ACUPUNCTURE Today

ACUPUNCTURE & ACUPRESSURE

Letter to the Editor

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On December 7, 1999, the U.S. FDA reclassified the status of acupuncture needles from class III (investigative devices subject to investigative device exemptions...) to class II (special controls). "The classification regulation (21 CFR 880.5580) for solid, stainless steel, acupuncture needles requires that these class II devices must comply with special controls for single use labeling, prescription labeling, biocompatibility, and sterility." Since that time, acupuncture needles have been available to "qualified practitioners" without prescription through distributors throughout the United States. The FDA allows individual states to regulate the sale and distribution of medical devices as they see fit. However, the FDA gives no specific direction regarding the distribution of acupuncture needles.

In February 2015, the California State Board of Pharmacy (CA B of P) started to enforce their interpretation of Business and Professions Code Sections 4160 and 4161. They have taken the unique position that all companies distributing acupuncture needles in their state must possess a California pharmacy license, even if the distributor is not located in California.

No other state besides California has so far chosen to specifically regulate the sale and distribution of acupuncture needles. Agents of the CA B of P visited offices of companies that supplied acupuncture needles and compelled them to stop all of their needle sales in California until they received a Board-issued pharmacy license. They required immediate Cease and Desist of distribution, shipping, mailing and/or delivering dangerous drugs and devices, into California until the Board-issued license was received, without due process and without notice.

The application is appropriate for interstate pharmaceutical companies, but not for small suppliers of acupuncture needles. The process takes six months or longer from start to finish and requires companies to:

1. Finger print the principle owners.

2. Hire a Designated Representative who has completed special training or hire a Pharmacy Technician.
3. Possess a surety bond, as well as several other requirements.

Because of the arduousness of the application process, many of the FDA registered Chinese herbal supplement suppliers have stopped offering acupuncture needles to their LAc customers. If the goal of the interpretation of Business and Professions Code Sections 4160 and 4161 is to limit the number and scope of suppliers of acupuncture needles to California licensed acupuncturists and increase the costs to these health care providers and the public, they have succeeded.

It would be appropriate for the CA B of P, if they continue to license companies that distribute acupuncture needles, to design a process appropriate for these kinds of business that have no intention to distribute Pharmaceutical products. Does any attempt by the Board to regulate the sale of acupuncture supplies into California by out-of-state suppliers violate the Interstate Commerce Clause of the U.S. Constitution?

Unfortunately, there have been advertisements sent to LAc's in California that give the impression that the CA B of P is hunting for them, with imagery of an officer taking someone away in handcuffs. While we are not attorneys and are not able to give legal advice, this was an obvious self-serving opinion of one California wholesaler and not, we believe, the intent of the CA B of P.

Questions to persons interested in the future profession of acupuncture and Oriental medicine:

- Is the pharmacy profession through the Board of Pharmacy working to inhibit the AOM Profession by limiting access to acupuncture needles?
- Should the regulation of acupuncture devices be guided by the pharmaceutical interests who are naturally hostile to our profession or should state acupuncture boards be the regulators?
- Should AOM professionals be restricted to suppliers licensed by pharmacy boards?
- Can the AOM profession allow restricted access and increased costs to the tools of their profession?
- What happens when 50 states regulate FDA-regulated acupuncture needles?
- Why did the FDA classify acupuncture needles as a "dangerous medical device?"
- Is there a more appropriate classification of acupuncture needles that would still restrict access to qualified providers?
- Is it possible for the FDA to promulgate a rule that would supersede states pharmacy board rules?
- Is it possible for the AOM/TCM community to work together to address this pressing issue?
- As acupuncture becomes more mainstream, which regulator will guide the future of the profession?

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