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August 19, 2016

By U.S. Mail

The Honorable Ellen Rosenblum
Oregon Attorney General
Department of Justice
1162 Court St., NE
Salem, OR 97301

Re: "Dry Needling" Falls Outside Oregon Physical Therapists' Scope of Practice

Dear Attorney General Rosenblum:

We write on behalf of the Oregon Association for Acupuncture and Oriental Medicine (OAAOM) to provide input on the legal question of whether so-called "dry needling" is authorized within Oregon's physical therapy scope of practice. Simply stated, and as evidenced by ORS 688.010(6) and OAR 848-040-0010(8), Oregon law does not permit physical therapists to insert acupuncture needles into patients as part of their scope of practice regardless of whether the treatment modality is referred to as "dry needling," or by its proper name, "acupuncture."

Under Oregon's statutory scheme, the practice of acupuncture (which perfectly encompasses the "dry needling") is governed by the Oregon Medical Board (OMB). Only licensed practitioners who have satisfied OMB requirements are permitted to stimulate "specific points on the surface of the body by the insertion on needles." *See* ORS 677.765 (defining "acupuncture").

In recent legal challenges to "dry needling," Washington and California courts have agreed that the insertion of needles, whether defined as "acupuncture" or "dry needling," falls outside the scope of those states' physical therapy practices. Similarly, the Oregon Court of Appeals has held that the practice of "physiotherapy" (a term the Oregon Attorney General's office has argued is synonymous with "physical therapy") does not include the treatment modality of "dry needling." *Oregon Ass'n of Acupuncture and Oriental Medicine v. Board of Chiropractic Examiners*, 260 Or App 676, 683, 320 P3d 575 (2014). The Washington Attorney General has also recently concluded that, under Washington law, the statutory definition of physical therapy does not encompass "dry needling."

In fact, federal law prohibits physical therapists from even obtaining FDA-regulated acupuncture needles instead limiting the sale of these needles to "qualified practitioners of acupuncture." 21 CFR § 880.5580(b)(1); 61 Fed. Reg. 64616 (Dec. 6, 1996). In light of

physical therapists' strenuous assertions that they are not practicing acupuncture, it is clear they are not "qualified practitioners of acupuncture" and, therefore, lack a legal basis for even acquiring acupuncture needles.

Any opinion that "dry needling" falls within the scope of "physical therapy" would directly contradict Oregon law defining the limits of physical therapy and would contradict OMB's statutory authority to govern the license and practice of acupuncture in violation of ORS 677.759(1). From a policy perspective, "dry needling" performed by physical therapists creates a substantial risk to the public safety of all Oregonians. As the American Medical Association recently explained in its policy critical of "dry needling by physical therapists, "[l]ax regulation and nonexistent standards surround this invasive practice. For patients' safety, practitioners should meet standards required for licensed acupuncturists and physicians..."[1]

1. Background

At the outset, it is important to note that "dry needling" is "acupuncture." Both involve the insertion of U.S. Food and Drug Administration (FDA)-defined and regulated acupuncture needles into reactive (painful) acupuncture points, known as "*ashi* points." "*Ashi* points," also sometimes referred to as "trigger points," have been used in acupuncture for more than 2,000 years for the exact same therapeutic purposes as "dry needling."[2]

The false notion put forth by "dry needling" promoters - that "dry needling" is somehow distinct from acupuncture because acupuncture involves the insertion of acupuncture needles into "distal points" and the use of "meridians" as opposed to "trigger

[1] *AMA Adopts New Policies on Final Day of Annual Meeting*, AMA-Assn.org, (June 15, 2016) http://www.ama-assn.org/ama/pub/news/news/2016/2016-06-15-new-policies-annual-meeting.page

[2] Yellow Emperor's Inner Classic (黃帝內經, *Huáng Dì nèi jīng*). China; compiled in the first century BCE. Trigger points are reactive (painful) acupuncture points that elicit a flinch reaction on palpation. The *Yellow Emperor's Inner Classic* explains: "a point of pain indicates a clinically relevant acupuncture point" (以痛爲腧, *yǐ tòng wéi shù*)." *See also* Sun SM. Essential prescriptions worth 1,000 liang of gold (千金要方, *Qiān jīn yào fāng*). China; 652 CE. Sun Si Miao (581-682 CE), a renowned physician of the Sui (581–618 CE) and Tang (618–907 CE) dynasties, called reactive (painful) acupuncture points that are eliciting this abnormality "ah yes! points" ("阿是穴"), from the words often uttered by the patient when pressure is applied to them. *See also* Fan, AY *et al.*, Evidence That Dry Needling is the Intent to Bypass Regulation to Practice Acupuncture in the United States, The Journal of Alternative and Complimentary Medicine, Vol. 22:8 (2016).

points" - reflects a fundamental lack of knowledge about acupuncture. The promotors also wrongly assert that "dry needling" is distinct from acupuncture because they claim that "dry needling" comes from a "Western medical" philosophy. As the Oregon Medical Board (OMB) explains, "acupuncture and 'dry needling' use the same tool (acupuncture needles), the same points[3], the same purpose (treating pain), and the same needling techniques. This is why the OMB concluded that the "dry needling" modality "is the practice of acupuncture."[4] As the AMA similarly concludes, "[d]ry needling is indistinguishable from acupuncture...."[5] Notably, "dry needling" also involves the same risks inherent in acupuncture, including organ puncture, nerve damage, and blood infections that are all obvious and FDA-recognized risks. 61 Fed. Reg. 64616 (Dec. 6, 1996). *See* Exhibit 1.

Oregon's physical therapists may have brought this question for Attorney General review at the behest of "dry needling" training companies, which have made a cottage industry of selling training seminars to physical therapists and chiropractors who, in large part, are not legally permitted to perform this modality under their respective state laws. Notably, one of the largest national "dry needling" training companies, Myopain Seminars, openly acknowledges that "dry needling falls within the scope of acupuncture," but asserts that physical therapists also possess the right to engage in it. *See* Exhibits 2 and 3. Even the national Federation of State Boards of Physical Therapy (FSBPT), which strongly advocates for "dry needling" frankly admits, "[w]hen performed by acupuncturists, dry needling is acupuncture."[6] The factors demonstrating that "dry needling" is acupuncture are addressed in a recently published paper titled, "Evidence That Dry Needling is the Intent to Bypass Regulation to Practice Acupuncture in the United States." *See* Exhibit 12.[7]

[3] Exhibit 2 shows photos posted on Twitter by a "dry needling" training company identifying acupuncture points marked on the recipient's skin.

[4] Letter from Kathleen Haley, Advisory Committee Chair Executive Director to Dave McTeague, Executive Director Oregon Board of Chiropractic Examiners, October 27, 2010.

[5] *Physicians Take on Timely Public Health Issues,* AMA Wire (June 15, 2016) http://www.ama-assn.org/ama/ama-wire/post/physicians-timely-public-health-issues

[6] FSBPT Resource Paper Regarding Dry Needling, 5th edition, December 2014, https://c.ymcdn.com/sites/www.nypta.org/resource/resmgr/Committees/DryNeedlingResourcePaper_5th.pdf.

[7] Fan, AY *et al., Evidence That Dry Needling is the Intent to Bypass Regulation to Practice Acupuncture in the United States,* The Journal of Alternative and Complimentary Medicine, Vol. 22:8 (2016).

Tellingly, the American Physical Therapy Association's ("APTA") primary white paper on "dry needling" cites to published *acupuncture studies* to support the effectiveness and benefits of "dry needling."[8] *See* Exhibit 4 which details the APTA's repeated reliance on published acupuncture studies to support the effectiveness of "dry needling."

Physical therapists engaged in "dry needling" may choose to ignore - or are genuinely unaware - that the act they are practicing is indistinguishable from acupuncture. They may claim they are not practicing acupuncture within Oregon's statutory definition, arguing "dry needling" is not an "Oriental health care practice." ORS § 677.757(1)(a). Factually, however, neither lack of awareness nor informed denial about the scope of acupuncture alters the fact that "dry needling" constitutes acupuncture as it has been practiced for millennia in China and for decades in the United States.[9]

2. Under Oregon law, "dry needling" falls outside the physical therapist scope of practice

For physical therapists to employ the modality of "dry needling," it must fall within the scope of "physical therapy" as set forth in ORS 688.010 and its accompanying rules, which permit physical therapists to engage in the "practice of physical therapy" without a physician's license. *University of Oregon Co-Op. Store v. State Dept. of Revenue*, 273 Or 539, 550, 542 P2d 900 (1975) ("An administrative agency may not, by its rules, amend, alter, enlarge, or limit the terms of a legislative enactment.") Any attempt to authorize "dry needling" by regulation or other means would exceed the scope of the Board's legal authority. *Oregon Newspaper Publishers Ass'n v. Peterson,* 244 Or 116, 123-124 (1966). (Board of Pharmacy's regulation prohibiting advertising of prescription drugs exceeded Board's statutory authority). As demonstrated below, "dry needling" does not fall within the physical therapists' scope of practice.

The "practice of physical therapy" means:

[8] FSBPT Resource Paper Regarding Dry Needling, 5th edition, December 2014, https://c.ymcdn.com/sites/www.nypta.org/resource/resmgr/Committees/DryNeedlingResourcePaper_5th.pdf; Description of Dry Needling In Clinical Practice: An Educational Resource Paper, American Physical Therapy Association (APTA) Public Policy, Practice, and Professional Affairs Unit, February 2013, http://www.apta.org/StateIssues/DryNeedling/ClinicalPracticeResourcePaper/.

[9] *See also* Exhibits 11 and 12.

> (a) Examining, evaluating and testing for mechanical, physiological and developmental impairments, functional limitations and disabilities or other neuromusculoskeletal conditions in order to determine a physical therapy diagnosis or prognosis or a plan of physical therapy intervention and to assess the ongoing effects of physical therapy intervention.
>
> (b) Alleviating impairments and functional limitations by designing, implementing, administering and modifying physical therapy interventions.
>
> (c) Reducing the risk of injury, impairment, functional limitation and disability by physical therapy interventions that may include as a component the promotion and maintenance of health, fitness and quality of life in all age populations.
>
> (d) Consulting or providing educational services to a patient for the purposes of paragraphs (a), (b) and (c) of this subsection.

ORS 688.010(6).

In short, physical therapists are permitted to treat and alleviate impairments, injuries, functional limitation and disability only through the employment of "physical therapy interventions." Although the legislature has not defined this term, the Physical Therapy Licensing Board has defined "physical therapy interventions" to mean:

> ...a treatment or procedure and includes but is not limited to: therapeutic exercise; gait and locomotion training; neuromuscular reeducation; manual therapy techniques (including manual lymphatic drainage, manual traction, connective tissue and therapeutic massage, mobilization/manipulation of soft tissue or spinal or peripheral joints, and passive range of motion); functional training related to physical movement and mobility in self-care and home management (including activities of daily living (ADL) and instrumental activities of daily living (IADL)); functional training related to physical movement and mobility in work (job/school/play), community, and leisure integration or reintegration (including IADL, work hardening, and work conditioning); prescription, application, and, as appropriate, fabrication of devices and equipment (assistive, adaptive, orthotic, protective, or supportive); airway clearance techniques; integumentary repair and protective techniques; electrotherapeutic modalities; physical

agents and mechanical modalities; and patient related instruction and education.

OAR 848-040-100(8).

This definition is consistent with the commonly understood definition of physical therapy as a non-invasive practice. Notably, nothing in the licensing board's definition expressly permits the insertion of acupuncture needles into a patient's skin. Even reliance on the general term "mechanical modalities" cannot be rationally interpreted as reflecting the Oregon Legislature's intent to allow physical therapists to perform "dry needling" or any similarly invasive act that could be called a "mechanical modality."

As your office has previously asserted, "physical therapy" (as defined by Webster's Third New Int'l Dictionary), means "the treatment of disease by physical and mechanical means (as massage, regulated exercise, water, light, heat, electricity)." *Oregon Ass'n of Acupuncture and Oriental Medicine v. Board of Chiropractic Examiners,* 260 Or App 676, 681 (2014). Yet, nothing in that definition permits a physical therapist to insert a man-made object into a patient's tissues. *Id.* at 674 (holding the use of "dry needling" to fall outside the chiropractic scope of practice under Oregon law.) Moreover, nothing in that definition (or the legislature's definition of "physical therapy") rationally supports that the Oregon Legislature intended to define "physical therapy" to include the insertion of FDA-regulated acupuncture needles into patients.

There is also no rational interpretation to support a broad generalized right for physical therapists to engage in invasive practices that plainly constitute the practice of medicine as defined in ORS 677.085.[10] Indeed, as the legislature's clear and specific regulation of acupuncture demonstrates, it was well aware of what the practice of acupuncture involved and, given its inherent risks, determined that a specific statutory framework for regulating it under the Oregon Medical Board was necessary. *See* ORS 677.757 *et seq.* Notably, in 2005, long after the legislature had clearly defined the practice of acupuncture, it redefined "physical therapy." 2005 Or. Laws 627; 2005 Ore. HB 3260, enacted July 22, 2005. The legislature could have easily added acupuncture into the

[10] The insertion of acupuncture needles falls well within what is medically considered to be "surgery" by the AMA. "Surgery" is defined by the American Medical Association (AMA), in part, as "the diagnostic or therapeutic treatment of conditions or disease processes by *any instruments causing localized alteration or transposition of live human tissue which include* lasers, ultrasound, ionizing radiation, scalpels, probes, and *needles.*" (emphasis added.) AMA - H-475.983 Definition of Surgery.

physical therapy scope of practice, but did not do so. And where the legislature has omitted language from a statute, it is improper for the courts to insert what has been omitted. ORS 174.010; *Filipetti v. Department of Fish and Wildlife,* 224 Or App 122,129, 197 P3d 535 (2008).

Recently, when faced with the question currently posed here, the Washington Attorney General concluded that Washington's scope of practice for physical therapy did not include "dry needling." As the Washington Attorney General correctly explained, "we do believe that where the legislature has adopted a detailed regulatory scheme for acupuncturists, we should be wary of interpreting broad language regulating the physical therapist profession as including a technique that at the very least is quite similar to acupuncture." *See* Exhibit 5, Washington Attorney General's Opinion, 2016 No. 3 at p. 5.

There is no dispute that the Oregon legislature could have defined "physical therapy" in a manner much broader than the term is commonly understood. But nothing in the current statutory language authorizing physical therapists to engage in "[a]lleviating impairments and functional limitations by designing, implementing, administering and modifying physical therapy interventions," can be rationally read to reflect this intent. Statutory interpretations, of course, must avoid the type of illogical results that would occur from reading the vague language in ORS 688.010(6) as reflecting a legislative intent to broadly authorize physical therapists to engage in highly invasive acts like "dry needling." *Holman Trf. Co. et al v. Portland et al,* 196 Or 551, 564, 249 P2d 175 (1952); *State v. Gaines,* 346 Or 160, 171, 206 P3d 1042, 1050 (2009); ORS 174.020(1)(a).

Indeed, interpreting ORS 688.010(6) to permit the Physical Therapy Licensing Board to deem "dry needling" a "physical therapy intervention" on the grounds that some physical therapists are already engaging in the practice effectively would give the Board and physical therapists themselves the legal authority to rewrite Oregon law. The precedent and public policy implications of such an interpretation would all but remove the legislative and public input involved in defining scope of practice limitations.

3. Outside Oregon, courts have ruled that "dry needling" falls outside the physical therapy scope of practice

Courts in Washington and California have found that "dry needling" falls outside the physical therapy scope of practice in those states. For example, Washington's King County Superior Court ruled that "dry needling" was outside the physical therapy scope of practice and constituted the unlicensed practice of medicine. It concluded that, "there was no

legislative intent to authorize physical therapists to insert acupuncture needles into human tissue for the purpose of dry needling or any similar purpose." *See* Exhibit 7, *South Sound Acupuncture Assoc. v. Kinetacore et al,* Order for Partial Summary Judgment, Case No. 13-2-04894-9 SEA, (Oct. 10, 2014)(hereafter "SSAA v. *Kinetacore*"). As the superior court explained, "[t]he penetration of human tissue with an acupuncture needle or any similar needle used for dry needling is outside the plain text of the authorized scope of practice for physical therapy as adopted by the Washington Legislature..." *Id.* at p. 3.

A recent consent decree approved by a California federal district court similarly noted that "dry needling" falls outside the legal scope of practice for physical therapy in California. As the consent decree states, "[t]he insertion of needles, whether described as acupuncture or dry needling, is presently outside the scope of practice for physical therapy in California..." *See* Exhibit 8, *International Center for Integrative Medicine v. Kinetacore et al, Consent Decree,* U.S. District Court Central District California, Case No. 8:16-cv-00736-JLS-CJS (C.D. Cal. July 7, 2016.)

4. Federal law designates acupuncture needles as a Class II prescription medical device and prohibits the sale and possession of acupuncture needles by persons not authorized to practice acupuncture

It is "undisputed" that physical therapists use FDA-defined "acupuncture needles" for "dry needling." *See* Exhibit 5, Washington Attorney General's Opinion, 2016 No. 3. However, under federal law, physical therapists cannot purchase or possess the acupuncture needles they use for "dry needling." While "dry needlers" prefer to call these needles "solid filiform needles," they are instead what the FDA has plainly defined and regulated as an "acupuncture needle." FDA regulations define an "acupuncture needle" as:

> ...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.*

21 C.F.R. § 880.5580(a) (emphasis added).

In regulating acupuncture needles, the FDA described the risks of acupuncture needles as including "sepsis [severe blood infection], excessive trauma, and perforation of blood vessels and organs." Exhibit 1, 61 Fed. Reg. 64616 (Dec. 6, 1996). As a result, FDA regulations provide specific rules controlling the sale, receipt, and possession of

acupuncture needles, including application of FDA's prescription requirements for medical devices that restrict sale of acupuncture needles to "qualified practitioners of acupuncture." 21 C.F.R. § 880.5580(b)(1); 61 Fed. Reg. 64616 (Dec. 6, 1996). In designating acupuncture needles as a prescription medical device, the FDA has explained that the sale of acupuncture needles "must be clearly restricted to *qualified practitioners of acupuncture* as determined by the States." 61 Fed. Reg. 64616 (Dec. 6, 1996) (emphasis added). 21 C.F.R. § 880.5580(b)(1); 21 C.F.R. § 801.109. The "FDA believes that information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any hazards, contradictions, side effects and precautions are commonly known to qualified practitioners of acupuncture." *See* Exhibit 9.[11]

As a result, the FDA requires that all acupuncture needles carry a warning label that states, "Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States," a warning that can be found in nearly identical text on every box of *legally* sold acupuncture needles in the United States today. *See* Seirin needle label depicted in Exhibit 10.

Physical therapists have no credible argument as to why they can legally purchase and possess acupuncture needles in light of the FDA's express provisions limiting acupuncture needle sales to authorized practitioners of acupuncture. Nevertheless, they assert that the FDA requirement allows the states to determine to whom acupuncture needles can be sold. This, of course, distorts the plain text and intent of the FDA's requirement. Nevertheless, even accepting this argument, a state must first determine who is a "qualified practitioner of acupuncture." The Oregon legislature has never designated physical therapists to be qualified acupuncture practitioners. Thus, the FDA's regulations expressly bar sales of acupuncture needle sales in Oregon to physical therapists who have no training or licensure in acupuncture.

5. "Dry needling" presents serious risk to public safety

To interpret the physical therapy scope of practice to include "dry needling" would seriously compromise the safety of Oregonians by permitting a modality that physical therapists are neither trained for nor tested on as a condition of licensure. A physical therapist can graduate and become licensed in Oregon without having any education or clinical training in the safe use and insertion of acupuncture needles. The Physical Therapy

[11] Letter to James Turner, Acupuncture Coalition from Dr. Susan Alpert, Director Office of Device Evaluation, U.S. Food and Drug Administration, Re: Reclassification Order, March 29, 1996.

Licensing Board has acknowledged this lack of training and calls "dry needling" "an advanced intervention requiring post graduate training and education."[12]

Even so, the typical education for "dry needling" consists of merely a weekend workshop and approximately 27 of training. By contrast, education for persons who want to practice acupuncture in Oregon is from a college or university that provides the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM) prescribed training and curriculum for acupuncture. *See* OAR 847-070-0016. That training devoted to acupuncture includes 1,905 hours of acupuncture education and over 1,000 hours of clinical, hands-on practice.[13] Even medical doctors with extensive training in the use of invasive medical devices, such as acupuncture needles, need to have 300 hours of training in acupuncture (including 100 hours of clinical training) to satisfy the minimal standards for certification from the American Board of Medical Acupuncture (ABMA).[14]

Not unsurprisingly, there have been a number of significant injuries caused by "dry needling." Some of the more high-profile injuries, including pnuemothoraces, are summarized in the attached document. *See* Exhibit 11.

6. The medical community has serious concerns about "dry needling"

The American Medical Association (AMA) at its June 2016 annual meeting adopted a policy in response to concerns about the minimal training many physical therapists receive before engaging in "dry needling." In the AMA's official press release, AMA Board Member Russell W. H. Kridel, M.D., explained, "Lax regulation and nonexistent standards surround this invasive practice. For patients' safety, practitioners should meet standards required for licensed acupuncturists and physicians..."[15] The AMA adopted a policy providing,

[12] *Oregon Physical Therapist Licensing Board 2.18.14 Board Updated Statement Relevant to Physical Therapists using the Intervention of Dry Needling.*
https://www.oregon.gov/PTbrd/docs/02.18.14.Revised.Statement.pdf

[13] *Credentialing Information Tool, Integrative Medicine Advisory Group to the Oregon Health Authority,* 2014. http://www.oregon.gov/oha/Transformation-Center/Resources/IMAG-Credentialing-Tool_FINAL_012015.pdf

[14] American Board of Medical Acupuncture, *Requirements for Certification in Medical Acupuncture,* http://www.dabma.org/requirements.asp (last visited August 18, 2016)

[15] *AMA Adopts New Policies on Final Day of Annual Meeting,* AMA-Assn.org, (June 15, 2016) http://www.ama-assn.org/ama/pub/news/news/2016/2016-06-15-new-policies-annual-meeting.page

"[O]ur AMA recognizes "dry needling" as an invasive procedure and maintains that "dry needling" should only be performed by practitioners with standard training and familiarity with routine use of needles in their practice, such as licensed medical physicians and licensed acupuncturists." *See* Exhibit 6.

Medical doctors with the American Association of Medical Acupuncture (AAMA) have also rebuked the practice of physical therapists engaging in "dry needling":

> To include dry needling into the scope of practice by physical therapists is unnecessarily to expose the public to serious and potentially hazardous risks. Because of this we feel a duty to inform legislators and regulating bodies about the inherent danger to the public of this practice.
>
> Therefore, the AAMA strongly believes that, for the health and safety of the public, this procedure should be performed only by practitioners with extensive training and familiarity with routine use of needles in their practice and who are duly licensed to perform these procedures, such as licensed medical physicians or licensed acupuncturists.[16]

The association of medical doctors who practice physiatry, the American Academy of Physical Medicine and Rehabilitation (AAPMR) "maintains that [dry needling] should only be performed by practitioners with standard training and familiarity with routine use of needles in their practice, such as licensed acupuncturists or licensed medical physicians."[17]

7. Conclusion

The Oregon legislature never intended for physical therapists to perform so-called "dry needling" or any other similarly invasive medical acts. This treatment modality falls outside the scope of their practice, and any attempt by the Physical Therapy License Board or the Attorney General's office to expand the physical therapy scope of practice without the legislature's intent would violate Oregon law.

[16] AAMA Position Paper, http://www.medicalacupuncture.org/For-Physicians/About-the-AAMA/AAMA-Position-Statement (last accessed August 18, 2016).

[17] *AAPM&R Position on Dry Needling*, June 2012, https://www.aapmr.org/docs/default-source/protected-advocacy/Position-Statements/aapmr-position-on-dry-needling.pdf?sfvrsn=2

OAAOM fully supports physical therapists obtaining the classroom, clinical training, and licensure required under Oregon law to safely and effectively practice acupuncture. Any finding, however, that physical therapists are immune from the safety, training, and licensing requirements applicable to the practice of acupuncture would be contrary to the law and the public interest.

Sincerely,

Thane W. Tienson
Patrick T. Foran
On behalf of the Oregon Association of Acupuncture and Oriental Medicine

Enclosures

Exhibit 1

Therefore, a regulatory flexibility analysis as provided in Public Law 96-354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act

This regulation imposes no reporting/recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: December 2, 1996.

Shirley S. Chater,

Commissioner of Social Security.

For the reasons set forth in the preamble, part 404, subpart P, chapter III of title 20 of the Code of Federal Regulations is amended as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950-)

Subpart P—[Amended]

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)-(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)-(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)).

2. Appendix 1 to subpart P of part 404 is amended by revising item 1 of the introductory text before part A to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

* * * * *

1. Growth Impairment (100.00): December 7, 1998.

* * * * *

[FR Doc. 96-31037 Filed 12-5-96; 8:45 am]

BILLING CODE 4190-29-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket Number 94P-0443]

Medical Devices; Reclassification of Acupuncture Needles for the Practice of Acupuncture

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is reclassifying acupuncture needles for the practice of acupuncture and substantially equivalent devices of this generic type from class III (premarket approval) into class II (special controls). FDA is also announcing it has issued an order in the form of a letter to the Acupuncture Coalition reclassifiying acupuncture needles. This action is in response to petitions filed by the Acupuncture Coalition and in keeping with, but not dependent upon, the recommendation of FDA's Anesthesiology Devices Advisory Panel (the Panel). This action is being taken because the agency believes that there is sufficient information to establish that special controls will provide reasonable assurance of the safety and effectiveness of acupuncture needles.

EFFECTIVE DATE: December 6, 1996.

FOR FURTHER INFORMATION CONTACT: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8879.

SUPPLEMENTARY INFORMATION: On December 6, 1995, FDA filed reclassification petitions from the Acupuncture Coalition, which includes representatives of the following manufacturers: Carbo (Mfg.), China; Hwa-To, China; Chung Wha, South Korea; Taki, South Korea; Dong Bang, South Korea; Tseng Shyh Co., Taiwan; HCD, France; Sedatelec, France; Seirin-Kasei (Mfg.), Japan; Ito Co., Japan; and Ido-No-Nippon-Sha, Japan, requesting reclassification of acupuncture needles from class III to class II. On March 29, 1996, FDA issued an order (Ref. 1) in the form of a letter, to the petitioners reclassifying acupuncture needles for the practice of acupuncture and substantially equivalent devices of this generic type from class III to class II. Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)) and § 860.134 (21 CFR 860.134) provide for the reclassification by order of devices not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments.

Under section 513(f)(2) of the act and § 860.134, FDA may refer a reclassification petition to an appropriate panel. Although FDA did not refer the reclassification petitions submitted by the Acupuncture Coalition to a panel, the Anesthesiology Devices Advisory Panel (the Panel) had previously considered the classification of acupuncture needles and other acupuncture devices and recommended that acupuncture needles be placed into class II, as reported in the Federal Register of November 2, 1979 (44 FR 63292 at 63299) (Ref. 2). The supplemental data sheet completed by the Panel on November 30, 1976 (Ref. 3), listed sepsis, excessive trauma, and perforation of blood vessels and organs as specific risks, and recommended restricting the device to prescription use. FDA's decision to reclassify acupuncture needles as class II is in keeping with, but not dependent upon, the recommendation of the Panel.

FDA determined that acupuncture needles could safely be reclassified from class III to class II with the implementation of special controls. Acupuncture needles are devices intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle and may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

The order identified the special controls needed to provide reasonable assurance of the safety and effectiveness of acupuncture needles. Those special controls are in compliance with: (1) Labeling provisions for single use only and the prescription statement in § 801.109 (21 CFR 801.109) (restriction to use by or on the order of qualified practitioners as determined by the States), (2) device material biocompatibility, and (3) device sterility. FDA believes that information for use, including: Indications, effects, routes, methods, and frequency and duration of administration; and any hazards, contraindications, side effects, and precautions are commonly known to qualified practitioners of acupuncture. Therefore, under § 801.109(c), such indications do not need to be on the dispensing packaging, but sale must be clearly restricted to qualified practitioners of acupuncture as determined by the States. Guidance on the type of information needed to support biocompatibility and sterility of

acupuncture needles is available in the General Hospital Branch guidance document entitled "Guidance on the Content of Premarket Notification (510(k)) Submissions for Hypodermic Single Lumen Needles" (draft), April 1993 (Ref. 4). A copy of this guidance document is available from the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850-4307, 301-443-6597 or 800-638-2041 and FAX 301-443-8818.

Consistent with the act and the regulations, after thorough review of the clinical data submitted in the petitions, and after FDA's own literature search, on March 29, 1996, FDA sent the Acupuncture Coalition a letter (order) reclassifying acupuncture needles for general acupuncture use, and substantially equivalent devices of this generic type, from class III to class II (special controls). As required by § 860.134(b)(7), FDA is announcing the reclassification of the generic type of device. Additionally, FDA is amending part 880 (21 CFR part 880) to include the classification of acupuncture needles for the practice of acupuncture by adding new § 880.5580.

Environmental Impact

The agency has determined that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Under 21 CFR 25.24(e)(2), the reclassification of a device is categorically exempt from environmental assessment and environmental impact statement requirements. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of devices from class III to class II will relieve some manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this final rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (Pub. L. 104-13). Rather, the proposed warning statements are "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA letter (order) to the Acupuncture Coalition dated March 29, 1996.

2. Classification of anesthesiology devices, development of general provisions; 44 FR 63292 at 63299, November 2, 1979.

3. Anesthesiology Devices Advisory Panel's supplemental data sheet, November 30, 1976.

4. Guidance on the Content of Premarket (510(k)) Submissions for Hypodermic Single Lumen Needles (draft), April 1993.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 880.5580 is added to subpart F to read as follows:

§ 880.5580 Acupuncture needle.

(a) *Identification.* 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.

(b) *Classification.* Class II (special controls). Acupuncture needles must comply with the following special controls:

(1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,

(2) Device material biocompatibility, and

(3) Device sterility.

Dated: November 20, 1996.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96-31047 Filed 12-5-96; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 5

[Docket No. FR-4154-C-02]

RIN 2501-AC36

Revised Restrictions on Assistance to Noncitizens; Correction

AGENCY: Office of the Secretary, HUD.

ACTION: Interim rule, correction.

SUMMARY: On November 29, 1996 (61 FR 60535), HUD published an interim rule implementing the changes made to Section 214 of the Housing and Community Development Act of 1980 by the Use of Assisted Housing by Aliens Act of 1996. Section 214 prohibits HUD from making certain financial assistance available to persons other than United States citizens, nationals, or certain categories of eligible noncitizens. The November 29, 1996 interim rule incorrectly provided for a public comment due date of November 29, 1996. The public comment due date should have been January 28, 1997, 60 days after publication of the November 29, 1996 interim rule. The purpose of this document is to correct the due date for public comments in the November 29, 1996 rule.

Exhibit 2

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Raymond Butts
@RayButtsDPTPhD

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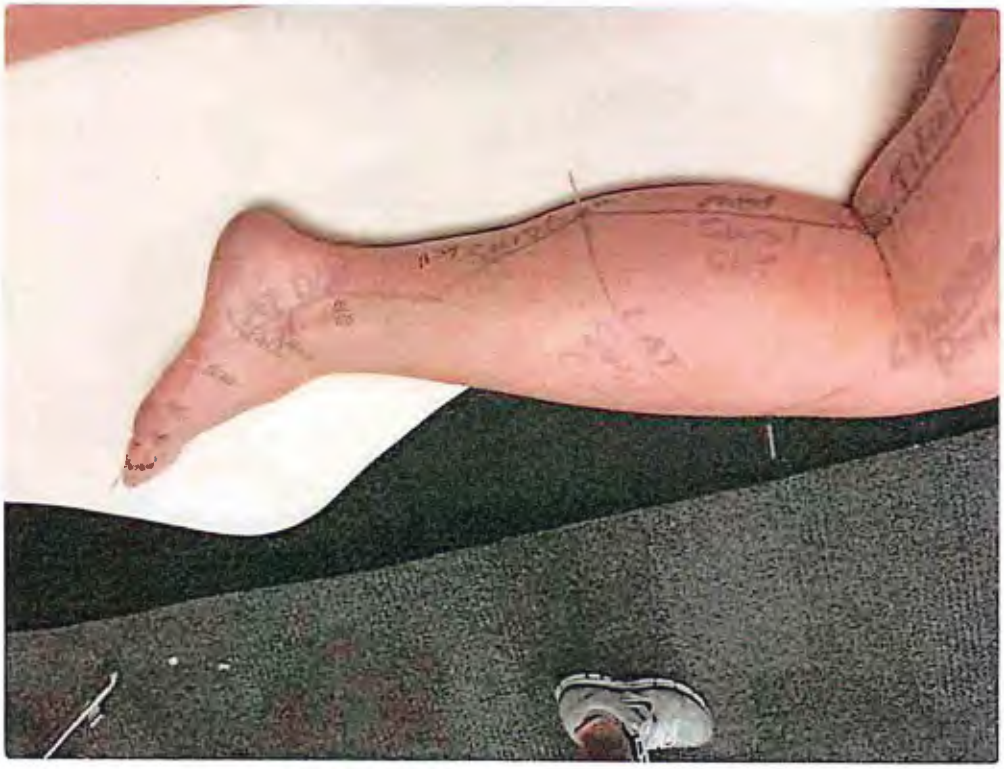
72 students learning Peri neural DN of superficial perineal and lat. dor. Cutaneous at DN-2 in Atlanta. @DrDunning



RETWEETS 9 LIKES 9

2:30 PM - 6 Feb 2016

Exhibit 2
Page 1 of 5

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DNI Tommy Perreault
@TommyDPT

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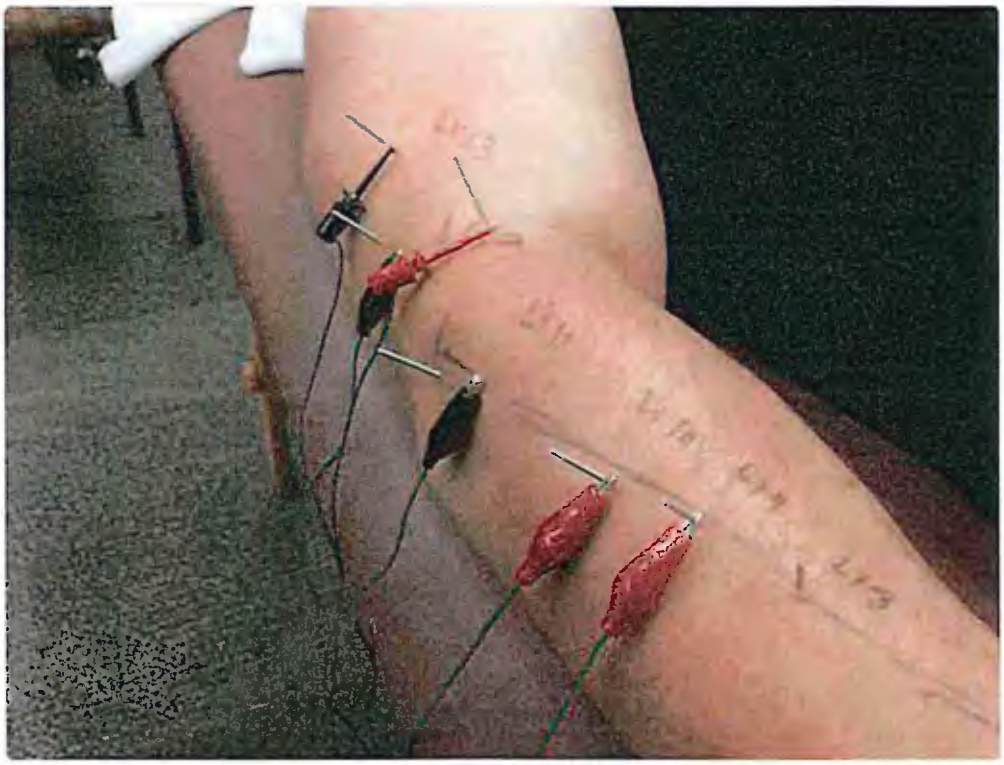
Gadau et al 2014 found needling better for lat elbow pain than conv therapy, including Injections @dryneedling



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Page 2 of 5

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Estee Pavkovich
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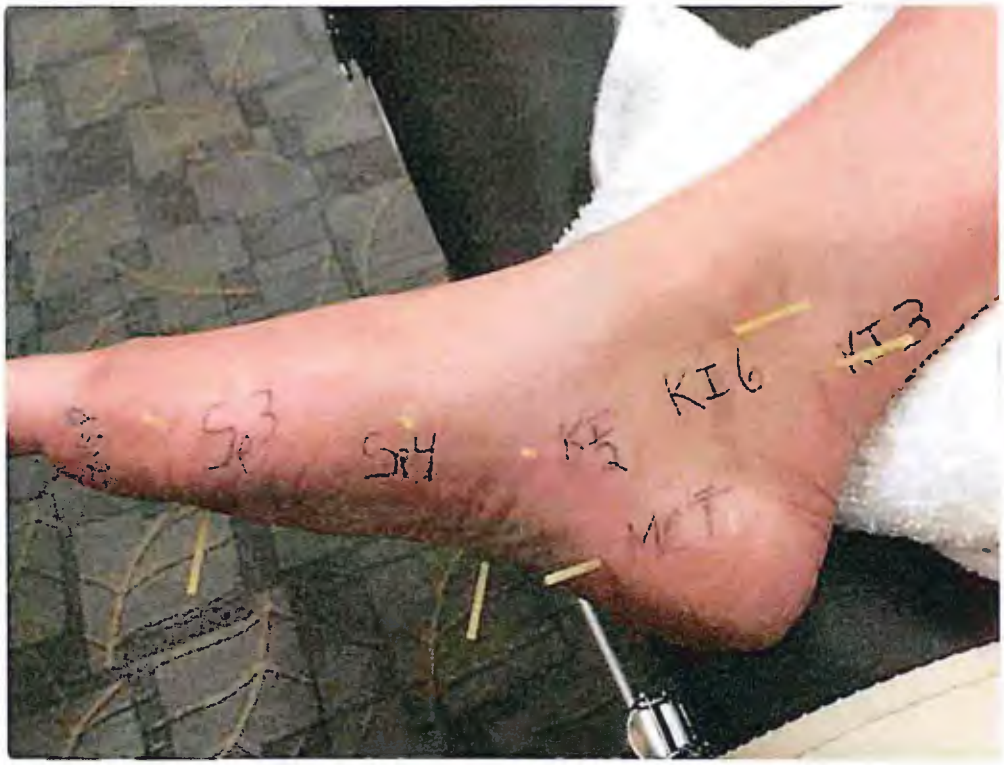
AAMT day 5 in Columbia SC! @DrRonPavkovich @caseyPT23 @suddarthbyrd @Amelious



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6:19 AM - 13 Aug 2015

Exhibit 2
Page 3 of 5

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DNI Dry Needling
@dryneedling

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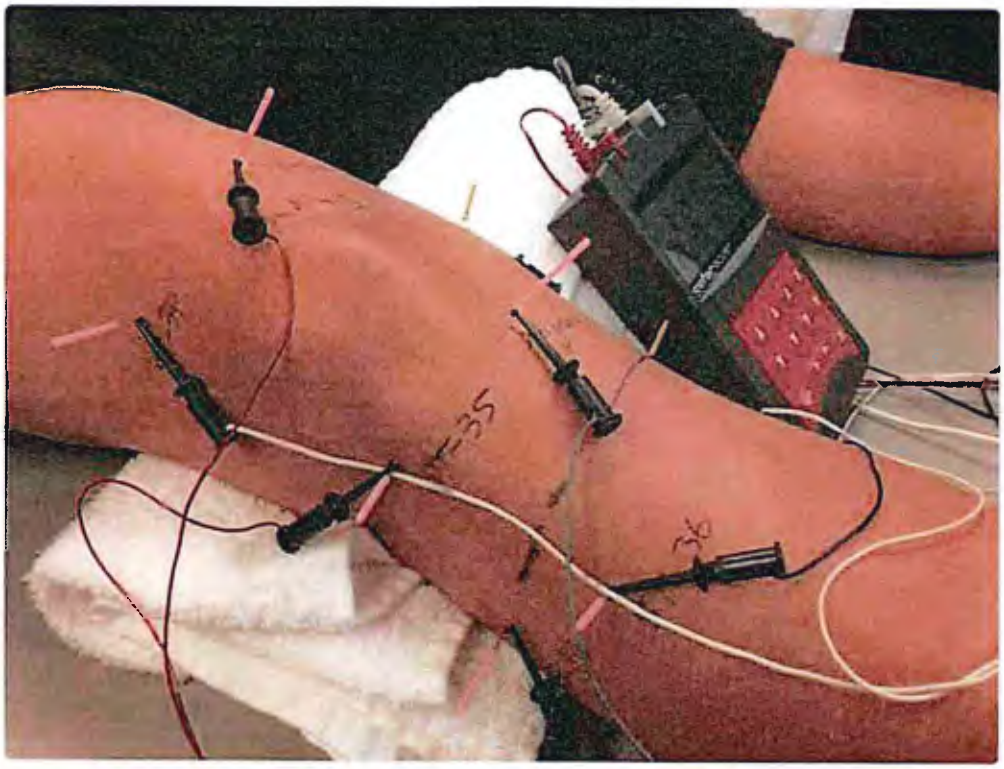
9-point semi-standardized electrical #dryneedling for knee osteoarthritis #DiplomaOsteopractic @FirasMourad



RETWEETS 2 LIKES 3

3:39 PM - 20 Sep 2014

Exhibit 2
Page 4 of 5

Home Moments Search Twitter Have an account? Log in

DNI Tommy Perreault
@TommyDPT

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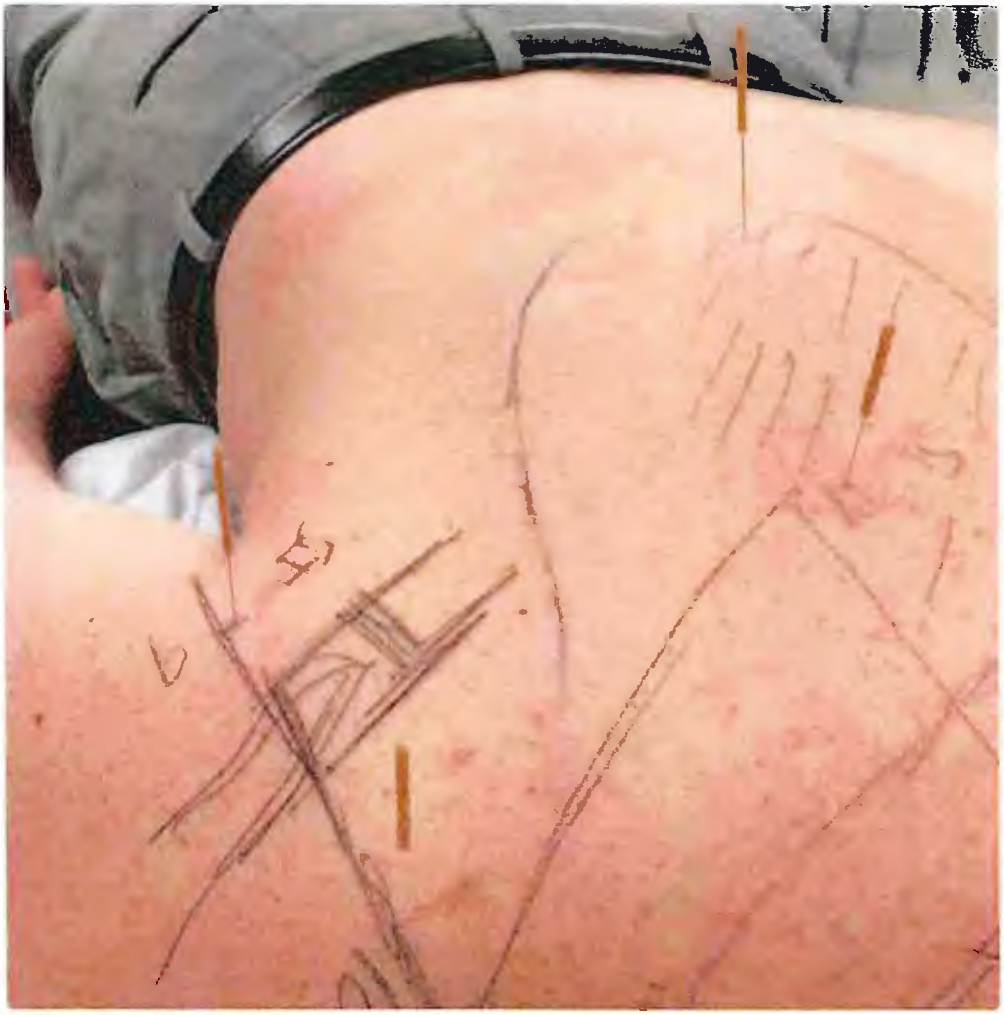
@dryneedling for chronic myofascial shoulder pain at DN-1 at Ohio State University



RETWEETS 4 LIKES 7

Exhibit 2
Page 5 of 5

Exhibit 3

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Myopain Seminars

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February 4 at 12:56pm

Prominent physical therapists admit that dry needling is acupuncture. Jan Dommerholt, who is the owner of Myopain Seminars, one of the outfits that actually trains PTs in dry needling, first denied that they were the same but then admitted "he was resorting to turf behavior". He later came around and said actually I was mistaken and admits now they are the same.

Incorrect: this is what I wrote in July 2008 (!):

I agree with the AAAOM that dry needling falls within the scope of acupuncture practice, which is why acupuncture practitioners are invited to attend our courses. I do not agree however, that dry needling would fall within the exclusive domain of any discipline, including acupuncture, physical therapy, or medicine.

There is no question that some of the trigger points have been described previously as acupuncture points, a shi points, kori, myogelosis, fibrosis, etc.

That does not mean however, that the phenomenon of a localized muscle contracture and its treatment with needles belong to one discipline only.

As Ms. Hobbs pointedly paraphrased, in some past articles I may have expressed a rather biased and simplistic opinion of acupuncture. After reviewing Ms. Hobbs' criticism, I believe that some of my comments were partially in response to assertive efforts of particular acupuncture practitioners to prohibit any needling procedures by physical therapists, and partially due to ignorance. In retrospect, I regret that sometimes I resorted to "turf behavior" and that I did not study the various schools of acupuncture in more detail to gain a better understanding of the varied perspectives of acupuncturists. I had restricted my perspective to the energetic concepts of traditional Chinese medicine. Interestingly, acupuncturist Amado wrote that when acupuncture is defined as an effort to control energy flow, there are few if any correlations with trigger point dry needling. He maintained that traditional Chinese medicine would be based on pre-scientific ideas, rather than the scientific neurophysiologic and anatomic principles underlying dry needling.

In the same paper, I also quoted Jane Goodall as "change happens by listening and then starting a dialogue with the people who are doing something you don't believe is right."

Nowhere in the article, or in any other publication or public statement have I ever stated that dry needling and acupuncture are the same. Andrew McIntyre does not seem to understand that the dialogue Jane Goodall referred to cannot happen by misquoting "prominent physical therapists". His statement is 100% incorrect, misleading and dishonest.

Fact checking on testimony on the Senate bill SB 6374 in Washington State: 9

For the full testimony, visit http://bit.ly/1SnpqVH -

Exhibit 3
Page 1 of 1

Exhibit 4

The American Physical Therapy Association's primary resource paper on "Dry Needling" repeatedly relies on published acupuncture studies to support and explain "dry needling"

APTA Paper: "Description of Dry Needling In Clinical Practice: An Educational Resource Paper"
Produced by the American Physical Therapy Association (APTA) Public Policy, Practice, and Professional Affairs Unit
February 2013

The citations within the APTA's article repeatedly rely on and cite to published studies on acupuncture to explain and discuss dry needling. Below we reference: 1. the text from the APTA's "Description of Dry Needling In Clinical Practice" Resource Paper; 2. the citation in the APTA's paper to the relevant acupuncture study; and 3. the abstract from the published paper on acupuncture.

Text Pertaining to Reference 31: (*See* page 2, column 1, paragraph 3)

Stimulation of TrPs activates the periaqueductal grey and anterior cingular cortex in the brain,[28-30] and enkaphalinergic, serotonergic, and noradrenergic inhibitory systems associated with A-Δ (A delta) fibers through segmental inhibition.[31,32]

Text Pertaining to Reference 31: (*See* page 2, column 2, paragraph 2)

DN has been shown to directly activate fibroblasts through mechanical manipulation of the needle,[31,64,65] which in turn activates the release of cytokines and other pro-inflammatory mediators.[66-70]

Reference 31:

31. Langevin HM, Bouffard NA, Badger GJ, Churchill DL, Howe AK. Subcutaneous tissue fibroblast cytoskeletal remodeling induced by acupuncture: Evidence for a mechanotransduction-based mechanism. *J Cell Physiol.* May 2006;207(3):767-774.

Abstract:

Acupuncture needle rotation has been previously shown to cause specific mechanical stimulation of subcutaneous connective tissue. This study uses acupuncture to investigate the role of mechanotransduction-based mechanisms in mechanically-induced cytoskeletal remodeling. The effect of acupuncture needle rotation was quantified by morphometric analysis of mouse tissue explants imaged with confocal microscopy. Needle rotation induced extensive fibroblast spreading and lamellipodia formation within 30 min, measurable as an increased in cell body cross sectional area. The effect of rotation peaked with two needle revolutions and decreased with further increases in rotation. Significant effects of rotation were

present throughout the tissue, indicating the presence of a response extending laterally over several centimeters. The effect of rotation with two needle revolutions was prevented by pharmacological inhibitors of actomyosin contractility (blebbistatin), Rho kinase (Y-27632 and H-1152), and Rac signaling. The active cytoskeletal response of fibroblasts demonstrated in this study constitutes an important step in understanding cellular mechanotransduction responses to externally applied mechanical stimuli in whole tissue, and supports a previously proposed model for the mechanism of acupuncture involving connective tissue mechanotransduction.

Text Pertaining to Reference 52: (*See* page 2, column 2, paragraph 1)

Superficial DN is associated with reduced local and referred pain and improved range of motion,[52,53] but it is not known at this time whether superficial DN has any impact on normalizing the chemical environment of active TrPs or reducing motor endplate noise associated with TrPs in general.

Reference 52:

52. Ceccherelli F, Rigoni MT, Gagliardi G, Ruzzante L. Comparison between superficial and deep acupuncture in the treatment of lumbar myofascial pain: a double-blind randomized controlled study. *Clin J Pain.* 2002;18:149-153.

Abstract:

Objective: The aim of the study was to compare the therapeutic effect of the superficial and in-depth insertion of acupuncture needles in the treatment of patients with chronic lumbar myofascial pain.

Design: A prospective randomized double-blind study of superficial and deep acupuncture was conducted.

Setting: The study was conducted in the Pain Service Unit of the University of Padova.

Patients: The study comprised 42 patients with lumbar myofascial pain who were divided into two equal groups (A and B).

Intervention: In group A, the needle was introduced in the skin at a depth of 2 mm, whereas in group B the needle was placed deeply into muscular tissue. The treatment was planned for a cycle of eight sessions.

Outcome Measures: The intensity of pain was evaluated with the McGill Pain Questionnaire before and after treatment and at the 3-month follow-up examination.

Results: Although at the end of the treatment there was no evidence of significant statistical differences between the two different groups, pain reduction was greater in the group treated with deep acupuncture. A statistical difference existed between the two groups at the 3-month follow up, with a better result in the deeply stimulated group.

Conclusions: Clinical results show that deep stimulation has a better analgesic effect when compared with superficial stimulation.

Text Pertaining to Reference 73: (*See* page 2, column 2, paragraph 2)

DN can play a substantial role in the process of mechanotransduction, which is described as the process by which the body converts mechanical loading into cellular responses.[20,71-76]

Reference 73:

73. Langevin HM, Churchill DL, Cipolla MJ. Mechanical signaling through connective tissue: a mechanism for the therapeutic effect of acupuncture. *FASEB J.* Oct 2001;15(12):2275-2282.

Abstract:

The mechanism of action of acupuncture remains largely unknown. The reaction to acupuncture needling known as 'de qi', widely viewed as essential to the therapeutic effect of acupuncture, may be a key to 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. We hypothesize that *1)* needle grasp is due to mechanical coupling between the needle and connective tissue with winding of tissue around the needle during needle rotation and *2)* 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.

Text Pertaining to Reference 107: (*See* page 3, column 1, paragraph 1)

TrPs have been identified in numerous diagnoses, such as radiculopathies,[78] joint dysfunction,[79] disk pathology,[80] tendonitis,[81] craniomandibular dysfunction,[82,83] migraines,[84,85] tension-type headaches,[86,87] carpal tunnel syndrome,[88,89] computer-related disorders,[90,91] whiplash associated disorders,[92-94] spinal dysfunction,[95] pelvic pain and other urologic syndromes,96-99 post-herpetic neuralgia,[100,101] complex regional pain syndrome,[102,103] nocturnal cramps,[104] phantom pain,[105,106] and other relatively uncommon diagnoses such as Barré Liéou syndrome,[107] or neurogenic pruritus,[108] among others.[109]

Reference 107:

107. Longbottom J. A case report of postulated 'Barré Liéou syndrome'. *Acupunct Med.* Mar 2005;23(1):34-38.

Abstract:

The case history presented is of a 32 year old woman suffering with severe occipital and bilateral temporal pain together with autonomic disturbances affecting her vision, balance and breathing, symptoms which have been postulated as 'Barré Liéou syndrome'. She complained of pain referred to the left arm and associated circulatory and sensory disturbance in keeping with the diagnosis of complex regional pain syndrome type I. Traditional Chinese and Western trigger point acupuncture techniques were used in order to treat her pain and autonomic dysfunction. Acupuncture was successful in reducing, but not totally alleviating, her pain, and was particularly effective in reducing the majority of autonomic symptoms.

Text Pertaining to Reference 108: (*See* page 3, column 1, paragraph 1)

TrPs have been identified in numerous diagnoses, such as radiculopathies,[78] joint dysfunction,[79] disk pathology,[80] tendonitis,[81] craniomandibular dysfunction,[82,83] migraines,[84,85] tension-type headaches,[86,87] carpal tunnel syndrome,[88,89] computer-related disorders,[90,91] whiplash associated disorders,[92-94] spinal dysfunction,[95] pelvic pain and other urologic syndromes,96-99 post-herpetic neuralgia,[100,101] complex regional pain syndrome,[102,103] nocturnal cramps,[104] phantom pain,[105,106] and other relatively uncommon diagnoses such as Barré Liéou syndrome,[107] or neurogenic pruritus,[108] among others.[109]

Reference 108:

108. Stellon A. Neurogenic pruritus: an unrecognised problem? A retrospective case series of treatment by acupuncture. *Acupunct Med.* Dec 2002;20(4):186-190.

Referenced Article:

Neurogenic Pruritus: An Unrecognised Problem? A Retrospective Case Series of Treatment by Acupuncture

Abstract:

Intractable localised segmental pruritus without a rash has been reported over the years under various titles depending on the area of the body affected. Notalgia paraesthetica and brachioradial pruritus are the two terms used for what is believed to be a form of neuropathy. The clinical observations reported here suggest that other localised cases of pruritus exist that share common clinical features, and the term neurogenic pruritus is suggested to encompass these under one clinical condition. Acupuncture has been used to treat skin conditions, of which pruritus is one symptom. This retrospective study looked at the symptomatic relief of neurogenic pruritus in 16 patients using acupuncture. In 12 cases the affected dermatomes of the body were innervated by cervical spinal nerves, seven

innervated by dorsal spinal nerves and four innervated by the lumbar spinal nerves. Seven patients had areas affected by two different regions of the spine. Restricted neck or back movements were noted in patients as were areas of paravertebral spasm or tenderness of the muscles. Total resolution of symptoms as judged by VAS occurred in 75% of patients. Relapse occurred in 37% of patients within 1-12 months following treatment. Acupuncture appeared to be effective in alleviating the distressing symptom of itching in patients presenting with neurogenic pruritus.

Text Pertaining to Reference 111: (*See* page 3, column 2, paragraph 14)

13. DN during the first trimester of pregnancy, during which miscarriage is fairly common, must be approached with caution, even though there is no evidence that DN has any potential abortifacient effects.[111-113]

Reference 111:

111. Betts D, Budd S. 'Forbidden points' in pregnancy: historical wisdom? *Acupunct Med.* 2011;29:137-139.

Referenced Article:

'Forbidden points' in pregnancy: historical wisdom?

Abstract:

Within the acupuncture literature there is debate on the safety of using specific acupuncture points during pregnancy. Termed 'forbidden' or contraindicated, they refer to acupuncture points that can be used to induce labour but may also include points withno known inducing or labour-enhancing effects. Recommendations range from avoiding these acupuncture points at any time in pregnancy to statements that despite the warnings in the literature, these points are not contraindicated during a normal pregnancy. This discussion paper examines the historical use of contraindicated points, the physiology of the pregnant body and the effect of these points during research trials. It is hoped that this will encourage further discussion and provide a background for practitioners to make informed choices about how they use these points in clinical practice.

Text Pertaining to Reference 112: (*See* page 3, column 2, paragraph 14)

13. DN during the first trimester of pregnancy, during which miscarriage is fairly common, must be approached with caution, even though there is no evidence that DN has any potential abortifacient effects.[111-113]

Reference 112:

112. Cummings M. 'Forbidden points' in pregnancy: no plausible mechanism for risk. *Acupunct Med.* 2011;29:140-142.

Referenced Article:
'Forbidden points' in pregnancy: no plausible mechanism for risk

Abstract:
It has been suggested that acupuncture may pose particular risks during pregnancy: by enhancing oxygenation to the developing embryo (presumably via increasing blood flow to the uterus); by affecting the level of maternal progesterone in early pregnancy; or by stimulating uterine contractions. This article examines the proposed risks and fails to find any plausible physiological mechanism for them.

Text Pertaining to Reference 113: (*See* page 3, column 2, paragraph 14)

13. DN during the first trimester of pregnancy, during which miscarriage is fairly common, must be approached with caution, even though there is no evidence that DN has any potential abortifacient effects.[111-113]

Reference 113:

113. Guerreiro da Silva AV, Uchiyama Nakamura M, Guerreiro da Silva JB. 'Forbidden points' in pregnancy: do they exist? *Acupunct Med.* 2011;29:135-136.

Referenced Article:
'Forbidden points' in pregnancy: do they exist?

Abstract:
Acupuncture has been used in numerous diseases and for many types of symptoms.It has been also used for obstetric complaints, such as nausea and vomiting, insomnia and low back and girdle pain. There has long been concern that some points—called forbidden—might harm pregnancy owing to a potential abortifacient effect, but itis difficult to confirm this proposition. The small number of available publications on this topic seems to show that this is not correct. Animal research examining possible harmful effects and a systematic review would be welcome to throw some light on this question.

Text Pertaining to Reference 120: (*See* page 4, column 2, paragraph 2)

For neuropathic pain, frequencies between 80 and 100 Hz are recommended, which are thought to affect the release of dynorphin, gamma-aminobutyric acid, and galanin.[120]

Reference 120:

120. Lundeberg T, Lund I. Is there a role for acupuncture in endometriosis pain, or 'endometrialgia'? *Med Acupunct.* Jun 2008;26(2):94-110.

Referenced Article:

Is there a role for acupuncture in endometriosis pain, or 'endometrialgia'?

Abstract:

Endometriosis is a common cause of pelvic pain in women, many of whom suffer a progression of symptoms over their menstrual life. Symptoms may include combinations of abnormal visceral sensations and emotional distress. Endometriosis pain, or 'endometrialgia' often has a negative influence on the ability to work, on family relationships and sense of worth.

Endometrialgia is often considered to be a homogeneous sensory entity, mediated by a specialised high threshold sensory system, which extends from the periphery through the spinal cord, brain stem and thalamus to the cerebral cortex. However, multiple mechanisms have been detected in the nervous system responsible for the pain including peripheral sensitisation, phenotypic switches, central sensitisation, ectopic excitability, structural reorganisation, decreased inhibition and increased facilitation, all of which may contribute to the pain.

Although the causes of endometrialgia can differ (eg inflammatory, neuropathic and functional), they share some characteristics. Endometrialgia may be evoked by a low intensity, normally innocuous stimulus (allodynia), or it may be an exaggerated and prolonged response to a noxious stimulus (hyperalgesia). The pain may also be spontaneous in the absence of any apparent peripheral stimulus.

Oestrogens and prostaglandins probably play key modulatory roles in endometriosis and endometrialgia. Consequently many of the current medical treatments for the condition include oral drugs, like non-steroid anti-inflammatory drugs, contraceptives, progestogens, androgenic agents, gonadotrophin releasing hormone analogues, as well as laparoscopic surgical excision of the endometriosis lesions. However, management of pain in women with endometriosis is currently inadequate for many. Possibly acupuncture and cognitive therapy may be used as an adjunct.

Text Pertaining to Reference 121: (*See* page 4, column 2, paragraph 2)

The needles can be placed directly in or at either side of a TrP.[121,122]

Reference 121:

121. Elorriaga A. The 2-Needle Technique. *Med Acupunct.* 2000;12(1):17-19.

Referenced Article:

The 2-Needle Technique

Abstract:
The "2-needle technique," a relatively unknown acupuncture method for the treatment of chronic musculoskeletal pain, is useful for trigger point inactivation in muscles, ligaments, and/or periosteum. Indications, procedure, treatment precautions, and the role of trigger point inactivation in the treatment of chronic musculoskeletal pain is discussed.

Exhibit 5

Opinion
Robert W. Ferguson
Attorney General of Washington

PHYSICAL THERAPISTS—Scope Of Practice Of Physical Therapy

The practice of dry needling does not fall within the scope of practice of a licensed physical therapist.

April 15, 2016

The Honorable Eileen Cody
State Representative, District 34
PO Box 40600
Olympia, WA 98504-0600

Cite As:
AGO 2016 No. 3

Dear Representative Cody:

By letter previously acknowledged, you have requested our opinion on the following question:

> **Is the practice of dry needling within a licensed physical therapist's scope of practice as defined in RCW 18.74?**

BRIEF ANSWER

No. The statute that defines the practice of physical therapy allows a variety of interventions, but we conclude that the best reading of the statute excludes dry needling from the practice of physical therapy. Our conclusion is based solely on the law as currently written; it is not our role to weigh the policy benefits and drawbacks of authorizing physical therapists to engage in dry needling. The legislature, of course, could also expand the scope of physical therapy by amending the relevant statutes.

ANALYSIS

We start by describing dry needling. As your letter summarizes, dry needling is a practice in which a solid (as opposed to hollow) needle is inserted through the skin for therapeutic effect. It is also known as intramuscular stimulation, intramuscular manual therapy, trigger point dry needling, or intramuscular needling. The American Physical Therapy Association describes dry needling as

> a skilled intervention that uses a thin filiform needle to penetrate the skin and stimulate underlying myofascial trigger points, muscular, and connective tissues for the management of neuromusculoskeletal pain and movement impairments. Dry needling (DN) is a technique used to treat dysfunctions in skeletal muscle, fascia, and connective tissue, and, diminish persistent peripheral nociceptive

> input, and reduce or restore impairments of body structure and function leading to improved activity and participation.

American Physical Therapy Ass'n, *Description of Dry Needling In Clinical Practice: An Educational Resource Paper* (*APTA Paper*) 2 (Feb. 2013).[1]

Put more simply, the person providing dry needling inserts a slim needle into a trigger point in the muscle and connective tissue of a patient for the purpose of stimulating the trigger point. *APTA Paper* at 2, 4. The American Physical Therapy Association supports the use of dry needling to address pain and movement impairments. *APTA Paper* at 3. But the insertion of a needle to reach muscle and connective tissue is invasive and it pierces the skin. As a result, it presents risks attendant to any such invasive procedure.[2]

Your question involves state regulation of physical therapy. Washington regulates the practice of physical therapy under RCW 18.74. That chapter of state law creates the Washington State Board of Physical Therapy, a Board with six members appointed by the governor. RCW 18.74.020. The Board consists of four physical therapists, one physical therapist assistant, and one public member. RCW 18.74.020. The chapter provides for licensing and regulation in order to advance two overarching purposes: "[1] to protect the public health, safety, and welfare, and [2] to provide for state administrative control, supervision, licensure, and regulation of the practice of physical therapy." RCW 18.74.005.

To answer whether dry needling comes within the scope of the practice of physical therapy, we start with the definition of physical therapy. "Physical therapy"

> means the care and services provided by or under the direction and supervision of a physical therapist licensed by the state. . . . [T]he use of Roentgen rays and radium for diagnostic and therapeutic purposes, the use of electricity for surgical purposes, including cauterization, and the use of spinal manipulation, or manipulative mobilization of the spine and its immediate articulations, are not included under the term "physical therapy" as used in this chapter.

RCW 18.74.010(9). This statute is too general to help in answering your question. It defines physical therapy simply as care and services provided by licensed physical therapists, which begs the question of what care and services fall within the scope of practice. The statute excludes three categories of services (radiation, use of electricity for surgical purposes, and spinal manipulations), but these exclusions indicate nothing regarding the scope of practice otherwise.

---

[1] This description is provided by the American Physical Therapy Association and a copy is accessible via http://www.apta.org/StateIssues/DryNeedling/ClinicalPracticeResourcePaper/ (last visited Apr. 12, 2016).

[2] We do not purport to evaluate the extent of risk, but note that we have cited to professional literature that discusses some risk of adverse results even from trained dry needling. Sarah Brady et al., *Adverse events following trigger point dry needling: a prospective survey of chartered physiotherapists*, 22 J. Manual & Manipulative Therapy 134 (Aug. 2014), http://www.maneyonline.com/doi/abs/10.1179/2042618613Y.0000000044.

Next, we turn to the statutory definition of the "practice of physical therapy." It provides that the practice "is based on movement science and means":

> (a) Examining, evaluating, and testing individuals . . . in order to determine a diagnosis, prognosis, plan of therapeutic intervention, and to assess and document the ongoing effects of intervention;
>
> (b) Alleviating impairments and functional limitations in movement *by designing, implementing, and modifying therapeutic interventions that include* therapeutic exercise; functional training related to balance, posture, and movement to facilitate self-care and reintegration into home, community, or work; manual therapy including soft tissue and joint mobilization and manipulation; therapeutic massage; assistive, adaptive, protective, and devices related to postural control and mobility except as restricted by (c) of this subsection; airway clearance techniques; physical agents or modalities; mechanical and electrotherapeutic modalities; and patient-related instruction;
>
> (c) Training for, and the evaluation of, the function of a patient wearing an orthosis or prosthesis as defined in RCW 18.200.010. . . . ;
>
> (d) Performing wound care services that are limited to sharp debridement, debridement with other agents, dry dressings, wet dressings, topical agents including enzymes, hydrotherapy, electrical stimulation, ultrasound, and other similar treatments. . . . ;
>
> (e) Reducing the risk of injury, impairment, functional limitation, and disability related to movement, including the promotion and maintenance of fitness, health, and quality of life in all age populations; and
>
> (f) Engaging in administration, consultation, education, and research.

RCW 18.74.010(10) (emphasis added).

Dry needling obviously falls outside most of these subsections, but could arguably fit within subsection (b), so we focus our analysis there. Subsection (b) allows "[a]lleviating impairments and functional limitations in movement *by designing, implementing, and modifying therapeutic interventions*[.]" In a very general sense, dry needling is a "therapeutic intervention," and the literature describing the practice indicates that it alleviates impairments or limitations in movement. But the remainder of subsection (b) narrows the expansive opening language by limiting the term "therapeutic interventions" with a list of interventions and practices. Under subsection (b), the scope of practice includes:

- therapeutic exercise;

- functional training related to balance, posture, and movement to facilitate self-care and reintegration into home, community, or work;
- manual therapy including soft tissue and joint mobilization and manipulation;
- therapeutic massage;
- assistive, adaptive, protective, and devices related to postural control and mobility except as restricted by (c) of this subsection;
- airway clearance techniques;
- physical agents or modalities;
- mechanical and electrotherapeutic modalities; and
- patient-related instruction.

The question, therefore is whether dry needling falls within any of these approved practices or is similar enough to them that it falls within the scope of practice. *See, e.g.*, AGO 2010 No. 2, at 5-6 (construing the scope of practice for occupational therapists in light of a statutory list of included practices); *Simpson Inv. Co. v. Dep't of Revenue*, 141 Wn.2d 139, 151, 3 P.3d 741 (2000) ("general terms, when used in conjunction with specific terms in a statute, should be deemed only to incorporate those things similar in nature or 'comparable to' the specific terms"). We conclude that dry needling was not intended to be included in the scope of practice because it is not explicitly described in subsection (b) and it does not fit into a fair or natural reading of any of the interventions that comprise the practice of physical therapy.

Most of the listed subjects (e.g., therapeutic exercise or massage, functional training, actions for posture control and mobility, airway clearance, and patient-related instruction) require no discussion. Dry needling falls far outside these subjects.

We considered whether dry needling fit within "manual therapy," a term used in connection with "soft tissue and joint *mobilization and manipulation*." RCW 18.74.010(10)(b) (emphasis added). But dry needling is not "manual therapy" as we understand the term.[3]

Similarly, we considered whether dry needling is a "physical agent" or "mechanical modality." Those terms are somewhat ambiguous and presumably have specialized meanings peculiar to the physical therapy profession. While a generous reading of those terms might cover dry needling, we think such a reading is inappropriate because it would cover a wide range of practices that clearly fall outside the practice of physical therapy. For example, the term

[3] A medical dictionary defines "manual therapy" as "[a] collection of techniques in which hand movements are skillfully applied to mobilize joints and soft tissues." Medical Dictionary, © 2009 Farlex and Partners.

"physical agents" could include medications, but physical therapists are not allowed to prescribe medications. Therefore, in context, we believe that the legislature intended a narrower meaning for "physical agents or modalities" and "mechanical and electrotherapeutic modalities." Whatever ambiguity exists, it seems unlikely that the legislature selected these obtuse phrases as a way of granting physical therapists broad discretion to use any device. *Cf.* 95 Op. Att'y Gen. 138, 146 (Md. 2010) (discussing Maryland statute with the phrase "treatment with . . . mechanical devices").

We received many comments urging that dry needling should be considered an unlicensed practice of acupuncture, and many other comments urging that dry needling is based on different principles and foundations than is acupuncture. It is undisputed that dry needling uses the same type of needles used in acupuncture, which is separately regulated under RCW 18.06. However, nothing in the statutes governing East Asian medicine show legislative intent to make it the only health care practice that uses inserted solid needles. Thus, we are unable to resolve the question asked based on distinctions, or similarities, between dry needling and acupuncture. However, we do believe that where the legislature has adopted a detailed regulatory scheme for acupuncturists, we should be wary of interpreting broad language regulating the physical therapist profession as including a technique that at the very least is quite similar to acupuncture. Put another way, while physical therapy includes "[a]lleviating impairments . . . in movement by designing, implementing, and modifying therapeutic interventions that include . . . mechanical . . . modalities" (RCW 18.74.010(9)(b)), it is risky to interpret that broad authority to include practices historically engaged in only by other regulated professions. For example, a root canal might "alleviate impairments" in jaw "movement" through use of a "mechanical modality," but no one would argue that it is within the practice of physical therapy.

In short, we believe that the best reading of current law is that dry needling falls outside the lawful practice of physical therapy. Admittedly, this reading of the statutory language may be debated by reasonable minds. But we also found no legislative history to suggest that the legislature intended to either include dry needling or to leave the matter open for individual practitioners to expand the scope of the profession by adopting a new practice.

We recognize that the lack of a legislative statement specifically directed to dry needling may simply reflect that dry needling is a relatively new approach for physical therapy. Reflecting the emergent nature of dry needling, several other Attorneys General have been called upon to opine on whether it is within the scope of their state's laws governing the practice of physical therapy. Some of these opinions have concluded that dry needling can be included in the practice of physical therapy, and one has not.[4] But each of these opinions is based upon the particular statutes of the various states, just as our analysis is guided by the text of Washington law.

[4] Finding statutory authority to regulate dry needling as physical therapy: 95 Op. Att'y Gen. 138 (Md. 2010); Op. Att'y Gen. 428 (Miss. 2012), 2012 WL 6065221; Op. Att'y Gen. 478 (Miss. 2012), 2012 WL 6086335; Op. Att'y Gen. 13-010 (Ky. 2013); Op. Att'y Gen. 14-0216 (La. 2015). Finding no authority: Op. Att'y Gen. 14-62 (Tenn. 2014).

Finally, many of the comments we received raised policy arguments concerning the value of dry needling and the benefits and drawbacks of allowing physical therapists to administer it, including issues related to safety, pain management, and quality of patient care. Attorney General Opinions, however, are not meant to decide what state policy *should be*; rather, they provide the best answer we can as to the meaning of current statutes. The concerns of these commenters would be best addressed to the legislature as it considers any possible changes to the laws. *See State v. Wilson*, 11 Wn. App. 916, 919, 528 P.2d 279 (1974) ("the scope of practice of persons engaged in the various healing sciences is exclusively a matter of legislative concern"); *see also* AGO 2010 No. 2, at 6 (citing *York v. Wahkiakum Sch. Dist. 200*, 163 Wn.2d 297, 342, 178 P.3d 995 (2008) (J.M. Johnson, J., concurring) (noting the role of legislative fact-finding in policy development)).

CONCLUSION

The definition of the practice of physical therapy indicates that the legislature did not intend to include dry needling within the scope of practice. We have been informed of many reasons for including dry needling in the practice of physical therapy and arguments to the contrary, but our role is not to resolve such public policy disputes. We conclude only that RCW 18.74, as currently written and implemented, does not encompass dry needling in the practice of physical therapy.[5]

We trust that the foregoing will be useful to you.

ROBERT W. FERGUSON
Attorney General

JAY D. GECK
Deputy Solicitor General
360-586-2697

wros

[5] We are grateful for the dozens of comments we received on this matter. These comments helped us understand the practice of dry needling, the concerns of other professions, and the legal landscape across the country as other states have considered similar questions.

Exhibit 6

PolicyFinder

Search policy

Search

Advanced Search

Practice Parameters

Dry Needling is an Invasive Procedure H-410.949

Topic: Practice Parameters

Policy Subtopic: NA

Meeting Type: Annual

Year Last Modified: 2016

Action: NA

Type: Health Policies

Council & Committees: NA

Our AMA recognizes dry needling as an invasive procedure and maintains that dry needling should only be performed by practitioners with standard training and familiarity with routine use of needles in their practice, such as licensed medical physicians and licensed acupuncturists.

Exhibit 7

SUPERIOR COURT FOR THE STATE OF WASHINGTON
COUNTY OF KING

ORIGINAL

STATE OF WASHINGTON *ex rel.* SOUTH SOUND ACUPUNCTURE ASSOCIATION, a State of Washington non-profit corporation,

Plaintiff,

vs.

KINETACORE, a Colorado LLC doing business in the State of Washington; EDO ZYLSTRA, CEO and owner of Kinetacore; KERI MAYWHORT, a Kinetacore instructor; EMERALD CITY PHYSICAL THERAPY SERVICES LLC doing business as SALMON BAY PHYSICAL THERAPY LLC, a limited liability company; JOHN DOES 1-10; and JANE DOES 1-10.

NO. 13-2-04894-9 SEA

ORDER FOR PARTIAL SUMMARY JUDGMENT

This matter came before the Court upon Plaintiff's Motion for Partial Summary Judgment and Defendants Motion for Summary Judgment which the parties argued before the Court on October 10th, 2014.

The Court has reviewed and considered the following:

1. Plaintiff's Motion for Partial Summary Judgment, and the declarations from Brent

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SEATTLE, WASHINGTON 98121-2510
206.292.9090 FAX 206.292.9736

Foster and Daniel Dingle and all supporting exhibits;

2. Defendants' Motion for Summary Judgment and supporting declarations and exhibits;

3. Plaintiffs Response to Defendants' Motion for Summary Judgment and supporting declarations and exhibits;

4. Defendants Response to Plaintiff's Motion for Partial Summary Judgment and supporting declarations and exhibits;

5. Plaintiffs Reply to Defendants' Response to Plaintiffs' Motion for Partial Summary Judgment and supporting declarations and exhibits;

6. Defendants Reply to Plaintiff's Response to Plaintiffs' Motion for Partial Summary Judgment and supporting declarations and exhibits;

7. The parties' oral arguments before the court;

Based on the foregoing, and after consideration of the standard in Civil Rule 56, NOW THEREFORE IT IS HEREBY ORDERED that Plaintiff's Motion for Partial Summary Judgment is GRANTED and Defendants Motion for Summary Judgment is DENIED. It is further declared that:

A. A person that "penetrates the tissues of human beings" with an acupuncture needle or any other needle for purpose of "dry needling" or any similar named act ("dry needling") is practicing medicine under the statutory definition provided at RCW § 18.71.011(3) and is prohibited absent a physicians license as required by RCW § 18.71.021; or other statutory authority?

B. There is no factual dispute that defendants are not licensed physicians but have penetrated the tissues of human beings with acupuncture needles during the Kinetacore workshop and subsequent to the workshop and describe such acts as

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"dry needling;"

C. The penetration of human tissue with an acupuncture needle or any similar needle used for dry needling is outside the plain text of the authorized scope of practice for physical therapy as adopted by the Washington Legislature in RCW § 18.74.010(8);

D. The plain text of the physical therapy statute, applicable case law, and the legislative history of RCW § 18.74.010(8) each support that there was no legislative intent to authorize physical therapists to insert acupuncture needles into human tissue for the purpose of dry needling or any similar purpose;

E. As such, physical therapists are not exempt from the requirement for a physicians license pursuant to RCW § 18.71.030(4) prior to the penetration of human tissue with acupuncture needles or similar needles.

F. Unless otherwise specifically authorized to practice acupuncture under another professional licensures, such as a physician or practitioner of East Asian Medicine, a licensed physical therapists lacks the legal authority to penetrate human tissue with acupuncture needles, or any similar needle, for the purpose of dry needling. Such act constitutes the unauthorized practice of medicine which is prohibited under Washington statute. RCW § 18.71.021; RCW § 18.71.011(3).

It is further declared that:

B. Defendants are hereby enjoined from inserting acupuncture needles or any similar needles for the purpose of dry needling in the State of Washington;

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206.292.9090 FAX 206.292.9736

H. Defendant Kinetacore is hereby enjoined from holding any workshops, classes or similar trainings in the State of Washington that involve ~~any~~ conducting penetration of human tissue with acupuncture needles or similar needles by physical therapists that lack the legal authority to penetrate human tissue pursuant to the findings above.

E. _____

Dated this 10 day of October, 2014.

Laura C Inveen

The Honorable Laura C. Inveen

Presented by:

CRANE DUNHAM PLLC
s/ Jason T. Leehan
s/Stephen J. Crane
WSBA No. 42463
2121 Fifth Ave
Seattle, WA 98121
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scrane@cranedunham.com
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LAW OFFICES OF BRENT FOSTER
s/ Brent Foster, Pro Hac Vice
Oregon Bar No. 99263
Attorneys for Plaintiff

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Exhibit 8

Craig A. Brandt, SB#133905
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Attorneys for Plaintiff

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Attorneys for Defendants Kinetacore LLC, US Dry Needling and Physio Products LLC, Dr. Paul Killoren, Dr. Edo Zylstra, and Dr. Austin Woods

JS-6

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

INTERNATIONAL CENTER FOR INTEGRATIVE MEDICINE, a State of California non-profit corporation,

Plaintiff,

vs.

KINETACORE, a State of Colorado limited liability company; **US DRY NEEDLING AND PHYSIO PRODUCTS LLC,** a State of Washington limited liability company; **IDRYNEEDLE,** a Washington-based company; **MEDBRIDGE, INC.,** a State of Washington corporation; **RED CORAL ACUPUNCTURE SUPPLIES PTY LTD,** an Australian private company; **PAUL KILLOREN; EDO ZYLSTRA; AUSTIN WOODS,**
Defendants.

Case NO.
8:16-cv-00736-JLS-GJS

~~[PROPOSED]~~CONSENT DECREE

I. BACKGROUND

1. This case was originally filed in Orange County Superior Court and was removed to the United States District Court for the Central District of California on April 19, 2016 by Defendants Kinetacore, LLC a Colorado limited liability company; US Dry Needling and Physio Products, LLC ("US Dry Needling"), a Washington limited liability company; Edo Zylstra ("Zylstra"), the managing member of Kinetacore and a member of US Dry Needling, Paul Killoren, a member of US Dry Needling ("Killoren"), and Austin Woods ("Woods"), a member of US Dry Needling. Collectively, Kinetacore, US Dry Needling, Zylstra, Killoren, and Woods are referred to herein as the "Defendants."

2. The Parties to this Consent Decree ("Decree") are the Defendants named in ¶ 1 and Plaintiff, International Center for Integrative Medicine ("ICIM" or "Plaintiff.") The Parties agree to this Decree to fully resolve the disputes alleged in Plaintiff's complaint file on February 16, 2016.

3. Idryneedle is a business trade name used by defendant US Dry Needling, as part of its website, idryneedle.com.

4. Zylstra is licensed as a physical therapist in the States of Colorado and Michigan. Killoren and Woods are licensed as physical therapists in the State of Washington.

5. Plaintiff's Complaint alleges that the insertion of needles[1] by

[1]Plaintiff contends the needles used by physical therapists are acupuncture needles. Defendants contend the needles are not acupuncture needles. As used herein, the term needle includes all needles used in the disciplines of acupuncture and/or physical therapy, however characterized, and regulated as Class II medical device by the FDA.

physical therapists[2]is inconsistent with provisions of California's Medical Practice Act and California's Acupuncture Licensure Act.Bus. & Prof. Code, §§ 2061, 4935.

6. The lawsuit also alleges the distribution of needles branded as "Myotech Dry Needles" is inconsistent with licensing and related requirements under California's Pharmacy Law. Bus. & Prof. Code, §§ 4051, 4059, 4161(b), 4163.

7. Defendants completely deny all of the allegations in Plaintiff's Complaint and believe they lack merit.

8. Defendant MedBridge, Inc., is not a party to this Decree and has been dismissed with prejudice from the case. Defendant Red Coral Acupuncture Supplies is also not a party to this Decree and is an Australian company that has not yet been served.

NOW, THEREFORE, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED AS FOLLOWS:

II. JURISDICTION AND VENUE

9. This case was first filed in Orange County Superior court under the California Declaratory Judgments Act. Cal. Civ. Proc. Code § 1060.Following removal, this Court has jurisdiction in this civil action pursuant to 28 U.S.C. § 1332(a) and 28 U.S. Code § 1441,as there is diversity of citizenship between the parties and the matter in controversy exceeds $75,000 exclusive of interest and costs. Venue is proper in this District pursuant to 28 U.S.C.§ 1391(b).

[2]Defendants describe the insertion of acupuncture needles into human subjects, as "dry needling" while Plaintiffs believes such acts constitutes "acupuncture."

III. AGREEMENT

10. To facilitate resolution of the instant case the parties agree for purposes of this consent decree that under current California law:

a. The insertion of needles, whether described as acupuncture or dry needling, is presently outside the scope of practice for physical therapy in California; and

b. The selling, distribution or furnishing of needles regulated as a Class II medical device by the Food and Drug Administration, is not authorized in California without appropriate licensure under the Pharmacy Law. Such needles may not be sold to an unauthorized person under the Pharmacy Law.

IV. INJUNCTIVE RELIEF

11. To facilitate resolution of the instant case the parties further agree:

a. Defendants shall not insert needles or engage in "dry needling "within the State of California. This injunctive relief will terminate without further need for application to the Court if California law changes to legally allow physical therapists to insert needles for the purpose of "dry needling."

b. Defendants shall not sell, deliver, mail, furnish, or otherwise distribute in any way needles regulated as Class II medical device by the FDA, including but not limited to Myotech Dry Needles, within the State of California without appropriate licensure under California's Pharmacy Law. Defendants agree to limit their sales to wholesale sales only, not direct sales to health practitioners or the public, and only sell

to legally authorized purchasers.

V. ENFORCEMENT

12. This Court retains jurisdiction to enforce this Decree for a period of five years from the date of entry. In any proceeding to enforce this Decree, the Court shall award attorneys' fees and costs to the prevailing party.

VI. ATTORNEY FEES AND COSTS

13. Defendants agree to pay Plaintiff's attorney fees and costs in the amount of $12,500 within 15 days of the date the Parties sign this Consent Decree.

VII. MODIFICATION

14. The terms of this Decree may be modified only by a subsequent written agreement signed by all Parties. Where the modification constitutes a material change to any term of this Decree, it shall be effective only upon approval by the Court.

15. This Decree constitutes the final, complete, and exclusive agreement between the Parties to resolve the lawsuit, and the Parties agree not to oppose the Entry of this Consent Decree by the Court, or subsequently to challenge any provision of the Decree.

VIII. FINAL JUDGMENT

16. Upon approval and Entry of this Decree by the Court, it shall constitute a final judgment of the Court.

IX. COUNTERPARTS

17. This Consent Decree may be executed by the Parties in multiple counterparts, and with electronic signatures, and all such counterparts shall together be deemed to constitute one final agreement, as if each Party had signed one document. Each such counterpart or electronic copy thereof shall

be deemed to be an original, binding the Parties subscribed thereto, and multiple signature pages or electronic signature pages affixed to a single copy of this Consent Decree shall be deemed to be a fully-executed original document.

X. SIGNATORIES

18. The undersigned representatives of the Parties certify that they are fully authorized to enter into the terms and conditions of this Consent Decree and to execute and legally bind such Party to this document.

IT IS SO STIPULATED AND AGREED BY THE PARTIES

_____ Date 5/10/2016
Amy Matecki
International Center for Integrative Medicine

_____ Date_____
Edo Zylstra
For Kinetacore LLC, US Dry Needling and Physio Products LLC, and on his own behalf

_____ Date_____
Paul Killoren
For US Dry Needling and Physio Products LLC, and on his own behalf

_____ Date_____
Austin Woods
For US Dry Needling and Physio Products LLC, and on his own behalf

IT IS SO ORDERED.

Dated: _____

_____
Josephine L. Staton
United States District Judge

IT IS SO STIPULATED AND AGREED BY THE PARTIES

_____ Date_____
Amy Matecki
International Center for Integrative Medicine

_____ Date 5/5/16
Edo Zylstra
For Kinetacore LLC, US Dry Needling and Physio Products LLC,
and on his own behalf

_____ Date_____
Paul Killoren
For US Dry Needling and Physio Products LLC,
and on his own behalf

_____ Date_____
Austin Woods
For US Dry Needling and Physio Products LLC,
and on his own behalf

IT IS SO ORDERED.

Dated: _____

_____
Josephine L. Staton
United States District Judge

IT IS SO STIPULATED AND AGREED BY THE PARTIES

_____ Date_____
Amy Matecki
International Center for Integrative Medicine

_____ Date_____
Edo Zylstra
For Kinetacore LLC, US Dry Needling and Physio Products LLC,
and on his own behalf

_____ Date 5/3/16
Paul Killoren
For US Dry Needling and Physio Products LLC,
and on his own behalf

_____ Date 5/5/16
Austin Woods
For US Dry Needling and Physio Products LLC,
and on his own behalf

IT IS SO ORDERED.

Dated: _____

_____
Josephine L. Staton
United States District Judge

IT IS SO STIPULATED AND AGREED BY THE PARTIES AND THEIR ATTORNEYS OF RECORD

_____/s/_____ Date: June 16, 2016
Craig A. Brandt,
Attorney for Plaintiff

_____/s/_____ Date: June 16, 2016
Matthew C. Elstein,
Attorney for Defendants

IT IS SO ORDERED.

Dated: July 7, 2016

Honorable Josephine L. Staton
District Judge, United States District Court,
Central District of California

Exhibit 9

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 29 1996

Acupuncture Coalition
C/O Mr. James S. Turner
and Mr. Frank M. Pascal
Swankin and Turner
1424 16th Street, N.W.
Suite 105
Washington, D.C. 20036

Re: Reclassification Order
Docket No. 94P-0443
Acupuncture Needles for the Practice of Acupuncture

Dear Mr. Turner and Mr. Pascal:

The Center for Devices and Radiological Health of the United States Food and Drug Administration (FDA) has completed its review of your petitions on behalf of the Acupuncture Coalition, which includes representatives of the following manufacturers: Carbo (Mfg.), China; Hwa-To, China; Chung Wha, South Korea; Taki, South Korea; Dong Bang, South Korea; Tseng Shyh Co., Taiwan; HCD, France; Sedatelec, France, Seirin-Kasei, Japan; Ito Co., Japan; Ido-No-Nippon-Sha, Japan and Seirin Kasei (Mfg.), for reclassification of acupuncture needles for the practice of acupuncture.

This order reclassifies acupuncture needles for the practice of acupuncture and substantially equivalent devices of this generic type into class II, under the generic name: acupuncture needles.

FDA identifies acupuncture needles as devices intended to pierce the skin in the practice of acupuncture by qualified practitioners as determined by the States. 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. The device is intended for single use only.

As you know, on December 6, 1994, FDA filed your reclassification petitions requesting reclassification of acupuncture needles from class III to class II. The petitions were submitted under section 513(f)(2) of the Federal Food, Drug and Cosmetic Act (Act), 21 U.S.C. 360c(f)(2), and 21 CFR 860.134 of the agency's regulations. Acupuncture needles were automatically classified into class III under section 513(f)(1) of the act in accordance with a Federal Register Notice of May 9, 1973 (38 FR 6419): Acupuncture Devices Labeling . That notice stated that until scientific evidence is obtained demonstrating that acupuncture is a safe and effective medical technique, acupuncture devices must be limited to investigational or research use and labeled accordingly.

94P-0443 PAV 1

Devices that were in investigational status before the enactment of the Medical Device Amendments of 1976 are not considered to have been in commercial distribution for purposes of section 513 of the Act.

After review of the information submitted in the petitions and its own literature search of safety information, FDA has determined that acupuncture needles intended for use in the practice of acupuncture by qualified practitioners as determined by the States could safely be reclassified from class III to class II with the implementation of special controls.

The special controls are compliance with 1) labeling provisions for single use only and the prescription statement in 21 CFR 801.109 (restriction to use by or on the order of qualified practitioners as determined by the States), 2) device material biocompatibility, and 3) device sterility. FDA believes that information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any hazards, contraindications, side effects and precautions are commonly known to qualified practitioners of acupuncture. Therefore, pursuant to section 801.109(c), such indications do not need to be on the dispensing packaging but sale must be clearly restricted to qualified practitioners of acupuncture. Guidance on the type of information needed to support biocompatibility and sterility can be found in the existing General Hospital Branch Guidance on the Content of Premarket [510(k)] Submissions for Hypodermic Single Lumen Needles, April 1993. A copy of this guidance is enclosed.

FDA's decision is also in keeping with but not dependent upon the recommendation of the Anesthesiology Devices Advisory Panel, published in the Federal Register of November 2, 1979 (44 FR 63299) that acupuncture needles be classified in class II. The supplemental data sheet completed by that panel, dated November 30, 1976, listed sepsis, excessive trauma and perforation of blood vessels and organs as specific risks, and recommended restricting the device to prescription use.

Therefore, FDA, for the reasons set forth in this letter, is ordering the reclassification of the generic type of device identified on page 1, from class III to class II. Further, since the reclassification is based upon scientific evidence demonstrating that general controls and the special controls provide a reasonable assurance of safety and effectiveness, the labeling requirements of the 1973 Federal Register document no longer apply to acupuncture needles intended for use in the practice of acupuncture by qualified practitioners. However, before acupuncture needles can be legally marketed, they must be the subject of a cleared premarket notification [510(k)] submission.

The clinical studies and safety information included in support of these petitions report few risks to health associated with the use of acupuncture needles and those that are reported have been clearly identified, documented and characterized. FDA's own search of the literature supports this finding. The risk to health most frequently found was infection. FDA believes that this risk to health is adequately addressed by the labeling requirements (for single use only and the prescription statement) and the biocompatibility and sterility performance requirements. The risks to health of excessive trauma and perforation of blood vessels and organs are also addressed by the prescription use requirement, restricting use to qualified practitioners of acupuncture as determined by the States.

The clinical studies and preclinical animal studies included in the petitions constitute valid scientific evidence in support of the clinical effectiveness of acupuncture needles for the performance of acupuncture treatment. However reference to a specific disease, condition, or therapeutic benefit requires additional valid scientific evidence in the form of well-controlled prospective clinical studies.

Accordingly, FDA is reclassifying acupuncture needles intended for the practice of acupuncture into class II (special controls) with the special controls identified as labeling, biocompatibility, and sterility requirements. A notice will be published in the Federal Register announcing the Agency's reclassification order.

Copies of this order and supporting documentation will be on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-23, 1220 Parklawn Drive, Rockville, MD 20857 and are available for inspection between 9 a.m.and 4 p.m., Monday through Friday.

If you have any questions concerning this reclassification order, please contact Timothy A. Ulatowski at (301) 443-8879. Please convey this information to your membership. Thank you for your cooperation throughout this review process.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 9
Page 3 of 3

Exhibit 10

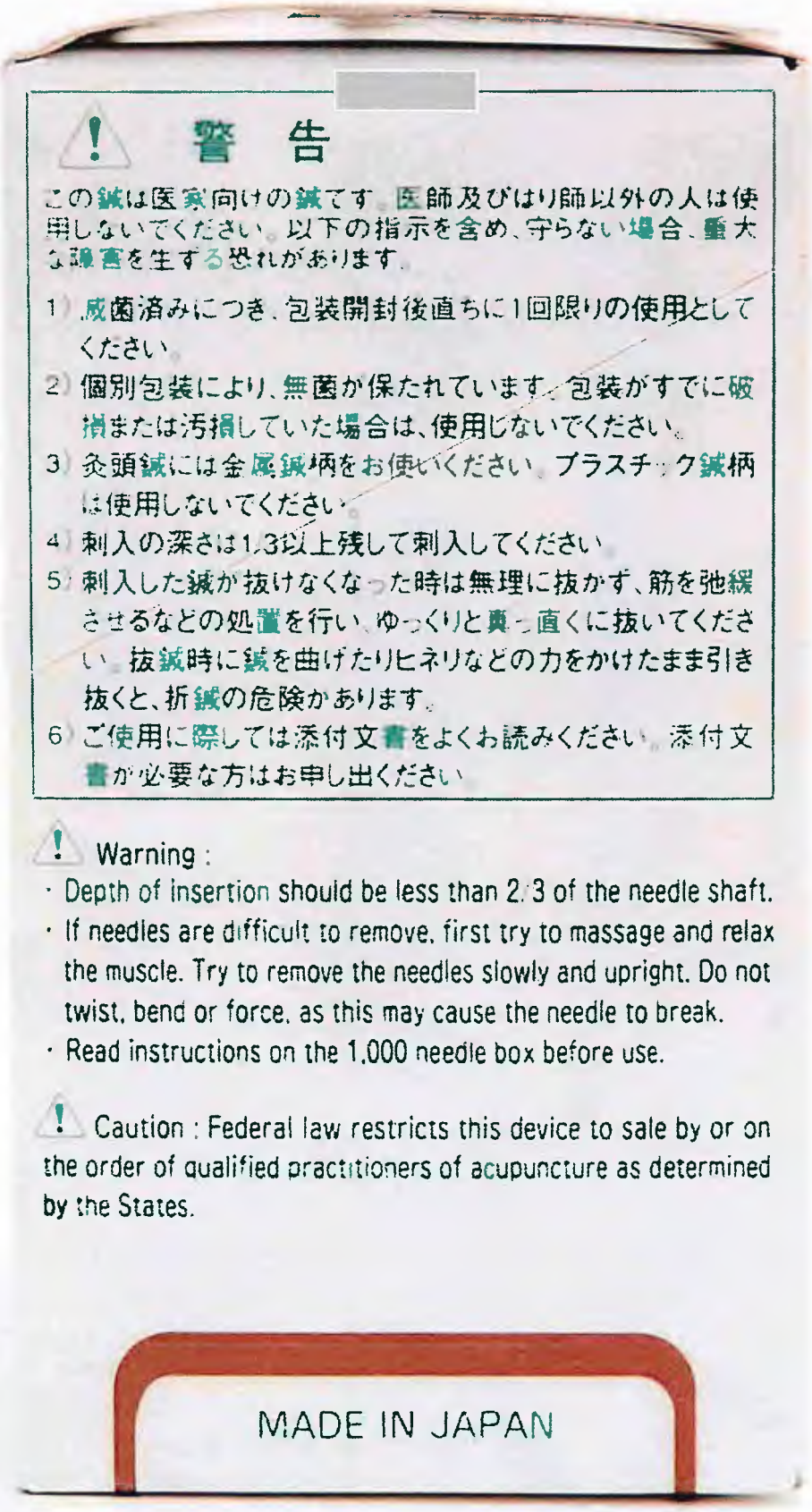


Exhibit 10
Page 1 of 1

Exhibit 11

Top Two Facts

You REALLY Need to Know about

DRY NEEDLING

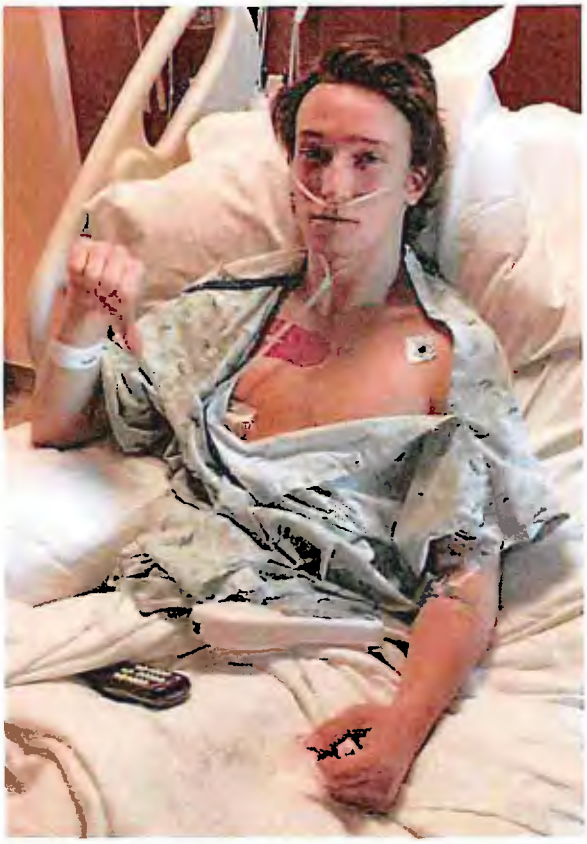
1. Dry needling is acupuncture.

More specifically, dry needling is acupuncture that involves inserting acupuncture needles (U.S. Food and Drug Administration [FDA]-regulated medical devices) through the skin and into reactive (painful) acupuncture points detected by a flinch reaction during palpation (*1*). These acupuncture points, now commonly referred to as trigger points, have been used in acupuncture for more than 2,000 years to treat or prevent musculoskeletal and connective tissue disorders, including musculoskeletal pain (*1*).

2. Dry needling is unsafe when performed by physical therapists.

Dry needling is safe when performed by qualified practitioners of acupuncture, such as physicians and acupuncturists, but it is unsafe when performed by physical therapists–due to inadequate and improper training in acupuncture–as evidenced by the following examples:

- In Colorado, a physical therapist punctured freeskier Torin Yater-Wallace's right lung with an acupuncture needle, causing damage to the lung that led to a pneumothorax (an accumulation of air between the lung and the chest wall, causing the lung to collapse) (*2,3*). He required surgery to treat the pneumothorax and was hospitalized for five days (*2*).
- In Georgia, a physical therapist performed dry needling on a 15-year-old girl without obtaining the consent of her mother (*4*). She collapsed from the dry needling (*4*).



Freeskier Torin Yater-Wallace gives a thumbs down in the St. Anthony Summit Medical Center in Frisco, Colorado, on November 29, 2013, during recovery from surgery to treat a pneumothorax that he suffered after a physical therapist punctured his right lung with an acupuncture needle. (Photo: @TorinWallace)

- In Maryland, a physical therapist punctured a nerve in high school teacher Emily Kuykendall's left leg with an acupuncture needle, causing damage to the nerve that led to pain, numbness, and paresthesias (abnormal sensations of

tingling [pins-and-needles]) (*5*). She required drugs to treat the pain (*5*).

"This is really taking a physical and emotional toll on me," Ms. Kuykendall wrote three weeks after the nerve injury. "There is almost not a minute in the day that goes by that I wish that I had not gone to see [the physical therapist]" (*5*).

- In Arizona, three physical therapists performed dry needling through patients' clothing, which resulted in "findings of substandard care" (*6-8*). This placed the patients at risk for injuries (e.g., to the heart or lungs) and infections (e.g., with "flesh-eating" *Streptococcus pyogenes* or methicillin-resistant *Staphylococcus aureus* [MRSA]) (*6*).
- In Arizona, a physical therapist disposed of used acupuncture needles in a public recycling container, which violated Arizona's Biohazardous Medical Waste Regulations (Arizona Administrative Code [A.A.C.] R18-13-1401 *et seq.*) (*9*). This placed the public and recycling workers at risk for needlestick injuries and infections (e.g., with hepatitis B virus [HBV], hepatitis C virus [HCV], or human immunodeficiency virus [HIV]).

"Dry needling is unsafe when performed by physical therapists."

CNA, a professional liability insurance company, provided the following examples:

- A physical therapist punctured a patient's right lung with an acupuncture needle, causing damage to the lung that led to a pneumothorax (*10*). She was hospitalized and underwent treatment for the pneumothorax (*10*).
- A physical therapist punctured a patient's left lung with an acupuncture needle, causing damage to the lung that led to a pneumothorax (*10*). She was hospitalized and underwent treatment for the pneumothorax (*10*).
- A physical therapist punctured a patient's lung with an acupuncture needle, causing damage to the lung that led to a pneumothorax (*10*). She required surgery to treat the pneumothorax and was hospitalized for three days (*10*).
- A physical therapist was performing dry needling on a patient's hip when the handle of the acupuncture needle broke off, leaving the shaft of the acupuncture needle lodged in the hip (*10*). This was probably due to the physical therapist using excessive force when manipulating (rotating or pistoning) the acupuncture needle. She was hospitalized and underwent surgery to remove the shaft of the acupuncture needle (*10*).
- A physical therapist performed dry needling on a patient's calf while failing to adhere to basic infection prevention and control practices, resulting in the patient developing a calf infection (*10*). She required "intravenous therapy and two surgical procedures" to treat the calf infection (*10*).

Patient safety and quality of care are paramount. Therefore, the National Center for Acupuncture Safety and Integrity (NCASI) agrees with the American Medical Association (AMA) that dry needling should only be performed by qualified practitioners of acupuncture, such as physicians and acupuncturists (*11*).

For More Information

For more information about dry needling, please visit *www.acupuncturesafety.org*.

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Exhibit 12

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Type: Policy

Policy

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Evidence That Dry Needling is the Intent to Bypass Regulation to Practice Acupuncture in the United States

Arthur Yin Fan, PhD,[1] Ling Zheng,[2] and Guanhu Yang[3]

Introduction

THE ACUPUNCTURE TECHNIQUE MOST often studied scientifically involves penetrating the skin with thin, solid, and metallic needles that are manually or electrically manipulated. Practiced in China and other Asian countries for thousands of years, acupuncture is a key component of Traditional Chinese Medicine.[1] Currently, acupuncture is being practiced in countries all around the globe and is rapidly attracting interest in Western countries.[1]

In this context of expanding public and professional interest in acupuncture in the United States, a practice called dry needling (DN) has become a hotly debated topic in both academic[2,3] and regulatory[4–6] circles. DN is an issue because some professionals, especially physical therapists (PTs) (and also some chiropractors, nurses, and others) are claiming the right to practice DN, which requires little training, as a practice distinct from acupuncture. DN is viewed by many, especially in the acupuncture community, as a strategic method to bypass laws that require rigorous training and oversight to engage in practice as an acupuncturist.

On November 6, 2015, the *Journal of Acupuncture in Medicine* published an article[2] titled "Dry Needling Versus Acupuncture: The Ongoing Debate." An accompanying editorial[3] concluded that DN, as used in treating musculoskeletal disorders, is a style of Western acupuncture that, while distinct from traditional acupuncture, is a form of the practice. This commentary reviews the origins of DN and reinforces that conclusion. Whatever rights to practice DN may be asserted or achieved by these professions, the historic evidence shows that there is no denying that DN is a form of acupuncture.

Acupuncturists Have Led Development and Education in DN

PTs and other professionals use the term *dry needling* to describe a therapeutic intervention that typically uses solid filiform needles (i.e., acupuncture needles) to puncture myofascial trigger points (TrPs). The clinical intent is to resolve pathologic myofascial tension and treat the myofascial and other pain. The method is sometimes called *myofascial trigger point dry needling* or *intramuscular manual therapy*.[7]

An overlap between the PT profession and that of licensed acupuncturists may be the origin of the DN debate. In the United States since roughly 2000, DN was mainly developed and advertised by licensed acupuncturists.[8–13] Some acupuncturists developed continuing education businesses and recruited large numbers of PTs as students.[8] Other acupuncturists were hired by PT schools to introduce acupuncture to their students and faculty. Still others of these acupuncturist educators attended PT schools to gain doctoral degrees in that field. Dry-needlers were not teaching how to use these needles. Acupuncturists were.

The earliest person in this field is Mark Seem, PhD, LAc, the founder of Tri-State College of Acupuncture in New York. Dr. Seem developed a classical Chinese acupuncture approach to integrate the work of a Western medical doctor, Janet Travell, MD, with acupuncture needling of myofascial pain.[11,13] Like some other doctors of her tradition, Dr. Travell mentioned DN in books or articles. Most did so via knowledge they gained in the 1970s through 1990s from clinical observation; the therapy was not widely used in their own daily practices.[2,11,12,14] In fact, most of the needles used by these doctors were the classic, hollow injection needles with a sharp point. Such needles are different from the acupuncture needles that are currently used in DN.[2,9,11,14] Dr. Seem shared this classical acupuncture technique with Dr. Travell by treating a chronic, complex whiplash syndrome to release such TrPs. Dr. Seem published *A New American Acupuncture* covering this topic of DN in 1993. He has taught this acupuncture method internationally for over 25 years.[11]

Such TrP needling has existed for over 2000 years since the *Huang Di Nei Jing* (*Yellow Emperor Inner Classics*). Acupuncturists call this *Ashi* (ah-yes) point acupuncture.[15,16] In the United States, such techniques have been used by both traditional and medical acupuncturists since the 1820s, including by Sir William Osler.[17] Such *Ashi* points, including TrPs, motor points, or tender points, are considered acupuncture points.[16–18]

The Influence of Acupuncturist Yun-Tao Ma on the Use of DN

In recent years, one of the featured scholars, developers, and teachers of DN to PTs, Yun-tao Ma, PhD, LAc,[10,19–21] published several books related to DN. Among these are

[1]McLean Center for Complementary and Alternative Medicine, PLC, Vienna, VA.
[2]LZ & Manhattan Acupuncture PC, New York, NY.
[3]Acupuncture Wellness Center of Cincinnati, Cincinnati, OH.

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Scientific Acupuncture for Health Professionals[22] and *Biomedical Acupuncture for Sports and Trauma Rehabilitation: Dry Needling Techniques*,[19,20] Dr. Ma, a member of the Acupuncture International Standard Working Committee in the World Federation of Acupuncture-Moxibustion Societies,[23] is a licensed acupuncturist.[19] He practiced DN under his acupuncture license. Dr. Ma indicates that DN is the practice of acupuncture, via biomedical "language" for pain management. Other important authors in the field, including Giles Gyer, Jimmy Michael, and Ben Tolson, also indicate that DN is acupuncture.[24]

There is confusion, however, created by Dr. Ma. He claims that the DN he teaches, about which he wrote later, is a modern Western medical modality that is not related to traditional Chinese acupuncture in any way. He argues that DN has its own theoretical concepts, terminology, needling technique, and clinical application[21] and that (1) DN is not practicing acupuncture, (2) it has no relationship with acupuncture, and (3) it was developed by PTs themselves. This challenges basic logic. Dr. Ma is a licensed acupuncturist. He himself uses acupuncture as a name or synonym for DN, although he technically calls it "biomedical acupuncture."[10,19,20] Also, DN uses acupuncture needles.[2,7,10,19,20] Dr. Ma did say, "DN originated in Traditional Chinese methods, and has developed from the ancient empirical approach to become modern, evidence-based practice."[20] Clearly, he merely developed a modern interpretation of acupuncture and renamed it "DN".[8] The practice of DN is simply another translation of the original name for this type of therapy, 针刺 *Zhen Ci*.[25]

Widespread Use of DN in the Practice of Licensed Acupuncturists

That DN is acupuncture is also evident from a look at acupuncture practice in the United States. Acupuncturists are well trained to use TrPs and motor point *Zhen Ci* or "DN" treatment. Thus, *Zhen Ci* (DN) represents a substantial daily practice among U.S. acupuncturists. The National Certification Commission for Acupuncture and Oriental Medicine, the certifying board for licensed acupuncturists, completed an analysis in 2003 that documented the prevalence of DN techniques in the practices of licensed acupuncturists. Of acupuncturists responding, 82% used needling of TrPs in patients who presented with pain. Of patients receiving acupuncture treatment, an estimated 56% present with TrPs pain. The other 18% of acupuncturists used acupuncture needling techniques in non-TrP locations for other types of pain or for nonpain conditions.[13]

With growing professional and public interest, the U.S. National Institutes of Health officially defined acupuncture as an actual insertion of a solid needle into the body.[1,26] Acupuncture, so defined, describes a family of procedures involving the stimulation of points on the body using a variety of techniques. Notably, the Food and Drug Administration classified acupuncture needles as Class II medical devices subject to strict regulations under the Federal Food, Drug, and Cosmetic Act (FDCA). Thus, individuals purchasing or receiving acupuncture needles, who are not licensed by law to practice acupuncture, are directly violating both civil and criminal provisions of the FDCA that is intended to protect public safety (21 U.S.C. § 331(a)–(c), (g)).

With this historic use, education, practice and federal language in mind, DN is clearly acupuncture, an invasive procedure. It is not a distinct manual therapy as claimed by PTs.

Rapid Development of DN Among PTs is Based on Low Training and is Associated with Harm

Yet the PTs' claim has led to the rapid development of DN in the United States within the past 10 years as the PTs have worked to expand their scope of practice and move toward doctoral level training. The American Physical Therapy Association states that "the physiological basis for DN treatment of excessive muscle tension, scar tissue, fascia, and connective tissues is not well-described in the literature."[7] DN, as a style of Western medical acupuncture, naturally belongs to a substyle of acupuncture. There are actually no major differences from traditional acupuncture in DN needling technique or in clinical applications of pain management or sports and trauma rehabilitation.[2]

As previously noted, DN educators in both continuing education and in schools are frequently licensed acupuncturists. DN has mainly been taught in continuing education level courses of 20–30 hours, although the duration proposed to increase to 54 hours in the future.[7,10,27] This low level of training increases the risk for injury and can be a threat to public health and safety. Reports of serious injuries associated with DN or acupuncture by PTs are not uncommon.[28–31] If a PT is practicing DN, how will a patient know that he or she has such limited training? The patients are not likely to know the practitioners' experience level when DN technique is applied; nor will the patient know whether the PT chooses to use needles for purposes beyond typical DN practice. This strategy is in line with the advice received from TrP pioneer Dr. David Simmons. He stated: "Your problem is largely one of semantics so the simple answer is to change the playing field and the semantics that go with it. If you... use the different terminology you leave other side without an argument."[32]

Conclusions

Current DN in the United States is an interpretation of traditional acupuncture focusing on musculoskeletal disorders but using PT language. The question is, How can we practice acupuncture using the name of DN and not claim this therapy as acupuncture? How we can say that a white horse is not a horse? Both are still a horse; one is just a subset of the other. The public has come to expect certain hard-earned standards of accredited education and licensing for those professionals who are using acupuncture needles on them therapeutically. The PTs do not meet these standards.

This denial is creating tension between the acupuncture profession and PTs and other professionals who are seeking to provide acupuncture by calling the horse by a different name. If lawmakers and regulators are to decide to allow PTs and others to provide acupuncture to citizens based on 20–30 or even 54 hours of training, they can certainly do that. The historic record shows, however, that these lawmakers should know that they are granting them the right to practice acupuncture.

Acknowledgments

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