

## Exhibit 1

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## Physicians take on timely public health issues

6/15/2016, 1:00 PM

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In Days 2 and 3 of policymaking at the 2016 AMA Annual Meeting, delegates adopted a variety of policies on important issues affecting the health of patients across the country. Issues range from controlled LED lighting to safe provision of dry needling procedures to better training for hemorrhage control.

### Attorney ads on drug side-effects

Late-night television is rampant with attorney ads that seek plaintiffs regarding complications from new medications. Potential complications are spoken about in an alarming way, and often, it is the first time the public learns about those potential complications and side effects.

These ads describe only the lethal side effects and not the benefits of the medications that many patients have experienced—but this is not explained to the viewers.

To protect the health of the public, physicians Tuesday adopted policy to advocate for a requirement that attorney commercials which may cause patients to stop using necessary medications to have appropriate and conspicuous warnings that patients should not discontinue medications without seeking the advice of their physician.

"The onslaught of attorney ads has the potential to frighten patients and place fear between them and their doctor," AMA Board Member Russell W. H. Kridel, MD, said in a news release. "By emphasizing side effects while ignoring the benefits or the fact that the medication is FDA approved, these ads jeopardize patient care. For many patients, stopping a prescribed medication is far more dangerous, and we need to be looking out for them."

### Standards of practice for dry needling

Ensuring patient safety is paramount for physicians. To that end, delegates adopted new policy that recognizes the procedure of dry needling as invasive.

Physical therapists are increasingly incorporating dry needling into their practice. Dry needling is indistinguishable from acupuncture, yet physical therapists are using this invasive procedure with as little as 12 hours of training, while the industry standard minimum for physicians to practice acupuncture is 300 hours of training.

Delegates agreed that the practice of dry needling by physical therapists and other non-physician groups should include—at a minimum—the benchmarking of training and standards to already existing standards of training, certification and continuing education that exist for the practice of acupuncture.

The policy also maintains that dry needling as an invasive procedure 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.

"Lax regulation and nonexistent standards surround this invasive practice," AMA Board Member Russel W.H. Kridel said in a news release. "For patients' safety, practitioners should meet standards required for acupuncturists and physicians."

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 reclassifying 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 3****Myopain Seminars**

Like Page

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> -



**Raymond Butts**  
@RayButtsDPTPhD

Exhibit 4

Follow

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



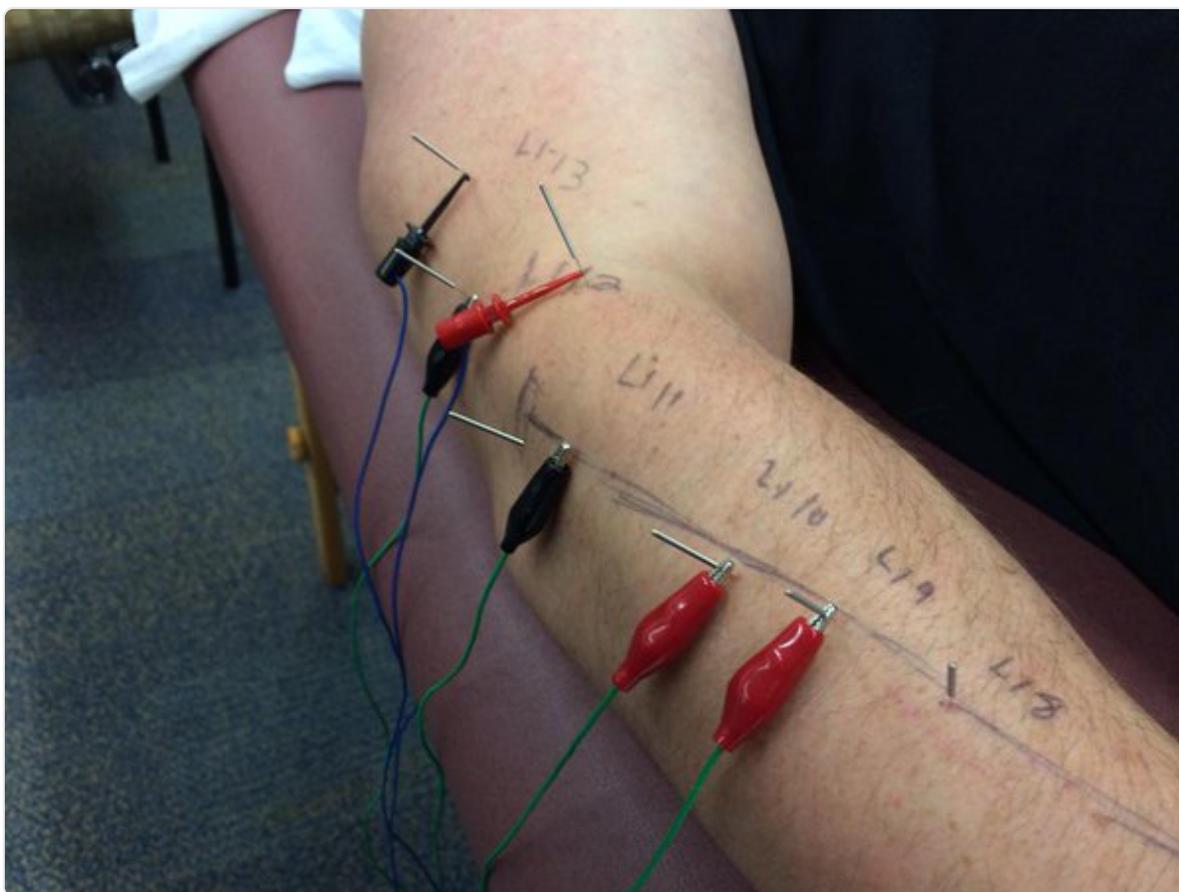


**DNI Tommy Perreault**

@TommyDPT

Follow

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



RETWEETS

6

LIKES

8



3:29 AM - 17 May 2015





**Estee Pavkovich**

@DrEsteeP

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



RETWEETS

7

LIKES

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6:19 AM - 13 Aug 2015



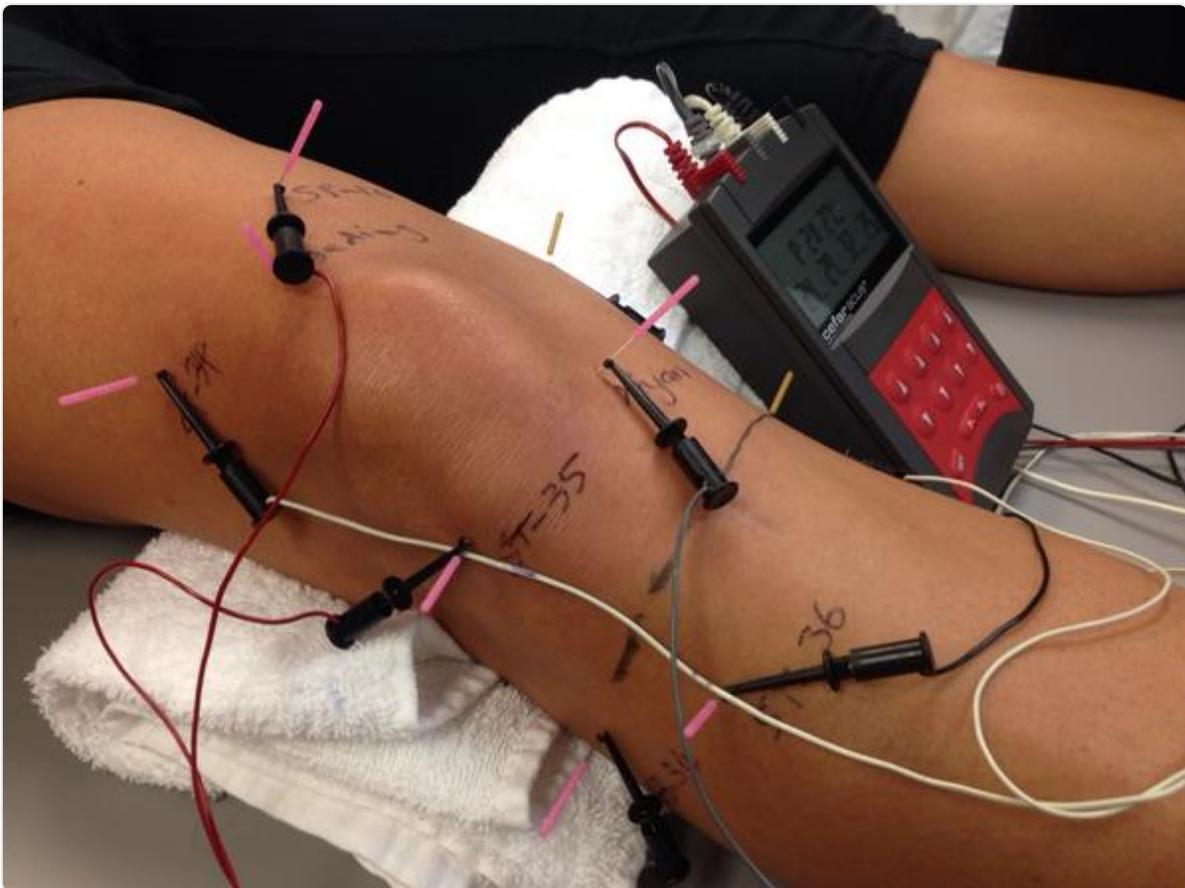


**DNI Dry Needling**

@dryneedling

Follow

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



RETWEETS

2

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3



3:39 PM - 20 Sep 2014



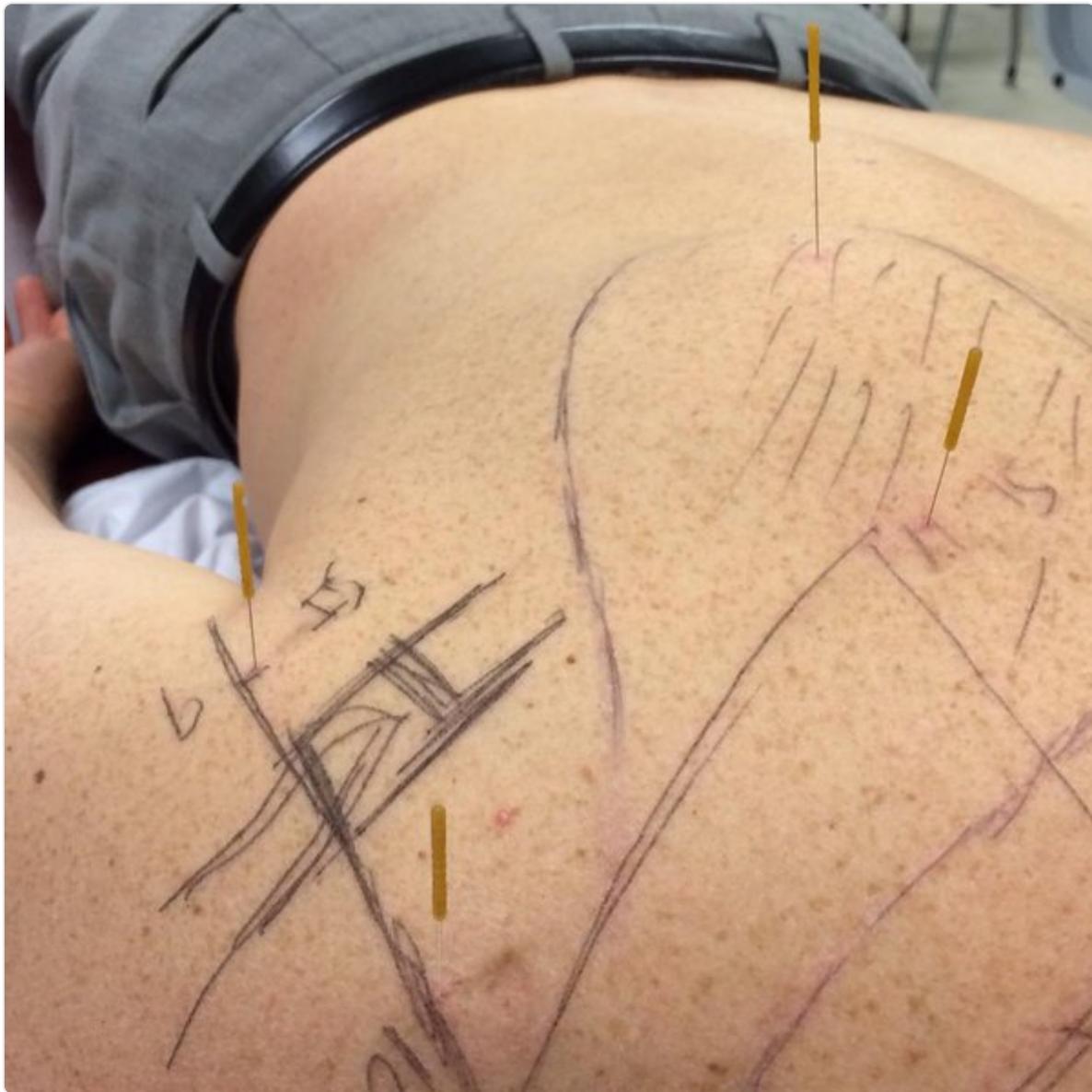


**DNI Tommy Perreault**

@TommyDPT

Follow

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



RETWEETS

4

LIKES

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**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,<sup>28-30</sup> and enkaphalinergetic, serotonergic, and noradrenergic inhibitory systems associated with A-Δ (A delta) fibers through segmental inhibition.<sup>31,32</sup>

**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,<sup>31,64,65</sup> which in turn activates the release of cytokines and other pro-inflammatory mediators.<sup>66-70</sup>

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,<sup>52,53</sup> 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.<sup>20,71-76</sup>

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

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

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.<sup>111-113</sup>

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 with no 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.<sup>111-113</sup>

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.<sup>111-113</sup>

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 it is 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.<sup>120</sup>

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.<sup>121,122</sup>

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.

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE  
Volume 22, Number 8, 2016, pp. 1–3  
© Mary Ann Liebert, Inc.  
DOI: 10.1089/acm.2016.0066

**Policy**

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

Arthur Yin Fan, PhD,<sup>1</sup> Ling Zheng,<sup>2</sup> and Guanhu Yang<sup>3</sup>

## Introduction

**T**HE 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.<sup>1</sup> Currently, acupuncture is being practiced in countries all around the globe and is rapidly attracting interest in Western countries.<sup>1</sup>

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<sup>2,3</sup> and regulatory<sup>4–6</sup> 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<sup>2</sup> titled “Dry Needling Versus Acupuncture: The Ongoing Debate.” An accompanying editorial<sup>3</sup> 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*.<sup>7</sup>

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.<sup>8–13</sup> Some acupuncturists developed continuing education businesses and recruited large numbers of PTs as students.<sup>8</sup> 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.<sup>11,13</sup> 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.<sup>2,11,12,14</sup> 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.<sup>2,9,11,14</sup> 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.<sup>11</sup>

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.<sup>15,16</sup> In the United States, such techniques have been used by both traditional and medical acupuncturists since the 1820s, including by Sir William Osler.<sup>17</sup> Such *Ashi* points, including TrPs, motor points, or tender points, are considered acupuncture points.<sup>16–18</sup>

## 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,<sup>10,19–21</sup> published several books related to DN. Among these are

<sup>1</sup>McLean Center for Complementary and Alternative Medicine, PLC, Vienna, VA.

<sup>2</sup>LZ & Manhattan Acupuncture PC, New York, NY.

<sup>3</sup>Acupuncture Wellness Center of Cincinnati, Cincinnati, OH.

*Scientific Acupuncture for Health Professionals*<sup>22</sup> and *Biomedical Acupuncture for Sports and Trauma Rehabilitation: Dry Needling Techniques*.<sup>19,20</sup> Dr. Ma, a member of the Acupuncture International Standard Working Committee in the World Federation of Acupuncture-Moxibustion Societies,<sup>23</sup> is a licensed acupuncturist.<sup>19</sup> 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.<sup>24</sup>

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<sup>21</sup> 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.”<sup>10,19,20</sup> Also, DN uses acupuncture needles.<sup>2,7,10,19,20</sup> Dr. Ma did say, “DN originated in Traditional Chinese methods, and has developed from the ancient empirical approach to become modern, evidence-based practice.”<sup>20</sup> Clearly, he merely developed a modern interpretation of acupuncture and renamed it “DN”.<sup>8</sup> The practice of DN is simply another translation of the original name for this type of therapy, 针刺 *Zhen Ci*.<sup>25</sup>

### 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.<sup>13</sup>

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.<sup>1,26</sup> 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.”<sup>7</sup> 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.<sup>2</sup>

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.<sup>7,10,27</sup> 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.<sup>28–31</sup> 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.”<sup>32</sup>

### 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

The authors would like to thank Ms. Sarah Faggert for editing support. This paper reflects the authors’ view only.

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Exhibit 7



# Top Two Facts

## You REALLY Need to Know about

# DRY NEEDLING

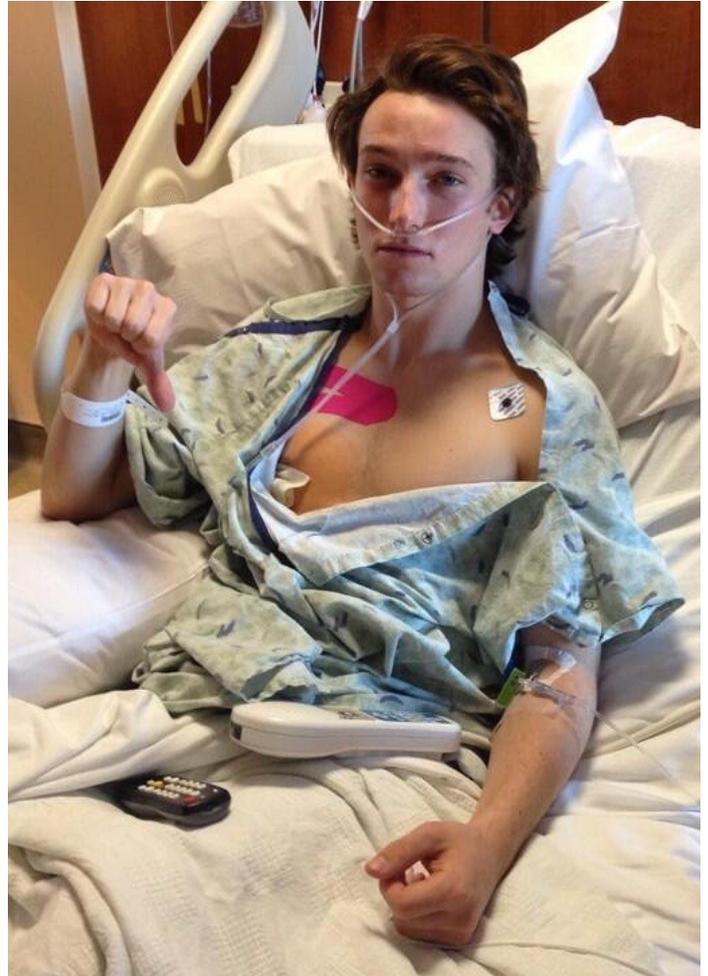
### 1. Dry needling is acupuncture.

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).
- 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



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)

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]).

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## “Dry needling is unsafe when performed by physical therapists.”

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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](http://www.acupuncturesafety.org).

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# FAQ Dry Needling Adverse Events



## Introduction

Dry needling is associated with risks that can lead to adverse events. Physiotherapists are legally obligated to ensure they obtain informed consent from their patients. The dry needling informed consent process requires material risks and special risks of treatment be disclosed to patients.<sup>14</sup>

Research into adverse events related to dry needling is continually evolving. There are wide variations in research design including differences in the classification of adverse events which, for physiotherapists, makes interpretation and comparison between studies difficult, thus adding to the complexity of the risk disclosure process.<sup>8</sup>

Prior to 2014, only large scale studies examining adverse events related to acupuncture were available.<sup>4,5,10,12,18,19-22</sup> Brady et al are the first to publish a prospective study of adverse events related to trigger point/IMS dry needling.<sup>1</sup>

To support physiotherapist's communication with patients about the risks of dry needling, questions about adverse events associated with acupuncture and trigger point needling are answered.

### 1. What types of adverse events are related to dry needling?

White et al used the following system to classify adverse outcomes associated with acupuncture combining several reports including a prospective study examining 31,822 treatments.<sup>19,21</sup>

- Mild (minor) - short duration, reversible, does not inconvenience the patient.
- Significant - requires medical intervention or interferes with patient's activities.
- Serious - requires hospital admission with potential persistent or significant disability or death.

Mild (Minor)	Significant	Serious
<ul style="list-style-type: none"> <li>• Bruising</li> <li>• Bleeding</li> <li>• Pain during treatment</li> <li>• Pain following treatment</li> <li>• Aggravation of symptoms followed by improvement</li> <li>• Feeling relaxed/energized</li> <li>• Feeling tired/drowsy</li> <li>• Feeling faint</li> <li>• Dizzy</li> <li>• Nausea</li> <li>• Sweating</li> </ul>	<ul style="list-style-type: none"> <li>• Prolonged pain at site</li> <li>• Extensive bruising</li> <li>• Profuse sweating</li> <li>• Severe nausea</li> <li>• Vomiting</li> <li>• Fainting</li> <li>• Headache</li> <li>• Extreme fatigue</li> <li>• Severe emotional reaction</li> <li>• Gastrointestinal disturbance</li> <li>• Skin irritation</li> <li>• Slurred speech</li> <li>• Forgotten needle/patient</li> <li>• Seizure</li> </ul>	<ul style="list-style-type: none"> <li>• Pneumothorax</li> <li>• Puncture of other vital tissue</li> <li>• Systemic Infection</li> <li>• Broken needle</li> </ul>

<sup>#</sup> Adapted from White 19-21, MacPherson 10 Witt 22

**Dry needling includes acupuncture, intramuscular stimulation, trigger point needling and other forms of needling with a solid filament style needle (i.e., Gohavi technique, motor point needling).**

**Adverse event: An unexpected and undesired incident directly associated with the care or services provided to the patient; an incident that occurs during the process of providing health care and results in patient injury or death; or an adverse outcome for a patient, including an injury or complication. The act of puncturing the skin comes with a number of predictable adverse events (bruising or bleeding, pain during or following treatment) which commonly occur and are mild in nature. A physiotherapist may consider these normal side effects of treatment. However, from the patient's perspective they may be considered adverse particularly if the patient has not been educated about the risks associated with their dry needling technique.**

Other prospective acupuncture safety studies describe similar events but may group the mild and significant events differently.<sup>5,10,12,18,23</sup> Between studies there is general agreement as to what constitutes a serious adverse event.

Brady et al studied adverse events in 7,629 dry needling/trigger point treatments and found that the types of adverse events that occurred are similar to that experienced with acupuncture.<sup>1</sup> A limitation of this groundbreaking study is the number of treatments is relatively small compared to acupuncture studies. All adverse events were classified as mild with the most frequent being bleeding, bruising, pain during treatment and pain after treatment.

Physiotherapists who perform needling are expected to regularly scan the literature to ensure their knowledge of probability and severity of risks associated with the dry needling technique they perform is current.

### 2. Are all significant or serious adverse events discussed in the information above?

No. For example cases of cardiac tamponade have been reported twice in the literature but in the large-scale prospective studies did not occur.<sup>4,20</sup> Only conditions that occurred more frequently in the large studies were listed herein.

### 3. How frequently do adverse events occur?

The European Commission Classification System for medicinal products<sup>7</sup> has been used to discuss adverse events related to dry needling.<sup>1,22</sup>

Very Common	Common	Uncommon	Rare	Very Rare
>1/10 people treated	1-10/100 people treated	1-10/1000 people treated	1-10/10,000 people treated	< 1/10000 people treated
≥10%	≥1-10%	≥0.1% - 1%	≥0.01% - 0.1%	<0.01%

The Health Quality of Council of Alberta compared dry needling adverse events across studies<sup>8</sup> and found that:

- Minor adverse events occur more frequently.
- Serious adverse event are very rare (0.04/10000 treatments).
- Pneumothorax is the most common serious adverse event and is very rare (0.01/10000 treatments).

Number of adverse outcomes reported in prospective research studies				
Research Study	# of treatments	Minor Adverse Outcome	Significant Adverse Outcome	Serious Adverse Outcome
White et al 2001	31,822 treatments	2,135	43	0
MacPherson et al 2001	34,407 treatments	10,920	43	0
Melchart et al 2004	760,000 treatments (97,733 patients)	6,936		6 (includes 2 pneumothorax cases)
Witt et al 2009	2.2 million treatments (229,230 patients)	1,976	4,963	5 (includes 2 pneumothorax cases)
Brady et al 2014	7,629 treatments	1,463	0	0
Total	3,033,858 treatments			11 serious events includes 4 pneumothorax cases

Case studies describing singular events of pneumothorax following dry needling indicate that patients were seeking treatment for a wide variety of conditions such as tension headaches, asthma, chronic cough or other breathing problems pain in the shoulder, neck, or low back regions, and complex regional pain syndrome.<sup>4,5</sup>

#### 4. Are there differences in occurrence of adverse events between acupuncture and trigger point needling?

Yes.

##### Acupuncture Adverse Event Rates

- Acupuncture studies report varying adverse event rates ranging from 0.9% to 11.4% (0.9%<sup>10</sup>, 0.14%<sup>23</sup>, 7%<sup>21</sup>, 8.6%<sup>22</sup>, 11.4%<sup>5</sup>).

- Acupuncture adverse event rates in 2.2 million acupuncture treatments performed by physicians.<sup>22</sup>
  - 19,726 of 229,230 (8.6%) patients reported experiencing at least one side effect of acupuncture.
  - Adverse events requiring treatment occurred in 2.2% of patients.
  - 39.4% of events occurred during treatment.
  - 60.6% of events occurred after treatment.
- Adverse events ranked in order of frequency of occurrence were:
  - Minor bleeding and haematoma (6.1%)
  - Pain during treatment (0.21%)
  - Pain any type (2.04%)
  - Vegetative (i.e., adverse autonomic nervous system) symptoms (0.7%)
  - Inflammation (0.31)
  - Nerve irritation/injury (0.26%)
- Adverse events due to negligence such as forgotten needle, pneumothorax comprised 0.1% of all events.
- There were no acupuncture-associated deaths or permanent injuries associated with the acupuncture treatments.

##### Trigger Point Dry Needling Adverse Event Rates<sup>1</sup>

- Based on 7,629 trigger point needling treatments performed by physiotherapists.
- 1,463 adverse events were reported (19.18%).
- Adverse events ranked in order of frequency of occurrence were:
  - Bleeding 7.5% (7.55/100)
  - Bruising 5% (4.65/100)
  - Pain during treatment 3% (3.01/100)
  - Pain after treatment 2% (2.19)

##### Key points

- Using the European Commission Classification system,<sup>1,7,22</sup> adverse events are:
  - A common occurrence when performing acupuncture.
  - A very common occurrence for trigger point dry needling.
- Most adverse events are mild in nature.
- When comparing studies on adverse events associated with acupuncture and with trigger point needling there are similarities and slight differences in the side effects patients experience.
  - Bleeding, bruising and pain are the top three side effects for dry needling and are mild in nature.

- Pain during needling occurs more frequently with trigger point needling than with acupuncture.
- Pain (during and following treatment) occurs more frequently with trigger point needling than with acupuncture.
- Serious adverse events from dry needling are very rare.
- Pneumothorax is the most common serious adverse event associated with dry needling and is very rare.

### 5. How do I apply this information to the disclosure process?

- When informing patients about dry needling risks, you do not have to quote statistics from the research reports. Disclose the material and special risks related to your practice context meeting your patient's informational needs.
- Bear in mind, the information provided herein provides an overview of dry needling risks from published studies. It paints a broad overview of dry needling risks. Rates of adverse events will vary from practitioner to practitioner as exemplified in Brady's study<sup>1</sup> which identified a subgroup of physiotherapists who had higher rates of mild adverse events than the overall group. You may be missing factual information about the rates of adverse events in your practice. As such your challenge is to combine the research information with your rate of adverse events occurrence and apply this to your disclosure process.
- Analyze your practice to gain a sense of how frequently adverse events occur. Use this information to inform the disclosure process.
  - Can you adapt the classification system for European Medicinal Products to analyze the number of adverse events that occur in your practice?
  - How frequently do your patients experience mild adverse events?
  - Are the frequency of risks reported here the same for your practice?
  - Can you use your practice data in the risk disclosure process?
- When discussing risks with patients:
  - Most physiotherapists will be able to say with confidence that they have never had a patient with a serious adverse event and defer to the research that there is a very rare risk of pneumothorax.
  - Other physiotherapists may have experienced significant or serious dry needling adverse events at rates greater than reported literature and should defer to their own practice data when discussing dry needling risks.
  - The fact that one has never experienced a serious patient safety event in their practice does not predict that one will never experience one in the future.
- Remember consent is an ongoing process. In subsequent dry needling treatments it is prudent to remind patients about the risks of dry needling and, when appropriate, educate patients on self-management of adverse events when they occur.

*References are listed in the Dry Needling Resources Reference List.*

Physiotherapy Alberta regulates and leads the practice of physiotherapy in Alberta. Contact us for more information on this or other practice guidelines.

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## Exhibit 10

October 22, 2012

To whom this may concern:

I am a 24-year-old woman who other than vulvodynia was perfectly healthy and now I am in a worst state after a first & last "dry needling" experience meant to just help with inner thigh muscle tightness associated with vulvodynia—diagnosed at Johns Hopkins in Baltimore, Maryland this past spring. My primary doctor believes that the location of the 2 inch "dry needling" bruise shows where the "dry needling" physical therapist hit a particular nerve--between the knee and bend of the leg, inner left thigh where the seam of a pants leg would be--which hit would explain the pain down my legs and up my spine. I have had sharp & dull pain from head to toe--literally from my both jaws to both feet. Please see attached of a bruise, approximately 2 inches in diameter on my upper inner left thigh near my knee. My acupuncturist, Dr. Tiru Liang, who has been practicing for over 35 years, examined the bruise on Friday, October 5<sup>th</sup>—she was appalled by the bruise left by the physical therapist, Ms. Dionne Hawkins, who does not have a medical degree and who has not been practicing “needling” nearly as long as she has.

I would like to share the specific details with you, because I would like to prevent this kind of incident from ever happening to anyone else in the state of Maryland; hopefully, this will come to light somehow at the national level.

As mentioned in the previous email, I have found it more difficult this weekend to reverse in order to park safely (I think that this comes in part from my back stiffening on the patient table, bracing from the excruciating “dry needling” on Thursday, October 4th, and from the stress of repeatedly crying and yelling “stop” to the physical therapist).

Unlike other teachers, a high school science teacher has added legal responsibilities to ensure the safety of adolescents during laboratory experiments. On Friday, October 5<sup>th</sup>, my primary doctor gave me two prescriptions to help alleviate the sharp and dull pain which I am experiencing literally from head to toe (left foot to left jaw—please note my bruise on my left leg, the “dry needle” caused immense “electrical” pain around my left knee cap—a pain I have never experienced in my whole life and I wish to never experience again). I am still experiencing sharp and dull pain even with Cymbalta for my muscular/neural pain, over-the-counter Aleve, and prescription Naproxen. Dr. Diener also gave me Alprazolam to help to calm me down from the “dry needling” pain, but I am still very emotionally distressed. I feel that the combination of prescriptions has made me very lethargic and less observant about my surroundings. As a high school science teacher, I need to be very sharp and on my toes constantly from the time the bell rings at 7:20am to 2:10pm—ready for any kind of medical emergency which may arise from using various chemicals or tools in the lab. I cannot simply call in for a substitute teacher easily, because substitute teachers do not have the necessary safety certification and substitutes would be a liability for the school system. I have already lost a week of work and may lose more time in order to see various neurologists.

Growing up in a household with a father who has a PhD in microbiology, I used Western medicine most of my life—until this past year. Since August, I have seen a wonderful acupuncturist and doctor, Dr. Tiru Liang in Clarksville, Maryland. Since the first time which I

saw her, I have had incredible positive results. I have experienced less pain and anxiety associated with the pain. I think very highly of her. Every time I see her, she asks me how I am doing on multiple levels—physically and emotionally. Once she administers the acupuncture needles, I hardly feel them (because she's that good)—the only thing that I feel is the slight burn of the alcohol, which is completely understandable to prevent any kind of infection. I know that I can count on her for a “same day” emergency appointment. I recommend Dr. Tiru Liang to various fellow co-workers, including my principal, assistant principal, retired board of education member, and my vulvodynia specialist at Johns Hopkins. In other words, I understand how “needling” should be done, because of my exceptional experience with an acupuncturist and medical doctor. That has acted as a baseline for comparison—the traumatizing “dry needling” experience with physical therapist Dionne Hawkins on Thursday, October 4<sup>th</sup>, 2012 at 6:30pm (who does not hold a medical degree).

Since October 4<sup>th</sup>, I have had a range of physical symptoms—sharp & dull pain from head to toe, “pins & needles” sensation down my legs, and numbing sensation down the legs and lower spine. I thought that the sharp pain was scary, but the numbness is terrifying. I will never forget the look of my students' faces as I sat stiffly in the front of the classroom that Friday, bawling in pain from the "dry needling," looking for substitute afternoon coverage, so I could have emergency visits with my doctors. My freshman gifted and talented biology students looked like they were about to cry--they were scared for me. I am in a position of authority. I am supposed to be the strong one for them.

I have been having horrible dreams since the "dry needling" incident and I do not know if they can be attributed to the prescriptions to deal with the "dry needling" or simply the anxiety behind the incident. I have had a dream that the "dry needling" was happening all over again and woke up terrified in the middle of the night. I think that the dream was caused by actual physical pain which felt like pricks of those needles in my right thigh--and the pain which I was actually feeling when I woke up was somehow manifested or integrated into the dream itself. I have also had a dream that my feet were turning blue in the emergency room of Howard County General Hospital and they had to call my neurologist in the middle of the night to come in. I woke up terrified that I wouldn't be able to move. Logically, though, I knew that I had had a dream. I was scared before I had gone to bed last night, because I went to our local Giant grocery store and I felt like I was walking with heavy shoes on as I was going down the aisles, because of the numbness sensation in my feet, legs, and bottom. Right before I had gone to bed, I told my parents that I was scared about the numbness progressing overnight as it rapidly as it had throughout the day yesterday and I did tell them that I was scared about not being able to move much in the morning. The anxiety before bed last night about the numbness may have contributed to the horrible dreams. Usually, I don't remember most of my dreams and usually, I hardly ever have nightmares. These dreams have truly scared me.

This is really taking a physical and emotional toll on me. **There is almost not a minute in the day that goes by that I wish that I had not gone to see Ms. Hawkins.** Almost every day I have cried either at home or work or both--and I look forward to the opportunity after doctors, and nurses, and specialists, and lawyers, when I can just go home and crawl in bed and rest my body from this new pain after such a long day.

Medical director & neurologist Dr. Gerwin (and well-known proponent of “dry needling”), concluded that I had been "violated" by physical therapist Ms. Dionne Hawkins--causing physical & emotional damage from the "dry needling." The appointment was nearly 3 hours long. He conducted a very thorough examination of me from head to toe, took very thorough notes on his laptop computer, and provided a lengthy medical explanation for my pain from head to toe--he is one of the best doctors I have ever meet--I can clearly see why he is a medical director. He said that he had consulted with his co-director Mr. Dommerholt, the first physical therapist to teach "dry needling" in the U.S. prior to my appointment. Dr. Gerwin is typing up a formal report, which he said that I can disseminate to whomever I wish, including Executive Director Curry of the Maryland Board of Physical Therapy Examiners.

I understand that Dr. Tracey Adler in Richmond, VA specializes in pelvic pain AND "dry needling." In her article, [“Trigger-Point Needle Helps Relieve Chronic Pain” \(PDF\)](#), in the July 26, 2008, *Richmond Times Dispatch*, Dr. Adler said, **"Inserting the needle doesn't hurt...and although patients may be sore afterward, their chronic pain is gone** because the pain is treated at the source." Dr. Adler assisted me in getting an appointment with medical director Dr. Gerwin. Logically, it seems that a tool which has the potential to be extremely beneficial to patients, also has the potential to be very detrimental if put into the wrong hands—I am still having sharp & dull pain weeks after my “dry needling” appointment despite taking Cymbalta, Naproxen, Alprazolam, Acetaminophen, Flexeril, Gabapentin, and taking a B12 supplement.

If you need the Physical Therapy Board to listen, here is an actual patient complaint of injury. There may be others out there who are not in the same position that I am in; others who may not have the financial resources/capital or knowledge to know how to be a self-advocate and/or find a legal advocate. There may be some in the medical field who are afraid to speak out—afraid of the possible repercussions to their medical career. As a public school science teacher and member of various science teacher organizations and associations at the local and national level, I believe in making the general public more knowledgeable in the field of science. It is a matter of individual safety and safety of their loved ones. “Dry needling” is an issue which not only Maryland citizens need to receive further education about, but also American citizens as a whole nationwide need to be better informed and protected. How many people will need to be hurt for the Board of Acupuncturists and the Board of Physical Therapists to agree upon the vague wording and misinterpretations of “dry needling” with respect to physical therapists? Change needs to happen now.

Please feel free to contact me by email with questions or concerns. Thank you for your time.

Respectfully,  
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# The San Diego Union-Tribune

## Lawsuit: Illegal acupuncture caused lung collapse

### Chiropractor was performing the treatment without a license, woman claims

By Kristina Davis February 2, 2015

**San Diego** — A San Diego woman has filed a lawsuit against a Chula Vista chiropractor accusing him of collapsing her lung during an acupuncture procedure that he is not licensed to perform.

The lawsuit, filed Jan. 16 in San Diego Superior Court, seeks unspecified damages, as well as a court order for Dr. Walker Scott to stop performing acupuncture on patients.

Acupuncture is a widely used practice based on ancient Chinese methods of inserting hair-thin needles at strategic points on the body to relieve pain. Most acupuncture points are on or near the surface of the skin, although some spots require needles to be inserted deeper.

Various medical studies and journals have identified dozens of cases of acupuncture-related pneumothorax, which is when air enters the membrane separating the chest wall from the lung and causes the lung to collapse.

State records show Scott does not have an acupuncture license, which is required. His website lists "electro-acupuncture" as an area of practice. He declined to be interviewed for this story.

According to the lawsuit, Scott sold his services to many of the mixed martial arts fighters who train at Alliance Training Center, including head coach and UFC trainer Eric Del Fierro and his now wife, Jamie, who is the gym's front office manager.

Jamie Del Fierro went for her first treatment in January 2014 and complained of tension headaches. Scott suggested acupuncture, and Del Fierro agreed, since she'd had the procedure done by others before and it had seemed to help, said her attorney, Sean Foldenauer.

The doctor began to put the fine needles in and along her neck, back and chest. He is accused of then piercing through her chest wall and into the tissue surrounding her lung, the lawsuit claims.

Del Fierro immediately told him she was experiencing pain in her chest and left arm and was having shortness of breath, but he waved off the complaints as common side effects, the suit says. He then followed up with a chiropractic adjustment before sending her home to rest, according to the lawsuit.

Del Fierro drove home but the symptoms continued, so she drove herself to an emergency room. Hospital staff quickly learned one of her lungs had collapsed.

Doctors drilled a hole in her chest and hooked her up to a machine that she had to carry around for the next week to regulate her breathing, while her body healed, her lawyer said.

She was 31 years old at the time and otherwise healthy, the lawsuit says. © Copyright 2016





## 警告

この鍼は医家向けの鍼です。医師及びはり師以外の人は使用しないでください。以下の指示を含め、守らない場合、重大な障害を生ずる恐れがあります。

- 1) 滅菌済みにつき、包装開封後直ちに1回限りの使用としてください。
- 2) 個別包装により、無菌が保たれています。包装がすでに破損または汚損していた場合は、使用しないでください。
- 3) 灸頭鍼には金属鍼柄をお使いください。プラスチック鍼柄は使用しないでください。
- 4) 刺入の深さは1/3以上残して刺入してください。
- 5) 刺入した鍼が抜けなくなった時は無理に抜かず、筋を弛緩させるなどの処置を行い、ゆっくりと真っ直ぐに抜いてください。抜鍼時に鍼を曲げたりヒネリなどの力をかけたまま引き抜くと、折鍼の危険があります。
- 6) ご使用に際しては添付文書をよくお読みください。添付文書が必要な方はお申し出ください。



### Warning :

- Depth of insertion should be less than 2/3 of the needle shaft.
- If needles are difficult to remove, first try to massage and relax the muscle. Try to remove the needles slowly and upright. Do not twist, bend or force, as this may cause the needle to break.
- Read instructions on the 1,000 needle box before use.



Caution : Federal law restricts this device to sale by or on the order of qualified practitioners of acupuncture as determined by the States.

MADE IN JAPAN

## Dry Needling Is One Type of Acupuncture

Heming Zhu, PhD, CMD, MD, MAcu, LicAcu, and Heidi Most, MAcu, LicAcu

### ABSTRACT

**Background:** Acupuncture has been practiced in Western countries for more than 40 years. One type of needling therapy termed dry needling has gained popularity rapidly since 2000. However a strong debate and conflict exists between proponents of dry needling by physical therapists and proponents of acupuncture.

**Objectives:** This review explores similarities and differences between dry needling and acupuncture and provides suggestions for debate and solutions for conflict between nonphysician dry needling practitioners and acupuncturists.

**Materials and Methods:** This review selected four features of needling technique and explored the similarities and differences between dry needling and acupuncture. The four features were: (1) needles used; (2) target points; (3) action mechanisms; and 4) therapeutic effects. A PubMed search for articles on dry needling and acupuncture for the years spanning 1941 to 2015 was also used to determine how many articles were retrieved for each topic and how levels of interest in each topic changed.

**Results:** It was observed that both dry needling and acupuncture shared needles, target points, action mechanisms, and therapeutic effects, and could be used to treat musculoskeletal disease effectively. However, because of a lack of adequate training and good regulation, acupuncturists question the safety of dry needling.

**Conclusions:** Acupuncture is more inclusive and dry needling is one type of acupuncture when acupuncture needles are used. Collaboration and integration should be strengthened between dry needling practitioners who are not physicians and acupuncturists so that the patients can receive safe and high-quality acupuncture treatment. Five suggestions were proposed for solutions to solve the conflict and debate between dry needling and acupuncture.

**Key Words:** Dry Needling, Acupuncture, Trigger Points, Acupoints

### INTRODUCTION

**N**EEDLES THAT HAVE BEEN USED in healthcare may be in different forms, mainly as solid or hollow. Hollow (hypodermic) needles are widely used by conventional medicine practitioners to inject solutions into, or withdraw body fluids from, the human body. Practitioners of acupuncture, a well-known component of Traditional Chinese Medicine (TCM), have been needling with solid needles for >3000 years. These needles are commonly called acu-

puncture needles. Dry needling as a newly developed needling therapy also uses acupuncture needles. Because this technique involves using the same treatment tool as acupuncture, a number of overlaps in history, theory, research, and practice have been generated, leading to serious debate and conflicts concerning professional interests, public benefits, policymaking, and healthcare service. However, scarce literature information exists that comprehensively compares the two needling techniques' history, theory, research, and practice.<sup>1</sup> Furthermore, there are

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no systematic suggestions on how these two needling techniques can be coordinated in order to provide optimal service for patients, and no systematic solutions for resolving the conflicts.

This review addresses some important differences regarding needles used, points targeted, action mechanisms, and therapeutic effects between dry needling and acupuncture. The review also explores professional development and offers potential solutions to the conflict in professional interest, research, public benefits, policy making and healthcare service.

## METHODS AND MATERIALS

Four features of needling technique were selected and the similarities and differences between dry needling and acupuncture were explored. The four features were: (1) needles used; (2) target points; (3) action mechanisms; and (4) therapeutic effects. To help understand why there are debates and conflicts between nonphysician dry needling practitioners and acupuncturists, three aspects of professional practice were studied: (1) growth of interest in dry needling and acupuncture from 1941 to 2015; (2) scope of practice; and (3) public safety. A PubMed search for articles on dry needling and acupuncture for these years was also used to determine how many articles were retrieved for each topic and how levels of interest in each topic changed.

## RESULTS AND DISCUSSION

### Small Needles but Large Issue

The conflict between dry needling and acupuncture begins with small needles. Acupuncture practitioners commonly use acupuncture needles that are solid, filiform metallic needles (although stone needles and bamboo needles were used in ancient times.) Dry needling practitioners, such as physical therapists who are not physicians or acupuncturists, use the same needles. However, they claim they are not practicing acupuncture. An American Physical Therapy Association (APTA) article, published in 2012, stated: “Dry needling is an invasive technique used by physical therapists (where allowed by state law) to treat myofascial pain that uses a dry needle, without medication or injection, which is inserted into areas of the muscle known as TrPs [trigger points].”<sup>2</sup>

It is well-accepted that acupuncture is the earliest modality using solid needles to treat diseases. In the term *acupuncture*, *acu-* means *needle* and *-puncture* is *penetration*. In Chinese medicine and culture, the term acupuncture always goes with the term *moxibustion*, as in *Zhen Jiu* acupuncture and *moxibustion*. *Moxibustion* is a therapy that involves burning an herb on or near the skin. Somehow, *moxibustion* was missed in *Zhen Jiu* after acupuncture

therapy entered the Western world. Both acupuncture and *moxibustion* are based on the channel theory of TCM but the former is Yin and the latter is Yang. This is a topic that the current authors might address in a future publication.

On the official website of the National Center for Complementary and Integrative Health of the U.S. National Institutes of Health, the definition of acupuncture has been reasonably expanded and well-described as

a family of procedures involving the stimulation of points on the body using a variety of techniques. The acupuncture technique that has been most often studied scientifically involves penetrating the skin with thin, solid, metallic needles that are manipulated by the hands or by electrical stimulation. Practiced in China and other Asian countries for thousands of years, acupuncture is one of the key components of traditional Chinese medicine.<sup>3</sup>

Legge<sup>4</sup> studied the history of dry needling and highly praised Brav and Sigmond’s work in 1941<sup>5</sup> because they found that pain could be relieved by simple hypodermic needling without injection of any substance. One group in the study who received injections without any substances had results that were a close second to the best-outcome group who received Novocain injections. This outcome was described as a “startling” result.<sup>5</sup> Although the term *dry needling* was not used, this was the first time the technique was used in a Western context. Similar situations in acupuncture also appeared in clinical trials of verum versus sham acupuncture. Results that show no difference statistically between treating pain with either verum acupuncture or sham acupuncture could indicate new mechanisms at work or suggest novel techniques and theory.<sup>6,7</sup>

Although Brav and Sigmond’s work should be widely recognized, they did not coin the term dry needling. It was Paulett who first used the term dry needling in 1947. Paulett reported that pain relief could be obtained not only from the injection of procaine by hypodermic needles but also by injecting saline and “even dry needling.”<sup>8</sup>

In a landmark article in 1952, Travell and Rinzler<sup>9</sup> pointed out that dry needling could be an effective method of treating myofascial TrPs (MTrPs); this article is commonly regarded as the earliest use of the term *dry needling*.

After the publication by Travell and Rinzler,<sup>9</sup> the term dry needling was widely accepted and used. However, the needles used in Western studies of dry needling were mainly hollow needles that were used for a control group or were offered as one option as a treatment for myofascial pain. In 1999, Simons et al.<sup>10</sup> further described the dry needling used as a control technique when studying the effects of injections of lidocaine. Thus, in this study and other early studies, hypodermic needles were used instead of acupuncture needles.

Acupuncture needles were not utilized for dry needling until 1979. Lewit published his dry needling study including an acupuncture group, on the relief of myofascial pain and found that the acupuncture needles were safer and

produced less bleeding and bruising.<sup>11</sup> One year later, results were published by Gunn et al. from their first clinical trial on treating low-back pain using dry needling that combined features of acupuncture (type of needles, needle techniques). Gunn, at the time, was president of the American Society of Acupuncture.<sup>12</sup>

In 1983, Macdonald et al. reported that treatment of an acupuncture group was superior to placebo in their dry needling study on treating chronic low-back pain.<sup>13</sup>

According to the abovementioned 3 studies on dry needling, it is clear that dry needling was not confined to hollow-core needles in a narrow sense. Lewit freely admitted to having borrowed acupuncture needles to perform his dry needling.<sup>11</sup> In addition, the earliest Western use of a dry needling technique (the term was not used as such) by Brav and Sigmond was not claimed to be dry needling but was called acupuncture, because the first line of this article stated: “The origin of the local and regional injection treatment of low back pain and sciatica dates back to the earliest description of acupuncture,” which referred to Churchill’s publications on acupuncture in 1821 and 1828.<sup>5</sup>

Since the 2000s, acupuncture needles have been widely used in the practice of dry needling by physical therapists. This is discussed more in later sections of the current review.

Historically, dry needling is, simply, acupuncture. It was first described in China’s earliest and most comprehensive extant medical treatise, *The Yellow Emperor’s Inner Classic (Huangdi Neijing)*. Dry needling involves inserting an acupuncture needle into a tender or painful point and then manipulating appropriately the needle for therapeutic purposes.<sup>14</sup>

Interestingly, the term dry needling (*Gan Zhen*) had been a folk name for acupuncture since the 1900s when Western medicine entered China. Acupuncture practitioners injected nothing with needles, while wet needling was used by Western medical doctors to inject antibiotics or anesthetics. *Nothing* here means *Gan/dry*. Thus, dry needling was created to be distinguished from the syringe needles used injecting of solutions. Dry needling has been referred to as acupuncture particularly in southern China. “*Gan Zhen/dry needling*” or “*Da Zhen/needling*” are also commonly used by many Chinese medicine practitioners.<sup>15,16</sup>

It is not surprising that the needles of contemporary dry needling started from wet needling with injectants in the practice of Western medicine. However, it was almost immediately influenced by TCM acupuncture; thus, acupuncture needles began to be used.

The acupuncture needles are small. However, both acupuncturists and physical therapists consider them to be cornerstones of their professions.

### Target Points: Trigger Points Are Acupuncture Points

The term *target points* means points or spots where dry needling and acupuncture practitioners put needles. The

target points would be called trigger points or myofascial trigger points in dry needling and acupoints or *Ashi* points in acupuncture.

There is no doubt that needling specific target points is the first step of needling therapy, including dry needling and acupuncture.<sup>17</sup> Discovery and classification of target points took place >2500 years ago in acupuncture and 75 years ago in dry needling.

The earliest acupoints (*Xue Wei/Location of Cave or Hole*) were defined as painful spots in the first known book of Chinese medicine, the *Huangdi Neijing (The Yellow Emperor’s Inner Classic, ~ 100 BC)*. In this classic book, a chapter on *Bei Shu/Back Acupoints* says “to check if it is [an] acupoint, press it and the pain is triggered and may be relieved during the pressing. Here is [an] acupoint.” The phenomenon is called *Yi Tong Wei Shu/Painful Spot Is Acupoint*. The well-known Chinese medical physician in the Tang dynasty, Sun Simiao (581–682 AD), named the painful spot the *Ashi* point because the patient would say: “ah, yes/ouch, right here,” when the painful spot was pressed. Sun also stated in his book *Beiji Qianjin Yaofan/Emergent Thousand Ducat Formulas, Volume 29*, in a chapter on moxibustion: “The method of locating *Ashi* points, is to press the painful spot. The patient may feel comfortable or painful saying *Ashi* (Ah, yes). Treatment with needles and moxibustion would work no matter if it is in the channel.”

With the increase of *Ashi* points, ancient Chinese medicine practitioners gave them certain names and set them down in their “homes” (i.e., the channels where they belonged) based on observation of the acupoint’s functions and indications. There were 201 acupoints when the *Huangdi Neijing* was published, 348 acupoints in *Zhenjiu Jiayi Jing/The Systemic Classic of Acupuncture and Moxibustion* (Huangfu Mi, Jing dynasty, 260 AD), 354 in the *Illustrated Classic of Acupoints on the Bronze Man (Wang Weiyi, Song dynasty, 1026 AD)*, and 361 acupoints in *Zhenjiu Fengyuan/Meeting the Source of Acupuncture and Moxibustion* (Li Xuechuan, Qing dynasty, 1817 AD). The 361 acupoints have been accepted worldwide since then.<sup>18</sup> It is believed that >1949 points have been discovered so far.<sup>16</sup> Most of them have not been placed on the channels because the channel–acupoint theory had been developed over thousands years. In fact, there is no difference between acupoints and *Jin Wai Qi Xue/Extraordinary acupoints* or *Ashi* points in nature because the origin is the same—the *Ashi* points.

The more important thing is that ancient Chinese medicine practitioners found certain relationships in physiology and pathophysiology between body-surface acupoints and deep tissues and visceral organs, which is how the channel theory was developed. According to the channel theory, one can needle the acupoints to treat diseases and pain in muscles, fascia, and visceral organs. Therefore, Chinese acupuncture has a very wide range of indications, from various kinds of musculoskeletal pain to digestive diseases, to allergic sinusitis, and even to health maintenance and longevity.<sup>19</sup>

While painful, tender, and tight nodules or spots in muscles have long been recognized in many cultures in the world, the spots' significance for pain was not yet acknowledged in Western countries until the twentieth century. Researchers Lewis, Kellgren, Harman and Young, Kelly, and Steindler did pilot work on this issue from 1938 to 1941. The term *trigger point* was first proposed by Kellgren in his low-back pain and sciatica study. He reported that sciatica seemed to have more referred pain from muscular, tendinous, and ligamentous structures rather than from sciatic-nerve irritation.<sup>21,22</sup> The term trigger point, however, was not restricted to myofascial trigger points.<sup>20–25</sup>

After Kellgren used the term trigger points, Travell, Rinzler, Simons, and their colleagues used it and modified it to *myofascial trigger points* (MTrPs), narrowing the concept to muscles,<sup>9,10,26</sup> calling a trigger point “a hyperirritable spot in skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band. The spot is tender when pressed and can give rise to characteristic referred pain, motor dysfunction and autonomic phenomena.” Since then, the APTA uses the term trigger points as target points for dry needling by physical therapists treating myofascial pain.<sup>2</sup>

In the past 2 decades, dry needling and acupuncture research has grown rapidly. After reviewing the literature, Dunning and his colleagues wrote that

physical therapists should not ignore the findings of the Western or biomedical “acupuncture” literature that have used the very same “dry needles” to treat patients with a variety of neuromusculoskeletal conditions in numerous, large scale randomized controlled trials. ... Physical therapy associations and state boards of physical therapy should consider broadening the definition of dry needling to encompass the stimulation of neural, muscular, and connective tissues, not just trigger point.<sup>27</sup>

How much do trigger points and acupoints overlap? Melzack, who introduced the gate control theory for pain mechanism in 1965, first compared the locations of trigger points and acupoints, with his colleagues, in 1977 and found a high degree of correspondence (71%) between trigger points and acupuncture points,<sup>28</sup> from which the researchers concluded that “‘trigger points and acupuncture points for pain, though discovered independently, and labeled differently, represent the same phenomenon and can be explained in terms of the same underlying neural mechanisms.’”<sup>28</sup>

In 2008, Dorsher and Fleckenstein investigated 255 common MTrPs and found that 238 (93.3%) MTrPs anatomically corresponded with classical acupoints. Furthermore, the researchers stated that “‘the marked correspondences of the pain indications (up to 97%) and somatovisceral indications (up to 93%) of anatomically corresponding common MTrP-classical acupoints pairs provide a second, clinical line of evidence that trigger points and acupuncture points likely describe the same physiologic phenomena.’”<sup>29,30</sup>

Thus, trigger points in dry needling and acupoints in acupuncture are derived from painful spots or tender/tight nodules. Muscle pain can be relieved effectively when the target points are needled. The same phenomenon is given different names. Lao Zi (the founder of Daoism in China, ~ 600 BC) said in his book *Dao De Jing*: “‘The *Dao* that can be spoken is not the eternal *Dao*. The name that can be named is not the eternal name.’” Hence, the names can truly help us recognize the world and we do not want to be attached to these names.

### The Same Needles Involve the Same Biologic Mechanisms

Zhou et al. reported that, between 1980 and April 2015, almost 200 publications were retrievable by a PubMed search using the term *dry needling*. The majority of this literature reported on the therapeutic effectiveness of dry needling, using solid filiform needles for various types of musculoskeletal pain.<sup>1</sup>

As was noted above, both trigger points and acupoints are just different expressions of target points for dry needling and acupuncture. In addition, acupoints are much broader than trigger points.

When the same needles are inserted in the same target points, is it possible that there are different therapeutic mechanisms involved? It should be impossible in nature. However, different times, philosophies, cultures, and kinds of education may induce different thoughts regarding the same phenomena. Acupuncture was mainly developed in pre-science times and dry needling was generated from the practice of conventional medicine. Thus, the two disciplines have different thoughts on the action mechanisms of needling.

Originally, acupuncture, as an ancient healing technique, was used to treat diseases and preserve health through balancing Yin and Yang and dredging the channels according to the theories and foundations of TCM. In the past 4 decades, acupuncture has grown rapidly in the West because of increasing research and has been widely integrated into the practice of conventional medicine in major Western countries.<sup>1,17</sup>

During the past 4 decades, acupuncture action mechanisms and channel-acupoint theory have been studied widely. Remarkable progress has been made and proposed mechanisms might include the gate control theory,<sup>31</sup> axon reflex,<sup>32</sup> theory of signal convergence-projection,<sup>33</sup> endogenous opioid peptides,<sup>33,34</sup> purinergic signaling system,<sup>35</sup> mechanical signal transduction in myofascial tissue,<sup>36</sup> plasticity and sensationalizing of acupoints,<sup>37</sup> and reflex arc theory.<sup>15</sup>

As the current first author's acupoints review stated in 2014, needling is the first step of acupuncture therapy. Needling reactions are the beginning of the healing process. Several research articles explored the three major needling reactions. These reactions are (1) neuronal, (2) biophysical,

and (3) biochemical in nature, leading to downstream effects. The messengers of the three reactions involved might include neurotransmitters, cytokines, hormones, and inflammatory factors. Healing may be potentiated through the messengers in neuronal and humoral pathways. The reactions may manifest as erythema and De Qi—both of which are common phenomena used as positive signs in acupuncture treatment—which could provide interesting evidence regarding the mechanisms of acupuncture actions.<sup>17,38</sup>

Dunning et al.'s 2014 review cited 24 action mechanism research articles on dry needling,<sup>27</sup> and most of them were derived directly from acupuncture research. Needles used in the majority of this research were acupuncture needles. The manipulations on the needles were either performed by hand or via electrical stimulation. Dunning et al. also concluded that, "while the terminology, theoretical constructs, and philosophies are different, the actual procedure of inserting thin monofilament needles, as used in the practice of acupuncture, without the use of injectate is very similar across professions."<sup>27</sup>

In comparison, dry needling originated from biomedicine and is firmly anchored in the body's anatomy, physiology, and pathology with regard to myofascial pain and therapeutic mechanisms. Essentially, all research results on needling reactions and mechanisms can be applied to dry needling. It is clear that research on dry needling is more focused on local structures—such as muscles, tendons, ligaments, connective tissue, nerves, and blood vessels—and somatic pain in these tissues because dry needling is a therapy or technique for treating myofascial pain. It is also common that acupuncture research would include dry needling research if acupuncture needles were used.

Although tremendous achievements in understanding needling mechanisms have been made and can be shared by the two needling techniques, very little is still known.

### Therapeutic Effects Overlap

Acupuncture as a technique was created in whole-systems of theory and practice of TCM and has very broad indications, including pain, arthritis, sinusitis, insomnia, and menopause, among other conditions. In total, acupuncture is recommended for treating 107 diseases, based on levels of evidence by the World Health Organization.<sup>39</sup> In fact, acupuncture has also been used as a healing art, for example, in the practice of constitutional Five-Element acupuncture focusing on whole-body regulation of *Shen*/Spirit and *Yi*/Mind, and *Qing*/Emotion and *Ti*/Body.<sup>40</sup> In Asian culture, acupuncture is commonly used to preserve well-being and promote longevity.<sup>19</sup>

Dunning reviewed acupuncture trials and noted that

the vast majority of the so-called "acupuncture" RCTs [randomized controlled trials] have used Western medical diagnoses...such as chronic neck pain, plantar fasciitis, knee

osteoarthritis, and carpal tunnel syndrome... Physical therapists should therefore not ignore the findings of large scale randomized controlled trials available in the Western or biomedical "acupuncture" literature that use the same "dry needles" to treat patients with neuromuscular conditions.<sup>27</sup>

Myofascial pain and dysfunction are important indications for most acupoints, but not every acupoint has the direct function of reducing pain. It is well known that myofascial pain is a shared indication for both dry needling and acupuncture. Biomedical progress in understanding needling action mechanisms by dry needling has promoted development of traditional acupuncture greatly, while many aspects of acupuncture and channel theory are not well-explained by contemporary science.

A very general search on PubMed using the term *acupuncture clinical trial* produced 5330 articles and *dry needling clinical trials* generated 74 articles (as of January 2016), which is further evidence that acupuncture has a very wide variety of indications. Although some theories in TCM such as Yin–Yang, Five-Element, Qi–Blood, Channels, and Meridians are not well-understood in contemporary bioscience, the therapeutic effectiveness of treating many Western-defined diseases with acupuncture cannot be limited or denied, although more high-quality studies are necessary. Why do the same needles have so much difference in their spectra of indications? The authors of the current review believe that the Chinese medical practitioner is steeped in the history, philosophy, and theoretical constructs of TCM, wherein the needles are tools used to affect the complexities of the body, mind, and spirit.

Indeed, there are many more similarities than differences between dry needling and acupuncture. Thus dry needling, as defined by Western medicine, is one type of acupuncture. Actually, traditional Chinese acupuncture was integrated with other cultures, generating new traditions such as Korean Acupuncture and Japanese Acupuncture and Five-Element Acupuncture. Contemporary science gave rise to electroacupuncture, scalp acupuncture, auricular acupuncture, wrist and ankle acupuncture, and abdominal acupuncture, etc. These techniques are used in Western medical acupuncture. Dry needling was derived from the practice of Western medical doctors. It should be part of Western medical acupuncture, as Zhou has explained.<sup>1</sup> Stated briefly, dry needling *is* acupuncture.

### What Caused the Conflicts and Debates in Professional Practice?

Acupuncture has been practiced in China for thousands of years and for >4 decades in the United States.<sup>1,17,19</sup> Unexpectedly, in recent years, an intense conflict and debate has developed between dry needling practitioners who are not physicians or acupuncturists and acupuncturists. A growing number of nonphysician physical therapists and other allied health professionals are now offering dry

needling to their patients. As discussed above, dry needling has a striking resemblance to acupuncture and uses the same needles. This raises two questions: (1) What happened? (2) How can the problem be solved?

There are three issues that might shed light on what happened.

The first issue is the growth of interest in both dry needling and acupuncture. The earliest mentions of dry needling and trigger points in the literature were made in the 1940s.<sup>5,8</sup> Acupuncture was formally introduced into Western countries since the visit of former U.S. President Richard Nixon (R) to China in 1972. Interestingly, based on a PubMed search, Table 1 shows that there was not much interest in dry needling (467 articles before the year 2001), compared to interest in acupuncture (8332 articles). Interest in both dry needling and acupuncture grew rapidly after 2000. The growth of interest in dry needling was 5.6% of acupuncture on average before 2001 and 10.86% after 2001.

Legge concluded: “The roots of dry needling, and the theory on which it is based, are quite distinct from the practice of acupuncture. However, without the interest in acupuncture in the mid-1970s and the introduction of acupuncture needles into contemporary practice it is likely that dry needling would never have become an established modality.”<sup>4</sup>

Clearly, once dry needling was established, it has overlapped with acupuncture in many ways, including needles used, points targeted, needling techniques, action mechanisms shared, therapeutic effects, and scope of practice.

Legge summarized some plausible reasons that can explain the rapid adoption of dry needling. These are that dry needling uses acupuncture needles, the basics of dry needling can be taught quite quickly, science supports the importance of myofascial trigger points as a potent source of pain, and the clinical experience of using dry needling can be very satisfying for both practitioners and patients.<sup>4</sup>

The second issue is scope of practice. So far, there are 44 states that allow acupuncture practice. The first state that approved dry needling practice by physical therapists was Georgia in 2012. As of 2015, dry needling practice by physical therapists is allowed by legislation and administrative rules in 11 states.<sup>41</sup> It is good to see that dry needling

can help more people who have musculoskeletal pain and dysfunction. However, dry needling practice by physical therapists lacks accredited education and regulations, although the APTA has claimed dry needling is in the scope of physical therapy. Acupuncture has established a complete system of professional regulation, licensing, education, and training. The overlap in scope of practice between dry needling and acupuncture is one important factor causing the debate and conflict.

The third issue is public safety. In general, both dry needling and acupuncture are safe. There are a few reports of adverse events from dry needling and acupuncture.<sup>42–47</sup> Among them are dry needling treatments that were referred to as acupuncture, because of the media not being aware of differences between dry needling and acupuncture. As physicians are well-trained in needling procedures and clinical management, safety is not considered to be a problem. Physical therapists and other allied professionals who are not physicians or acupuncturists might lack the necessary training to do dry needling.<sup>1</sup> In contrast, licensed acupuncturists have received a minimum of 1905 hours of education (660 hours of hands-on supervised clinical training and 1245 hours of didactic instruction), while some physical therapists and other allied health professionals have had only a weekend training in needling techniques.<sup>48</sup>

## CONCLUSIONS

Both dry needling and acupuncture are needling therapies and share many things, such as solid filiform needles, target points, possible action mechanisms, therapeutic effectiveness, and some theories and foundations of biomedicine. Dry needling is one type of acupuncture. While dry needling is more widely practiced by nonacupuncture or nonphysician professionals, collaboration and integration between both groups is important in order to provide optimal service for patients. In addition to the competent treatment of musculoskeletal disorders and other diseases, safety of needling is most imperative, because inappropriate needling can be life-threatening. Acupuncture has established a

TABLE 1. GROWTH OF INTEREST IN DRY NEEDLING AND ACUPUNCTURE

Span of years	# of years	Key words		Average interest in dry needling as a % of acupuncture
		Dry needling # of articles	Acupuncture # of articles	
1941–1970	30 years	17	551	3.10%
1971–1980	10 years	27	1821	1.48%
1981–1990	10 years	123	2925	4.21%
1991–2000	10 years	300/467 (1941–2000)	3035/8332 (1941–2000)	9.88%/5.6%
2001–2015	15 years	1696	15615	10.86%

Based on a PubMed Search spanning the years 1941 to 2015.

complete body of regulations that should be useful for dry needling practitioners. Collaboration and development will be good news for needling practitioners and patients.

What solutions could resolve the conflict and debate between dry needling practitioners and acupuncturists? The following suggestions are proposed:

- (1) Share the resource of needling techniques and promote more collaboration and integration with conventional medicine and the healthcare system. Dry needling research would help in understanding the nature of needling action mechanisms and the theory of channels and acupoints in terms of biomedicine. Acupuncture would broaden applications of dry needling, for example, trigger points are not necessarily myofascial problems but may be visceral diseases manifesting through neural reflexes. Finally, trigger points might not be only phenomena of myofascial diseases, which could also include skin lesions, skin temperature changes, tightness, joint inflexibility, and numbness.<sup>15</sup> Acupoints can be physiologic points or pathologic points. *Ashi* points are pathologic points. Trigger points should be pathologic points that might be caused by joint structures instead of by muscles and fascia only or by distant problems. Thus, selection of distant acupuncture points is an important strategy for treating topical pain. Because of the association between the dermatomes and the viscera, acupuncture can be used to help treat visceral diseases.<sup>15</sup>
- (2) All needling practitioners should receive training in clean-needle skills, handling needles, and safety of needling in the body. Inadequate training would put patients in higher risk situations. Zhou et al. state: “Although needling therapy has been proven to be safe in general, healthcare professionals who are not physicians or acupuncturists need to develop their competence in order to provide skilled and proficient treatment and to prevent possible adverse events related to needling.”<sup>1</sup> These adverse events could include injury of blood vessels, nerves, and organs.
- (3) Acupuncture needles are classified as Class II medical devices subject to strict regulations of the U.S. Food and Drug Administration<sup>48</sup> and need to be treated as such by anyone who uses them.
- (4) To avoid conflicts and confusion, and to guarantee public safety, establishment of regulations for dry needling is necessary so that individuals who are not physicians will receive adequate education and training and develop good competence for treating musculoskeletal disorders and perhaps other conditions.
- (5) Continuing education should be required for dry needling practitioners to update their knowledge and techniques; this education should be similar to what acupuncturists are required to complete.

## ACKNOWLEDGMENT

Special thanks to James Snow, MA, RH (AHG) for his great suggestions, comments and editing, and his wisdom and passion that went with the article all the time.

## AUTHOR DISCLOSURE STATEMENT

No financial conflicts exist.

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