Background

Dolly triggers human cloning debate

Overall debate includes stem cell research

Embryonic stem cells: After the egg divides for several days, it produces embryonic stem cells, that are **not yet fate determined and hence each type of cell, tissue possible** further **they divide indefinitely** (as opposed to adult stem cells). Note: egg cells never fertilized by sperm.

"Research/Therapeutic Cloning Vs. Reproductive Cloning. Depends on end use of nuclear transplantation procedure.

Presently, work on excess embryos from fertility treatments

Some believe, that if cells used for tissue transplants, therapeutic cloned tissues with same genetic makeup of patient **would reduce/eliminate the risk of immune rejection.**

Legislation

In July 2001, the House of Representatives passed **Weldon-Stupak:** criminalizes nuclear transplantation in humans, whether for reproductive or research purposes. In Senate, was introduced as **Brownback-Landrieu** bill; endorsed by President Bush.

Many science groups back **Specter-Feinstein**, which would prohibit reproductive cloning but allow nuclear transplantation research to go forward. Criminal penalties for uterus implantation of clone zygote.

The current federal bill to allow human cloning for research purposes (S. 303) mandates the destruction of cloned embryos when they are 14 days old. However, biotechnology interests in many states have already dropped this arbitrary time limit to support broader proposals.

The US Food and Drug Administration (FDA) has claimed jurisdiction over human cloning, but is mandated by law to consider only safety and efficacy, and not to consider social, political, or moral issues.

Differences between two bills **BL**, **SF**: Both ban human cloning.

Definition of human cloning. BL: transfer of nuclear material from one or more somatic cells into a fertilized/unfertilized nuclear oocyte whose nuclear material has been inactivated or removed. SF: transfer of product of nuclear transplantation to uterus.

Importing. BL: Limits importation of any product produced or derived from human cloning (as defined by BL). SF: much narrower; limits the same only if for the purpose of human cloning (as defined by SF).

Penalties. Essentially the same. Criminal up to 10 years, civil up to \$1million or two times the pecuniary gain resulting from the violation. SF adds forfeiture.

Ethical Requirements. SF: adds ethical requirements for the Nuclear Transplantation research: informed consent, institutional review board, protection for safety and privacy. BF: no such thing

Scientific Medical Research. BL allows for all cloning except that results in a human embryo or human.

Report. BL: GAO will present report 4 years after enactment of the bill to review amendments. SF: no such thing.

Internationally

As of March 2002 approximately 33 countries have formally banned human cloning. This represents only 16% of all countries and less than one-third of the world's population. Some European countries, notably France, Germany, and Switzerland, explicitly ban the creation of clonal embryos. In January 2001 the United Kingdom authorized the creation of clonal embryos for medical research. Sweden, China and Israel has also declared that they are not opposed to the creation of clonal embryos for research. There is pressure in the United States, Germany and elsewhere from the biomedical and biotechnology community to allow this as well.

Positions against nuclear transplantation research (NTR)

Religious conservatives: embryos should have the same **status as human beings**. Research cloning could **open the door** to reproductive cloning.

Coalition of Environmental, Women's Health, and Bioethics Groups. Not wholly opposed to NTR; concerned about "open door". Would rather wait till strict regulations in place before permitting NTR.

Positions for NTR

Coalition of science organizations, patient groups, and the biotechnology industry:

Support ban on reproductive cloning **that would permit** nuclear transplantation research

Moral status of a human embryo is less than that of a full human being **Must be weighed against the potential cures** from research using nuclear transplantation.

Contend that a ban on implantation on the product of nuclear transplantation would be **no more difficult to enforce** than a ban on nuclear transplantation itself

Criminalizing scientific research, done only very rarely in the past, sets a bad precedent.

Anti-NTR Organization Positions:

The Americans to Ban Cloning (ABC) coalition. "Group of concerned Americans and U.S. based organizations that promote a global, comprehensive ban on human cloning." Working on passing S. 245, the Human Cloning Prohibition Act of 2003 (Brownback-Landrieu).

Reasons:

exploits women who donate eggs (poor woman monetary benefits, ovarian cancers risks)

funding cloning is irresponsible as more promising research from adult stem cells rather than embryonic stem cells

cloning is high tech slavery, cloning would poison human community in the US with a class of humans being regarded as objects and property and then this would spread

therapeutic cloning necessitates the killing of the human embryo and thus violates the Nuremberg Code that no medical experimentation will a priori destroy or disable human life,

not an issue of compassion for sick/disabled as alternative adult stem cell therapy available, not against scientific research but against amoral research

Brownback Landrieu (BL) permits cloning of cells, tissues, DNA but not human embryos

Alternatives to BL would require killing of embryo, BL is prudent: can private industry decide the future of humanity?

Family Research Council: "Believing that God is the author of life, liberty, and the family, we promote the Judeo-Christian worldview as the basis for a just, free, and stable society." American Renewal is the legislative arm.

Similar arguments, in addition: only a complete ban is enforceable, redefinition of 'poisoning' as violation of American Principle of Equality, only ban on cloning enforceable, reproductive cloning damages family relationships, good science is ethical science, most Americans and countries support a ban on cloning.

National Right to Life: Founded in 1973, in response to SC decision on Roe vs. Wade. The ultimate goal of the National Right to Life Committee is to restore legal protection to innocent human life. The primary interest of the National Right to Life Committee and its members has been the abortion controversy; however, it is also concerned with related matters of medical ethics which relate to the right to life issues of euthanasia and infanticide. The Committee does not have a position on issues such as contraception, sex education, capital punishment, and national defense.

Similar arguments: in addition concern for the sale of human embryos as "medical models" by biotechnology industry, criticize 14 day rule and cite Justice Department's concern that monitoring life of embryo by agencies is unenforceable.

U.S. Conference of Catholic Bishops: main argument is that egg fertilization (IVF), embryos destruction is not Christian and a sin.

Moratorium on NTR:

Our Bodies Ourselves (OBOS), founded in, also known as the Boston Women's Health Book Collective (BWHBC), is a nonprofit, public interest women's health education, advocacy, and consulting organization.

Calls for a moratorium of 5 years on embryonic cloning for research purposes (ban or reproductive cloning), as it believes it's the most "prudent" thing to do. Time would allow for better study of embryonic stem cell research and work out the thorny issues of embryonic stem cell behavior and its use while meanwhile further investigation can be done into alternative approaches to immune system rejection. Further, cites concerns for a resurgence of a eugenics movement of genetic modification. Concerns for cloning also revolve around fears of the dangers of unethical mass experimentation with women and children, risks of use of super-ovulation drugs, moratorium would not halt scientific progress, time would allow for proper debate and the set up of adequate regulatory mechanisms.

Center for Genetics and Society. Similar arguments as expressed by OBOS.

Friend of the Earth: similar to CGS and OBOS. Specifically, calls for federal oversight and regulatory mechanisms for laboratories and research institutes in embryonic cloning for research purposes. Is concerned about "genetic pollution". Does not specifically moratorium for further scientific investigation.

International Center for Technology Assessment. Outside of religious statements, very similar to arguments presented by the Anti-NTR lobby. Explicitly against the Specter-Feinstein-Kennedy Bill.

Pro-NTR Positions

Coalition for the Advancement Medical Research. is comprised of nationally-recognized patient organizations, universities, scientific societies, foundations, and individuals with life-threatening illnesses and disorders, advocating for the advancement of breakthrough research and technologies in regenerative medicine

Advocacy Ensuring that somatic cell nuclear transfer (SCNT), also known as therapeutic cloning, remains a legal and viable form of scientific research, and opposing any effort that would allow reproductive cloning. Against a moratorium as that would prevent important scientific breakthroughs, stigmatize the research and the regulatory mechanisms are already in place under FDA.

Reasons: suffering of millions could end, federal funding would for more responsibility than private funding, clinics now destroy embryonic excess stem cells, public opinion strong favors embryonic stem cell research.

American Society for Cell Biology

Supports ban on reproductive cloning but points out that technology is far away. "Unfortunately, an onerous cloud has been cast on the term cloning because it has been used in the public discourse both to refer to attempts to create genetically identical adult humans and to describe other procedures that are less controversial." Further, states that cloning is a scientific term that describes the preparation of an infinite number of copies of, for example a single molecule, cell, virus or bacterium. Cloning of different biological entities required for genome sequence, fighting bioterrorism, forensic procedures, medical diagnostics, vaccine development, discovery of drugs and agricultural breakthroughs.

Nobel Laureates

Brownback bill prevents the importation into the United States of medical treatments developed in other parts of the world using nuclear transplantation. It seems unbelievable that the United States Senate would deny advanced medical treatment to millions of suffering Americans because of an aversion to a technology that was used in its development.

By declaring scientifically valuable biomedical research illegal, Senator Brownback's legislation, if it becomes law, would have a chilling effect on all scientific research in the United States. Such legal restrictions on scientific investigation would also send a strong signal to the next generation of researchers that unfettered and responsible scientific investigation is not welcome in the United States.

We, the undersigned, urge that legislation to impose criminal and civil sanctions against attempts to create a cloned human being be enacted.

AAMC. The Association of American Medical Colleges is a non-profit association founded in 1876 to work for reform in medical education. Originally representing only medical schools, the AAMC represents the nation's 126 accredited medical schools, nearly 400 major teaching hospitals, more than 105,000 faculty in 98 academic and scientific societies, and the nation's 66,000 medical students and 97,000 residents.

Similar arguments to CAMR. Additionally, also strongly opposes the amendment offered by Senator Sam Brownback (S.A. 3843) to S. 2600, the Terrorism Risk Insurance Act. This amendment is a "back door" effort to impose a prohibition on somatic cell nuclear transfer research, also know as nuclear transplantation or therapeutic cloning. The amendment is both unnecessary and unwise. The amendment would prevent patenting of the process of human cloning.

AAU. The Association of American Universities (AAU) was founded in 1900 by a group of fourteen universities offering the Ph.D. degree. The AAU currently consists of sixty American universities and two Canadian universities.

Similar to AMC, CAMR.

CuresNow. CuresNow is a coalition of scientists, patient groups and leaders of the entertainment business and religious community that have joined together to support science. It also includes leaders in the scientific, health, education, business and entertainment communities.

While CuresNow vehemently opposes reproductive cloning, it strongly supports therapeutic cloning

Federation of American Societies for Experimental Biology. Comprised of 22 societies and 66,000 members, making it the largest coalition of biomedical research associations in the United States.

Self-imposed moratorium presently for **human reproductive cloning** (extended for 5 years in Feb) and supports ban. Supports NTR, SCTN under strict ethical oversight. Agrees with National Academies in recommending that vital stem cell research move forward.

Will endless sources of eggs from women be required to develop this technology?

Eggs contain special factors to "reprogram" the genes in the nucleus so that the resulting cells are undifferentiated and totipotent, meaning that they can become virtually any cell type. As we learn more about control of genes and this process of reprogramming, alternative methods of creating cell lines to replace or correct defective tissues will be available.

Biotechnology Industry Organization. Same as above, but:

However, the cells currently available to researchers are insufficient because:

They do not allow full investigation of the genetic causes of disease. For example, scientists need to create new cells that actually contain genetic diseases in order to study how these diseases affect the growth and development of other cells and tissue

They are not sufficiently racially or ethnically diverse. Certain diseases are more prevalent in people of particular races (such as sickle cell disease). By creating new stem cells from people of specific races, scientists could help unravel the causes of these diseases. An Institute of Medicine study from 2002 noted that the fewer cell lines that are available to researchers, the lower the genetic diversity they represent.

Scientists need more cell lines to fulfill the promise of stem cell research.

The Franklin Society is a non-partisan group of individuals who support the American tradition of free scientific inquiry and technological innovation in the pursuit of knowledge and the betterment of human life.

Concerns: black market for therapies, force ill Americans to be exiled, force biomedical research to take place outside the US, criminalization of scientists or patients for medical therapies sets dangerous precedent, the BF bill is neither necessary nor sufficient to stop reproductive cloning (which is the creation of babies in utero, rather than cells in vitro). The people trying to clone babies are not reputable American biologists—the people the Brownback-Landrieu bill is aimed at—but rogue fertility doctors working outside the United States.

Union Of Orthodox Jewish Congregations Of America Rabbinical Council Of America

Largest Orthodox Jewish synagogue umbrella organization and Orthodox Jewish rabbinical organization

The potential to save and heal human lives is an integral part of valuing human life from the traditional Jewish perspective. Moreover, our rabbinic authorities inform us that an isolated fertilized egg does not enjoy the full status of person-hood and its attendant protections. Thus, if embryonic stem cell research can help us preserve and heal humans with greater success, and does not require or encourage the destruction of life in the process, it ought to be pursued. Support a rigorous ethical oversight for all NTR/SCTN. Humanity begins only post 40 days. Not human (as equal to mother) till head is delivered.