

MEMORANDUM

TO: APTA Component Leaders, State Legislative Chairs, Component Executives, and Chapter Lobbyists

FROM: Paul Rockar, Jr, PT, MS, DPT
President, American Physical Therapy Association

DATE: January 6, 2014

RE: Letter from National Center for Acupuncture Safety and Integrity (NCASI)

APTA is aware that a number of state regulatory boards are in receipt of a November 13, 2013, letter from the National Center for Acupuncture Safety and Integrity (NCASI) alleging, among other things, that physical therapists' (PT) use of acupuncture needles in "trigger point dry needling" (TPDN) procedures, and various state boards' determination that TPDN is within the physical therapist scope of practice, are inconsistent with the requirements for acupuncture needles under the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 301 et seq., and U.S. Food and Drug Administration (FDA) implementing regulations. APTA commissioned a legal analysis from the law firm of Hogan Lovells US LLP to investigate whether NCASI's allegation against physical therapists and the physical therapy licensing boards has merit.

Based on the legal analysis, we believe the conclusions of the NCASI letter are without merit. FDA regulates acupuncture needles as class II medical devices. When the FDA down-classified acupuncture needles and promulgated 21 C.F.R. § 880.5580, the FDA stated that acupuncture needles are for use by qualified practitioners as determined by the states. We believe that the FDA, in doing this, was clearly signaling that it would not involve itself in determining who is a qualified practitioner to use acupuncture needles, leaving it to the states to decide. The regulations require that acupuncture needles comply with the following special controls: (1) "labeling for single use only and conformance to the requirements for prescription devices set out in 21 C.F.R. § 801.109" ("prescription device regulation"), (2) "material biocompatibility," and (3) "sterility." *Id.* § 880.5580(b). This regulation does not designate acupuncture needles as restricted devices but rather categorizes them as prescription devices requiring compliance with 21 C.F.R. § 801.109.

To comply with the prescription device regulation special control generally, according to 21 C.F.R. § 801.109(b)(1), prescription devices must bear the following statement:

“Caution: Federal law restricts this device to sale by or on the order of a _____”, the blank to be filled with the word “physician”, “dentist”, “veterinarian”, or with the description designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device.” (emphasis added)

Together, the FDA regulations at 21 C.F.R. §§ 880.5580 and 801.109 make clear that the determination of who is authorized to use acupuncture needles is a matter left to the states.

This approach is consistent with the principle behind § 1006 of the FDC Act, 21 U.S.C. § 396, which says that nothing in the FDC Act limits the authority of a health care practitioner to administer a legally marketed device for any condition within a legitimate practitioner-patient relationship. The legislative history for this provision indicates that Congress intended to emphasize that FDA should not interfere in the practice of medicine.

I hope this information is helpful. If you need any further information or have any questions, please contact Justin Elliott, Director, State Affairs at justinelliott@apta.org or 703-706-8533. Thank you for your service to the profession.

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