

Testimony of
Prof. Henry T. Greely

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Madam Chairman and members of the Senate Judiciary Committee, my name is Hank Greely. I am a professor of law and a professor, by courtesy, of genetics at Stanford University.

Since early 1999, I have been a member of the California Advisory Committee on Human Cloning, which made its statutorily-mandated report, entitled *Cloning Californians? Report of the California Advisory Committee on Human Cloning*, to the California legislature on January 11, 2002. I have made copies of that report available to the Committee's staff; I am only attaching its Executive Summary to this testimony.

I am here today both to report the findings of that Committee and to provide my own insights into legislation now pending before this body concerning human cloning. Except as specifically noted, the views I express today are my own and not necessarily those of the California Committee or of Stanford University. Those views lead me to support, strongly, Senate Bill 1758.

I want to discuss four things in my testimony: The California report, reproductive cloning, non-reproductive cloning, and the implementation of any legislation related to human cloning.

The California Report

In 1997 California became the first U.S. jurisdiction to ban human reproductive cloning. The ban was to last for five years, until January 1, 2003. As part of this statute, the legislature required the executive branch to appoint a committee to make recommendations back to the legislature about appropriate policy on human cloning by December 31, 2001. The legislature and the governor would thus have a full year to consider the report before the existing ban on reproductive cloning expired.

The California Advisory Committee on Human Cloning was appointed in early 1999. Its twelve members, identified below, represented a variety of professional backgrounds and a wide range of political viewpoints.

Francine Coeytaux, MPH Public
Prof. Theodore Friedmann, MD Genetics
. Dr. David Gollaher, PhD Biotechnology
Prof. Henry T. Greely, JD Law
Dr. Roger Hoag, MD Medicine
Prof. Bernard Lo, MD Ethics
Dr. Bert Lubin, MD Medicine
Prof. Margaret R. McLean, MDiv, PhD Religion Francis C. Pizzulli, JD Law
Prof. Radhika Rao, JD Law

Prof. Larry Shapiro, MD Medicine
Dr. Tracy Trotter, MD Medicine

Under the leadership of Dr. George Cunningham, Chief of the Genetic Disease Branch, California Department of Health Services, the Committee held five public meetings, beginning in May 1999, and innumerable closed meetings. It discussed, debated, negotiated, and argued about the subject and about its report up until the day before it delivered that report to the State. But, remarkably, the report it delivered contained five unanimous recommendations, as the Committee achieved a consensus on these very difficult issues.

The exact recommendations are contained in the Executive Summary of the Committee report, attached at the end of this statement. The most important recommendations were the first - that California should ban human reproductive cloning - and the second - that California should not ban, but should regulate, human non-reproductive cloning.

Those recommendations are not, in themselves, novel. Other groups, and other jurisdictions, including the United Kingdom, have reached similar conclusions. What was remarkable about the Committee's conclusions, I believe, is not what they were but how they were reached. The twelve members of this Committee started with very different positions on both reproductive and non-reproductive human cloning. As we heard more testimony and public comment, read more deeply in the literature, and began writing (and arguing about) our report, our views began to converge. They never converged completely. We have some different reasons for believing human reproductive cloning should be banned; although all of us agree more regulation of human non-reproductive cloning is needed, we have different ideas for the appropriate extent of such regulation. But, in 32 months of study and effort, we came much closer together. I believe our experience is evidence that, although the issues raised by human cloning are both profound and complex, a latent consensus exists, in California and, I believe, in the United States, on these issues. Government should not allow human cloning to be used to make people; it should allow - with due care - human cloning research to proceed to find ways to relieve diseases and conditions that cause suffering to existing people. Senate Bill 1758, introduced by Senator Feinstein and others, reflects that emerging consensus; Senate Bill 790, introduced by Senator Brownback and others, does not.

Human Reproductive Cloning

No responsible authority has supported the current use of human reproductive cloning. The California Committee was no exception. Every member of our Committee concluded that the issues of the physical health and safety of any children produced by such cloning compelled its prohibition. Every member also had concerns about human reproductive cloning even if it were proven safe. A large majority of the Committee concluded that other issues would justify a ban on reproductive cloning even if it were proven safe, although there was no agreement on just which non-safety issues were compelling.

The safety concerns are not a smoke-screen for the other worries; they are only too real. Many strong theoretical reasons cast doubt on the safety of this procedure. The empirical results to date with reproductive cloning in other mammals are a daunting record of miscarriages, still-births, birth defects at ten times the normal rate, and at least some possible indications of late onset

illness. The almost total failure of efforts to clone non-human primates, in spite of substantial efforts, is yet another reason for concern. One should not demand perfect safety - the usual way of making babies has its own serious risks for both mother and child - but before we should consider seriously allowing human reproductive cloning, the procedure should have demonstrated, in non-human mammals (and preferably primates), that it is as safe or nearly as safe as normal reproduction or in vitro fertilization technologies.

Statutory prohibitions of reproductive cloning, such as exist in California and a few other states, would be useful. It is not clear that they are essential - the unanimous condemnation of the procedure by professional groups; the potential for civil liability; the assertion by the Food and Drug Administration, no matter how questionable, of jurisdiction over cloning; and their own professional duty to "first do no harm" should stop all but the most reckless physicians. Adding a statutory prohibition, with clear and serious penalties, would, however, be another useful measure to limit such unjustified experiments.

Human Non-reproductive Cloning

The California report's position on human non-reproductive cloning is more complicated. We believe that its medical promise meant that it should not be banned. At the same time, we do not believe that the existing regulation of this research is sufficient. Both parts of that recommendation were essential to our unanimous conclusion. Only Senate Bill 1758 combines those two crucial points.

Consideration of human non-reproductive cloning can usefully begin with analysis of the arguments against it. Almost every argument about human non-reproductive cloning is, in fact, an argument against any destructive research with the human embryos. Arguments about the moral status of the embryo, the possible commodification of human life, the risk of oppression to egg donors have been made for more than a decade about human embryo research, as well as human fetal research. Our society has not reached a consensus about any of those arguments, but our governments have reached a compromise resolution. The federal government does not fund research that entails the destruction of human embryos; nor does it, under President Bush's August 9, 2001 position, fund research on embryonic stem cell lines derived from human embryos that were destroyed after that date. But neither the federal government nor most states forbid such research if it is privately funded. This resolution makes both sides unhappy, but it has proven, to date, an acceptable compromise. There is no reason to treat human embryonic research differently because the embryo involved was created through cloning.

Only one argument against non-reproductive human cloning is not just a recycled argument against human embryo research. Some have argued that human non-reproductive cloning must be banned to forestall human reproductive cloning. This "slippery slope" argument is largely silly. One could make the same argument for banning automobiles because they might be used for get-aways from bank robberies or banning electricity because it might be used to commit a murder. In the case of human cloning, the argument requires that someone who is willing to violate the law (and incur its penalties) by performing human reproductive cloning would not be able to make his own embryos, but would be able to beg, borrow, or steal a most likely anonymous cloned embryo from a research laboratory and, using an in vitro fertilization clinic, implant the transported cloned embryo into a willing woman. If the production of cloned human

embryos proves possible, it is most likely that, as with other cloned mammals, the creation of the cloned embryo will be the easy part of the work - bringing it successfully to term will be the hard part.

This slippery slope argument does have one good use. It highlights the value of increasing the regulation of human non-reproductive cloning. The California Committee concluded that the State should regulate non-reproductive cloning by at least a) forbidding all research with cloned human embryos after the appearance of the so-called "primitive streak" at about 14 days from its creation, b) requiring the informed consent of all those who donated cells to the process, and, last but not most importantly, c) requiring the review and approval of any such work by an Institutional Review Board. Such IRB review will help ensure that the research is documented, that the researchers are accountable, and that the means and goals of the research are appropriate. This review is not now generally required for research that does not involve federal funding, Food and Drug Administration approval, or major research institutions. I am pleased that Senate Bill 1758 includes this extension of IRB review to human non-reproductive cloning.

Issues of Implementation

Finally, the California Committee discussed not just what policy the State should adopt, but how that policy should be implemented. We strongly recommended that the legislature delegate the details of regulation, including the detailed definition of the covered procedure, to an administrative agency. The same concerns clearly exist at the federal level.

It is difficult for a legislature to regulate science effectively, particularly in a fast-moving field. Drafters of the legislation, in spite of their best efforts, may not understand scientific terms in the same way the scientists do. Even if their understanding is correct at the time the legislation passes, the science can and will change much more quickly and easily than statutory language. I have studied the definition of human cloning in the numerous bills introduced and the few statutes passed in various jurisdictions after Dolly. See Henry T. Greely, Banning "Human Cloning": A Study in the Difficulties of Defining Science, *So. Cal. Interdisc. Law Rev.* 8:131-152 (1998).

Many of those bills would not have achieved their goals because their loose use of terms like "cloning", "somatic cell," or "diploid" left loopholes that could be exploited. Some used definitions that made no sense at all. Several bills would have banned "the replication of a human individual by cultivating a cell with genetic material through the egg, embryo, fetal and newborn stages into a new human individual." Unless the term "replication," itself undefined and ambiguous, has special meaning, this definition seems to describe the age-old method of human reproduction. A bill introduced in Florida would have banned human cloning, defined as "creating a new individual by using the complete nuclear genetic material of an existing human being to create a second genetic duplicate of that human being." Presumably the first duplicate would have been permitted. Even the California legislation, which, in my professional view, has the best definition of human reproductive cloning, could be read to exclude some advanced reproductive technologies that involve transfer of a nucleus into an egg but do not involve human cloning - the resulting egg would later be fertilized with sperm.

Although the Congress is likely to avoid making some of these mistakes, it cannot avoid the unpredictability of the future course of this science. Any legislation passed, therefore, should define human reproductive cloning broadly - probably as the intentional creation of a fetus or child that is substantially genetically identical to a previously existing human - and delegate the power to define the subject matter more precisely to an administrative agency.

Conclusion

The explosion of our knowledge about biology confronts us all - as legislators, as citizens, as moral actors - with new challenges. It holds the promise of unprecedented reductions in human suffering; it also holds the threat of unprecedented changes . . . and dangers . . . to our humanity. The combination of a science that is both unclear and rapidly changing with a host of moral questions of great depth makes perfect solutions impossible. We cannot know what is right; we can only act, humbly, in ways that, after due consideration, seem right based on what we now know. The various dangers of human reproductive cloning, as we now understand them, demand that it be banned. The various promises of human non-reproductive cloning, with the benefits they now seem likely to offer, compel its continuation but with appropriate new regulation. This mixed verdict is not the perfect solution to the challenge of human cloning; it is merely the best solution we fallible humans can come up with today. As such, Congress should enact it into federal law through adopting Senate Bill 1758.

It has been an honor, and a pleasure, to appear before you. Thank you for the opportunity to discuss these fascinating and compelling issues.