

## **FDA May Remove Blood Donor Restrictions for Acupuncture Patients**

### **Advisory Committee Recommends Dropping Deferral Period**

By Editorial Staff

Prompted by dwindling blood supplies and a growing acceptance of alternative medicine, federal health officials are considering rescinding a 10-year old rule that currently prohibits acupuncture patients from giving blood.

The proposed change in policy comes on the heels of a recommendation from the Food and Drug Administration's Blood Products Advisory Committee, which has recommended unanimously that the FDA lift the current ban on donations from acupuncture patients.

Under current regulations, people who have been treated with acupuncture in the previous 12 months may be "deferred" from donating blood. The regulation states that individuals "be deferred from donating whole blood, blood components, source plasma or source leukocytes, who within one year of donation have undergone acupuncture, ear piercing, ear piercing or tattooing in which sterile procedures were not used."

The FDA's rule regarding acupuncture and blood donations was written in 1992, when concerns began to emerge about the safety of the nation's blood supply and hepatitis C, a disease that can severely damage the liver. At the time, hepatitis C was the leading cause of all hepatitis cases resulting from blood transfusions, but because of improved screening procedures, the risk from transfusions is now estimated at less than one in 10,000.

Long before the FDA's regulation was imposed, however, the acupuncture profession identified the use of sterile needles as a top priority. In the early 1980s, the National Certification Commission for Acupuncture and Oriental Medicine developed the *Clean Needle Technique Manual* and mandated that every national

board-certified practitioner pass an approved clean needle technique (CNT) course; in 1991, the commission added a clean needle technique portion to its written exam. A CNT course is now administered by the Council of Colleges of Acupuncture and Oriental Medicine and is a requirement for licensure throughout the U.S.

The safety of the profession gained further credibility in 1996, when the FDA reclassified disposable acupuncture needles as Class II devices. Under the new classification, acupuncture needles were marketed as a single use sterile product. Manufacturers of needles were required to label the packages for single use only, and to provide information about device sterility. Additionally, the classification stipulated that needles were to be used only by licensed, registered or certified acupuncture practitioners.

On March 14, the FDA decided to reinvestigate the matter. It convened a meeting of the Blood Products Advisory Committee (BPAC) to seek input on the safety of the blood supply from donors who had a history of receiving acupuncture, tattoos and skin or body piercing. The advisory committee received oral and written testimony from several members of the health care field, including licensed acupuncturists, registered nurses, medical doctors and government disease specialists.

After a brief introduction, Dr. Miriam Alter of the Centers for Disease Control began the discussion with an interactive slide show that evaluated the risk of contracting hepatitis from acupuncture, tattooing or body piercing. She cited two studies, one conducted in Taiwan, the other in Japan, which showed an association between acupuncture and hepatitis. However, she added that the association was "highly dependent on where the study was done," and that "the risk where there is one could very well substantially vary depending on the circumstances and the setting."

Among those who testified in favor of having the deferral removed was Tierney Tully, the executive director of the Acupuncture and Oriental Medicine Alliance. In a letter submitted to the committee, Ms. Tully highlighted acupuncture's safety record as it pertains to the transmission of communicable diseases:

"Communication of disease through acupuncture has not been an issue in the U.S., a record few other health care professions can claim. There is no known transmission of AIDS through acupuncture and, according to the National Acupuncture Foundation's memo on the Safety Record of Acupuncture, only one documented incidence of transmission of hepatitis by an individual licensed without examination or education in national clean needle technique over 12 years ago. In over 17 years of national board certification, the NCCAOM has received no complaint of transmission of disease through acupuncture,

nor to our knowledge has any state board.

"The use of excellent national standards in the U.S. and the emphasis on clean needle technique have created an outstanding safety record for our profession," she added. "We ask that you support the removal of acupuncture from the blood donor questionnaire where its categorization with non-medical activities such as tattooing and ear and skin piercing discredits our profession and may discourage consumers from qualified acupuncture services."

Although Ms. Tully was not in attendance at the meeting, another member of the Alliance, Alexandra Knox, was. Knox reiterated many of the claims made by Ms. Tully in her letter, and provided further information on the cost and use of acupuncture needles.

"We really have some good statistics in our profession" regarding the transmission of diseases through acupuncture, Knox said. "Whether it's possible for somebody to be very sloppy, absolutely. But I think that's true with any medical device that's going to enter the skin."

"An acupuncture needle costs four cents," she continued. "There is no reason to reuse your needles. I mean, there's no economic incentive, certainly, and there is a lot of reason not to. As a practitioner you will also know that if you try to use the same needle on the same person twice, it dulls and you can't get it in and it hurts. There's a lot of reasons you don't do it apart from safety."

Also speaking before the committee was Margaret Hoffman, a registered nurse and licensed acupuncturist from Maryland. A member of the Maryland Acupuncture Society, she began her testimony by stating simply, "I'm not here representing any particular organization per se; however, I am representing acupuncture."

In addition to the deferral for blood donors, Ms. Hoffman took issue with the fact that acupuncture was grouped together with body piercing and tattooing. She believed that such an association gives the impression that acupuncture is not a professional form of health care, and that acupuncture treatment - even if it is received from a licensed, registered or certified acupuncturist - could place a patient at unnecessary risk for transmission of blood-borne diseases.

"I believe this is an uninformed understanding that potentially sheds a damaging view on acupuncture," Ms. Hoffman said. "Based on the current donation guidelines, a certain portion of the population may be totally excluded from donating blood. With an increase in demand to build the blood supply, it seems that the

decision to defer or exclude because of acupuncture treatment is an inappropriate one."

Following her speech, Ms. Hoffman was asked several questions by the committee about the practice of acupuncture and the use of disposable acupuncture needles. She also described the clean needle technique to the committee to give them a better idea of the sterility procedures used by licensed acupuncturists.

Dr. Louis Katz, a medical doctor representing the American Association of Blood Banks, also appeared supportive of having the acupuncture deferral removed.

"The science, the medicine has changed," Dr. Katz said in an interview with the *Richmond Times-Dispatch*. "We're deferring people who are probably not at risk for the things we've been deferring them for."

At the conclusion of the meeting, committee members were asked to individually vote on whether blood donors should be deferred for tattooing, body piercing or acupuncture. The committee voted 14-3 to continue the deferral period for both piercing and tattooing, but voted unanimously to remove acupuncture as a consideration for deferral of blood donation, reasoning that the practice is a regulated medical procedure with an outstanding safety record. Three committee members added a clarification to their votes, requesting that removing the deferral be limited only to states that currently regulate the practice of acupuncture. The committee also agreed that a state or locally licensed practice could be used as evidence of sterility.

A final decision on the blood donor policy is expected by the FDA later this year. Stay tuned to *Acupuncture Today* for more updates in an upcoming issue.

### *References*

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- Letter from Tierney Tully, MSOM, Dipl.Ac., to Linda Smallwood, PhD, Center for Biological Evaluation & Research, Food and Drug Administration, March 5, 2002.
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