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Advancing Excellence

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May 8, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

The College of American Pathologists (CAP) appreciates the opportunity to provide comments in response to the Food and Drug Administration (FDA) proposed rule "Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement". The CAP is a national medical specialty society representing more than 16,000 physicians who practice anatomic and/or clinical pathology. College members practice their specialty in clinical laboratories, academic medical centers, research laboratories, as well as tissue banks. Pathologists perform a number of key activities in the procurement and distribution of tissue and the College supports the efforts being made by FDA to develop regulations that will ensure the safety of harvested tissue. In that regard, the College would encourage the FDA to utilize current industry standards and, to the degree possible, utilize existing approved private accreditation programs for the inspection and oversight of tissue bank manufacturers.

The College is pleased that FDA has recognized many of the current industry standards for tissue banks or other similar facilities in the proposed rule. FDA's final rule for good tissue practice regulations should fully utilize these existing standards. These standards reflect the collective expertise of tissue bank professionals to provide a comprehensive foundation for the guidance of tissue bank activities.

The oversight of healthcare quality in the United States is accomplished through professionally based, private sector accrediting bodies and also through federal and state regulatory agencies. Because parallel oversight mechanisms are duplicative and inefficient, regulatory agencies commonly defer to private accrediting bodies that meet their performance criteria. Part of being an accredited facility is to be in compliance with a strict timetable of inspection and auditing procedures spelled out within the guidelines of that specific accrediting body. Therefore, FDA regulation should fully utilize existing approved private accreditation programs to reduce the need for additional oversight and inspection by FDA.

The College appreciates this opportunity to submit comments on these proposed regulations and commends the FDA in taking steps to safeguard harvested tissue. For more information or any questions that you may have, please contact Heather Wilford at (202) 354-7123 or hwilfor@cap.org in our Government and Professional Affairs Office.

Sincerely,

Paul Bachner, MD

Paul Bachner, MD, FCAP
President

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