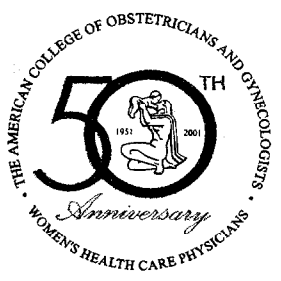




May 8, 2001

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

**Re: Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement [Docket No. 97N-484P]**

On behalf of the American College of Obstetricians and Gynecologists (ACOG), an organization representing over 42,000 physicians dedicated to improving women's health care, I am pleased to provide comments on the Food and Drug Administration's (FDA) proposed rule on tissue practice for manufacturers of human cellular and tissue-based products [56 Federal Register 5, 1508-1559].

ACOG supports compliance of all manufacturers of human cellular and tissue-based products with current good tissue practices (CGTPs). We believe these standards effectively protect public health and ensure quality patient care. However, there needs to be clarification regarding the application of these regulations to human reproductive technologies.

ACOG strongly objects to the near-uniform application of the proposed rule to all human cellular and tissue-based products used for insemination because it exceeds the amount of regulation necessary to achieve FDA's public health goals and would significantly interfere with the practice of reproductive medicine.

Since male problems account for over 40% of the causes of infertility, artificial insemination procedures are among the most basic treatments for infertility and are commonly offered by ob-gyn practices throughout the U.S. as one of the first-line therapies for couples having difficulty conceiving. ACOG is concerned that many ob-gyns will stop offering these services for their patients if they are forced to incur the significant administrative costs to comply with the proposed rule, thus causing additional burdens for patients at a difficult time of their lives.

In section VIII D "Small Entity Impacts," a cost-benefit analysis is provided for "very small banks described by an industry expert as typically functioning within a physician office practice (e.g., that of an obstetrician or a gynecologist)." After outlining the significant costs of compliance you state, "Thus, it seems likely that physician practices that currently operate small-scale sperm banking may prefer to discontinue banking, and

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refer their patients to a commercial bank for this service." ACOG objects to the FDA making a determination that these services are a "generally nonessential" part of physicians' practices. Decisions on which services are offered should be left to physicians in consultation with their patients. **Regulating these insemination procedures violates the "practice of medicine exemption" to the Federal Food, Drug, and Cosmetic Act and interferes with physicians' treatment of their patients.**

Although the FDA provides an exception in Section 1271.90 for required testing and screening for reproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use, ACOG believes that this category of human cellular tissue and tissue-based products should be exempted entirely from the proposed rule.

Additionally, we would like to urge the FDA to consider existing standards which have been developed by the industry which address the realities of medical practice in the field of reproductive medicine. The majority of reproductive medicine currently practiced adheres to joint standards issued by the American Society for Reproductive Medicine (ASRM) and the College of American Pathology (CAP). These standards, which have been self-imposed by the industry, by their very nature are more appropriate to medical practice in the unique area of human reproduction. ACOG urges the FDA to adopt these standards and make compliance mandatory.

As umbilical cord blood is also addressed by the proposed rule, we are including ACOG's Committee Opinion No. 183, "Routine Storage of Umbilical Cord Blood for Potential Future Transplantation" (April 1997).

We appreciate the opportunity to comment on the FDA's approach to regulating human cellular and tissue-based products and would be pleased to discuss our comments in more detail.

Sincerely,

Ralph W. Hale MD

Ralph W. Hale, MD, FACOG
Executive Vice President