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 “flash-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, at any liquid, prior to inserting an acupuncture needle, because this can “lead to the formation of glove microspVenous...and subsequent hand contamination.”
  - 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 § 1910.1360(d)(2)(vi).

- 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.

- 21 CFR § 808.5580(d)(1); see also 21 U.S.C. § 321(g)(1); 29 CFR § 1910.1360(d)(2)(vi).

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 ©TornWallace

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.acupuncture-safety.org

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

In the interest of public health and safety, it is imperative that...
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 that is related to the acupuncture needle manually for diagnostic and/or therapeutic purposes.

2. Trigger points are acupuncture points.
   All acupuncture points are located through careful palpation.

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

4. 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.

5. Acupuncture needles are both “prescription devices” and “restricted devices” under federal law and regulations.

6. 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.

7. 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 also 21 U.S.C. § 360(a)(2)(B); 21 CFR §§ 801.109(b)(1), 807.36.

8. 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 and possess acupuncture needles. See 21 U.S.C. §§ 331(q)-(f).

Furthermore, “no State at 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. § 360(k)(1)-(2) (emphasis added).

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

7. 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 may have the public believe that they are not actually using acupuncture needles to perform trigger-point dry needling, when, in fact, they are.

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 also have successfully completed 609 (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 promoting 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.