DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

January 19, 2001

Raymond C. Scheppach
The National Governors Association
444 N. Capitol Street
Washington, D.C. 20001-1512

Dear Mr. Scheppach:

The Food and Drug Administration (FDA) is soliciting comments on its proposed rule for "Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement," ("proposed good tissue practice rule"), published January 8, 2001, in the Federal Register. The proposed rule is part of the agency's proposed comprehensive new system of regulating human cellular and tissue-based products ("the proposed approach"), announced in February 1997. The proposed approach describes a rational and comprehensible framework under which tissue manufacturers could develop and market products without hindering innovation. At the same time, the proposed approach should provide physicians and patients with the assurance of safety that the public has come to expect from drugs, biologics, medical devices, and other products overseen by the FDA.

FDA has been soliciting comments since the announcement of the proposed approach in February 1997. FDA held a public meeting in March 1997 to solicit information and views from the interested public. The agency has published the provisions of the proposed regulatory approach in three separate proposed rules for comment. FDA first published the proposed rule for the "Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products" on May 14, 1998, in the Federal Register (63 FR 26744). The agency subsequently published the proposed rule “Suitability Determination for Donors of Human Cellular and Tissue-Based Products” on September 30, 1999 (64 FR 52696). The proposed good tissue practice rule is the third and final proposed rule that would implement the proposed regulatory approach.

With this letter, FDA seeks consultation from the States on the proposed good tissue practice rule, and specifically on any preemption issues raised by the proposed rule. In considering preemption issues, the agency would appreciate your comment on: (1) the need for the proposed good tissue practice rule to prevent communicable disease transmission through human cellular and tissue-based products; (2) alternatives that would limit the scope of such national requirements or otherwise preserve State prerogatives and authority; (3) the proposed good tissue practice provisions; and (4) any other issues raised by this proposed rule possibly affecting State laws and authorities.

In addition to the Federal Register (66 FR 1508, 1/8/01), the proposed good tissue practice rule can be found at **www.fda.gov/cber/rules.htm.**

Please send written comments by May 8,2001, to: Docket No. 97N-484P, Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Md. 20852.

If your organization has designated a contact person for this issue, please advise us. The agency's contact person at the Center for Biologics Evaluation and Research is Paula McKeever, who can be reached at 301-827-6210.

Sincerely,

Kathryn C. Zoon, Ph.D.
Director,
Center for Biologics Evaluation
and Research