

Testimony of R. Alta Charo
Elizabeth S. Wilson – Bascom Professor of Law & Bioethics
UW Law School and UW Medical School Department of Medical History and Bioethics
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Senator Zien, Representative Kestell and committee members,

Thank you for the opportunity to testify today. My name is Alta Charo, and I am the Elizabeth S. Wilson Professor of Law and Bioethics at the University of Wisconsin, with appointments in both the Law and Medical Schools. I am pleased to testify in support of legislation that criminalizes irresponsible experimentation that involves the use of somatic cell nuclear transfer - that is, cloning - to produce a live-born child, but urge you to resist efforts to ban potentially life-saving research that relies on the same cloning techniques but in no way is related to reproductive cloning.

Because cloning is not, and may well never be, a safe method for conceiving children, there is virtually perfect consensus that such attempts ought to be discouraged. Medical societies tell their members not to try it. The federal Food and Drug Administration has already effectively intervened to prevent it. It would be malpractice to attempt it, and there has been state and federal legislation introduced that would criminalize it. Clearly, there are many ways to stop the small number of publicity-hungry, irresponsible people who might want to risk the health of women and children by using reproductive cloning.

But the legislation now before you would ban not only the irresponsible use of cloning to make babies, but also the responsible use of non-reproductive cloning for research or therapy. Debates over reproductive and therapeutic cloning as well as stem cell therapy have become almost hopelessly entangled in the last five years. I urge you today to separate these debates, both to protect the valuable scientific and medical advances that may emerge from non-reproductive cloning research, and to pave the way to effective action to discourage attempts to use this technique to produce children.

Critics express concern that legislation that simply outlaws reproductive cloning will be difficult to enforce, and they urge policymakers to ban basic research, lest it lead to the prohibited act of transferring a cloned embryo into a womb for development. But criminal law is almost always grounded in a theory of deterrence. We do not prohibit the manufacture of guns in order to guard against the possibility of their future misuse in homicide. Rather, we criminalize misuse of guns and prosecute the offenders accordingly. The same can and should be done for reproductive cloning. Many states, including California, New Jersey, Connecticut and Massachusetts have done this, by criminalizing any effort to initiate a pregnancy with an embryo created by somatic cell nuclear transfer, that is, cloning. At the same time, these states have left potentially life-saving research that uses cloning techniques legal and regulated.

Opponents of non-reproductive uses of cloning techniques for research and therapy argue that

the technique creates embryos solely to use and destroy them. Yet even prominent and lifelong opponents of the right to choose an abortion have nonetheless become strong proponents of research and therapeutic cloning. Senator Orrin Hatch and the late Senator Strom Thurmond, for example, introduced federal legislation to regulate non-reproductive uses of cloning rather than to ban it. Senator Hatch has stated that he does not view the cloned embryo in the same way he views a developing fetus. Similarly, the Missouri legislature, which has frequently passed measures to restrict access to abortion, has concluded that the use of cloned embryos in research is actually less problematic than the use of so-called "surplus" embryos left in fertility clinics. For some, the distinction lies in the fact that a cloned embryo does not represent a new and novel potential person in our human community. For others, tolerance of this research comes from the fact that cloned embryos have little potential for healthy development and, in the absence of transfer to a woman's body, no potential at all for development into a fetus or a baby. However one arrives at the distinction, it is important to note that for many members of Congress and for many state legislators around the country, opposition to abortion does not require opposition to non-reproductive research and therapeutic uses of cloning techniques.

Furthermore, we know - indeed, we fully expect - that embryos will be lost by the thousands every year at in vitro fertilization (IVF) clinics. Every couple who begins an attempt at IVF for purely reproductive purposes is the beneficiary of research that involved the deliberate creation of IVF embryos, solely for the purpose of doing research designed to increase the safety and efficiency of the procedure for infertile couples. And even now, every couple who begins an attempt at IVF for purely reproductive purposes knows that many, if not most, of the embryos they create will never develop into babies. Even if in vitro fertilization is done perfectly, and even if everyone who wants to "adopt" an embryo is successful, thousands would still be left behind. Criminalizing therapeutic cloning cannot alter the scale of embryo loss that we anticipate and tolerate each year. And since almost no one thinks in vitro fertilization could be outlawed, criminalizing a technique that might involve an exceedingly small number of embryos represents at best a symbolic effort at embryo protection.

Now, symbolic efforts are both powerful and important. They remind us that life is a gift that should be experienced with awe and gratitude. But a symbol can be badly tarnished if it is adopted at the expense of pain and suffering.

While reproductive cloning is a danger to children, non-reproductive cloning could save their lives. Cloning cells from someone with a genetic disease could produce tissue in which we study how the defective gene malfunctions, and help us develop drug treatments, perhaps reducing the number of human volunteers at risk in later clinical trials. Used to generate stem cells, it might become the fastest route to transplantation without risk of rejection. And perhaps most importantly, studying how cloning reprograms adult cells will help us learn how to reprogram cells directly, without cloning and without the use of embryos, to create tissue for research, transplantation and organ regeneration to alleviate paralysis and extend healthy life.

Let me give you an example. A tragically large number of younger women are destined to develop breast or ovarian cancer because they have the BRCA-1 or BRCA-2 mutation, a genetic defect. Today, we can diagnose the mutation and then give these thousands of women two terrible options. They can have their breasts and ovaries removed, maiming their bodies,

destroying their fertility, and putting them into menopause as early as the age of 21. Or they can engage in so-called “watchful waiting,” in which they are monitored so that when the cancer appears – and it will appear – they have a somewhat better chance that the chemotherapy and radiation treatment will kill the cancer before the cancer kills them.

The reason these women have such terrible options is that while we can diagnose the mutation, we simply do not know how or why the mutation causes cancer. But cloning techniques may hold the key.

Today we can scrape some tissue from the inside of the mouth of one of these women. Then we use cloning techniques to activate the mouth tissue, creating a so-called “cloned embryo” from the activated cells of the mouth. After a few days, embryonic stem cells can be removed and used to grow breast and ovarian tissue in the laboratory that has the same genetic defect, the same BRCA-1 mutation that causes cancer. Now there is a laboratory model of the disease, one where scientists can observe how the mutation functions, and test methods to slow or stop its lethal march toward breast cancer.

And it isn't just breast cancer that might be understood using this technique. It's any disease that has a genetic component, whether diseases of the elderly like Alzheimer's or the devastating, heartbreaking birth defects suffered by our children.

Yes, there are other promising avenues of research, and although none of them offer all the promise of cloning research, they most certainly should be pursued. But that is no argument for criminalizing this research. America is not a country in which basic research or personal choices are illegal until someone has persuaded the government to grant permission. Quite the contrary. We celebrate the freedom to think and to act and to inquire into the secrets of nature, until a compelling case can be made that it must be stopped. Identifying complementary areas of research falls far short of making that case.

You will also hear some argue that cloning research is only the tip of the iceberg, and that underneath the surface lies the spectre of eugenics. But research and therapeutic cloning is neither the beginning nor the end of a slippery slope toward eugenics. It is not even the most important landmark.

Our power over human reproduction is as old as ancient contraceptive potions. And the first announcements about in vitro fertilization were greeted with the same chorus of concerns about genetic engineering, designer babies, and the commodification of life, because it was in vitro fertilization that first made the embryo amenable to study and manipulation outside the body.

By contrast, therapeutic cloning does not design or engineer the embryo, and precisely because it is not about making babies, it neither designs nor engineers our children. It is not basic research, but rather our choices about its applications, that will shape the future.

Legislation that protects valuable non-reproductive uses of cloning technology while also guarding against its dangerous use to make a baby is largely consistent with the recommendations of the National Bioethics Advisory Commission and with the

recommendations in the National Academy of Sciences' two reports on stem cell research and reproductive cloning. The National Academy of Science Committee on the Biological and Biomedical Application of Stem Cell Research states in its report to the National Academy that "there is a scientific rationale for not foreclosing this avenue of research and for distinguishing clearly between SCNT (somatic cell nuclear transfer) to prevent transplant rejection and SCNT to create a fetus." Similarly, after two years of review, the California Advisory Committee on Human Cloning, which was commissioned by the California Legislature to conduct a comprehensive review of the issues raised by human cloning, unanimously recommended that California should ban human reproductive cloning but should not introduce legislation that would prohibit therapeutic cloning.

Nor is research cloning an unregulated field. Quite the contrary. In addition to banning reproductive cloning, the FDA also regulates how people donate eggs and cells for cloning research; how good laboratory practices are ensured; and how and when we proceed to human clinical trials of any therapies related to this research. Other federal regulations that apply include the human research subjects protections overseen by the Office of Human Research Protections at HHS and implemented at every institution by their local Institutional Review Board; oversight of recombinant DNA research and therapy by the Recombinant DNA Advisory Committee and implemented at every institution by their local Institutional Biosafety Committee; protection of medical confidentiality through the Health Insurance and Portability Protection Act; and, where applicable, coverage by the federal Animal Welfare Act and the local Institutional Animal Care and Use Committee.

In light of recent developments, the National Academy of Sciences has also developed a supplementary comprehensive set of ethical guidelines designed for self-regulation by the research community. These guidelines include a requirement for justification for the use of cloning techniques to derive customized stem cells; special oversight by a new local committee; and additional protections for the human subjects who donate their biological materials. These guidelines have already been adopted in California, have been endorsed by the American Association of Medical Colleges, and are in the process of being implemented in institutions across the country, including the UW-Madison.

I would also suggest to you that given the extensive regulation that already exists, and the proposals for extending that regulation even further, outright prohibitions on cloning research are unduly burdensome and subject to constitutional challenge.

For thirty years, federal courts and nationally recognized scholars have discussed the scope of the First Amendment and its protection of scientific research as part of the freedom of thought, inquiry, and dissemination of knowledge that is at the core of that aspect of the Bill of Rights. Research is an integral part of the scientific method, a form of inquiry that fits uniquely within the purposes, histories, and structures of the First Amendment. Thought and the testing of thoughts through science facilitates the dissemination of ideas just as much as monetary contributions to political candidates facilitates the expression of political ideas.

Indeed, in many cases, research is in and of itself a form of challenging political ideas. In other places and other times, governments have sought to ban the dissection of human bodies, because

it would interfere with deeply felt notions of the body as a reflection of the divine order, or have sought to ban investigation of the orbits of the planets, as it would interfere with essential views about the place of humankind in the universe. So, too, does investigation of the origins of life, of the secrets of conception and development, threaten our deepest views concerning the sources of life. But the First Amendment exists precisely to protect the development and dissemination of knowledge and truth and opinion, so that they may be tested and re-tested over time in the marketplace of ideas.

Of course even protected activities are subject to reasonable regulation to avoid interfering with the rights of others. But where prohibitions are designed merely to guard against the development of knowledge, for fear it might someday lead to new and controversial ways to manipulate cells and genes, those prohibitions run afoul of the very basis of the First Amendment protection of inquiry, association, and dissemination. Any law that goes beyond reasonable regulation of cloning research and bans this form of scientific inquiry is thus vulnerable to challenge in court as an interference with the First Amendment rights of patients and researchers.

In sum, if the legislature wishes to take action with regard to reproductive cloning, I urge it to focus on legislation that prevents that unsafe practice. But to ask for more, to halt basic research, is to sacrifice the diabetic children, the paralyzed veterans, the skin-scorched firefighters and the declining elderly of the present for a future that is neither certain nor imminent.

To be sure, we should deter those who would use cloning for reproductive ends despite its dangers. But we should go no further. Criminalizing research and therapeutic cloning is not the way to protect embryos or to guard against the future. It merely gambles with the hope held by many people today that they may live to see tomorrow, whatever it holds.

Thanks very much.