,' not a 'corporation.'" *North Carolina Bd. Of Dental Eximiners*, 151 F.T.C. 607, 614 (Fed. 3, 2011).

Contrary to the FTC's decision, the Dental Board is not a person within the meaning of § 5(a)(2), 15 U.S.C. § 45(a)(2). The word "persons" in that context must refer to natural persons. Otherwise, the words "partnerships" and "corporations" would be surplusage because they would be subsumed within the term "persons" as interpreted by the FTC. This result cannot be correct because "legislative enactments should not be construed to render their provisions mere surplusage." *Dunn v. Commodity Futures Trading Commission*, 519 U.S. 465, 472 (1997). It does not "respect Congress" decision to use different terms to describe different categories of people or things." *Mohamad v. Palestinian Authority*, 132 S.Ct. 1702, 1708 (2012).

The FTC attempts to justify its position that the Dental Board is a "person" in two ways. First, it relies on the fact that it "has many times exercised jurisdiction over state boards as 'persons' under the FTC Act." 151 F.T.C. at 614. The FTC cites as support three of its prior decisions -- *Va. Bd. Of Funeral Dirs.* & *Embalmers*, 138 F.T.C. 645 (2004); *S.C. State Bd. of Dentistry*, 138 F.T.C. 229 (2004); and *Mass. Bd. Of Registration in Optometry*, 110 F.T.C. 549 (1988).

However, the FTC can hardly demonstrate the validity of its position based on its own prior decisions that were never reviewed by a court. By those decisions, the FTC cannot give itself jurisdiction that Congress did not confer upon it.

Second, the FTC argues that "[t]he Supreme Court has held that states and their regulatory bodies constitute 'persons' under the antitrust laws." 151 F.T.C. at 614 (citing *Jefferson County Pharm. Ass'n v. Abbott Labs*, 460 U.S. 150, 155 (1983); *Lafayette v. La Power & Light Co.*, 435 U.S. 389, 394 (1978); and *Georgia v. Evans*, 316 U.S. 159, 162 (1942)). However, the question before this Court is the meaning of the phrase "persons, partnerships, or corporations" as used in § 5(a)(2) of the FTC Act – not the meaning of the word "persons" under the Sherman Act or the Clayton Act. Significantly, the limiting phrase "persons, partnerships, or corporations" appears nowhere in the Sherman or Clayton Acts. Thus, none of the cases cited by the FTC addresses the specific jurisdictional limitation that is unique to the FTC Act.

In this connection, it is instructive to juxtapose the Clayton Act and the FTC Act because both Acts were enacted by the 63rd Congress in 1914. *See United States v. Bldg. Maint. Industries*, 422 U.S. 271, 277 (1975). The 63rd Congress provided in Section 1 of the Clayton Act that "the word 'person' or 'persons,' wherever used in this Act shall be deemed to include corporations and associations existing under or authorized by the laws of either the United States, the laws of any

of the Territories, the laws of any State, or the laws of any foreign country." 15 U.S.C. § 12(a). By use of this broad definition of "persons," Congress made the Clayton Act, like the Sherman Act before it, applicable to all entities affecting commerce. Notably, that definition applies only "wherever used in this Act" – not wherever used in the FTC Act.

The 63rd Congress carefully limited the jurisdiction of the FTC to "persons, partnerships, or corporations." The FTC has not explained, and cannot explain, why the same Congress enacted a very different jurisdictional reach under the FTC Act as compared with the Clayton Act if that Congress intended for the jurisdictional reach of the two statutes to be the same. There is, however, a compelling explanation for the difference.

The FTC was established in 1914 to regulate ordinary commercial practices of business entities – whether natural persons, partnerships, or corporations. At that time, there was a widespread belief that existing judicial enforcement of the Sherman Act against industrial and commercial enterprises and combinations thereof had been inadequate. *See* S. Rep. No. 1326, 62nd Cong., 3d Sess. 13 (1913); S. Rep. No. 597, 63rd Cong., 2d Sess. 8-9 (1914); H.R. Rep. No. 1142, 63rd Cong., 2d Sess. 18-20 (1914). Congress expected that the new Trade Commission that it was establishing would develop such unique expertise concerning industrial and commercial entities that it would be better able to apply national antitrust

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policy to these entities than would a court.⁴ Accordingly, the whole thrust of the legislative history is that the Act was passed to apply to "industrial business" and, specifically, to manufacturers, dealers and associations, or other combinations thereof.⁵ There was no testimony or discussion related to giving the Commission jurisdiction over State Regulatory Boards. This fact is particularly telling since such Boards had long been in operation in 1914. *See Dent v. West Virginia*, 129 U.S. 114 (1889); *Hawker v. New York*, 170 U.S. 189 (1898).

The limitation on jurisdiction in the FTC Act, but not in the Sherman or Clayton Act, makes perfect sense. The words "persons, partnerships, or corporations" accurately convey the intent of Congress to limit the scope of the FTC's jurisdiction to the three forms in which business is carried on for profit – by persons, by partnerships, and by corporations. This history confirms that Congress did not give the FTC power to second-guess the judgments of State Boards vested with authority by State legislatures to regulate the professions.

Yet another consideration militating against the FTC's reliance on the word "persons" to support its assertion of jurisdiction over the Board is that this

⁴ The legislative history repeatedly emphasized the conviction of Congress that the Trade Commission would be "an administrative body of practical men thoroughly informed in regard to business." H.R. Rep. No. 1142, 63rd Cong., 2d Sess. 18-19 (1914), and would have unique expertise concerning "the business and economic conditions of . . . industry." S. Rep. No. 597, 63rd Cong., 2d Sess. 8-9 (1914).

⁵ See, e.g., n. 6, supra; S. Rep. No. 597, supra, at 11, 28; 51 Cong. Rec. 8840 (Rep. Covington) ("covers industrial business"); *id.* at 8851 (Rep. Stevens (retailers and manufacturers discussed); *id.* at 8986 (Rep. Montague); Community Blood Bank v. FTC, 405 F.2d 1011, 1017-18 (8th Cir. 1969) (quoting letter to Sen. Newlands discussing associations of manufacturers and dealers).

approach renders incorrect or meaningless prior positions taken by the FTC and adopted by the courts in cases such as *California Dental Association v. F.T.C.*, 526 U.S. 756 (1999); *American Medical Association v. F.T.C.*, 638 F.2d 443 (2nd Cir. 1980); *F.T.C. v. National Commission On Egg Nutrition*, 517 F.2d 485 (7th Cir. 1975); and *Community Blood Bank of the Kansas City Area, Inc. v. F.T.C.*, 405 F.2d 1011 (1969). In each of these cases, the FTC took the position that it had jurisdiction over the respondent, not because that entity came within the term "persons" in § 5, but because it came within the term "corporations."

In California Dental, the Supreme Court agreed with the FTC that the term "corporations" encompasses private membership associations that provide substantial economic benefits to their for-profit members. Accord, American Medical Ass'n and Nat'l Comm'n on Egg Nutrition. In Community Blood Bank, by contrast, the Eighth Circuit rejected the FTC's argument that the not-for-profit blood bank organizations and nonprofit hospital associations that were the subject of the complaint were nevertheless corporations under § 5, holding that "the reality of [the corporate petitioners] being in law and in fact charitable organizations places them beyond the reach of the Act." 405 F.2d at 1019. If the FTC's reliance in this case on the word "persons" were correct, then the in-depth analyses in the decision of the Supreme Court in California Dental, and in the decisions of the Courts of Appeals in American Medical Ass'n, National Comm'n on Egg Nutrition

and *Community Blood Bank*, would be rendered meaningless because the Commission would have had jurisdiction over each of these entities as "persons."

In sum, the language and the legislative history of the FTC Act, as well as positions taken by the FTC and the courts in prior cases, point to the inescapable conclusion that the FTC lacks jurisdiction over State Regulatory Boards.

II. The Federal Antitrust Laws Do Not Apply To The Challenged Actions Of The North Carolina State Board of Dental Examiners.

The Supreme Court has consistently held that the federal antitrust laws do not apply to actions taken by state agencies. The Court first announced this "state action doctrine" in the seminal case of *Parker v. Brown*, 317 U.S. 341 (1943). There, plaintiff sued under the Sherman Act to enjoin a California state agency from enforcing a raisin marketing program that sought to stabilize prices under the auspices of the State's Agricultural Prorate Act. Although the program was anticompetitive, the Supreme Court held that it was immune from challenge under the Sherman Act because it "derived its authority . . . from the legislative command of the State." *Id.* at 350.

The Court found nothing in the language or legislative history of the Sherman Act to suggest "that its purpose was to restrain a state or its officers or agents from activities directed by the legislature." *Id.* at 350-51. Rather, "[i]n a dual system of government in which, under the Constitution, the states are sovereign, save only as Congress may constitutionally subtract from their

authority, an unexpressed purpose to nullify a state's control over its officers and agents is not lightly to be attributed to Congress." *Id.* at 350-51. Thus, the Court concluded that the actions of a duly constituted state agency are not subject to the federal antitrust laws.

Thirty-seven years later, in *California Liquor Dealers v. Midcal Aluminum*, 445 U.S. 97 (1980), the Supreme Court summarized its jurisprudence regarding the state action doctrine in cases against non-governmental entities as follows: Where a non-governmental defendant raises the state action doctrine as a defense to an antitrust action, the defendant must show that the challenged restraint was (a) imposed pursuant to a "clearly articulated and affirmatively expressed" state policy and (b) "actively supervised" by the State. *Id.* at 105-106. These two prongs of the *Midcal* test are referred to as the "clear articulation" and the "active state supervision" requirements. The question presented here is how the *Midcal* test governing actions of private entities under the state action doctrine applies to the actions of a State Board.

With respect to the "clear articulation prong," it is enough that the agency is acting pursuant to a general grant of authority to legislate in a specific area. Thus, in *Town of Hallie v. City of Eau Claire*, 471 U.S. 34 (1985), the Supreme Court directly addressed "how clearly a state policy must be articulated for a municipality to be able to establish that its anticompetitive activity constitutes state

action." 471 U.S. at 40. The Court rejected the proposition that, for the conduct of a municipality to qualify for immunity, the state legislature would have had "to have stated explicitly that it expected the City to engage in conduct that would have anticompetitive effects." *Id.* at 42. Rather, the Court held that it is enough if "anticompetitive effects logically would result from the broad authority to regulate." *Id.* Similarly, in *City of Columbia v. Omni Outdoor Adv., Inc.*, 499 U.S. 365 (1991), the Court held that a general grant of zoning power was a "clear articulation" of an intent to displace competition. Thus, a general delegation of authority by the legislature to a State Regulatory Board to regulate a specific profession satisfies the "clear articulation" requirement.

That is precisely the holding of the case most directly on point – *Earles v.*State Board of Certified Pub. Accountants, 139 F.3d 1033 (5th Cir. 1988). There, the Fifth Circuit addressed whether a general grant of authority to the State Board of Certified Public Accountants, an agency comprised entirely of CPAs who competed in the profession regulated by the Board, satisfied the "clear articulation" prong. The Court held that a statute which authorized the Board to "[a]dopt and enforce all rules and regulations, bylaws, and rules of professional conduct as the board may deem necessary and proper to regulate the practice of public accounting in the State of Louisiana" was a sufficient expression of state policy to satisfy the "clear articulation" requirement.

Article 2 of Chapter 90 of the North Carolina Statutes ("Dentistry") explicitly establishes the general authority of the Dental Board to regulate the practice of dentistry in the State. It provides, in part: (1) "[t]he practice of dentistry . . . is hereby declared to affect the public health, safety and welfare and to be subject to regulation and control in the public interest."; (2) "The [Dental Board] . . . is . . . the agency of the State for the regulation of the practice of dentistry in this State"; (3) "The [Dental Board] shall be and is hereby vested, as an agency of the State, with full power and authority to enact rules and regulations governing the practice of dentistry within the State "; and (4) "No person shall engage in the practice of dentistry in this State, or offer or attempt to do so, unless such person is the holder of a valid license or certificate of renewal of license duly issued by the [Dental Board]". N.C. Gen. Stat. §§ 90-22(a) and (b), 90-28(a), 90-29, and 90-48.

Article 2 also includes a detailed list of thirteen "acts or things which . . . constitute the practice of dentistry" that may not be engaged in without "a valid license or certificate of renewal of license duly issued by the [Dental Board]."

N.C. Gen. Stat. § 90-29(a) & (b). Although *Amici* take no position on the merits of the actions of the Dental Board with respect to tooth whitening clinics, it is relevant to the "clear articulation" prong that the list created by the legislature

includes that "[a] person shall be deemed to be practicing dentistry in this State who . . . (2) Removes stains, accretions or deposits from the human teeth."

Here, as in *Town of Hallie*, the enabling statute shows that "the legislature contemplated the kinds of acts complained of." *Id.* 471 U.S. at 41-42 (citations omitted). *See also*, *Cine 42nd Street Theater Corp. v. Nederlander Org.*, 790 F.2d 1032, 1043-44 (2d Cir. 1986). In these circumstances, the "clear articulation" prong is satisfied.

Turning to the "active state supervision" requirement, the Supreme Court observed in *Town of Hallie* that where "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." Id., 471 U.S. at 46, fn.10. Since then, the consensus of federal appellate courts has been that state agencies and other political units created by the State are exempt from this prong. See, e.g., Charley's Taxi Radio Dispatch v. SIDA of Hawaii, Inc., 810 F.2d 869, 876 (9th Cir. 1987) (decisions of the Hawaii Dept. of Transportation and its director entitled to state action immunity); Cine 42nd Street Theater Corp., 790 F.2d at 1047 (Urban Development Corporation authorized by state legislature need not satisfy the state supervision requirement); Porter Testing Lab v. Board of Regents, 993 F.2d 768, 772 (10th Cir. 1993) (showing of active supervision is unnecessary for the State Board of Regents to qualify for state action antitrust immunity). As these cases reflect, where the

action of a state agency is at issue, the very concept of applying an "active state supervision" requirement makes little sense. In essence, it would amount to a requirement that the State supervise itself.⁶

The FTC argues that this case is different because "the decisive majority of the [Dental] Board . . . earns a living by practicing dentistry." 151 F.T.C. at 608. The FTC's theory is that, because the Dental Board is dominated by practicing dentists with an alleged interest in competition by non-dentist providers of teethwhitening services, the actions of the Dental Board are not actions of the State. In effect, the FTC argues that actions of State Regulatory Boards made up of members of the regulated trade or profession are nothing more than anticompetitive activity of private parties clothed in a "gauzy cloak of state involvement." *See Midcal*, 445 U.S. at 106. *See also*, Phillip E. Areeda & Herbert Hovenkamp, *IA Antitrust Law: An Analysis of Antitrust Principles And Their Application*, ¶ 227b, at 501 (3d ed. 2009). Once again, the FTC is wrong.

In support of its position, the FTC relies (151 F.T.C. at 619) on *Goldfarb v*. *Virginia State Bar*, 421 U.S. 773 (1975). That case involved a minimum fee

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⁶ The difficulty of applying the "active state supervision" requirement in this context is reinforced by the FTC's definition of "active state supervision," in this case. The FTC expressed its view that three factors are relevant in determining whether there is active state supervision: "(1) the development of an adequate factual record; (2) a written decision on the merits; and (3) a specific assessment – both quantitative and qualitative – of how the private action in question comports with the substantive standards established by the legislature." 151 F.T.C. at 629. But none of these factors has anything to do with active state supervision. The third factor in particular is a thinly veiled attempt to incorporate the "clearly articulated" prong through the back door of the "active state supervision" prong.

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schedule issued by a county bar association and backed up by ethical opinions of the Virginia State Bar. The Supreme Court held that the fee schedule was not protected by the state action doctrine even though the Virginia State Bar was, for certain purposes, an agency of the State Supreme Court.

Goldfarb does not support the FTC's position for three reasons. First, the challenged fee schedule was issued by a private entity, the county bar association, that did not even purport to be a state agency. Second, although the Virginia State Bar was a state agency for some purposes, it was not acting as a state agency in issuing opinions that deviation from the county bar's fee schedule was unethical. Third, unlike the Dental Board here, the bar associations in Goldfarb were not acting pursuant to an explicit directive from the State legislature.

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⁷ The FTC argues that "there is ample support for the proposition that financially interested governmental bodies must meet the active supervision prong of Midcal." 151 F.T.C. at 620. None of the cases on which the FTC relies involved a State Regulatory Board, such as the Dental Board, acting on matters squarely within its legislative grant of authority. For example, although in Washington State Elec. Contractors Ass'n v. Forest, 930 F.2d 736 (9th Cir. 1991), the Ninth Circuit expressed the view that an Apprentice Council of the State of Washington may not be a state agency under the state action doctrine because it includes private members that may have their own agenda, the one page per curiam decision contains no reasoning, on its face is inconsistent with the Ninth Circuit's decision in Hass v. Oregon State Bar, 883 F.2d 1453 (9th Cir. 1989), where the Oregon State Bar was held not to be subject to the "active" state supervision" requirement even though twelve of the fifteen members of its Board were attorneys, and in any event does not hold that the Apprentice Council is not a state agency, but merely remands the case to the district court for findings on this issue. *Id.* at 737. In FTC v. Monahan, 832 F.2d 688 (1st Cir. 1987), the First Circuit suggests, not surprisingly, that a State Board of Registration in Pharmacy may not be a state agency for purposes of the state action doctrine if it engages in activities outside of its purview or if its actions were not justified by legitimate regulatory purposes." Id. at 689. In Norman's on the Waterfront, Inc. v. Wheatley, 444 F.2d 1011 (3d Cir. 1971), it was not actions of the Board of Alcoholic Beverages that the court declared unlawful, but the law passed by the Legislature of the Virgin Islands, on the grounds that it violated the prohibition in § 3 of the Sherman Act against price fixing by imposing a mandatory price stabilization scheme. Id. at 1016. Finally, in Asheville Tobacco Bd. V. F.T.C., 263 F.2d 502 (4th Cir. 1959), this Court held that the local tobacco board of trade involved there was not a state agency because under the applicable state statute such a board "is organized primarily for the benefit of

Far from finding support in precedent, the FTC's argument is directly contrary to two appellate decisions. As reflected in *Hass v. Oregon State Bar*, 883 F.2d 1453 (9th Cir. 1989), and in *Earles*, 139 F.3d at 1033, the "active supervision" prong does not apply to a State Regulatory Board even when that Board is composed of financially interested members. In *Hass*, the Oregon State Bar was held not to be subject to the "active state supervision" requirement even though twelve of the fifteen members of its Board were practicing attorneys. 883 F.2d at 1460. Similarly in *Earles*, a State Board of CPAs was found to be not subject to the "active state supervision" requirement even though the Board was "composed entirely of CPAs who compete in the profession they regulate" 139 F.3d at 1041.

More fundamentally, the argument that the Dental Board is not a state agency because it consists of practicing dentists is without merit because it rests on the FTC's untenable assertion that whether a governmental entity is "the state" for purposes of the state action doctrine "should not focus on the formalities of state law . . . but rather on the realities of the decision-maker's independent judgment." 151 F.T.C. at 620. That assertion has two basic flaws. First, quite apart from the

those engaged in the business; its articles of association and bylaws constitute a contract amongst the members by which each member consents to reasonable regulations pertaining to the conduct of the business." *Id.* at 509. This description of the nature of the local tobacco board of trade is not remotely applicable to the Dental Board.

fact that it is an *ipse dixit* which finds no support in Supreme Court precedent or logic, it ignores the federalism considerations that underlie the state action doctrine. For federalism purposes, the "formalities of state law" – dismissed by the FTC as irrelevant – are critical in determining whether a regulatory body is the State. In that regard, the FTC would simply ignore that the applicable North Carolina statute expressly declares that the Dental Board is "an agency of the State." N.C. Gen. Stat. § 90-48.

Second, the FTC's position is in conflict with *Parker v. Brown* itself. There, the agency in question instituted agricultural proration programs that were recommended by a committee chosen by market participants. Indeed, 65% of the crop producers, owning 51% of the acreage devoted to the regulated crop, were required to ratify the program before the agency could enforce it. *Id.*, 317 U.S. at 352. Given these facts, the Commission's position simply cannot be squared with *Parker v. Brown*.

Contrary to the FTC's position, the Dental Board – even though comprised of practicing dentists – is a legitimate state agency for purposes of the state action doctrine. The Dental Board is established by action of the state legislature. N.C. Gen. Stat. § 90-22(b). The North Carolina State Ethics Commission regulates the Dental Board's conduct as it pertains to compliance with the North Carolina Ethics Act and Lobbying Law. N.C. Gen. Stat. § 138A-10;

http://www.ethicscommission.nc.gov/coverage/pubBoards.aspx . The members of the Dental Board are appointed or otherwise selected in accordance with procedures determined by the legislature. N.C. Gen. Stat. § 90-22(c). The Board may initiate appropriate legal proceedings for violations of the provisions of Article 2 or of Article 16. N.C. Gen. Stat. § 90-41(c). Moreover, any actions of the Board are subject to repeal or modification if the legislature is not in accord with them.

Not surprisingly, therefore, virtually every decision to address the issue has held that a State Board of Medicine or a State Board of Dentistry is a legitimate state agency. *See, e.g., Bettencourt v. Bd. Of Registration in Medicine*, 904 F.2d 772, 781 (1st Cir. 1990); *Neuwirth v. Louisiana State Bd. Of Dentistry*, 845 F.2d 553, 555 (5th Cir. 1988); *Howard v. Miller*, 870 F. Supp. 340, 343 (N.D. Ga. 1994); *Connolly v. Becket*, 863 F. Supp. 1379, 1381 (D. Colo. 1994). The fact that a State Dental Board may be composed entirely or largely of practicing dentists does not change the analysis. The composition of a State Board is determined by act of the state legislature – not by decree of a dental or medical society or other private entity.

In the circumstances, the FTC's position that the composition of a State Board undermines the Board's status as a state agency is a frontal assault on the sovereignty of the State and its right to determine by legislation the nature of its regulatory bodies. Such a position would involve courts in subjective and unpredictable judgments regarding the extent to which membership of market participants on a State Board deprives that Board of status as a state agency for purposes of the state action doctrine. This is not a proper inquiry for the courts.

Finally, the FTC may argue that its decision should be upheld on the theory that the decision rests on the narrow ground that "the Board evaded judicial review of its decision to classify teeth whitening as the practice of dentistry by proceeding directly to issue cease and desist orders purporting to enforce that unsupervised decision." 151 F.T.C. at 632. This supposed basis for the FTC's decision was given very limited prominence in its Opinion – and then only as one of many reasons why the Dental Board's actions allegedly did not meet the active state supervision test. *See* 151 F.T.C. at 628-633. In any event, such an argument it is not a defensible basis for overcoming the state action doctrine.

The FTC does not cite any state court ruling that the Board lacks the power to send letters demanding that recipients cease and desist from what the Board regards as violations of the statute which it is charged with implementing. Instead, the FTC appears to rely on the fact that the Dental Act contains no express authorization for such letters. *See* 151 F.T.C. at 618. Through this argument, the FTC would anoint itself as a state appellate court to sit in judgment on the procedures followed by a state agency.

Neither the words nor the legislative history of the FTC Act support that such a role was ever envisioned for the FTC. Indeed, having the FTC function in this capacity would – in the words of the Supreme Court in *Parker v. Brown*, "nullify a state's control over its officers and agents." 317 U.S. at 350-351. Specifically, it is the responsibility of state courts, applying state law, to determine whether a State Regulatory Board has exceeded its authority. Likewise, it is for the state legislature and the governor, if a state agency takes action contrary to the public policy of the state, to amend the law or to replace the members of the agency.

In what the Supreme Court referred to in *Parker v. Brown*, 317 U.S. at 350-351, as our "dual system of government" in which, under the Constitution, the states are sovereign, save only as Congress may constitutionally subtract from their authority, it is not the job of the FTC -- applying the "gauzy cloak" of the federal antitrust laws – to pass judgment on the procedures and policy decisions of a duly constituted agency of state government. The FTC's approach, if upheld, would place a chill on all State Regulatory Boards, and on the persons and entities they regulate, because there could be no confidence that the Board's implementation of the applicable state statute would survive second-guessing by the FTC. That approach is not authorized by the antitrust laws and is not in accordance with basic tenets of federalism.

CONCLUSION

The Court should refuse to enforce the FTC's Order below on the ground that the FTC lacks jurisdiction over the North Carolina State Board of Dental Examiners. If it finds that the FTC has jurisdiction, the Court should refuse to enforce the Order because the federal antitrust laws do not apply to actions by a State Regulatory Board addressing issues within its legislative grant of authority.

Respectfully Submitted,

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Dated: May 16, 2012

CERTIFICATE OF COMPLIANCE

In accordance with Fed. R. App. P. 32(a)(7)(C)(i), I certify that the foregoing *Amicus* Brief contains 5,601 words, not including the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and complies with the type-volume limitations of Fed. R. App. P. 29(d) and 32(a)(7)(B).

This brief has been prepared in proportionally spaced typeface using Microsoft Word 2007 in Times New Roman, 14 pt. typeface and complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6).

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the Appellate CM/ECF System on May 16, 2012.

I certify that all parties to this case are registered CM/ECF users and that service will be accomplished by the Appellate CM/ECF System.

Executed this 16th day of May, 2012.

Jack R. Bierig
Jack R. Bierig
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UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

WASHINGTON, D.C. 20580

Office of Policy Planning Bureau of Economics Bureau of Competition

November 3, 2010

Patricia E. Shaner, Office of General Counsel Alabama State Board of Medical Examiners Post Office Box 946 848 Washington Avenue (36104) Montgomery, Alabama 36101-0946

Dear Ms. Shaner:

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition¹ appreciate this opportunity to comment on the proposed regulation of interventional pain management services (Proposed Rule) issued by the Alabama State Board of Medical Examiners.² The Proposed Rule restricts the "interventional treatment of pain" to "qualified, licensed medical doctors and doctors of osteopathy," who "may not delegate to non-physician personnel the authority to utilize such procedures to diagnosis [sic], manage or treat chronic pain patients." The rule appears to prohibit certified registered nurse anesthetists (CRNAs) from performing, under the supervision of a physician, pain management procedures that the Board of Nursing considers within the scope of CRNA practice.⁵ Absent evidence that the proposed restrictions are necessary to protect the public, there appears to be no reason to sacrifice the benefits of CRNA pain management services as currently available under Alabama law.

Unnecessary restrictions on the ability of physicians to provide pain management services in collaboration with CRNAs are likely to reduce the availability, and raise the prices, of pain management services in Alabama. In particular, the Proposed Rule may burden cancer

¹ This letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition. The letter does not necessarily represent the views of the Federal Trade Commission ("Commission") or of any individual Commissioner. The Commission has, however, voted to authorize us to submit these comments.

² See Alabama State Board of Medical Examiners, Proposed Rule 540-X-15, Interventional Pain Management, available at http://www.ala-crna.org/download/ALANA-Call-to-action-BMEP-rule.pdf [hereinafter Proposed Rule].

³ Id. at 540-X-15-.01, 540-x-.05.

⁴ Id. at 540-x-.04.

⁵ See, e.g., In re Steve Sykes, MD, Petition for Declaratory Ruling Before the Alabama Board of Nursing, 4-6 (Mar. 19, 2010), available at http://www.abn.state.al.us/UltimateEditorInclude/UserFiles/docs/Declaratory-Ruling/AP-Steve-Sykes.pdf (enumerating various interventional pain management procedures currently within the scope of CRNA practice).

patients and others with chronic pain, rural Alabamans and others whose access to health care, or ability to pay for it, is limited, and hospice patients.

We therefore urge the Board to consider carefully the impact of the Proposed Rule and to avoid adopting provisions that would limit the role of CRNAs in pain management more strictly than patient protection requires. The Proposed Rule provides no evidence that the current practice has harmed patients. Further, studies that have examined CRNA provision of anesthesia services have not found safety or quality defects in CRNA practice.⁶

Interest and Experience of the Federal Trade Commission

The FTC is charged under the FTC Act with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. Competition is at the core of America's economy, and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, more choices, and greater innovation. Because of the importance of health care competition to the economy and consumer welfare, anticompetitive conduct in health care markets has long been a key target of FTC law enforcement, research, and advocacy, such as this letter. Recently, FTC staff have urged several states to reject or narrow restrictions that limit health care access and raise prices to consumers by limiting competition among health care providers and professionals.

⁶ See, e.g., A.F. Smith, et al., Comparative Effectiveness and Safety of Physician and Nurse Anaesthetists: A Narrative Systematic Review, 93 BRIT. J. ANAESTHESIA 540, 544 (2004) (review article examining U.S. and foreign studies finding "no recent, high-level evidence that there are significant differences in safety between different anaesthesia providers"); Paul F. Hogan et al., Cost Effectiveness Analysis of Anesthesia Providers, 28 NURSING ECON. 159, 161 (2010) ("there are no studies that show a significant difference between CRNAs and anesthesiologists in patient outcomes.").

⁷ Federal Trade Commission Act, 15 U.S.C. § 45.

⁸ See National Society of Professional Engineers v. United States, 435 U.S. 679, 695 (1978) ("The heart of our national economy long has been faith in the value of competition.").

⁹ See generally, e.g., FEDERAL TRADE COMMISSION (FTC), FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (Mar. 2008), available at http://www.ftc.gov/bc/0608hcupdate.pdf; see also Competition in the Health Care Marketplace: Formal Commission Actions, available at http://www.ftc.gov/bc/healthcare/ antitrust/commissionactions.htm.

¹⁰ See, e.g., FTC & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Chapter 7 (2004), available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

¹¹ FTC and staff advocacy may comprise letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, amicus briefs, or reports. *See, e.g.*, Letter from FTC Staff to Hon. Timothy Burns, Louisiana Legislature, (May 1, 2009) (regarding proposed restrictions on mobile dentistry); available at http://www.ftc.gov/os/2009/05/V090009 louisianadentistry.pdf; FTC and Department of Justice Written Testimony before the Illinois Task Force on Health Planning Reform Concerning Illinois Certificate of Need Laws (Sept. 2008), available at http://www.ftc.gov/os/2008/09/V080018illconlaws.pdf; FTC Amicus Curiae Brief in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* Concerning Drug Patent Settlements Before the Court of Appeals for the Federal Circuit (Case No. 2008-1097) (Jan. 2008), available at http://www.ftc.gov/os/2008/01/080129cipro.pdf; FEDERAL TRADE COMMISSION AND THE DEPARTMENT OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (July 2004), available at http://www.usdoj.gov/atr/public/health care/204694.htm.

¹² See, e.g., Letter from FTC Staff to Hon. Timothy Burns, supra note 11; Letter from FTC Staff to Elain Nekritz, Illinois Legislature (May 29, 2008) (regarding proposed LSC regulations); available at

I. Background

A. Brief Background on CRNAs

In Alabama, CRNAs are licensed under the Alabama Code¹³ and Alabama Board of Nursing regulations.¹⁴ In general, "[p]ractice as a certified registered nurse anesthetist (CRNA) means the performance of or the assistance in any act involving the determination, preparation, administration, or monitoring of any drug used to render an individual insensible to pain for surgical and other therapeutic or diagnostic procedures. . . . [by the CRNA] under the direction of a physician licensed to practice medicine, or a dentist, who is immediately available."¹⁵

Under Board of Nursing regulations, CRNAs are required to have:

- (a) An active Alabama registered nurse license. . . .
- (b) Met all requirements for completion of or graduation from an organized program of study and clinical experience beyond the basic educational preparation as a registered nurse that prepares nurse anesthetists and is accredited by the Council on Accreditation of Nurse Anesthesia Educational Programs/Schools . . . and recognized by the Board of Nursing.
- (c) Earned at least a master's degree, or post-master's certificate in advanced practice nursing . . . [and]
- (d) Current certification as a registered nurse anesthetist ¹⁶

B. The Proposed Rule

As noted above, the Proposed Rule restricts the "interventional treatment of pain" to "qualified, licensed medical doctors and doctors of osteopathy," who "may not delegate to non-physician personnel the authority to utilize such procedures to diagnosis [sic], manage or treat chronic pain patients." "Interventional pain management" is defined broadly as "the

http://www.ftc.gov/os/2008/06/V080013letter.pdf; Letter from FTC Staff to Massachusetts Dep't of Health (September 27, 2007) (regarding proposed LSC regulations); available at http://www.ftc.gov/os/2007/10/v070015massclinic.pdf. Many of these advocacy efforts have been successful in preserving competition. For example, following the above referenced advocacy letters, the Louisiana and Illinois legislatures rejected the proposed restrictions on competition, and Massachusetts followed FTC Staff recommendations in adopting its final LSC regulations.

¹³ Code of Ala. §§ 34-21-81, 34-21-90 (2010) (definitions and certification, respectively, for advance practice nurses, including CRNAs).

¹⁴ Ala. Admin. Code r. 610-X-9-.01 (2010) (Qualifications For Approval To Practice As A Certified Registered Nurse Anesthetist). Statutory authority to adopt standards of nursing practice is assigned to the Alabama Board of Nursing by statute. Code of Ala. § 34-21-2(j) (2010).

¹⁵ Code of Ala. § 34-21-81(4)(c) (2010).

¹⁶ Ala. Admin. Code r. 610-X-9-.01 (2010)

¹⁷ Id. at 540-X-15-.01, 540-x-.04.

¹⁸ Id. at 540-x-.04.

diagnosis and treatment of pain-related disorders with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain."²⁰ The Proposed Rule also includes examples of "interventional techniques," which

often involve injection of steroids, analgesics, and anesthetics and include: lumbar, thoracic, and cervical spine injections, intra-articular injections, intrathecal injections, epidural injections (both regular and transforaminal), facet injections, discography, nerve destruction, occipital nerve blocks, lumbar sympathetic blocks and vertebroplasty, and kyphoplasty.²¹

The Proposed Rule also provides a non-exhaustive list of several dozen specific interventions.²²

Because the proposed rule effectively prohibits non-physicians from providing interventional pain treatment, and physicians from delegating authority to provide such treatment to other licensed health care professionals, the Proposed Rule appears to prevent CRNAs from performing many of the pain management procedures that the Board of Nursing considers to be within the scope of CRNA practice in Alabama, subject to physician supervision. For example, the scope of CRNA practice includes "intradermal, subcutaneous, or intramuscular administration of a local anesthetic agent in a specified amount designated by order of a licensed physician or dentist," and "the monitoring and adjustment of local anesthetic agent(s) and analgesic agent(s) infusing via an epidural, brachial plexus, or femoral catheter placed by a qualified [CRNA] or qualified licensed physician may be performed by a registered nurse . . . as ordered by a licensed prescriber."

¹⁹ It is not clear from the plain language of the Proposed Rule whether "interventional treatment of pain" is meant to be co-extensive with "interventional pain management" or a broader concept that includes it.

²⁰ Proposed Rule at 540-X-15-.02.

²¹ Id.

²² Specific interventions include SI joint injections; spinal punctures; epidural blood patches; epidural injections; epidural/spinal injections; lumbar injections; epidural/subarachnoid catheters; occipital nerve blocks; axillary nerve blocks; intercostal nerve blocks; multiple intercostal nerve blocks; ilioinguinal nerve blocks; peripheral nerve blocks; facet joint injections; cervical/thoracic facet joint injections; lumbar facet injections; multiple lumbar facet injections; transforaminal epidural steroid injections; transforaminal cervical steroid injections; sphenopalatine ganglion blocks; paravertebral sympathetic blocks; neurolysis of the lumbar facet nerve; neurolysis of the cervical facet nerve; and destruction of the peripheral nerve. Proposed Rule at 540-X-15-.02.

²³ See, e.g., In re Steve Sykes, MD, supra note 5 (enumerating various interventional pain management procedures within the scope of CRNA practice).

²⁴ Supra note 5, at 4. The Board of Nursing reports that, when it recently invited public comment regarding revisions to the pertinent standards of practice, the Board of Medical Examiners did not question CRNA qualification to perform such procedures. *Id.* at 5 (regarding November 2009 letter submitted by Board of Medical Examiners Executive Director, Larry Dixon).

II. Consumer Protection Concerns and the Scope of Practice

Patient safety or consumer protection concerns can justify licensure requirements and scope of practice restrictions.²⁵ FTC staff recognize that particular pain management procedures may require the specific training and experience of a board certified anesthesiologist and that other particular interventions may require the special skills of a certified surgical sub-specialist. Staff notes, however, that the Proposed Rule applies broadly and does not identify such particular procedures.²⁶

Available evidence indicates that CRNAs operating within the scope of their licensure provide pain management services safely.²⁷ Published data tend to indicate that the baseline risk of anesthesia is extremely low across all providers, and provider settings, with several studies indicating that recent decades have seen "a remarkably abrupt decrease in anesthetic related death rates, morbidity, and risk of perioperative deaths." In publishing its final rule regarding the provision of hospital anesthesia services under the Medicare and Medicaid programs, the U.S. Department of Health and Human Services (HHS) concluded that, "the anesthesia-related death rate is extremely low, and that the administration of anesthesia in the United States is safe relative to surgical risk." Moreover, HHS found no "need for Federal intervention in State professional practice laws governing CRNA practice. . . . [and] no reason to require a Federal rule in these conditions of participation mandating that physicians supervise the practice of [state-licensed CRNAs]."

²⁵ In competition terms, licensure requirements or scope of practice restrictions may sometimes offer an efficient response to certain types of market failure that can occur in professional services markets. See CAROLYN COX & SUSAN FOSTER, FEDERAL TRADE COMMISSION, BUREAU OF ECONOMICS, THE COSTS AND BENEFITS OF OCCUPATIONAL REGULATION, 5-6 (1990), available at http://www.ftc.gov/be/consumerbehavior/docs/reports/CoxFoster90.pdf.

²⁶ In addition, the Proposed Rule does not appear to restrict the scope of any pain management practices to any particular physician specialists, instead referring generally to "qualified, licensed medical doctors and doctors of osteopathy." *Id.* at 540-X-15-.01, 540-x-.04.

²⁷ See supra note 6; cf. Brian Dulisse & Jerry Cromwell, No Harm Found When Nurse Anesthetists Work Without Supervision by Physicians, 29 HEALTH AFFAIRS 1469, 1469 (2010) ("adverse events related to anesthesia are rare regardless of the provider."). Much of the public data appears to regard the provision of anesthesia generally, without distinguishing profession-related risks particularly related to chronic or acute pain management. FTC staff notes a general question regarding the scope of Proposed Rule's intended limitation to chronic pain management settings, in addition to the question whether there is evidence of consumer harms associated with CRNA practice in particular chronic care contexts.

²⁸ J.P. Abenstein & Mark A. Warner, Anesthesia Providers, Patient Outcomes, and Costs, 82 ANESTHESIA & ANALGESIA 1273, 1277 (1996) (citing, e.g., Mark A. Warner, et al., Major Morbidity and Mortality Within 1 Month of Ambulatory Surgery and Anesthesia, 270 JAMA 1437 (1993)); see also Dulisse & Cromwell, supra note 27, at 1469 ("adverse events related to anesthesia are rare regardless of the provider.").

²⁹ Department of Health and Human Services (HHS), Health Care Financing Administration (HCFA), Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 42 CFR Parts 416, 482, and 485, Final Rule, 66 Fed. Reg. 4674, 4675 (Jan. 18, 2001).

³⁰ Id. at 4674.

The Proposed Rule appears to provide no countervailing evidence that CRNAs operating within their established scope of practice impose substantial risks on Alabama health care consumers in chronic care settings or otherwise.³¹

III. Likely Effects on Alabama Health Care Consumers

The Proposed Rule's restrictions on the ability of physicians to direct and supervise CRNA provision of interventional pain treatments to chronic pain patients practice may increase prices for pain management services and decrease access to such services. By limiting the number of health care professionals licensed to provide pain management services, the Proposed Rule would reduce price competition. Further, prices may rise to the extent that physician services are substituted for lower-cost CRNA services. Finally, the Proposed Rule may thwart innovation in health care delivery by limiting the ability of health care providers to develop, test, and implement the most efficient teams of pain management professionals.

Moreover, the burdens imposed by the Proposed Rule may be felt especially by some of the most vulnerable citizens of Alabama. For example, CRNA practices disproportionately serve

³¹ A study by the Lewin Group notes directly that "there are no studies that show a significant difference between CRNAs and anesthesiologists in patient outcomes." Paul F. Hogan et al., supra note 6, at 161 (reviewing literature on safety and efficiency of anesthesia). FTC staff recognize that the published evidence regarding aggregate or comparative risks of anesthesia are complex, and staff do not wish to suggest that some particular anesthesia staffing model is optimal. See, e.g., Abenstein & Warner, supra note 28, at 1276 (comorbidities and other difficulties in attributing adverse events to anesthesia); cf. Smith et al., supra note 6, at 541 (studies too dissimilar to admit formal meta-analysis). Still, published data generally indicate that CRNAs, working under physician supervision or separately, provide pain management services safely -see supra notes 6, 27 - 30, and accompanying text - and there does not appear to be countervailing evidence that CRNAs generally, or in particular chronic care contexts, are unsafe. In addition, there are studies that compare various anesthesia workforce models. See, e.g., Laurent G. Glance, The Cost Effectiveness of Anesthesia Workforce Models: A Simulation Approach Using Decision Analysis Modeling, 90 ANESTHESIA & ANALGESIA 584 (2000). FTC staff could find no evidence comparing the relative safety, efficacy, or efficiency of CRNA pain management services with those provided by the larger population of physicians and doctors of osteopathy. There is, however, some evidence that the risk of "failure to rescue" is substantially higher in hospitals in which relatively few of the anesthesiologists are board-certified. Id. at 587 (2.5 times higher when 0-33% anesthesiologists board-certified than those where 66-99% of anesthesiologists are board certified). Such studies could raise questions about when or whether it is safe to substitute physicians and osteopaths who are not board-certified anesthesiologists for those who are.

³² Compare ALISON J. TERRY, ALABAMA BOARD OF NURSING, BIANNUAL ANALYSIS OF ALABAMA'S REGISTERED NURSE WORKFORCE: 2008, p. 9, Table 4 (April 2009), available at http://www.abn.state.al.us/UltimateEditorInclude/UserFiles/docs/research/VIII%20E%202%20Report%20of%202008%20RN%20Renewal%20Workforce%20Survey.pdf (indicating 1,378 CRNAs in Alabama) with Alabama Department of Industrial Relations, Occupational Employment Projections in Alabama for Anesthesiologists for a base year of 2006 and a projected year of 2016, available at http://216.226.191.114/vlmi/analyzer/qsoccproj.asp?quicksearch=True&setvar=True&cat=OCC&session=OCCPROJ&subsession=99&areaname (estimating 760 Alabama anesthesiologists in 2006 and projecting 950 for 2016), last checked 10/18/10.

³³ See, e.g., Editorial, Who Should Provide Anesthesia Care?, N.Y. TIMES, Sept. 6, 2010 (relative costs of physician and nurse provided care).

³⁴ Glance, *supra* note 31, at 588-91 (regarding cost-effective models of anesthesia care for low, intermediate, and high risk cases, and concluding that, "the *physician-intensive* model, in which physicians working alone anesthetize all patients, is also not cost effective.")

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smaller, rural hospitals.³⁵ In addition, hospice providers and patients may face both increased prices and reduced access to care if only physicians can provide palliative care for chronic pain.

It is possible that the Proposed Rule may, on balance, reduce patient safety. As noted, economic or geographic access problems may place some Alabamans at risk of inadequate care. Also, if CRNA pain management specialists are sometimes replaced not by board certified anesthesiologists, but by physicians and osteopaths who do not specialize in pain management, the average quality of interventional pain management in Alabama, or certain parts of Alabama, could be reduced.

Conclusion

If particular interventional pain treatment services demonstrably require more specialized training and experience than CRNAs working under physician supervision posses, then the Board should tailor the rule to address those particular services. To the extent that there is no evidence that CRNA practice harms patients, staff recommend that the Board reject the Proposed Rule outright.

We appreciate your consideration of these issues.

Respectfully submitted,

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³⁵ See, e.g., Dulisse & Cromwell, supra note 27, at 1469 (CRNAs "provide thirty million anesthetics annually in the United States and represent two-thirds of anesthetists in rural hospitals."); cf. Abenstein & Warner, supra note 28, at 1279 (nurse anesthetist only practices found predominantly in smaller, rural hospitals).

ADDENDUM

<u>United States Code</u>

15 U.S.C. § 12. Definitions; short title

(a) "Antitrust laws," as used herein, includes the Act entitled "An Act to protect trade and commerce against unlawful restraints and monopolies," approved July second, eighteen hundred and ninety; sections seventy-three to seventy-six, inclusive, of an Act entitled "An Act to reduce taxation, to provide revenue for the government, and for other purposes," of August twenty-seventh, eighteen hundred and ninety-four; an Act entitled "An Act to amend sections seventy-three and seventy-six of the Act of August twenty-seventh, eighteen hundred and ninety-four, entitled 'An Act to reduce taxation, to provide revenue for the Government, and for other purposes," approved February twelfth, nineteen hundred and thirteen; and also this Act.

"Commerce," as used herein means trade or commerce among the several States and with foreign nations, or between the District of Columbia or any Territory of the United States and any State, Territory, or foreign nation, or between any insular possession or other places under the jurisdiction of the United States, or between any such possession or place and any State or Territory of the United States or the District of Columbia or any foreign nation, or within the District of Columbia or any Territory or any insular possession or other place under the jurisdiction of the United States: *Provided*, That nothing in this Act contained shall apply to the Philippine Islands.

The word "person" or "persons" wherever used in this Act shall be deemed to include corporations and associations existing under or authorized by the laws of either the United States, the laws of any of the Territories, the laws of any State, or the laws of any foreign country.

(b) This Act may be cited as the "Clayton Act".

15 U.S.C. § 44. Definitions

The words defined in this section shall have the following meaning when found in this subchapter, to wit:

* * *

"Corporation" shall be deemed to include any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, which is organized to carry on business for its own profit or that of its members, and has shares of capital or capital stock or certificates of interest, and any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, without shares of capital or capital stock or certificates of interest, except partnerships, which is organized to carry on business for its own profit or that of its members.

* * *

15 U.S.C. § 45. Unfair methods of competition unlawful; prevention by Commission

- (a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade
- (1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.
- (2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 57a(f)(3) of this title, Federal credit unions described in section 57a(f)(4) of this title, common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to part A of subtitle VII of Title 49, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended, except as provided in section 406(b) of said Act, from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

* * *

North Carolina Statutes

§ 90-22. Practice of dentistry regulated in public interest; Article liberally construed; Board of Dental Examiners; composition; qualifications and terms of members; vacancies; nominations and elections; compensation; expenditures by Board.

- (a) The practice of dentistry in the State of North Carolina is hereby declared to affect the public health, safety and welfare and to be subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the dental profession merit and receive the confidence of the public and that only qualified persons be permitted to practice dentistry in the State of North Carolina. This Article shall be liberally construed to carry out these objects and purposes.
- The North Carolina State Board of Dental Examiners heretofore created by (b) Chapter 139, Public Laws 1879 and by Chapter 178, Public Laws 1915, is hereby continued as the agency of the State for the regulation of the practice of dentistry in this State. Said Board of Dental Examiners shall consist of six dentists who are licensed to practice dentistry in this State. Said Board of Dental Examiners shall consist of six dentists who are licensed to practice dentistry in North Carolina, one dental hygienist who is licensed to practice dental hygiene in North Carolina and one person who shall be a citizen and resident of North Carolina and who shall be licensed to practice neither dentistry nor dental hygiene. The dental hygienist or the consumer member cannot participate or vote in any matters of the Board which involves the issuance, renewal or revocation of the license to practice dentistry in the State of North Carolina. The consumer member cannot participate or vote in any matters of the Board which involve the issuance, renewal or revocation of the license to practice dental hygiene in the State of North Carolina. Members of the Board licensed to practice dentistry in North Carolina shall have been elected in an election held as hereinafter provided in which every person licensed to practice dentistry in North Carolina and residing or practicing in North Carolina shall be entitled to vote. Each member of said Board shall be elected for a term of three years and until his successor shall be elected and shall qualify. Each year there shall be elected two dentists for such terms of three years each. Every three years there shall be elected one dental hygienist for a term of three years. Dental hygienists shall be elected to the Board in an election held in accordance with the procedures hereinafter provided in which those persons licensed to practice dental hygiene in North Carolina and residing or practicing in North Carolina shall be entitled to vote. Every three years a person who is a citizen and resident of North Carolina and licensed to practice neither dentistry nor dental hygiene shall be

appointed to the Board for a term of three years by the Governor of North Carolina. Any vacancy occurring on said Board shall be filled by a majority vote of the remaining members of the Board to serve until the next regular election conducted by the Board, at which time the vacancy will be filled by the election process provided for in this Article, except that when the seat on the Board held by a person licensed to practice neither dentistry nor dental hygiene in North Carolina shall become vacant, the vacancy shall be filled by appointment by the Governor for the period of the unexpired term. No dentist shall be nominated for or elected to membership on said Board, unless, at the time of such nomination and election such person is licensed to practice dentistry in North Carolina and actually engaged in the practice of dentistry. No dental hygienist shall be nominated for or elected to membership on said Board unless, at the time of such nomination and election, such person is licensed to practice dental hygiene in North Carolina and is currently employed in dental hygiene in North Carolina. No person shall be nominated, elected, or appointed to serve more than two consecutive terms on said Board.

- (c) Nominations and elections of members of the North Carolina State Board of Dental Examiners shall be as follows:
- (1) An election shall be held each year to elect successors to those members whose terms are expiring in the year of the election, each successor to take office on the first day of August following the election and to hold office for a term of three years and until his successor has been elected and shall qualify; provided that if in any year the election of the members of such Board for that year shall not have been completed by August 1 of that year, then the said members elected that year shall take office immediately after the completion of the election and shall hold office until the first of August of the third year thereafter and until their successors are elected and qualified. Persons appointed to the Board by the Governor shall take office on the first day of August following their appointment and shall hold office for a term of three years and until such person's successor has been appointed and shall qualify; provided that if in any year the Governor shall not have appointed a person by August first of that year, then the said member appointed that year shall take office immediately after his appointment and shall hold office until the first of August of the third year thereafter and until such member's successor is appointed and qualified.
- (2) Every dentist with a current North Carolina license residing or practicing in North Carolina shall be eligible to vote in elections of dentists to the Board. Every dental hygienist with a current North Carolina license residing or practicing in North Carolina shall be eligible to vote in elections of dental hygienists to the

Board. The holding of such a license to practice dentistry or dental hygiene in North Carolina shall constitute registration to vote in such elections. The list of licensed dentists and dental hygienists shall constitute the registration list for elections to the appropriate seats on the Board.

- (3) All elections shall be conducted by the Board of Dental Examiners which is hereby constituted a Board of Dental Elections. If a member of the Board of Dental Examiners whose position is to be filled at any election is nominated to succeed himself, and does not withdraw his name, he shall be disqualified to serve as a member of the Board of Dental Elections for that election and the remaining members of the Board of Dental Elections shall proceed and function without his participation.
- (4) Nomination of dentists for election shall be made to the Board of Dental Elections by a written petition signed by not less than 10 dentists licensed to practice in North Carolina and residing or practicing in North Carolina. Nomination of dental hygienists for election shall be made to the Board of Dental Elections by a written petition signed by not less than 10 dental hygienists licensed to practice in North Carolina and residing or practicing in North Carolina. Such petitions shall be filed with said Board of Dental Elections subsequent to January 1 of the year in which the election is to be held and not later than midnight of the twentieth day of May of such year, or not later than such earlier date (not before April 1) as may be set by the Board of Dental Elections: provided, that not less than 10 days' notice of such earlier date shall be given to all dentists or dental hygienists qualified to sign a petition of nomination. The Board of Dental Elections shall, before preparing ballots, notify all persons who have been duly nominated of their nomination.

* * *

- (14) From any decision of the Board of Dental Elections relative to the conduct of such elections, appeal may be taken to the courts in the manner otherwise provided by Chapter 150B of the General Statutes of North Carolina.
- (15) The Board of Dental Elections is authorized to make rules and regulations relative to the conduct of these elections, provided same are not in conflict with the provisions of this section and provided that notice shall be given to all licensed dentists residing in North Carolina.

* * *

§ 90-28. Bylaws and regulations; acquisition of property.

- (a) The North Carolina State Board of Dental Examiners shall have the power to make necessary bylaws and regulations, not inconsistent with the provisions of this Article, regarding any matter referred to in this Article and for the purpose of facilitating the transaction of business by the Board.
- (b) The Board shall have the power to acquire, hold, rent, encumber, alienate, and otherwise deal with real property in the same manner as a private person or corporation, subject only to approval of the Governor and the Council of State. Collateral pledged by the Board for an encumbrance is limited to the assets, income, and revenues of the Board.
- § 90-29. Necessity for license; dentistry defined; exemptions.
- (a) No person shall engage in the practice of dentistry in this State, or offer or attempt to do so, unless such person is the holder of a valid license or certificate of renewal of license duly issues by the North Carolina State Board of Dental Examiners.
- (b) A person shall be deemed to be practicing dentistry in this State who does, undertakes or attempts to do, or claims the ability to do any one or more of the following acts or things which, for the purposes of this Article, constitute the practice of dentistry:
- (1) Diagnoses, treats, operates, or prescribes for any disease, disorder, pain, deformity, injury, deficiency, defect, or other physical condition of the human teeth, gums, alveolar process, jaws, maxilla, mandible, or adjacent tissues or structures of the oral cavity;
- (2) Removes stains, accretions or deposits from the human teeth;
- (3) Extracts a human tooth or teeth;
- (4) Performs any phase of any operation relative or incident to the replacement or restoration of all or a part of a human tooth or teeth with any artificial substance, material or device;
- (5) Corrects the malposition or malformation of the human teeth;

- (6) Administers an anesthetic of any kind in the treatment of dental or oral diseases or physical conditions, or in preparation for or incident to any operation within the oral cavity; provided, however, that this subsection shall not apply to a lawfully qualified nurse anesthetist who administers such anesthetic under the supervision and direction of a licensed dentist or physician;
- (6a) Expired pursuant to Session laws 1991, c. 678, s. 2.
- (7) Takes or makes an impression of the human teeth, gums or jaws;
- (8) Makes, builds, constructs, furnishes, processes, reproduces, repairs, adjusts, supplies or professionally places in the human mouth any prosthetic denture, bridge, appliance, corrective device, or other structure designed or constructed as a substitute for a natural human tooth or teeth or as an aid in the treatment of the malposition or malformation of a tooth or teeth, except to the extent the same may lawfully be performed in accordance with the provisions of G.S. 90-29.1 and 90-29.2;
- (9) Uses a Roentgen or X-ray machine or device for dental treatment or diagnostic purposes, or gives interpretations or readings of dental Roentgenograms or X rays;
- (10) Performs or engages in any of the clinical practices included in the curricula of recognized dental schools or colleges;
- (11) Owns, manages, supervises, controls or conducts, either himself or by and through another person or other persons, any enterprise wherein any one of more of the acts or practices set forth in subdivisions (1) through (10) above are done, attempted to be done, or represented to be done;
- (12) Uses, in connection with his name, any title or designation, such as "dentist," "dental surgeon," "doctor of dental surgery," "D.D.S.," "D.M.D.," or any other letters, words or descriptive matter which, in any manner, represents him as being a dentist able or qualified to do or perform any one or more of the acts or practices set forth in subdivisions (1) through (10) above;
- (13) Represents to the public, by any advertisement or announcement, by or through any media, the ability or qualification to do or perform any of the acts or practices set forth in subdivisions (1) through (10) above.

* * *

§ 90-41. Disciplinary action.

(a) The North Carolina State Board of Dental Examiners shall have the power and authority to (i) Refuse to issue a license to practice dentistry; (ii) Refuse to issue a certificate of renewal of a license to practice dentistry; (iii) Revoke or suspend a license to practice dentistry; and (iv) Invoke such other disciplinary measures, censure, or probative terms against a licensee as it deems fit and proper;

In any instance or instances in which the Board is satisfied that such applicant or licensee:

* * *

(6) Has engaged in any act or practice violative of any of the provisions of this Article or violative of any of the rules and regulations promulgated and adopted by the Board, or has aided, abetted or assisted any other person or entity in the violation of the same;

* * *

(c) The Board may, on its own motion, initiate the appropriate legal proceedings against any person, firm or corporation when it is made to appear to the Board that such person, firm or corporation has violated any of the provisions of this Article or of Article 16.

* * *

§ 90-48. Rules and regulations of Board; violation a misdemeanor.

The North Carolina State Board of Dental Examiners shall be and is hereby vested, as an agency of the State, with full power and authority to enact rules and regulations governing the practice of dentistry within the State, provided such rules and regulations are not inconsistent with the provisions of this Article. Such rules and regulations shall become effective 30 days after passage, and the same may be proven, as evidence, by the president and/or the secretary-treasurer of the Board, and/or by certified copy under the hand and official seal of the secretary-treasurer. A certified copy of any rule or regulation shall be receivable in all courts as prima facie evidence thereof if otherwise competent, and any person, firm, or corporation violating any such rule, regulation, or bylaw shall be considered a separate offense.

The Board shall issue every two years to each licensed dentist a compilation or supplement of the Dental Practice Act and the Board rules and regulations, and upon written request therefor by such licensed dentist, a directory of dentists.

North Carolina Regulations

North Carolina State Ethics Commission

- § 138A-10. Powers and duties.
- (a) In addition to other powers and duties specified in this Chapter, the Commission shall:
- (1) Provide reasonable assistance to covered persons in complying with this Chapter.
- (2) Develop readily understandable forms, policies, and procedures to accomplish the purposes of the Chapter.
- (3) Identify and publish the following:
- a. A list of nonadvisory boards.
- b. The names of individuals subject to this Chapter as covered persons and legislative employees under G.S. 138A-11.
- (4) Receive and review all statements of economic interests filed with the Commission by prospective and actual covered persons and evaluate whether (i) the statements conform to the law and the rules of the Commission, and (ii) the financial interests and other information reported reveals actual or potential conflicts of interest. Pursuant to G.S. 138A-24(e), this subdivision does not apply to statements of economic interest of legislators and judicial officers.
- (5) Conduct inquiries of alleged violations against judicial officers, legislators, and legislative employees in accordance with G.S. 138A-12.
- (6) Conduct inquiries into alleged violations against public servants in accordance with G.S. 138A-12.
- (7) Render advisory opinions in accordance with G.S. 138A-13 and G.S. 120C-102.

- (8) Initiate and maintain oversight of ethics educational programs for public servants and their staffs, and legislators and legislative employees, consistent with G.S. 138A-14.
- (9) Conduct a continuing study of governmental ethics in the State and propose changes to the General Assembly in the government process and the law as are conducive to promoting and continuing high ethical behavior by governmental officers and employees.
- (10) Adopt procedures and guidelines to implement this Chapter.
- (11) Report annually to the General Assembly and the Governor on the Commission's activities and generally on the subject of public disclosure, ethics, and conflicts of interest, including recommendations for administrative and legislative action, as the Commission deems appropriate.
- (12) Publish annually statistics on complaints filed with or considered by the Commission, including the number of complaints filed, the number of complaints referred under G.S. 138A-12(b), the number of complaints dismissed under G.S. 138A-12(f), the number of complaints referred for criminal prosecution under G.S. 138A-12, the number of complaints dismissed under G.S. 138A-12(h), the number of complaints referred for appropriate action under G.S. 138A-12(h) or G.S. 138A-12(k)(3), and the number and age of complaints pending action by the Commission.
- (13) Perform other duties as may be necessary to accomplish the purposes of this Chapter.
- (b) The Commission may authorize the Executive Director and other staff of the Commission to evaluate statements of economic interest on behalf of the Commission as authorized under subdivision (a)(4) of this section.
- (c) Except as otherwise provided in this Chapter, the Commission shall be the sole State agency with authority to determine compliance with or violations of this Chapter and to issue interpretations and advisory opinions under this Chapter. Decisions and advisory opinions by the Commission under this Chapter shall be binding on all other State agencies.