WISCONSIN CATHOLIC CONFERENCE

TESTIMONY IN OPPOSITION TO SENATE BILL 379
PARTIAL BAN ON HUMAN CLONING
Presented by John Huebscher, Executive Director
January 16, 2002

On behalf of the Wisconsin Catholic Conference, I speak in opposition to this bill as it is currently drafted.

Every generation must deal with the question of how or whether to use new technologies and seek to define the relationship between means and ends. The realization that something can be done must always be accompanied by the question should it be done. As Senator Meyer said when he introduced his first cloning ban four years ago, "we must control the technologies we invent."

The capacity to engage in human cloning compels us to evaluate anew the moral question of whether the end justifies the means. This is not a question for only scientists alone to answer, or solely the concern of researchers, venture capitalists, or patients. It is a question for all of us. The cloning of humans should be preceded by a significant moral and ethical debate in our state and our nation over its potential effects on society. That debate is only beginning.

Any decision or policy regarding human cloning must always be assessed in view of its impact on the dignity of human life. As an intrinsic good, human life may not be reduced to a means to some other end. No human individual should intentionally be sacrificed for someone else's advancement.

We oppose this bill because, by banning only one type of cloning, it protects the dignity of some human individuals while legitimizing the destruction of others. It does so by making an ethically flawed distinction between cloning for reproductive purposes and research purposes.

As Lincoln said, slavery confronted the nation with the moral question of whether any of us should be allowed to prosper at the expense of another person's uncompensated labor. The debate over human cloning confronts us with the moral question of whether any of us should benefit at the price of another human being's very existence.

Let me deal first with the issue of human life.

The position of the Catholic Church on the beginning of human life has always deferred to the established scientific knowledge on the question. Just as Aquinas relied on Aristotle and others to determine that life was present at quickening, so does the Church now rely on what science is able to establish in light of technology and insights unavailable in past centuries.

OVER

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Science, not theology, tells us that from the time an ovum is fertilized a new life has begun. Science, not theology, tells us that this being is unique, with its own genetic code. Science, not theology, tells us that an embryo possesses a unity in which the parts of the embryo interact with each other and compensate for the good of the whole. That is, to sustain the embryo's life and foster its development. Even in the early stages when an embryo could differentiate into twins, it possesses what is both actual and potential about its human nature. As such, we believe, the embryo is an actual individual with a human nature and as such is entitled to respect and a right to life that cannot be intentionally taken.

Some may argue that life at this early stage does not deserve respect or legal protection. Some say that those who take my position extend the concept of the human person too far.

If the law treated only those born of a woman as legal persons, our argument would suffer. But Courts and legislators have not been so rigid. For instance, the Supreme Court held--and continues to hold--that a corporation is a person covered by the terms of the Fourteenth Amendment and thus entitled to the state's protection. So, too, a ship is a legal person, similarly protected in its rights.

It takes more creativity than I have to argue that an embryo is less like a fully developed, adult human being than is a corporation or a ship. And, if our laws can hold that a ship or a corporation is a person than it is hardly a "stretch" for our laws to hold that an embryo formed by the union of two human cells is also a person, at least to the extent of preventing actions that intend its destruction.

The bill appears to reflect that understanding in its ban on reproductive cloning. But it fails to ban research cloning. More fundamentally, where as an embryo cloned for reproduction would be born, an embryo cloned for research would not. Thus, by permitting cloning for research purposes this bill, in effect, creates a class of human beings that the state says it is illegal <u>not</u> to kill.

The question is "why?" If one truly believes that an embryo is not due the respect of a human person, why does this bill make such a distinction?

The best its supporters seem to offer is that "therapeutic" cloning promotes a public purpose that is somehow more laudable than the private purpose served by reproductive cloning. Thus does the end of better health care seem to justify the means of cloning -- and destroying --a human being.

One doubts that Lincoln would have accepted the argument that it was somehow unjust to enslave one human being for the private purpose of working a plantation but acceptable to enslave another human being for the public purpose of building a railroad or digging a canal. The common good cannot be served by undermining the humanity of the most vulnerable members of our human community.

In his Inaugural Address, John Kennedy said "The Rights of Man come not from the generosity of the state but from the Hand of God." In his retirement address, Tiny Krueger said, "human dignity is not a privilege dependent on prosperity."

This bill seems to imply otherwise. It suggests that human life and dignity are somehow subservient to motives of researchers. Such a statement is not consistent with best of our traditions.

We can do better. We can affirm that human life is not a tool to serve other ends and that cloning of human for any purpose is wrong. We urge you to amend Senate Bill 394 to achieve this result. Thank you.

THE
GRADUATE
SCHOOL
UNIVERSITY OF WISCONSIN-MADISON

TESTIMONY BEFORE THE SENATE COMMITTEE ON HEALTH, UTILITIES, VETERANS AND MILITARY AFFAIRS
IN SUPPORT OF SENATE BILL ~~397~~ 379
JANUARY 16, 2002

R. Timothy Mulcahy, Ph.D.
Professor of Pharmacology
Associate Dean for Biological Sciences
University of Wisconsin - Madison

I would like to thank Senator Moen and other members of the committee for providing an opportunity to comment on Senate Bill 397. My name is Tim Mulcahy and I am a Professor of Pharmacology at the University of Wisconsin-Madison and serve as Associate Dean for the Biological Sciences in the Graduate School. I would like to offer the following statement in support of Senate Bill 397.

With the introduction in February 1997 of Dolly, a sheep cloned by a scientific process known as somatic cell nuclear transfer, scientists shepherded in a new era in reproductive technology. The accomplishment was immediately heralded by many as a major scientific advancement offering substantial benefits for animal husbandry and agriculture. But condemnation by opponents who considered it the first step in a slippery slope culminating in human cloning was equally swift. Although the proponents of these divergent views could agree on little else, there was immediate recognition that Dolly had launched science and society on a contentious journey of exploration through the complicated scientific, ethical and political landscapes associated with human cloning.

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Cloning by somatic cell nuclear transfer involves placement of the nucleus of a somatic cell from an adult donor into an egg from which the nucleus has been removed. Following appropriate manipulation, the egg gives rise to blastocysts or pre-embryos. This technique can be applied in two very distinct ways: 1) to generate an embryo which can be transplanted into a uterus to give rise to a cloned individual, so called "reproductive cloning" or 2) to generate embryos as a source of donor-matched embryonic stem cells, so-called "therapeutic" or "research" cloning. The significance of this distinction within the context of this bill will become evident as I proceed.

While public opinion with respect to cloning of animals is generally favorable, there is strong public opposition to the use of reproductive technologies to clone human beings. Recent polls conducted by several news services consistently report that greater than 90% of Americans find human cloning unacceptable, even repugnant. Interestingly, when current findings are compared with polling data gathered shortly after the introduction of Dolly, the level of acceptance by the public has not changed significantly. If anything public opposition to human reproductive cloning has intensified, bolstered by recent announcements by fringe groups of their plans to be the first to clone humans. Though religious, ethical and social concerns are most often cited, many factors contribute to the current public revulsion to reproductive cloning.

Although consensus has not been achieved, there is also strong opposition to human reproductive cloning from the scientific community. In addition to ethical concerns, the reservations expressed by most scientists are based on a compelling body of scientific evidence from animal cloning studies which indicates that current cloning technologies, including somatic

cell nuclear transfer, are not sufficiently safe to justify their application in humans. Experiments in multiple animal species have consistently demonstrated that the probability of obtaining healthy, viable clones is currently only 1-4%. Many implanted clones die early in development. Others survive to later stages of gestation, at which point they frequently show evidence of severe developmental defects incompatible with survival. Many of the very few that survive to term die in early infancy of respiratory or other abnormalities. The ultimate fate of clones, such as Dolly, who survive long term in apparent health is still unknown, but the emergence of significant health issues later in life is beginning to be documented. In fact, Dolly was recently diagnosed with arthritis, a degenerative condition virtually unheard of in conventional sheep of comparable age. Although this ailment cannot with certainty be attributed to physiological consequences of cloning, there is speculation that Dolly is showing signs of premature aging. It is possible that the manifestations of accelerated aging reflect Dolly's aggregate age; that is, the sum of her chronological age and that of the donor animal at the time of somatic cell donation. Given the high mortality frequency, the severe morbidity and uncertainty about the future health and well being of cloned individuals, it is unconscionable to attempt to create genetic duplicates of people through reproductive cloning strategies. Consideration of the profound ethical, psychological and social dilemmas inherent in human reproductive cloning only serves to further amplify the objectionable nature of ths activity.

Proponents of human cloning most often identify procreative freedom, treatment of infertility or cloning of loved ones who have died as justifications for their support of reproductive cloning. However, these justifications fail miserably by comparison to the scientific and ethical rationale to reject such activity. Clearly the physical, psychological and social

uncertainties associated with reproductive cloning of humans have profound and unpredictable implications for clones, surrogate mothers, nuclear donors and society. Our current knowledge, limited though it is, of the significant risks associated with reproductive cloning and the marginal benefits to be derived therefrom preclude ethical applications of this technology in humans. The University of Wisconsin therefore concludes that efforts to create a genetic duplicate of a human individual via reproductive cloning is inappropriate.

However, in our opinion, applications of "therapeutic" or "research" cloning technology pose less serious ethical and safety concerns and offer greater potential benefits. Like reproductive cloning, therapeutic cloning involves introduction of a nucleus derived from a somatic cell into an enucleated egg. In contrast to reproductive cloning, there is no intent to induce a pregnancy, bring a clone to term or create a genetic duplicate of an individual, living or dead. Rather, this approach is intended to provide blastocysts or pre-embryos for basic research into human reproduction and embryology and for therapeutic purposes. Possible research applications of this type of cloning include but are not limited to: studies of human embryology to enhance our knowledge of the etiology of birth defects and to identify effective treatments; research to increase our understanding of the earliest stages of human development; the study and prevention of miscarriages and spontaneous abortions; and the development of improved treatments for infertility.

Perhaps the most compelling reason to support therapeutic cloning is the important role it is expected to play in the development of effective cell replacement therapies based on embryonic stem cell technology. It is widely acknowledged that human embryonic stem cells, originally developed by Dr. James Thomson at the University of Wisconsin, offer great hope as

potential treatments for debilitating diseases affecting millions of Americans. Prevailing evidence indicates that embryonic stem cells offer significant therapeutic advantages over other sources of stem cells, including adult stem cells, even though the latter have demonstrated limited clinical applicability. Research with both types of stem cells is necessary to define the relative merits of either in specific disease settings. Possible rejection of stem cells by a patient's immune system which might recognize the cells as foreign poses a potential barrier to therapeutic applications. Derivation of stem cells from a blastocyst developed by means of therapeutic cloning using the nucleus of a somatic cell obtained from individual patients is argued by many to represent a possible solution to this problem. The merits of such an approach will require additional research employing blastocysts developed by "research 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."

In light of these considerations, the University supports Senate Bill 379, which by prohibiting human reproductive cloning while allowing therapeutic cloning, strikes a reasonable and responsible balance between these two applications of cloning technology. This legislation is consistent with the recommendations recently presented to the Legislature of the state of California by the California Advisory Committee on Human Cloning. The Committee was commissioned by the Legislature to conduct a comprehensive review of the issues raised by human cloning. At the conclusion of over two years of review the committee unanimously recommended that California should ban human reproductive cloning but should not introduce

legislation that would prohibit human non-reproductive (therapeutic) cloning. Senate Bill 397 is also very similar to S. 1758 introduced by Senators Feinstein, Kennedy and Boxer in the U.S. Senate. The bill would "prohibit human cloning while preserving important areas of medical research, including stem cell research" by providing clear exceptions for cloning for research and therapeutic purposes. The basic tenets of Senate Bill 397 are also compatible with the findings of the University of Wisconsin's Bioethics Advisory Committee which concluded that, "It may ultimately be necessary to create embryos for the purpose of deriving stem cell lines ..... if it were necessary as a component in clinical applications (e.g., to provide cell lines that are genetically compatible with the patient). Although arguments for and against creation of embryos specifically for research purposes were identified, the Committee concluded that there were no compelling moral arguments for outright prohibitions on the creation of embryos for research under such circumstances." We have provided the committee with copies of both reports.

In summary, Senate Bill 397 at once provides for the health and well being of future generations of Wisconsin children by protecting them from adverse consequences of reproductive cloning, while providing for the health and well being of current generations of Wisconsin citizens (as well as people world-wide) by allowing important research vital to the development of therapies based on embryonic stem cell technology. It deserves the support of the State Legislature.

Testimony of Mary Matuska, Legislative Director
Pro-Life Wisconsin

In Opposition to
Senate Bill 379

Committee on Health, Utilities, Veterans and Military Affairs
January 16, 2002

Good morning, Chairman Moen, and committee members.

My name is Mary Matuska; thank you for your time.

You can fool some of the people all of the time and all of the people some of the time but you cannot fool all the people all of the time.

SB 379 claims to be a bill that would ban human cloning in Wisconsin. This is not true. A human clone is a human clone; a new human life has been formed.

Sen. Meyer's bill would allow cloning human life to be cloned as long as it is destroyed. They call this "therapeutic" cloning.

William Saunders, a senior fellow at the Family Research Council, said that it was "a serious misuse of language" to call human cloning therapeutic. He goes on to say, "Once cloning results, reproduction, by definition, has occurred. Even if the aim of the experiment is to produce a therapy for a disease or injury that was suffered by someone else, the research is lethal for the subject of the research (the human embryo) and is, therefore, not therapeutic at all."

The people of Wisconsin want a comprehensive cloning bill in our state. Rep. Steve Kestell has responded to the people by introducing AB 699 which would ban reproductive and therapeutic cloning, and parthenogenesis. This bill has 48 co-sponsors with bipartisan support.

Do not be fooled by Sen. Meyer's bill. It does not stop cloning in our state.

Thank you.

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WARF

Andrew Cohn
Government and Public Relations Manager, Wisconsin Alumni Research Foundation

Wednesday, January 16, 2002

RE: Testimony to the Health, Utilities, Veterans and Military Affairs Committee – SB 379

Chairman Moen and members of the Committee, thank you for the opportunity to speak with you today about this important issue.

My name is Andrew Cohn. I am the Government and Public Relations Manager for the Wisconsin Alumni Research Foundation -you may know us as WARF. We are an independent non-profit organization that has been providing support for the University of Wisconsin-Madison for over 76 years. WARF exists to support scientific research at UW-Madison. We carry out this mission by moving inventions of University faculty, staff and students from the lab bench to the marketplace. Recently this has been done in part by licensing faculty start-up companies. Through our licensing efforts, University ideas benefit the public and bring resources back to the University to continue the cycle of investment, research and invention. Last year WARF's gift to the University totaled $38 million. WARF has contributed or committed over $620 million since 1925.

I am here today in **support of SB 379 which prohibits reproductive cloning but allows research cloning to continue**. University of Wisconsin-Madison is a world-class research institution; WARF believes that this bill will help the university continue its leadership position. We believe that it is important to protect the right of the University to conduct medical research and this bill does that. We are joined in this position by the Coalition for the Advancement of Medical Research (CAMR). CAMR is a national organization of patients' organizations, universities, scientific and academic societies and other entities that support stem cell research.

Wisconsin has an opportunity to be a leader in finding treatments and cures for the world's most deadly diseases. Clearly there will be significant discoveries from this research. WARF is a proven leader in protecting those discoveries and making sure that they are developed with the highest ethical standards to benefit, humankind as well as the University of Wisconsin-Madison.

I thank you for the opportunity to speak with you this afternoon and would be glad to answer any questions you may have.

Wisconsin Council of Catholic Women

Founded 1915
Miss Mary Connor, Honorary Founder

Jan Holzbauer
5009 Flad Avenue
Madison, WI 53711

The Most Rev. Rembert Weakland, O.S.B.
Archbishop of Milwaukee, Spiritual Advisor

January 16, 2002

To: Senator Rod Moen, Chair
All members of the Health, Utilities, Veterans and Military Affairs Committee

From: Jan Holzbauer, Legislative Chair
Wisconsin Council of Catholic Women

Since 1999 when reports that biotechnology companies and researchers had begun their long-expected lobbying campaign to secure federal funding of destructive embryonic stem cell research, despite evidence indicating such research is unnecessary for medical progress, the Wisconsin Council of Catholic Women has actively opposed any attempt to negate the ban, in effect since 1995, on funding of research in which human embryos are destroyed.

Ensuing developments in this research have intensified our concern about this blatant disregard for further slippery slope effects such as cloning.

The many conflicting opinions so assiduously reported by the media should present no more problems than any other troublesome legislative issue. The basic requirement of any morally sound law is the common good, which can never be achieved nor justified if research results in the death of an innocent human being.

The audacity of the private research done by the Advanced Cell Technology of Worcester, Massachusetts is a prime example of the slippery slope cloning. In announcing the supposedly successful cloned human embryo, in which only 3 of 8 divided only once or twice, and 6 of 22 survived for five days, the ACT is guilty of gross "rhetorical misdirection", as stated by the NRL News.

This research totally ignored the U.S. House of Representatives which passed a the Human Cloning Prohibition Act in July, 2001 by vote of 265 to 63. Additionally, "a June 2001 poll conducted by International Communications Research found that 86% of Americans oppose the cloning of human life for purposes of performing destructive research", as reported by NRL News,*

*National Right to Life

December 2001 issue.

The moral imperative applies to all legislation, federal or state. Since Senator Meyers' bill not only authorizes cloning for therapeutic purposes, but could allow unauthorized embryonic stem cell research, the WCCW urges that it be rejected by your committee.

Thank you.

SB379

WISCONSIN STATE SENATE

RODNEY C. MOEN

SENATOR – 31ST DISTRICT

State Capitol, P.O. Box 7882, Madison, Wisconsin 53707-7882 Phone: (608) 266-8546 Toll-free: 1-877-ROD-MOEN

TO: Members, Senate Committee on Health, Utilities and Veterans and Military Affairs

FROM: Senator Rod Moen, Chair

RE: Senate Bill 379, relating to banning human cloning and the sale or purchase of an ovum, embryo or fetus for the purpose of cloning a human, prohibiting the use of state funds for cloning and providing penalties.

DATE: January 17, 2002

Attached please find a paper ballot on passage of Senate Bill 379 without any amendments. Senator Lazich's proposed amendment (WLC 0244/1) failed on a vote of 5 to 4. Senator Meyer withdrew his amendment (LRB a1096/1) after discovering a drafting error in the language.

Please return the paper ballot to my office by 2:00 PM on Friday, January 18, 2002. If you have any questions, please do not hesitate to contact me.

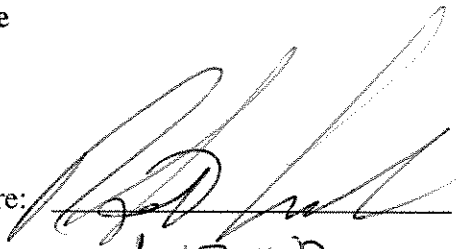
MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Introduction and adoption of WLC 0244/1 to Senate Bill 379.

☒ **Aye**

☐ **No**

Signature: 

Date: 1-17-02

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Introduction and adoption of WLC 0244/1 to Senate Bill 379.

☒ **Aye**

☐ **No**

Signature: Scott Fitzgerald

Date: 1-17-02

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Introduction and adoption of WLC 0244/1 to Senate Bill 379.

☑ **Aye**

☐ **No**

Signature: Mary A. Lazich

Date: 1-17-02

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Introduction and adoption of WLC 0244/1 to Senate Bill 379.

☒ **Aye**

☐ **No**

Signature: Roger Breske

Date: 1/17/02

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Introduction and adoption of WLC 0244/1 to Senate Bill 379.

☐ **Aye**

☑ **No**

Signature: Peggy Rosenzweig

Date: 1-17-02

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Introduction and adoption of WLC 0244/1 to Senate Bill 379.

☐ **Aye**

☑ **No**

Signature: Mark Meyer

Date: 1-17-02

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Introduction and adoption of WLC 0244/1 to Senate Bill 379.

☐ **Aye**

☒ **No**

Signature: Jon Erpenbach

Date: 1-17-02

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Introduction and adoption of WLC 0244/1 to Senate Bill 379.

☐ **Aye**

☒ **No**

Signature: Judy Robson

Date: 1-17-02

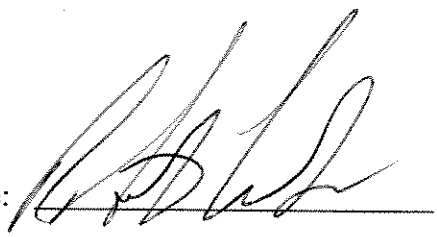
MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Passage of Senate Bill 379.

☐ **Aye**

☒ **No**

Signature: 

Date: _____

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Passage of Senate Bill 379.

☐ **Aye**

☒ **No**

Signature: [signature]

Date: 18 Jan 02

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Passage of Senate Bill 379.

☐ **Aye**

☒ **No**

Signature: Logan Burke

Date: _____

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Passage of Senate Bill 379.

☐ **Aye**

☒ **No**

Signature: Mary H. Lazich

Date: 1-29-02

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Passage of Senate Bill 379.

☒ **Aye**

☐ **No**

Signature: Jon Erpenbach

Date: 1.18.02

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Passage of Senate Bill 379.

☑ **Aye**

☐ **No**

Signature: Mark Mesa

Date: 1-17-02

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Passage of Senate Bill 379.

☒ **Aye**

☐ **No**

Signature: R.C. Moen

Date: _____

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Passage of Senate Bill 379.

☒ **Aye**

☐ **No**

Signature: Judy Rohrer

Date: 1-16-01

MOTION: SENATE BILL 379, RELATING TO BANNING HUMAN CLONING AND THE SALE OR PURCHASE OF AN OVUM, EMBRYO OR FETUS FOR THE PURPOSE OF CLONING A HUMAN, PROHIBITING THE USE OF STATE FUNDS FOR CLONING AND PROVIDING PENALTIES.

Move adoption of the following motion:

Moved: Passage of Senate Bill 379.

☒ **Aye**

☐ **No**

Signature: Leo Rosenthal

Date: 1-18-02

THE BIOETHICS ADVISORY COMMITTEE
OF THE UNIVERSITY OF WISCONSIN-MADISON

SECOND REPORT ON HUMAN EMBRYONIC STEM CELL RESEARCH
November 7, 2001

Introduction
The Bioethics Advisory Committee was appointed in 1998 by the Dean of the Graduate School, to review ethical, legal and social issues regarding specified research at UW-Madison and to advise on the development of University policy. The Committee convened on October 6, 1998 and held eight meetings resulting in the January 1999 publication of a report on human stem cell research at UW-Madison.

Since that report was issued, the committee met nine times between April-October 2001 to discuss further developments in human stem cell research. This second report summarizes the Committee's discussions and sets out a revised set of recommendations.

The Committee paid close attention to concerns about academic freedom; to the scientific goals and methods of the research, including possible alternative methods; the risks and benefits; potential and probable clinical and commercial applications; and other related research projects at UW-Madison and other institutions.

In its consideration of the ethics of research using human embryos, the Committee also paid close attention to public debate and diverse religious views about the moral status of the embryo; the procedures by which embryonic stem cells are obtained, including the process and content of informed consent; animal welfare and ecological issues; and relevant state and federal law or regulations regarding research using human embryos.

The committee also took into consideration the review of the research by the UW-Madison Health Sciences Human Subjects Committee; reports and recommendations of other committees and commissions that have considered ethical issues in research involving human embryos, including those from the United States, Canada, and Great Britain; and scholarly papers on ethical issues from leading writers in this field.

In reviewing developments since our first report, the Committee paid particular attention to the following issues:

The Acceptability of Human Embryo Research
The Committee continues to endorse its earlier conclusion that research using human embryos is ethically defensible. Considerable attention was paid to the role of public opinion concerning stem cell research, particularly in the context of a publicly funded institution. This included consideration of the arguments of those with objections to some aspects of such research, as well as consideration of the public interest in advancing knowledge and enhancing medical treatment of common serious disorders. The Committee concluded that research on human embryos should be conducted with an attitude of respect. This respect suggests that research using human

embryos should not be done without clear justification, and that human embryos should be used in the smallest numbers and at the earliest stages of development consistent with good science.

Sources of Human Embryos for Research

Human embryos used for derivation of stem cells are most commonly obtained from in vitro fertilization (IVF) clinics following donation of excess blastocysts (embryos) by couples who consent to their use for research purposes. As these embryos would otherwise be discarded, IVF clinics represent the preferred source of embryos for stem cell research. It may ultimately be necessary to create embryos for the purpose of deriving stem cell lines should available IVF embryos prove inappropriate for scientific reasons, or if it were necessary as a component in clinical applications (e.g., to provide cell lines that are genetically compatible with the patient). Although arguments for and against creation of embryos specifically for research purposes were identified, the Committee concluded that there were no compelling moral arguments for outright prohibitions on the creation of embryos for research under such circumstances. However, the Committee agreed that this approach should be reserved for situations when important research or treatments cannot be accomplished in any other way.

Mixing Human Embryonic Stem Cells with Experimental Animals

Mixing of human stem cell lines with experimental animals (i.e., creating chimeras) is essential to developing knowledge about stem cells and their potential clinical applications. If appropriate attention is paid to considerations of animal welfare and potential ecological hazards, these studies are not likely to be problematic when human cell lines are introduced in laboratory animals late in fetal development, after organ development has occurred and particularly after reproductive germ cells have differentiated.

Mixing human stem cell lines with experimental animals late in the animal's fetal development may result in the development of non-neural human structures (such as liver, heart or kidney) in the experimental animal. This raises some concerns about animal welfare and possible environmental hazards such as propagation of viruses. These concerns should be addressed by the relevant campus committees before such research is undertaken.

Mixing human stem cell lines with experimental animals early in the animal's fetal development may also result in the development of human neural tissue in the experimental animal, which raises at least the theoretical possibility that such tissue could become integrated in a way that human experiences become possible. After consulting with biologists, the Committee concluded, based on current knowledge of developmental biology, that this risk is extremely remote unless such mixing occurred very early in embryonic life. It is for this reason that introducing human stem cells into developing animals very early in embryonic life raises greater concerns about the creation of chimeras with human-like characteristics, and such experiments should receive careful ethical and scientific scrutiny.

Recommendations

Based on these discussions, the Committee unanimously finds that human embryonic stem cell research is scientifically important; has potential scientific and clinical benefits that are not expected to be equally achievable by other means; is consistent with existing law, regulations and

guidelines; and is consistent with the University's mission and its commitment to academic freedom. In light of these considerations, the Committee concludes that such research is ethically appropriate, subject to the following guidelines:

First, such research should be done only with the fully informed and voluntary consent of the donors. Donors should be told of their other options concerning the care and disposition of their embryos, including freezing for later use, donation to others for reproductive uses, or discard without research use. To the extent possible, donors should be informed of the range of future research uses before giving consent to donate embryos for research. In addition, donors who are undergoing fertility treatments or other medical interventions should not have their care altered specifically to make embryos available for research.

Second, researchers should use embryos that would otherwise be discarded unless the relevant scientific or medical research cannot best be done in this fashion. These embryos can be either fresh or frozen, provided that they are donated by couples who have given voluntary, informed consent..

Third, human embryonic stem cells and cell lines should not be used for introduction into a woman's uterus without further University of Wisconsin review and approval, because the extent of biologic risks of such procedures are uncertain at the present time.

Fourth, human embryonic stem cells and cell lines should not be introduced into any non-human species without review by appropriate animal care committees. Attention should be paid to ensuring full consideration of any ecological or developmental consequences of such research

Fifth, studies involving introduction of human embryonic stem cells or their derivatives into developing animals should have strong scientific justification and receive special review when human cells are introduced prior to development of organs or germ cells.

Committee Members:
Jan Brahms
R. Alta Charo
Norman Fost (Chair)
R. Timothy Mulcahy
John D. Pirsch
Elliott R. Sober
Robert Streiffer
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HEALTH

Research, Red Ink: An Academic Group Seeks Balance

By Antonio Regalado
Staff Reporter of The Wall Street Journal

When scientists at the University of Wisconsin-Madison discovered the human embryonic stem cell in 1998, the school thought it had a surefire financial hit.

But so far, the university is $1.5 million in the red in its effort to make money on the stem cells. And making money from stem cells still isn't a certainty, even after the school last week won back major rights to the discovery. The university's licensing arm—the Wisconsin Alumni Research Foundation, or WARF—and its principal commercial partner last week agreed to narrow their stem-cell alliance, settling a lawsuit between them.

In loosening the bonds of their partnership, WARF, like so many other academic researchers, was struggling to balance financial interests with its mission of bolstering scientific progress.

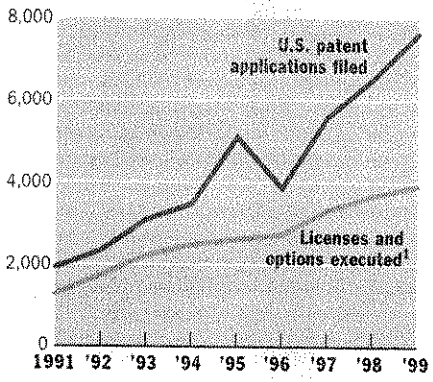
WARF, located in an imposing office tower near the Madison campus, was founded in 1925 with $900 donated by nine alumni. The organization since has plowed $625 million back into the university's research laboratories. The first invention it made good on was a synthetic form of vitamin D, licensed to **Quaker Oats** Co. in 1927 as a cereal supplement.

WARF is a leader in the growing, $700 million business of patenting and selling professors' inventions. The nonprofit organization's 39 employees aren't selling just stem cells; other technologies being marketed by WARF include a herpes treatment and a super-absorbent gel that can soak up more than 400 times its weight in water.

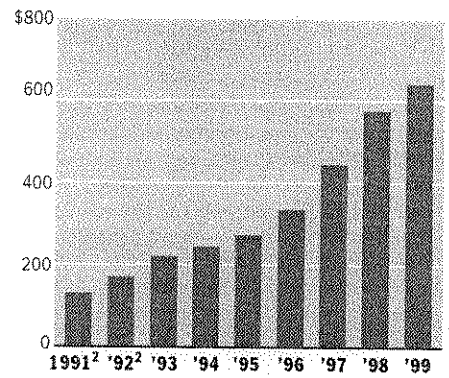
Most universities have found it notoriously difficult to turn laboratory discoveries into royalty streams, an effort known as "tech transfer" to its practitioners. Instead, they tend to look for a more subtle mix of payback, such as boosting regional development through spinoff companies or retaining professors who might otherwise decamp for industry.

Ivory Tower Entrepreneurs

Number of U.S. patent applications by U.S. universities; number of patent licenses signed with companies



U.S. universities' gross income from licensed technology, in millions



[1]Includes U.S. and Canadian universities, colleges, hospitals and not-for-profit research institutions
[2]Gross, uncorrected for double counting Note: Number of survey respondents varies by year

Source: Association of University Technology Managers FY 1999 Licensing Survey

In 1999, U.S. universities filed a record 7,612 patent applications, according to the Association of University Technology Managers, a professional group representing licensing personnel. Schools also executed more than 3,000 licensing deals with companies. "Sponsored research" agreements also are common, with many schools deriving as much as 10% of their research budgets from corporate underwriting—about $2 billion per year overall, according to the latest AUTM data.

Critics see many problems with the system. Researchers delay publishing papers to secure patents. And the thicket of patent rights can make complex legal negotiations necessary simply for colleagues to share research results.

But by most accounts, the system has been a resounding success, generating billions of dollars in economic activity (with many of the benefits accruing outside universities).

Louis Berneman, who heads up technology transfer at the University of Pennsylvania, says if pure financial gain were the aim, universities "would get a better return on their money with a McDonald's franchise on their campus." But schools do make money on the occasional big hits: The University of Florida pulled in millions from its thirst-quenching formula for Gatorade.

WARF expected a home run when scientist James Thomson first isolated stem cells from embryos in his University of Wisconsin laboratory. Stem cells are the primordial cells that can be extracted from week-old embryos and transformed into any cell in the human body, offering hope of treating degenerative diseases such as diabetes or Parkinson's.

But WARF didn't have complete control. **Geron** Corp., of Menlo Park, Calif., a small publicly traded biotechnology firm, had been funding the work since the mid-1990s, and as a result had first dibs on negotiating a deal.

WARF managing director Carl Gulbrandsen says that because of the original funding contract, WARF was compelled to sign a deal it didn't particularly like. He concedes the group may have erred in giving Geron an exclusive license or option to nearly every important medical application arising from stem cells. At the time of the negotiations, however, stem cells still were unproven, unpatented and highly controversial.

After President Bush announced in August that federal money would be available to study the cells, it became clear that WARF stem-cell patent and its exclusive deal with Geron threatened to drastically slow the pace of development.

Last week, under mounting pressure from the National Institutes of Health and academic scientists, the Geron deal finally unraveled. In August WARF had sued Geron in a bid to restrict the company's rights. Last week, WARF and Geron reached a settlement that cleared the way for wider exploitation of the technology by more companies.

In the settlement, Geron retained commercial rights to create medical treatments using three cell types that can be created from embryonic stem cells—heart, pancreas and nerve. While WARF now controls the rest, it may end up making less money from its intellectual property than it had once imagined. Already, WARF has agreed that academic scientists can freely use its technology in their research.

"We all wish and pray for the home run," says the University of Pennsylvania's Mr. Berneman. "But we depend on groups like WARF to make sure they do things in the right way."

—Jill Carroll contributed to this article.

Text of state panel's report on cloning

Friday, January 12, 2002

URL: http://www.sfgate.com/chronicle/cloningreport/

Here is the text of a report by a state-appointed advisory panel, urging a state Senate committee to permanently extend the state's current ban on human reproductive cloning but permit the cloning of human embryonic stem cells for medical research.

EXECUTIVE SUMMARY

In 1997, when California adopted a five year ban on human reproductive cloning, the legislation required the appointment of an expert group to provide advice to the Governor and Legislature about how to proceed when the five years had ended. This is the report of that California Advisory Committee on Human Cloning. It is not, in any sense, a report of the Governor, the Legislature, or the State. Instead, it is our effort to provide useful advice to California, laying out the background on the issues, analyzing the arguments, and presenting our recommendations. The Committee, made up of twelve Californians from a wide range of backgrounds, has studied these issues for over two years. In five public meetings around the State, we have heard testimony from international experts and comments from ordinary Californians. We heard many different views and, indeed, our most fundamental conclusion may be that, on many of these questions, reasonable people can and do disagree. Nonetheless, the Committee has found itself in unanimous agreement on five main recommendations:

1. The Committee unanimously agrees that California should ban human reproductive cloning. Many arguments support this position, some dealing with physical and psychological safety, some with ethical or social concerns and some with regulatory and political issues. We all believe, based on current knowledge on physical safety, that California should prohibit human reproductive cloning. Moreover, while not all members of the Committee were persuaded by the same set of arguments, most Committee members have concluded that some combination of the other arguments should also lead to prohibition of human reproductive cloning even if it were proven physically safe.

2. The Committee unanimously agrees that California should not prohibit but should reasonably regulate human non-reproductive cloning. We believe that use of this technology offers potential medical and scientific benefits while not raising many of the same concerns as human reproductive cloning. Such uses might include cloning technology as a source of human stem cells that would not be rejected by a patient's immune system. California should regulate all human non-reproductive cloning in the State, public or private. That regulation should do at least three things: a) prohibit the use of pre-embryos after development of the primitive streak, b) ensure that the persons providing cells for this purpose gave informed consent, and c) require that the research be permitted by an approved Institutional Review Board ("IRB").*

3. In banning or regulating human cloning, California may be affected by actions of the federal government. Federal regulation needs to be watched carefully to ensure that California's actions are both necessary and appropriate. So do the actions of other states, which might provide experience useful to the California regulatory plan.

4. Regulating a scientific field undergoing rapid change is difficult for a legislature. The California Legislature should define the terms of its prohibition on human reproductive cloning carefully and its regulation of human non-reproductive cloning carefully but broadly. It should delegate the implementation, including further definition, of that regulation to a state agency.

5. The Committee strongly believes that California will increasingly face complex challenges arising from genetic and reproductive technologies. "Cloning" by embryo-splitting is one of many such technologies. We recommend that California establish an on-going mechanism to advise the Governor and the Legislature on this and related issues of human biotechnology.

We discuss the reasoning behind these recommendations, and much more, in this report.

INTRODUCTION

This report is the product of over two years of work and meetings by the California Advisory Committee on Human Cloning. The Committee, made up of 12 Californians from different backgrounds and fields, has listened to expert testimony; studied the scientific, ethical, and legal literature; and discussed at length the many issues raised by the possible application to humans of the technique, known as nuclear transfer cloning, used to produce Dolly, the world's most famous sheep.

Members of the Committee began their work with different opinions on various aspects of human cloning. Some of those differences have disappeared; others remain. In spite of our continuing disagreements on some points, though, this group has reached a consensus on several important recommendations. We unanimously agreed that California should not ban non-reproductive human cloning, that California should prohibit reproductive human cloning, and that the State should create a more permanent body to provide advice and expertise on other important ethical, legal, and policy issues that will arise from our increased understanding of human biology.

This report sets out our recommendations and the analysis behind them. It does so, in part, by laying out arguments for and against human cloning. No Committee member agrees with every argument in the report; for most of the arguments, the Committee concluded that reasonable people could reach varying conclusions. Nonetheless, our eventual conclusions are strongly and unanimously held.

The report is organized in four sections. The first section provides background information about the Committee, human cloning, and the legal and public reaction to its prospect. The second section discusses non-reproductive human cloning. The third section analyzes the arguments concerning reproductive human cloning. The final section describes some issues about the implementation of the Committee's recommendations.

I. BACKGROUND

This section of the Committee's report provides background information. It begins with information about the Committee itself, then continues with some basic information about the science of human cloning. It then describes the legal status of human cloning, in the United States and elsewhere. It ends with discussion of the public opinion about human cloning.

A. The California Advisory Committee on Human Cloning

On February 23, 1997, the British newspaper The Observer published a report of the successful

production of a sheep named Dolly from the nucleus of an adult cell injected into an enucleated egg. The report set off an international debate about the ethical, legal and social ramifications of a powerful new technology for cellular and embryological and related biomedical research, as well as for genetic design of mammalian species, in particular, the human species.

Like many other major scientific discoveries that resulted in major changes in our worldview, cloning was immediately controversial. The next day President Clinton requested a report within 90 days from the National Bioethics Advisory Commission (NBAC) and, without waiting for the report, issued an executive order barring federal funding of cloning research on March 4, 1997.

The NBAC conducted a rapid review of published opinions and reports, held public hearings, and published a report on June 9, 1997.[1] The conclusions of the NBAC were that there were clearly such great safety and efficacy concerns with cloning procedures that had until then been reported that it would be immoral and contrary to good public policy to attempt cloning in humans. They recommended legislation to place a moratorium on attempts to clone humans. They reached no conclusion with respect to the question as to whether, if research improved safety and efficacy, the procedure itself was intrinsically immoral, calling for a broad public dialogue to clarify this issue.

Legislation has been introduced several times in Congress to ban or restrict cloning. Congress has considered such legislation in the aftermath of public announcements of plans to clone humans, first in 1998 by Dr. Seed and then in 2001 by Drs. Zavos and Antinori and by a company called "Clonaid," which is connected to a religious group called the Raelians. As a result of the recent announcements, the House Energy and Commerce subcommittee held a public hearing on human cloning on March 29, 2001. A second hearing on May 2, 2001 was held by the Senate Commerce Subcommittee on Science, Technology and Space. Federal legislation banning reproductive cloning has been introduced and one bill has passed the House of Representatives, but, to date, Congress has not enacted any law on the subject. [2]

There has also been activity at the state level, which led to legislation banning human cloning in at least four states, including California. In 1997, the California legislature passed two enactments about human cloning: Senate Bill 1344 and Senate Concurrent Resolution 39 (Appendix No.2). S.B. 1344, passed unanimously in the Senate and 44 to 17 in the Assembly, defined cloning as "the practice of creating or attempting to create a human being by transferring the nucleus from a human cell from whatever source into a human egg cell from which the nucleus has been removed for the purpose of, or to implant, the resulting product to initiate a pregnancy that could result in the birth of a human being."

The legislation established "a five year moratorium on cloning of an entire human being." The State Director of Health Services was "called upon to establish a panel of representatives from the fields of medicine, religion, biotechnology, genetics, law, bioethics, and the general public" to evaluate the "medical, ethical and social implications," review public policy and "advise the Legislature and the Governor in this area." Senate Concurrent Resolution 39 required the report to be submitted "not later than December 31, 2001."

Implementation of the legislation was assigned to the Genetic Disease Branch of the California Department of Health Services. On December 23, 1998, the Director of the Department of Health Services, S. Kimberly Belshé, formally appointed a group of twelve individuals with the expertise required by the legislation to be members of the California Advisory Committee on Human Cloning. No staff or funding was provided for the Committee's work; Committee members were not paid for their work beyond reimbursement of some travel expenses.

The Committee had its first orientation and organization meeting on May 8, 1999. Over the next 18 months the Committee held five advertised public meetings at different locations throughout California. The Committee's approach focused each meeting on a specific area of interest and invited knowledgeable speakers to make presentations on that topic, followed by questions from the Committee. Each meeting included a period for public comment and dialogue with the Committee and each public meeting was open to the media. Agendas for all meetings are attached as Appendix No. 3. All meetings were recorded and minutes were produced for each meeting. A selection of articles from the press and scientific publications and any correspondence received were included in the Committee's material for each meeting.

The Committee's task was made more manageable by the fact that a great many of the issues and most of the scientific and ethical arguments had been addressed by the NBAC. The voluminous literature about the issue in books and articles was also available for Committee review. A partial reading list is attached as Appendix No. 4.

After the first round of public hearings was complete, the Committee held a series of five closed meetings to develop the text of a report, including recommendations. This is that report. It represents the consensus of the twelve members of the Committee as to their recommendations to the California government. Probably no member of the Committee agrees with every statement in this report, but it does embody, in general, our unanimous recommendations. This report is not a position of the state government and it has not been subject to advance approval by any state body.

Although the NBAC report called for broad public dialogue on the issue, no agency of the federal government undertook the organization or funding of such educational and consensus building effort. None of the other states which passed cloning legislation engaged in any process of public participation in developing the issues, technical, legal and moral, raised by the technology.

Although a large majority of the public continues to oppose human cloning, neither legislatures nor scholars have reached a consensus on the appropriate action. Most of the scientific community continues to echo the findings of the NBAC that reproductive cloning remains a risky and inefficient technology, not ready to be attempted in humans. While the prospect of premature application of current technology has been widely condemned, differing opinions exist on whether human reproductive cloning, if physically safe for the cloned embryo, fetus, and child, should be banned.

The California Committee agrees with the NBAC that there is a need to "provide information and education to the public" and has adopted this concept in the preparation of this report. In the 4 1/2 years since Dolly's birth was announced, there have been innumerable articles about human cloning, but few attempts to work through, in an even-handed way, the arguments on both sides We believe, whatever the merits of our report, the State of California should be congratulated for making an effort to advance public understanding and discussion of the issues surrounding human cloning. We hope our report will advance that discussions, among policymakers and among the public.

B. SCIENTIFIC BACKGROUND

In 1997, the report of the production of a newborn lamb by a process that involved the transfer of a nucleus from an adult cell of a donor sheep to a recipient enucleated egg sparked the interest of the world. "Dolly" became an instant celebrity and a public dialogue was rapidly initiated to

explore the possibilities of human reproductive cloning and to consider the ethical, legal, and social issues that might be raised should such technology be developed and put to use. While the achievements of Ian Wilmut, Keith Campbell, and their colleagues at the Roslin Institute in Scotland are notable from both a practical and a fundamental scientific standpoint, as with virtually everything else in science, this work rested on the prior contributions of many others.

1. Cloning Before Dolly

Since the beginning of the 20th century, scientists had speculated on the nature of the early events in embryonic growth that result in the differentiation of the various cells' tissues and organs that constitute a mature animal. The cell's nucleus was known to be the repository of the genetic program that guided development, but the nature of the changes that took place in the nucleus during differentiation was (and to a considerable extent still is) unknown. The German embryologist August Weismann first theorized that the nucleus of the single cell zygote, i.e., a fertilized egg, must be totipotent, that is, it contains all of the information required to direct the development of a complete animal.[1] He also incorrectly believed that with subsequent cellular and nuclear division, there was a progressive loss of genetic information that resulted in the restriction of developmental potential of the daughter cells. He attempted to demonstrate this experimentally, but inevitably encountered many technical difficulties in an attempt to prove what we now know to be an incorrect hypothesis.

In 1892, Hans Driesch, using sea urchin eggs and embryos, was able to separate the daughter cells resulting from early embryonic cell division and showed that each cell from two and four celled embryos could continue to divide independently and to give rise to a complete and intact sea urchin.[2] This was probably the earliest example of reproductive cloning by the process of embryo splitting. In the 1920's and 1930's Hans Spemann carried out some technically extraordinary experiments that demonstrated that totipotency, i.e., the ability to develop into all the cells needed to make an adult, could be retained by embryonic nuclei through a number of cell divisions.[3] Using a "noose" constructed from a human hair, he was able to partition part of the cytoplasm of early developing salamander embryos. Then he was able to coax nuclei that were produced via cell division (mitosis) in another part of the embryo to move into the isolated bud of embryo cytoplasm. Here the "transplanted" nucleus, though in the same embryo, would initiate the development of a second distinct embryo. This work suggested that at the eight or even sixteen cell stage, nuclei still retained the ability to specify the development of a complete new individual. In subsequent experiments, for which he was awarded the Nobel Prize in 1935, Spemann showed that there were changes that determined the fate of cells later in development. Thus transplanted cells and tissues derived from embryos further along in development retained their differentiated characteristics even when moved to a new location within the embryo. Clearly there were restrictive changes, i.e., loss of totipotency that occurred to the nuclear genetic program as development progressed, but whether these changes could be reversed was still not known.

By the early 1950's techniques had been developed which enabled individual cell nuclei from amphibians to be removed from their surrounding tissues and to be injected into eggs whose own nucleus had been removed or destroyed. With these methods, called "nuclear transfer," new questions could be asked regarding the restrictive changes in the programming of nuclei with development. Briggs and King demonstrated in 1951 that nuclei removed from early frog embryos called blastocysts, which contained several thousand cells, could be introduced into enucleated eggs and direct development at least until the tadpole stage. John Gurdon then carried out some key experiments in which intestinal cell nuclei derived from tadpoles were transferred to enucleated eggs in a similar fashion and gave rise (albeit with low efficiency) to mature adult

frogs. This research demonstrated that even the well-differentiated cell nuclei of tadpoles could be reprogrammed to direct full embryonic development. In subsequent experiments, Gurdon used nuclei from adult frog skin cells and showed that these could direct differentiation up to the tadpole stage (although apparently not beyond this point). All of this work suggested that much of differentiation and development was not associated with any irreversible changes in the nucleus.

Success in cloning and nuclear transplantation in mammals required overcoming many new technical hurdles as compared to work with sea urchins or amphibians. Mammalian eggs are much smaller, more fragile, and, unlike the eggs of frogs and sea urchins, which are released by the mother, mammalian eggs need to complete their development internally. By 1979, Willadsen had achieved the artificial production of identical twin sheep by splitting very early embryos.[4] Although this could be considered a form of cloning, it merely reproduced artificially the natural process that causes identical twins; it did not create a genetic duplicate of a sheep that had already lived.

Throughout the 1980's conflicting results were reported regarding the possibility of achieving embryonic development following nuclear transfer in mice. In retrospect, these results were difficult to interpret because of incomplete scientific understanding and imperfect technique. Subsequent work seems to indicate that, at least in mammals, eggs that are in the process of the second meiotic division are more competent recipients for nuclear transfer studies than are zygotes due to the presence of high levels of a molecule known as maturation promoting factor (MPF). Furthermore, reprogramming of the donor nucleus is markedly facilitated by causing it to stop its progression through the cycle of events required for cell division (the cell division cycle or mitosis) prior to transfer to the enucleated egg. In 1986, Willadsen made use of this new information to produce the first mammals utilizing nuclear transfer technology from eight or sixteen cell embryos into enucleated sheep eggs.[5] He was able to obtain live born lambs from these experiments that in some instances were genetically identical to one another; that is, they were clones. Shortly thereafter, First and colleagues obtained similar results in cattle in efforts to accelerate genetic improvements in dairy herds. Thus, nuclear transfer technology had been used to create cloned mammals a decade before Dolly, but these clones were all created using cells taken from early stage embryos, not from adult animals. Based on the work with amphibians, DNA from adult cells was not thought capable of directing the new development of a complete animal.

2. Dolly

In the early 1990's Drs. Keith Campbell and Ian Wilmut worked together in Scotland to investigate systematically the requirements for successful nuclear transfer by manipulating both donor cells and recipient eggs. This work culminated in the discovery that cultured embryonic epithelial cells could act as nuclear donors if the cells were first induced to leave the active cell division cycle and enter the so-called quiescent (Go) state. Five live born lambs resulted from the early efforts.[6] Two of the lambs died within minutes of birth and the third succumbed after ten days. However, two other animals that came to be known as Megan and Morag lived well into adulthood. This work was highly significant because it demonstrated for the first time that mammals could be cloned from nuclei derived from well-differentiated cells that had been maintained in tissue culture. Yet, these were still cells that had originally been derived from fetal sheep.

Subsequently, Campbell and Wilmut extended their efforts to the use of cultured cells from an adult donor, and this work produced Dolly.[7] Dolly was part of a wide-ranging experiment that involved the transfer of donor cell nuclei into nearly one thousand enucleated sheep eggs.

Roughly a third of the eggs received nuclei from embryonic cells, a third from fetal cells, and a third from a cell line created with cells from the mammary tissue of a six year old ewe. Although the adult cells were used to create numerous embryos that were implanted into ewes, Dolly was the only successful pregnancy. Her distinction is not that she is the first cloned mammal - sheep and cattle had been produced through nuclear transfer cloning since the mid-1980s. Dolly, however, was the first mammal successfully cloned from an adult cell, thus opening, for the first time, a plausible scientific prospect for cloning living humans.

3. Reproductive Cloning Since Dolly

In the 4 1/2 years since the announcement of Dolly's birth, researchers have used nuclear transfer cloning with adult donor cells to produce cattle, goats, pigs, mice, and one gaur (an endangered wild ox native to South Asia). At the same time, research in other species has not been successful. Well-financed efforts to clone house pets - dogs and cats - have thus far been unsuccessful. No primates of any kind have been successfully cloned from adult cells; only two primates (two monkeys) have been successfully cloned by nuclear transfer from embryonic cells. As far as we know, no human clones have been born, or have even been implanted for possible birth. It is not known at this point whether human cloning by nuclear transfer is even possible, although each new mammalian species cloned makes human cloning seem more plausible.

Even if human cloning by nuclear transfer is possible, several scientific issues regarding this kind of cloning need to be emphasized. These affect the relationship between the clone and the source of the donated cell nucleus, as well as the likely safety of such a procedure.

Technically, "clones" produced by these methods are not completely genetically identical to the individual that donated the nucleus. The donor cell has DNA in both the nucleus and in its mitochondria, which are cellular energy producing organelles - structures in the cytoplasm of cells separate from the nucleus. When a nucleus is transferred to an enucleated egg, the donor mitochondria are either left behind entirely or grossly outnumbered by the mitochondria in the recipient egg. As a result, the new embryo derives its mitochondria from the recipient egg. While this is theoretically significant, the size of the nuclear genome is approximately 200,000 times larger than the mitochondria genome, and as far as is known, the mitochondria genes only encode proteins that relate to energy production. Nevertheless, mutations in the mitochondrial genes can produce serious disorders in humans.

Another unresolved scientific issue relates to internal changes, called epigenetic changes, in the nucleus of somatic cells. It is now fairly clear that the DNA in most differentiated somatic cells is not fundamentally different from the DNA in the single celled zygote. It has the same sequence of adenine, cytosine, guanine, and thymine that make up the organism's genetic code. But a series of chemical changes to the primary structure of DNA, such as the addition of methyl groups to DNA, regularly occur during development. Another example of such epigenetic changes is genomic imprinting. In mammals, the paternally inherited copy of the genome and the maternally inherited copy of the genome are not functionally equivalent. A heritable "imprint" is created during gametogenesis (the formation of sperm and eggs) so that subsequently certain genes are expressed by only one of these contributions, i.e., only from maternal or only from paternal genome. To be successful in directing development, an adult nucleus would have to have maintained a stable imprinting pattern and this pattern would need to be preserved or replaced following nuclear transfer. The success of producing live-born animals by this procedure suggests that such issues are not insurmountable, but there may be imprinting errors that contribute to the high failure rate seen in cloning experiments to date.

Another issue relates to the possibility that genetic damage (mutations) may have accumulated in the differentiated adult somatic cell selected to be the donor nucleus. The longer cells are maintained in culture and the more divisions that they undergo either in vitro or in the body, the greater is the possibility that an error in DNA replication might occur or that some other form of DNA damage might accrue. Any one cell uses only a small fraction of the 30,000 or more genes encoded in a person's DNA. A skin cell uses the genes it needs to function as a skin cell; a liver cell uses some of the same genes and some different genes. A skin cell could function perfectly well as a skin cell in spite of a crucial mutation in a gene vital to, for example, liver function. A cloned fetus produced from such a cell might not be able to produce a functioning liver and therefore would die. Such mutations might render certain somatic cells incapable of directing full and normal development.

Questions of telomere shortening and cellular senescence are also important and unresolved.[8] Telomeres are the ends of chromosomes that shorten each time a cell divides and that therefore represent a log of the functional age of a somatic cell. There is a lower limit to the size of telomeres that is compatible with cell life, and therefore adult cells that have undergone many rounds of replication during the life of an animal have fewer additional divisions still available to them - they are "aged cells." Germ cells and cancer cells seem to evade this problem of cellular aging because they possess an active telomerase enzyme, which repairs and re-elongates the chromosome ends. In the case of the use of an adult, presumably "aged" somatic cell for nuclear transfer and cloning, it is not certain at present what effect such telomere shortening of the chromosome in the donor nuclei might have on the longevity of the resulting animal following nuclear transfer. Conflicting evidence has been presented with respect to the length of the telomeres in Dolly's cells and it is not yet established whether or not Dolly is aging at a rate different from other sheep her birth-defined age. Yanagamachi's group has serially cloned mice for up to six generations by using somatic cell nuclei from cloned mice as the donors in subsequent rounds of embryo transfer experiments.[9] This might suggest that telomere shortening will not be a problem, but the normal lifespan of a mouse is only two years, and the scientists did encounter progressive difficulty in creating clones with each succeeding generation.

A final scientific issue, very poorly understood at present, has to do with precisely what is occurring during the so-call reprogramming process when the somatic cell nucleus is first placed inside an egg's cytoplasm. Normal reprogramming occurs within sperm and egg and takes place over a prolonged period of time. Because cell division is usually triggered shortly after nuclear transfer, in such systems there is a very short period of time in which reprogramming may occur. This may result in incomplete reprogramming in some instances.

Work carried out to date in the various animals that have been the subjects of reproductive cloning experiments suggests that there are important species differences in procedures and outcomes among them. This will be vital to keep in mind before any human cloning attempts might be made. Furthermore, the efficiency of obtaining healthy live born clones is very low (on the order of 1% of attempts implanted) in essentially every species that has been studied to date. Many of the embryos die early in development and others progress to later stages of gestation, but often demonstrate severe defects incompatible with further normal development and life. A significant number of nuclear transfer cloned animals have died in early infancy of either respiratory problems or overwhelming infections. And, in some species, such as cattle, the newborns that result from such pregnancies are larger than normal, giving rise to the so-called large calf syndrome.[10] Finally, and quite disturbingly, more recent work suggests that some animals that appear normal at birth may have significant health issues later in life including the sudden onset of obesity without apparent increase in caloric intake, although other work on cloned cattle indicates that those who appear normal at birth remain normal as they age.

4. Non-Reproductive or Therapeutic Cloning

In addition to the reproductive potential for human cloning, a number of other applications have been described under the general headings of "non-reproductive" or "therapeutic" cloning. These methods would not be intended to produce living, fully developed human beings, but rather to provide a source of what have come to be called embryonic "stem cells" for the cellular treatment of human diseases that otherwise cannot be treated effectively by established drug- or cell-based methods. These embryonic "stem" cells are found only in the early human and other mammalian embryos or in particular locations in the early fetus. They are called "stem cells" because they have a potential to develop into any and all types of cells that are found in a fully developed human or other mammalian organism. Embryonic stem cells from mice were isolated more than a decade ago; human embryonic stem cells were only isolated in 1998. A full discussion of the science of stem cells is beyond the scope of this report. A brief summary follows; one clear and useful reference is a primer on stem cells issued by the Office of the Director of NIH in May 2000.

As a result of extensive studies in other mammals, especially the mouse, researchers believe that only these embryonic stem cells are "pluripotent;" that is, they have been shown to be able to differentiate into all cell types in the adult animal. In the mouse system, such cells can, entirely on their own, develop into all cell types found in a fully developed and normal mouse after they are placed into the properly supportive location in a mouse embryo. Since by most current methods they require such support, they are usually termed "pluripotent" rather than "totipotent." Totipotent would indicate that they can, without help, develop into a fully mature mouse. While some experiments have suggested that these cells may, in fact, turn out to be totipotent, most researchers still consider that as unproven and therefore prefer the term "pluripotent" to describe the embryonic stem cells.

These embryonic stem cells have exciting therapeutic potential because, when they are exposed in the laboratory to one or another of the many known kinds of "growth factors," they convert to more adult-like fully differentiated cells such as muscle cells, neurons, glandular cells and others. In the case of the mouse, when these manipulated stem cells are introduced into tissues in a fully developed mouse, they can become part of the tissue into which they have been introduced and take part in the normal structure and function of that tissue. It has therefore become possible to envision the use of "stem cells" to treat serious human disorders such as Parkinson's disease, muscular dystrophy, cancer, many forms of genetic disease and many other disorders. For example, "stem cells" derived from human embryos might be introduced into the brain of patients with Parkinson's disease to provide normal neurological functions that are damaged in the disease as the nerve cells degenerate. Similar use can be imagined to restore normal liver cells to patients with life-threatening liver damage, cardiac muscle cells to patients with heart damage, muscle cells to patients with muscular dystrophy, and so on.

Embryonic stem cells could be used without any human cloning in the sense used in this report. Nuclear transfer cloning may be attractive for stem cell use, however, because of its implications for a patient's immune system. If a patient received embryonic stem cells that had been grown into heart muscle cells, his immune system might recognize those cells as invaders and attack them. As a result, the attempted treatment might fail or might require expensive and dangerous suppression of the patient's immune system. It is plausible that the nucleus from one of the patient's own cells could provide the DNA for the stem cells. This might be done in one of two ways. First, doctors might create an embryonic clone of the patient, transferring the nucleus of one of his cells into an enucleated eggs. That pre-embryo would then be destroyed in order to

harvest stem cells from it. Alternatively, it might be possible to insert DNA from the patient into an already isolated embryonic stem cell. In either case, if effective the procedure would produce heart muscle cells with the patient's DNA. The patient's immune system would presumably consider these cells part of itself, and thus not attack them.

Research has identified other kinds of "stem cells" from the adult tissues in mammals. These cells have been called "adult stem cells" and have been identified in organs such as the bone marrow, the brain, liver, muscle and other tissues. These special cells are rare in each of these organs and their isolation is a difficult task. Some recent evidence indicates that some of these adult stem cells can, in some circumstances, be converted to other cell types when exposed to growth factors or when transplanted into new body environments. For instance, some researchers have found that the best known of these adult stem cell, those found in the bone marrow, can become muscle cells when introduced into adult muscle.

The recently discovered multipotent "stem"-like cells from many kinds of adult tissue can theoretically be used in the same way as embryonic stem cells. Human embryonic or fetal tissue may therefore not be required to isolate functional and therapeutic "stem cells" for the treatment of many human diseases. If adult stem cells from the patient can be used, the immune system problems should not arise. If the adult stem cells used come from another person, cloning by nuclear transfer might still be used to produce adult stem cells with the patient's DNA. At this stage, adult stem cells appear to be more difficult to maintain in culture and their ability to change may not be as unlimited as embryonic stem cells. Research in this area is still limited and much remains to be learned.

C. LEGAL BACKGROUND

The legal status of human cloning is complex and unclear.[1] Although many nations have banned human cloning, variously defined, it has not been banned by the federal government or by most states.

1. Regulation of Cloning by the Federal Government

Federal legislation on human cloning could have serious implications for regulation by California, possibly making it unnecessary or ineffective. Many bills have been introduced in Congress to regulate human cloning but, as of the date of this report, none has been enacted. These bills have had widely differing provisions and would have very different implications for cloning regulation by California.

The federal government has taken some action without new legislation. President Clinton issued an order barring any federal funding for research on human cloning. More significantly, in January 1998, in response to Congressional and public concern over the statement by Dr. Richard Seed that he would soon clone himself, the Food and Drug Administration (FDA) announced that it had regulatory jurisdiction over human cloning under existing federal statutes. This jurisdiction, it said, was the same as its jurisdiction over the use of "more than minimally manipulated" cells for treatment purposes, which includes such fields as gene therapy. The FDA stated that anyone seeking to do human cloning would need to get permission from the FDA for such experiments; it implied that, on the present state of knowledge, such permission would not be forthcoming.

It is not at all clear that the FDA does have jurisdiction over human reproductive cloning under existing statutes.[2] It has never asserted jurisdiction over similar assisted reproduction procedures even when they also involved "more than minimally manipulated" human cells, such

as zygotes that had been fertilized in vitro or through intracellular sperm injection. At least two published law review articles have concluded that it does not have jurisdiction over at least human reproductive cloning.[3, 4] For the FDA to have such jurisdiction, the cloned embryo would have to be, for purposes of the statutory definitions, a "product" that was being used for treatment of a disease or condition. Both conditions are questionable; the second is particularly problematic when reproductive cloning is not being used to overcome infertility but by a fertile couple or person for the purpose of having a child with a particular genotype. Ultimately, whether the FDA has jurisdiction would be a question for the courts; at this point, we know of no lawsuit challenging its authority.

Although the FDA's power over human reproductive cloning is uncertain, it does clearly have power over non-reproductive cloning when used as a treatment for human diseases or conditions. The use of cloned cells or tissues in such treatments would have to be approved by the FDA; experimentation with such cells or tissues in humans would also be governed by the agency.

Because it would probably require the creation of pre-embryos via cloning technology, non-reproductive cloning is affected by national rules on embryo research. This issue has been extremely controversial at the federal level with regard to federal funding for such research. A 1994 National Institutes of Health Human Embryo Research Panel would have allowed the use of human embryos for federally funded research, including, with specific limitations, the production of embryos for this purpose. The report was not adopted as policy by NIH. Congress, however, in 1996 banned "the creation of a human embryo and embryos for research purposes." The National Bioethics Advisory Commission issued its report, "Ethical Issues in Human Stem Cell Research," in January 2000. This was followed by release in August 2000 by NIH of its Guidelines for Research Involving Human Pluripotent Stem Cells. The guidelines allowed NIH funded investigators to conduct research on embryonic stem cells obtained from private services, provided the source is excess embryos produced to treat infertility that are donated without compensation. Federal funding for the creation of stem cells from abortions, their derivation from embryos, and the production of embryos to serve as sources of stem cells, either by sexual combination or by nuclear transfer for research, was prohibited.

These guidelines were in turn limited by President Bush's August 9, 2001 decision to allow federal funding for embryonic stem cell research only for cell lines established before the date of his announcement. This would prohibit federal funding for research with embryonic stem cells produced through cloning as no such cell lines existed on August 9, 2001.

It is important to note that these rules apply only to research that involves federal funds - privately funded research on non-reproductive cloning is not affected by these policies although it would, at some point, be regulated by the FDA. This limitation was highlighted by the work by Advanced Cell Technologies in using nuclear transfer technology and human eggs to produce what it called early embryos (although none grew to be larger than six cells in size.)

2. Regulation of Cloning by the States

In the first year after the announcement of Dolly's birth, more than half the state legislatures considered bills that would have banned human cloning. Only five states have, thus far, passed statutes prohibiting human cloning: California in 1997, Michigan and Rhode Island in 1998, Louisiana in 1999, and, most recently, Virginia in 2001. The California statute, the first one adopted, bans reproductive cloning for a period of five years. It does not deal with non-reproductive cloning, but is restricted to situations where a cloned embryo is implanted in a woman's uterus. The Rhode Island and Louisiana statutes were modeled generally on California's.

The Michigan statute is much different. It bans reproductive and non-reproductive cloning and contains no sunset date. Virginia's statute is similarly broad, banning completely the transfer of any human cell nucleus into oocytes. Several other states have passed legislation barring state funding for human cloning research or prohibiting such research at state institutions. It is not clear why more states have not acted. After an initial flurry of introduced bills, four states passed statutes by 1999 and only one since then. The FDA's assertion of jurisdiction in early 1998, along with the clearly early stage of the technology, may have made state action seem less important.

More than 20 states have laws banning or restricting research with human embryos. These laws were typically passed many years ago in response to concerns expressed largely by "pro-life" groups. These statutes could prohibit certain forms of non-reproductive cloning. They could also be construed to prohibit reproductive cloning at least at its early, experimental, and "research" stages. In an effort to avoid regulating in vitro fertilization and other forms of assisted reproduction, however, many of these statutes expressly state that they do not govern research that seeks to result in the birth of a living child.

3. Regulation of Cloning Outside the United States

Since the announcement of Dolly's birth, many countries have banned human cloning, and several international bodies-including the United Nations, the United Nations Educational, Social and Cultural Organization (UNESCO), the Council of Europe, the European Parliament, the G7 (the group of leading economic powers), and the World Health Assembly-have taken strong stands against the cloning of human beings.

In 1997 UNESCO adopted a Declaration on the Human Genome and Human Rights signed by 186 nations. Article 11 of the Declaration prohibits "practices which are contrary to human dignity, such as reproductive cloning of human beings." The Declaration is not binding and, in any event, the United States is not a member of UNESCO.

The most authoritative multilateral initiative banning human cloning is that of the Council of Europe, an organization made up of European governments but not part of the European Union. In 1998, it approved a protocol to its Convention on Human Rights and Dignity with Regard to Biomedicine. The protocol prohibits "any intervention seeking to create a human being genetically identical to another human being, whether living or dead." It was opened for signatures on 12 January 1998 in Paris. As of April 2001 it has been signed by 29 of the Council's 41 member states and has been ratified by six of these (Greece, Slovakia, Slovenia, Georgia, Spain, and most recently, Romania). Ratifying the Protocol commits the nation involved to implement it, but the Protocol is not self-enforcing; national legislation must be passed to make it effective. In a political compromise, the Protocol leaves up to member countries the definition of a human being. This is significant in that different nations might or might not define human beings in ways that include techniques for non-reproductive cloning.

Other countries that have passed national legislation restricting human reproductive cloning include Australia, Austria, Argentina, Belgium, Brazil, Costa Rica, Denmark, France, Germany, India, Israel, Italy, Japan, Mexico, the Netherlands, Norway, Peru, Portugal, Russia, South Africa, Sweden, Switzerland, Trinidad and Tobago, and the United Kingdom. All together, as of April 2001, 38 of the world's nearly 200 countries have banned human reproductive cloning.

We have not attempted to survey definitively laws and policies outside the United States on non-reproductive human cloning, but we have looked at some countries.

A Canadian Discussion Group on Embryo Research endorsed research on human embryos prior to 14 days after conception. They recommended a ban on "fertilization of human ova for research and research into human cloning chimeras, production of interspecies embryos and transgenic embryos." However, they also recommended a National Regulatory Body, which, subject to specific limitations, would be empowered to permit and regulate broad use of embryos in research.

In contrast the Human Genetics Advisory Committee and the Human Fertilization and Embryology Authority in the United Kingdom, while limiting research to embryos less than 14 days, would permit the direct production of embryos for research by nuclear transfer when done in licensed facilities.

The Deutsche Forschungsgemeinschaft (DFG), Germany's main research funding agency, issued guidelines that would allow research on imported human embryonic stem cells. The DFG also endorsed legislation, if needed, to allow use of surplus embryos produced in Germany to be used and to form a commission to study the ethics of public and private research involving embryos. This issue has been extremely controversial in Germany and remains, at this time, unresolved.

D. PUBLIC OPINION

Over the last four years polling in the United States has consistently shown that a large majority of Americans oppose reproductive human cloning. A poll taken by Time/CNN in February 2001 revealed that 90% of respondents think it is a bad idea to clone human beings. An April 2001 poll by the American Museum of Natural History concluded that 92% of Americans would not approve of cloning to reproduce a favorite person. These results are remarkably similar to polls taken four years earlier, shortly after the announcement of Dolly. For example, a February 1997 Time/CNN poll found that 93% of Americans opposed the cloning of humans. All polling results depend on the exact wording and approach of the poll, but it seems indisputable that human reproductive cloning is not popular in the United States. On the other hand, approximately two thirds of Americans support embryonic stem cell research, although there is no agreement on the source of the embryos.

In general, public opinion toward animal cloning is more positive than toward human cloning. However, the majority of Americans still oppose even animal cloning. For example, the 2001 Time/CNN poll showed that 67% believed it was a bad idea to clone animals such as sheep, and the 1997 Time/CNN poll showed that 66% opposed the cloning of animals.

II. CALIFORNIA SHOULD PROHIBIT HUMAN REPRODUCTIVE CLONING

RECOMMENDATION

The Committee unanimously agrees that California should ban human reproductive cloning. Many arguments support this position, some dealing with physical and psychological safety, some with ethical or social concerns and some with regulatory and political issues. We all believe, based on current knowledge on physical safety, that California should prohibit human reproductive cloning. Moreover, while not all members of the Committee were persuaded by the same set of arguments, most Committee members have concluded that some combination of the other arguments should also lead to prohibition of human reproductive cloning even if it were proven physically safe.

The Committee unanimously believes that human reproductive cloning should be prohibited. Every Committee member agrees that grave questions about the physical safety of the cloning process for any resulting children require a prohibition unless and until the method is proven safe. Most Committee members have concluded that some combination of the other arguments should also lead to prohibition of human reproductive cloning even if it were proven physically safe. The Committee has reached these conclusions after reviewing arguments in favor of human reproductive cloning as well as arguments against it. This section of our report discusses those arguments, looking first at the arguments for cloning and then at the arguments against cloning. Each argument is summarized with its counter-arguments. In almost all cases, this section of the report tries to lay out the different positions without choosing among them.

A. ARGUMENTS FAVORING HUMAN REPRODUCTIVE CLONING

The arguments made in favor of human reproductive cloning fall into two categories: an argument for reproductive liberty, as a normative and as a legal matter; and a series of examples of "good" uses of cloning, based primarily on the benefits of its use as a treatment for certain kinds of infertility.

1. Reproductive Liberty

One of the deepest consequences of the American belief in liberty is that whatever is not prohibited is permitted. Implicit in that approach is the idea that actions should not be prohibited without good reasons. This general preference for liberty has special resonance in the area of reproduction. Reproduction is an activity of profound importance both to the individual and to society. Its special significance lies in the fact that it generally commences with the intimacy of coitus and always culminates in the creation of a child who not only forges new relationships among individuals and between families, but also serves to perpetuate society. For this reason, some commentators, notably Professor John Robertson, argue that individuals should possess the freedom to choose whether or not to reproduce by means of somatic cell nuclear transfer cloning so long as their actions do not cause any harm to others or pose a threat to society. "Procreative liberty includes a strong presumptive right to have genetically related children noncoitally" and "cloning may provide a useful [noncoital] alternative, unless harmful." Of course, the Robertson test leaves open questions of the extent of the necessary harm or threat, to whom the harm or threat must be directed, and who should bear the burden of proof. Those opposed to a ban on human reproductive cloning argue that this reproductive method has not, or cannot, be shown to fail that test, at least in some circumstances.

This argument from reproductive liberty might be made not only as a general normative position but as a legal argument. Reproduction is not only a basic human urge, but it may also qualify as a fundamental liberty shielded from government intrusion by the Constitution. The Supreme Court has already found a fundamental right to avoid reproduction, whether by means of contraception or abortion. Some scholars infer a parallel fundamental right to reproduce with the assistance of new technologies, including somatic cell nuclear transfer cloning, an inference that is supported by broad language in a number of contraception and abortion cases. In striking down a statute prohibiting the distribution of contraceptives to unmarried persons, for example, the Supreme Court declared: "If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child." More recently, in reaffirming the right to an abortion in 1992, the Court explained that "[o]ur law affords constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing, and education."

One other Supreme Court precedent offers support for a fundamental right to procreate. In 1942 in Skinner v. Oklahoma, the Court invalidated a state statute that authorized the forcible sterilization of persons thrice convicted of a felony involving moral turpitude, declaring that "[m]arriage and procreation are fundamental to the very existence and survival of the race." But the Skinner decision is "indeterminate," and "may be read in several different ways, all of which are equally consistent with current constitutional doctrine." The Court's ruling was quite narrow: because the law permitted the sterilization of chicken thieves but not embezzlers, the Court determined that it discriminated against certain categories of criminals in violation of the Equal Protection Clause. Thus Skinner may not even establish a right to be free from compulsory sterilization, so long as the law is administered in a nondiscriminatory fashion. Moreover, compulsory sterilization laws implicate the same concerns regarding bodily integrity and social equality that animated the Court in the contraception and abortion decisions, thus they are distinguishable from laws regulating medically assisted reproduction.

At least one federal district court has interpreted these decisions to establish a constitutional right to beget children with the assistance of technology, including in vitro fertilization and embryo transfer using a donated embryo, based upon the following reasoning: "[I]t takes no great leap of logic to see that within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included within that cluster the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy."

The constitutional argument about human reproductive cloning is not frivolous, but neither is it powerful; it is not generally accepted by constitutional scholars. The proponents of cloning support it as an issue of unwarranted restriction of reproductive freedom. However, it can be argued that the freedom to reproduce should not encompass human reproductive cloning because it lacks the essential elements that give reproduction meaning; it is neither coital nor collaborative, and it does not involve the random recombination of genes to create a child with a new and unique genetic identity. Although human productive cloning may ultimately serve the same function as other modes of reproduction by bringing into being a child, opponents argue that it is radically different because it results in genetic duplication-the replication of existing human beings. On this view, cloning should be classified as "replication" rather than "reproduction."

The supporters of human reproductive cloning cited the constitutional protection of procreative decisions and methods as justifying cloning. However, one reproductive right, i.e., human reproductive cloning, does not necessarily follow from others, i.e., contraception, abortion. The Supreme Court relied heavily upon two factors in the contraception and abortion cases that are conspicuously missing from the cloning context. Because pregnancy entails a massive invasion and occupation of a woman's body, constitutional protection for the right to avoid reproduction is essential both to safeguard bodily autonomy and to ensure gender equality. But these precedents erect no constitutional barrier to a ban upon human reproductive cloning, which neither results in invasion of the integrity of the body nor endangers women's equality. Thus, the contraception and abortion cases cannot be read to guarantee a constitutional right to create a child with the assistance of technology.

Even if there were a fundamental constitutional right to reproduce, such a right might not encompass human reproductive cloning. On the one hand, some argue that cloning is clearly procreative to the extent that it is used "to bear and beget a child." Indeed, if procreation is important because it involves the passing on of one's genes, one scholar suggests that "in comparison with the parent who contributes half of the sexually reproduced child's genetic formula, the clonist is conferred with more than the requisite degree of biological parenthood,

since he is the sole genetic parent." Under this view, cloning appears to merit at least the same degree of constitutional protection as other assisted reproductive technologies. On the other hand, the Supreme Court has generally looked to history and tradition to determine the contours of constitutional protection. As a matter of history and tradition, sexual reproduction seems to fall within "the private realm of family life which the state cannot enter." Yet such an approach would probably afford little protection to human reproductive cloning, which is radically different from other technologies that serve as a substitute for reproduction by sexual intercourse because it is not sexual reproduction - it does not involve sperm and eggs.

If human reproductive cloning were deemed a fundamental right under the U.S. Constitution, any state or federal laws regulating or prohibiting cloning would be subject to the strictest scrutiny of the judicial system. Governments could restrict cloning only for compelling reasons, and any regulations would need to be narrowly tailored so as not to infringe unnecessarily upon individual rights. As a matter of existing federal constitutional law, however, the argument for a right to human reproductive cloning seems weak. The Supreme Court has never held that there is an affirmative right to reproduce that is free from government regulation. Indeed, the power of the Food and Drug Administration to regulate the safety of contraceptives and abortifacients and of states to make reasonable safety-based regulations for abortions seem well-established. The California Constitution provides residents of California another source of rights, including an express right to privacy, but, like the U.S. Supreme Court, California's courts have never held that there is a state constitutional right to be free from all regulation of reproductive methods. It seems very unlikely that either the U.S. Supreme Court or the California Supreme Court would rule human reproductive cloning to be a fundamental right or liberty interest. Thus, reasonable regulation of human reproductive cloning, including a ban, would likely be upheld as constitutional if government could show a rational basis for its policy.

2. Examples of "Good" Human Reproductive Cloning

Discussion of human reproductive cloning has often focused on evil or frivolous uses of cloning such as to create clones of Adolph Hitler, of superior warriors, of excellent athletes, or of rich egomaniacs. Supporters of human reproductive cloning have responded by pointing out that, in the real world, cloning may serve compelling human needs. They have drawn attention to more sympathetic possible uses of the process. Three examples are commonly used: human reproductive cloning as a treatment for certain kinds of infertility, as a way of producing transplantable tissue (typically bone marrow) to save another life, and as a way of coping with the grief of a loved one's death. Some advocates for human reproductive cloning have argued that cloning should be limited to only certain approved uses. No one proposed to the Committee a detailed plan for selecting the approved uses of cloning or the approved parents, but at least two witnesses before the Committee, Professors John Robertson and Glenn McGee, argued that cloning should only be allowed for parents with some set of "good reasons." We discuss below three arguably "good reasons."

a. Human Reproductive Cloning to Treat Infertility

Cloning could provide an innovative method to treat the problem of infertility. Assisted reproductive technologies can help many infertile couples, but people who do not produce viable gametes - eggs or sperm - cannot produce children who are genetically "their own." A couple where one member is infertile from such a cause currently must turn to an egg or sperm donor in order to create a child who is biologically connected to at least one prospective parent. But human reproductive cloning affords the power to produce a child with a genetic connection to at least one parent, while simultaneously keeping the couple's relationship free of the ghost of such third