March 28, 2001

Dear

The purpose of this letter is to remind your organization and its members that the Food and Drug Administration (FDA) has jurisdiction over clinical research using cloning technology to clone a human being, and to inform you of the FDA regulatory process that is required. You are receiving this letter because of a number of recent reports in the media describing the use of cloning technology to clone human beings. As described more fully below, the appropriate mechanism to pursue such clinical investigation using cloning technology is the submission of an investigational new drug application (IND) to FDA's Center for Biologics Evaluation and Research (CBER). Please inform the members of your organization of the information provided below.

Clinical research using cloning technology to clone a human being is subject to FDA regulation under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. Under these statutes and FDA's implementing regulations, before such research may begin, the sponsor of the research is required to: submit to FDA an IND describing the proposed research plan; obtain authorization from a properly constituted institutional review board (IRB); and obtain a commitment from the investigators to obtain informed consent from all human subjects of the research. Such research may proceed only when an IND is in effect. Since the FDA believes that there are major unresolved safety questions pertaining to the use of cloning technology to clone a human being, until those questions are appropriately addressed in an IND, FDA would not permit any such investigation to proceed.

FDA may prohibit a sponsor from conducting a study proposed in an IND application (often referred to as placing the study on "clinical hold") for a variety of reasons. If the Agency finds that "human subjects are or would be exposed to an unreasonable and significant risk of illness or injury," that would be sufficient reason to put a study on clinical hold. Other reasons listed in the regulations include "the IND does not contain sufficient information required…to assess the risks to subjects of the proposed studies," or "the clinical investigators…are not qualified by reason of their scientific training and experience to

The procedures and requirements governing the use of investigational new drugs, including those for the submission and review of INDs, are set forth in Title 21 of the Code of Federal Regulations (CFR), Part 312. Additional responsibilities of the sponsor of an IND include: selecting qualified investigators and overseeing the conduct of the investigators; ensuring that the investigations are performed in accordance with the protocols of the IND; submitting adverse experience reports and annual reports; and other duties as outlined in the regulations.

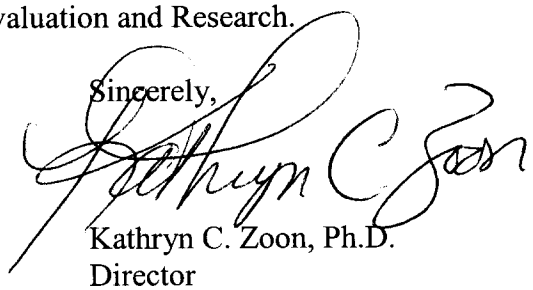
The responsibilities of an investigator include: ensuring that the study is conducted in accordance with the protocols; obtaining informed consent from study participants; and ensuring that an IRB that complies with the requirements of 21 CFR Part 56 reviews and approves the proposed clinical study and the informed consent form and procedures for obtaining informed consent, among other requirements specified in the regulations.

Clinical investigators are encouraged to obtain a copy of the current "Information Sheets for IRBs and Clinical Investigators" (which contains useful information regarding clinical investigations) from CBER's Manufacturers Assistance and Technical Training Branch at 1-800-835-4709. This document is also available at: http://www.fda.gov/oc/oha/irb/toc.html.

Additional information on how to submit an IND can be found on CBER's website at: http://www.fda.gov/cber/ind/ind.htm. Copies of the relevant sections of 21 CFR, including Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application) can be found at: http://www.gpo.gov/nara/cfr. Information on ways to communicate with CBER is available for you or members of the association at: http://www.fda.gov/cber/pubinquire.htm.

We encourage your members to meet with the Agency prior to submitting any IND application. Such a meeting would be arranged through the Office of Therapeutics Research and Review of FDA's Center for Biologics Evaluation and Research.

Sincerely,



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Center for Biologics
Evaluation and Research

Note: the link for the "Information Sheets for IRBs and Clinical Investigators" has been changed to http://www.fda.gov/oc/ohrt/irbs/.