

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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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.

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].

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 Miǎo*) (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

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).

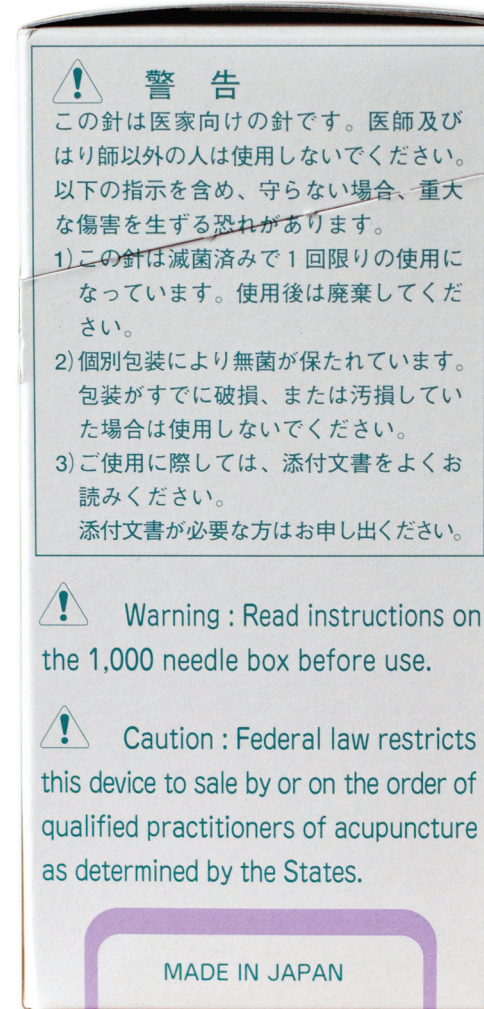


Figure 2. The label of Seirin-brand acupuncture needles bears the prescription statement “Caution: Federal law restricts this device to sale by or on the order of qualified practitioners of acupuncture as determined by the States.”

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.

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.