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Re: Dry Needling and Violations of the U.S. Food, Drug, and Cosmetic Act (FDCA) and Food and Drug Administration Rules

Dear State Board of Physical Therapy:

I write on behalf of the National Center for Acupuncture Safety and Integrity (NCASI), a nonprofit corporation working to protect the public from the unlicensed practice of acupuncture and the illegal sale and use of acupuncture needles. NCASI is aware that a number of state boards of physical therapy have authorized physical therapists to practice what is referred to as "trigger-point dry needling" ("TPDN"), also known as "dry needling." Those promoting "TPDN" openly acknowledge that they are using labeled acupuncture needles to practice "TPDN," but claim that "TPDN" falls outside the statutory and regulatory definitions of practicing acupuncture. While specific state laws vary on the definition of the practice of acupuncture, the federal Food and Drug Administration ("FDA") strictly regulates the sale of acupuncture needles as Class II prescription medical devices under the U.S. Food, Drug, and Cosmetic Act (FDCA) only to qualified and licensed acupuncture practitioners. Specifically, FDA regulations restrict that the sale of acupuncture needles to anyone but a person *authorized to practice acupuncture* and *for use in acupuncture*. The sale of acupuncture needles to anyone other than a qualified and licensed acupuncture practitioner is a violation of both the FDCA and the FDA rules described below.

Please be aware that to the extent your board authorizes the use of acupuncture needles by persons who are not explicitly authorized to practice *acupuncture*, your actions are inconsistent with federal law and could expose your state board to liability in the event a person is injured by one of the practitioners your board regulates. There is no dispute that the practice of "TPDN" absolutely depends on the use of FDA-regulated acupuncture needles. Any official sanctioning of "TPDN" by a state professional board signals to potential patients that those practicing "TPDN" are qualified, trained and legally authorized to possess, purchase and use acupuncture needles, a Class II prescription medical device under FDA regulations. As a result, state regulatory and professional boards that endorse the practice of "TPDN" by persons who are not explicitly authorized to practice acupuncture is inconsistent with federal law.

FDA's regulation of acupuncture needles as Class II prescription medical devices

Acupuncture needles are regulated under the FDCA as Class II prescription medical devices that are subject to FDA's strict prescription sale requirements. *See* 21 CFR § 880.5580

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(Exhibit A); 61 Fed. Reg. 64616–64617 (Dec. 6, 1996) (Exhibit B); Reclassification Order Docket No: 94P-0443 Acupuncture Needles for the Practice of Acupuncture (Mar. 29, 1996) (Exhibit C); 21 CFR § 801.109 (Exhibit D). In authorizing the sale of acupuncture needles, the FDA was explicit that such needles "must be clearly restricted to *qualified practitioners of acupuncture* as determined by the States." 61 Fed. Reg. 64616 (Dec. 6, 1996) (emphasis added).

In reclassifying acupuncture needles from Class III to Class II prescription medical devices, the FDA also plainly defined acupuncture needles stating: "[a]n acupuncture needle is a device intended to pierce the skin *in the practice of acupuncture.* ..." 21 CFR § 880.5580(a) (emphasis added). The sale and introduction of acupuncture needles into interstate commerce for any purpose other than for "the practice of acupuncture" is outside the scope of FDA's approval and would make such needles legally "adulterated" and/or "misbranded" under the FDCA. 21 U.S.C. § 352(f)(1); 21 U.S.C. § 331(p); 21 U.S.C. § 352(o).

Consistent with this directive, the FDA requires that acupuncture needles, including those that are being used for "TPDN," carry a prescription label stating: "Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States." 21 CFR 801.109(b)(1); 61 Fed. Reg. 64616 (Dec. 6, 1996) (emphasis added); *See also* Exhibit E. NCASI is committed to seeing enforcement of this common sense public safety requirement.

Sale of acupuncture needles to those who are not qualified to practice acupuncture

NCASI is aware that many individual physical therapists, occupational therapists, naturopaths, chiropractors, athletic trainers and others are attempting to skirt state acupuncture licensing laws by claiming they are using acupuncture needles to practice "TPDN" as opposed to "acupuncture." Some state regulatory boards have authorized "TPDN" by regulation absent any apparent awareness or consideration of FDA's regulation of acupuncture needles as Class II prescription medical devices.

The FDA, however, has explicitly limited the sale of acupuncture needles to those *authorized to practice acupuncture* and has only approved the use of such needles *for the purpose of acupuncture*. It is therefore illegal for an individual to sell, purchase, receive or use an acupuncture needle unless it is intended to be used for the practice of acupuncture by a person who is authorized under state law to practice acupuncture.

The purchase and receipt of acupuncture needles by individuals who are not qualified to practice acupuncture or for intended uses other than acupuncture make such needles legally "adulterated" and/or "misbranded" under the FDCA and is in direct violation of the FDCA and FDA's implementing regulations. 21 U.S.C. §§ 331(a)–(c), (p); 21 U.S.C. § 352(o); 21 U.S.C. § 352(f)(1); 21 U.S.C. § 351(f); 21 CFR § 801.109(a). While a number of companies are illegally selling acupuncture needles on-line to persons who are not authorized to practice acupuncture, this does not legalize the practice. NCASI is currently investigating these sales and has submitted targeted complaints to the FDA.

With this letter your board and your state have notice that to the extent your board approves or otherwise endorses the use of acupuncture needles for the practice of "TPDN" by persons who are not legally authorized to practice acupuncture you may be exposing your board to liability for endorsing a practice that involves the violation of FDA regulations and the unauthorized use of a Class II medical device.

NCASI encourages your board to carefully review the enclosed regulations and other documents related to the regulation of acupuncture needles. To the extent your board has already endorsed or approved the practice of "TPDN" by persons who are not authorized to practice acupuncture, NCASI encourages your board to reconsider such actions. If your board has yet to address the issue of "TPDN," we encourage you to take a position that is consistent with the FDA's regulation of acupuncture needles as Class II prescription medical devices.

Thank you for your careful consideration of these issues.

Very truly yours,

R. Scott Jerger
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cc: client
Enclosures