

Congress of the United States

Washington, DC 20515

SPECIAL

March 15, 1999

The Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

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GENERAL COUNSEL
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Dear Madam Secretary:

Thank you for responding so quickly to our February 11 letter concerning federal funding of research in which human embryos are destroyed. Unfortunately, your letter was not responsive to our concerns but only raises further questions.

Consequently, we once again are compelled to point out that well-established rules of statutory construction have been ignored by the HHS General Counsel's memorandum reinterpreting current law on embryo research. The Supreme Court of the United States, as we noted in our earlier correspondence, has ruled that two parallel clauses of a law may not be interpreted in the same way if Congress expresses one provision narrowly and the other broadly. Had Congress intended only to ban the use of funds for the specific act of destroying or discarding embryos, Congress would have done that. Instead, Congress prohibited funding of "research in which" embryos are destroyed or discarded. For this reason, your contention that "the plain language of the statute supports the opinion issued by the General Counsel" remains unconvincing.

In fact, your conclusion that the ban was not intended to cover "research preceding or following" such destruction contradicts NIH's own policy and practice ever since the funding ban was first enacted. In 1997, for example, researcher Mark Hughes was found to be in violation of this law and dismissed from NIH. His violation was that he had used NIH-funded equipment to analyze genetic material obtained from human embryos. NIH funds were used in research which followed the harvesting of a cell from an embryo; in cases where a genetic defect was found, the analysis may also have preceded the discarding of an embryo. There was never any indication that the NIH equipment was used to destroy embryos. Yet in testimony before the House Commerce Subcommittee on Oversight and Investigations on June 19, 1997, NIH Director Harold Varmus agreed that the ban had been violated -- and he assured Congress that NIH had taken "several steps to further diminish the risk of subsequent violations." Now HHS proposes that these types of violations become the norm.

We would also point out that the context in which the funding ban was enacted supports NIH's enforcement of the law from its enactment in January 1996 until Dr. Varmus's announcement in January 1999. Congress passed the law in response to a 1994 report from the NIH Human Embryo Research Panel. The panel recommended taxpayer support of "research involving the development of embryonic stem cells" as part of its recommendations on funding of

“various areas of research involving the ex utero preimplantation human embryo.” The panel treated embryonic stem cell research as a form of embryo research because it knew that the cells would have to be obtained by destroying embryos. When Congress rejected the recommendations of the NIH panel by enacting the current funding ban, it did not make any exceptions. It rejected this form of experimentation as well.

In this context, it is remarkable that your February 23 letter proposes the Advisory Committee to the Director of NIH as the body that will ensure respect for ethical and legal standards in this research. This committee unanimously endorsed the original recommendations of the Human Embryo Research Panel -- including proposals for special creation of embryos for research purposes that were immediately rejected by President Clinton. This same committee openly planned a lobbying campaign to prevent Congress from enacting the ethical protections that remain in law today. Thus we are more concerned than ever that HHS's current course is less a good-faith interpretation of the law than an attempted end-run by those who have always opposed the law.

With regard to the definition of human embryo¹, we are not troubled at all by HHS's use of a scientific definition of the word “organism.” As the HHS General Counsel rightly states, an “organism” includes any “individual constituted to carry out all life functions,” including a one-celled individual. Rather, we are troubled by the paragraph in which she completely ignores this definition and states that “a human embryo, as that term is virtually universally understood, has the potential to develop in the normal course of events into a living human being.” Ms. Rabb declares on behalf the Department, with an appeal to no authority in science or law, that virtually no one considers a human embryo to actually be a living human being. This position simply contradicts the definitions which Ms. Rabb used a few lines before this in her memo to establish that a human embryo is an organism, and, as such, is an “individual constituted to carry out all life functions” of a human being. In other words, an embryo is a human being.

Ms. Rabb's statement that certain cells “do not have the capacity to develop into a human being, even if transferred to a uterus” leaves a doubt in our mind as to the point in biological development when Ms. Rabb considers a “human being” to come into existence, or whether she considers any child before birth to be a “human being.” This is not an insignificant point. If the potential or capability of something “to develop... into a living human being” is the standard used to determine whether an organism is a human embryo, and HHS does not consider a “human being” to exist before live birth, then the entire law on embryo research, as well as President Clinton's directive against special creation of research embryos, is undermined. Scientists have already offered to conduct their destructive experiments on damaged embryos not expected to survive to live birth, or to engineer lethal defects into embryos in advance, so that the human embryos they create for purposes of destructive research will not legally be “embryos” at all.

¹ Current law provides that, “For purposes of this section, the term ‘human embryo or embryos’ include any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.”

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This new and arbitrary use of the term "human being" also contradicts the entire history of federal regulations on human experimentation which, since 1975, have treated the child in the womb at every stage of development as a "human subject" to be protected from harmful research. In commissioning studies of ethical issues in genetics, Congress has urged respect for "the essential equality of all human beings, born and unborn" (42 USC §300v-1). Clearly, in science and law, a human embryo has no need to "develop into" a human being because it already is a human being. The fact that a particular embryo may ultimately have a longer or shorter life span is irrelevant in this regard. It would be akin to HHS claiming that a seriously ill infant is not really an infant because he or she most likely will not "develop into" a live adult.

Even if HHS's arbitrary definition were valid, the General Counsel's statement that pluripotent stem cells "do not have the capacity to develop into a human being, even if transferred to a uterus" is open to question. On January 26, Dr. Varmus testified that he does not know whether these stem cells may sometimes reaggregate in culture to begin developing as a human embryo. He added that it would be "grossly unethical" to transfer these cells into a woman's uterus to try to answer this question. Would it not also be grossly unethical to simply ignore this question and pursue such embryonic stem cell research, particularly if NIH admits that it may violate the law?

Finally, your letter makes no reference to the precedent established by current law on the use of fetal tissue from induced abortions. Under this law, which also specifically covers cells and tissue obtained from embryos, the harvesting procedure itself must not destroy prenatal life, and the timing and method for taking life must not be influenced solely by the needs of the federally funded research project. These principles are violated by the Administration's proposal for stem cell research.

Madam Secretary, because these are complex and important issues, we urge you once again to address our very serious concerns. For three years the ban on taxpayer funding of harmful research involving human embryos was enforced clearly and appropriately. The change in policy proposed by Dr. Varmus, based on the faulty reasoning in your General Counsel's memo, would violate the funding ban and mark a tragic step backward in federal standards for research involving human subjects.

Sincerely,





Long White

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