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GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

SHELLY EDGERTON
DIRECTOR

MICHIGAN BOARD OF ACUPUNCTURE MEETING OF APRIL 22, 2016

APPROVED MINUTES

In accordance with the Open Meetings Act, 1976 PA 267, as amended, the Michigan Board of Acupuncture met in regular session on April 22, 2016, at 611 W. Ottawa, Conference Room 4, Upper Level Conference Center, Lansing, Michigan.

CALL TO ORDER

David Krofcheck, OMD, Chairperson, called the meeting to order at 10:24 a.m.

ROLL CALL

Members Present: David Krofcheck, OMD, Chairperson
Julie Silver, MSW Dipl. Ac., Vice Chairperson
Beth Converse, Rac
Rosanne Emanuele, MAC
Jonell Underwood, Public Member
Sarah Wernert, Public Member

Members Absent: Brenda Donaldson, MD
Annie Haas, MSTOM
Renee Hubbs, Rac
Xiaohong Tan, OMD
Jonathan Zaidan, MD

Staff Present: Erin Londo, Board Support, Board and Committees Section
Karen Carpenter, Policy Analyst

APPROVAL OF AGENDA

MOTION by Converse, seconded by Underwood, to approve the agenda as presented.

A voice vote was taken.

MOTION PREVAILED

APPROVAL OF MINUTES

MOTION by Wernert, seconded by Silver, to approve the minutes of the July 17, 2015 meeting as presented.

A voice vote was taken.

MOTION PREVAILED

REGULATORY CONSIDERATIONS

None

OLD BUSINESS

HPRC Appointment

MOTION by Silver, seconded by Converse, to approve the appointment of Deborah Lincoln to the Health Professional Recovery Committee (HPRC).

Discussion was held.

A roll call vote followed:

Yeas – Converse, Emanuele, Underwood, Wernert, Silver, Krofcheck
Nays – None

MOTION PREVAILED

NEW BUSINESS

Online sources for Human Trafficking CE

Carpenter reported to the Board that all acupuncturists are required to participate in a one-time training in identification of victims of human trafficking as a condition of registration renewal. In five years, completion of the training will be a requirement for initial registration. The training is different than a continuing education requirement. Pursuant to the current Public Health Code, the Board is not authorized to require continuing education. Carpenter explained there are many online resources to complete the training requirement. Under the rule, a registrant is allowed to self-certify completion of the training.

Dry Needling

Henry Buchtel from the Michigan Association of Acupuncture and Oriental Medicine (MAAOM) gave a presentation about dry needling and safety issues related to the procedure. (See addendum #1 and #2)

AcupunctureDIY.com

Kropcheck discussed the impact of self-help and non-professional acupuncture websites on the practice of acupuncture and to the public health and safety. Depending on the information contained in the website, a concerned individual should file an allegation with the appropriate regulatory agency.

Department Update

Carpenter introduced herself as the new Board Analyst and explained that her role is to work with the Board on the rules.

PUBLIC COMMENT

None

ANNOUNCEMENTS

The next regularly scheduled meeting will be held July 22, 2016 at 10:00 a.m. in the Ottawa Building, 611 W. Ottawa, Conference Room 4, Upper Level Conference Center, Lansing, Michigan.

ADJOURNMENT

MOTION by Underwood, seconded by Silver, to adjourn the meeting at 11:32 a.m.

Minutes approved by the Board on October 21, 2016.

Prepared by:
Erin Londo, Board Support

April 25, 2016

Addendum #1

MAAOM

*Michigan Association of
Acupuncture & Oriental Medicine*

MAAOM Presentation to Michigan Board of Acupuncture

Dry Needling

April 22, 2016

Introduction:

- Dry needling is an acupuncture technique that is defined as the insertion of solid filament needles (i.e. acupuncture needles) into the skin and underlying tissue to disrupt pain sensory pathways and relax contracted fibers.
- Dr. Janet Travell, MD (President John F. Kennedy's personal physician) coined the term "dry needling" in the 1960's to distinguish it from "wet needling," which involved injection of anesthetics or other substances in conjunction with the insertion of a needle.
- Historically, dry needling is considered to be a sub-category of the traditional "a-shi" needling techniques, which involve palpation for and needling of tender areas in the tissues. "A-shi" needling has been part of the practice of acupuncture for at least 1,400 years.
- In Michigan state law, acupuncture is defined as "the insertion and manipulation of needles through the surface of the human body at specific locations on the human body for the prevention or correction of disease, injury, pain, or other condition."
- From a regulatory standpoint it is impossible to distinguish between dry needling and acupuncture.

Safety Issues

- NCASI 10 Key Facts, #9: Risks involved with dry needling include transmission of infectious disease, and injury to blood vessels, nerves, muscles, bones, and internal organs.

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- Dry needling as a specific technique involves insertion of needles up to 5 inches deep into myofascial trigger points (MTrPs) in muscles throughout the body, which in many cases are close to internal organs, major arteries, and nerve branches.
- There is no mandatory national reporting system for dry needling adverse events. As such, there is no source for comprehensive documentation of injuries caused by dry needling. There have been numerous reports of dry needling injuries in the mediaⁱⁱⁱ and from other sourcesⁱⁱⁱⁱ.
- The 2014 BMJ article “Pneumothorax Complication of Deep Dry Needling” details a case of pneumothorax (puncture and collapse of the lung) caused by an experienced MD performing dry needling of the ileocostalis muscle (VIDEO)^v. The article concluded that although pneumothorax is a rare adverse event, “deep dry needling over the thorax is very likely to be associated with a higher incidence of pneumothorax.”
- National minimum standard for non-physicians is at least 1365 hours of acupuncture specific training, including 705 hours of acupuncture specific didactic material and **660 hours of supervised clinical training**^{vi}.
- The American Board of Medical Acupuncture requires licensed physicians (MD/DO) receive a minimum of 300 hours of systematic acupuncture education in order to receive certification in medical acupuncture^{vii}.
- Recently in Michigan, a 3-day, 27 hour Dry Needling course offered April 22-24 and Nov 4-6, 2016, has been advertised to all licensed PT, MD, DO, DC, PA, and NP’s^{viii}.
 - The course description promises that participants will be able to “... offer this to your patients the very next day.”
 - Course participants are expected to “... practice the dry needling and also have it practiced on you.”



Legal Issues

- In 2012 the Michigan Board of Physical Therapy submitted a formal request for an opinion from the Attorney General regarding dry needling. In 2013 they received informal advice from the Attorney General's Office that "Dry Needling is not within the scope of practice for physical therapists."^x
- In 2015 the Federation of State Boards of Physical Therapy conducted an Analysis of Competencies for Dry Needling by Physical Therapists^x.
 - The FSBPT report states, "Because dry needling requires a strong clinical education in assessment, diagnosis, clinical reasoning, and constant assessment and reassessment, it is not an entry-level technique [...]."
 - The FSBPT also states that "In terms of skill and ability requirements, psychomotor skills needed to handle needles and palpate tissues requires specialized training."
 - The FSBPT report further stated that "86% of the knowledge requirements needed to be competent in dry needling is acquired during the course of PT clinical education [...]." and "14% of the knowledge requirements related to competency in dry needling must be acquired through post-graduate education or specialized training in dry needling."
 - Taking 3,000 hours as the average length of entry-level DPT training, 14% is equivalent to a **minimum of 420 hours of advanced or specialized training including a residency program.**
 - There are no training programs for physical therapists in the US that follow the guidelines in the FSBPT report, and any state physical therapy board that approves PT dry needling but that does not take the FSBPT recommendations as the minimum standard for education is violating their mandate to protect the public.
- The American Academy of Medical Acupuncture (AAMA) and the American Academy of Physical Medicine and Rehabilitation (AAPM&R) have both published position papers on dry needling acknowledging the risks and emphasizing the importance of restricting the practice of dry needling to licensed acupuncturists and physicians^{xixi}.



- All individuals performing acupuncture in Michigan (including licensed healthcare professionals) are required to do so under the supervision and delegation of a licensed physician^{xiii}.

ⁱ USA Today, "Torin Yater-Wallace bounces back from collapsed lung with top run" (Physical Therapist, Breckenridge, CO)

<http://www.usatoday.com/story/sports/olympics/sochi/2013/12/13/torin-yater-wallace-dew-tour-ion-mountain-championship-halfpipe-qualifying/4019707/>

ⁱⁱ San Diego Tribune, "Lawsuit: Illegal acupuncture caused lung collapse" (Chiropractor, San Diego, CA)

<http://www.sandiegouniontribune.com/news/2015/feb/02/lawsuit-acupuncture-lung-collapse-scott/>

ⁱⁱⁱ MAUDE FDA Adverse Event Report: Acupuncture Needle

A pt of a physical therapist, (b)(6), pt, received a pneumothorax after a dry needling treatment and was hospitalized at (b)(6) hospital on (b)(6).

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=3122096

^{iv} Cotchett, Matthew P., Karl B. Landorf, and Shannon E. Munteanu. "Effectiveness of Trigger Point Dry Needling for Plantar Heel Pain: A Randomized Controlled Trial." *Journal of Foot and Ankle Research* 6.Suppl 1 (2013): O8. Abstract. (n.d.): n. pag. Print.

"The frequency of minor transitory adverse events was significantly greater in the real dry needling group [...]"

^v <http://aim.bmj.com/content/early/2014/09/19/acupmed-2014-010659.long>

^{vi} <http://www.nccaom.org/applicants/eligibility-requirements/>

^{vii} <http://www.dabma.org/requirements.asp>

^{viii} <https://www.kinetacore.com/store/functional-dry-needling-level-1-team-rehabilitation-madison-heights-michigan-april-22-24-2016.html>

^{ix} lara_pt_011513min_418507_7.pdf

^x https://www.fsbpt.org/Portals/0/documents/free-resources/DryNeedlingFinalReport_20150812.pdf

^{xi} <http://www.medicalacupuncture.org/Portals/2/PDFs/AAMADryNeedlingPolicyOct15.pdf>

^{xii} <https://www.aapmr.org/docs/default-source/protected-advocacy/Position-Statements/aapmr-position-on-dry-needling.pdf?sfvrsn=2>

^{xiii} <http://legislature.mi.gov/doc.aspx?mcl-333-16215>

Addendum #2

NCASI | National Center for Acupuncture Safety and Integrity

The Illegal and Unsafe Practice of Medicine in General and Acupuncture in Particular Under the Term "Trigger-Point Dry Needling"

Across the country, a growing number of physical therapists (and other allied health professionals such as athletic trainers and occupational therapists) are circumventing state licensure requirements and regulations for the practice of medicine in general and acupuncture in particular by advertising and providing acupuncture services to an unsuspecting public under the term "trigger-point dry needling" (or an analogous term). This is a serious threat to public health and safety.

Acupuncture

Acupuncture is a form of minimally invasive surgery that involves inserting an acupuncture needle (a slender, sharp-pointed, stainless-steel medical device) through the skin into the body, or more specifically, into an acupuncture point (a functional anatomical site found in muscles and connective tissue), and then manipulating the acupuncture needle manually for diagnostic and/or therapeutic purposes. The length of the acupuncture needle—varying from one to six inches—is dictated by the location of the acupuncture point to be stimulated; deeper muscles and connective tissue require longer acupuncture needles.

Acupuncture (the science or practice of the diagnosis, treatment, and prevention of disease or injury based on an integrated understanding of anatomy, physiology, environment, pathology, and treatment) has its origin in China and has been in use for more than 2,000 years.

As with any form of minimally invasive surgery, acupuncture is not without risk, including injury to blood vessels, nerves, muscles, bones, and internal organs, and transmission of infectious agents, including human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), methicillin-resistant *Staphylococcus aureus* (MRSA), and *Streptococcus pyogenes*, which is sometimes called "flesh-eating bacteria." These and other risks can only be avoided or minimized through appropriate formal education and clinical training in the use of acupuncture needles.

In fact, Seirin, the world's leading manufacturer of acupuncture needles, warns: "Use [of acupuncture needles] by individuals other than licensed physicians or acupuncturists may lead to serious injury."¹

For example, on June 21, 2006, Kimberly Ribble-Orr, a former Olympic athlete from Hamilton, Ontario, Canada, suffered a punctured left lung caused by incorrect angle and/or depth of

insertion of an acupuncture needle by a massage therapist. Her punctured left lung resulted in pneumothorax (the presence of air in the cavity between the lungs and the chest wall, causing collapse of the lung) and subsequent life-threatening infection requiring surgeries and 11 days in the hospital (Figure 1). According to court records, "She now has only 55% function in her left lung."²

In the interest of public health and safety, it is imperative that



Figure 1. Kimberly Ribble-Orr shows the aftermath of surgeries she had after a massage therapist punctured her left lung with an acupuncture needle. Photograph: National Post

the public be assured that individuals who perform this invasive procedure are licensed physicians (doctors of medicine or osteopathy) or acupuncturists.

¹ Contact. *Seirin*. Available at <http://www.seirin.tv/english/contact.html> (accessed January 7, 2015).
² *Spurrell v. College of Massage Therapists of Ontario*, 2013 ONSC 4117 (CanLII).

10 Key Facts related to the illegal and unsafe practice of medicine in general and acupuncture in particular under the term “trigger-point dry needling”

1. Trigger-point dry needling is acupuncture.

Trigger-point dry needling is acupuncture that involves inserting an acupuncture needle through the skin into the body, or more specifically, into an acupuncture point that exhibits the abnormality of sudden, wince-inducing local and/or referred pain on pressure, which has come to be known in the West as a “trigger point,” and then manipulating the acupuncture needle manually for diagnostic and/or therapeutic purposes.

It is important to emphasize that trigger-point dry needling—particularly for the diagnosis and treatment of neuromusculoskeletal pain and dysfunction—was described in detail in the first century BCE in the *Yellow Emperor’s Inner Classic* (黃帝內經, *Huáng Dì nèi jīng*), the earliest comprehensive Chinese medical text on the subject.³

2. Trigger points are acupuncture points.

All acupuncture points are located through careful palpation.

To be clear, trigger points are acupuncture points that exhibit the abnormality of sudden, wince-inducing local and/or referred pain on pressure. The *Yellow Emperor’s Inner Classic* instructs: “[The point of] pain indicates a [clinically relevant] acupuncture point (以痛為腧, *yǐ tòng wéi shù*).”⁴

Sun Si Miao (孫思邈, *Sūn Sī Miào*) (581–682 CE), a renowned physician of the Sui (隋, *Suí*) (581–618 CE) and Tang (唐, *Táng*) (618–907 CE) dynasties, called an acupuncture point that exhibits the abnormality of sudden, wince-inducing local and/or referred pain on pressure an “Ah yes! point (阿是穴, *ā shì xué*),”⁵ because when such an acupuncture point is pressed, the patient winces in pain and often says “Ah yes! That is the spot.”

In a landmark study published in 1977 in *Pain*, the official journal of the International Association for the Study of Pain, Dr. Ronald Melzack, who revolutionized the study and treatment of pain, and colleagues examined the correlation between trigger points and acupuncture points. The results of their analysis showed that “every trigger point [reported in the Western medical literature] has a corresponding acupuncture point.”⁶ In other words, trigger points and acupuncture points are one and the same.

3. Trigger-point dry needling is acupuncture, not manual therapy.

Physical therapists make some contention that their right to

practice trigger-point dry needling arises by virtue of their right to practice manual therapy. This term means simply a remedial treatment consisting of manipulating a part, or the whole, of the body with the hand. In plain English, it means massage, manually performed. It certainly does not include the practice of surgery (*i.e.*, the severance or penetration of tissue) in any form.

Their contention is in line with advice received from Dr. David Simons in October 2007, which states: “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 different terminology you leave the other side without an argument.”⁷

However, given the risks, circumventing state licensure requirements and regulations for the practice of medicine in general and acupuncture in particular by advertising and providing acupuncture services to an unsuspecting public under the term “trigger-point dry needling” (or an analogous term) is a serious threat to public health and safety.

It bears repeating: trigger-point dry needling is acupuncture, not manual therapy.

4. The act of inserting an acupuncture needle through the skin into the body for diagnostic and/or therapeutic purposes constitutes the practice of medicine in general and acupuncture in particular.

Indeed, acupuncture literally means “piercing with a needle,” from Latin *acū* “with a needle” and *punctūra* “piercing.”

5. It is illegal for physical therapists who are not qualified practitioners of acupuncture as determined by the States to purchase or possess acupuncture needles.

Acupuncture needles are Class II (special controls) medical devices and must comply with all applicable requirements of the Federal Food, Drug, and Cosmetic Act (FDCA) and US Food and Drug Administration (FDA) regulations.

Federal law and regulations require that the sale of acupuncture needles “must be clearly restricted to *qualified practitioners of acupuncture as determined by the States.*” See 61 Fed. Reg. 64616 (Dec. 6, 1996) (emphasis added); 21 CFR § 880.5580(b)(1); see also 21 U.S.C. § 360j(e)(1)(A)–(B); 21 CFR §§ 801.109, 807.3(i). FDA determined that this restriction is required for the safe and effective use of acupuncture needles. See *id.*

Acupuncture needles are both “prescription devices” and “restricted devices” under federal law and regulations. See *id.*

Accordingly, federal law and regulations require that the label

³ *Yellow Emperor’s Inner Classic* (黃帝內經, *Huáng Dì nèi jīng*). Compiled in the first century BCE.

⁴ *Id.*

⁵ Sun SM. *Important Prescriptions Worth a Thousand Gold Pieces* (千金要方, *Qiān jīn yào fāng*). 652 CE.

⁶ Melzack R, Stillwell DM, Fox EJ. Trigger points and acupuncture points for pain: correlations and implications. *Pain*. 1977 Feb;3(1):3–23.

⁷ Simons DG. Letter to the editor. *J Man Manip Ther*. 2007 Oct;15(4):246.

of acupuncture needles bears the prescription statement "Caution: Federal law restricts this device to sale by or on the order of qualified practitioners of acupuncture as determined by the States." See the label of Seirin-brand acupuncture needles (Figure 2) (emphasis added); 61 Fed. Reg. 64616 (Dec. 6, 1996); 21 CFR § 880.5580(b)(1); see also 21 U.S.C. § 360j(e)(2); 21 CFR §§ 801.109(b)(1), 807.3(i).

Therefore, physical therapists who are not qualified practitioners of acupuncture as determined by the States are violating civil and criminal provisions of the FDCA intended to protect public health and safety when they purchase or possess acupuncture needles. See 21 U.S.C. §§ 331(a)–(c), (g).

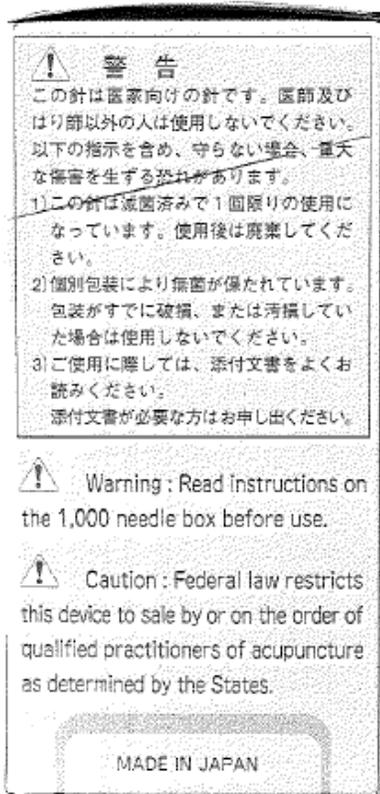


Figure 2. The label of Seirin-brand acupuncture needles bears the prescription statement "Caution: Federal law restricts this device to sale by or on the order of qualified practitioners of acupuncture as determined by the States."

The FDCA addresses the issue of the practice of medicine and expressly states in part: "This section shall not limit any existing authority of the Secretary [of Health and Human Services] to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations." See 21 U.S.C. § 396 (emphasis added).

Furthermore, "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement... which is different from, or in addition to, any requirement [under the FDCA]." See 21 U.S.C. § 360k(a)(1)–(2) (emphasis added).

6. It is illegal for physical therapists to bill Medicare for trigger-point dry needling disguised under physical therapy codes.

Trigger-point dry needling is acupuncture, which is not a covered service under the Medicare program. See 42 U.S.C. § 1395y(a)(1)(A). Use of acupuncture needles is not a covered service under the Medicare program (whether a licensed acupuncturist or any other provider renders the service). See *id.*

It is fraud when physical therapists bill Medicare for trigger-point dry needling disguised under physical therapy codes, such as Current Procedural Terminology (CPT) code 97110 (therapeutic exercises), CPT code 97112 (neuromuscular re-education), or CPT code 97140 (manual therapy). See 31 U.S.C. §§ 3729–3733.

To report suspected fraud, you can call the Medicare Fraud Hotline at 1-800-447-8477. TTY users should call 1-800-377-4950.

7. Because it is illegal for them to purchase or possess acupuncture needles, physical therapists who are not qualified practitioners of acupuncture as determined by the States would have the public believe that they are not actually using acupuncture needles to perform trigger-point dry needling, when, in fact, they are. Any claim that they are not actually using acupuncture needles to perform trigger-point dry needling is false.

8. Physical therapists who are not qualified practitioners of acupuncture as determined by the States are not qualified to use acupuncture needles.

In order to become a licensed acupuncturist, an applicant must have successfully completed 1,245 (some states require more) hours of formal education in the medical sciences, including anatomy, physiology, pathology, diagnosis, and treatment. Treatment includes information for the safe and effective use of acupuncture needles, including indications, effects, routes, methods, and frequency and duration of administration, and relevant hazards, contraindications, side effects, and precautions. The applicant must have also successfully completed 660 (some states require more) hours of formal clinical training, under direct supervision, in the use of acupuncture needles.

Yet a growing number of physical therapists (and other allied health professionals such as athletic trainers and occupational therapists) are circumventing state licensure requirements and regulations for the practice of medicine in general and acupuncture in particular by advertising and providing acupuncture services to an unsuspecting public under the term "trigger-point dry needling" (or an analogous term) with such limited exposure as a weekend workshop in the use of acupuncture needles.

9. There are very real risks associated with the use of acupuncture needles (with or without the passage of electrical current through the acupuncture needles) by physical therapists who are not qualified practitioners of acupuncture as determined by the States.

These risks include, but are not limited to, the following:

- Injury to blood vessels, nerves, muscles, bones, and internal organs caused by, but not limited to, the following:
 - Incorrect angle and/or depth of insertion of an acupuncture needle.
 - Inappropriate manipulation of an acupuncture needle.
 - Inappropriate passage of electrical current through an acupuncture needle.
- Transmission of infectious agents, including HIV, HBV, HCV, MRSA, and “flesh-eating bacteria,” caused by, but not limited to, the following:
 - Poor clinic hygiene and maintenance.
 - Poor personal hygiene, particularly hand hygiene. It is critical to emphasize that the use of gloves does not replace the need for hand hygiene.
 - Failure to establish and maintain a clean field.
 - Washing of gloved hands with alcohol-based hand rub, or any liquid, prior to inserting an acupuncture needle, because this “can lead to the formation of glove micropunctures...and subsequent hand contamination.”⁸
 - Touching the shaft of an acupuncture needle before, during, or after use.
 - Needling through clothing.
 - Inappropriate handling or disposal of a contaminated acupuncture needle. For example, re-tubing a contaminated acupuncture needle. See 29 CFR § 1910.1030(d)(2)(vii).
 - Re-inserting a single-use acupuncture needle, also referred to as a disposable acupuncture needle. It is critical to emphasize that a single-use acupuncture needle is intended to be inserted only once and then discarded. See 21 CFR § 880.5580(b)(1); see also 21 U.S.C. § 321(l)(1); 29 CFR § 1910.1030(d)(2)(vii).

10. There have been recent reports of serious injury associated with the use of acupuncture needles by physical therapists who are not qualified practitioners of acupuncture as determined by the States.

On October 4, 2012, Emily Kuykendall, a high-school teacher from Ellicott City, Maryland, suffered a punctured left-leg nerve caused by incorrect angle and/or depth of insertion of an acupuncture needle by a physical therapist. Her punctured left-leg nerve resulted in severe, debilitating pain—literally from head to toe—requiring prescription drugs.

On November 29, 2013, Torin Yater-Wallace, a high-school student and Olympic hopeful from Basalt, Colorado, suffered a punctured right lung caused by incorrect angle and/or depth of insertion of an acupuncture needle by a physical therapist.



Figure 3. Torin Yater-Wallace gives the thumbs down while recovering from surgery he had after a physical therapist punctured his right lung with an acupuncture needle. Photograph: @TorinWallace

His punctured right lung resulted in pneumothorax requiring surgery and three days in the hospital (Figure 3).

For more information related to the illegal and unsafe practice of medicine in general and acupuncture in particular under the term “trigger-point dry needling,” please visit: <http://www.acupuncturesafety.org>

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⁸ Centers for Disease Control and Prevention. Guidelines for infection control in dental health-care settings—2003. *MMWR*. 2003;52(RR-17):[inclusive page numbers].