

Contrary to this limited scope of review, the Acupuncturist Association recently served expansive expert designations revealing its intent to attack the policies underlying the Board's rules and to inject extraneous matters into the litigation. These efforts, if allowed, could distract the Court from its proper analysis and would drive up the burden and expense of this litigation, wasting the public resources available to the Board and this Court. The Board and Intervenor therefore request a discovery order tailored to the applicable scope of review, as well as a corresponding limitation on the issues for the Court's decision.

II. Argument

A. The Scope of the Court's Review is Narrow and Focused on Text.

Since the Acupuncture Association filed this case in 2014, the Supreme Court of Texas has emphatically restated the narrow limits of a court's inquiry in a § 2001.038 rule challenge. *See Tex. State Bd. of Exam'rs of Marriage & Family Therapists v. Tex. Med. Ass'n*, 511 S.W.3d 28 (Tex. 2017) and *Tex. Bd. of Chiropractic Exam'rs v. Tex. Med. Ass'n*, 616 S.W.3d 558 (Tex. 2021). The issue for the Court in such a case is whether the presumptively valid rules run counter to the specific language or objectives of the agency's enabling statute. *See Tex. Bd. of Chiropractic Exam'rs*, 616 S.W.3d at 570. The Court must determine those objectives directly from the statutory text itself. *See Tex. State Bd. of Exam'rs of Marriage & Family Therapists*, 511 S.W.3d at 33. Thus, under Texas Supreme Court precedent, a rule's validity turns on a "textual analysis." *Tex. Bd. of Chiropractic Exam'rs*, 616 S.W.3d at 571. The purpose of this limited review is "[t]o prevent expensive and time-consuming usurpations of administrative agencies' policymaking work." *Id.* ("Judges are experts in statutory analysis, not in healthcare.").

In this case, the Third Court of Appeals has even further narrowed the issues in dispute. First, the appellate court affirmed the validity of the Board's choice to define the term "incision" to be a "cut or surgical wound," noting that the definition was neither unreasonable nor inconsistent with the

Chiropractic Act. *Tex. Ass'n of Acupuncture & Oriental Med. v. Tex. Bd. of Chiropractic Exam'rs*, 524 S.W.3d 734, 742 (Tex. App.—Austin 2017, no pet.). More importantly, it affirmed the validity of the Board's then-existing rule authorizing chiropractors to use needles for nonincisive, non-surgical procedures. *Id.* at 743. In doing so, the Third Court held that the rule: (a) “reflected the Chiropractic Board's position that needles may be either incisive or nonincisive”; and (b) was not “unreasonable or inconsistent with the Chiropractic Act's use of the term ‘incisive.’” *Id.* The Third Court then held that, to invalidate the rules expressly authorizing chiropractors to practice acupuncture by summary judgment, the Acupuncture Association “was required to conclusively establish that acupuncture is ‘incisive,’ which, as we have explained has been reasonably interpreted to mean ‘cut.’” *Id.* Because the Acupuncture Association had failed to make this showing and because the Board had not offered any proof that acupuncture needles do not cut, the appellate court remanded the case to this court for further proceedings on the issue of the validity of Board rules 78.1(e)(2)(C) (formerly Rule 78.13(e)(2)(c)) and 78.14. *Id.* at 746.

As a result, the only issues remaining unresolved are: (1) whether acupuncture needles “cut,” as that term is used in the Board's rules (such that, if they do not, their use would be within the proper scope of chiropractic practice); and (2) whether Rules 78.1(e)(2)(C) and 78.14, when read in conjunction with the rest of the Board's rules, limit chiropractors' use of acupuncture to purposes that are consistent with the statutory text.¹ However, because of the Acupuncture Association's recent designation of experts, the Board and Intervenor seek an order identifying the disputed fact issues and contested questions of law in the case and limiting any further discovery to those issues.

¹ The Board and the Chiropractic Association have filed a joint traditional Motion for Summary Judgment on both of these issues. A more extensive analysis of *Tex. Bd. of Chiropractic Exam'rs'* limiting principles is set out in the “Legal Standard” section of the summary judgment motion.

B. The Acupuncture Association’s Designation of Experts Vastly Exceeds the Narrow Scope of Review.

Notwithstanding the Supreme Court’s clear demarcation of a trial court’s limited role in a § 2001.038 rule challenge, the Acupuncture Association has now designated four experts to testify on extraneous matters. *See* Exhibit A, a true and complete copy of the Acupuncture Association’s designation of experts.² Many of the matters on which these experts are designated to testify are either: (1) related to policy decisions made by the Board in promulgating its rules; or (2) otherwise invite the Court to make factual determinations that exceed the textual analysis mandated by the Supreme Court in a rule challenge case.³ For example, the Acupuncture Association has designated experts to testify on the following subjects:

Qualifications of chiropractors:

1. “chiropractors [who are not licensed by the State Board of Acupuncture Examiners] lack the expertise, training, or knowledge to safely practice” acupuncture (Levy; Schnyer, Howlett & Doggett);
2. “acupuncture, as provided by chiropractors marginally trained in acupuncture, is directly equivalent to spinal adjustments delivered by acupuncturists marginally trained in biomechanical manipulation of the spine” (Schnyer);
3. the treatment of conditions within the scope of chiropractic by a chiropractor using acupuncture is a “threat to public safety” (Schnyer);
4. there is no overlap between the training of acupuncturists and the training of chiropractors (Howlett);
5. the dangers of needle use (Schnyer, Howlett and Doggett); and
6. clean needling technique and federal standards and guidelines governing it (Howlett);

² Because Dr. Schnyer’s opinions were included as Exhibit B to the Designations, Exhibit A contains only Exhibit B to the Designations.

³ The Acupuncture Association has designated Dr. Howlett, Mr. Doggett, and, potentially, its other two experts to testify about the Acupuncture Association’s standing. This is unnecessary. The Board’s Special Exceptions challenged only the Acupuncture Association’s standing to assert the claim that, by using acupuncture to treat their patients, chiropractors were practicing medicine without licenses to do so. The Acupuncture Association has abandoned this claim in its Fourth Amended Petition.

Standing:

7. the curriculum and cost of acupuncture school and the continuing education requirements for acupuncturists (Howlett);
8. acupuncturists are economically disadvantaged by allowing chiropractors to treat their patients with acupuncture without the chiropractors' having first attended acupuncture school and having become licensed as acupuncturists (Howlett);

Irrelevant Procedural Issues:

9. the history of interactions and negotiations between the Acupuncture Association, the Texas Medical Board/Texas State Board of Acupuncture Examiners, and the Board regarding the use of acupuncture by chiropractors (Doggett);
10. "that the Chiropractic Board did not negotiate in good faith during informal stakeholder meetings and has consistently demonstrated a greater interest in protecting the profession than following the law and protecting patients" (Doggett); and

Irrelevant Unauthorized Practices:

11. "examples of misrepresentations regarding training and standards and of misleading advertisements by chiropractors who practice acupuncture" (Doggett);
12. a chiropractor's treatment of in-scope conditions with acupuncture "will constitute a **misrepresentation** of the evidence-based clinical efficacy of acupuncture" (Schnyer; emphasis in original);
13. "there are chiropractors offering treatment with acupuncture for conditions outside the chiropractic scope of practice" (Doggett).

None of these opinions assist the Court in deciding, after reviewing evidence about the shape of acupuncture needles, the two remaining issues – namely, whether such needles “cut” and whether the Board’s rules are otherwise consistent with the Chiropractic Act. Under the proper scope of review, such matters are patently irrelevant because they have no tendency to make “more or less probable” any fact that is “of consequence in determining the action,” particularly in light of the limitations reiterated in *Tex. Bd. of Chiropractic Exam’rs.* See Tex. R. Evid. 401.

The Acupuncture Association’s experts offer to opine on matters that the Supreme Court specifically identified as considerations that are improper in deciding the legal question of a rule’s validity. See *Tex. Bd. of Chiropractic Exam’rs*, 616 S.W.3d at 569 (noting that it was obligated to decide a rule’s validity “based on the relevant Texas statutes” and “not on whether [therapists] are **qualified** to make DSM diagnoses”, emphasis added); *id.* at 571 (chiding trial court for failing to apply the standard set in *Marriage & Family Therapists* by “weigh[ing] evidence”—specifically witness testimony presenting each side’s view of the appropriate line between chiropractic and medical neurology—“as if it were doing the Board’s work anew” and admonishing trial courts to abide by the appropriate scope of review in a rule challenge case “[t]o prevent expensive and time-consuming usurpations of administrative agencies’ policymaking work”); *id.* at 575 (“Whether VONT *should* be used by chiropractors is a policy judgment for the Legislature and for the Board, not for the courts. The sole question for courts is whether the text or objectives of the Act forbid chiropractors from using VONT.” Emphasis in original.); and *id.* at 572 (“Rule 79, governing ‘Unprofessional Conduct, states that . . . [a] licensee *may not* . . . perform or attempt to perform procedures for which the licensee is untrained.’ Licensees who engage in unprofessional conduct are ‘subject to disciplinary action.’ Far from authorizing chiropractors to stray beyond the Act’s boundaries, the Board’s rules, taken together, seek to ensure that chiropractors remain inside them.” Citations omitted; emphasis in original).

In addition, evidence of standing is unnecessary because it is undisputed. See *Tex. Bd. of Chiropractic Exam’rs*, 616 S.W.3d at 567 (competition is sufficient injury for standing). The Board’s Special Exceptions challenged only the Acupuncture Association’s standing to assert that chiropractors using acupuncture were practicing **medicine** without proper licensure. That standing challenge was mooted because the Acupuncture Association abandoned the claim in its Fourth Amended Petition.

C. Discovery and the Issues for Decision Should Be Limited to Relevant Matters Within the Narrow Scope of Review.

Because the Court may not consider any of these issues in deciding the legal question of whether the Board's rules are valid, discovery on these immaterial issues – and the presentation of this type of information at trial – is exactly the type of “expensive and time-consuming usurpation of administrative agencies’ policy-making work” that the Supreme Court directed trial courts to prevent by engaging in a limited “textual analysis.” *Tex. Bd. of Chiropractic Exam’rs*, 616 S.W.3d at 571. Consequently, the Board and the Intervenor respectfully request that the Court limit further discovery, as well as the issues to be resolved at trial, to matters that will enable the Court to answer the only question in this rule challenge case: whether, despite the presumption of the rules’ validity, they conflict with specific language in the Chiropractic Act or its objectives, as drawn from its text. Such a limitation is appropriate and well within the Court’s discretion. *See, e.g.*, Tex. R. Civ. P. 192.4(b); *In re K & L Auto Crushers, LLC*, 627 S.W.3d 239, 248 (Tex. 2021) (noting discovery subject to proportionality overlay, and even when information sought is relevant and not privileged, courts may impose reasonable discovery limits, “particularly when ‘the burden or expense of the proposed discovery outweighs its likely benefit.’”); *In re USAA Gen. Indemnity Co.*, 624 S.W.3d 782, 793 (Tex. 2021) (limiting appropriate scope of discovery by requiring proponent to “show a reasonable expectation of obtaining information that will aid the dispute’s resolution . . .”); *In re CSX Corp.*, 124 S.W.3d 149, 152 (Tex. 2003) (although scope of discovery is usually within trial court’s discretion, it must “make an effort to impose reasonable discovery limits.”).

Absent a limitation on further discovery (including the depositions of experts) and on the issues to be resolved in the rule challenge, the Acupuncturist Association will impose on the Board and the Chiropractic Association a Hobson’s choice: either (a) avoid the unnecessary and substantial expense of conducting discovery from these experts on matters that the Court cannot consider in

deciding the rule challenge; or (b) forego discovery from these experts on the immaterial issues and risk being blindsided by something at trial. As a result, the Board and the Intervenor seek an order limiting further discovery and the issues to be tried (if any remain after the Court rules on the pending Motion for Summary Judgment), to matters essential to the Court's resolution of the rule challenge under the standard set out in *Texas Board of Chiropractic Examiners v. Texas Medical Association*.

IV. Prayer

For these reasons, the Board and the Chiropractic Association respectfully ask this Court to set this motion for hearing and issue an order: (1) identifying the contested issues of fact and law in the case, consistent with the limited scope of review articulated in the Texas Supreme Court decisions cited above, including the two remaining issues identified in Part II.A., above; and (2) limiting further discovery in the case to the matters relevant to those issues, specifically excluding policy-related and other extraneous matters which are legally irrelevant per the Texas Supreme Court decisions cited above, including the topics identified in Part II.B., above. The Board and the Intervenor also request that the Court grant them all other and further relief, either at law or in equity, to which they show themselves to be entitled.

Respectfully submitted,

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First Assistant Attorney General

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 /s/ Karen L. Watkins

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CERTIFICATE OF CONFERENCE

We, the undersigned counsel for the identified parties, certify that we spoke with Ms. Shelby O’Brien, counsel for the Association of Acupuncture and Oriental Medicine, concerning the relief requested in this motion by telephone on June 2, 2022. Ms. Shelby represented that the Acupuncture Association is opposed to the relief granted in this motion.

/s/ Karen L. Watkins
Karen L. Watkins
Counsel for Defendant Texas Board of
Chiropractic Examiners

/s/ Matt C. Wood
Matt C. Wood
Counsel for Intervenor Texas Chiropractic
Association

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing Joint Motion to Limit Discovery and Issues for Decision was sent as described below on this the 3rd day of June 2022, to the following:

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Attorneys for Plaintiff Texas Association of
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/s/ Karen L. Watkins
KAREN L. WATKINS

Exhibit A

executive director of the Texas State Board of Medical Examiners (now called the Texas Medical Board) and, ultimately, the executive director of the Texas State Board of Acupuncture Examiners. He will testify regarding the reasons and propriety of acupuncture becoming a regulated, licensed profession in Texas. He will also testify that acupuncture needles—and needles in general—are incisive instruments.

Acupuncture became a regulated profession in Texas under the Texas Medical Board to ensure qualified, properly trained individuals are performing acupuncture in this state. It is Dr. Levy's opinion that chiropractors who do not hold a license issued by the Texas State Board of Acupuncture Examiners lack the expertise, training, or knowledge to safely practice the procedure. It is also Dr. Levy's opinion that needles (including acupuncture needles) are incisive instruments because they break the skin. The incision caused by the insertion of a needle is just a matter of degree. These opinions are based upon his years of experience as a physician and as executive director of the Texas State Board of Medical Examiners and the Texas State Board of Acupuncture Examiners.

Dr. Levy was provided or reviewed the following:

- TAAOM's Third Amended Petition
- TAAOM's Fourth Amended Petition
- Texas Occupations Code, Chapter 201 (Chiropractic Chapter)
- Texas Occupations Code, Chapter 205 (Acupuncture Chapter)
- 22 TEX. ADMIN. CODE § 78.1
- 22 TEX. ADMIN. CODE § 78.2
- 22 TEX. ADMIN. CODE § 78.14
- *Texas Association of Acupuncture and Oriental Medicine v. Texas Board of Chiropractic Examiners*, 524 S.W.3d 734 (Tex. App.—Austin, Feb. 17, 2017, no pet.)
- *Texas Board of Chiropractic Examiners v. Texas Medical Association*, 616 S.W.3d 558 (Tex. 2021)
- *Texas Board of Chiropractic Examiners v. Texas Medical Association*, 375 S.W.3d 464 (Tex. App.—Austin 2012, pet. denied)
- Tex. Atty. Gen. Op. DM-415 (1996)
- Tex. Atty. Gen. Op. DM-471 (1998)
- Tex. Atty. Gen. Op. DM-472 (1998)

Dr. Levy's resume is attached as Exhibit A.

Dr. Rosa Schnyer (Retained)

c/o Shelby O'Brien
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(512) 615-1225

The subject matter on which Dr. Schnyer will testify, the general substance of her mental impressions and opinions, and a brief summary of the bases for them is found in Exhibit B. Dr. Schnyer's work papers and resume are included in Exhibits B and C.

Dr. Beth Howlett (Retained)

c/o Shelby O'Brien
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Dr. Howlett will testify regarding the intensive training/education/examination requirements for a person to become a licensed acupuncturist in Texas, including the curriculum required as part of this training and the clinical and clean needle technique components of the training. Dr. Howlett will also testify regarding the costs of attending an acupuncture school and the continuing education requirements for acupuncturists. Additionally, Dr. Howlett will testify that no acupuncture-specific credit from a chiropractic school would be eligible for transfer to AOMA Graduate School of Integrative Medicine. Dr. Howlett will testify that acupuncture needles are incisive and can cause bleeding, infections, punctured lungs, and other complications. Dr. Howlett will also testify regarding clean needle technique, including federal standards and guidelines governing clean needle technique.

Dr. Howlett's opinion is that the 100 hours of training provided for in the Chiropractic Board's rule is inadequate for the safe and competent performance of acupuncture. The privilege of practicing acupuncture is diminished in quality and standards if chiropractors may practice the procedure without competent training at an accredited acupuncture school. Additionally, acupuncturists are placed at an economic disadvantage by being required to complete significantly more hours of training, at a greater cost, than the 100 hours of training chiropractors must complete under the Chiropractic Board's acupuncture rule. Dr. Howlett will testify that there is no overlap between acupuncture and chiropractic training, including as evidenced by the fact that chiropractic school acupuncture-specific credits cannot transfer into an acupuncture school such as AOMA. Dr. Howlett will testify that acupuncture needles are incisive because they break or separate the skin, and it is just a matter of the degree to which they are incisive. Acupuncture needles can cause bleeding, infections, punctured organs, and other complications and injuries. These opinions are based upon her years of practice as an acupuncturist, her training as a Doctor of Acupuncture and Oriental Medicine, her position as Vice President of Academics at AOMA Graduate School of Integrative Medicine, her previous positions at other acupuncture schools, and various work papers.

Dr. Howlett was provided or reviewed the following:

- TAAOM's Fourth Amended Petition
- 22 TEX. ADMIN. CODE § 78.14
- AOMA Graduate School of Integrative Medicine Program Catalog (2021-2022)
- AOMA 2021-22 Student and Clinic Manual
- Masters Program Degree Plan for Transfers
- Council of Colleges of Acupuncture and Herbal medicine, Clean Needle Technique, Policies and Procedures
- Council of Colleges of Acupuncture and Herbal Medicine, Know Your Acupuncturist
- Council of Colleges of Acupuncture and Oriental medicine, *Clean Needle Technique Manual: Best Practices for Acupuncture Needle Safety and Related Procedures* (7th Edition 2015, Revised Feb. 2020)
- American Academy of Medical Acupuncture Policy on Dry Needling (Dec. 9, 2014, Updated Feb. 2, 2016)
- American Academy of Physical Medicine and Rehabilitation Position on Dry Needling (June 2012)

Dr. Howlett's resume and work papers are attached as Exhibit D.

Wally Doggett

c/o Shelby O'Brien
7600 N. Capital of Texas Hwy, Building B, Suite 200
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(512) 615-1225

Mr. Doggett will provide factual and expert testimony. His factual and expert testimony will include the following: (1) factual matters related to the standing of the Texas Association of Acupuncture and Oriental Medicine (Acupuncture Association) to bring this lawsuit, (2) the history of interactions and negotiations between the Acupuncture Association, the Texas Medical Board/Texas State Board of Acupuncture Examiners, and the Chiropractic Board regarding the practice of acupuncture by chiropractors, (3) the history of the practice of acupuncture by chiropractors in Texas, (4) a discussion of the types of needles used in acupuncture, (5) examples of misrepresentations regarding training and standards and of misleading advertisements by chiropractors who practice acupuncture, and (6) any other factual testimony relevant to this dispute.

It is Mr. Doggett's opinion that the interests the Acupuncture Association seeks to protect through this lawsuit are germane to the organizational purpose of the Acupuncture Association and that the Acupuncture Association seeks to protect the value of its members' right to practice acupuncture. It is Mr. Doggett's opinion, based upon his participation in negotiations with the Chiropractic Board, that the Chiropractic Board did not negotiate in good faith during informal stakeholder meetings and has consistently demonstrated a greater interest in promoting the profession than following the law and protecting patients. It is Mr. Doggett's opinion that there are chiropractors in Texas who are misleading the public by claiming they are acupuncturists when they do not hold a license issued by the Texas State Board of Acupuncture Examiners and by making other inaccurate statements as to credentials related to their practice of acupuncture. It is also Mr. Doggett's opinion that there are chiropractors offering treatment with acupuncture for conditions outside the chiropractic scope of practice. It is Mr. Doggett's opinion that acupuncture needles are incisive because they penetrate the skin. The Chiropractic Board's claim that acupuncture needles are not "incisive" defies federal definitions, defies previous Chiropractic Board and other agency statements, and is factually incorrect. These opinions are based upon his position as president of the Acupuncture Association, his training as a licensed acupuncturist, his years of practice as an acupuncturist, and various work papers.

Mr. Doggett was provided or reviewed the following:

- TAAOM's Fourth Amended Petition (and previous filed versions of the petition) and other pleadings/filings/briefs/amicus briefs/exhibits in this case
- Other court opinions, such as *Texas Board of Chiropractic Examiners v. Texas Medical Association*, 375 S.W.3d 464 (Tex. App.—Austin 2012, pet. denied) and *North Carolina State Board of Dental Examiners v. Federal Trade Commission*, 574 U.S. 494 (2015)
- 22 TEX. ADMIN. CODE § 78.14 and other Chiropractic Board and Acupuncture Board rules, including preambles to rules
- Texas Occupations Code, Chapter 201 (Chiropractic Chapter)
- Texas Occupations Code, Chapter 205 (Acupuncture Chapter)
- Documents exchanged between the Texas State Board of Acupuncture Examiners, the Texas Board of Chiropractic Examiners, and/or the Texas Association of Acupuncture and Oriental Medicine
- Correspondence and reports between parties in this case and state legislators or to the Sunset Advisory Commission
- The Chiropractic Board's website, including previous iterations of the website
- Position Statements of the Texas State Board of Acupuncture Examiners and the Texas Board of Chiropractic Examiners

- Statements from the Sunset Advisory Commission
- Code of Federal Regulations (21 CFR § 880.5580)
- Comprehensive Dry Needling Courses by Dr. Mark Hanson
- Comments at Sunset Advisory Commission Hearings
- FDA Removes Bar to Coverage of Acupuncture by Insurance, Washington Post
- Texas Chiropractic Association, TCA to Fight for Right of Chiropractors to Perform Acupuncture
- Do You Perform Dry-Needling?, Texas Chiropractic Board Report
- Realigning Chiropractic Oversight, A Report from the Texas Performance Review
- Texas Board of Physical Therapy Examiners, Letter to the Texas Attorney General
- Dictionary/Thesaurus Definitions
- Samples of Websites, Signage, and Advertisements by Chiropractors who Perform Acupuncture

Mr. Doggett's resume and work papers are attached as Exhibit E.

Other Parties' Experts

Without necessarily adopting their opinions or positions, Plaintiff designates all expert witnesses, retained and non-retained, designated by any party to this lawsuit.

RESERVATION OF RIGHTS

Plaintiff reserves the right to seek factual or opinion testimony from any witness the Court allows to testify as an expert in this cause. Plaintiff is not necessarily adopting any of these witnesses' opinions, but is merely reserving the right to seek opinions on cross-examination, opinion testimony, adverse testimony, expert testimony, or by records.

Plaintiff reserves the right to call, by deposition or at trial, any expert witness designated by any party to this lawsuit. In the event a present party designates an expert and then is dismissed for

any reason from the suit or fails to call any designated expert, Plaintiff reserves the right to designate and/or call such party and any such experts previously designated by any party.

Plaintiff reserves the right to elicit expert opinions, lay opinion testimony, and/or rebuttal expert testimony from any witness at the time of trial. Some of the witnesses that Plaintiff has designated as experts may also be fact witnesses in this matter, and Plaintiff may present other fact witnesses at trial.

Plaintiff reserves the right to amend this designation of expert witnesses after Defendants file any amended pleadings or serve or amend their designation of expert witnesses, as may be appropriate. Plaintiff reserves the right to supplement this designation as appropriate and permissible, including if subsequent discovery brings to light new evidence or issues in this case.

Plaintiff further reserves the right to withdraw the designation of any expert or to aver positively that any such previously designated expert will not be called as a witness at trial, and to re-designate same as a consulting expert, which cannot be called by opposing counsel.

Each witness designated above is also designated to rebut any testimony regarding the aforementioned subject areas or any other areas in his or her expertise.

Plaintiff has not produced as work papers statutes, rules, or other legal documents readily available to all parties in this case, but these documents are available upon request.

Respectfully submitted,

By: /s/ Shelby O'Brien

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CERTIFICATE OF SERVICE

I hereby certify that, on May 20, 2022, a true and correct copy of the above and foregoing has been served by electronic filing service on the following:

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Exhibit B

Name: Rosa N. Schnyer, DAOM, IFMCP, L.Ac. Dipl. OM (NCCAOM)

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Subject Matter: Texas Association of Acupuncture & Oriental Medicine. vs. Texas Board of Chiropractic Examiners and Texas Chiropractic Association, Cause No D-1-GN-14-000355, in the 201st District Court of Travis County, Texas.

I have been retained as a subject matter expert by Texas Association of Acupuncture and Oriental Medicine ("Association"), the plaintiff in the above-referenced matter ("Matter"), in connection with the Matter.

Impressions and Opinions and Brief Summary: The assertion by the Texas Chiropractic Board that acupuncture is a non-incisive procedure (and therefore, allowable under the chiropractic statute) is incorrect and unsubstantiated. In my best expert opinion both as an acupuncture researcher and professional acupuncture provider, research evidence into the mechanisms and physiological effects of acupuncture, indicate that the safe and effective practice of acupuncture requires specialized training in needling techniques that by definition breach the skin surface, and are thus incisive.

Furthermore, acupuncture, as provided by chiropractors marginally trained in acupuncture, is directly equivalent to spinal adjustments delivered by acupuncturists marginally trained in biomechanical manipulation of the spine. **It is a threat to public safety.** Moreover, acupuncture provided by marginally trained in acupuncture chiropractors will constitute a **misrepresentation** of the evidence-based clinical efficacy of acupuncture --which derives from research on acupuncture *when* provided *by* trained and qualified professional acupuncturists. While chiropractors are highly trained experts in their field, their education does not effectively include invasive techniques that penetrate the skin surface nor the vast body of information on using needling therapeutically. Acupuncture needling is an incisive technique and therefore it should remain outside of the scope of practice of chiropractic.

Definitions

→ **Incise:** According to the Merriam-Webster dictionary¹, the word *incisive* derives from the Latin verb caedere, meaning "to cut."

→ Breaching the skin with an acupuncture needle, by definition creates an incision in the skin. Common synonyms of *cutting through a surface* such as the skin, include *piercing, pricking or penetrating*, as in the insertion of an acupuncture needle.

→ Acupuncture is defined specifically by needle insertion

- NCCIH-National Center for Complementary and Integrative Health²- Acupuncture is a technique in which practitioners stimulate specific points on the body—most often by inserting thin needles through the skin. It is one of the practices used in traditional Chinese medicine.
- Merriam Webster Dictionary³ An originally Chinese practice of inserting fine needles through the skin at specific points especially to cure disease or relieve pain (as in surgery)
- Oxford Languages Dictionary⁴ Acupuncture is a system of integrative medicine that involves pricking the skin or tissues with needles, used to alleviate pain and to treat various physical, mental, and emotional conditions. Originating in ancient China, acupuncture is now widely practiced in the West.
- Oxford English Dictionary A method of medical treatment, originating in China, in which fine needles are inserted into the skin at specific points on the body surface⁵.
- John Hopkins Medicine⁶ Acupuncture is the practice of penetrating the skin with thin, solid, metallic needles which are then activated through gentle and specific movements of the practitioner's hands or with electrical stimulation.

The FDA defines acupuncture needles as devices intended to pierce the skin: “An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless-steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.”⁷

Acupuncture needles are classified by the FDA as Class II devices that must conform to the requirements for prescription devices, which provides they are unsafe except under the supervision of a practitioner licensed by law to direct the use of such devices⁸.

KEY POINTS

- Research evidence into the mechanisms and physiological effects of acupuncture indicate that the safe and effective practice of acupuncture requires specialized training in needling techniques that by definition breach the skin surface, and are thus incisive.
- Acupuncture provided by marginally trained in acupuncture chiropractors will constitute a misrepresentation of the evidence-based clinical efficacy of acupuncture --which

derives from research on acupuncture when provided by trained and qualified professional acupuncturists.

- Acupuncture provided by marginally trained in acupuncture chiropractors **endangers the public safety**, and it is equivalent to acupuncturists marginally trained in biomechanical manipulation of the spine, conducting spinal adjustments.
- Acupuncture practice is therefore **outside the scope of practice of Texas doctors of chiropractic**.

Background and Rationale

Acupuncture is a therapeutic modality commonly used by patients in the management of cancer treatment related symptoms, to support fertility and manage other women's health concerns, to reduce anxiety and stress related symptoms, to support rehabilitation in stroke sequelae, as well as neuropathic, visceral, and musculoskeletal pain. It is increasingly offered in a variety of medical settings such as hospitals, medical school clinics, veterans' healthcare centers, oncology facilities, and rehabilitation centers.

Professional Acupuncturists Training and Qualifications

Acupuncturists in the United States are skilled, licensed practitioners who are highly educated in the complex therapeutic system from which acupuncture arose and in the technical aspects of its utility as a treatment modality. Most acupuncture medicine training programs are undertaken at an accredited educational institution and are approximately 4 years in length. Upon completion of this training, students receive a master's degree or master's level certificate. Students may continue into a doctoral level degree at a later time if they choose to, but a doctoral degree is not required for licensure. The NCCAOM, the national-level certifying body for licensed acupuncturists, seeks to ensure the public's safety and well-being while advancing the professional practice of acupuncture by establishing and promoting national, evidence-supported standards of minimal competence and credentialing. NCCAOM Diplomates must agree to and adhere to the NCCAOM Code of Ethics and must recertify every four years to maintain their certifications. Recertification includes a minimum of 60 hours of continuing education: 30 of these hours must include retraining in acupuncture core competencies. Recertifying diplomates must complete at least four hours of safety and ethics training, including education on blood-borne pathogens, and hold a current CPR certification⁹.

Physiological and Anatomical Effects of Acupuncture

Scientific progress from over fifty years of research conducted primarily in the United States, Europe, and Asia provides supporting evidence of significant physiological effects of acupuncture. These effects span from changes in fibroblasts in the connective tissue to cortical neuronal effects in the brain. These effects are unlike the effects of non-penetrating devices which have been used as sham acupuncture controls.

Upon insertion into the skin, acupuncture needles affect numerous structural and biochemical changes to connective tissue and fascia. When the inserted needle is manually stimulated by twirling and thrusting, these effects are enhanced^{10, 11}. In these and other studies, acupuncture has been shown to change gene transcription and translation^{12 13 14 15}, reduce peripheral inflammation^{16 17 18}, increase blood flow^{19 20}, and alter the biochemical environment of tissues surrounding the needle²¹.

In addition, acupuncture has been shown to change the concentrations of different peripheral neurotransmitters^{22 23} modulating the excitability of peripheral nerve cells that carry information from the rest of the body to the central nervous system.

One of the most well studied actions of acupuncture is its ability to activate the body's own innate pain-relieving mechanism, the endogenous opioid system.^{24 25 26 27}

Human neuroimaging studies have demonstrated that acupuncture can reverse maladaptive neuroplasticity in the brain.²⁸

Mechanisms of Needle Insertion in Acupuncture

- **Research evidence indicates that Acupuncture needling insertion has *specific* biomechanical properties**

There are significant biomechanical properties of needle insertion (incisive) with acupuncture. Research indicates that there are differential biomechanical forces such as insertion and pullout force, which contribute to the sensation of insertion with acupuncture needles.²⁹

- **A key mechanism of acupuncture's effect on pain (analgesia) is *directly dependent* on incisive needle insertion and breaching of the skin.**

The immediate pain relief from acupuncture has been linked to counter-irritation or conditioned pain modulation (CPM), which in animal models is known as diffuse noxious inhibitory control (DNIC). DNIC refers to an endogenous (internal) pain modulatory pathway which has often been described as "pain inhibits pain".³⁰ It occurs when response from a painful stimulus is inhibited by another, often spatially distant, noxious stimulus (i.e. actually, or potentially, damaging to tissue and liable to cause pain), operates as a normal physiological process within the perception of pain (nociception). **Therefore, any applied painful or noxious stimulus (such as an acupuncture needle) will attenuate existing pain.**³¹ It is suggested that this works by both peripheral and central systems. The effect of acupuncture, therefore, requires this nociceptive stimulus, obtained by incisive needle insertion and breaching of the skin. This is *just one* of the many mechanisms of acupuncture identified to date.

- **Needle insertion with acupuncture not only releases the body's natural pain killers, but it *uniquely increases* the binding strength of the Mu opioid receptors (the body's internal system for regulating pain)**

In a neuroimaging study of fibromyalgia patients using PET (Positron emission tomography)³², when comparing penetrating real acupuncture needling (Traditional acupuncture-TA) at specific acupuncture points compared to a non-skin penetrating pricking sensation at 9 non-acupuncture point locations (Sham false acupuncture- SA) using a previously validated sham procedure, the effects were markedly different. Acupuncture (TA) not only elicited the release of endogenous opioids (natural pain killers) but also by penetrating the skin at acupuncture points, TA increased the Mu opioid receptors binding strength. Following acupuncture, patients with greater increases in receptor binding had long-term greater reductions in pain.

- **Needle grasp, and the accompanying “deqi” sensation, considered essential to the therapeutic effect of acupuncture are key in understanding acupuncture mechanism of action and require incisive breaching of the skin.**

Traditional acupuncture needling evokes a reaction known as 'de qi', widely viewed as essential to the therapeutic effect of acupuncture, and it is considered to be key in understanding its mechanism of action. De qi includes a characteristic needling sensation, perceived by the patient, and 'needle grasp' perceived by the acupuncturist. During needle grasp, the acupuncturist feels pulling and increased resistance to further movement of the inserted needle. The needle grasp has been hypothesized to be due to mechanical coupling between the needle and connective tissue with winding of tissue around the needle during needle rotation and that needle manipulation transmits a mechanical signal to connective tissue cells via mechanotransduction. Such a mechanism may explain local and remote, as well as long-term effects of acupuncture. Needle grasp, and the accompanying “deqi” sensation, cannot be obtained without penetration of the skin by needling³³.

- **Needle grasp, and the accompanying “deqi” sensation, compared to superficial insertion produced a pronounced increase in both skin and muscle blood flow.**

Compared to superficial insertion (SI) and to insertion into the anterior tibial muscle (MU), insertion into the muscle including manipulation of the needle in order to elicit the distinct sensation of distension, heaviness or numbness (DeQi), which characterizes acupuncture, the DeQi stimulation resulted in the most pronounced increase in both skin and muscle blood flow³⁴.

- **The modulating effect of electroacupuncture on persistent inflammatory pain depends on the specific parameter (frequency, intensity, treatment duration, and pulse width), and the specific points needed.**

Indicating that incisive penetration of the skin, at specific points determines in great part the effect of acupuncture.³⁵

- Stimulating different acupoints, produces a range of cardiovascular effects influenced by the anatomic location of somatic nerves beneath the acupoints, with deep nerves exerting strong influence and superficial cutaneous nerves demonstrating little or no attenuation of cardiovascular reflex responses.³⁶

Indicating that acupuncture's effects extend beyond the treatment of the musculoskeletal system.

Safety

- **The safety profile of acupuncture is significantly better than most other medical interventions, when performed by trained, qualified and licensed acupuncture practitioners.**

Licensed acupuncturists (LAc's) are the only medical professionals who are trained comprehensively to perform acupuncture within the context of the whole-body system of medicine from which it originates and who use the full scope of all other adjunct modalities. In all but 3 states, acupuncturists are required to be licensed and are generally regulated by the state regulatory agencies that address other medical professions. Licensed acupuncturists are generally also nationally board certified through the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) or in California via the California Acupuncture Licensing Exam (CALE). As with other licensed healthcare professionals, maintenance of licensure varies somewhat state to state but generally requires ongoing certifications in CPR and a minimum number of continuing education units in such topics as patient safety, ethics, biomedicine, and acupuncture-related therapies and theory. Licensed acupuncturists must have a degree from an accredited acupuncture school that requires more than 1300 hours of acupuncture specific training for entry-level competency. This includes anatomy relevant to safe acupuncture practice and supervised clinical training.

- **While chiropractors are highly trained experts in their field, their education does not effectively include invasive techniques that penetrate the skin surface nor the vast body of information on using needling therapeutically.**

"The practice of chiropractic is limited to diagnosing, analyzing, examining, or evaluating the biomechanical condition of the spine and musculoskeletal system, and performing **nonsurgical, nonincisive procedures**, including adjustment and manipulation, to improve the subluxation complex or the biomechanics of the musculoskeletal system."³⁷

- **It is not in the public's best interest to extend the practice of acupuncture to other health care professionals, marginally trained in the practice of acupuncture.**

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- ² NCCIH: Acupuncture in Depth <https://www.nccih.nih.gov/health/acupuncture-in-depth> Page last Updated January 2016. (accessed 05/03/2022).
- ³ "acupuncture" *Merriam-Webster.com* 2022 <https://www.merriam-webster.com/dictionary/acupuncture> (accessed May 3, 2022)
- ⁴ "acupuncture" Google English dictionary, provided Oxford Languages Dictionary. 2022 <https://languages.oup.com/google-dictionary-en/> (accessed May 16, 2022) (see printed document or search acupuncture AND Oxford languages on Google).
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- ⁶ John Hopkins Medicine <https://www.hopkinsmedicine.org/health/wellness-and-prevention/acupuncture>. (accessed May 3, 2022).
- ⁷ Code of Federal Regulations 21 C.F.R. § 880.5580 § 880.5580 Acupuncture needle. Effective: December 30, 2019.
- ⁸ Code of Federal Regulations 21 C.F.R. § 801.109 § 801.109 Prescription devices. Effective: September 13, 2016
- ⁹ <https://www.nccaom.org/certification/> Accessed May 10, 2022
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