HUMAN CLONING

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIME

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

ON

H.R. 1644 and H.R. 2172

JUNE 7 AND JUNE 19, 2001

Serial No. 40

Printed for the use of the Committee on the Judiciary

Available via the World Wide Web: http://www.house.gov/judiciary

U.S. GOVERNMENT PRINTING OFFICE

72–982 PDF WASHINGTON : 2001

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON THE JUDICIARY

F. JAMES SENSENBRENNER, JR., WISCONSIN, *Chairman*

HENRY J. HYDE, Illinois
GEORGE W. GEKAS, Pennsylvania
HOWARD COBLE, North Carolina
LAMAR SMITH, Texas
ELTON GALLEGLY, California
BOB GOODLATTE, Virginia
STEVE CHABOT, Ohio
BOB BARR, Georgia
WILLIAM L. JENKINS, Tennessee
ASA HUTCHINSON, Arkansas
CHRIS CANNON, Utah
LINDSEY O. GRAHAM, South Carolina
SPENCER BACHUS, Alabama
JOE SCARBOROUGH, Florida
JOHN N. HOSTETTLER, Indiana
MARK GREEN, Wisconsin
RIC KELLER, Florida
DARRELL E. ISSA, California
MELISSA A. HART, Pennsylvania
JEFF FLAKE, Arizona

JOHN CONYERS, JR., Michigan
BARNEY FRANK, Massachusetts
HOWARD L. BERMAN, California
RICK BOUCHER, Virginia
JERROLD NADLER, New York
ROBERT C. SCOTT, Virginia
MELVIN L. WATT, North Carolina
ZOE LOFGREN, California
SHEILA JACKSON LEE, Texas
MAXINE WATERS, California
MARTIN T. MEEHAN, Massachusetts
WILLIAM D. DELAHUNT, Massachusetts
ROBERT WEXLER, Florida
TAMMY BALDWIN, Wisconsin
ANTHONY D. WEINER, New York
ADAM B. SCHIFF, California

PHILIP G. KIKO, *Chief of Staff-General Counsel*
JULIAN EPSTEIN, *Minority Chief Counsel and Staff Director*

SUBCOMMITTEE ON CRIME

LAMAR SMITH, Texas, *Chairman*

MARK GREEN, Wisconsin
HOWARD COBLE, North Carolina
BOB GOODLATTE, Virginia
STEVE CHABOT, Ohio
BOB BARR, Georgia
ASA HUTCHINSON, Arkansas,
Vice Chair
RIC KELLER, Florida

ROBERT C. SCOTT, Virginia
SHEILA JACKSON LEE, Texas
MARTIN T. MEEHAN, Massachusetts
WILLIAM D. DELAHUNT, Massachusetts
ADAM B. SCHIFF, California

JAY APPERSON, *Chief Counsel*
SEAN MCLAUGHLIN, *Counsel*
ELIZABETH SOKUL, *Counsel*
BOBBY VASSAR, *Minority Counsel*

CONTENTS

HEARING DATES

	Page
June 7, 2001	
HUMAN CLONING	1
June 19, 2001	
HUMAN CLONING PROHIBITION ACT OF 2001 AND THE CLONING PROHIBITION ACT OF 2001	41

June 7, 2001

OPENING STATEMENTS

The Honorable Lamar Smith, a Representative in Congress From the State of Texas, and Chairman, Subcommittee on Crime	1
The Honorable Ric Keller, a Representative in Congress From the State of Florida	2

WITNESSES

Mr. Leon Kass, Professor of Bioethics, The University of Chicago	
Oral Testimony	2
Prepared Statement	4
Mr. Daniel Callahan, Director of International Programs, Hasting Center, Garrison, NY	
Oral Testimony	18
Prepared Statement	19
Mr. David A. Prentice, Ph.D., Professor of Life Sciences, Indiana State University	
Oral Testimony	22
Prepared Statement	23
Mr. Robyn S. Shapiro, Professor of Bioethics, Medical College of Wisconsin	
Oral Testimony	30
Prepared Statement	32

June 19, 2001

OPENING STATEMENTS

The Honorable Lamar Smith, a Representative in Congress From the State of Texas, and Chairman, Subcommittee on Crime	41
The Honorable Adam B. Schiff, a Representative in Congress From the State of California	42

WITNESSES

Mr. Alex Capron, Professor of Law and Medicine, University of Southern California School of Law, Los Angeles, CA	
Oral Testimony	44
Prepared Statement	46
Ms. Jean Bethke Elshtain, Professor of Social and Political Ethics, The University of Chicago, Chicago, IL	
Oral Testimony	51
Prepared Statement	53

Page

Mr. Gerard Bradley, Professor of Law, Notre Dame Law School, Notre Dame, IN
Oral Testimony 54
Prepared Statement 56
Dr. Thomas Okarma, President and CEO, Geron Corporation
Oral Testimony 61
Prepared Statement 63

APPENDIX

STATEMENTS SUBMITTED FOR THE RECORD

June 7, 2001

The Honorable Bob Barr, a Representative in Congress From the State of Georgia 81
The Honorable Sheila Jackson Lee, a Representative in Congress From the State of Texas 82

June 19, 2001

The Honorable Lamar Smith, a Representative in Congress From the State of Texas 83

MATERIAL SUBMITTED FOR THE RECORD

June 7, 2001

Post Hearing Questions and Answers from the Honorable Sheila Jackson Lee 84
George Will's Article From *The Washington Post* on "Human Cloning a Major Threat" dated, Monday, January 22, 2001 88

June 19, 2001

Letter From American Society for Reproductive Medicine 89
Letter From the Federation of American Societies for Experimental Biology ... 91
Newsletter from the United States Catholic Conference 92
Letter From National Bioethics Advisory Board 94

REFERENCE MATERIAL

Cloning Human Beings, Volume I, Report and Recommendations of the National Bioethics Advisory Commission, Rockville, MD, June 1997 95
Ethical Issues in Human Stem Cell Research, Volume I, Report and Recommendations of the National Bioethics Advisory Commission, Rockville, MD, September, 1999 95

HUMAN CLONING

THURSDAY, JUNE 7, 2001

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIME,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to notice, at 11 a.m., in Room 2237, Rayburn House Office Building, Hon. Lamar Smith [Chairman of the Subcommittee] presiding.

Mr. SMITH. The Subcommittee on Crime will come to order. We appreciate the great interest this hearing has attracted, and I want to say by way of an announcement at the outset that we do not expect any votes for the next hour, so we should be able to proceed uninterrupted. Also, I want to mention that the Ranking Member, Bobby Scott of Virginia, is in another Subcommittee meeting and will be late, otherwise we would be waiting for him before we started. We do appreciate the attendance of the gentleman from Florida, Mr. Rick Keller, and we expect other Members to join us shortly, as well. I am going to recognize myself for an opening statement and other Members, if they have opening statements, and then I will introduce the witnesses and we will proceed with our hearing.

Today the Subcommittee on Crime holds the first of two hearings on the issue of human cloning. We all recognize that biotechnology has enhanced our lives in many ways, and I am a strong supporter of it, but there are some lines that we should not cross. Our efforts to improve humanity should never devalue humanity. The theoretical ability to clone humans raises profound moral and ethical issues. Since reports indicate that scientists and physicians are soon planning to produce the first human clone, it is critical that Congress examine whether or not this type of experimentation should be allowed to proceed.

This hearing will focus on the ethical issues and the possible consequences of cloning human beings. The second hearing will examine the legal issues relating to Federal regulation of human cloning. The issue of human cloning came to the public's attention first when scientists announced they had successfully cloned Dolly, the sheep, in February 1997. A February, 2001 Time-CNN poll found that 90 percent of all Americans oppose cloning humans. The science of cloning has advanced rapidly since 1997. Scientists have successfully cloned monkeys, cattle, pigs, mice and other animals. Because of this, there are a growing number of groups who claim they can and will clone a human being.

We should not rush to prove what can happen until we first consider whether it should happen. How does the scientific community

define a successful cloning experiment? Scientists often downplay the fact that the cloning failure rate is extremely high. It took 277 stillborn, miscarried or dead sheep to make one Dolly. That failure rate has remained steady since 1997. Even if human cloning were ethically acceptable, it should not cost even one human life. The most celebrated cloning experiment failed 277 times before succeeding. The National Bioethics Advisory Commission has stated that such a failure rate is morally unacceptable.

What happens to those who survive? Attempts to clone human beings could carry massive risks of producing unhealthy, abnormal and malformed children. If scientists successfully create a Brave New World, will we lose our humanity along the way? Proponents of human cloning argue that the possible benefits for mankind outweigh the concerns. One of the issues that will be addressed today is whether or not there are alternative means available to obtain some of the medical benefits claimed for human cloning. Cloning arguably is a product of manufacturer, not the result of procreation.

The manufacture of human beings is a proposition that alarms an overwhelming majority of Americans. Today, we will hear from a panel of four witnesses who have extensive backgrounds in the field of bioethics, and I thank the witnesses in advance who are coming before the Subcommittee today and, certainly, we all look forward to your testimony. I will now recognize any other Member who has an opening statement. Does the gentleman from Florida have an opening statement?

Mr. KELLER. Thank you, Mr. Chairman. I would just like to take a few seconds to acknowledge and recognize and appreciate my colleague from Florida, Dr. Weldon, for his outstanding work in this area, also to thank the witnesses on both sides of the issue for coming and educating folks like me on this cutting-edge issue. I yield back, Mr. Chairman.

Mr. SMITH. Thank you, Mr. Keller. You were right to do so. I see our colleague, Dave Weldon, in the second row, and we appreciate his attendance here as well. Let me introduce the witnesses and we will proceed: Dr. Leon Kass, Professor of Bioethics at the University of Chicago; Dr. Daniel Callahan, Director of International Programs, Hastings Center, Garrison, New York; Dr. David Prentice, Professor of Life Scientists, Indiana State University; and Dr. Robyn S. Shapiro, Professor of Bioethics, Medical College of Wisconsin.

We welcome you all and we will begin with Dr. Kass.

STATEMENT OF LEON KASS, PROFESSOR OF BIOETHICS, THE UNIVERSITY OF CHICAGO

Dr. KASS. Thank you, Mr. Chairman and Members of the Committee. My name is Leon Kass and I have been, for over 30 years, concerned with the ethical implications of biomedical advance. Originally trained in medicine and biochemistry, I remain enthusiastic about biomedical research and its promise to cure disease and relieve suffering, yet it has been obvious for some time that new biotechnologies are providing powers to intervene in human bodies and minds in ways that threaten fundamental changes in human nature and in the meaning of our humanity.

These technologies have now brought us to a crucial fork in the road, where we are compelled to decide whether we wish to travel down the path that leads to the Brave New World, and that, and nothing less, I submit, is what is at stake in your current deliberations about what whether we should tolerate the practice of human cloning. I am here to testify in favor of a national ban on human cloning and, in particular, in favor of H.R. 1664, the Human Cloning Prohibition Act of 2001 for two reasons.

First, I believe that human cloning is unethical, both in itself and in what it surely leads to; and secondly, I believe that this bill offers us the best, indeed, the only reasonable chance of preventing human cloning from happening. The vast majority of Americans object to human cloning, and on multiple grounds. In my written testimony, I have outlined these. This is just the summary. It constitutes unethical experiments on the child to be, it threatens identity and individuality, it represents a giant step toward turning procreation into manufacture, especially when understood as the harbinger of genetic manipulations to come, legitimizing in advance the eugenic redesigning of our children according to our specifications. It is a radical form of parental despotism and of child abuse. Permitting human cloning means saying yes to the dangerous principle that we are entitled to determine and design the genetic makeup of our children.

If we do not wish to travel down this eugenic road, an effective ban on cloning human beings is needed and needed now before we are overtaken by events. The majority of Members in Congress, I believe, are, like most Americans, opposed to human cloning, but opposition is not enough. For if we do nothing about it, we shall have human cloning and we shall have it soon. Our failure to try to stop human cloning and by the most effective means will, in fact, constitute our tacit approval. What, then, is the most effective way to ban reproductive human cloning?

Two legislative bans competed with each other last time Congress considered this matter. One bill would have banned only so-called reproductive cloning by prohibiting the transfer of a cloned embryo to a woman to initiate the pregnancy. The other bill would have banned all cloning by prohibiting the creation even of the embryonic human clones. Both sides opposed reproductive cloning, but because of the divide over the question of embryo research, we got no ban at all. It would be tragic if we again failed to produce an effective ban on cloning human beings, especially now that certain people are going ahead with it and defying us to try to stop them.

A few years ago, I was looking for a middle way between the two alternatives that failed us last time. But, I am now convinced that we need an all-out ban on human cloning, including the creation of the embryonic human clones. I submit that anyone who is truly serious about preventing human reproductive cloning must seek to stop the process from the beginning, and here is why.

Once cloned embryos are produced and available in laboratories and assisted reproduction centers, it will be virtually impossible to control what is done with them. Stockpiles of cloned human embryos could be produced and bought and sold in the private sector without anybody knowing it. Efforts at clonal reproduction would take place out of sight, within the privacy of the doctor-patient re-

lationship, making outside scrutiny extremely difficult. Moreover, a ban on only reproductive cloning will turn out to be unenforceable. Should the illegal practice be detected, governmental attempts to enforce the reproductive ban would run into a swarm of practical and legal challenges, both to any efforts aimed at preventing transfer to the woman, and even worse, to efforts seeking to prevent birth after the transfer has occurred. Should an "illicit clonal pregnancy" be discovered, no Government agency is going to compel the woman to abort the clone, and there would be an understandable swarm of protest, should she be fined or jailed before she gives birth.

For all these reasons and others that I elaborate on in the written testimony, the only practically effective and legally-sound approach is to block human cloning at the start, at the production of the embryonic clone. Such a ban can be rightly characterized not as interference with reproductive freedom, nor even as an interference with scientific inquiry, but as an attempt to prevent the unhealthy, unsavory and unwelcome manufacture of and traffic in human clones.

The bill introduced by Dr. Weldon and his nearly 100 co-sponsors is, in my view, extremely carefully drafted, and its substantial criminal and monetary penalties will shift the incentives for renegades who are tempted to proceed. The bill makes very clear that there is to be no interference with the scientifically and medically useful practices of animal cloning or the cloning of human DNA fragments, somatic cells, or stem cells and tissue culture. Moreover, if enacted, this bill would bring the United States into line with the already, and soon to be enacted, practices of other nations. In collaboration with those efforts, it offers us the best and, I think, the only realistic chance we have of keeping human cloning from happening or happening much.

The issue of cloning is most emphatically not an issue of pro-life versus pro-choice. It is not mainly about death and destruction and it is not about a woman's right to choose. It is only and emphatically about baby design and manufacture, the opening skirmish of what will be a long battle against eugenics and against the posthuman future. Once the embryonic clones are produced in laboratories, the eugenic revolution will have begun and we will have lost our best chance to do anything about it and to assume responsible control over where biotechnology is taking us. The present danger posed by human cloning is, paradoxically, also a golden opportunity. The prospect of cloning, so repulsive to contemplate, is the occasion for deciding whether we shall be slaves of unregulated innovation and ultimately its artifacts or whether we shall remain free human beings who guide our medical powers toward the enhancement of human dignity. The humanity of our human future is now in our hands. Thank you.

[The prepared statement of Dr. Kass follows:]

PREPARED STATEMENT OF LEON R. KASS, M.D., PH.D.[1]

Mr. Chairman and Members of the Committee. My name is Leon Kass, and I am the Addie Clark Harding Professor in the Committee on Social Thought and the Col-

[1] Leon R. Kass, M.D., Ph.D. is the Addie Clark Harding Professor, The Committee on Social Thought and the College, The University of Chicago, and co-author (with James Q. Wilson) of

lege at the University of Chicago. Originally trained both as a physician and a biochemist, I have for more than thirty years been professionally concerned with the social and ethical implications of biomedical advance. In fact, my first writing in this area, in 1967, was on the moral dangers of human cloning. I am therefore very grateful for the opportunity to testify before this Committee on the ethics of human cloning and in support of HR 1644, the "Human Cloning Prohibition Act of 2001." And I am profoundly grateful to Rep. Weldon and the many co-sponsors of this bill for their vision in recognizing the momentous choice now before us and for their courage in stepping forward to protect us from what is surely a very great danger to the future of our humanity.

My testimony takes the form of an essay written precisely to gain support for such a bill. It has been published in the May 21, 2001 issue of The New Republic, under the title, "Preventing a Brave New World: Why We Should Ban Human Cloning Now." I begin by calling attention to what is humanly at stake in the decision about human cloning and also to the fact that we have here a golden opportunity to exercise deliberate human command over where biotechnology may be taking us. I argue that we stand now at a major fork in the road, compelled to decide whether we wish to travel down the path to the Brave New World, a path made possible by the genetic control of future generations. I next present four arguments against reproductive cloning of human beings: (1) it constitutes unethical experimentation on the child-to-be; (2) it threatens identity and individuality; (3) it is a giant step toward turning procreation into manufacture (especially when understood as the harbinger of genetic manipulations to come); and (4) it means despotism over children and perversion of parenthood. I conclude by arguing, on multiple grounds, that the only effective way to prevent reproductive cloning is to stop the process at the start, at the stage of creating the embryonic clones, just as is provided for in HR 1644, and I show the weaknesses of the other widely discussed alternative. Once embryonic clones are produced in laboratories, the eugenic revolution will have begun. And we shall have lost our best chance to do anything about it and to assume responsible control over where biotechnology is taking us. I heartily endorse HR 1644 not only because it offers our only real hope of preventing the cloning of human beings, but also because it will give us for the first time some control over those biotechnological powers that threaten to bring about a "post-human" future.

Here is the essay, in full. (I also provide a one-page summary)

PREVENTING A BRAVE NEW WORLD: WHY WE SHOULD BAN HUMAN CLONING NOW

BY LEON R. KASS

I.

The urgency of the great political struggles of the twentieth century, successfully waged against totalitarianisms first right and then left, seems to have blinded many people to a deeper and ultimately darker truth about the present age: all contemporary societies are travelling briskly in the same utopian direction. All are wedded to the modern technological project; all march eagerly to the drums of progress and fly proudly the banner of modern science; all sing loudly the Baconian anthem, "Conquer nature, relieve man's estate." Leading the triumphal procession is modern medicine, which is daily becoming ever more powerful in its battle against disease, decay, and death, thanks especially to astonishing achievements in biomedical science and technology—achievements for which we must surely be grateful.

Yet contemplating present and projected advances in genetic and reproductive technologies, in neuroscience and psychopharmacology, and in the development of artificial organs and computer-chip implants for human brains, we now clearly recognize new uses for biotechnical power that soar beyond the traditional medical goals of healing disease and relieving suffering. Human nature itself lies on the operating table, ready for alteration, for eugenic and psychic "enhancement," for wholesale re-design. In leading laboratories, academic and industrial, new creators are confidently amassing their powers and quietly honing their skills, while on the street their evangelists are zealously prophesying a post-human future. For anyone who cares about preserving our humanity, the time has come to pay attention.

Some transforming powers are already here. The Pill. In vitro fertilization. Bottled embryos. Surrogate wombs. Cloning. Genetic screening. Genetic manipulation. Organ harvesting. Mechanical spare parts. Chimeras. Brain implants. Ritalin for

---

The Ethics of Human Cloning. Mailing Address: The University of Chicago, 1116 E. 59th Street, Chicago, IL 60637. Telephone number: 773–702–8571. E-address: <lrk1@midway.uchicago.edu>.

the young, Viagra for the old, Prozac for everyone. And, to leave this vale of tears, a little extra morphine accompanied by Muzak.

Years ago Aldous Huxley saw it coming. In his charming but disturbing novel, *Brave New World* (it appeared in 1932 and is more powerful on each re-reading), he made its meaning strikingly visible for all to see. Unlike other frightening futuristic novels of the past century, such as Orwell's already dated *Nineteen Eighty-Four*, Huxley shows us a dystopia that goes with, rather than against, the human grain. Indeed, it is animated by our own most humane and progressive aspirations. Following those aspirations to their ultimate realization, Huxley enables us to recognize those less obvious but often more pernicious evils that are inextricably linked to the successful attainment of partial goods.

Huxley depicts human life seven centuries hence, living under the gentle hand of humanitarianism rendered fully competent by genetic manipulation, psychoactive drugs, hypnopaedia, and high-tech amusements. At long last, mankind has succeeded in eliminating disease, aggression, war, anxiety, suffering, guilt, envy, and grief. But this victory comes at the heavy price of homogenization, mediocrity, trivial pursuits, shallow attachments, debased tastes, spurious contentment, and souls without loves or longings. The Brave New World has achieved prosperity, community, stability, and nigh-universal contentment, only to be peopled by creatures of human shape but stunted humanity. They consume, fornicate, take "soma," enjoy "centrifugal bumble-puppy," and operate the machinery that makes it all possible. They do not read, write, think, love, or govern themselves. Art and science, virtue and religion, family and friendship are all passe. What matters most is bodily health and immediate gratification: "Never put off till tomorrow the fun you can have today." Brave New Man is so dehumanized that he does not even recognize what has been lost.

Huxley's novel, of course, is science fiction. Prozac is not yet Huxley's "soma"; cloning by nuclear transfer or splitting embryos is not exactly "Bokanovskification"; MTV and virtual-reality parlors are not quite the "feelies"; and our current safe and consequenceless sexual practices are not universally as loveless or as empty as those in the novel. But the kinships are disquieting, all the more so since our technologies of bio-psycho-engineering are still in their infancy, and in ways that make all too clear what they might look like in their full maturity. Moreover, the cultural changes that technology has already wrought among us should make us even more worried than Huxley would have us be.

In Huxley's novel, everything proceeds under the direction of an omnipotent—albeit benevolent—world state. Yet the dehumanization that he portrays does not really require despotism or external control. To the contrary, precisely because the society of the future will deliver exactly what we most want—health, safety, comfort, plenty, pleasure, peace of mind and length of days—we can reach the same humanly debased condition solely on the basis of free human choice. No need for World Controllers. Just give us the technological imperative, liberal democratic society, compassionate humanitarianism, moral pluralism, and free markets, and we can take ourselves to a Brave New World all by ourselves—and without even deliberately deciding to go. In case you had not noticed, the train has already left the station and is gathering speed, but no one seems to be in charge.

Some among us are delighted, of course, by this state of affairs: some scientists and biotechnologists, their entrepreneurial backers, and a cheering claque of sci-fi enthusiasts, futurologists, and libertarians. There are dreams to be realized, powers to be exercised, honors to be won, and money—big money—to be made. But many of us are worried, and not, as the proponents of the revolution self-servingly claim, because we are either ignorant of science or afraid of the unknown. To the contrary, we can see all too clearly where the train is headed, and we do not like the destination. We can distinguish cleverness about means from wisdom about ends, and we are loath to entrust the future of the race to those who cannot tell the difference. No friend of humanity cheers for a post-human future.

Yet for all our disquiet, we have until now done nothing to prevent it. We hide our heads in the sand because we enjoy the blessings that medicine keeps supplying, or we rationalize our inaction by declaring that human engineering is inevitable and we can do nothing about it. In either case, we are complicit in preparing for our own degradation, in some respects more to blame than the bio-zealots who, however misguided, are putting their money where their mouth is. Denial and despair, unattractive outlooks in any situation, become morally reprehensible when circumstances summon us to keep the world safe for human flourishing. Our immediate ancestors, taking up the challenge of their time, rose to the occasion and rescued the human future from the cruel dehumanizations of Nazi and Soviet tyranny. It is our more difficult task to find ways to preserve it from the soft dehumanizations of well-meaning but hubristic biotechnical "re-creationism"—and to do it with-

out undermining biomedical science or rejecting its genuine contributions to human welfare.

Truth be told, it will not be easy for us to do so, and we know it. But rising to the challenge requires recognizing the difficulties. For there are indeed many features of modern life that will conspire to frustrate efforts aimed at the human control of the biomedical project. First, we Americans believe in technological automatism: where we do not foolishly believe that all innovation is progress, we fatalistically believe that it is inevitable ("If it can be done, it will be done, like it or not"). Second, we believe in freedom: the freedom of scientists to inquire, the freedom of technologists to develop, the freedom of entrepreneurs to invest and to profit, the freedom of private citizens to make use of existing technologies to satisfy any and all personal desires, including the desire to reproduce by whatever means. Third, the biomedical enterprise occupies the moral high ground of compassionate humanitarianism, upholding the supreme values of modern life—cure disease, prolong life, relieve suffering—in competition with which other moral goods rarely stand a chance. ("What the public wants is not to be sick," says James Watson, "and if we help them not to be sick, they'll be on our side.")

There are still other obstacles. Our cultural pluralism and easygoing relativism make it difficult to reach consensus on what we should embrace and what we should oppose; and moral objections to this or that biomedical practice are often facilely dismissed as religious or sectarian. Many people are unwilling to pronounce judgments about what is good or bad, right and wrong, even in matters of great importance, even for themselves—never mind for others or for society as a whole. It does not help that the biomedical project is now deeply entangled with commerce: there are increasingly powerful economic interests in favor of going full steam ahead, and no economic interests in favor of going slow. Since we live in a democracy, moreover, we face political difficulties in gaining a consensus to direct our future, and we have almost no political experience in trying to curtail the development of any new biomedical technology. Finally, and perhaps most troubling, our views of the meaning of our humanity have been so transformed by the scientific-technological approach to the world that we are in danger of forgetting what we have to lose, humanly speaking.

But though the difficulties are real, our situation is far from hopeless. Regarding each of the aforementioned impediments, there is another side to the story. Though we love our gadgets and believe in progress, we have lost our innocence regarding technology. The environmental movement especially has alerted us to the unintended damage caused by unregulated technological advance, and has taught us how certain dangerous practices can be curbed. Though we favor freedom of inquiry, we recognize that experiments are deeds and not speeches, and we prohibit experimentation on human subjects without their consent, even when cures from disease might be had by unfettered research; and we limit so-called reproductive freedom by proscribing incest, polygamy, and the buying and selling of babies.

Although we esteem medical progress, biomedical institutions have ethics committees that judge research proposals on moral grounds, and, when necessary, uphold the primacy of human freedom and human dignity even over scientific discovery. Our moral pluralism notwithstanding, national commissions and review bodies have sometimes reached moral consensus to recommend limits on permissible scientific research and technological application. On the economic front, the patenting of genes and life forms and the rapid rise of genomic commerce have elicited strong concerns and criticisms, leading even former enthusiasts of the new biology to recoil from the impending commodification of human life. Though we lack political institutions experienced in setting limits on biomedical innovation, federal agencies years ago rejected the development of the plutonium-powered artificial heart, and we have nationally prohibited commercial traffic in organs for transplantation, even though a market would increase the needed supply. In recent years, several American states and many foreign countries have successfully taken political action, making certain practices illegal and placing others under moratoriums (the creation of human embryos solely for research; human germ-line genetic alteration). Most importantly, the majority of Americans are not yet so degraded or so cynical as to fail to be revolted by the society depicted in Huxley's novel. Though the obstacles to effective action are significant, they offer no excuse for resignation. Besides, it would be disgraceful to concede defeat even before we enter the fray.

Not the least of our difficulties in trying to exercise control over where biology is taking us is the fact that we do not get to decide, once and for all, for or against the destination of a post-human world. The scientific discoveries and the technical powers that will take us there come to us piecemeal, one at a time and seemingly independent from one another, each often attractively introduced as a measure that will "help [us] not to be sick." But sometimes we come to a clear fork in the road

where decision is possible, and where we know that our decision will make a world of difference—indeed, it will make a permanently different world. Fortunately, we stand now at the point of such a momentous decision. Events have conspired to provide us with a perfect opportunity to seize the initiative and to gain some control of the biotechnical project. I refer to the prospect of human cloning, a practice absolutely central to Huxley's fictional world. Indeed, creating and manipulating life in the laboratory is the gateway to a Brave New World, not only in fiction but also in fact.

"To clone or not to clone a human being" is no longer a fanciful question. Success in cloning sheep, and also cows, mice, pigs, and goats, makes it perfectly clear that a fateful decision is now at hand: whether we should welcome or even tolerate the cloning of human beings. If recent newspaper reports are to be believed, reputable scientists and physicians have announced their intention to produce the first human clone in the coming year. Their efforts may already be under way.

The media, gawking and titillating as is their wont, have been softening us up for this possibility by turning the bizarre into the familiar. In the four years since the birth of Dolly the cloned sheep, the tone of discussing the prospect of human cloning has gone from "Yuck" to "Oh?" to "Gee whiz" to "Why not?" The sentimentalizers, aided by leading bioethicists, have downplayed talk about eugenically cloning the beautiful and the brawny or the best and the brightest. They have taken instead to defending clonal reproduction for humanitarian or compassionate reasons: to treat infertility in people who are said to "have no other choice," to avoid the risk of severe genetic disease, to "replace" a child who has died. For the sake of these rare benefits, they would have us countenance the entire practice of human cloning, the consequences be damned.

But we dare not be complacent about what is at issue, for the stakes are very high. Human cloning, though partly continuous with previous reproductive technologies, is also something radically new in itself and in its easily foreseeable consequences—especially when coupled with powers for genetic "enhancement" and germline genetic modification that may soon become available, owing to the recently completed Human Genome Project. I exaggerate somewhat, but in the direction of the truth: we are compelled to decide nothing less than whether human procreation is going to remain human, whether children are going to be made to order rather than begotten, and whether we wish to say yes in principle to the road that leads to the dehumanized hell of *Brave New World*.

Four years ago I addressed this subject in these pages, trying to articulate the moral grounds of our repugnance at the prospect of human cloning ("The Wisdom of Repugnance," *TNR*, June 2, 1997). Subsequent events have only strengthened my conviction that cloning is a bad idea whose time should not come; but my emphasis this time is more practical. To be sure, I would still like to persuade undecided readers that cloning is a serious evil, but I am more interested in encouraging those who oppose human cloning but who think that we are impotent to prevent it, and in mobilizing them to support new and solid legislative efforts to stop it. In addition, I want readers who may worry less about cloning and more about the impending prospects of germline genetic manipulation or other eugenic practices to realize the unique practical opportunity that now presents itself to us.

For we have here a golden opportunity to exercise some control over where biology is taking us. The technology of cloning is discrete and well defined, and it requires considerable technical know-how and dexterity; we can therefore know by name many of the likely practitioners. The public demand for cloning is extremely low, and most people are decidedly against it. Nothing scientifically or medically important would be lost by banning clonal reproduction; alternative and non-objectionable means are available to obtain some of the most important medical benefits claimed for (non-reproductive) human cloning. The commercial interests in human cloning are, for now, quite limited; and the nations of the world are actively seeking to prevent it. Now may be as good a chance as we will ever have to get our hands on the wheel of the runaway train now headed for a post-human world and to steer it toward a more dignified human future.

II.

What is cloning? Cloning, or asexual reproduction, is the production of individuals who are genetically identical to an already existing individual. The procedure's name is fancy—"somatic cell nuclear transfer"—but its concept is simple. Take a mature but unfertilized egg; remove or deactivate its nucleus; introduce a nucleus obtained from a specialized (somatic) cell of an adult organism. Once the egg begins to divide, transfer the little embryo to a woman's uterus to initiate a pregnancy. Since almost all the hereditary material of a cell is contained within its nucleus,

the re-nucleated egg and the individual into which it develops are genetically identical to the organism that was the source of the transferred nucleus.

An unlimited number of genetically identical individuals—the group, as well as each of its members, is called "a clone"—could be produced by nuclear transfer. In principle, any person, male or female, newborn or adult, could be cloned, and in any quantity; and because stored cells can outlive their sources, one may even clone the dead. Since cloning requires no personal involvement on the part of the person whose genetic material is used, it could easily be used to reproduce living or deceased persons without their consent—a threat to reproductive freedom that has received relatively little attention.

Some possible misconceptions need to be avoided. Cloning is not Xeroxing: the clone of Bill Clinton, though his genetic double, would enter the world hairless, toothless, and peeing in his diapers, like any other human infant. But neither is cloning just like natural twinning: the cloned twin will be identical to an older, existing adult; and it will arise not by chance but by deliberate design; and its entire genetic makeup will be pre-selected by its parents and/or scientists. Moreover, the success rate of cloning, at least at first, will probably not be very high: the Scots transferred two hundred seventy-seven adult nuclei into sheep eggs, implanted twenty-nine clonal embryos, and achieved the birth of only one live lamb clone.

For this reason, among others, it is unlikely that, at least for now, the practice would be very popular; and there is little immediate worry of mass-scale production of multicopies. Still, for the tens of thousands of people who sustain more than three hundred assisted-reproduction clinics in the United States and already avail themselves of *in vitro* fertilization and other techniques, cloning would be an option with virtually no added fuss. Panos Zavos, the Kentucky reproduction specialist who has announced his plans to clone a child, claims that he has already received thousands of e-mailed requests from people eager to clone, despite the known risks of failure and damaged offspring. Should commercial interests develop in "nucleus-banking," as they have in sperm-banking and egg-harvesting; should famous athletes or other celebrities decide to market their DNA the way they now market their autographs and nearly everything else; should techniques of embryo and germline genetic testing and manipulation arrive as anticipated, increasing the use of laboratory assistance in order to obtain "better" babies—should all this come to pass, cloning, if it is permitted, could become more than a marginal practice simply on the basis of free reproductive choice.

What are we to think about this prospect? Nothing good. Indeed, most people are repelled by nearly all aspects of human cloning: the possibility of mass production of human beings, with large clones of look-alikes, compromised in their individuality; the idea of father-son or mother-daughter "twins"; the bizarre prospect of a woman bearing and rearing a genetic copy of herself, her spouse, or even her deceased father or mother; the grotesqueness of conceiving a child as an exact "replacement" for another who has died; the utilitarian creation of embryonic duplicates of oneself, to be frozen away or created when needed to provide homologous tissues or organs for transplantation; the narcissism of those who would clone themselves, and the arrogance of others who think they know who deserves to be cloned; the Frankensteinian hubris to create a human life and increasingly to control its destiny; men playing at being God. Almost no one finds any of the suggested reasons for human cloning compelling, and almost everyone anticipates its possible misuses and abuses. And the popular belief that human cloning cannot be prevented makes the prospect all the more revolting.

Revulsion is not an argument; and some of yesterday's repugnances are today calmly accepted—not always for the better. In some crucial cases, however, repugnance is the emotional expression of deep wisdom, beyond reason's power completely to articulate it. Can anyone really give an argument fully adequate to the horror that is father-daughter incest (even with consent), or bestiality, or the mutilation of a corpse, or the eating of human flesh, or the rape or murder of another human being? Would anybody's failure to give full rational justification for his revulsion at those practices make that revulsion ethically suspect?

I suggest that our repugnance at human cloning belongs in this category. We are repelled by the prospect of cloning human beings not because of the strangeness or the novelty of the undertaking, but because we intuit and we feel, immediately and without argument, the violation of things that we rightfully hold dear. We sense that cloning represents a profound defilement of our given nature as procreative beings, and of the social relations built on this natural ground. We also sense that cloning is a radical form of child abuse. In this age in which everything is held to be permissible so long as it is freely done, and in which our bodies are regarded as mere instruments of our autonomous rational will, repugnance may be the only

voice left that speaks up to defend the central core of our humanity. Shallow are the souls that have forgotten how to shudder.

III.

Yet repugnance need not stand naked before the bar of reason. The wisdom of our horror at human cloning can be at least partially articulated, even if this is finally one of those instances about which the heart has its reasons that reason cannot entirely know. I offer four objections to human cloning: that it constitutes unethical experimentation; that it threatens identity and individuality; that it turns procreation into manufacture (especially when understood as the harbinger of manipulations to come); and that it means despotism over children and perversion of parenthood. Please note: I speak only about so-called reproductive cloning, not about the creation of cloned embryos for research. The objections that may be raised against creating (or using) embryos for research are entirely independent of whether the research embryos are produced by cloning. What is radically distinct and radically new is reproductive cloning.

Any attempt to clone a human being would constitute an unethical experiment upon the resulting child-to-be. In all the animal experiments, fewer than two to three percent of all cloning attempts succeeded. Not only are there fetal deaths and stillborn infants, but many of the so-called "successes" are in fact failures. As has only recently become clear, there is a very high incidence of major disabilities and deformities in cloned animals that attain live birth. Cloned cows often have heart and lung problems; cloned mice later develop pathological obesity; other live-born cloned animals fail to reach normal developmental milestones.

The problem, scientists suggest, may lie in the fact that an egg with a new somatic nucleus must re-program itself in a matter of minutes or hours (whereas the nucleus of an unaltered egg has been prepared over months and years). There is thus a greatly increased likelihood of error in translating the genetic instructions, leading to developmental defects some of which will show themselves only much later. (Note also that these induced abnormalities may also affect the stem cells that scientists hope to harvest from cloned embryos. Lousy embryos, lousy stem cells.) Nearly all scientists now agree that attempts to clone human beings carry massive risks of producing unhealthy, abnormal, and malformed children. What are we to do with them? Shall we just discard the ones that fall short of expectations? Considered opinion is today nearly unanimous, even among scientists: attempts at human cloning are irresponsible and unethical. We cannot ethically even get to know whether or not human cloning is feasible.

If it were successful, cloning would create serious issues of identity and individuality. The clone may experience concerns about his distinctive identity not only because he will be, in genotype and in appearance, identical to another human being, but because he may also be twin to the person who is his "father" or his "mother"—if one can still call them that. Unaccountably, people treat as innocent the homey case of intra-familial cloning—the cloning of husband or wife (or single mother). They forget about the unique dangers of mixing the twin relation with the parent-child relation. (For this situation, the relation of contemporaneous twins is no precedent; yet even this less problematic situation teaches us how difficult it is to wrest independence from the being for whom one has the most powerful affinity.) Virtually no parent is going to be able to treat a clone of himself or herself as one treats a child generated by the lottery of sex. What will happen when the adolescent clone of Mommy becomes the spitting image of the woman with whom Daddy once fell in love? In case of divorce, will Mommy still love the clone of Daddy, even though she can no longer stand the sight of Daddy himself?

Most people think about cloning from the point of view of adults choosing to clone. Almost nobody thinks about what it would be like to be the cloned child. Surely his or her new life would constantly be scrutinized in relation to that of the older version. Even in the absence of unusual parental expectations for the clone—say, to live the same life, only without its errors—the child is likely to be ever a curiosity, ever a potential source of *déjà vu*. Unlike "normal" identical twins, a cloned individual—copied from whomever—will be saddled with a genotype that has already lived. He will not be fully a surprise to the world: people are likely always to compare his doings in life with those of his alter ego, especially if he is a clone of someone gifted or famous. True, his nurture and his circumstance will be different; genotype is not exactly destiny. But one must also expect parental efforts to shape this new life after the original—or at least to view the child with the original version always firmly in mind. For why else did they clone from the star basketball player, the mathematician, or the beauty queen—or even dear old Dad—in the first place?

Human cloning would also represent a giant step toward the transformation of begetting into making, of procreation into manufacture (literally, "handmade"), a process that has already begun with *in vitro* fertilization and genetic testing of embryos. With cloning, not only is the process in hand, but the total genetic blueprint of the cloned individual is selected and determined by the human artisans. To be sure, subsequent development is still according to natural processes; and the resulting children will be recognizably human. But we would be taking a major step into making man himself simply another one of the man-made things.

How does begetting differ from making? In natural procreation, human beings come together to give existence to another being that is formed exactly as we were, by what we are—living, hence perishable, hence aspiringly erotic, hence procreative human beings. But in clonal reproduction, and in the more advanced forms of manufacture to which it will lead, we give existence to a being not by what we are but by what we intend and design.

Let me be clear. The problem is not the mere intervention of technique, and the point is not that "nature knows best." The problem is that any child whose being, character, and capacities exist owing to human design does not stand on the same plane as its makers. As with any product of our making, no matter how excellent, the artificer stands above it, not as an equal but as a superior, transcending it by his will and creative prowess. In human cloning, scientists and prospective "parents" adopt a technocratic attitude toward human children: human children become their artifacts. Such an arrangement is profoundly dehumanizing, no matter how good the product.

Procreation dehumanized into manufacture is further degraded by commodification, a virtually inescapable result of allowing baby-making to proceed under the banner of commerce. Genetic and reproductive biotechnology companies are already growth industries, but they will soon go into commercial orbit now that the Human Genome Project has been completed. "Human eggs for sale" is already a big business, masquerading under the pretense of "donation." Newspaper advertisements on elite college campuses offer up to $50,000 for an egg "donor" tall enough to play women's basketball and with SAT scores high enough for admission to Stanford; and to nobody's surprise, at such prices there are many young coeds eager to help shoppers obtain the finest babies money can buy. (The egg and womb-renting entrepreneurs shamelessly proceed on the ancient, disgusting, misogynist premise that most women will give you access to their bodies, if the price is right.) Even before the capacity for human cloning is perfected, established companies will have invested in the harvesting of eggs from ovaries obtained at autopsy or through ovarian surgery, practiced embryonic genetic alteration, and initiated the stockpiling of prospective donor tissues. Through the rental of surrogate-womb services, and through the buying and selling of tissues and embryos priced according to the merit of the donor, the commodification of nascent human life will be unstoppable.

Finally, the practice of human cloning by nuclear transfer—like other anticipated forms of genetically engineering the next generation—would enshrine and aggravate a profound misunderstanding of the meaning of having children and of the parent-child relationship. When a couple normally chooses to procreate, the partners are saying yes to the emergence of new life in its novelty—are saying yes not only to having a child, but also to having whatever child this child turns out to be. In accepting our finitude, in opening ourselves to our replacement, we tacitly confess the limits of our control.

Embracing the future by procreating means precisely that we are relinquishing our grip in the very activity of taking up our own share in what we hope will be the immortality of human life and the human species. This means that our children are not our children: they are not our property, they are not our possessions. Neither are they supposed to live our lives for us, or to live anyone's life but their own. Their genetic distinctiveness and independence are the natural foreshadowing of the deep truth that they have their own, never-before-enacted life to live. Though sprung from a past, they take an uncharted course into the future.

Much mischief is already done by parents who try to live vicariously through their children. Children are sometimes compelled to fulfill the broken dreams of unhappy parents. But whereas most parents normally have hopes for their children, cloning parents will have expectations. In cloning, such overbearing parents will have taken at the start a decisive step that contradicts the entire meaning of the open and forward-looking nature of parent-child relations. The child is given a genotype that has already lived, with full expectation that this blueprint of a past life ought to be controlling the life that is to come. A wanted child now means a child who exists precisely to fulfill parental wants. Like all the more precise eugenic manipulations that will follow in its wake, cloning is thus inherently despotic, for it seeks to make one's

children after one's own image (or an image of one's choosing) and their future according to one's will.

Is this hyperbolic? Consider concretely the new realities of responsibility and guilt in the households of the cloned. No longer only the sins of the parents, but also the genetic choices of the parents, will be visited on the children—and beyond the third and fourth generation; and everyone will know who is responsible. No parent will be able to blame nature or the lottery of sex for an unhappy adolescent's big nose, dull wit, musical ineptitude, nervous disposition, or anything else that he hates about himself. Fairly or not, children will hold their cloners responsible for everything, for nature as well as for nurture. And parents, especially the better ones, will be limitlessly liable to guilt. Only the truly despotic souls will sleep the sleep of the innocent.

IV.

The defenders of cloning are not wittingly friends of despotism. Quite the contrary. Deaf to most other considerations, they regard themselves mainly as friends of freedom: the freedom of individuals to reproduce, the freedom of scientists and inventors to discover and to devise and to foster "progress" in genetic knowledge and technique, the freedom of entrepreneurs to profit in the market. They want large-scale cloning only for animals, but they wish to preserve cloning as a human option for exercising our "right to reproduce"—our right to have children, and children with "desirable genes." As some point out, under our "right to reproduce" we already practice early forms of unnatural, artificial, and extra-marital reproduction, and we already practice early forms of eugenic choice. For that reason, they argue, cloning is no big deal.

We have here a perfect example of the logic of the slippery slope. The principle of reproductive freedom currently enunciated by the proponents of cloning logically embraces the ethical acceptability of sliding all the way down: to producing children wholly in the laboratory from sperm to term (should it become feasible), and to producing children whose entire genetic makeup will be the product of parental eugenic planning and choice. If reproductive freedom means the right to have a child of one's own choosing by whatever means, then reproductive freedom knows and accepts no limits.

Proponents want us to believe that there are legitimate uses of cloning that can be distinguished from illegitimate uses, but by their own principles no such limits can be found. (Nor could any such limits be enforced in practice: once cloning is permitted, no one ever need discover whom one is cloning and why.) Reproductive freedom, as they understand it, is governed solely by the subjective wishes of the parents-to-be. The sentimentally appealing case of the childless married couple is, on these grounds, indistinguishable from the case of an individual (married or not) who would like to clone someone famous or talented, living or dead. And the principle here endorsed justifies not only cloning but also all future artificial attempts to create (manufacture) "better" or "perfect" babies.

The "perfect baby," of course, is the project not of the infertility doctors, but of the eugenic scientists and their supporters, who, for the time being, are content to hide behind the skirts of the partisans of reproductive freedom and compassion for the infertile. For them, the paramount right is not the so-called right to reproduce, it is what the biologist Bentley Glass called, a quarter of a century ago, "the right of every child to be born with a sound physical and mental constitution, based on a sound genotype . . . the inalienable right to a sound heritage." But to secure this right, and to achieve the requisite quality control over new human life, human conception and gestation will need to be brought fully into the bright light of the laboratory, beneath which the child-to-be can be fertilized, nourished, pruned, weeded, watched, inspected, prodded, pinched, cajoled, injected, tested, rated, graded, approved, stamped, wrapped, sealed, and delivered. There is no other way to produce the perfect baby.

If you think that such scenarios require outside coercion or governmental tyranny, you are mistaken. Once it becomes possible, with the aid of human genomics, to produce or to select for what some regard as "better babies"—smarter, prettier, healthier, more athletic—parents will leap at the opportunity to "improve" their offspring. Indeed, not to do so will be socially regarded as a form of child neglect. Those who would ordinarily be opposed to such tinkering will be under enormous pressure to compete on behalf of their as yet unborn children—just as some now plan almost from their children's birth how to get them into Harvard. Never mind that, lacking a standard of "good" or "better," no one can really know whether any such changes will truly be improvements.

Proponents of cloning urge us to forget about the science-fiction scenarios of laboratory manufacture or multiple-copy clones, and to focus only on the sympathetic cases of infertile couples exercising their reproductive rights. But why, if the single cases are so innocent, should multiplying their performance be so off-putting? (Similarly, why do others object to people's making money from that practice if the practice itself is perfectly acceptable?) The so-called science-fiction cases—say, *Brave New World*—make vivid the meaning of what looks to us, mistakenly, to be benign. They reveal that what looks like compassionate humanitarianism is, in the end, crushing dehumanization.

v.

Whether or not they share my reasons, most people, I think, share my conclusion: that human cloning is unethical in itself and dangerous in its likely consequences, which include the precedent that it will establish for designing our children. Some reach this conclusion for their own good reasons, different from my own: concerns about distributive justice in access to eugenic cloning; worries about the genetic effects of asexual "inbreeding"; aversion to the implicit premise of genetic determinism; objections to the embryonic and fetal wastage that must necessarily accompany the efforts; religious opposition to "man playing God." But never mind why: the overwhelming majority of our fellow Americans remain firmly opposed to cloning human beings.

For us, then, the real questions are: What should we do about it? How can we best succeed? These questions should concern everyone eager to secure deliberate human control over the powers that could re-design our humanity, even if cloning is not the issue over which they would choose to make their stand. And the answer to the first question seems pretty plain. What we should do is work to prevent human cloning by making it illegal.

We should aim for a global legal ban, if possible, and for a unilateral national ban at a minimum—and soon, before the fact is upon us. To be sure, legal bans can be violated; but we certainly curtail much mischief by outlawing incest, voluntary servitude, and the buying and selling of organs and babies. To be sure, renegade scientists may secretly undertake to violate such a law, but we can deter them by both criminal sanctions and monetary penalties, as well as by removing any incentive they have to proudly claim credit for their technological bravado.

Such a ban on clonal baby-making will not harm the progress of basic genetic science and technology. On the contrary, it will reassure the public that scientists are happy to proceed without violating the deep ethical norms and intuitions of the human community. It will also protect honorable scientists from a public backlash against the brazen misconduct of the rogues. As many scientists have publicly confessed, free and worthy science probably has much more to fear from a strong public reaction to a cloning fiasco than it does from a cloning ban, provided that the ban is judiciously crafted and vigorously enforced against those who would violate it.

Five states—Michigan, Louisiana, California, Rhode Island, and Virginia—have already enacted a ban on human cloning, and several others are likely to follow suit this year. Michigan, for example, has made it a felony, punishable by imprisonment for not more than ten years or a fine of not more than $10 million, or both, to "intentionally engage in or attempt to engage in human cloning," where human cloning means "the use of human somatic cell nuclear transfer technology to produce a human embryo." Internationally, the movement to ban human cloning gains momentum. France and Germany have banned cloning (and germline genetic engineering), and the Council of Europe is working to have it banned in all of its forty-one member countries, and Canada is expected to follow suit. The United Nations, UNESCO, and the Group of Seven have called for a global ban on human cloning.

Given the decisive actions of the rest of the industrialized world, the United States looks to some observers to be a rogue nation. A few years ago, soon after the birth of Dolly, President Clinton called for legislation to outlaw human cloning, and attempts were made to produce a national ban. Yet none was enacted, despite general agreement in Congress that it would be desirable to have such a ban. One might have thought that it would be easy enough to find clear statutory language for prohibiting attempts to clone a human being (and other nations have apparently not found it difficult). But, alas, in the last national go-around, there was trouble over the apparently vague term "human being," and whether it includes the early (pre-implantation) embryonic stages of human life. Learning from this past failure, we can do better this time around. Besides, circumstances have changed greatly in the intervening three years, making a ban both more urgent and less problematic.

Two major anti-cloning bills were introduced into the Senate in 1998. The Democratic bill (Kennedy-Feinstein) would have banned so-called reproductive cloning by

prohibiting transfer of cloned embryos into women to initiate pregnancy. The Republican bill (Frist-Bond) would have banned all cloning by prohibiting the creation even of embryonic human clones. Both sides opposed "reproductive cloning," the attempt to bring to birth a living human child who is the clone of someone now (or previously) alive. But the Democratic bill sanctioned creating cloned embryos for research purposes, and the Republican bill did not. The pro-life movement could not support the former, whereas the scientific community and the biotechnology industry opposed the latter; indeed, they successfully lobbied a dozen Republican senators to oppose taking a vote on the Republican bill (which even its supporters now admit was badly drafted). Owing to a deep and unbridgeable gulf over the question of embryo research, we did not get the congressional ban on reproductive cloning that nearly everyone wanted. It would be tragic if we again failed to produce a ban on human cloning because of its seemingly unavoidable entanglement with the more divisive issue of embryo research.

To find a way around this impasse, several people (myself included) advocated a legislative "third way," one that firmly banned only reproductive cloning but did not legitimate creating cloned embryos for research. This, it turns out, is hard to do. It is easy enough to state the necessary negative disclaimer that would set aside the embryo-research question: "Nothing in this act shall be taken to determine the legality of creating cloned embryos for research; this act neither permits nor prohibits such activity." It is much more difficult to state the positive prohibition in terms that are unambiguous and acceptable to all sides. To indicate only one difficulty: indifference to the creation of embryonic clones coupled with a ban (only) on their transfer would place the federal government in the position of demanding the destruction of nascent life, a bitter pill to swallow even for pro-choice advocates.

Given both these difficulties, and given the imminence of attempts at human cloning, I now believe that what we need is an all-out ban on human cloning, including the creation of embryonic clones. I am convinced that all halfway measures will prove to be morally, legally, and strategically flawed, and—most important—that they will not be effective in obtaining the desired result. Anyone truly serious about preventing human reproductive cloning must seek to stop the process from the beginning. Our changed circumstances, and the now evident defects of the less restrictive alternatives, make an all-out ban by far the most attractive and effective option.

Here's why. Creating cloned human children ("reproductive cloning") necessarily begins by producing cloned human embryos. Preventing the latter would prevent the former, and prudence alone might counsel building such a "fence around the law." Yet some scientists favor embryo cloning as a way of obtaining embryos for research or as sources of cells and tissues for the possible benefit of others. (This practice they misleadingly call "therapeutic cloning" rather than the more accurate "cloning for research" or "experimental cloning," so as to obscure the fact that the clone will be "treated" only to exploitation and destruction, and that any potential future beneficiaries and any future "therapies" are at this point purely hypothetical.)

The prospect of creating new human life solely to be exploited in this way has been condemned on moral grounds by many people—including *The Washington Post*, President Clinton, and many other supporters of a woman's right to abortion—as displaying a profound disrespect for life. Even those who are willing to scavenge so-called "spare embryos"—those products of *in vitro* fertilization made in excess of people's reproductive needs, and otherwise likely to be discarded—draw back from creating human embryos explicitly and solely for research purposes. They reject outright what they regard as the exploitation and the instrumentalization of nascent human life. In addition, others who are agnostic about the moral status of the embryo see the wisdom of not needlessly offending the sensibilities of their fellow citizens who are opposed to such practices.

But even setting aside these obvious moral first impressions, a few moments of reflection show why an anti-cloning law that permitted the cloning of embryos but criminalized their transfer to produce a child would be a moral blunder. This would be a law that was not merely permissively "pro-choice" but emphatically and prescriptively "anti-life." While permitting the creation of an embryonic life, it would make it a federal offense to try to keep it alive and bring it to birth. Whatever one thinks of the moral status or the ontological status of the human embryo, moral sense and practical wisdom recoil from having the government of the United States on record as requiring the destruction of nascent life and, what is worse, demanding the punishment of those who would act to preserve it by (feloniously!) giving it birth.

But the problem with the approach that targets only reproductive cloning (that is, the transfer of the embryo to a woman's uterus) is not only moral but also legal and strategic. A ban only on reproductive cloning would turn out to be unenforce-

able. Once cloned embryos were produced and available in laboratories and assisted-reproduction centers, it would be virtually impossible to control what was done with them. Biotechnical experiments take place in laboratories, hidden from public view, and, given the rise of high-stakes commerce in biotechnology, these experiments are concealed from the competition. Huge stockpiles of cloned human embryos could thus be produced and bought and sold without anyone knowing it. As we have seen with *in vitro* embryos created to treat infertility, embryos produced for one reason can be used for another reason: today "spare embryos" once created to begin a pregnancy are now used in research, and tomorrow clones created for research will be used to begin a pregnancy.

Assisted reproduction takes place within the privacy of the doctor-patient relationship, making outside scrutiny extremely difficult. Many infertility experts probably would obey the law, but others could and would defy it with impunity, their doings covered by the veil of secrecy that is the principle of medical confidentiality. Moreover, the transfer of embryos to begin a pregnancy is a simple procedure (especially compared with manufacturing the embryo in the first place), simple enough that its final steps could be self-administered by the woman, who would thus absolve the doctor of blame for having "caused" the illegal transfer. (I have in mind something analogous to Kevorkian's suicide machine, which was designed to enable the patient to push the plunger and the good "doctor" to evade criminal liability.)

Even should the deed become known, governmental attempts to enforce the reproductive ban would run into a swarm of moral and legal challenges, both to efforts aimed at preventing transfer to a woman and—even worse—to efforts seeking to prevent birth after transfer has occurred. A woman who wished to receive the embryo clone would no doubt seek a judicial restraining order, suing to have the law overturned in the name of a constitutionally protected interest in her own reproductive choice to clone. (The cloned child would be born before the legal proceedings were complete.) And should an "illicit clonal pregnancy" be discovered, no governmental agency would compel a woman to abort the clone, and there would be an understandable storm of protest should she be fined or jailed after she gives birth. Once the baby is born, there would even be sentimental opposition to punishing the doctor for violating the law—unless, of course, the clone turned out to be severely abnormal.

For all these reasons, the only practically effective and legally sound approach is to block human cloning at the start, at the production of the embryo clone. Such a ban can be rightly characterized not as interference with reproductive freedom, nor even as interference with scientific inquiry, but as an attempt to prevent the unhealthy, unsavory, and unwelcome manufacture of and traffic in human clones.

VI.

Some scientists, pharmaceutical companies, and bio-entrepreneurs may balk at such a comprehensive restriction. They want to get their hands on those embryos, especially for their stem cells, those pluripotent cells that can in principle be turned into any cells and any tissues in the body, potentially useful for transplantation to repair somatic damage. Embryonic stem cells need not come from cloned embryos, of course; but the scientists say that stem cells obtained from clones could be therapeutically injected into the embryo's adult "twin" without any risk of immunological rejection. It is the promise of rejection-free tissues for transplantation that so far has been the most successful argument in favor of experimental cloning. Yet new discoveries have shown that we can probably obtain the same benefits without embryo cloning. The facts are much different than they were three years ago, and the weight in the debate about cloning for research should shift to reflect the facts.

Numerous recent studies have shown that it is possible to obtain highly potent stem cells from the bodies of children and adults—from the blood, bone marrow, brain, pancreas, and, most recently, fat. Beyond all expectations, these non-embryonic stem cells have been shown to have the capacity to turn into a wide variety of specialized cells and tissues. (At the same time, early human therapeutic efforts with stem cells derived from embryos have produced some horrible results, the cells going wild in their new hosts and producing other tissues in addition to those in need of replacement. If an *in vitro* embryo is undetectably abnormal—as so often they are—the cells derived from it may also be abnormal.) Since cells derived from our own bodies are more easily and cheaply available than cells harvested from specially manufactured clones, we will almost surely be able to obtain from ourselves any needed homologous transplantable cells and tissues, without the need for egg donors or cloned embryonic copies of ourselves. By pouring our resources into *adult* stem cell research (or, more accurately, "non-embryonic" stem cell research), we can also avoid the morally and legally vexing issues in embryo research. And more to

our present subject, by eschewing the cloning of embryos, we make the cloning of human beings much less likely.

A few weeks ago an excellent federal anti-cloning bill was introduced in Congress, sponsored by Senator Sam Brownback and Representative David Weldon. This carefully drafted legislation seeks to prevent the cloning of human beings at the very first step, by prohibiting somatic cell nuclear transfer to produce embryonic clones, and provides substantial criminal and monetary penalties for violating the law. The bill makes very clear that there is to be no interference with the scientific and medically useful practices of cloning DNA fragments (molecular cloning), with the duplication of somatic cells (or stem cells) in tissue culture (cell cloning), or with whole-organism or embryo cloning of non-human animals. If enacted, this law would bring the United States into line with the current or soon-to-be-enacted practices of many other nations. Most important, it offers us the best chance—the only realistic chance—that we have to keep human cloning from happening, or from happening much.

Getting this bill passed will not be easy. The pharmaceutical and biotech companies and some scientific and patient-advocacy associations may claim that the bill is the work of bio-Luddites: anti-science, a threat to free inquiry, an obstacle to obtaining urgently needed therapies for disease. Some feminists and pro-choice groups will claim that this legislation is really only a sneaky device for fighting *Roe* v. *Wade*, and they will resist anything that might be taken even to hint that a human embryo has any moral worth. On the other side, some right-to-life purists, who care not how babies are made as long as life will not be destroyed, will withhold their support because the bill does not take a position against embryo twinning or embryo research in general.

All of these arguments are wrong, and all of them must be resisted. This is not an issue of pro-life versus pro-choice. It is not about death and destruction, or about a woman's right to choose. It is only and emphatically about baby design and manufacture: the opening skirmish of a long battle against eugenics and against a post-human future. As such, it is an issue that should not divide "the left" and "the right"; and there are people across the political spectrum who are coalescing in the efforts to stop human cloning. (The prime sponsor of Michigan's comprehensive anti-cloning law is a pro-choice Democratic legislator.) Everyone needs to understand that, whatever we may think about the moral status of embryos, once embryonic clones are produced in the laboratories the eugenic revolution will have begun. And we shall have lost our best chance to do anything about it.

As we argue in the coming weeks about this legislation, let us be clear about the urgency of our situation and the meaning of our action or inaction. Scientists and doctors whose names we know, and probably many others whose names we do not know, are today working to clone human beings. They are aware of the immediate hazards, but they are undeterred. They are prepared to screen and to destroy anything that looks abnormal. They do not care that they will not be able to detect most of the possible defects. So confident are they in their rectitude that they are willing to ignore all future consequences of the power to clone human beings. They are prepared to gamble with the well-being of any live-born clones, and, if I am right, with a great deal more, all for the glory of being the first to replicate a human being. They are, in short, daring the community to defy them. In these circumstances, our silence can only mean acquiescence. To do nothing now is to accept the responsibility for the deed and for all that follows predictably in its wake.

I appreciate that a federal legislative ban on human cloning is without American precedent, at least in matters technological. Perhaps such a ban will prove ineffective; perhaps it will eventually be shown to have been a mistake. (If so, it could later be reversed.) If enacted, however, it will have achieved one overwhelmingly important result, in addition to its contribution to thwarting cloning: it will place the burden of practical proof where it belongs. It will require the proponents to show very clearly what great social or medical good can be had only by the cloning of human beings. Surely it is only for such a compelling case, yet to be made or even imagined, that we should wish to risk this major departure—or any other major departure—in human procreation.

Americans have lived by and prospered under a rosy optimism about scientific and technological progress. The technological imperative has probably served us well, though we should admit that there is no accurate method for weighing benefits and harms. And even when we recognize the unwelcome outcomes of technological advance, we remain confident in our ability to fix all the "bad" consequences—by regulation or by means of still newer and better technologies. Yet there is very good reason for shifting the American paradigm, at least regarding those technological interventions into the human body and mind that would surely effect fundamental (and likely irreversible) changes in human nature, basic human relationships, and

what it means to be a human being. Here we should not be willing to risk everything in the naive hope that, should things go wrong, we can later set them right again.

Some have argued that cloning is almost certainly going to remain a marginal practice, and that we should therefore permit people to practice it. Such a view is shortsighted. Even if cloning is rarely undertaken, a society in which it is tolerated is no longer the same society—any more than is a society that permits (even small-scale) incest or cannibalism or slavery. A society that allows cloning, whether it knows it or not, has tacitly assented to the conversion of procreation into manufacture and to the treatment of children as purely the projects of our will. Willy-nilly, it has acquiesced in the eugenic re-design of future generations. The humanitarian superhighway to a Brave New World lies open before this society.

But the present danger posed by human cloning is, paradoxically, also a golden opportunity. In a truly unprecedented way, we can strike a blow for the human control of the technological project, for wisdom, for prudence, for human dignity. The prospect of human cloning, so repulsive to contemplate, is the occasion for deciding whether we shall be slaves of unregulated innovation, and ultimately its artifacts, or whether we shall remain free human beings who guide our powers toward the enhancement of human dignity. The humanity of the human future is now in our hands.

SUMMARY

New biomedical technologies are rapidly providing powers to intervene in human bodies and minds in ways that threaten fundamental changes in human nature and the meaning of our humanity. We now stand at a major fork at the road, compelled to decide whether we wish to travel down the path to the Brave New World: we must decide whether to tolerate the practice of human cloning, the asexual reproduction of human beings, made as genetic copies of already (or previously) existing individuals. Reputable scientists have announced plans to clone human beings in the coming year and are daring us to stop them. Our failure to try to do so constitutes our tacit acquiescence.

The vast majority of Americans object to human cloning, and on multiple moral grounds. It constitutes unethical experimentation on the child-to-be. It threatens identity and individuality. It represents a giant step toward turning procreation into manufacture, legitimizing in advance the eugenic redesigning of our children. And it is a radical form of parental despotism and child abuse. Permitting human cloning means saying yes to the dangerous principle that we are entitled to determine the genetic make-up of our children. If we do not wish to travel down this eugenic road, an effective ban on cloning human beings is needed, and needed now before we are overtaken by events.

Two legislative alternatives have been proposed: one would ban only so-called reproductive cloning by prohibiting the transfer of a cloned embryo to a woman to initiate a pregnancy; the other would ban *all* cloning by prohibiting the creation even of the embryonic human clones. Arguments are given why the latter proposal is much to be preferred. Once cloned embryos are produced and available in laboratories and assisted-reproduction centers, it will be virtually impossible to control what is done with them. Stockpiles of cloned human embryos could be produced and bought and sold without anyone knowing it. Efforts at clonal reproduction would take place out of sight, within the privacy of the doctor-patient relationship. Moreover, a ban on only reproductive cloning will turn out to be unenforceable. Should "illicit cloning" be discovered, governmental attempts to enforce the reproductive ban would run into a swarm of legal and practical challenges, and the practice will prove impossible to police or regulate. Anyone truly serious about preventing human reproductive cloning must seek to stop the process from the beginning.

This is not an issue of pro-life vs. pro-choice. It is not about death and destruction or about a woman's right to choose. It is only and emphatically an issue of baby-design and manufacture, the opening skirmish of a long battle against eugenics and against a "post-human" future. Once embryonic clones are produced in laboratories, the eugenic revolution will have begun. And we shall have lost our best chance to do anything about it and to assume responsible control over where biotechnology is taking us. The humanity of the human future is now in our hands.

Mr. SMITH. Thank you, Dr. Kass. Dr. Callahan.

STATEMENT OF DANIEL CALLAHAN, DIRECTOR OF INTERNATIONAL PROGRAMS, HASTING CENTER, GARRISON, NY

Mr. CALLAHAN. Thank you, Mr. Chairman. I want to talk about two things today. First, I would like to say a little bit about my opposition, ethically, to cloning, but then I would like to deal with the question of whether it would be ethically appropriate to ban scientific research on cloning. I want to argue that there are obvious legal issues involved in the scientific ban, but it seems to me that there is a fundamental ethical question of whether that is a way to go in the first place.

Let me very briefly sum up my general objection to cloning. I come down to one point most decisively; that is, I see a profound threat to the individuality of children so born. I think it is part of our human nature, part of what we consider our fundamental individuality and identity, that we're different from other people. Surely it is the case, as many have pointed out, that a cloned person would not be genetically absolutely identical, and because of environmental forces, it is also the case at the person would not even be psychologically identical, but as we know from twin studies, approximately 50 percent of personal traits are shared by identical twins. More importantly, even if a clone is not going to be totally identical, it would be identical enough that there would be a fundamental threat to what is distinctive about ourself, which is partly our appearance, partly the fact that there is no one on earth quite like us. I begin with that basic point.

On the question of the relationship of law and ethics, which is obviously a major problem in American society, and always has been, the question of what moral principles do we want to enact into law, which ones do we want to leave free of the law, subject to stigmatization, personal pressure, political forces and the like, is an issue long debated. I believe in this case that a ban would be appropriate and justifiable. The main justification needed for a ban is that there is a fundamental threat to important social and public values, and in this case I believe there is such a threat.

The question, though, is still, given the important precedent that would be set by banning research at this fundamental level, whether the very powerful burden of argument in favor of it—against it—can be discharged. I think that the bias in our society, an appropriate bias, is that anyone who would want to ban scientific research has a very difficult burden to discharge. I believe in this case that the burden can be discharged. First of all, the simple fact that we would be changing the nature of procreation and parenthood in a radical way is, itself, a very strong argument, but I think we can anticipate that scientists would feel this is a fundamental threat to their liberty and to an important part of the American and scientific tradition.

A fundamental response to this argument can be made. First of all, we certainly have restricted science in many ways in our society. We have a requirement with human subject research that people give informed consent before being used as subjects, and we simply do not allow practical or utilitarian considerations to overturn that very firm ban. We have certainly regulated science in many ways, and, it seems to me, by enacting a ban here, we will not be doing something fundamentally different, but granted we

are taking one further step. I think the fundamental reason for a ban, part of which has been really developed by Dr. Kass, is that if we do not have a ban at the very fundamental research level with the techniques for human cloning, the ability to really control in the long run will not be possible.

I am struck by the fact that too much of our current interest in biomedical research is, seems to me, fueled by a kind of single-minded passion to eliminate disease, often likened to a war, in fact, we use the language of a war against disease very often. I think the worst possible analogy of biomedical research is that of warfare. Illness, death and suffering are terrible human threats, but to approach them as if nothing less than all out battle with no holds barred will demonstrate our moral seriousness is a profound mistake. Health is a great and vital human good, but not the only such good.

The point of a ban on research for human cloning is to make certain that some time-tested critical means of human procreation and human individuality are protected. They are an as important part of our Western American heritage as freedom of scientific inquiry, the freedom that has well co-existed for some years with ethical limitations and has managed to flourish is the face of and sometimes because of those limitations. In short, I do not think that a ban would in any way fundamentally be a threat to the future of scientific research here. I believe there are alternatives to the proposed lines of research which ought to be explored, and in any case, it seems to me, that the very basic necessity to protect our children and children in the future and to protect our very fundamental commitment to a procreation that generates individual, unique people is something that ought not to be in anyway overcome. Thank you.

[The prepared statement of Mr. Callahan follows:]

PREPARED STATEMENT OF DANIEL CALLAHAN

I am Daniel Callahan, Director of the International Program of The Hastings Center, Garrison, N.Y., a research center devoted to biomedical and environmental ethics. I pleased to take part in this hearing. It focuses on a topic of great important for the human future and the proper use of scientific research as it moves toward that future. Research on human cloning would chart not only a new direction for biomedical research but also, in its implications, a new direction for the procreation of human life.

I oppose such research, for reasons I will shortly present, but the main purpose of my testimony will be to discuss proposals to ban such research, at both the federal and the private levels. I want to combine the topics of the ethics of human cloning and the ethics of controlling the research for one simple reason: if research on human cloning is a bad direction in which to go, what can be done about that? What is the appropriate connection, with the issue of human cloning, between ethics and the law? The connection is particularly important in this instance because, so far as I can determine, the federal government has never before tried to use the police power of the state to ban a particular line of biomedical research.

While there have been a variety of moral objections voiced against human cloning, the one that has most persuaded me is the two-fold argument that: (a) children have a right to their own genetic identity, an identify which, if not interfered with, will be unlike any other person's identify; and that (b) parents ought not to manufacture children to their specifications or to serve their needs, even understandable needs.

Our moral and political tradition has always understood each of us to be individuals in our own right, to be accorded respect precisely because of our unique individuality. Human cloning would jeopardize that identity. It is true, as many scientists have noted, that a cloned human being would not, even genetically, be exactly like the person from whom he or she was cloned. It is also true that the different envi-

ronmental and social context of the clone would lead to a person with many different traits and even personality. But twin studies have suggested that at least 50% of their personal traits are similar; and the simple fact that we would have the same appearance as the source of the clone is not something to be lightly dismissed. Common sense, moreover, suggests that there would be no point in cloning a person unless that person shared many of the traits of the genetic originator. The fact that genetically identical twins occur in nature does not, by itself, prove that it is acceptable to manufacture them.

The very first question to be asked about human cloning is whether it would benefit the clone. That question is, surprisingly, hardly addressed at all by those favorable to cloning. The best that can be said is that some cloned children might not be alive at all but for the fact that its parents would or could only procreate in a way that would produce a clone. By far the greater emphasis of proponents has been a claim that the idea of reproductive rights can extend to cloning a child, and that once such a right is recognized—satisfying the desires of the parent—then there is little more of moral interest to be said.

There is, in short, little apparent concern for what was not long ago called "responsible parenthood." That important concept has been pushed aside by the seemingly unlimited notion of reproductive rights, not only the right to have or not have a child, but to have a child with the traits, any traits, of one's own choosing and procreated in any manner. Yet responsible parenthood is still an important concept, one that needs to be reinvigorated. To be sure, people have always had children to satisfy their own needs and interests: to carry on family lines, to care for them in old age, to provide helpers on the farm, to provide parents with the pleasure of having and raising children. But there has always been a powerful, and parallel, tradition that children are demeaned in their meaning and personhood if they are not loved and respected and reared for their own good and not that of the parents.

There is surely something of a paradox here in observing why people have children—for their own sake and that of the child at one and the same time—but the final desired outcome had been less mixed in its ideals. That outcome is simply that the child must grow into an adult who is his or her own person, shaped by, educated by, cherished by his or her parents, but not made in the image of, or according to the plan of, the parents. Jokes are often made about pushy parents, and sometimes children thank parents for moving them in one direction rather than another; but for children who have been forced to live up to some predetermined parental notion of what the child must be or do there can be, and often has been, great tragedy. To say each of us ought, in the end, to be our own person is to say it all. That cloning does not deprive someone entirely of his identity is beside the point. It badly compromises it, and that is grounds enough for condemnation.

There is, however, a long-standing and important difference between ethics and law. The former is meant to shape our individual virtues and principles, and to provide a foundation for making distinctions between right and wrong, good and bad. The latter may and often does embody our ethical values, but its purpose is primarily to establish those rules and prohibitions necessary for a society to function well, in reasonable peace and harmony. Not every ethical principle or belief is appropriate for law, and not every law embodies moral principles (though law should never be incompatible with them).

So, even if we can come to some agreement that research on human cloning is wrong-headed, and morally wrong, does that mean that we should ban it? We could, after all, leave matters as they now stand, with a prohibition against federal grants to support such research, with most professional and public opinion hostile to it, and with little apparent interest in the private sector, which apparently sees no great profit in it. Would not that be enough to stop it from ever happening?

Probably not. Not only is there a minority body of scientific and lay opinion that human cloning is worth pursuit, but also some well-publicized instances of individuals and groups who have told us they will do the research necessary to produce a clone. They should be taken seriously. If they succeed, or others who come later do, then those of us—and our children and our children's children—will have to live with the result: a radical change in the procreation of children, a change that offers a minor promise of some therapeutic benefit and a major promise of social harm.

But, even so, is *that* a good enough reason to enact a federal ban? A ban would be a most drastic response, unprecedented at the level of the combined basic and applied research that would be needed to create a human clone. That should be enough to give pause to anyone who appreciates the great contribution that a free science can make to our health and welfare. It is easy to imagine many scientists, legislators, and lay people agreeing that research on cloning to be morally wrong, like with most harmful consequences—and yet fearing the precedent for research restrictions that could be even worse in its consequences. Moreover, is not the di-

lemma made all the worse when it is proposed, as is the case with one bill before the House of Representatives, to ban not just direct research into human cloning—called "reproductive cloning"—but also a ban on embryo cloning as well for research purposes, which might best be called "cloning for research."

Such a proposed ban lays a heavy burden of proof on its proponents: to show that the harms to be averted are serious threats to the public interest; that dangerous precedents for the future of science would not be established; and that the loss to scientific research, of opportunities for knowledge foregone, would not be unacceptably high.

I believe that burden can be discharged. First, human cloning would change the nature of procreation and parenthood in a radical way and, in the process, change its social as well as individual meaning. There is good reason to believe such a change would be harmful and no good reason to believe such a change would produce any important benefit for procreation or, as often alleged, for the relief of infertility. As for the precedents that might be set, there has always been a recognition that scientific freedom is not an absolute value. The international covenants requiring informed consent for clinical research, for instance, draw a sharp line against the use of human being as research subjects against their will—however great might be the research or medical benefits of doing so. Few seem to reject the idea that it would be wrong to put children at risk to make human cloning work. The physical safety of child-to-be who is part of human cloning research is taken to be a value overriding that of scientific knowledge or benefits to parental infertility.

Scientists with no particular interest in human cloning might, however, worry about the research opportunities that would be lost if legislation banned cloning for research as firmly as it banned cloning for reproduction. A strong reason for doing such research is to assist in stem cell investigations, which would be particularly helped if immunological incompatibility and tissue rejection problems can be overcome. Cloning could help solve that problem.

Two points can be made in response. One of them is that it would be almost pointless to ban research on human cloning without banning research—cloning as well; the former would provide the necessary knowledge to do the latter, and would make it all the harder to have any kind of oversight over what would be done with the knowledge.

The second point is that, as with much of genetic and biomedical research, there is rarely anything such as a one-and-only way to gain knowledge, and this is as true of stem cell research and its potential clinical applications as it is of most other research. There is no reason in principle to say that, much less any way to show, that other approaches to stem cell research will and must fail—just as there is no reason in principle to assume that research-oriented human cloning is the only way to deal with the immunological compatibility problem. This is not to deny there could be some scientific loss. Progress might come more slowly and with more difficulty with a ban in place; but even there the best one can say is "might" because there is no necessary correlation between methods that will at any historical moment appeal to scientists and those that will, in the long run, prove most successful.

If there are no exact precedents for a ban on research of this kind, it is worth noting that the National Bioethics Advisory Commission called for such a ban on reproductive cloning research (though it also asked for a sunset-clause and Congressional Review after 3–5 years). France and Germany have enacted a ban on that kind of research as well. A ban on cloning for research purposes goes a step further, but it is the only logical way to help insure that research on reproductive cloning does not have other research off of which too easily to feed. It should be self-evident, finally, that a ban can be revoked, that science can change, that what seems methodologically valid at the moment can give way to methods even better in the future.

Too much of the current research drive is fueled by a singleminded passion to eradicate disease, often likened to a war. The worst possible analogy for biomedical research is that of warfare. Illness, death, and suffering are terrible human threats, but to approach them as if nothing less than all-out battle, with no holds barred, will demonstrate our moral seriousness is a profound mistake. Health is a great and vital human good, but not the only such good. The point of a ban on research for human cloning is to make certain that some time-tested, critical means of human procreation and human individuality are protected. They are as important part of our American and Western heritage as freedom of scientific inquiry—a freedom that has well coexisted for some years with ethical limitations and has managed to flourish in the face of (and sometimes because of) those limitations.

Mr. SMITH. Thank you, Dr. Callahan. Dr. Prentice?

STATEMENT OF DAVID A. PRENTICE, Ph.D., PROFESSOR OF LIFE SCIENCES, INDIANA STATE UNIVERSITY

Mr. PRENTICE. Mr. Chairman and distinguished Members of the Subcommittee, thank you for the opportunity to testify today at this important hearing regarding human cloning. There is almost uniform agreement against what has been termed reproductive cloning, creating a cloned human being and allowing that clone to develop to a live birth, but some scientists proposed therapeutic cloning, the production of human embryos by cloning for the purpose of harvesting embryonic stem cells from the early embryo. But, is cloning really necessary for production of embryo stem cells? No. If necessary, those cells can be derived from so-called excess human embryos from *in vitro* fertilization. Proposals already exist to design methods to prevent transplant rejection.

Of course, the debate will continue as to whether such excess human embryos should be donated to research or perhaps instead adopted through programs such as the Snowflakes Embryo Adoption Program. The real crux of the debate rests on the necessity for embryonic stem cells for regenerative medicine; are they really necessary? Is there the potential for these cells to provide actual clinical treatments for disease versus other, less ethically contentious alternatives? There is no dispute that embryonic stem cells, the inner cells of the very early embryo, have the potential to produce all human tissues under normal developmental circumstances, but despite the initial enthusiasm for the use of these cells, they have been disappointing.

Considerable technical problems remain to be surmounted, including the difficulty in growth and maintenance of the cells, slow growth rate of the cells, potential chromosomal instability, difficulty in directing the production of specific desired tissues and potential tumor formation. The National Bioethics Advisory Commission in September 1999 expressed it this way, "In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable, only if no less morally problematic alternatives are suitable for advancing the research." Such an alternative does exist, adult stem cells.

Since that first statement in 1999, there has been an avalanche of research reports describing success after success with adult stem cells. The published scientific research voids all the arguments that have been made against adults stem cells. Sufficient numbers of adults stem cells can be easily generated and cultured for clinical applications. A recent study showed that only one transplanted adult stem cell from bone marrow in a mouse could regenerate tissue in several parts of the body. That single, transplant in cell expanded in number sufficiently and in enough time to rescue the host mouse, into which it was transplanted from lethal irradiation. Since the original stem cell came from another mouse, you might term that technique mouse-to-mouse resuscitation.

However, there have been various studies that now show adult stem cells from many tissues are pluri-potent. They have the ability to form many different tissues, in fact, the indications are adults stem cells can regenerate all human tissues. Examples include transformation of brain stem cells in the blood, umbilical cord blood into nerve, and bone marrow stem cells into an array of tis-

sues such as cartilage, bone, muscle, liver, nerve endocardiac tissue. Even fat has been recently found to contain stem cells. Placenta is a rich source of stem cells. Adult stem cells have also shown that they can form functional tissues when injected into animal models. Bone marrow stem cells have been shown to transform into functional liver, muscle and even into heart tissue, repairing cardiac damage. Bone marrow and umbilical cord blood stem cells have been shown to provide therapeutic benefit after stroke in a mouse model.

Adult pancreatic stem cells have reversed diabetes in mice and bone marrow stem cells have regenerated muscle in a mouse model of muscular dystrophy. In addition, adult stem cells are already being used successfully for therapeutic benefit in humans, treatments associated with cancer, relieving lupus, multiple sclerosis, arthritis, immunodeficiencies, restoration of sight by regeneration of corneas. Initial clinical trials have begun to repair heart damage using the patient's own adult stem cells. The weight of published scientific evidence seems to clearly indicate an acceptable, less morally problematic alternative to embryonic stem cells does exist.

Adult stem cells are making good on what are only promises of embryonic stem cells. Now, if the purpose of human cloning is as a source of donor cells and tissues for others, there is no justification for such a practice. Therapeutic cloning takes a utilitarian view of human embryos, useful for a purpose, not valued in and of themselves. They are not viewed as people, but as property, a commodity. Dr. Irwin Chargaff, renowned biochemist, characterized this attitude as a kind of capitalist cannibalism. A complete ban on human cloning, as proposed in the Brownback-Weldon bill, is the only sufficient answer. Thank you, sir.

[The prepared statement of Mr. Prentice follows:]

PREPARED STATEMENT OF DR. DAVID A. PRENTICE, PH.D.

Mr. Chairman, distinguished Members of the Subcommittee, thank you for the opportunity to testify today at this important hearing regarding human cloning.

There is almost uniform agreement against what has been termed "reproductive cloning"—creating a cloned human being and allowing that clone to develop to a live birth. And there are good scientific reasons for opposition to reproductive cloning. Of the half-dozen or so mammals which have been cloned thus far, almost all (95–99%) do not survive, either dying during embryological development or soon after birth. It has even been said that there are no normal clones, in that even the few that survive after birth have various physiological problems, possibly genetic problems as well. This seems due to problems with the necessary re-programming of the genetic material in the transplanted nucleus to allow normal development. Cloning is thus a wasteful, inefficient, and even dangerous process for the clones themselves. In addition, the surrogate mothers of the clones experience physiological problems. In short, this whole notion is fraught with peril and should be banned.

But some scientists propose "therapeutic cloning", or euphemistically "cellular replacement through nuclear transfer". This involves production of human embryos by cloning for the purpose of harvesting embryonic stem (ES) cells from the early embryo. On the surface the goal seems noble—to produce genetically-matched tissues for clinical use. However, there are significant scientific problems with therapeutic cloning as well, revolving primarily around both the claim of the necessity for production of embryonic stem cells in this manner and the claim that embryonic stem cells are the only or the most promising route to clinical success in regenerative medicine.

First in terms of the need for production of embryonic stem cells via cloning. The proposals for use of this technique cite the very real probability that ES cells from "excess" human embryos frozen for *in vitro* fertilization (IVF) will not be an immunological match for patients, leading to rejection of transplanted tissues created from such ES cells, as with organ transplant rejection. While this is a real pos-

sibility, there are research proposals to design methods to mask the incompatibilities of stem cells from any source, allowing the transplanted cells to be accepted in a transplant host. This would obviate the need to clone the patient in order to produce genetically-matched cells and tissues and ES cells, if necessary, could be derived from frozen IVF embryos. Of course, the debate continues as to whether such "excess" human embryos should be donated to research, or rather adopted through programs such as the Snowflakes embryo adoption program. Nonetheless, a telling point regarding the production of cloned human embryos for derivation of ES cells is that the Stem Cell Research Act of 2001 (S.723) introduced by Senators Specter and Harkin, which supports human embryonic stem cell research, still requires that the research involved shall not result in the creation of human embryos.

The crux of the debate regarding human cloning actually rests then on the necessity for production of embryonic stem cells for clinical use. Further, the question of the necessity of embryonic stem cells for "regenerative medicine" has to do with the potential of such human embryonic stem cells to provide actual clinical treatments for disease versus other, less ethically contentious alternatives. There is no dispute that embryonic stem cells, the inner cells of the very early embryo (approximately 5–9 days old), have the potential to produce all human tissues, *under normal developmental circumstances*. However, despite the initial enthusiasm for use of embryonic stem cells and the media hype, in laboratory cultures as well as in animal transplant experiments, embryonic stem cells have been disappointing. Considerable technical problems remain to be surmounted regarding both laboratory and potential clinical work with these cells, including the difficulty in growth and maintenance of the cells in culture, the relatively slow growth rate of ES cells, potential chromosomal instability of some ES lines, difficulty in directing specific desired differentiation of the cells, and potential tumor formation.

The National Bioethics Advisory Commission (NBAC) expressed it this way in its report in September of 1999:

> "In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research . . . The claim that there are alternatives to using stem cells derived from embryos is not, at the present time, supported scientifically. We recognize, however, that this is a matter that must be revisited continually as science advances."
>
> *Ethical Issues in Human Stem Cell Research, Volume I,* (Rockville, MD; September 1999; p. 53

The question is thus whether a less morally problematic, and scientifically acceptable, alternative exists at this time. Such an alternative *does* exist: adult stem cells. The name is somewhat of a misnomer, since these same stem cells can be found in newborns as well as adults, and can also come from umbilical cords and placentas after delivery of an infant. A better term might be "tissue stem cells" or "post-natal stem cells", but since the term adult stem cells is widely known I will continue to use it here.

Since the NBAC statement in 1999, there has been an avalanche of research reports describing success after success with adult stem cells. Early detractors of adult stem cells raised several questions regarding these cells and their abilities. For example, it has been said that stem cells in adults are often present in only minute quantities, are difficult to isolate and purify, and their numbers may decrease with age, and further that any attempt to use stem cells from a patient's own body for treatment would require that stem cells would first have to be isolated from the patient and then grown in culture in sufficient numbers to obtain adequate quantities for treatment. Numerous research papers have voided these arguments. Studies have shown that previously reported human stem cell frequencies and their self-renewal activity have been markedly underestimated, and that sufficient numbers of adult stem cells can be easily generated in culture for clinical applications. In fact, a recent study showed that only one transplanted adult stem cell from bone marrow could possibly regenerate tissue in several parts of the body. The single transplanted bone marrow stem cell actually expanded its numbers sufficiently and in short enough time to rescue the host mouse in which it was transplanted from lethal irradiation, allowing the transplant recipient to survive. Since that single original stem cell came from another mouse, the technique could have been termed "mouse-to-mouse resuscitation".

As far as difficulty in isolation of adult stem cells, this might be true were we to target extraction of neural stem cells from the brain. However, various studies now show that adult stem cells from many tissues are "pluripotent", that is, they have the ability to form many different tissues in the body, not just regenerate the one tissue from which they were taken. In fact, the indications are that adult stem

cells can regenerate all human tissues. This potential answers another criticism, that an individual stem cell has not yet been found for each of the 210 tissues of the human body. The proven potential of adult stem cells to transform from one tissue type to another negates the necessity to find 210 different adult stem cells, since one or a small set can suffice. Examples include transformation of neural stem cells into blood,, umbilical cord blood stem cells into nerve, and bone marrow stem cells into an array of tissues as diverse as cartilage, fat, bone, muscle, liver, nerve, lung, gastrointestinal tissue, and cardiac tissue. Even fat was recently found to contain stem cells which show indications of the ability to transform into other tissue types. For our nation, this source might truly provide an unlimited quantity of stem cells. Another recent report suggests that the placenta is rich in stem cells which might be transformed into other tissues. And the Scottish company involved in the original cloning of Dolly the sheep, PPL Therapeutics, recently reported that they have developed a technique to reprogram normal adult somatic cells into pluripotent stem cells which can be induced to form almost any tissue; their original experiment involved turning a skin cell from a cow into a heart cell.

If the only thing that could be accomplished were to turn adult stem cells from one tissue type into another in a lab dish, then this would be simply a cute scientific trick. However, adult stem cells have shown that they can form functional tissues when injected into the body. Bone marrow stem cells have been shown to transform into functional liver and muscle; these adult stem cells could potentially "mend broken hearts"—the cells can transform into functional heart tissue, repairing cardiac damage. Bone marrow and umbilical cord blood stem cells have also been shown to migrate to the brain, and in published reports have provided therapeutic benefit after stroke in animal models. Adult pancreatic stem cells have reversed diabetes in mice and regenerated muscle in an animal model of muscular dystrophy.

Adult stem cells are already being used successfully for therapeutic benefit in humans. This includes treatments associated with various types of cancer, to relieve systemic lupus, multiple sclerosis, rheumatoid arthritis, anemias, and immunodeficiency diseases, and restoration of sight through regeneration of corneas. And initial clinical trials have begun to repair heart damage using the patient's own adult stem cells. Per the NBAC statement, if we now revisit the science of stem cells, the weight of published scientific evidence would seem to clearly indicate that an acceptable, less morally problematic alternative to embryonic stem cells does exist. Adult stem cells are making good on what are only promises of embryonic stem cells.

On balance then, is it necessary to destroy some human beings to save other human beings? Is it ethical when viable alternatives exist? The evidence would indicate that it is neither necessary nor ethical. If the purpose of human cloning would be as a source of donor cells and tissues for others, there is no justification for such a practice. Therapeutic cloning takes a utilitarian view of human embryos, useful for a purpose and not valued in and of themselves. They are not viewed as people, but as property, a commodity. Dr. Erwin Chargaff, renowned biochemist, characterizes this attitude as "a kind of capitalist cannibalism".

To artificially try to separate types of human cloning based on the end purpose of the embryo is absurd. What is to prevent embryos which have been manufactured for destruction and harvesting of embryonic stem cells from being implanted into the uterus? If production in the laboratory of cloned humans for the purpose of embryonic stem cell harvesting results in excess embryos beyond that of clinical need, will these excess embryos simply be discarded? Will they be frozen for storage? How would stored embryos created by cloning be distinguished from stored embryos created by *in vitro* fertilization? The techniques used for reproductive cloning and therapeutic cloning are identical, only the intent for use of the cloned human being is different. And how are we to judge intent? How shall we provide oversight of intent?

A complete ban on human cloning as proposed in the Brownback-Weldon bill is the only sufficient answer.

Mr. Chairman, distinguished Members, I thank you for the opportunity to provide testimony on this important issue, and I would be pleased to answer any questions.

REFERENCES

PLURIPOTENT NATURE OF ADULT STEM CELLS

Showed the ability of a *single* adult bone marrow stem cell to repopulate the bone marrow of mice, forming functional marrow and blood cells, and also differentiate into functional cells of liver, lung, gastrointestinal tract (esophagus, stomach, intestine, colon), and skin. Indications that it could also form functional cells in heart and skeletal muscle. Evidence that the stem cells "home" to sites of tissue damage.

Reference: Krause DS *et al.*; "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell"; Cell 105, 369–377; May 4, 2001

Research with mice indicates that adult stem cells from brain can grow into a wide variety of organs—heart, lung, intestine, kidney, liver, nervous system, muscle, and other tissues. The study by Swedish scientists, reported in the June 2, 2000 issue of Science, confirms that adult stem cells are in fact much more adept at redefining themselves than previously thought. The study involved growing adult stem cells from brain with embryonic cells and within an embryo. Even lone neural adult stem cells had the ability to differentiate into various cell types. The authors observe that the "most striking indication" of this complete cellular redefinition was the finding of apparently normal and beating embryonic mouse hearts that contained very large amounts of the stem cells.

According to Dr. Ihor Lemischka, professor of developmental biology at Princeton University, "This is a very exciting and interesting result," and if the research can be confirmed in human cells it would "nip in the bud" the moral and ethical concerns that now block federal funding of human embryonic stem cell research. The authors of the study state that "This demonstrates that an adult neural stem cell has a very broad developmental capacity and may potentially be used to generate a variety of cell types for transplantation in different diseases." They also note that ". . . these studies suggest that stem cells in different adult tissues may be more similar than previously thought and perhaps in some cases have a developmental repertoire close to that of ES cells."

Reference: Clarke *et al.*; "Generalized potential of adult neural stem cells"; Science 288, 1660–1663, June 2, 2000.

STEM CELLS FROM FAT

Isolated adult stem cells from HUMAN fat. Cells could be expanded and maintained in culture for extended periods, and could be differentiated into fat, cartilage, muscle, and bone. Characteristics similar to bone marrow stem cells.

Reference: Zuk PA *et al.*; "Multilineage cells from human adipose tissue: Implications for cell-based therapies"; Tissue Engineering 7, 211–228; 2001

STEM CELLS FROM PLACENTA

Anthrogen, Inc. in a press release reports that they can isolate stem cells from placenta after delivery, and that these stem cells so far have been induced to form bone, nerve, cartilage, bone

REPAIRING CARDIAC DAMAGE

Used bone marrow stem cells from mice expressing green fluorescent protein to track the cells. Injected the stem cells into area of heart where damage had been induced. Newly formed myocardium occupied 68% of the infarcted portion of the ventricle 9 days after transplanting the bone marrow cells. The developing tissue comprised proliferating myocytes and vascular structures. The studies indicate that locally delivered bone marrow cells can generate de novo myocardium, ameliorating the outcome of coronary artery disease.

Reference: Orlic D *et al.*; "Bone marrow cells regenerate infarcted myocardium"; Nature 410, 701–705; April 5, 2001

Human bone-marrow-derived stem cells were implanted into rats with cardiac damage. The cells participated in formation of new cardiac blood vessels and stimulated existing vessels. The authors note that "The use of cytokine-mobilized autologous human bone marrow—derived angioblasts for revascularization of infarcted myocardium (alone or in conjunction with currently used therapies) has the potential to significantly reduce morbidity and mortality associated with left ventricular remodeling."

Reference: Kocher AA *et al.*; "Neovascularization of ischemic myocardium by human bone-marrow-derived angioblasts prevents cardiomyocyte apoptosis, reduces remodeling and improves cardiac function"; Nature Medicine 7, 430–436; April 2001.

Cell transplantation is a potential therapeutic approach for patients with chronic myocardial failure. Experimental transplantation of neonatal and fetal cardiac myocytes showed that the grafted cells can functionally integrate with and augment the function of the recipient heart. Clinical application of this approach will be limited by shortage of donors, chronic rejection, and because it is ethically contentious. By contrast skeletal myoblasts (satellite cells) are abundant and can be grafted successfully into the animal's own heart even after genetic manipulation *in vitro*.

Reference: El Oakley RM *et al.*; "Myocyte transplantation for cardiac repair: A few good cells can mend a broken heart"; Ann Thorac Surg 71, 1724–1733; 2001

TREATING STROKE

Marrow Stromal Cells delivered to ischemic brain tissue through an intravenous route in rats provide therapeutic benefit after stroke. MSCs may provide a powerful autoplastic therapy for stroke.

Reference: Chen J *et al.*; "Therapeutic benefit of intravenous administration of bone marrow stromal cells after cerebral ischemia in rats"; Stroke 32, 1005–1011; April 2001

These data suggest that intracerebral transplantation of bone marrow could potentially be used to induce plasticity in ischemic brain.

Reference: Li Y *et al.*; "Adult bone marrow transplantation after stroke in adult rats"; Cell Transplant 10(1), 31–40; Jan-Feb 2001

Researchers at the University of South Florida have reported at the meeting of the American Association for the Advancement of Science (Jan 2001) and the American Academy of Neurology meeting (May 2001) that human cord blood stem cells can be induced to form neurons. When injected into the bloodstream of rats which had suffered stroke, the adult stem cells found their way to the brain and repaired much of the damage. Rats which were previously paralyzed showed 80% recovery.

TREATING MUSCULAR DYSTROPHY

Multipotent stem cells were isolated from mouse muscle, capable of differentiating into muscle and multiple blood cell types. The adult stem cells were injected into bloodstream of mdx mice, a model of Duchenne muscular dystrophy. The stem cells migrated to muscle, participated in formation of muscle fibers, and helped in regeneration of muscle and restoration of production of dystrophin protein, which is deficient in muscular dystrophy.

Reference: Torrente Y *et al.*; "Intraarterial injection of muscle-derived CD34+Sca-1+ stem cells restores dystrophin in mdx mice"; Journal of Cell Biology 152, 335–348; January 22, 2001

REVERSING DIABETES

Were able to reverse diabetes in mice using the animals' own adult stem cells; after treatment, the mice no longer needed insulin shots to survive.

Reference: Ramiya VK *et al.*; "Reversal of insulin-dependent diabetes using islets generated *in vitro* from pancreatic stem cells"; Nature Medicine 6, 278–282; March 2000

TRANSFORMING BONE MARROW TO BRAIN

Adult stem cells from mouse bone marrow injected into mouse blood stream, could be found developing neuron characteristics in brain. Generation of brain cells from adult bone marrow "demonstrates a remarkable plasticity of adult tissues with potential clinical applications."

Reference: Brazelton TR *et al.*; "From marrow to brain: expression of neuronal phenotypes in adult mice"; Science 290, 1775–1779; Dec 1 2000

Showed in mice that intraperitoneally transplanted adult bone marrow stem cells can migrate into brain and differentiate into neuronal cells. "These findings raise the possibility that bone marrow-derived cells may provide an alternative source of neurons in patients with neurodegenerative diseases or central nervous system injury";

Reference: Mezey E *et al.*; "Turning blood into brain: Cells bearing neuronal antigens generated in vivo from bone marrow"; Science 290, 1779–1782; Dec 1 2000

ADULT STEM CELLS CAN MIGRATE WITHIN BRAIN TO SITES OF DAMAGE

Implanted neural stem cells infiltrate brain tumors. The neural stem cells show the ability to migrate extensively throughout the brain to reach sites of damage. The results "suggest that NSC migration can be extensive, even in the adult brain and along nonstereotypical routes."

Reference: Aboody KS *et al.*, "Neural stem cells display extensive tropism for pathology in adult brain: evidence from intracranial gliomas"; Proc Natl Acad Sci U S A 97, 12846–12851; Nov 7 2000

GENERATION OF NERVES STARTING WITH A SINGLE ADULT STEM CELL

Cultures of adult stem cells from spinal cord can be grown from single cells, and can differentiate into neural cells when injected into the spinal cord or brain of rats. The adult stem cells generate region-specific neurons in the body, including neurons, astrocytes, oligodendrocytes, and glial cells.

Reference: Shihabuddin S *et al.*; "Adult spinal cord stem cells generate neurons after transplantation in the adult dentate gyrus"; J Neuroscience 20, 8727–8735; December 2000

LARGE-SCALE GROWTH OF ADULT STEM CELLS

Human and animal adult stem cells shown to be able of extensive proliferation in culture, providing potentially unlimited supplies of adult stem cells for clinical treatments.

References:

Bhardwaj G *et al.* "Sonic hedgehog induces the proliferation of primitive human hematopoietic cells via BMP regulation", Nature Immun. 2, 172–180; 2001

Cashman JD and Eaves CJ; "High marrow seeding efficiency of human lymphomyeloid repopulating cells in irradiated NOD/SCID mice"; Blood 96, 3979–3981; Dec. 1 2000

Gilmore GL *et al.*; "Ex vivo expansion of human umbilical cord blood and peripheral blood CD34(+) hematopoietic stem cells"; Exp. Hematol. 28, 1297–1305; Nov 1 2000

Woodbury D *et al.*; "Adult rat and human bone marrow stromal cells differentiate into neurons"; J. Neuroscience Research 61, 364–370; August 15, 2000

SOME CURRENT CLINICAL APPLICATIONS OF ADULT STEM CELLS

CANCER TREATMENTS

Brain Tumors

Dunkel, IJ; "High-dose chemotherapy with autologous stem cell rescue for malignant brain tumors"; Cancer Invest. 18, 492–493; 2000.

Kawa, K *et al.*; "Long-Term Survivors of Advanced Neuroblastoma With MYCN Amplification: A Report of 19 Patients Surviving Disease-Free for More Than 66 Months"; J Clin Oncol 17:3216–3220; October 1999

Abrey, LE *et al.*; "High dose chemotherapy with autologous stem cell rescue in adults with malignant primary brain tumors"; J. Neurooncol. 44, 147–153; Sept., 1999

Ovarian Cancer

Schilder, RJ and Shea, TC; "Multiple cycles of high-dose chemotherapy for ovarian cancer" Semin. Oncol. 25, 349–355; June 1998;used autologous, purified peripheral blood stem cells

Solid Tumors

Schilder, RJ *et al.*; "Phase I trial of multiple cycles of high-dose chemotherapy supported by autologous peripheral-blood stem cells"; J. Clin. Oncol. 17, 2198–2207; July 1999 used for malignant solid tumors. Overall response rate 96%, complete clinical response rate 67%.

Multiple Myeloma

Vesole, DH *et al.*; "High-Dose Melphalan With Autotransplantation for Refractory Multiple Myeloma: Results of a Southwest Oncology Group Phase II Trial"; J Clin Oncol 17, 2173–2179; July 1999.

Breast Cancer

Stiff P *et al.*; "Autologous transplantation of ex vivo expanded bone marrow cells grown from small aliquots after high-dose chemotherapy for breast cancer"; Blood 95, 2169–2174; March 15, 2000

Koc, ON *et al.*; "Rapid Hematopoietic Recovery After Coinfusion of Autologous-Blood Stem Cells and Culture-Expanded Marrow Mesenchymal Stem Cells in Advanced Breast Cancer Patients Receiving High-Dose Chemotherapy"; J Clin Oncol 18, 307–316; January 2000

Non-Hodgkin's Lymphoma

Josting, A; "Treatment of Primary Progressive Hodgkin's and Aggressive Non-Hodgkin's Lymphoma: Is There a Chance for Cure?"; J Clin Oncol 18, 332–339; 2000

AUTOIMMUNE DISEASES

(multiple sclerosis, systemic lupus, juvenile rheumatoid arthritis, rheumatoid arthritis)

Traynor AE *et al.*; "Treatment of severe systemic lupus erythematosus with high-dose chemotherapy and haemopoietic stem-cell transplantation: a phase I study"; Lancet 356, 701–707; August 26, 2000

Burt, RK and Traynor, AE; "Hematopoietic Stem Cell Transplantation: A New Therapy for Autoimmune Disease"; Stem Cells 17, 366–372; 1999

Burt RK *et al.*; "Hematopoietic stem cell transplantation of multiple sclerosis, rheumatoid arthritis, and systemic lupus erythematosus"; Cancer Treat. Res. 101, 157–184; 1999

Martini A *et al.*; "Marked and sustained improvement 2 years after autologous stem cell transplant in a girl with system sclerosis"; Rheumatology 38, 773; August 1999

Anemia

Gonzalez MI *et al.*; "Allogeneic peripheral stem cell transplantation in a case of hereditary sideroblastic anaemia"; British Journal of Haematology 109, 658–660; 2000

Kook H *et al.*; "Rubella-associated aplastic anemia treated by syngeneic stem cell transplantations"; Am. J. Hematol. 64, 303–305; August 2000

Stroke

Kondziolka D *et al.*; "Transplantation of cultured human neuronal cells for patients with stroke"; Neurology 55, 565–569; August 2000

Corneal scarring

Schwab IR *et al.*; "Successful transplantation of bioengineered tissue replacements in patients with ocular surface disease"; Cornea 19, 421–426; July 2000.

Tsai *et al.*; "Reconstruction of damaged corneas by transplantation of autologous limbal epithelial cells."; New England Journal of Medicine 343, 86–93, 2000.

Tsubota K *et al.*; "Treatment of severe ocular-surface disorders with corneal epithelial stem-cell transplantation"; New England Journal of Medicine 340, 1697–1703; June 3, 1999

Osteogenesis imperfecta (leads to bone and cartilage deformities)

Horwitz, EM *et al.*; "Transplantability and therapeutic effects of bone marrow-derived mesenchymal cells in children with osteogenesis imperfecta"; Nat. Med. 5, 309–313; March 1999.

Gene Therapy

Cavazzana-Calvo M *et al.*; "Gene therapy of human severe combined immunodeficiency (SCID)-X1 disease"; Science 288, 669–672; April 28, 2000

*First successful trial of human therapy, re-injecting the infants' own bone marrow stem cells containing a normal copy of the gene that they lacked.

Disclosure of federal grants, contracts, or subcontracts received in the current and preceding two fiscal years

National Institutes of Health
Indiana University School of Medicine, Indiana University-Purdue University at Indianapolis (collaborative research sub-contract with Dr. David A. Williams); 1 January 2000–31 July 2000; $11,000; "Molecular and Functional Characterization of a Novel Mutation in Murine Stem Cell Factor"

National Institutes of Health
Indiana University School of Medicine, Indiana University-Purdue University at Indianapolis (collaborative research sub-contract with Dr. David A. Williams); 1 August 2000–30 June 2001; $16,000; "Molecular and Functional Characterization of a Novel Mutation in Murine Stem Cell Factor" (renewal)

SUMMARY

There is almost uniform agreement against "reproductive cloning"—creating a cloned human being and allowing that clone to develop to a live birth. But some scientist propose "therapeutic cloning", production of human embryos by cloning for the purpose of harvesting embryonic stem (ES) cells.

If necessary, ES cells can be derived from "excess" human embryos frozen for *in vitro* fertilization. But are ES cells really necessary for regenerative medicine? Despite the initial enthusiasm, ES cells to date have been disappointing. A less morally problematic and scientifically viable alternative exists—adult stem cells. Studies have shown that sufficient numbers of adult stem cells can be generated in culture for clinical applications. Even one transplanted adult stem cell from bone marrow could possibly regenerate tissue in several parts of the body. Various studies now show that adult stem cells from many tissues are "pluripotent", with the ability to form many different tissues. The indications are that adult stem cells can regenerate all human tissues. Examples include transformation of neural stem cells into blood, umbilical cord blood stem cells into nerve, and bone marrow stem cells into an array of tissues as diverse as cartilage, fat, bone, muscle, liver, nerve, lung, gas-

trointestinal tissue, and cardiac tissue. Even fat was recently found to contain stem cells. Another report suggests that placenta is rich in stem cells. And the Scottish company involved in the original cloning of Dolly the sheep, PPL Therapeutics, has reported that they have developed a technique to reprogram normal adult somatic cells into pluripotent stem cells which can be induced to form almost any tissue.

Adult stem cells have shown that they can form functional tissues when injected into the body. Bone marrow stem cells have been shown to transform into functional liver and muscle, as well as functional heart tissue, repairing cardiac damage. Bone marrow and umbilical cord blood stem cells have also been shown to migrate to the brain and provide therapeutic benefit after stroke in animal models. Adult pancreatic stem cells have reversed diabetes in mice and regenerated muscle in an animal model of muscular dystrophy.

Adult stem cells are already being used successfully for therapeutic benefit in humans. This includes treatments associated with various types of cancer, to relieve systemic lupus, multiple sclerosis, rheumatoid arthritis, anemias, and immunodeficiency diseases, and restoration of sight through regeneration of corneas. And initial clinical trials have begun to repair heart damage using the patient's own adult stem cells. An acceptable, ethical alternative to embryonic stem cells does exist. Adult stem cells are making good on what are only promises of embryonic stem cells.

Therapeutic cloning is therefore unnecessary and unjustifiable. It takes a utilitarian view of human embryos, viewing them not as people, but as property, a commodity; this is "a kind of capitalist cannibalism"". It will be virtually impossible to provide oversight of the intent for cloning a human embryo, or distinguishing stored IVF embryos from stored cloned embryos. A complete ban on human cloning as proposed in the Brownback-Weldon bill is the only sufficient answer.

Mr. SMITH. Thank you, Dr. Prentice. Ms. Shapiro, we have you down as both doctor and Ms. Which would you prefer?

Ms. SHAPIRO. Attorney.

Mr. SMITH. We can say Counselor Shapiro then.

STATEMENT OF ROBYN S. SHAPIRO, PROFESSOR OF BIOETHICS, MEDICAL COLLEGE OF WISCONSIN

Ms. SHAPIRO. Perfect, thank you. It is a pleasure to be here. I am not here, though, to stand by Richard Seed's side and advocate that we immediately clone a human being. What I am here to do today is to point out my concerns about any prospective notion of criminalizing cloning. Unfortunately, Dolly the sheep set off a frenzy of horrific and hypothetical human cloning scenarios, which were picked up by the press in large measure as evildoers or rich people cloning themselves time and time again, middleman deciding that they were going to hire women to bear the clones of Michael Jordan or Michael Jackson or somebody like that. This tended to overlook the potential benefits of cloning, which are enormous.

With cloning animal cells and tissues with particular traits and a high degree of DNA similarity can be produced much more easily, and for that reason, there is tremendous interest on the part of so many for progressing with these advances. Veterinary geneticists, agricultural biotechnology experts firmly support cloning animals to do things like replicating transgenic cows or sheep that have been genetically engineered to produce in their milk therapeutic proteins that are valuable to humans. When we get to the human side, facilitating the integration of DNA synthesis and new reproductive technologies through cloning allows us to greatly advance cellular and tissue transplants by allowing us to clone genetically matched cells and tissues for transplantation into patients who suffer from disorders that result from tissue loss or tissue dysfunction.

Beyond that, we have the capability through cloning of being able to turn human cells into specific tissue types, to regenerate nerve cells in individuals with Parkinson's or Alzheimer's or heart muscle cells in those with heart disease; and additional positive spinoffs of cloning in the field of genetic engineering include producing human proteins, like blood clotting factors that can help us heal wounds. We also, down the line, perhaps would see important benefits from cloning in human reproduction. If both a male and a female in a couple had a recessive—carried a recessive gene for a serious disorder, cloning might allow them, down the road, to avoid conceiving an embryo with that disorder and thereby avoid the prospect of having to choose abortion.

The regulation that we have today applicable to human cloning seems appropriate to me. In 1997, the White House issued a directive on cloning, applicable both to research and to clinical application—that bans all Federal funding for human cloning. We have Federal regulations applicable to all federally funded human subjects research and under these where safety concerns about human cloning certainly would preclude IRB approval of any advance along those lines. The Food and Drug Administration has claimed that clinical research using cloning technology to create a human being is subject to its jurisdiction, under the Public Health Service Act and also the Food, Drug and Cosmetic Act. There is some controversy about whether they are right, but they claim that to be true and they intend to exercise that jurisdiction.

So, if we were to move beyond that to any thought of criminalizing cloning, we would encounter some ill-advised effects, I believe. First and probably foremost, there are real dangers in mixing medical and scientific work with criminalization. If a statute were to create criminal penalties, for example, for the performance of any somatic cell nuclear transfer in order to create a human being (and that is what many proposals have suggested) enforcement really would require monitoring the intent of scientists engaged in what may very well be very beneficial research, and that certainly would create a huge and disturbing, chilling effect on scientific inquiry.

Added to this problem of trying to come up with a criminal prohibition that would be appropriately circumscribed and that could be easily enforced are problems of obsolescence. It is likely that any statute that we could conceive of that would criminalize human cloning would be outpaced by technological advances—and we have already seen that. In California, they have a statute that prohibits cloning and that uses a definition of cloning that uses the term "human" when talking about enucleated eggs. In other words, it prohibits putting the DNA from another cell into a human enucleated egg. That could be evaded, for example, by using a cow's enucleated egg to incubate the nucleic DNA of a human, which certainly appears feasible in light of our very own University of Wisconsin researcher's success in using enucleated cow eggs to serve as incubators for other mammalian species' nucleic DNA.

Finally, with all due respect, any Congressional act that would create criminal penalties for human cloning would open important aspects of scientific development to political tug-of-war, and we have seen this with debates about fetal tissue and embryonic research. The risk is that we will end up with laws that cover too

much for reasons that do not have to do with human cloning, and that, unfortunately, make it impossible to attain the promises of the technology. So, given all these hazards, the three main hazards that I pointed out, criminalizing cloning because human cloning, at the moment, is unsafe and/or because certain applications of the technology would be unethical, threatens, unnecessarily, given the regulation we currently have, to stifle scientific progress.

To balance the dangers that I have talked about against the promise of the research, which is significant, informed regulation, to me, seems the better approach and this has worked in the past. We have to recall, in the 1970's, that there were heated discussions about how to prevent abuses of recombinant DNA technology. Some called for criminalization. We did not get that. We got standards; we got guidelines and we certainly have seen the benefits, the huge benefits in medicine, of those advances. We need to ensure that our approach today to cloning similarly allows research in the field to progress.

Thank you.

[The prepared statement of Ms. Shapiro follows:]

PREPARED STATEMENT OF ROBYN S. SHAPIRO, J.D.

The debate about human cloning raises a number of important ethical, legal, and social issues. While the emotionally-charged nature of the issues now has led some to insist that human cloning should be criminalized, a more appropriate approach is to assure, through regulation or guidelines, that cloning technology is used to enhance, rather than limit, individual freedom and welfare.

Dolly the sheep—the first mammal to be cloned from a single adult cell—set off a frenzy of horrific hypothetical human cloning scenarios, including evil-doers or rich or powerful persons cloning themselves time and again, or commercial entrepreneurs hiring women to bear clones of movie stars or sports heroes to sell to others. But the potential benefits of cloning are enormous. For example, animals, cells and tissues with particular traits and a high degree of DNA similarity can be produced much more easily. For this reason, veterinary geneticists and agricultural biotechnology experts firmly support cloning in animals in order to advance animal research (for example, replicating transgenic cows or sheep that have been genetically engineered to produce in their milk therapeutic proteins valuable to humans—such as clotting factors or hormones). Perhaps more importantly, by facilitating the integration of DNA synthesis and new reproductive technologies, cloning will greatly advance cellular and tissue transplants by allowing us to clone genetically matched cells and tissues for transplantation into patients suffering from a variety of disorders that result from tissue loss or dysfunction. Beyond that, therapeutic cloning has the capability of turning human cells into specific tissue types—to regenerate nerve cells in patients suffering with Parkinson's or Alzheimer's, or heart muscle cells in those with heart disease. Additional positive spin-offs of cloning in the field of genetic engineering include the production of human proteins such as blood clotting factors that aid in healing wounds. Research on somatic-cell nuclear transfer will also yield important information on stem cell differentiation, which could provide valuable information about the mechanism of aging and the causes of cancer. Cloning also may offer important potential benefit in human reproduction. For example, if both the male and female in a couple carried a recessive gene for a serious disorder, cloning would allow them to avoid conceiving an embryo with the disorder and thereby avoid the prospect of selective abortion.

The regulation currently applicable to human cloning seems appropriate—for now. A 1997 White House Directive on Cloning, applicable to both research and clinical application, bans all federal funds for human cloning; under regulations applicable to federally-funded human subjects research, safety concerns would preclude approval of human cloning research; and the Food and Drug Administration has claimed that clinical research using cloning technology to create a human being is subject to FDA regulation under the Public Health Service Act and the Food, Drug and Cosmetic Act.

Moving beyond that regulation to criminalization of cloning would be ill-advised. First, there are significant dangers in criminalizing medical and scientific work. If

a statute were to create criminal penalties, for example, for the performance of any somatic cell nuclear transfer in order to create a human being, enforcement would require monitoring the intent of scientists engaged in beneficial research—thereby creating a disturbing chilling effect on scientific inquiry.[1]

Added to problems of crafting a criminal prohibition that would be appropriately circumscribed and capable of being reasonably enforced are problems of obsolescence. It is likely that any statute criminalizing human cloning would be outpaced by technological advances. California's statute prohibiting cloning, for example, uses a definition of cloning that uses the term "human" when referencing enucleated eggs.[2] That statutory prohibition could be evaded by using a cow's enucleated egg to incubate the nucleic DNA of a human—a procedure that appears entirely feasible in light of University of Wisconsin researchers' success in using enucleated cow eggs as incubators for other mammalian species' nucleic DNA.

Moreover, any Congressional act creating criminal penalties for human cloning would open important aspects of scientific development to a political tug-of-war—as has been the case with debates about fetal tissue and embryo research. The risk is the creation of laws that cover too much for reasons that have nothing to do with human cloning, and that make it impossible to attain the promises of the technology.

Given these hazards, criminalizing cloning because human cloning currently is unsafe and/or because some applications of the technology would be unethical threatens unnecessarily to stifle scientific progress. To balance these dangers against the promise of research, informed regulation seems the better approach. This approach has worked in the past. In the 1970's, there were heated discussions about how to prevent abuses of recombinant DNA technology. While guidelines and standards were adopted, criminal legislation was not passed, and this technology certainly has yielded tremendous benefits in medicine. We need to assure that our approach to regulating cloning similarly allows research in the field to progress.

Mr. SMITH. Thank you, Ms. Shapiro. Let me thank you all for your testimony, as well, and we will now go to our question period.

Let me begin, Dr. Kass, with a question for you—and by the way, I noticed in your more extensive written testimony, and all your testimonies will be made a part of the record without objection—that you have been writing on human cloning since 1967. I'm tempted to ask you what gave you the idea in 1967 the we would be wrestling with human cloning?

Dr. KASS. The first cloning of frogs—there was an article in the Washington Post by Joshua Letterburg saying that if we could develop this for human beings we could end the unpredictable variety that comes as a result of sex.

Mr. SMITH. I was just curious. That was not a legitimate first question, but it does seem to me that we are wrestling with trying to establish a balance, as described by Dr. Callahan, and that is a balance between the need for free scientific inquiry and the need to establish ethical standards. You really do have to have some restraint on what we do. Dr. Kass and Dr. Callahan, my first question is really why do you believe that we do need to have criminal penalties and ban human cloning; and why do you not think that current regulations are sufficient, as Ms. Shapiro does?

Dr. KASS. Well, the first point is that I treat the danger as much greater than Ms. Shapiro does. I think we stand on the threshold of something terribly important and that merely withholding Federal funds, and having Federal regulations of research done with

[1] Some have argued that the First Amendment right to free speech encompasses the right of scientific inquiry. In *Branzburg* v. *Hayes*, 408 U.S. 665, 705 (1972), the United States Supreme Court specifically analogized the information function performed by academic researchers to that performed by the press; and in *Meyer* v. *Nebraska*, 262 U.S. 390 (1923), the Supreme Court stated that 14th Amendment liberty rights encompass freedom to "acquire useful knowledge—and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men."

[2] Cal. Bus. & Prof. Code § 2260.5

Federal funds, does not touch what goes on in the private sector where this research is proceeding pell-mell, and under great secrecy, partly conditioned by the competition in the field.

Second, *in vitro* fertilization, which we have lived with and has brought great benefits to many infertile couples, is a completely unregulated and unstudied practice. If this goes on, not covered by the FDA, and were the clonal embryos available created commercially, they could be bought and sold and used in reproductive clinics and no one would know. So, I think that if we regard this as a serious and important matter and that we see this as an opportunity to place the burden of proof on the other side to say we absolutely have to have human cloning for these and these reasons—and I do not think they can meet that burden—this is the time to do it and to put down this marker.

Mr. SMITH. Dr. Callahan, do you agree with that?

Mr. CALLAHAN. I very much agree. I would simply add that I think it would be extraordinarily difficult to regulate the private sector. This would require a great deal of snooping around laboratories, of trying to find out what is going on, breaking through proprietary restraints. We find it very difficult now to know what's going on in the private sector. This would be very difficult particularly if the scientist and whoever was doing it knew that it was likely to be controversial research, they would do everything possible, it seems to me, to make it difficult to find out what they were doing. It seems to me that this is one of those horrible situations. Regulation seems the moderate, reasonable, middle way to go, but I simply don't think it would effectively work and, hence, we have to go a more Draconian route.

Mr. SMITH. Dr. Callahan, one more question—a lot of people are concerned, I think, that we, in our scientific discoveries, might gain the world, but sell our soul at the same time. You mentioned in your written testimony that scientific freedom is not an absolute value. Aren't there other instances where we have banned or prohibited scientific experiments as unethical or criminal, and this is not unprecedented, were we to go in this direction?

Mr. CALLAHAN. Well, certainly, a number of European countries have already banned cloning. I guess what is different here is that this research is at what might be called the basic—somewhere between basic and applied research—and there I think it is probably difficult to find very good legal precedents for efforts to ban research at that level, but other countries have indeed done it, for many of the reasons Dr. Kass has presented. It seems to me that when one is faced with what seems to be a very difficult decision, you really have to ask the question what is going to be good for us in the long run?

Science is doing terrific these days. The National Institute of Health has lots of money. The private sector has money. The public sector has money. Research will go forward. Some research may be slowed down. Some may be slightly harmed, but it seems to me, in general, we are going to find it very much in the whole biological realm in years to come, and this is not going to make a great deal of difference if it is stopped.

Mr. SMITH. Thank you, Dr. Callahan. Dr. Prentice, you made the point that there are alternatives to the medical benefits that we

might enjoy from cloning and you mentioned adult stem cells as an example. What if it were shown or proved that we really could not achieve everything that we wanted to in the way of medical advances by using adult stem cells? Would you still be opposed to human cloning and if so, why?

Mr. PRENTICE. Yes, Mr. Chairman, I would, and I think it relates back more to the idea what some people have termed human dignity. I think the vast weight of scientific evidence says that it is probably the other way around, that the embryonic stem cells are not going to be able to make good on those sorts of promises and the adult cells are already doing that. But, I think it comes back to the idea of a human being and the way we view humanity or how we view ourselves as a society, and science tells us that even at one cell we are a human being. This is not some other species, not fish nor fowl. It is a question now of how we view other members of our species. I think this is a particular route down which we just do not need to go.

Mr. SMITH. Thank you, Dr. Prentice. I'm going to say Dr. Shapiro. I think all attorneys should be called doctor because of J.D.s.

Mr. SMITH. My time this up, but let me squeeze in one brief question and that is, I understand your point about relying on current regulation rather than criminalize human cloning. A couple of your objections, though, to me, seem to be technical in the sense that they could be overcome. You mentioned enforcement problems. You mentioned definitional problems. It seems to me if you write the laws well or if you update the legislation, you can address those kinds of concerns. Therefore, we could justify going beyond just the regulations. Do you want to comment on that?

Ms. SHAPIRO. Two responses. One is I hope that is true, but problems in doing that could happen on account of the third factor that I mentioned, and that is the political tug-of-war aspect of all of this. Probably the most important response I would have to that is the chilling effect that a statute like that would have regardless. That is, even if we could try to craft it very specifically, we have seen physicians and scientists could read it in a different way, and if the threat of going to jail for life is hanging over them, they are very likely to be conservative about what might be permissible.

Mr. SMITH. Thank you, Dr. Shapiro. The gentleman from Virginia, the Ranking Member, Mr. Scott, is recognized for his questions.

Mr. SCOTT. No questions.

Mr. SMITH. The gentlewoman is recognized.

Mr. JACKSON LEE. Let me thank the witnesses very much, and please accept my apologies—I was detained on the floor of the House—for not hearing the testimony of earlier witnesses, but I have had the opportunity and will have the opportunity further to review your testimony. Let me applaud the legislation's intent. I am going to remain open—that is what hearings are for, as we move toward trying to find the best solution. I do want to commend Dr. Weldon for the intent and his reaching out to Members of this Committee and others to further explain this particular legislation.

The first, if you will, response to human cloning is for those of us who grew up on Frankenstein, is extremely negative. Frankly, as we watched that creation, we didn't want to add to it. It may

not have been cloning. It may have been just be piecing things together, but we are in a new century and I think we have to be open minded on what helps us to solve today's problems, particularly medical research. Might I, Dr. Shapiro, since we are going to adhere to the new title, probe you a little bit and then I have some questions for the other individuals? I want to pursue your line of reasoning on the chilling effect, which, I think, has great merit. I would offer and ask you how this might reach out into stem cell research, which is so important for people suffering from Parkinson's disease and other aspects, and tell me where that would reach if you are talking about *in vitro* fertilization? I am interested in the concept of banning implantation for scientific research, but possibly the work you do in the lab can be distinguished, because hopefully you are there in the lab to do good, as opposed to do ill. Would you comment on those two concepts, please?

Ms. SHAPIRO. Sure. I think part of your question actually is your answer, and that is, in my mind, the threat, the chilling effect threat, could very well reach to reluctance or refusal on the part of scientists and medical personnel to explore stem cell research and/or even in *in vitro* fertilization, and we certainly have seen the promise and the reality of the benefits of those procedures. In terms of prohibiting implantation, we heard remarks earlier about what European countries are doing, and actually Britain is allowing for embryonic cloning as long as there is no implantation, on account of just what you're suggesting; that is, that the research is potentially very beneficial, but we want to avoid creating a cloned human being.

Mr. JACKSON LEE. You are from the medical school in Wisconsin, as I understand.

Ms. SHAPIRO. Yes.

Mr. JACKSON LEE. Research is done at the school, to your knowledge?

Ms. SHAPIRO. Well, actually, there are two medical schools. I am from the Medical College of Wisconsin and a mere hour-an-a-half away is the University of Wisconsin where Dr. Jamie Thompson has led great efforts in stem cell research.

Mr. JACKSON LEE. You might include them in your answer. My question really goes to the point, the broader point, that I come from a community where the Texas Medical Center is and several medical schools; would you view legislation like this permeating the research that is done in those institutions, in light of the sensitivity that I imagine physicians have who are not lawyers, in not wanting to have their lab criminalized?

Ms. SHAPIRO. Absolutely. Without any legislation, and I can speak about the experience we are going through at the moment at the Medical College of Wisconsin, there is tremendous caution in going into this sort of research simply because of the important ethical issues involved. But, with any sort of a criminal statute, I can tell you that they would run the other way as far as they could.

Mr. JACKSON LEE. Let me raise this question for all of you, and I'm going to refer you to—if you have in front of you—but if the Chairman would indulge me, it is the definition section of the legislation that I think we are presently looking at, H.R. 1644, human cloning. Let me just quickly go over it. Human cloning means

human asexual reproduction, accomplished by introducing the nuclear material of a human somatic cell into a fertilized or unfertilized oocyte whose nucleus has been removed or inactivated to produce a living organism in any stage of development with a human or predominately human constitution. I'm not sure if this has been amended. I know we have not marked it up and forgive me for reading so quickly, but I would appreciate Dr. Kass, Dr. Callahan, Dr. Prentice and Dr. Shapiro—as I read it as a lawyer, engaged only in this ethically, and not from the perspective of being in a lab, this is enormously broad.

Mr. SMITH. Ms. Jackson Lee, let me interrupt you just for a minute. I would like you to get a brief response from one individual, but actually our second hearing is going to be on the legislation itself. So, there will be more opportunity to question the legislation.

Mr. JACKSON LEE. I'll take a first answer. Would you mind if Dr. Kass and Dr. Shapiro, and I will not have the other——

Mr. SMITH. If you all would briefly reply.

Mr. JACKSON LEE. Thank you, Mr. Chairman.

Dr. KASS. I think this is very narrow, especially when read with the other section, which indicates what is does not cover. This is very, very precise. I think everybody would understand what this means.

Mr. JACKSON LEE. You think it's narrow.

Dr. Shapiro?

Ms. SHAPIRO. I don't think so. I have to tell you, I have not yet read this, so, I don't know where the definition or how the definition is being used in the bill, but it seems broad to me.

Mr. JACKSON LEE. Thank you very much, Mr. Chairman.

Mr. SMITH. Thank you, Ms. Jackson Lee. The gentleman from Florida, Mr. Keller, is recognized for his questions.

Mr. KELLER. Thank you, Mr. Chairman. Let me just say, Dr. Shapiro, like you and many others here, I also am a lawyer by trade and, unfortunately, there are some folks that say we are a good example of why human cloning is a bad idea.

Let me begin by asking you, Dr. Kass, a question. Some people will argue or say that cloning is really not morally different from *in vitro* fertilization, and I suspect you have a different view. What is your thought on that?

Dr. KASS. No, I do have a different view. I think cloning is in some respects continuous, but in the decisive respect something radically different. In *in vitro* fertilization, the egg and sperm come together by the usual sexual activity of chance. There's a chance meeting of and egg and a sperm and the individual that is produced is the product of that chance union. In the case of cloning, deliberate efforts are made to produce an individual who is genetically identical or virtually identical, not just to some contemporary, but to an individual who already exists and, in fact, who could have existed and is now deceased. In this respect, cloning is the first of a foreseeable group of technologies that will enable us to control, not just whether a child is born, but precisely what the genetic constitution of that child is.

Mr. KELLER. Okay. Dr. Prentice, what is the gist again and the difference between reproductive cloning and what they call therapeutic cloning?

Mr. PRENTICE. Congressman, essentially the idea behind reproductive cloning would be to clone the individual and actually bring them to a live birth. Therapeutic cloning, frankly, the intent is not to bring them to a live birth, but at a very early embryonic stage, approximately five to 9 days—at that point we look like a hollow ball with some cells inside—is to harvest those cells from the inside, the embryonic stem cells, and in doing so you do have to destroy the embryo to put those cells in the culture.

Mr. KELLER. Okay. It is my understanding from some of your previous writings that of the mammals cloned so far, approximately 95 to 99 percent do not survive. Would you anticipate a similar failure rate on attempts to clone humans?

Mr. PRENTICE. Definitely so. Now, obviously, techniques can improve, but there's so much unknown at this point in terms of the whole cloning procedure. It sounds very simple on paper or drawn on the board, but we do not know too much about what actually goes on in terms of reprogramming that nucleus which is inserted into that oocyte, and that appears to be, at least to a large extent, what gives us the problems with many of the clones not even making it to term, and virtually all of them not surviving even after term. The possibility could be genetic problems that develop in terms of this technique.

Mr. KELLER. Thank you, Dr. Prentice. Mr. Chairman, I'll yield back the balance of my time.

Mr. SMITH. Thank you, Mr. Keller. What was the last question you had, Mr. Keller?

Mr. KELLER. The last question—I asked him the difference between therapeutic cloning and reproductive cloning.

Mr. SMITH. Thank you. The gentleman from Virginia, Mr. Scott, is recognized for his questions.

Mr. SCOTT. Thank you. On this morning's radio, I heard a piece on the cell research to help hemophiliacs. They would take a piece of skin, do something with it in the lab, and it would produce Factor VIII. That is about all I remember about it, and that would help blood-clotting for hemophiliacs. Would any of the legislation in this area affect that kind of research?

Mr. PRENTICE. No, sir, it actually would not. The bill which I have seen, I think is very carefully crafted, very tight. The type of research you are discussing is covered under this section, which talks about no prohibition for the use of nuclear transfer or other cloning techniques to produce molecules, including the Factor VIII clotting factor, DNA, cells other than human embryos, tissues, organs, plants or animals other than humans. In my reading of this, this has no chilling effect on medically necessary research. It only prohibits the actual production by this cloning technique of a human individual.

Mr. SCOTT. Would the violations start with the implantation or would it start earlier?

Mr. PRENTICE. I guess I will take that one, too. My assumption in reading this is that the violation would start at the point where the nucleus was inserted into that enucleated oocyte. At that point,

you have the clone. The problem, again, in terms of distinguishing between reproductive and therapeutic cloning is, if you were to take an embryo produced by reproductive cloning, therapeutic cloning, *in vitro* fertilization and put them under a microscope, you could not distinguish how that embryo was produced. So, as my colleague referred to earlier, there is no way we can judge intent. It could be that we might clone an individual, clone an embryo, and the original intent could have been for therapeutic cloning, deriving the embryonic stem cells, but, if we put some of those excess embryos in the freezer and take them out, how are we going to judge whether that was an IVF embryo put in there, one that was going to be used for reproductive cloning or one that might be used for therapeutic cloning? There is no real way to tell the difference.

Mr. SCOTT. Therefore, your suggestion is not to have any therapeutic cloning?

Mr. PRENTICE. Yes, sir, that's it. I think we should follow the Brownback-Weldon bill and totally ban human cloning.

Mr. SCOTT. Did somebody else want to comment on whether that would be a good thing or bad thing, to prohibit all therapeutic cloning, Dr. Kass?

Dr. KASS. Yes, I would like to comment. Dr. Prentice and others have indicated that, to our great amazement, the work with stem cells derived from adults, from cord blood, is providing us with the kinds of tissues we need to do exactly this kind of therapy. We have a morally unproblematic alternative to the so-called therapeutic cloning. That would be the first point, so I do not think there is a great deal we are losing if we give this up.

Second, if you're serious, really serious about trying to prevent so-called reproductive cloning, that is, the birth of cloned children, I don't think you can actually make that ban effective unless you ban that process at the beginning. Once the embryos are there, you are not going to be able to control what is done with them. We have learned that with the so-called spare embryos to this point.

Mr. SCOTT. Let me ask you a practical question. If we create a criminal statute prohibiting therapeutic cloning, all kinds of cloning, that criminal statute would only have an effect within the jurisdiction of the United States?

Dr. KASS. Actually, sir, we are behind the curve on this one. Many, many nations—the Council of Europe has called for this. The U.N. has called for a ban on this and on germ line modification, and it seems to me they look upon us as being something of a rogue nation in this way. I would not call this a ban on therapeutic cloning. I think what one wants to say is this is a ban on the cloning of human beings in the most effective way possible, and I think the bill is carefully drawn and could be made effective and would not chill the other necessary and desirable, medically beneficial and therapeutic research.

Mr. SCOTT. Is your testimony that if we passed a criminal statute, there would be nowhere that the research would move to totally unregulated, without any oversight at all, and whether that would be better or worse than trying to regulate it the best we could in the United States?

Dr. KASS. Well, for most things, I am not in favor of legal bans. Bans are a blunt instrument, and you cannot prevent—you do not

prevent all cases of incest by laws against incest and we do not prevent the buying and selling of organs for transportation in other parts of the world, but we have made this a crime in the United States and it has been enforced. So, I don't say we are going to absolutely prevent this, but if we are serious about trying to do something, this is our best shot. In collaboration with other nations I think we have a fighting chance to make sure that it doesn't happen or doesn't happen much. I don't think you can do better with law.

Mr. SCOTT. Ms. Shapiro, did you want to respond?

Ms. SHAPIRO. I'm not a doctor. However, what I read is that 1 day the literature may suggest that adult stem cells are going to be equally as promising as embryonic stem cells and the next day that is controverted. That is the point. If we snuff out the ability to do this research, we may never know. I do not think that it is as easy from what I read, and again, with all the disclaimers I put on the table before, to simply say we will be losing nothing if we prohibit this sort of research from going forward.

Mr. SMITH. Thank you, Mr. Scott, and also I would like to thank all of the witnesses today for their expert testimony, even if they are lawyers, and it is much appreciated and very helpful and useful. Also, I will let you know as well as the audience know that the second hearing on human cloning is scheduled for June 19th. That is a Tuesday, at 4 in the afternoon, and the subject of that hearing will be more the Federal regulation of human cloning; and also we will be talking about, certainly, Dr. Weldon of Florida's bill that has been introduced and perhaps Mr. Greenwood of Pennsylvania's bill if it has been introduced at that time. Thank you again for your testimony. The gentlewoman from Texas has a comment.

Mr. JACKSON LEE. Mr. Chairman, may I submit a question for the witnesses to respond to in writing?

Mr. SMITH. Absolutely. Without objection, anyone who has written questions can submit them and we will hope for answers within 2 weeks if you can accommodate us on that score, as well.

Mr. SCOTT. Mr. Chairman, I ask unanimous consent to include this statement in the record.

Mr. SMITH. Without objection, Mr. Scott, we will make a part of the record your opening statement.

Mr. JACKSON LEE. I'm sorry. Likewise, if I may.

Mr. SMITH. All Members are welcome and without objection, will be allowed to make their full opening statements a part of the record.

Mr. JACKSON LEE. Mr. Chairman, simply, I will not give the question, but it regards the impact of this legislation on *in vitro* fertilization and the embryo. Thank you.

Mr. SMITH. Thank you, Ms. Jackson Lee. Thank you again to all of our witnesses. We appreciate your being here and the hearing stands adjourned.

[Whereupon, at 12:03 p.m., the Subcommittee was adjourned.]

HUMAN CLONING PROHIBITION ACT OF 2001 AND THE CLONING PROHIBITION ACT OF 2001

TUESDAY, JUNE 19, 2001

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIME,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to notice, at 4:05 p.m., in Room 2141, Rayburn House Office Building, Hon. Lamar Smith [Chairman of the Subcommittee] presiding.

Mr. SMITH. The Subcommittee on Crime will come to order. We welcome our witnesses.

I have an opening statement, then I will recognize other individuals who are here, who might have opening statements, and then we will proceed to hear from our expert witnesses.

Today the Subcommittee on Crime holds the second of two hearings on the issue of human cloning. At our last hearing, the Subcommittee focused on the ethical issues and possible consequences of cloning human beings.

Now we will examine the legal issues relating to the Federal regulation of human cloning and hear testimony regarding two bills on the issue, H.R. 1644 and H.R. 2172.

Prior testimony revealed that there are a growing number of groups who claim they can and will clone a human being. Currently, no clear regulations exist in the United States that would prevent a private group from attempting to create a human clone. In this sense, the United States lags behind most other industrialized nations.

Even though the Federal Food and Drug Administration has asserted that it has the authority to regulate this activity, legal scholars have expressed doubt as to whether this claimed authority would stand a legal challenge. Furthermore, the consequences for any scientist who ignores the FDA's claimed authority are unclear.

Legal challenges to any Federal regulation of human cloning will be swift. Opponents will argue against any ban on human cloning because it allegedly interferes with the desire for scientific inquiry. Yet an overwhelming majority of Americans oppose cloning.

Scientific advancement can enrich our lives, but not when it erodes our most fundamental principles. While there is room to roam, it is not an open range.

Although Congress may not prohibit research in an attempt to prevent the development of new knowledge, it may restrict or pro-

hibit the means used by researchers that threaten interest in which the citizens of this country have a legitimate concern.

The two bills before us today would prohibit the cloning of human beings. However, the scope of that prohibition is treated in very different and important ways.

H.R. 2172, introduced by Congressman Greenwood of Pennsylvania, requires courts to determine a scientist's intent. If the scientist clones a human to initiate a pregnancy, he is in the wrong. If he clones without that intent, he is right.

H.R. 1644, introduced by Congressman Weldon of Florida, prohibits the use of human cloning technology to produce a living human organism at any stage of development. The Weldon bill would make it a criminal act to clone a human embryo for any reason, scientific or reproductive.

Neither of these bills places any restrictions on the use of cloning technology to clone molecules, DNA, cells, tissues, organs, plants, or animals. They would not interfere with the use of *in vitro* fertilization, fertility-enhancing drugs, or other medical procedures that help women to become or remain pregnant.

Today we will hear from a panel of four witnesses who have extensive backgrounds in the field of law and bioethics. I would like to thank the witnesses for appearing before the Subcommittee on this important issue.

The Chair now recognizes the gentleman from California, Mr. Schiff, for his opening statement.

Mr. SCHIFF. Thank you, Mr. Chairman.

The image of Dolly, a sheep cloned in Scotland in 1997, is a vivid one in all of our recollections. All our impressions at the time, of what that scientific achievement meant and the important ethical issues it raised, have not been far from our thoughts ever since.

Although Dolly's cloning was a scientific success, the process of cloning remains a highly contentious issue. Most people have a fairly narrow notion of what the term cloning means, particularly in regard to humans. In fact, it encompasses a number of scientific processes with widely diverse meanings, whether applied to animals or humans.

Today we'll hear about two different types of cloning. One is human reproductive cloning designed to create a human child. The other is the cloning of human cell for the purpose of medical achievement.

In 1997, the Clinton Administration asked the National Bioethics Advisory Commission to study the ethical and legal implications of cloning. A ban on the use of any Federal funding for cloning was quickly put into place. Since then, researchers, ethicists, scientists, religious leaders, and politicians have debated the issue.

With the possibilities offered by biomedical research, we have an incredible opportunity to potentially clone our own cells to replace diseased or defective cells with no chance for rejection, since it is already a cell familiar to our body.

This research is playing a crucial role in the advancement of modern science and may be the key to transforming the way diseases are treated in the United States and around the world.

Some cells can be used to generate specialized cells that are destroyed or damaged in various diseases and disabilities, which

could in turn lead to vastly improved treatments or cures for Alzheimer's disease, AIDS, Parkinson's, cancer, birth defects, and countless other conditions.

Last year, the National Institutes of Health ensured that this scientific research would be conducted in accordance with the highest scientific and ethical standards. Since then, the Bush Administration has put a hold on Federal funding for stem cell research while it reviews the guidelines put forward by NIH.

In fact, the very first meeting scheduled for April of this year, where an NIH committee was to review the first applications from scientists seeking Federal funds for human embryo cell research, was canceled after officials from the Department of Health and Human Services requested they do so.

For the sake of everyone out there who has suffered from the dreaded diseases that we now have a chance of attacking with new methods, including my own mother-in-law who passed away with Alzheimer's disease earlier this year, I'm hopeful that we can bridge our differences on the issue of research and advance the cause and course of medical science.

Today we are faced with the issue of how to best prevent human cloning with a bill drafted broadly enough to ban human cloning itself but narrow enough so that it doesn't prevent vital lifesaving and highly desirable biomedical research.

The two bills before this Committee take a somewhat different approach. One bill, H.R. 1644, introduced by Representatives Weldon and Stupak, makes it a crime to participate in any type of human cloning for any purpose. The other bill, H.R. 2172, introduced by Representative Greenwood, is focused on reproductive cloning but is more narrowly crafted and perhaps more protective of scientific study.

Both bills include an exception for the use of cloning techniques to produce copies of DNA, tissues, organs, plants, or animals other than humans. But the use of cloning to produce embryos is still forbidden.

We already have certain restrictions on the use of Federal funds for human cloning. And the FDA has declared that cloning experiments cannot proceed without its approval. These restrictions prevent human cloning while allowing beneficial scientific research to proceed, although questions have been raised as to whether the FDA has the necessary power to deter improper cloning.

There was a broad consensus that we are not ready for the cloning of a human being. Perhaps we never will be. Perhaps we never should be.

How we prohibit cloning and protect vital research is the subject of our inquiry. I look forward to the testimony of the witnesses and the insight they provide to us on this complex issue.

Thank you, Mr. Chairman.

Mr. SMITH. Thank you, Mr. Schiff.

And let me mention that Mr. Schiff is an able stand-in for Bobby Scott, the Ranking Member, who had a conflict this afternoon and could not be with us.

Let me introduce all the witnesses and then we'll begin.

Alex Capron, Professor of Law and Medicine, University of Southern California School of Law, Los Angeles, California; Jean

Bethke Elshtain, Professor of Social and Political Ethics, the University of Chicago, Chicago, Illinois; Gerard Bradley, Professor of Law, Notre Dame Law School, Notre Dame, Indiana; and Thomas Okarma, President and CEO, Geron Corporation.

Thank you all again for being here.

And, Professor Capron, we will begin with you.

STATEMENT OF ALEX CAPRON, PROFESSOR OF LAW AND MEDICINE, UNIVERSITY OF SOUTHERN CALIFORNIA SCHOOL OF LAW, LOS ANGELES, CA

Mr. CAPRON. Good afternoon.

Thank you, Mr. Chairman, for this opportunity to testify before your Subcommittee. I will attempt to summarize the main points of my written statement that has been submitted for the hearing record.

Though I must be brief, I want to make clear that my remarks are in two parts, as I have been invited to speak both as a member of NBAC, the National Bioethics Advisory Commission, and as an expert in legal issues and bioethics. I will first present relevant NBAC conclusions and then state my personal views.

NBAC began its work in October 1996. Not long thereafter, President Clinton, in response to the news reports that scientists in Scotland had succeeded in cloning an adult mammal for the first time, asked the commission to examine the "serious ethical issues" raised by "possible uses of this technology to clone human beings."

NBAC immediately undertook and intensive and open examination of the topic, hearing from experts in law, science, medicine, ethics, religion, as well as members of the general public.

A little more than 3 months later, on June 9, 1997, we submitted our report, "Cloning Human Beings," to the President, and a copy of that report has been submitted for the record as well.

In the light of the "unacceptable risks to the fetus and/or potential child," we wrote, and of the many other serious ethical concerns," which "require much more widespread and careful public deliberation," the commission concluded that "at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer."

To this end, we recommended, among other things, that a Federal moratorium be imposed on human reproductive cloning for 3 to 5 years, at the end of which an appropriate oversight body would evaluate the current state of the science and of the ethical and social debate.

We made no recommendations regarding research cloning, the creation of embryos through somatic cell nuclear transfer that would not be placed in a uterus to attempt to create a pregnancy.

Though sometimes labeled therapeutic cloning because of the hope that someday such cells might be used to generate cells, tissues, or even whole organs for transplantation, a lot remains to be learned before the label therapeutic would even possibly be appropriate or before, in the commission's words, "it would be scientifically sound and therefore potentially morally acceptable to go forward with this approach."

The announcement in November 1998 that researchers at the University of Wisconsin and Johns Hopkins University had for the first time succeeded in creating human pluripotent stem cells from IVF embryo and aborted fetuses resulted in NBAC being asked to undertake another study.

The following September we recommended that changes be made in the statutes and regulations to allow Federal funding of research involving the derivation and use of human stem cells from aborted fetuses and from embryos remaining after infertility treatments, subject to appropriate ethical standards and procedures that include public oversight and review.

We also said that research involving stem cells from human embryos made using somatic cell nuclear transfer should not be eligible for Federal funding at this time. We did not address whether this research should be allowed in the private sector.

I would now like to turn to the legislation before you, H.R. 1644, the Human Cloning Prohibition Act of 2001. NBAC did not directly address the question that is before this Committee, namely whether effective control of reproductive cloning requires controlling the creation of cloned human embryos. Therefore, what I have to say now reflects my personal views rather than those of the commission.

H.R. 1644 would ban both reproductive and research cloning. The first is not controversial. Indeed, a ban on any attempt at cloning a baby is favored by the majority of the American people for reasons that you have already heard from witnesses at the prior hearing.

The ban could be a moratorium for a term of years, as NBAC recommended, or it could be of unlimited term, which is the view that I have come to favor as I've become more concerned with both the physical and psychological risk to any child produced through cloning, and more convinced that the reasons offered for its use are slight compared with its potential harm to society, the family, and, indeed, to the prospects of a decent future for humankind.

Why, then, hasn't some form of prohibition been enacted? Largely, as far as I can tell, due to partisan politics and disagreements over other topics, such as the permissibility of embryonic stem cell research. I regard this as tragic, and I am here to plead with Members of this Committee and with your colleagues in both houses of Congress to seek a way of halting reproductive cloning effectively and without further delay.

As I think you can see, to be effective, a ban needs to encompass the creation of cloned embryos in the lab, if you're going to avoid aiding reproductive cloning indirectly or perhaps directly.

As can be seen by looking at H.R. 2172, if cloned embryos exist in labs, it will be very hard to stop people who want to use them to create a pregnancy. The highly entrepreneurial fertility field is characterized by a lack of effective professional or governmental oversight, and a history of ethical scandals, including poor control over embryos.

Thus, simply from a strategic viewpoint, if you want to halt reproductive cloning, you need, at this point, to control research cloning as well.

The second strategic argument concerns getting a bill adopted. It hasn't happened in the past 4 years. People are going to have to find common ground and to agree on a compromise result, albeit for different reasons.

One way of reaching a compromise would be to apply the method that NBAC recommended for reproductive cloning and change the absolute ban on research cloning in H.R. 1644 to a moratorium.

You need to indicate to the research community not only that the ban on the creation of embryos through somatic cell nuclear transfer is carefully limited to that one type of cloning, but also that it is not necessarily permanent but will be reviewed in, say, 5 years.

Meanwhile, other lines of research can go forward on the cloning of animals, on adult stem cells, on perfecting the means to differentiate stem cells into specific cell tissue and even organs that function normally if transplanted, and on the antigenicity of such cells, tissues, and organs, creating from stem cells that are not clonally matched with a recipient.

If researchers arrive at the point where the use of cloned embryos offers a means of achieving a lifesaving therapy that is otherwise unobtainable, they can then ask the public to weigh those no longer merely hypothetical benefits against the risks of leakage to reproductive cloning and against the well-being of the embryos that would be destroyed.

Since they feel so confident of the eventual therapeutic outcome, this is a burden that should not worry the biotechnologists.

Therefore, I urge you to change the ban to a time-limited moratorium as a compromise that should satisfy both sides and would more effectively stop reproductive cloning without preventing scientists pursuing many other lines of research that are needed before the hypothesized therapeutic benefits of research cloning can be realized.

When our descendants—and I do hope they are truly our descendants and not manufactured replicants—look back to this time, let them find that we were equal to this unprecedented challenge.

The United States should take a lead in protecting our human future by locking the barn door on reproductive cloning and by persuading other nations that, at this time, a ban on cloning of human embryos represents the best way to ensure that the cows stay in the barn.

Thank you.

[The prepared statement of Mr. Capron follows:]

PREPARED STATEMENT OF ALEXANDER MORGAN CAPRON

As Commissioner, National Bioethics Advisory Commission

Thank you, Mr. Chairman. I am Alexander Capron, and I have been invited to testify before the Subcommittee in two capacities today: as a member of the National Bioethics Advisory Commission (NBAC) and as an expert on legal issues in bioethics. In this statement, I summarize relevant conclusion of the Commission, and in a separate statement I present my personal views.

NBAC was chartered by President Clinton in 1995 and began work on October 4, 1996. It studies ethical issues arising from biomedical and behavioral research and makes recommendations to the President, the National Science and Technology Council, and others. My fellow commissioners include physicians, theologians, ethicists, scientists, and lawyers, psychologists, and members of the general public.

On February 24, 1997, the day that the American news media reported that scientists in Scotland had succeeded in cloning an adult mammal for the first time, President Clinton asked NBAC to examine the "serious ethical questions" raised

by"possible use of this technology to clone human beings." NBAC immediately undertook an intensive and open examination of the topic, hearing from experts in law, science, medicine, ethics, religion as well as from members of the general public. A little more than three months later, we submitted our report, *Cloning Human Beings*, to the President.

NBAC focused on a very specific aspect of cloning, namely where genetic material would be transferred from the nucleus of a somatic cell of another human being, living or dead, to an enucleated human egg with the intention of creating a child. We did not revisit issues raised by human cloning by embryo-splitting in fertility clinics: only cloning through the new somatic cell nuclear transfer (SCNT) technique. We examined only "reproductive cloning," not "research cloning," the creation of embryos which would not be implanted in a uterus.

The Commission discovered that the potential ability to clone human beings through SCNT raises a host of complex scientific, religious, legal, and ethical issues—some new and some old. Especially noteworthy were the medical risks to any child conceived in this manner, as well as the diversity of views that we heard among religious scholars, indeed even among those within the same religious tradition.

The Commission concluded that no one—whether federally or privately supported—should be permitted to create babies through cloning at this time. To this end, we recommended that a moratorium be imposed on such research. A moratorium gives society a safeguard not only against the extreme risks to any child created in this fashion but also against the possible harms that might accompany crossing the line to controlled, asexual "reproduction." A moratorium also provides a period of time both for further knowledge to be accumulated about mammalian cloning and for serious and sustained reflection about the sort of world that human cloning could create. Then, say three to five years hence, Congress and the President would need to decide whether the results of the scientific research and of the debate on the risks and potential benefits of human cloning had provided sufficiently strong reasons to lift the prohibition and permit human cloning under any circumstances.

Because our *Cloning* report was prepared in a relatively short period of time, and when the technology was still in its infancy, we made no attempt to write the final word but instead provided a starting point for what we hoped would be the "profound and sustained reflection" our Nation needs on the subject of human cloning.

While the commission has not deliberated any further on this topic since submitting the *Cloning* report to President Clinton in June 1997, our main conclusions still stand. Indeed, in a letter to President Bush on March 16, 2001, NBAC Chair, Harold T. Shapiro, stated:

> While we did not resolve all of those [ethical] issues, we unanimously concluded that given the current state of the science, any attempt to create a human being through somatic cell nuclear transfer would be terribly premature and unacceptably dangerous. Besides being morally unacceptable on safety grounds, the creation of human clones would involve risks to the children—and more broadly to society—that are serious enough to merit further reflection and deliberation before this line of research goes forward.

Issues relating to cloning emerged again with the announcement in November 1998 that researchers at the University of Wisconsin and Johns Hopkins University had for the first time succeeded in creating human pluripotent stem cell lines from embryos remaining after infertility treatments and aborted fetuses. President Clinton requested that NBAC also review the issues associated with that research. Again, the commission heard testimony from a wide range of experts and commentators as well as the public. After many months of public deliberation we concluded in our report *Ethical Issues in Human Stem Cell Research* that changes should be made in statutes and regulations to allow federal funding of research involving the derivation and use of human stem cells from aborted fetuses and from embryos that would otherwise be discarded, subject to appropriate ethical standards and procedures that include public oversight and review.

In that report, the commission recommended that research involving the derivation or use of stem cells from human embryos made using SCNT should not be eligible for federal funding at this time. However, NBAC noted that there was significant reason to believe that use of stem cells from such embryos may have therapeutic potential, due to the utility of matched tissue for autologous cell replacement therapy, and stated that scientific progress and medical utility in this area of research should be monitored closely. NBAC did not address whether or not this research should occur in the private sector.

At the time it considered the question of cloning, NBAC had several courses of action under consideration. One would have been no moratorium on any activities. The second would have been a moratorium on both reproductive as well as research cloning. The third, which is the one that the commission actually chose, was a temporary moratorium on reproductive cloning, but no moratorium on research cloning. In so doing, NBAC recognized that while important moral considerations are at stake, with respect to research and reproductive cloning, the nature of those moral considerations are different in kind. With respect to research cloning, the issues are those associated, in general, with the embryo research debate. With respect to reproductive cloning, however, the issues pertain to the safety of the fetus and mother and the potential impact of reproductive cloning on the resultant children and our institutions of parenting and child bearing. It was because of the difference between these types of considerations that a moratorium was considered appropriate in one case (reproductive cloning) but not the other (research cloning). At the time it considered stem cell research, the commission once again considered the question of research cloning. Here it concluded that the case had not yet been made for a need for federal funding for this activity. It did not, however, propose a moratorium on privately funded activity in this area.

Those are the recommendations of NBAC. While I suspect that the commissioners hold a range of views on the consequences to society of the development and use of SCNT to create children, all of us—like the overwhelming majority of Americans—agree that those consequences would be profound; and further, that the risks have not yet been adequately explored, much less carefully balanced against competing interests, whatever they might be.

As Co-Director, Pacific Center for Health Policy and Ethics, University of Southern California

I will now state my own understanding of NBAC's reports, but my views are my own, and I am aware that they do not reflect those of all my fellow commissioners.

One of the bills before you, H.R. 1644 "The Human Cloning Prohibition Act of 2001," would permanently prohibit the use of SCNT to create human embryos for any purpose, including reproductive cloning and the creation of embryos as a source of embryonic stem cells. NBAC did not directly address one of the questions that is before this Committee, namely, whether the control of reproductive cloning requires controlling the creation of embryos by SCNT for research purposes. It is my opinion, however, that our *Cloning* report—when read in light of subsequent developments in that field and of the *Stem Cell* report—supports completely halting all attempts to create human embryos through SCNT at this time.

Obviously, the most contentious issue in H.R. 1644 is the prohibition on the use of SCNT to create cloned embryos from which stem cells of a predetermined genetic background could be derived. Though often labeled "therapeutic cloning" because of the hope that someday such cells could then be used to generate cells, tissues, or even whole organs for transplantation, I believe the term "research cloning" is more accurate. As NBAC recognized in *Cloning Human Beings*, an essential step before the label "therapeutic' would even possibly be appropriate would be for scientists to understand how to direct cellular differentiation along a specific path to produce the desired material for transplantation: "Given current uncertainties about the feasibility of this, however, much research would be needed in animal systems before it would be scientifically sound, and therefore potentially morally acceptable, to go forward with this approach" (p. 30).

We reinforced and expanded on this conclusion in the *Stem Cell* report. Although limited to the question of federal funding, I believe that report has wider implications, because we favored such funding not only to help ensure that the federal government would be in a position to set ethical standards to guide all researchers in this field but also because we felt that serious public detriment would be arise from leaving the development of science in this field entirely to private, and often commercial, researchers while excluding scientists at federal institutes (such as the NIH) and those conducting studies with federal support.

Had a stronger justification been shown for using SCNT to create embryos for stem cell research, I do not believe that we would have opposed federal funding. The need for cloning human embryos was simply not established, given the rudimentary state of the science on such matters as mammalian cloning in general or controlling the differentiation and development of cells and organs from pluripotent stems cells. In addition, NBAC recognized the availability of human embryos remaining after fertility treatments to meet the needs of researchers. In my opinion, that picture has not improved in the subsequent 21 months. If anything, the arguments for emphasizing basic research with nonhuman stem cells is even greater in light, for example, of the sad results involving unregulated cellular activity in the brains of

some Parkinson's patients who received fetal tissue transplants in experiments in New York and Colorado. Furthermore, the problems with development of the few cloned animals that have survived to birth provide a warning signal that we cannot simply assume that stem cells generated from cloned human embryos would themselves function normally.

Not only are we years away from having a good basis for using cloned embryos for "therapeutic" research on human patient—subjects, but other avenues are being pursued that might mean that cloned embryos will never be needed to achieve good results in transplantation. First, scientists are investigating whether embryonic stem cells are, as some believe, less likely to stimulate rejection following transplantation. If that proves to be the case, transplantation could be performed using tissues and organs derived from existing cell lines without having to produce cells that are clonally identical to transplant patients. Second, promising laboratory work on adult stem cells harvested from a number of tissues offers the prospect of achieving autologous cellular therapy and transplantation without the need for cloned embryonic stem cells.

In light of the ethical and moral concerns raised by the use of human embryos for research, NBAC concluded that "it would be far more desirable to explore the direct use of human cells of adult origin to produce specialized cells or tissues for transplantation into patients," though we noted that the possible use of adult stem cells "will be greatly aided by an understanding of how stem cells are established during embryogenesis" (*Cloning Human Beings*, p. 31). Thus, while such research with adult cells does not obviate the need for research with embryonic stem cells, all these lines of research—including research in animals—have much further to go before questions arise that can only be answered through the creation of human embryonic stem cells cloned through SCNT.

I have already mentioned the NBAC *Cloning* report recommended a prohibition on human reproductive cloning, but only for a time period of three to five years, after which time Congress and the President should revisit the issue and decide whether the prohibition would stay in place. H.R. 1644 includes a permanent prohibition on all SCNT. For myself, I would be comfortable with the bill as written, namely that the ban on reproductive cloning (but not research cloning) not be time-limited. Many reasons have been offered by those who favor cloning, from the wish to create a copy of oneself or of another esteemed person to the desire to replicate a deceased relative (particularly a child) to simply having an alternative means of reproduction, whether as a means of overcoming infertility or otherwise. None of these reasons seem compelling to me. Beyond the risk of physical harm to child and perhaps to mother, cloning poses potential psychological and social harm to the children produced by this technology. More fundamentally, the use of cloning to produce children would not merely be the ultimate form of eugenics but an alteration of the basic relationship between generations. In the context of other means of genetic manipulation—indeed, the very means that Dolly's makers had in mind in developing SCNT in mammals, namely the creation of large numbers of animals whose genotype had been modified to produce a desired phenotype—allowing reproductive cloning would be the decisive step toward the Brave New World. Since I do not think that such a state of affairs would advance the "more perfect Union" enshrined as the aspiration of the American people for more than 200 years, I would have no problem with going further than NBAC went, enacting the prohibition now and leaving to those who would so radically alter the manner in which human beings are created the burden of showing that the benefits clearly outweigh the risks.

It does seem to me, however, that the idea of a moratorium—that is, a time-limited ban—can be usefully applied to the second activity addressed by H.R. 1644, namely the creation of cloned embryos for research purposes. NBAC did not recommend the use of federal funds to support creation of cloned embryos for research at this time. Although NBAC did not recommend a prohibition in the private sector, I have already explained why I think our recommendations can (though need not) be read more broadly to suggest that this area of research should not be pursued by anyone at this time. Thus, it seems fair to me to read Recommendation 4 in our *Stem Cell* report as consistent with prohibiting efforts to use SCNT to create human embryos for research purposes at this time. I personally agree with the premise of H.R. 1644 that the best (probably the only) way to stop what we all think should be stopped—namely reproductive cloning—is to impose a moratorium on research cloning as well. Producing normal human embryos through cloning is probably going to be a challenge, but once such embryos are on hand (available in laboratories and perhaps even as items of commerce) I believe it will prove impossible to prevent efforts to implant them and achieve a pregnancy behind the privacy veil of the physician-patient relationship. The slope here is slippery not just because the step may be taken surreptitiously but because the slide downward will be accelerated by con-

tradictory ethical imperatives. On the one hand, once the cloned embryos have been created, some who oppose reproductive cloning will feel so strongly that the embryos have a right to life that they will insist that the embryos be used to attempt to achieve a pregnancy. On the other hand, once a pregnancy has been established defenders of women's right to control their own reproduction—including those who are appalled by reproductive cloning—would be as loathe as any anti-abortionist to tell a woman carrying a cloned fetus that she must abort it.

Thus, any serious effort to stop asexual reproduction needs in my opinion to encompass all efforts to create cloned embryos. I believe that placing research cloning off-limits at this time is fully consistent with NBAC's recommendation that such research not go forward now with federal funding because much more work needs to be done in the basic science as well as with adult and noncloned embryonic stem cells before we can possibly know whether the cloning of embryos offers the only means of achieving a potentially life-saving therapy for certain patients.

A moratorium may not initially appeal to anyone who believes that it is always wrong to create, much less to destroy, a human embryo for research or therapy unconnected with that embryo's own well-being. Yet to these people, I would say that a moratorium achieves the very end that they seek, which is to forbid the creation of cloned embryos. Conversely, for those who do not take that view, a moratorium carries the promise that the issue of research with cloned embryos will be revisited. Just as NBAC favored a moratorium on reproductive cloning so that the issue could be reconsidered, so too Section 4 of H.R. 1644 says that the National Bioethics Advisory Commission or a successor group will study and report back within five years on "the need (if any) for human cloning to produce medical advances" as well as the possible impact of permitting research cloning "upon efforts to prevent human cloning for reproductive purposes." Again, I want to stress that the commissioners did not directly face or decide this particular question, but they did agree with the objective of forestalling the cloning of human babies and that grounds for cloning human embryos at this time are not so strong that federally funded scientists need to conduct such research.

A moratorium was accepted by biomedical researchers 27 years ago, at the dawn of the era of genetic engineering, when leading scientists recognized the unpredictable risks associated with some of the experiments and persuaded the community to halt them until the risks could be better assessed and appropriate preventive measures adopted. Last year, on the 25th anniversary of the famous Asilomar meeting that was held to decide whether and how the moratorium should be lifted, I chaired a symposium back at Asilomar in which 50 scientists, social scientists, ethicists, lawyers, government officials, and journalists examined that earlier moratorium and its continuing relevance today. In some ways, the decision to halt work was more difficult a quarter of a century ago because some of what was stopped was "the next logical step" in research and was being actively pursued by the leading scientists, which is not true of cloning human embryos today. Yet in other ways, the gene splicing moratorium was easier to accomplish because the risks to be avoided were immediate, physical harms, from injuries to laboratory personnel to potential epidemics of novel pathogens, whereas the ethical and social issues that really underlay the public's concern (and that are the category of risks that arise from human cloning) were not debated at Asilomar. Moreover, as we concluded at the symposium in February 2000, the commercialization of biotechnology has changed the pressures to pursue research as well as the freedom of scientists and their credibility in calling for a halt to research. Thus, while a moratorium—putting some research out of bounds while its risks can be assessed and possible safeguards can be developed—is something that biomedical researchers have accepted in the past, the impetus for a moratorium on human embryo cloning probably now must come from the government.

Researchers must be assured that the moratorium will not prevent other lines of research, either on stem cells not derived from cloned embryos or the cloning of molecules, cells, or the like that does not involve embryos. H.R. 1644 seems to me to accomplish this objective. That leaves the question of whether the moratorium should be framed as a sunset provision that lets the prohibition lapse if not renewed or as ban that remains in place after the mandatory review unless reversed by a majority. Reasonable people may differ on this point, but given both the importance of the subject and the confidence with which biotechnologists predict that the creation of cells from cloned embryos will provide benefits not otherwise available, I conclude that the burden of proof should be left with the proponents of the research when the ban is reconsidered. If they have arrived at the point where the use of cloned embryos offers a means of achieving a life-saving therapy that has been found to be otherwise unobtainable, then I believe they will persuade a majority of

people that such steps should be allowed under the most stringent of ethical and practical safeguards.

Agreeing on this course will require each side to compromise. It would seem to me—if I may be so bold, and speaking as a citizen and a person concerned with the ethical and policy implications of science and medicine rather than as a member of NBAC—that this is one time that people on both sides of the aisle should do all they can to avoid allowing their disagreements on other matters, such as abortion and stem cell research, to stand in the way of a compromise that achieves the central aim that is overwhelmingly supported—and rightly so—by the American people, and indeed, by most people around the world.

I hope that these hearings can help promote a genuine dialogue among people holding a range of views on the subject and that a compromise, perhaps along the lines I have urged here, can be forged. In recommending a moratorium on reproductive cloning, NBAC hoped that during the period of three to five years before the issue was reconsidered in Congress, our Nation would engage in "profound and sustained reflection" on the issues. Regrettably, four years to the month after we submitted our report, this sort of serious, broadly based public discussion has yet to occur. Partisan disputes have prevented Congress from acting even though it appears that there is overwhelming agreement here that reproductive cloning should not be allowed at this time, And while a good deal of academic debate has occurred, as time has passed the press seems to have found the topic too weighty for continued public scrutiny. Hence, the plans announced by various groups in recent months to develop reproductive cloning are today more often the objects of comedians' humor than commentators' analysis. Indeed, from the tone of the inquiries I have had lately from reporters and from some (though certainly not all) of the media coverage, I sense that the simple familiarity of the topic has served to trivialize it. The initial reaction of many people to the technology and to the prospect of its being applied to human beings—disbelief and repugnance—has been replaced by disinterest. As one reporter said to me recently, "Doesn't cloning seem more acceptable now? After all, despite the original objections, nothing bad has happened, has it?" Well, of course not, because as far as we know, no one (thankfully) has yet tried to clone a human baby. Yet the risk of that happening is great if the serious problems with such a step are not brought before the public and if legislation is not adopted to make clear that no one may take such a step at this time.

In conclusion, I want to return to Chairman Shapiro's March 16 letter to President Bush, in which he stressed how seriously the present, announced efforts to engage in human cloning ought to be taken. He also stated that adopting a moratorium would bring the United States "into line with the position adopted by the Council of Europe" and would "encourage other nations to do likewise." As recommended by the G8 nations at the Denver Summit, and as emphasized in a number of the bills pending before Congress (including H.R. 1644), international cooperation is going to be essential for success. Humankind stands now at an historic juncture. When our descendants—and I do hope they are truly our descendants, not our manufactured replicants—look back to this time, let them find that we were equal to what I think may fairly be labeled an unprecedented challenge. In my view, the United States should take the lead in protecting our human future by locking the barn door now on reproductive cloning and by persuading other nations that at this time a ban on the cloning of human embryos represents the best way to ensure that the cows stay in the barn.

Thank you for the opportunity to present my views on this subject, and I am happy to answer any questions that you may have.

Mr. SMITH. Thank you, Professor Capron.

Professor Elshtain.

STATEMENT OF JEAN BETHKE ELSHTAIN, PROFESSOR OF SOCIAL AND POLITICAL ETHICS, THE UNIVERSITY OF CHICAGO, CHICAGO, IL

Ms. ELSHTAIN. Thank you, Mr. Chairman. Thank you for the opportunity to offer reflections on the political, ethical, and legislative issues presented by the prospect of human cloning.

I teach social and political ethics at the University of Chicago, where I am a member of the Divinity School and Department of Political Science.

My work for nearly 30 years has been devoted to examining the ethical implications of political and social policies and proposals. I consider myself a realist, indeed, a hard-headed realist.

As such, it seems to me that the path down which we are headed, unless we intervene to stop human cloning, is one that will deliver harm in abundance. And that harm can be stated clearly and decisively now, whereas any potential benefit is highly speculative and likely to be achievable through less drastic and damaging methods in any case.

The harms, in other words, are known, not a matter of speculation, whereas the benefits are a matter of conjecture, in some cases, rather farfetched conjecture—this according to the bulk of current scientific opinion.

Now, one of the basic rules of medicine is also a basic rule of politics: First, do no harm.

We are on the pathway to harm. That is why I support H.R. 1644.

Last August, I was in Berlin, Germany, for an international conference. On that occasion, the Lutheran bishop of Berlin presented a talk in which he expressed alarm at the direction much of the genetics ideology of the present is tending. That ideology identifies the true essence of what is human with a particular genotype.

This ushers into a kind of genetic fundamentalism that reduces our humanity to clusters of traits we phenotypically exhibit or fail to—everything from a desirable height, hair and eye color, skin color, I.Q., physical attractiveness, and so on. And I don't think I need to remind anyone of why they are particularly sensitive to this issue in Germany.

The hope of genetic fundamentalists is that we can increasingly control for that which is deemed desirable and eliminate that which is not.

The aim in all this is not to prevent devastating illnesses but precisely to reflect and to reinforce certain societal prejudices in and through genetic selection. There is a word for this so-called genetic enhancement, and that word is "eugenics."

Human cloning belongs to this eugenics project. All the ethical, political, scientific, and juridical arguments against eugenics apply to the prospect of human cloning.

Hans Jonas, the distinguished philosopher and scientist, has already written that cloning is, and I quote, "both in method the most despotic and in aim the most slavish form of genetic manipulation; its objective is not an arbitrary modification of the hereditary material but precisely its equally arbitrary fixation in contrast to the dominant strategy of nature." That's the end of the quote.

Public policy reflects our understanding of who we are as a people. It indicates where we are going and our appreciation of where we have been. I see this country and our people as strong, determined, energetic, creative, concerned, and realistic, rather than careless and chaotic and sentimentalist.

Banning ill-considered, harmful ventures in human cloning will show us at our best. It will demonstrate that the untrammeled profit motive behind runaway and reckless—by contrast to responsible and controlled—developments in the area of genetics will not

be given full sway no matter how many powerful interests may be involved.

It will show that the representatives of the American people are not interested in pushing us into a post-human future dominated by what President Vaclav Havel of the Czech Republic has called the arrogant anthropocentrism that so ravaged the previous century.

It will say that we will not turn our children into objects and products of manufacture and design.

It will say that we have said no to the threat of a damaging biogenetic uniformity of the sort that cloning portends.

It will say that we will not permit the emergence of unused products—failed clonees, poor, misbegotten children of distorted imaginations.

It will say that we are determined to protect and to sustain what we know to be the best context for child nurture—a child who is not a product but a precious and unique human being, a child who has not been deprived a unique identity through the terms of its production, but precisely given a unique identity through the terms of its begetting.

I see, Mr. Chairman, that my time is up. And I hope that I will be able to revisit this and a number of other issues during the question and answer.

[The prepared statement of Ms. Elshtain follows:]

PREPARED STATEMENT OF JEAN BETHKE ELSHTAIN

Good afternoon. Thank you for the opportunity to offer reflections on the political and ethical issues presented by the prospect of human cloning. I am Jean Bethke Elshtain. I teach social and political ethics at the University of Chicago where I am a member of the Divinity School and the Department of Political Science. My work for nearly thirty years now has been devoted to examining the ethical implications of political and social policies and proposals. I consider myself a hard-headed realist, one obliged, therefore, to avoid utopian scenarios that assure us that paradise is just around the corner if only we implement this ideology or enact this policy and, as well, to challenge dark, nightmarish sketches of what the future will hold if a certain proposal is implemented or a technology developed. That said, it seems clear to me that the path down which we are headed unless we intervene now to stop human cloning is one that will deliver harm in abundance—and that harm can be stated clearly and decisively now—whereas any potential benefits are highly speculative and likely to be achievable through less drastic and damaging methods, in any case. The harms, in other words, are known—not a matter of speculation—whereas the hypothesized benefits are a matter of conjecture, in some cases rather far-fetched conjecture: this according to the bulk of current scientific opinion.

One of the basic rules of medicine is also a basic rule of politics: first, do no harm. We are on the pathway to harm. That is why I support H.R. 1644, the "Human Cloning Prohibition Act of 2001." Last August, I was in Berlin, Germany, for an international conference. On that occasion, the Lutheran Bishop of Berlin presented a talk in which he expressed alarm at the direction much of the genetic ideology of the present—not science, but an ideology that piggy-backs off scientific and technological developments and prospects—tends. That ideology increasingly identifies the true essence of what is human with a particular genotype. This ushers into a kind of genetic fundamentalism that reduces our humanity to the clusters of traits we phenotypically exhibit, or fail to—everything from desirable height, hair and eye color, skin color, I.Q., physical attractiveness, and so on. The hope of genetic fundamentalists is that we can increasingly control for that which is deemed desirable and eliminate that which is not. The aim in all this is not to prevent devastating illnesses but precisely to reflect and to reinforce certain societal prejudices in and through genetic selection. There is a word for this so-called 'genetic enhancement'. That word is eugenics. Human cloning belongs to this eugenics project. All the ethical, political, scientific , and juridical arguments against eugenics apply to the prospect of human cloning. Hans Jonas, the distinguished philosopher and scientist, has

already written that cloning is "both in method the most despotic and in aim the most slavish form of genetic manipulation; its objective is not an arbitrary modification of the hereditary material but precisely its equally arbitrary *fixation* in contrast to the dominant strategy of nature."

Public policy reflects our understanding of who we are as a people. It indicates where we are going and our appreciation of where we have been. Americans are a strong, but not a reckless people when we are at our best. We are a determined but not a willful people when we are at our best. We are an energetic but not a frenetic people when we are at our best. We are a creative but not a chaotic people when we are at our best. We are a concerned but not a sentimentalist people when we are at our best. We are a realistic but not a narrow-minded people when we are at our best. Banning ill-considered, harmful ventures in human cloning will show us at our best. It will demonstrate that the untrammeled profit motive behind runaway and reckless, by contrast to responsible and controlled, developments in the area of genetics will not be given full sway, no matter how many powerful interests may be involved. It will show that the representatives of the American people are not interested in pushing us into a post-human future dominated by what President Vaclav Havel of the Czech Republic has called the "arrogant anthropocentrism" that so ravaged the previous century. It will say that we will not turn our children into objects and products of manufacture and design. It will say that we have said no to the threat of a damaging biogenetic homogenization or uniformity of the sort that cloning portends. It will say that we will not permit the emergence of unused 'products', failed clonees, poor misbegotten 'children' of our distorted imaginations. It will say that we are determined to protect and to sustain what we know to be the best contexts for child nurture—a child who is not a product but a precious and unique human being, a child who has not been deprived of a unique identity through the terms of its production but precisely given a unique identity through the terms of its begetting.

There are those who tell us that banning this harmful procedure is an unacceptable diminution of human freedom. I do not understand the view of freedom they promote. Responsible freedom has never been a notion that we should simply move full steam ahead on whatever strikes our fancy or seems doable or promises profit and glory and newspaper headlines. Freedom is always limited by my presence among others. Rights are never absolute because we are not. Those who claim that to prevent human cloning cuts into an unlimited right to 'reproductive freedom' ignore politics, ethics, and history. All decent societies restrict this freedom and set boundaries to its operation. Banning human cloning would not, in this sense, be unprecedented but well within our established traditions. Authentic freedom and responsibility should never be reliquished in favor of an abstract, ideological claim that feeds and fuels narcissitic imaginings of *radical sameness*, for one can see in the arguments of those who express enthusiasm for cloning a real fear of the different and the unpredictable, a yearning for a world of guaranteed self-replication. At base such a world flies in the face of everything we know about the importance of bio-diversity and of social and political pluralism. I urge you to pass HR 1644, a bill consistent with our traditions and our sense of who we are as a people when we are at our very best.

Mr. SMITH. Thank you, Professor Elshtain.

Professor Bradley.

STATEMENT OF GERARD BRADLEY, PROFESSOR OF LAW, NOTRE DAME LAW SCHOOL, NOTRE DAME, IN

Mr. BRADLEY. Mr. Chairman, Members of the Subcommittee, thank you for this opportunity to evaluate the two anticloning bills before you. I propose to evaluate them from both a constitutional viewpoint and also from the viewpoint of criminal law and its enforcement.

My judgment is that bill 1644 is a lawful exercise of Congress's power over interstate commerce and that it is entirely consistent with relevant constitutional doctrines, particularly those protecting privacy and reproductive freedom.

The Greenwood bill is also, in my view, a lawful exercise of Congress's interstate commerce power, though the matter with Greenwood is a little more difficult than with 1644. And the Green-

wood bill does raise questions regarding the privacy cases which 1644 does not raise.

But most important, the Greenwood prohibition, in my opinion, is unenforceable. Practically speaking, the bill will not attain its stated objective of banning cloning intended to initiate pregnancy.

My judgment is this: The only effective way to prohibit human reproductive cloning is to prohibit all human cloning, as 1644 does, and it does so free of constitutional difficulty.

I should like to amplify, in these few minutes available to me, two points I make in my prepared testimony.

One is the Commerce Clause question. It is true that since 1995, starting with the Lopez case, the Supreme Court has engaged in at least some modest pruning of congressional power under the Commerce Clause. Nevertheless—and here I shall speak only of 1644—I am confident that that bill is free of constitutional difficulty and doubt on the Commerce Clause point.

It's critical at the outset to exactly identify the activity whose relation to interstate commerce is in question. That activity is not precisely somatic cell nuclear transfer. It is, rather, the whole prospective set of activities in connection with human reproductive cloning and with cloning for scientific purposes which would arise in due course absent the prohibition of 1644.

It seems to me that your judgment, if it is your judgment, that this whole prospective market or web of activities in connection with all types of human cloning does substantially affect interstate commerce, if that is your opinion, I believe it is a reasonable view and it is safe from constitutional doubt.

I turn to my second of two points. It's the practical futility of the Greenwood bill's ban on reproductive cloning. I simply don't think it will work.

I have two points in connection with this of my second two main arguments.

One is constitutional, and that is by prohibiting only cloning with the intent to initiate pregnancy, Greenwood may well create a plausible constitutional argument against itself. That is, once any embryos are created, it is at least a plausible constitutional argument that some of them will be implanted or, to put it differently, that some women will have a right to have those embryos implanted.

I say this especially with regard to a perspective female nucleus donor asking, after a change of mind, perhaps, for her embryos back from a scientific researcher in order to have them implanted in her own womb.

She has a plausible constitutional argument in favor of controlling her reproductive freedom and controlling the terms and circumstances under which she becomes a parent.

And these cases, the cases that are most in point here, are the few cases we have dealing with the resolution of the status of embryos frozen, which are left over in an IVF clinic and a question arises about what to do with them after the couple, which gave the rise to the embryo, was divorced.

I say this, there is at least a plausible constitutional argument that once any embryo is created, parental rights with regard to those embryos are created along with them. If you don't want to

create parental rights in the embryos, however created and for whatever purpose, don't create the embryos in the first place.

My second of two points in this regard: I don't think the Greenwood prohibition is practically going to be successful. Note that any embryo created for research purposes is also suited for reproductive purposes. Note also well that the Greenwood bill does not take any position and certainly does not prohibit implantation of embryos. Nor does it make unlawful the mere possession of embryos.

It attaches criminal liability to the point of creation with the intent to initiate a pregnancy.

In short, the opportunity arises—and this is conduct that would be completely consistent with the Greenwood bill and, therefore, lawful—for a researcher, having created embryos for research purposes, to have a change of mind and then to make them simply available to someone else, who would then take possession of them, with the intent to implant them and go ahead and implant them in women willing to, if you want to say, rescue these embryos.

That scenario, it seems to me, is not a matter of evading the strictures of the Greenwood bill; that is to say, a kind of undetectable violation of the Greenwood bill. This scenario, it seems to me, is lawful. It is not prohibited by the Greenwood bill.

[The prepared statement of Mr. Bradley follows:]

PREPARED STATEMENT OF GERARD V. BRADLEY

Mr. Chairman and members of the Subcommittee. I am grateful for this opportunity to evaluate the proposed anti-cloning bills, both from a constitutional viewpoint and from the viewpoint of criminal law and its enforcement. A copy of my entire C.V. is attached to the written testimony. I should like to note, however, that I have taught, and published widely, in the areas of constitutional law and criminal procedure throughout my eighteen years as a professor. Before that, I was a prosecutor in New York City, serving as an Assistant to Robert Morgenthau, District Attorney of New York County.

I shall focus principally on H.R. 1644, and especially on its constitutionality. My judgment is that this bill is a proper exercise of Congress' power over interstate commerce, and that it is entirely consistent with relevant constitutional doctrines, particularly those protecting privacy and reproductive freedom. The Greenwood bill is also a legitimate exercise of Congress' interstate commerce power. But it raises serious constitutional questions which H.R. 1644 does not. Moreover, the Greenwood "prohibition"is unenforceable: practically speaking, the bill will not attain its stated objective of banning cloning intended to initiate a pregnancy. My judgment is this: the *only* effective way to prohibit human reproductive cloning is to prohibit all human cloning, as H.R.1644 does. And H.R. 1644 provides the route to that end free of constitutional difficulty.

The Constitutionality of H.R. 1644

The first question about H.R. 1644, as with every act of Congress, is whether a specific constitutional authorization supports the proposed exercise of Congressional power. This bill identifies the Commerce Clause as Congress's lawmaking authority. The controlling Commerce Clause precedents are summarized in *U.S. v. Lopez*, 514 U.S. 549 (1995). *Lopez* supplies the criteria for my analysis.

On one view of H.R. 1644, there cannot be any question concerning the Commerce Clause. The bill states that it "shall be unlawful for any person or entity, public or private, in or affecting interstate commerce" to engage in any of the prohibited acts. It is *possible* to read the jurisdictional (i.e., interstate commerce) language here as constituting *an element of the offense*. On this reading, a successful prosecution under the act would require proof either that the particular defendant's activities (in general) affected interstate commerce, or that the charged act(s) of cloning did. In other words, no one could be convicted under the proposed act without proof of the requisite effect upon interstate commerce. Where that proof failed, the prohibition could not attach. On this view of the bill, no facial attack on commerce clause grounds is possible.

I mention this reading not because I think it is the one intended by the bill's drafters. H.R. 1644 intends, it rather seems to me, a flat prohibition of human

cloning, as an exercise of Congressional power over interstate commerce. I turn to the constitutionality of *that* momentarily. I mention this alternative reading to support the following caveat: if a court down the line, reviewing an enforcement action under the enacted bill, doubts the constitutionality of a flat prohibition, that court will not hold the bill unconstitutional. Instead, that doubting court will adopt the narrower, and safer, reading I just described. Again: there is almost no chance that this bill will be held unconstitutional on Commerce Clause grounds by any court. There is, however, some chance that a court will adopt the safer reading of the jurisdictional language.

Let us henceforth treat H.R. 1644 as a flat prohibition of human cloning. My judgment is that, even with the modest pruning of Congressional commerce authority in recent Supreme Court cases, the bill is constitutional.

First, there is no doubt that Congress may regulate interstate commerce for non-commercial purposes. Congress may go so far as to prohibit certain activities, in or affecting interstate commerce, *solely* because they are deemed immoral, injurious to human dignity, or violative of human rights. Many cases support this proposition. The most compelling may be those upholding the Civil Rights Act of 1964, specifically, its ban on racial discrimination in motels and restaurants serving (in even minuscule part) interstate travelers. *See Katzenbach v. McClung*, 379 U.S. 294 (1964); *Heart of Atlanta Motel v. United States*, 379 U.S. 241 (1964).

H.R. 1644 prohibits human cloning for a number of reasons, recited in the "Findings" section. That most, or even all, may be non-commercial therefore raises no interesting constitutional question.

Does a flat prohibition on human cloning have the requisite connection to interstate commerce? The prevailing Supreme Court tests, as found in the *Lopez* majority opinion, recognize plenary Congressional power over the instrumentalities of interstate commerce, a protective power extending to *intrastate* activities which threaten the instrumentalities of interstate commerce. *Most* of the activity prohibited by H.R. 1644—"ship[ping]" or "receiv[ing]" products of human cloning, for example—could be supported by these twin powers. Congress could, without constitutional question, flatly prohibit all use of the mail and wires in furtherance of human cloning, prohibit all entities receiving any federal funds from human cloning, and even utilize its special maritime and admiralty jurisdiction in aid of a total ban.

My judgment is, however, that these powers, either alone or in tandem, may not be sufficient to support *all* that is banned by the bill. My opinion is that some portion of the flat ban on human cloning must rely upon the third type of Congressional commerce power, that over intrastate activity affecting interstate commerce.

The *Lopez* court emphasized, over against some prior authority, that the test was whether the regulated activity "substantially" affects interstate commerce. H.R. 1644 does not use the modifier "substantial". But that alone does not affect the bill's constitutionality, so long as it can be shown, in a later judicial test, that a "substantial" effect exists. Does Congress have a reasonable basis for asserting that "substantial" effect? I surely believe so.

Here is the argument that Congress does. It is important at the outset to exactly identify the activity whose relation to interstate commerce is in question. That activity is *not* somatic cell nuclear transfer, the scientific act prohibited by H.R. 1644. For that prohibition is merely the means chosen by Congress to forestall a different, much more substantial economic activity: the whole prospective set of activities in connection with human reproductive cloning, *and* with cloning for more limited scientific, medical, academic purposes—which would arise in due course *absent* H.R. 1644.

This projected web of activities would be high tech; it would be dependent upon the interstate transportation of raw materials, lab equipment, and products; and it would rely upon the national and international communication of needs, research results, and opportunities. Though precisely speaking not a commodity for sale, cloned human embryos could reasonably be projected to becomes articles of exchange, traded for "service" fees. In short, Congress could reasonably conclude that H.R. 1644 is a pre-emptive strike against a potentially *enormous* interstate traffic in connection with human cloning.

The central aim of H.R. 1644 is to forestall this projected commodification of the results of human cloning. Nothing in the Constitution or the case law requires Congress to wait and see how things play out before acting. That Congress is poised to act pre-emptively against an evil is neither unusual nor constitutionally troublesome. True, if the bill succeeds in its goals, we will never know in fine what the unregulated market in human cloning would have looked like. But that fact weighs in favor of constitutionality. For to strike down the bill as unconstitutional, a reviewing court would have to overrule, without any contrary *facts* in hand, Congress's informed judgment about the future.

In my professional opinion, there is little chance that a court, reviewing a factual basis like the one just described, will upset, as an unwarranted exercise of the interstate commerce power, Congress's judgment to prohibit human cloning,

THE PRIVACY CASES

According to the Supreme Court, its privacy cases have established constitutional protection for the right: to marry; to have children; to direct the education and upbringing of one's children; to marital privacy; to use contraception; to bodily integrity; and to abortion. *See Washington v. Glucksberg*, 117 S.Ct. 2258, 2267 (1997) (citations omitted). Only two of these rights are in the neighborhood of cloning. For the proposition in favor of a right to "have children", the Court relied upon a 1942 decision against involuntary sterilization. For the right to "marital privacy" the Court cited *Griswold*, its 1965 decision in favor a right of married couples to use contraception. There is therefore no Supreme Court authority nearly in line against a ban on human cloning.

There is, generally, Supreme Court precedent in favor of a woman's right to decide, by herself, whether to "bear or beget" a child. But the cases giving rise to that right make clear that "begotten" is surely not made—or cloned. And "bear" unequivocally refers to the abortion liberty. There is also authority for the proposition that, in no exact sense, one has a right not to be a become a parent against one's wishes. But that right is limited to pregnant women; a man either deceived or the victim of contraceptive failure has no constitutional traction whatsoever upon the decision of the woman to abort their child, or to carry their child to term. Besides, this woman's right is surely asymmetrical. A right *not* to be a parent does not imply or entail a right, simply, to *be* a parent.

No case, *in any court*, has ever held in favor of a constitutional right to reproduction by cloning. In fact, no case has ever held that anyone has a right to reproduce by *in vitro fertilization* (IVF).

To generate a "privacy" argument against H.R. 1644 one would have to go beyond *all* prior holdings of *all* the courts. The only way that I can think of to make that argument would detach a commodious phrase, such as the "right to have children", from its jurisprudential moorings, and then (somehow) maintain that the broad concept implies a right to reproduce by cloning. But no such argument could possibly succeed, as I understand the Supreme Court's stance towards all such novel claims of constitutional rights.

The Court has repeatedly emphasized two fundamental requirements for any "privacy" argument in favor of an unrecognized liberty interest. First, the asserted liberty must be, objectively speaking, "deeply rooted in this nation's history and tradition". *See Glucksberg* at 2268. Cloning clearly does not satisfy this requirement. Not only is it an entirely new technology. By reducing reproduction to asexual replication, it is radically unlike all rights sounding in "reproductive liberty" heretofore recognized. In other words, even argument by analogy will not work for cloning.

Second, the Supreme Court has cautioned, in very strong terms, against arguments relying upon spacious phrasing. The Court has *insisted* that the asserted liberty be described in specific, concrete terms. Vague, open-ended generalities will not do. For example, the Court has rejected characterizations of its *Cruzan* holding as favoring a "right to die". Instead, the Court, in its own description, held for a "constitutionally protected right to refuse lifesaving hydration and nutrition". Nor was *Glucksberg* itself, according to the Court, about a "right to die" or a "right to commit suicide". It was instead about "a right to commit suicide which itself includes a right to assistance in doing so." *Id.*

According to this second requirement, no general "right to reproduce", "to be a parent", or "to have a child" will be credited, either as a conclusion or as a premise, in any argument in the Supreme Court. The Court will insist that a claimant defend a right *specifically* to cloning. Given the high burden of persuasion imposed by the high Court upon such claimants, the chances of success in the are virtually nil.

The Supreme Court has said: "We must therefore 'exercise the utmost care whenever we are asked to break new ground in this field'. . .lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the members of this Court". *Id.* This statement of judicial restraint implies that "policy" is the business of Congress, at least where the Court does not stake a claim to constitutional supervision. The Court has not and, in my judgment, will not, with regard to cloning.

Let me explain, in one more way, why members of Congress are constrained in this matter by their sworn duty to uphold the Constitution and to legislate for the common good, *unconstrained* by judicial doctrine. It is true that cloning has *some* features in common with acts that are constitutionally protected. Cloning is, for ex-

ample, a way to have a baby, and people (women especially) have a right to decide whether to have a baby. Also, let us say for argument sake, that individuals have a right to have babies outside of marriage. (They do, in the limited sense of being immune to penalties for doing so. But individuals do not actually have a constitutional right to unwed parenthood.) Again, you do not have to be married to have baby by cloning.

But, to observe that cloning is *like* protected acts in *two* respects is not saying much. It is not saying much because cloning posses *several additional* features, and it is precisely those *additional features* which are the grounds of the proposed ban—features included in the description of cloning as the asexual manufacture of genetic replicas. We may presume that members of Congress voting for this bill do not do so because they are opposed to people having babies, even outside of wedlock. So far considered, then, members do not adopt as a reason for action any adverse moral judgment upon any act (or feature of an act) declared by courts to be private, or none of Congress's business. Congress, in this thought experiment, regulates *only* for reasons entirely left open to their policy judgment by the courts. There is no good reason to anticipate authoritative judicial action which would block Congressional action upon those reasons. There is every good reason to conclude that none will be forthcoming.

A comparison might help to make this point clearer. There is no doubt now that movies are a constitutionally protected mode of speech. Individuals therefore may be said to have a right to make movies. And, so long as amenities are preserved, they have a right to make movies about children, using child actors. Francis Ford Coppola, for example, may be said to have a right to do a remake of "Heidi", using the Olson twins as stars. Should Congress attempt to suppress this project, so far described, Congress would be acted unconstitutionally.

But, does anyone think that if a particular director wished to make a *porno* version of "Heidi", using child actresses, he has a *right* to do so? That Congress would be acting *unconstitutionally* by prohibiting child pornography?

Of course not, even though porno "Heidi" possesses, we may suppose, every feature of Coppola's "Heidi". And that is because porno "Heidi" possesses one additional feature—sexual exploitation of children—which is not constitutionally protected.

Cloning possesses *many* unprotected features.

A NOTE ON IVF

As I noted above, no court in any American jurisdiction has held in favor of a federal constitutional right to have a child by *in vitro fertilization*. It is nevertheless permitted in most, if not all, jurisdictions. At least one state court (Tennessee), construing its *state* constitution, may have implicitly recognized some right to use IVF. Does approval of IVF imply or suggest approval of cloning? Is a ban on cloning somehow inconsistent with approval of IVF? Would a projected court decision in favor of a constitutional right to IVF implicitly undermine the constitutionality of this bill?

The answer to all these questions is "No".

IVF and cloning are both methods of asexual human reproduction which rely upon scientific technique to bring an embryo into being. Both techniques require the implantation of the embryo into a woman's womb in order to bring forth a fully developed baby approximately nine months later. But, otherwise, cloning is radically discontinuous with IVF, and much more distant from human reproduction as traditionally morally approved, and as recognized in Due Process cases.

For: the principle of reproduction in IVF procedures is the human couple. The child born is the issue of two parents, who become mother and father of that child. That child is genetically unique, the unrepeatable combination (genetically speaking) of his/her mom and dad. None of the problems of individuality and identity created by cloning plague IVF. Though assisted by the lab technician, the embryo is created in IVF as it is within the woman's body in intercourse: by the spontaneous fusion of gametes—egg and sperm. Most important, because of the unique and spontaneous genetic constitution of the IVF baby, there is scarcely a trace of the manufactured product status that would be characteristic of cloning.

By contrast, cloning is the impersonal, individualized undertaking to make a person to the specifications of a single (genetic) parent. It is replication, not true reproduction, and it is radically de-humanized. The way to think of IVF in relation to cloning is an aggravated form of the relation between the two Heidi movies.

MAY CONGRESS BAN ALL HUMAN CLONING?

My opinion so far has noticed only H.R. 1644, and that insofar as it bans all human *reproductive* cloning. But H.R. 1644 goes further, and that further step is

what most distinguishes it from H.R.——(the Greenwood bill). H.R. 1644 would prohibit *all* human cloning, as the only practical way to make a ban on reproductive cloning effective. The Greenwood bill would instead ban cloning 'with the intent to initiate a pregnancy". In my opinion, the comprehensive ban of H.R. 1644 raises no new or interesting constitutional questions.[1] Also, it is the only practical way to ban reproductive cloning. The Greenwood bill, by contrast, raises difficult constitutional questions, and would be wholly ineffective.

Let me explain.

The comprehensive ban will obviously curtail the activities of researchers who may have no direct interest in or connection to reproductive cloning. But the judgement that their activities would imperil the ban on reproductive cloning is entirely for Congress to make. Since research of the type involved here is a mixture of speech and act, it is *not* protected as pure speech is by the Constitution. Congress has the constitutional power to limit these speech acts in the public interest. H.R. 1644 does that.

What new constitutional questions does the Greenwood bill raise? First, by limiting the scope of its prohibition to some fraction of the comprehensive ban of H.R. 1644, Greenwood *necessarily* weakens the Commerce Clause argument in its favor. Recall that the basis for concluding that H.R. 1644 was on safe interstate commerce ground was the potentially huge interstate traffic in *all* types of cloning. By prohibiting one subset of cloning Greenwood *may* have to justify itself by reference to imagined traffic in just that subset. Also,Greenwood does not have the fall-back interpretation available to H.R. 1644. Nothing in Greenwood suggests that "affecting interstate commerce" may be an element of each prosecution under it.

By prohibiting only cloning "with the intent to initiate a pregnancy" Greenwood creates a plausible constitutional argument against itself. It *requires*, as a matter of federal law, the intentional destruction of human embryos, which many consider to be incipient human life. The requirement thus creates a constituency who will be both opposed to human cloning, and to the Greenwood bill (for its required destruction of embryos). This constituency will be motivated to locate plaintiffs with standing to save from destruction at least some of those embryos. A nuclear donor, especially a female nuclear donor asking for 'her" embryos in order to have them implanted in her own womb, has a plausible constitutional argument in favor of a right to do so.

This female plaintiff will say that, notwithstanding any contractual agreement with researchers, the fact is that her very tiny child now exists, and that the courts have two choices. They may authorize the destruction of her tiny child, or they may restore that tiny child to its mother. She will rely upon the few decided cases involving frozen embryos, derived from IVF, cases usually arising out of conflicts engendered by divorce. Those courts have recognized *parental* rights in embryos, frozen and in possession of laboratories. Some of these courts were even willing to put aside contractual agreements for the destruction of embryos, in light of parental claims to he embryos. In other words, parents may have the right to change their minds.

Simply put, allow the creation of embryos *by anyone for any purpose*, and you create parental rights. The only way to avoid creating parental rights is to avoid creating embryos.

The Greenwood ban is not only dubious as a matter of law. It is untenable and unworkable in practice. Sections 8 (a) and (b) of H.R. 1644 provide sound reasons for concluding that evasions of the Greenwood ban would be all but undetectable. I should like to add a different set of observations, not about evading Greenwood, but about the porous quality of its coverage. I shall speak about human reproductive cloning which is *not unlawful* under the Greenwood bill.

Greenwood does *not* ban the implantation of embryos obtained by cloning. It does not ban the possession of embryos created by cloning; only knowing "ship[ping]" and "transport[ing]" the "cellular product" of cloning are prohibited. Greenwood explicitly immunizes from its reach "other medical procedures to assist a woman in becoming or remaining pregnant". Simply getting pregnant with a cloned embryo is entirely outside the scope of this self-styled "prohibition against human cloning". In sum, the Greenwood "prohibition" would actually privilege the creation of an untold number of embryos suitable for implantation, and does not make any act in connection with implantation itself unlawful. And a human embryo created for research

[1] This is probably the best place to note a shortcoming of draftsmanship in H.R. 1644. It omits all explicit mention of *mens rea.* This omission appears to make its provisions binding in strict liability. Since the ten-year sentence authorized strongly suggests that either *knowing*, or perhaps *reckless*, misconduct is the target of the bill, some *mens rea* should be made explicit.

purposes is just as suitable for implantation as one created for that end, and vice-versa.

Now consider this very simple, eminently workable scenario.

The act's main prohibition attaches at the moment of cloning. A researcher must not clone "with the intent to initiate a pregnancy". A researcher who undergoes a change of heart could therefore *lawfully* tell another person, whom we shall call the "mule", to deliver a vial of embryos (which the researcher had created days ago in good faith) to an office across town. That deliverer would not be guilty of "knowingly" shipping or transporting cloning products. Across town, a doctor takes possession of the embryos, and implants them in a like number of women. Neither the doctor or the women are guilty of anything. None created embryos with the intent to cause pregnancy, and none shipped or transported them at all.

CONCLUSION

H.R. 1644 makes good moral sense, is free of constitutional infirmities, and it is practically enforceable. The Greenwood alternative is morally dubious, constitutionally questionable, and practically unenforceable.

Mr. SMITH. And are you finished, Professor Bradley?

Mr. BRADLEY. Yes, I am, unless you have a question.

Mr. SMITH. Okay, thank you, Professor Bradley. Dr. Okarma.

STATEMENT OF DR. THOMAS OKARMA, PRESIDENT AND CEO, GERON CORPORATION

Dr. OKARMA. Thank you. Good afternoon, I'm Tom Okarma, president and CEO of Geron Corporation in Menlo Park, California.

Geron is a biopharmaceutical company focused on discovering, developing, and commercializing therapeutic and diagnostic products for applications in oncology, drug discovery, and regenerative medicine.

I'm testifying today on behalf of my company and the Biotechnology Industry Organization, BIO. BIO, as you know, represents over 950 biotechnology companies, academic institutions, State biotechnology centers, and related organizations in all 50 U.S. States and 33 other nations.

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to testify today at this important hearing on cloning.

In my testimony today, I'd like to make three points. First, Geron Corporation, BIO, and the overwhelming portion of scientists and physicians oppose human reproductive cloning of human beings. On this point, I think we are all in agreement.

However, my second point: In our shared zeal to prevent reproductive cloning, we must not prevent research on tissue cloning, which is fundamental to enable the development of safe and effective cellular transplantation therapies that could revolutionize medicine in our lifetimes.

My third point is that the objective of this research is to develop a scalable process to enable the direct conversion of a somatic or body cell into a pluripotent cell without consuming oocytes and without generating blastocysts or embryos. Such a process would allow the generation of transplantable replacement cells that would not be rejected by the immune system.

First, ban reproductive cloning. It would be extremely dangerous to attempt human reproductive cloning. As we know, it took over 270 attempts before Dolly was successfully cloned. In fact, in most animals, reproductive cloning has no better than a 3 to 5 percent success rate.

That is, very few of the cloned animal embryos implanted in a surrogate mother animal survive. The others either die in utero, sometimes at very late stages of pregnancy, or die soon after birth. It is simply unacceptable to subject humans to those risks.

To allow human reproductive cloning would be irresponsible. Worse yet, it could lead to a backlash that would stifle the numerous beneficial applications of therapeutic cloning technology, some of which I will describe today, that could lead to cures and treatments for some of our most deadly and disabling diseases.

My second point: It is critical to distinguish use of cloning technology to create a new human being, so-called reproductive cloning, from other appropriate and important uses of the technology, such as cloning specific human cells, genes, and other tissues that do not and cannot lead to a cloned human being, therapeutic cloning.

The full potential of this technology comes from its applications in regenerative medicine. Many diseases result in the disruption of cellular function or the disruption of tissue. Heart attacks, stroke, diabetes are all example of common conditions in which critical cells are lost to disease.

Today's medicine is completely unable to restore this loss of function. Regenerative medicine, a new therapeutic paradigm, holds the potential to cause an individual's currently malfunctioning cells to begin to function properly again or even to replace dead or irreparably damaged cells with fresh, healthy ones, thereby restoring organ function.

The goal of our regenerative medicine program is to produce transplantable cells that provide these therapeutic benefits without triggering immune rejection of the transplanted cells.

This could be used to treat numerous chronic diseases, such as diabetes, heart disease, stroke, Parkinson's disease, spinal cord injury, and many others.

For example, in our current work, we are learning how to turn the undifferentiated human pluripotent stem cell into human neurons, human liver cells, and human heart muscle cells. So far these cells function normally *in vitro*, raising the possibility of their application in the treatment of devastating chronic diseases affecting these tissue types.

This would, for instance, allow patients with heart disease to receive new heart muscle cells that would improve cardiac function.

Cellular cloning techniques are a critical step in the production of sufficient quantities of vigorous replacement cells for the clinical treatment of patients.

Somatic cell nuclear transfer is essential if we are to achieve our goals in regenerative medicine. We must understand the biological properties of the egg cell and the transferred nucleus that cause a differentiated cell to turn into a pluripotent one. This process is called reprogramming, and we're still not sure how it works, which is why we need to continue to perform the research.

At Geron, our aim is to harness and therapeutically apply this biology. Once we fully understand reprogramming, we'll be able to develop specific cells for transplantation without immune rejection. We'll do that by taking a differentiated cell from a particular individual, reprogramming it back to form a pluripotent cell, from which we can produce the differentiated cells we need for trans-

plantation back into that individual. By using the patient's own cells as starting material, we avoid complications due to immune rejection.

This, however, is precisely the research that would be banned by the Weldon bill. Because the Weldon bill does not distinguish between reproductive cloning and use of cloning for research purposes, it will cut off this work and prevent its therapeutic applications from reaching patients.

In contrast, the bipartisan bill introduced by Representatives Greenwood and Deutsch and others bans reproductive cloning but allows the continuation of research. BIO supports Greenwood-Deutsch because it strikes the appropriate balance between prohibiting acts that unsafe and unethical while promoting vital medical research.

Lastly, it is critical to emphasize that once we understand the molecular biology of reprogramming, we will no longer need to use egg cells or to create blastocysts. The commercial process would transform a somatic cell, such as a skin cell, into a pluripotent cell directly, without the use of oocytes and without the creation of blastocysts.

Moreover, understanding the biology of reprogramming is a critical step to improve the usefulness of so-called adult stem cells. Ironically, the Weldon bill will also be a setback for adult stem cell research.

In conclusion, Mr. Chairman, human reproductive cloning remains unsafe and the ethical issues it raises have not been reasonably resolved. It should be prohibited.

However, as Congress seeks to outlaw reproductive cloning, it must not write legislation that would stop research using cloning technology. Unfortunately, the Weldon bill fails this test. Simply put, enactment of the Weldon bill will stop critical therapeutic work in its tracks. Only Greenwood-Deutsch strikes the right balance.

Thank you, and I would be happy to answer questions.

[The prepared statement of Dr. Okarma follows:]

PREPARED STATEMENT OF THOMAS OKARMA

Good afternoon. My name is Thomas Okarma. I am the President and CEO of Geron Corporation in Menlo Park, California. Geron is a biopharmaceutical company focused on discovering, developing, and commercializing therapeutic and diagnostic products for applications in oncology, drug discovery and regenerative medicine. Geron's product development programs are based upon three patented core technologies: telomerase, human pluripotent stem cells, and nuclear transfer.

I am testifying today on behalf of my company and the Biotechnology Industry Organization (BIO). BIO represents more than 950 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

Mr. Chairman, and members of the Subcommittee, thank you for the opportunity to testify today at this important hearing on cloning. Let me start by making our position perfectly clear: BIO opposes human reproductive cloning. It is simply too dangerous technically and raises far too many ethical and social questions.

That's why BIO wrote to President Bush earlier this year and urged him to extend the voluntary moratorium on human reproductive cloning which was instituted in 1997. I would respectfully ask for this letter to be included in the hearing record.

It would be extremely dangerous to attempt human reproductive cloning. It took over 270 attempts before Dolly was successfully cloned. In fact, in most animals, re-

productive cloning has no better than a 3–5% success rate. That is, very few of the cloned animal embryos implanted in a surrogate mother animal survive. The others either die in utero—sometimes at very late stages of pregnancy—or die soon after birth. Only in cattle have we begun to achieve some improvements in efficiency. However, scientists have been attempting to clone many other species for the past 15 years with no success at all. Thus, we cannot extrapolate the data from the handful of species in which reproductive cloning is now possible to humans. This underlines that this would be an extremely dangerous procedure.

It is simply unacceptable to subject humans to those risks. Rogue and grandstanding so-called scientists who claim they can—and will—clone humans for reproductive purposes insult the hundreds of thousands of responsible, reputable scientists who are working hard to find new therapies and cures for millions of individuals suffering from a wide range of genetic diseases and conditions.

The Food and Drug Administration (FDA) has publicly stated that it has jurisdiction over human reproductive cloning experiments and that it will not approve them. BIO supports that view and hopes that the next FDA commissioner—whoever that might be—will assert FDA's current statutory authority forcefully.

There are also many ethical concerns raised by the specter of cloning. As noted in BIO's letter to the President, "Cloning humans challenges some of our most fundamental concepts about ourselves as social and spiritual beings. These concepts include what it means to be a parent, a brother, a sister and a family.

"While in our daily lives we may know identical twins, we have never experienced identical twins different in age or, indeed, different in generation. As parents, we watch with wonder and awe as our children develop into unique adults. Cloning humans could create different expectations. Children undoubtedly would be evaluated based on the life, health, character and accomplishments of the donor who provides the genetic materials to be duplicated. Indeed, these factors may be the very reasons for someone wanting to clone a human being."

As you can see, Mr. Chairman, many of these issues strike at the heart of beliefs and values that are inherent in the human condition. What does it mean to be an individual? How should we view our parents, brothers, sisters, and children? How does the world around us influence our intellectual, physical and spiritual development? These are just a few of the questions raised by human cloning. In my view, reproductive cloning would devalue human beings by depriving them of their own uniqueness.

To allow human reproductive cloning would be irresponsible. Worse yet, it could lead to a backlash that would stifle the numerous beneficial applications of therapeutic cloning technology—some of which I will describe today—that could lead to cures and treatments for some of our most deadly and disabling diseases.

BENEFICIAL USES OF CLONING TECHNOLOGY

It is critical to distinguish use of cloning technology to create a new human being (reproductive cloning) from other appropriate and important uses of the technology such as cloning specific human cells, genes and other tissues that do not and cannot lead to a cloned human being (therapeutic cloning). These techniques are integral to the production of breakthrough medicines, diagnostics and vaccines to treat many diseases. They could also produce replacement skin, cartilage and bone tissue for burn and accident victims, and result in ways to regenerate retinal and spinal cord tissue.

Let me briefly explaining a cloning technology—somatic cell nuclear transfer—and how it is used for research purposes. First, the nucleus of an egg cell is removed. In its place, we insert the nucleus of an already differentiated cell (a cell that performs a specific function in the body). Chemicals are added to stimulate the egg to start dividing. At about 3–5 days, a blastocyst is formed which contains an inner cell mass comprised of undifferentiated, pluripotent cells. These cells are removed and used for research. The research value of these cells is enormous. These stem cells have the potential to form any cell in the body and can replicate indefinitely. Studies in animals demonstrate that this could lead to cures and treatments for millions of Americans who suffer from diseases and disabilities such as diabetes, stroke, Parkinson's Disease, heart disease, and spinal cord injury.

As exciting as that is—it's only a part of the story. The full potential of this technology comes from its use in regenerative medicine.

REGENERATIVE MEDICINE

Many diseases result in the disruption of cellular function or destruction of tissue. Heart attacks, strokes, and diabetes are examples of common conditions in which critical cells are lost to disease. Today's medicine is unable to completely restore this

loss of function. Regenerative medicine, a new therapeutic paradigm, holds the potential to cause an individual's currently malfunctioning cells to begin to function properly again or even to replace dead or irreparably damaged cells with fresh healthy ones, thereby restoring organ function.

The goal of Geron's regenerative medicine program is to produce transplantable cells that provide these therapeutic benefits without triggering immune rejection of the transplanted cells. This could be used to treat numerous chronic diseases such as diabetes, heart disease, stroke, Parkinson's Disease and spinal cord injury.

At Geron, therapeutic cloning technology is one of the techniques we use to create pure populations of functional new cells that can replace damaged cells in the body. For example, we are learning how to turn undifferentiated human pluripotent stem cells into neurons, liver cells and heart muscle cells. Thus far, these human replacement cells appear to function normally *in vitro*, raising the possibility for their application in the treatment of devastating chronic diseases affecting these tissue types. This would, for instance, allow patients with heart disease to receive new heart muscle cells that would improve cardiac function. Cellular cloning techniques are a critical and necessary step in the production of sufficient quantities of vigorous replacement cells for the clinical treatment of patients.

Somatic cell nuclear transfer research is essential if we are to achieve our goals in regenerative medicine. We must understand the biological properties of the egg cell (and the transferred nucleus) that cause a differentiated cell to turn into a pluripotent cell. This process is called "re-programming"—and we're still not sure how it works. That's why we need to continue to perform research.

At Geron, our aim is to harness and therapeutically apply the power of this biology. Once we fully understand re-programming we will be able to develop specific cells for transplantation without immune rejection. We'll do that by taking a differentiated cell from a particular individual and re-programming it to form a pluripotent cell from which we can produce the differentiated cells we need for transplantation back into that individual. By using the patient's own cells as starting material, we will avoid complications due to immune response rejection.

However, this is precisely the research that would be banned by the Weldon bill. Because the Weldon bill does not distinguish between reproductive cloning and use of cloning for research purposes, it will cut off this work and prevent its therapeutic applications from reaching patients. In contrast, the bi-partisan bill introduced by Reps. Greenwood, Deutsch, and others bans reproductive cloning but allows the continuation of research. BIO supports Greenwood/Deutsch because it strikes the appropriate balance between prohibiting acts that are unsafe and unethical, while promoting vital medical research.

It is important to emphasize that *once we understand the molecular biology of re-programming, we will no longer need to use egg cells or create blastocysts.* Therefore, this technology is likely to be used only for a short, finite period of time. Moreover, understanding the biology re-programming is a critical step to improve the usefulness of adult stem cells. Ironically, therefore, the Weldon bill will also be a setback to adult stem cell research.

CONCLUSION

As the current Congress pursues legislative prohibitions on human reproductive cloning, we urge caution and a distinction between reproductive and therapeutic cloning. We all agree that given the current safety and social factors, human reproductive cloning is repugnant. However, it is critical that in our enthusiasm to prevent reproductive cloning, we not ban vital research, turning wholly legitimate biomedical researchers into outlaws, and thus squelching the hope of relief for millions of suffering individuals.

Our nation is on the cusp of reaping the long dreamed of rewards from our significant investment in biomedical research. The U.S. biotech industry is the envy of much of the world, especially our ability to turn basic research at NIH and universities into applied research at biotech companies and in turn, into new therapies and cures for individual patients. Using somatic cell nuclear transfer and other cloning technologies, biotech researchers will continue to learn about cell differentiation, re-programming, and other areas of cell and molecular biology. Armed with this information, they can eventually crack the codes of diseases and conditions that have plagued us for hundreds of years, indeed, for millennia.

In conclusion, Mr. Chairman, human reproductive cloning remains unsafe, and the ethical issues it raises have not been reasonably resolved. It should be prohibited. However, as Congress seeks to outlaw reproductive cloning, it must not write legislation that will stop research using cloning technology. Unfortunately, the Weldon bill fails that test. Simply put, enactment of the Weldon bill will stop critical

therapeutic research in its tracks. Only Greenwood/Deutsch strikes the right balance.

Thank you for the opportunity to testify. I'll be happy to answer any questions.

Mr. SMITH. Thank you, Dr. Okarma.

It seems to me that there is agreement at least among our witnesses today that reproductive cloning should not be allowed. We have various suggestions, ranging from outright ban to a 3- to 5-year moratorium.

The question, then, is whether we should have reproductive cloning. Three of you all say we should not. Dr. Okarma feels that we should.

What I would like to do, to start with, is, Dr. Okarma, read you some of the statements by Professor Capron and Dr. Elshtain, and ask you respond to what they said in their testimony.

And then I would like you all to respond to what Dr. Okarma says.

Dr. OKARMA. Thank you. I'll be responding extemporaneously. I have not had the opportunity to review the written copy, so I'm responding from my hearing——

Mr. SMITH. I'll read you the statement. I hope it won't be out of context and it will give you a feel for what the argument is, and then you could respond, if you would.

Let's see, Professor Capron, let me read from your statement.

The need for cloning human embryos was simply not established. If anything, the arguments for emphasizing basic research with nonhuman stem cells is even greater in light, for example, of the sad results involving unregulated cellular activity in the brains of some Parkinson's patients who received fetal tissue transplants in experiments in New York and Colorado.

And then in Professor Elshtain's testimony, she said:

It seems clear to me that the path down which we are headed, unless we intervene now to stop human cloning, is one that will deliver harm in abundance, whereas any potential benefits are highly speculative. The harms are known; the benefits are a matter of conjecture.

Dr. Okarma, I gather you feel that research cloning would be beneficial, it might alleviate the suffering of many individuals who have a number of diseases or might suffer those diseases in the future. But how do you respond to the arguments that it doesn't look like the research cloning is that effective or that helpful? And, in fact, recently there has been some doubt cast on it.

Dr. OKARMA. I can respond to that, actually, quite clearly. In point of fact, the demonstration of the ability to produce mouse embryonic stem cells through cloning has been reduced to practice and has been published, so that we know in an animal model of nuclear transfer that one can generate histocompatible cells through the nuclear transfer process that will produce embryonic stem cells that are pluripotent.

So the notion that this is hypothesis or fanciful thinking is not in fact true. It has been reduced to practice in animals.

However, in fairness, we do not know whether this process is even possible in humans.

To the point that there are other ways to prevent immune rejection, this is also possibly true. And we and others are pursuing them in parallel.

They would, for example, involve genetically altering the embryonic stem cell to render it immunologically null, not recognizable by the immune system. And the notion would be that all cells derived from that engineered cell would also be not recognized.

That requires, however, an enormous leap in the technology. We are asking for a genetic change to be carried through many leaps of production of cells, to breed true, so to speak.

They also could have the disastrous consequence of losing that nullness after the cells were in fact transplanted, leading to a rejection.

So the facts of the matter, as we understand them and as they've been published in peer-review literature, argue that the approach of nuclear transfer would in fact be a final solution to the problem.

As for——

Mr. SMITH. Dr. Okarma, let me interrupt you, because I want to hear from the two professors, as well.

Professor Capron, if you would respond first.

Mr. CAPRON. In the first place, I want to underline what, it seems to me, is a slippery use of the word therapeutic cloning in Dr. Okarma's statement. He uses that to describe not only the creation of research embryos for an eventual therapeutic purpose but cells and so forth. And both the bills before us, as you have heard, are very clear that we are not talking about any prohibitions on the duplication of DNA, the duplication of stem cells and so forth, other kinds of cloning other than the creation of an embryo.

As to the question of whether we need research cloning now in order to achieve results of a therapeutic nature, it seems to me that we have not heard a refutation of the two lines of argument that are presented in the statement.

On the one hand, there is the argument about other ways that need to be explored: the use of adult stem cells and the use of nonclonally derived human stem cells, embryonic stem cells, to see if their antigenicity, and, therefore, their chance of causing a rejection phenomena, can be reduced. And these are both under active research.

Obviously, if either of those pan out, there is no need to use cloned stem cells to create cellular tissues.

The second——

Mr. SMITH. Let me, real quickly, get a response from Dr. Okarma——

Mr. CAPRON. Okay.

Mr. SMITH [continuing]. As to that point.

If we get to that point, would you favor a ban, if we get to the point where we didn't need to have those cells?

Dr. OKARMA. Well, it's hard to answer the hypothetical, sir. I think the decision would really turn on its merits. We would really need to know the viability and degree of immune-nullness that cells produced by those alternative methods produced.

Mr. SMITH. Okay, thank you.

Professor Capron, I would like to go to Dr. Elshtain——

Mr. CAPRON. Okay.

Mr. SMITH [continuing]. And hear her response as well. Thank you.

Ms. ELSHTAIN. Thank you, Mr. Chairman.

I ran out of time before I indicated the reasons, the specific reasons, for why I favored H.R. 1644 by contrast to H.R. 2172, and it's quite specifically because it would not create an effective, workable ban on the cloning of human beings for a number of reason, including the fact that the bill permits the use, as we've already heard, of human somatic cell nuclear transfer technology, the act that creates a human clone.

It says only that people are prohibited to do this if they intend to begin a pregnancy. Well, it's easy to see that people would have a stake in saying they intend no such thing as they went ahead with the process and then, through a variety of means, found ways to sidestep the law, the law criminalizing, if you will, an intent.

And one of the things I learned as a graduate student in political science was that legislation is usually not very effective in the business of trying to discern and to punish an intent, that it is in fact acts, it's deeds, over which legislation can be effective. Intent is very difficult, it is very difficult to legislate.

So H.R. 1644 prohibits a specific deed or, in effect, a chain of deeds at the end of which you have a cloned human being. So, in other words, we have to prohibit the creation of embryonic human clones in order to prevent the cloning of human beings.

And it seems to me that H.R. 1644 does that. H.R. 2172 does not, because of the emphasis on intent by contrast to actual deeds or webs. I think Professor Bradley called it webs of activities.

And the other point I would make is that, in fact, the scenario sketched by Dr. Okarma, or the possible whole panoply of possible therapeutic benefits, again, is highly hypothetical, as he himself indicated, in effect, in his response to you when he said that the scientists at this point didn't even know if some of the techniques that have now been worked, workable—are proven to be workable with mice, if those are possible in human beings. And yet we're promised the cure to a whole long list of diseases.

If there are alternative ways to begin to go after some of these devastating conditions and illnesses that do not trail in their wake the harm that human cloning does and the possibility of a technology that is unleashed that will lead inevitably to that result, then that's the direction we should go.

Mr. SMITH. Okay, thank you, Dr. Elshtain.

Professor Bradley, you mentioned in your testimony a few minutes ago the distinction between the two bills and how each bill banned reproductive cloning. You said one was constitutional, one was not constitutional, as I recall.

In any case, what I wanted to ask you was about two constitutional rights that sometimes come into play when we discuss this subject. Do you feel that there is a constitutional right to procreate? And do you think there's a constitutional right to scientific inquiry?

Mr. BRADLEY. Well, first I should say that I think that the Greenwood raises constitutional questions. I'm not sure that I want to be heard to say that it is unconstitutional.

Mr. SMITH. Okay.

Mr. BRADLEY. But it's not free of constitutional difficulty——

Mr. SMITH. Fair enough.

Mr. BRADLEY [continuing]. As I think 1644 is.

Although, as you're suggesting, my conclusion about 1644 includes an opinion about a right to scientific inquiry. I think no such right, you know, just as such exists. And there are rights to pursue unimpeded by Government information and knowledge.

But scientific inquiry, at least in this context, is not a matter of pure speech, because we're talking about research and experimentation. It's a speech act or even principally an act.

So, therefore, the acts that we're talking about—let's call them scientific research and experiment—are not governed by traditional free speech doctrines, which are themselves not absolutes. Government can regulate speech under certain circumstances. But we're not talking about pure free speech.

So I don't think there is, at least in the relevant sense, a right of free scientific inquiry involved.

Now, there is something—or a multifaceted——

Mr. SMITH. Professor Bradley, I better stop you there. I am way over time.

Mr. BRADLEY. Okay.

Mr. SMITH. And if you need to return to that later, let me know. But you've really answered my question. And it was a fine distinction you made, and I was glad to hear it. Thank you.

Let me say also that, without objection, all of your statements, complete statements, will be made a part of the record.

The gentleman from California, Mr. Schiff, is recognized for his questions.

Mr. SCHIFF. Thank you, Mr. Chairman.

I wanted to address a question to the three witnesses that testified in opposition to research cloning, as we're describing it today. And I understand that it can be used in different ways, but we're talking about, essentially, human somatic cell nuclear transfer, not for the purpose of pregnancy or to create a child, but for research purposes.

I've listened to the points you've made, and I have to say that I don't find them all that compelling, and I wonder if there's a reason that we haven't talked about that is more compelling to each one of you.

Professor Capron, you make the point that we need to prevent this because, in the lab, loosely regulated environment, it could be going on for one purpose. It could be then taken and used for an illicit purpose.

And while I suppose that's true, that logic would lead us also to preclude a whole lot of infertility treatments in Irvine, California. And I come from California.

We had a huge problem with people's eggs being sold, and enormous ethical lapses and criminality. Now, we wouldn't preclude those kinds of fertility treatments because of that prospect, and I don't think it would be compelling to do so here.

Dr. Elshtain, you make the point that intent is difficult to legislate, and yet our criminal laws—and this is a criminal law that we're contemplating—are replete with requirements of intent and, in fact, very definite states of intent, depending on the crime.

It is very rare that we find crimes that require no requirement of intent, that are per se violations merely because you conduct a certain act. And I would submit, even as you're proposing, there would be a certain level of intent required.

I also don't think the benefits are all that much a matter of conjecture. And I have to say I put this on the spectrum of things that are not conjecture at all and then, perhaps, national missile defense being more on the speculative side.

And where this fits within that spectrum, I'm not sure, but I would hate to see us prevent an important medical research opportunity merely because we haven't seen the documented success of it yet when there is so much progress being made.

I found the constitutional theory to be a very interesting one, that the narrower bill has a greater constitutional problem than the broader bill. I'm not sure that's correct. I think it's a very interesting idea.

To the degree any court is going to find that you have a constitutional right to procreate, using different scientific techniques, my guess is, if they're going to find you have that right, and I think at the point we're talking about, it's probably not likely, but if they were going to find you had that right, you probably have the right to go through the cloning process. It wouldn't simply be created once you had undergone part of the process. But I think it's interesting theory.

I think your other point, though, is very well-taken, that there does need to be some tightening up of the bill in that there are certain things precluded, that if there were a mental change along the way might not bar the cloning that we are all attempting to bar.

But I guess what I'm trying to say is that, or what I would like to ask is, of the three of you, if we could see today the measurable benefits—if they were not speculative, if the benefits we knew were real right now in treating Alzheimer's, cancer, a whole host of things—if we could be certain that it wouldn't be subject to any greater likelihood of risk and that we had great oversight of our laboratories, if there was no greater constitutional threat, would the three of you still be opposed to this type of research cloning simply because you believe that it is immoral and unethical without more?

Mr. CAPRON. No, I would not. And it seems to me that the issue is, at the moment, what is the correct characterization?

In order to get to the point of therapeutic benefit, we need research that amounts to building blocks. We need research on the differentiation of stem cells, not cloned stem cells, but other stem cells, into tissues and even organs in a way which will reliably function in the human body if transplanted. You don't need cloned research embryos to do that.

We need research on reprogramming. That can be done with animal cells. We don't need cloned human cells to do that.

And as I said, there are other ways that are under research that might offer a way, which I think everybody favors, the commission certainly favored, of avoiding the use of cloned embryos entirely, if we could the therapeutic benefits.

Mr. SCHIFF. Professor, if this was the only way, would you support it?

And I realize——

Mr. CAPRON. I said yes, in answer to your question. Yes.

Mr. SCHIFF. And one of the reasons I ask this question is, you know, you've made the point, and the doctor makes it also, that this may be a temporary problem, in that we may find other cells we can use for these purposes 5 or 10 or 15 years down the road.

And that's wonderful, but for someone who is afflicted now, and you may have seen recently, I think there was a press conference today about Geraldine Ferraro and her use of——

Ms. ELSHTAIN. Thalidomide.

Mr. SCHIFF [continuing]. Thalidomide. Exactly.

Very promising in her treatment today. Now, there may be other remedies in 5 years for her. But had it not been for the discovery of the productive use of thalidomide now, she may not live to see those other therapies.

Yes?

Mr. CAPRON. You answered—I answered your question but I—if I may put it in form of a question: If we do not now have the ability to use cloned research embryos for therapy, if that is, as everyone would say, is speculative—so we're not asking patients to forego a treatment that we now have. If that is speculative, and if, given the examples, like Irvine—we know that there is huge leakage in the whole fertility field.

It's a very entrepreneurial, almost Wild West phenomenon, very different than all the rest of experimental medicine, for reasons that I won't take your time with now.

In that circumstance, doesn't it seem prudent to draw the perimeter around reproductive cloning to include for the moment work which isn't essential now?

If it gets to be the point of being essential, we could then do it in a limited number of labs, which are specifically producing an organ for a particular patient or a tissue for a particular patient.

Mr. SCHIFF. Professor——

Mr. SMITH. Mr. Schiff?

Mr. SCHIFF. Yes.

Mr. SMITH. Let me interrupt you for a minute and apologize to you and to the other Members up here. The 5-minute clock that we have at our desk is working. However, the 5-minute notification devise on the witness table is not. And, therefore, I'm having to keep time as the Chairman.

And even though your 5 minutes has lapsed, I'd like for the witnesses to respond to your question. But I just wanted to let you know that's the reason for the red light that has been constant during all your questions.

Would the other witnesses please respond briefly to Mr. Schiff's question?

Ms. ELSHTAIN. I'll respond to the question of intent, Mr. Schiff, that you raised.

You indicated that, in fact, legislation deals with intent all the time, and I think you mentioned criminal law and the fact that one evaluates the seriousness in certain kinds of infractions with reference to intent.

But I don't think that I need to remind that you that, in fact, it is not the intent to murder that is against the law, but it is actually murdering someone.

And then, if there is the objective fact of a body, one goes on in the criminal—in the phase, the penalty phase, to evaluate the role of intent and so on.

But you're dealing with an objective fact. You're dealing with a deed.

That was my reference point, that it's concrete. It's stopping concrete deeds.

If the intent to murder were a crime, we'd all be in prison——

Mr. SCHIFF. Well, the intent——

Ms. ELSHTAIN [continuing]. Because all of us, at one point or another——

Mr. SCHIFF. The intent——

Ms. ELSHTAIN [continuing]. Have harbored——

Mr. SCHIFF. The intent to kill——

Ms. ELSHTAIN [continuing]. Murderous thoughts.

Mr. SCHIFF. The intent to kill is an element, and without the element, you never get to the——

Ms. ELSHTAIN. That's right.

Mr. SCHIFF [continuing]. The judge and sentencing.

Ms. ELSHTAIN. But the law prohibits the deed.

Mr. SCHIFF. And the——

Ms. ELSHTAIN. And that's—and that's precisely what I'm——

Mr. SCHIFF. Prohibits the deed with the intent.

Ms. ELSHTAIN. It prohibits the—but by definition, the deed involves the intent because murder is wrongful killing, which already involves an intent. But to an—the objective fact—I mean, this could get us into a long discussion, obviously.

The objective fact of a body—so what I'm saying is that when you say, "Well, the thing that we're going to criminalize is the intent to, if you will, do harm," to lead down this slippery slope, someone can, it seems to me, very effectively evade that by claiming there was no such intent and things simply got out of control.

As Dr. Capron pointed to with the infertility business at the present time, things often get out of control.

When you have the end result, one that everyone acknowledges is harmful, why would you want to take steps that would, it seems to me, inevitably lead to that harm? And I—it seems to me that, in fact, 2172 would lead to that harm or it would do nothing to prohibit it, whereas 1644 would more effectively try to prohibit the harm that everyone at this table, and I think everyone you've heard, probably agrees is a harm.

Mr. BRADLEY. Representative Schiff, I'll try to answer your question as straightforwardly as I can.

I do oppose, for moral reasons, the creation of embryos in order to perform research experiments on them and then—with the idea of discarding them. But that conviction of mine is not a premise of anything I've said to this Committee today, nor is it a premise of anything in my written remarks.

Mr. SCHIFF. Thank you.

Mr. SMITH. Okay, Thank you, Mr. Schiff.

The gentleman from North Carolina, Mr. Coble, is recognized for his questions.

Mr. COBLE. Thank you, Mr. Chairman.

And thank you all for being with us.

I say to the panelists, Mr. Chairman, I missed about three-fourths of the testimony. I had to go take a phone call regarding a patent matter on which I am working, so I regret that I didn't—was not privy to most of what was today.

I think you and the gentleman from California pretty thoroughly covered it.

Mr. Okarma, I have been advised by third parties that your corporation has performed outstanding bio work and research, and I will say that to you——

Dr. OKARMA. Thank you, sir.

Mr. COBLE [continuing]. Before I make my statement.

I'll say this to the panel, all of whom are experts, it seems to me that this issue conjures up many descriptive words defining the process: contentious, controversial, exciting, explosive, polarizing, complex.

It is indeed a complex subject matter. Cuts across all sorts of disciplines, some of which are represented here today: medicine, ethics, the law, science, political science.

I have no question, Mr. Chairman, specifically, but to say that I am not a man of letters to the extent that I can delve into this with the expertise that we've heard here, and the expertise that you and the gentleman from California have expressed, for that matter.

But I know that this Subcommittee and the Judiciary Committee as a whole, I am confident, will continue to keep a close lookout, and perhaps, I guess it's fair to say, Mr. Chairman, this may be the first of many steps to follow before the matter is resolved with finality.

And I thank you again for having staged this hearing today and again express my thanks to the panelists for being here.

Mr. SMITH. Thank you, Mr. Coble. And I might say that anyone who serves as Chairman of the Intellectual Property Subcommittee has a lot of intellectual understanding, so you don't need to worry——

Mr. COBLE. Thank you, sir.

Mr. SMITH. The gentleman from Virginia, Mr. Goodlatte, is recognized for his questions.

Mr. GOODLATTE. Thank you, Mr. Chairman, and thank you for holding this hearing.

I agree with much of what my good friend from North Carolina said. I'm not sure about whether we can be as deliberative as we'd like to be.

And I'd like to ask the panel what they can tell us about how imminent it may be that there'll be actual efforts at human cloning where an actual human being is cloned from the embryonic cells that might be cloned.

Start with Professor Capron.

Mr. CAPRON. For a number of years——

Mr. GOODLATTE. I've read articles that said——

Mr. CAPRON. Right.

Mr. GOODLATTE [continuing]. This could happen, it could be happening right now, so on.

Mr. CAPRON. Yes. The—for a number of years, various parties have said that they intended to go forward. The statements in the last 6 months by two groups in particular and the funding that they have and apparently, in the case of one of the groups, the willing volunteers, in terms of people to serve as the surrogate mothers, makes it more urgent.

It's hard to evaluate the credibility. And it is certainly true that on the scientific side, there are—most of the scientific opinion that I have read is that it would not only be highly irresponsible as a form of totally premature experimentation, but probably not successful and perhaps even extremely harmful to the women who were serving in the role.

That does not mean, it seems to me, that we can sit back and say, "Well, they'll never make it happen," or, "It's a long way off."

There is every reason to think that——

Mr. GOODLATTE. Are there people so unethical that they would be willing to try without the—I mean, as I understand it——

Mr. CAPRON. They have publicly announced——

Mr. GOODLATTE [continuing]. When there has been animal cloning, there have been lots of misfit-type failures that, it would seem to me, you'd be likely to encounter with human cloning as well.

Mr. CAPRON. I think that is the scientific opinion, that it is very likely to encounter exactly those, because of difficulties in the reprogramming of the genetic material when it goes from the somatic cell back to its pluripotent state to begin the organogenisis.

And it is for these reasons, among others, that the National Bioethics Advisory Commission said that there should be a moratorium on any reproductive cloning.

What I believe, however, is that the groups that have announced have the backing and have the intention to go forward. And I think it would be a great mistake for Congress to rely on the scientific improbability of their success as the protection that we need against the steps that they propose to take.

Mr. GOODLATTE. Dr. Elshtain?

Ms. ELSHTAIN. Yes. Unfortunately, Mr. Goodlatte, as you know, society always contains people who are unethical and people who are driven to garner all kinds of sensationalistic headlines. And this would certainly produce them.

There have been a number of very publicized intentions announced in the press, people who said that if human cloning were banned in the United States that they would move offshore and set up their laboratories and so on.

So I think that we have to take—I quite agree with Dr. Capron. I think we must take these people seriously and I think that these attempts are now under way. I don't think that this is a fantastic, futuristic scenario.

And I think that the prospect of a kind a traffic in cloned embryos with a possibility of trying to bring them to term as human clonees, and the number of failures this would involve, and what kinds of entities would one have, and what would their fates be, I think that is something that one should——

Mr. GOODLATTE. Let me interrupt and ask——

Ms. ELSHTAIN [continuing]. Really shudder at.

Mr. GOODLATTE [continuing]. Another question.

Do any of you know, is there an active investigation ongoing by any governmental entity, you know, a law enforcement agency or a consumer protection agency or anybody, a State licensing board for the practice of medicine? Anybody who is investigating these statements made by people and attempting to stop this under any current laws that they might be able to utilize?

Mr. BRADLEY. I'm not aware of any. There wouldn't be any law enforcement cause unless cloning is contrary to the criminal laws of some State that we're talking about. And to my knowledge, few if any States have criminalized cloning.

Mr. GOODLATTE. Dr. Okarma, would you respond to my first question?

Dr. OKARMA. Well, I actually agree with much of what was said a moment ago, and would perhaps extend it in the realm I'm comfortable in, which is the technical end.

These proponents of reproductive cloning, the Raelians and such, make the argument that we are much now like we were at the beginning of IVF, and, therefore, IVF has turned out to be a successful and safe alternative to reproduction, so there's no reason why the cloning nuclear transfer could not also do the same.

But that obfuscates the very fundamental difference in the biology. IVF is still, although in a test tube, the normal mechanism of procreation of humans. They haploid genomes of egg and sperm joining.

That is not, in fact, what happens somatic cell nuclear transfer. We are asking an oocyte, which has had its own nucleus removed, to completely reprogram an adult nucleus that is only expressing the genes required for that particular tissue, to take that nucleus all the way back to the beginning of development and to recapitulate Mother Nature's tape of development.

That's a huge biological burden for the egg. And, therefore, the likelihood of equal success that is enjoyed by IVF is very low.

Mr. GOODLATTE. Now, as I understand it, the difference between your perspective and the other three witnesses here relates to where you draw the line in terms of what can be done. Is there a clear, bright line that can be drawn?

I very much respect Dr. Elshtain's concern about intent. I think that is a very serious problem here, and I can see people with unethical motives attempting to cover up their intent somehow.

But would the type of research that you're advocating involve the placement of these cells in a woman to carry on the research at all? I mean, is that a line you can draw there, that——

Dr. OKARMA. The research that we advocate absolutely would not do that. We are, in fact, all in agreement to proscribe the transfer of any cloned embryo into a human uterus.

Mr. GOODLATTE. Dr. Elshtain, how would—it seems to me the law could very clearly say that that was the—I'm not advocating this, because I'm inclined to your side of the perspective here, that we shouldn't get into this at all.

But given the arguments of Dr. Okarma and others, that there are medical benefits to be derived from this, is it simply a way of

determining what the intent is, to say that if they go across that line and place these into a uterus, that that is the dividing line that would clearly show intent?

Ms. ELSHTAIN. Well, I think that, in fact, there isn't a bright line and there can't be, that sometimes we really—there really is a slippery slope and this is one.

That is, it seems to me that once you start creating embryonic human clones, that you can imagine a subterranean traffic, if you will, in those—in those clones. And that those who were—the originators of them, so to speak, could deny the intent of creating actual cloned human beings out if it.

But once you start doing that, and doing that en masse, it seems to me that you would start to get this traffic in cloned human embryos.

Mr. GOODLATTE. It's kind of like nuclear proliferation, is it?

Ms. ELSHTAIN. And it would simply—yeah. And it would be, yes, some kind of genetic equivalent of an arms race. And you would have a situation that really would be out of control.

And I think that's really what must be forestalled at this stage of the game.

Again, I think it's important to emphasize, as my colleagues have, that the Weldon bill does not stop animal cloning or the cloning of human DNA fragments. It doesn't stop duplication of somatic cells. It doesn't stop stem cells and tissue culture research and so on.

So the medical——

Mr. GOODLATTE. Let me interrupt you there.

Ms. ELSHTAIN [continuing]. Technology and medical benefits——

Mr. GOODLATTE. And, Dr. Okarma, that's enough, all of those other tools still being available?

Dr. OKARMA. Well, none of those tools speak to the essential issue of trying to prevent immune rejection of the transplanted cells.

And there are some technical subtleties here. It may seem to you that since this is a form of transplantation, much like an organ, why not simply rely on available immunosuppressive drugs, notwithstanding their toxicity and their expense? And the difference is actually quite profound.

Our intent is to transplant small numbers of highly purified cells, which may not survive the toxic side effects of currently available immunosuppressive therapy. That's why there is urgency here in this research.

And one other point I would like to make. While I do really respect and sustain both Dr. Capron and Dr. Elshtain's caveat about over-promising and under-delivering in this technology, I appreciate that point, however neither of them have spent much time in our laboratory, so I can tell you that we do in fact have the data now on differentiation, that the three cell types that we have deliberately chosen to manufacture from the embryonic stem cell, each represent one of the three germ layers of embryonic development, thereby enabling the notion that we can in fact produce any cell from these embryonic stem cells.

Mr. GOODLATTE. And where—what is the source of embryonic——

Dr. OKARMA. The embryonic stem cell is derived from *in vitro* fertilized blastocysts that are no longer needed to achieve pregnancy and are donated under informed consent for research.

These cells are infinitely self-renewing. That means they grow forever in the undifferentiated state, which we have, in fact, documented. And they are pluripotent, meaning because of their derivation from early embryos, they literally grow into all the cells and tissues in our body.

And I would add——

Mr. GOODLATTE. The source of this——

Dr. OKARMA. We——

Mr. GOODLATTE. If I might just interrupt for a second, and then you can finish.

The source of the cells that you use for this purpose are not from fetuses, then?

Dr. OKARMA. That's correct. Although we do have a different technology, the embryonic germ, that is derived from therapeutic abortions. It is somewhat different and has properties that are frankly inferior from a therapeutic perspective from ES cells.

I just would like to make one point in closing about the differentiation argument, about how near and present the technology is. Because we can scalably make these cells, as opposed to the adult stem cells—which are so rare and slow-growing that you cannot, at this point, produce many of them—we can expose these manufactured cells to rigorous functional testing, just as if they were a monoclonal antibody or a chemical made by a pharmaceutical firm.

And these cells withstand that scrutiny. They make—for example, the liver cells make all the drug metabolizing enzymes of our livers. The nerve cells make all of the appropriate synaptic materials. We are currently in animal studies with these neurons in animal model of Parkinson's disease and have in fact seen human neurons that we've implanted in this animal making synaptic connections in the damaged part of the brain.

So while I'm not saying that we are ready to initiate a human clinical trial, the data on differentiation and functionality of cells that we manufacture from the ES cells are very solid and are here today.

Mr. GOODLATTE. Thank you, Mr. Chairman.

Mr. SMITH. Thank you, Mr. Goodlatte.

I would like to ask you all a quick question to end on, and it is this: Do you feel that the Food and Drug Administration had the power to regulate cloning or to ban cloning?

Mr. Okarma, I believe you think they do have the power?

Dr. OKARMA. Let me simply answer that question from the perspective of appropriateness in their statements. I'm not a legal scholar, as you know, so I really——

Mr. SMITH. Okay.

Dr. OKARMA [continuing]. Cannot comment on the legal framework for their position. I do think, however, that the FDA is in an informed and appropriately judicial position to do that regulation.

Mr. SMITH. Okay, thank you.

Professor Bradley?

Mr. BRADLEY. No, I would have to say I don't know for sure. If it pleases you, I would be happy to work up something as a response that I would have more confidence in giving to you.

Mr. SMITH. Okay, fair enough. Thank you.

Dr. Elshtain?

Ms. ELSHTAIN. I'm not sure about whether it has the legal power, but I think the presupposition would be that the embryo is like an ordinary drug, in a sense. And I think that it would be—there would be a substantial problem in treating human embryos in the way that one treats a drug.

Mr. SMITH. That's what I've got as well.

Professor Capron?

Mr. CAPRON. Well, the FDA asserted, back in October 1998, to the institutional review boards that it had that authority. And it may well have that authority over the embryos as a biologic agent.

But the problem is that the authority they are asserting is something which they have never asserted in the fertility field before, and it is odd—a lot of the challenges and the doubts that are raised about that authority among legal scholars, who I think pretty uniformly doubt that the present statute has it.

And secondly, that what their authority would be limited to would be entirely issues of safety. So that if researchers establish that there was a wide enough, within the margin of safety, and combined with the arguments that Professor Bradley gave you about people asserting their reproductive rights and treating this as just a fertility method, at that point, it would be very hard, it seems to me, for the FDA to stand in the way.

One other issue about this whole treating this as the FDA, as the Greenwood bill does, it throws a cloak of confidentiality over all the proceedings and treats all the information as proprietary information.

In the cloning field itself, research results that came out early on from the American—for the Advanced Cell technology in the use of the cow oocyte as a vehicle for cloning of human nucleus never end up being published. Those are, so far as I know, retained as proprietary information.

We know from the debacle around some of the dangers with gene transfer that the open body, the recombinant DNA advisory committee, was not getting the information that the FDA was getting about some of the research risks and was holding as a matter or proprietary information.

If we put things in a kind of a registration, leave it to the FDA mode, what we're in effect saying is the public won't know.

Mr. SMITH. Okay. Thank you, all, for those answers.

I want to recognize the gentleman from California, Mr. Schiff, for a request to insert some materials into the record.

Mr. SCHIFF. Thank you, Mr. Chairman. Just to ask that we include a letter received by the Committee from American Society for Reproductive Medicine, and a second letter from the Federation of American Societies for Experimental Biology, and ask that be added to the record.

Mr. SMITH. Without objection, those documents will be made a part of the record.

Mr. SMITH. Thank you all again for your testimony today. This was our second hearing, as I mentioned at the outset. It concludes our series of hearings on the subject, and we will see which bill we consider next.

But thank you a lot for being here.

We stand adjourned.

[Whereupon, at 5:19 p.m., the Subcommittee was adjourned.]

APPENDIX

STATEMENTS SUBMITTED FOR THE HEARING RECORD

Congressman Bob Barr
Opening Statement
Subcommittee on Crime
Hearing on : "Ethics of Human Cloning"
June 7, 2001, 11:00 a.m. in Room 2237 of the Rayburn House Office Building

Thank you, Mr. Chairman, for holding this hearing today.

The use of either embryo splitting or nuclear replacement technology deliberately for the purposes of human reproductive cloning, to produce genetically identical human beings, raises serious ethical issues.

Beyond the fact that the scientific community has yet to establish the safety and efficacy of the procedure, the ability to produce an exact genetic replica of a human being, alive or deceased, carries with it an incredible responsibility. We are talking about human experimentation taken to the furthest extreme. While we hear about the possibilities this technology holds in treating infertility, developing treatments which would cure diseases, even producing organs for transplantation, in reality, there is nothing humanitarian or compassionate about creating and destroying human life for some theoretical, technical benefit that is far from established.

Consider how this technology could be manipulated in the hands of those with less than noble intentions: trying to reproduce deceased loved ones, genetically engineering mutations, manufacturing so-called genetically superior beings. The bizarre possibilities are endless.

Mr. Chairman, nothing scientifically or medically important would be lost by banning human reproduction by cloning. Indeed, at this time, there is no clinical, scientific, therapeutic or moral justification for it.

The question of "therapeutic cloning" -- that is, manufacturing embryos to harvest embryonic stem cells -- also must be addressed. We hear from scientists claiming embryonic stem cells, harvested from cloned embryos which are subsequently destroyed, are desperately needed for "regenerative" medicinal purposes. There is abundant evidence that alternatives to this procedure already exist; stem cells which can be harvested from placentas and umbilical cords, even from human fat cells. Indeed, the National Bioethics Commission reported in 1999: "the derivation of stem cells from embryos...is justifiable only if no less morally problematic alternatives are available for advancing the research." Today, we will be hearing from a variety of professionals in the medical and scientific community who will discuss these alternatives in greater detail, and I look forward to their testimony.

Thank you Mr. Chairman.

PREPARED STATEMENT OF THE HONORABLE SHEILA JACKSON LEE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you, Mr. Chairman.

I want to thank Chairman Smith and Ranking Member Scott for holding a hearing on this important public policy matter. With this topic we step into the vast unknown. Cloning is a fascinating, promising issue but one that remains to be more fully explored. It is crucial that Congress carefully consider all options regarding this issue before it proceeds. We must carefully balance society's need for lifesaving scientific research against the numerous moral, ethical, social and scientific issues that this issue raises.

Just over four years ago, the world learned of the first successful cloning of a sheep, "Dolly." Recognizing the urgent dilemma that this momentous occasion brought, President Clinton wisely instituted an immediate ban on federal funding related to attempts to clone humans. Further, at his request, the National Bioethics Advisory Commission recommended a voluntary moratorium on human cloning. It appears that in this country, this moratorium has been observed, and that human cloning has been discouraged in other nations as well.

It is generally accepted that Americans are not yet comfortable for the reproduction of a human clone. The legal, ethical, physical and psychological implications of such an act are not yet fully understood. The existence of these unresolved questions greatly overwhelms the need to create a cloned human being. We do not yet know the long term health risks for a cloned human being, nor have we even determined what the rights of a clone would be as against the person who is cloned or how either would develop emotionally. Mr. Chairman, we do not seem ready to start down the road of cloning.

What we can accept as a useful and necessary practice, however, is the use of the cloning technique to conduct embryonic stem cell research. This work shows promise in the effort to treat and even cure many devastating diseases and injuries, such as sickle cell anemia, spinal cord damage and Parkinson's disease. This research also brings great hope to those who now languish for years or die waiting for a donor organ or tissue. Yet just as we are seeing the value of such research, there are those among us who would seek not only to stop this research, but also to criminalize it. We must pause for a moment to consider what conduct should be definitely criminalized. There is an irresistable tendency to consider that science will be utilized to bring about undesirable results—full human replications.

Those who support such drastic action will claim that we must do so merely because we do not fully understand it. I contend that quite the opposite action is necessary. *We must study what we do not understand.* We would not know progress if we were to criminalize every step that yielded some possible negative results along with the positive.

In addition to unknown scientific ramifications of human cloning, we face some legal uncertainties. First, we face the argument that reproductive cloning may be constitutionally protected by the right to privacy. We must also carefully consider whether we take a large step towards overturning *Roe* v. *Wade* when we legislatively protect embryos. We do not recognize embryos as full-fledged human beings with separate legal rights, and we should not seek to do so.

There may also be some who seek to impose criminal penalties on cloning in reaction to claims by individuals who are attempting to plunge into the unknown by claiming to be planning to create clones abroad to help infertile couples. But we must throw out the bunch of apples because one in the bunch is bad. The majority who would engage in therapeutic cloning are ethical and would not attempt such negative activity. In fact, research scientists do not have ready access to infertility laboratories, which would be the link needed to complete the reproductive cloning process. And crimininalizing cloning would not deter those who are intent on doing it.

Hence, I am concerned at this time about any legislation that bans cloning, such as H.R. 1644, the Human Cloning Prohibition Act of 2001. The more prudent approach may be that supported by Dr. Shapiro, who advises that Congress refrain from regulating cloning and instead engage in informed regulation.

Mr. Chairman, I am looking forward to hearing the testimony of the panel of experts on this important topic of cloning and to the dialogue that will ensue as we address this controversial and complex matter. Thank you.

PREPARED STATEMENT OF THE HONORABLE LAMAR SMITH

Today the Subcommittee on Crime holds the second of two hearings on the issue of human cloning. In our last hearing, the Subcommittee focused on the ethical issues and possible consequences of cloning human beings. Today, we will examine the legal issues relating to the federal regulation of human cloning and hear testimony regarding two bills on the issue, H.R. 1644 and H.R. 2172.

Testimony from our last hearing revealed that there are a growing number of groups who claim they can, and will, clone a human being. Currently, no clear regulations exist in the United States that would prevent a private group from attempting to create a human clone. Even though the Food and Drug Administration has asserted that it has the authority to regulate this activity, legal scholars have expressed doubt as to whether this claimed authority would stand a legal challenge. Furthermore, the consequences for any scientist who would ignore the FDA's claimed authority is unclear. For this reason, this Congress must act to protect the health and safety of its citizens.

Legal challenges to any federal regulation of human cloning will be swift. Opponents will argue that any ban on human cloning will be unconstitutional because it unduly interferes with a scientific right of inquiry and denies a person's "fundamental right to reproductive freedom." I believe that these arguments will fail. Although Congress may not prohibit research in an attempt to prevent the development of new knowledge, it may restrict or prohibit the means used by researchers that threaten interests in which the citizens of this country have a legitimate concern. Furthermore, human cloning is not sexual reproduction, it is asexual replication for which there is no guaranteed "fundamental right."

The two bills before us today would prohibit the cloning of human beings, however, the scope of that prohibition is treated in very different and important ways. H.R. 1251, introduced by Congressman Greenwood of Pennsylvania, would only prohibit the use of human cloning technology when the intent of the scientist is to ini-

tiate a pregnancy. The prohibition in this bill would still allow for the cloning of human embryos for experimental purposes as long as the scientist creating that embryo does not intend to bring a fully mature human being into existence.

H.R. 1644, introduced by Congressman Weldon of Florida, goes beyond the Greenwood bill and prohibits the use of human cloning technology to produce a living human organism at any stage of development. The Weldon bill would make it a criminal act to clone a human embryo even if the scientist had no intention of trying to initiate a pregnancy.

I should point out that neither of these bills place any restrictions on the use of cloning technology to clone molecules, DNA, cells, tissues, organs, plants or animals. They would not interfere with the use of *in vitro* fertilization, the administration of fertility-enhancing drugs, or the use of other medical procedures to assist a woman in becoming or remaining pregnant.

Today we will hear from a panel of four witnesses who have extensive backgrounds in the field of law and bioethics. I would like to thank the witnesses for appearing before the Subcommittee on this important issue and I look forward to hearing their testimony. The Chair now recognizes Bobby Scott, the ranking Member for an opening statement.

MATERIAL SUBMITTED FOR THE HEARING RECORD

POST HEARING QUESTIONS AND ANSWERS FROM THE HONORABLE SHEILA JACKSON LEE

Witness Questions

1. Dr. Leon Kass, Professor of Bioethics, the University of Chicago:

   Isn't it likely that even if human cloning is banned, there are some who will engage in it anyway, unregulated?

   Doesn't the prohibition of embryonic cloning have the secondary effect of defining an embryo as a life, and thereby outlawing abortion?

2. Dr. David Prentice, Professor of Life Sciences, Indiana State University:

   Nobel laureate and Caltech President David Baltimore, along with Stanford University researcher Irving Weissman have stated that a moratorium on the use in research and transplantation of fetal or embryonic stem cells would be "devastating" as it is likely that only fetal or embryonic stem cells have the capacity generate a number of specific tissues. The National Bioethics Advisory Commission has also described the use of adult stem cells as scientifically and technically limited. How do you respond to these statements?

   Have the adult stem cells been used successfully in treatment for sickle cell anemia? If not, have embryonic stem cells?

3. Dr. Daniel Callahan, Director of International Programs, Hasting Center:

   You have stated "too much of the current research drive is fueled by a single minded passion to eradicate disease." Eradication of disease and consequent improvement of the human condition are the primary purposes of health research.

4. Dr. Robyn S. Shapiro, Professor of Bioethics, Medical College of Wisconsin:

   You have opposed criminalization of cloning and endorsed a voluntary moratorium on it.

   Does the rapid pace at which technology changes render it difficult for legislators to criminalize cloning. Why?

   What is your response to the debate over the success and progress of embryonic stem cell research versus adult stem cell research?

   To what extent do you support regulation of cloning? Would you be more likely to support regulation through Congress or the Food and Drug Administration?

5. Question to all witnesses:

   How would criminalizing both reproductive and research cloning affect treatment and prevention of infertility and research into new contraceptive technologies?

ANSWERS TO THE HONORABLE SHEILA JACKSON LEE FROM DR. DANIEL CALLAHAN

Question 1: You have stated "too much of the current research drive is fueled by a single minded passion to eradicate disease." Eradication of disease and consequent improvement of the human condition are the primary purposes of health research. Please explain your comments.

First, the passion to combat disease is often pressed at the expense of other values, as if the conquest of disease is the highest of human obligations. It is not, but simply one of many obligations. Too much of the talk, say, of therapeutic cloning or embryonic stem cell research treats the conquest of disease as trumping all moral values. There seems to be almost a systematic effort to disabuse people of their ethical scruples in the name of medical research.That is wrong. Those scruples are just as important as research, and ought not to be put aside in the name of research.

Question 2: How would criminalizing both reproductive and research cloning affect treatment and prevention of infertility and research into new contraceptive technologies.

Second, well before the idea of therapeutic cloning was even thought of, there were many research possibilities for the relief of infertility being pursued—and there are many still. It is a mistake to assume that, without therapuetic cloning, no further medical progress is necessary. That is wrong. The NIH and the private sector have all kinds of non-cloning research underway. Therapuetic cloning is one possible route to the development of new contraceptives and the relief of infertility—but is only one route; there are many others.

ANSWERS TO THE HONORABLE SHEILA JACKSON LEE FROM LEON R. KASS, M.D.

Question 1: Isn't it likely that even if human cloning is banned, there are some who will engage in it anyway, unregulated? Doesn't the prohibition of embryonic cloning have the secondary effect of defining an embryo as a life, and thereby outlawing abortion?

A ban on cloning will not guarantee *that it will never be done, any more than a ban on murder or incest prevents all cases of these crimes. But the ban will surely curtail all attempts by all reputable scientists and physicians, and will strongly deter even the rogues from doing it, or at least standing up to claim the credit and notoriety that they are seeking. It will also deter prospective clients from seeking to clone. We must remember that the law also functions as a teacher in these matters, setting forth the community's deep values—just as it does in outlawing slavery, hate crimes, and child abuse. It is also not true that if we ban cloning the practice will go offshore. Many other nations have already banned cloning and regard us as an outlaw nation in this respect. American leadership now will help galvanize the international community in developing a powerful deterrent to human cloning everywhere.*

To the second part of the question, the answer is NO. The ban on creating the embryonic clones does not ban the use of existing embryos for research, nor does it even ban the creation of such embryos by means other than somatic cell nuclear transfer. The ban simply tries to stop the cloning activity at its start—at the most difficult step and the one where we have the best chance of controlling this matter. The fact that the NARAL is not opposed to this ban and that vigorous pro-choice advocates have testified for the strict ban indicates that this is a far-fetched concern.

Question 2: How would criminalizing both reproductive and research cloning affect treatment and prevention of infertility and research into new contraceptive technologies.

Such treatment and research will be unaffected. The proposed ban is very carefully drafted so as not to affect IVF or any other (non-cloning) means of helping a woman become pregnant. Research seeking new contraceptive techniques does not require CLONED embryos, and the law is silent on research using embryos derived by IVF. It simply bans the production of clones.

ANSWERS TO THE HONORABLE SHEILA JACKSON LEE FROM ROBYN S. SHAPIRO

Question 1: Does the rapid pace at which technology changes render it difficult for legislators to criminalize cloning? Why?

It is likely that any statute that might be enacted to criminalize human cloning would be quickly outpaced by technological advances. As an example, California's statute prohibiting cloning adopts a definition of cloning that uses the term "human"

enucleated egg.[1] *This statutory cloning prohibition could be evaded by use of a* cow's *enucleated egg to incubate the nucleic DNA of a human—a procedure that appears entirely feasible in light of University of Wisconsin researchers' success in using enucleated cow eggs as incubators for other mammalian species' nucleic DNA.*

Question 2: What is your response to the debate over the success and progress of embryonic stem cell research versus adult stem cell research?

While studies have reported the successful use of adult stem cells, there are three important reasons to also advance embryonic stem cell research.

First, it is not clear that adult stem cells can give rise to the variety of tissue types that embryonic stem cells can.

Second, on account of greater difficulties in harvesting and culturing sufficient numbers of adult stem cells that are appropriate for transplantation, the utility of embryonic stem cell therapy is likely to be much greater than that of adult stem cell therapy. Any attempt to use stem cells for treatment of an adult's own body would require harvesting the stem cells from the patient (which is technically difficult and can be painful and risky) and then growing them in culture in sufficient numbers to obtain adequate quantities for treatment. For some rapidly progressing disorders, there likely would not be sufficient time to grow enough cells to use for treatment. In addition, with respect to disorders caused by a genetic defect, the genetic error likely would be present in the patient's stem cells, making them inappropriate for transplantation. Also, adult stem cells may contain more DNA abnormalities caused by exposure to daily living (e.g. sunlight, toxins, etc.) than are found in embryonic stem cells.

Finally, even if adult stem cell research is seen in the most positive light, true scientific progress demands that we proceed with both. Unless all stem cell types are studied, the differences between adult stem cells and embryonic stem cells simply will not be known. As the NIH has said: "[G]iven the enormous potential of stem cells to the development of new therapies for the most devastating diseases, it is important to simultaneously pursue all lines of promising research. It is possible that no single source of stem cells is best or even suitable or usable for all therapies. . . In order to determine the very best source of many of the specialized cells and tissues of the body for new treatments and even cures, it is vitally important to study the potential of adult stem cells for comparison to that of stem cells derived from embryos and fetuses. Unless all stem cell types are studied, the differences between adult stem cells and embryo and fetal-derived stem cells will not be known."

Question 3: To what extent do you support regulation of cloning? Would you be more likely to support regulation through Congress or the Food and Drug Administration?

Physical safety concerns as well as potential psychological and social harms from reproductive cloning indicate the need for regulation. Regulation through the Food and Drug Administration is preferable because regulation through Congress would open important aspects of scientific development to a political tug-of-war—as has been the case with debates about fetal tissue and embryo research. The risk is the creation of laws that cover too much for reasons that have nothing to do with human cloning, and that make it impossible to attain the promises of the technology.

Question 4: How would criminalizing both reproductive and research cloning affect treatment and prevention of infertility and research into new contraceptive technologies?

Scientists believe that the creation of research embryos may be the only way to conduct certain kinds of research, such as research into the process of human fertilization. Moreover, aside from this specific research use of cloned embryos, as a more general matter, a ban on research cloning could greatly inhibit embryonic stem cell research. While today there are an estimated 100,000 embryos in frozen storage (some of which will be used for privately-funded stem cell research), as in vitro fertilization techniques improve (e.g., as we acquire the ability to freeze oocyctes), it is possible that the supply of embryos for stem cell research from this source will dwindle.

ANSWERS TO THE HONORABLE SHEILA JACKSON LEE FROM DR. DAVID PRENTICE

Question 1: Nobel laureate and Caltech President David Baltimore, along with Stanford University research Irving Weissman have stated that a moratorium on the use in research and transplantation of fetal or embryonic stem cells would be "devastating" as it is likely that only fetal or embryonic stem cells have the capacity to generate a number of specific tissues. The National Bioethics Advisory Commis-

[1] Cal. Bus. & Prof—Code § 2260.5

sion has also described the use of adult stem cells as scientifically and technically limited. How do you respond to these statements?

Despite the exaggerated claims, it is much more likely that adult stem cells (including cord blood and placental stem cells) will be the ones to provide all therapeutic treatments for patients. In debates, several proponents of embryonic stem cell research have admitted that this will be the case, and that the desire for human embryonic stem cells will be for basic research purposes only. And in fact, very few specific tissues have actually been derived from embryonic stem cells, and even those are not pure cultures but contain only a few percent of the desired cell type mixed with many other types, as well as growing cells which are known to contribute to tumor formation when injected into animals.

Indeed, the actual statement from the National Bioethics Advisory Commission in September of 1999 was that "In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research. . . . The claim that there are alternatives to using stem cells derived from embryos is not, at the present time, supported scientifically. We recognize, however, that this is a matter that must be revisited continually as the demonstration of science advances." Since that time, the vast majority of advances have been made with adult stem cells, and all clinical treatments have used adult stem cells. Even proponents of embryonic stem cell research such as Dr. Douglas Melton of Harvard now admit, for example, that "bone marrow stem cells probably can form any cell type."

Question 2: Have adult stem cells been used successfully in treatment for sickle cell anemia? If not, have embryonic stem cells?

Yes, adult stem cells have been used successfully for treatment of sickle cell anemia (see sample references below). Embryonic stem cells have not yet been used to treat ANY patients for ANY disease.

Steen, RG et al.; "Improved cerebrovascular patency following therapy in patients with sickle cell disease: initial results in 4 patients who received HLA-identical hematopoietic stem cell allografts"; Annals of Neurology 49(2), 222–229; Feb. 2001.

Gore, L et al., "Successful cord blood transplantation for sickle cell anemia from a sibling who is human leukocyte antigen-identical: implications for comprehensive care", Journal of Pediatric Hematology and Oncololgy 22(5), 437–440; Sep-Oct, 2000

Question 3: How would criminalizing both reproductive and research cloning affect treatment and prevention of infertility and research into new contraceptive technologies?

Criminalizing human cloning of any type would have no effect whatsoever on research or treatment of infertility or contraception. Cloning is totally unnecessary to further such research.

Monday, January 22, 2001

1-22-01 SA X-Press

Human cloning a major threat

George Will

There are some things humanity cannot get used to without jeopardizing its humanness — without becoming beastly. Creeping toward us, as on little cat feet — little monkey feet, actually — is perhaps the gravest imaginable crisis, one that could result in the end of history as a distinctively human, and humane, story.

Recently a rhesus monkey named ANDi ("inserted DNA," backwards) became the first genetically altered primate ever created. Created, not begotten; the result of manufacture, not procreation. There is a world of difference. Humans are primates. We are next. Or at any rate, we are in line for genetic "enhancement."

Not until ANDi reaches sexual maturity will scientists know if the jellyfish gene inserted into his genetic makeup — a gene which seems to be in all his tissues — is in his reproductive cells and will be passed along, making possible a man-made line of primates. But such an outcome is just a matter of time. So, probably, is the maximum genetic transfer — human cloning.

Let us stipulate that genetic manipulations can yield therapeutic blessings. Genetically altered animals can illuminate causes and possible cures or ameliorations of diseases. Genetic manipulations in humans can be therapeutic for diseases, even injuries (e.g., to spinal cords), and will make possible research clarifying the roles of nature and nurture in shaping humans.

Enhancement is not therapy, it is eugenics. Genetic selection — the negative eugenics of preventing certain traits in children — is already common, through genetic screening and amniocentesis. However, at least negative eugenics is supposed to serve an existing norm of health. But positive eugenics, any tailoring of an individual's genetic endowment, even when less ambitious than cloning, will put us on a slippery slope to the abolition of man. Leon Kass, a biologist and ethicist with the University of Chicago, explains why in his essay "The Wisdom of Repugnance."

Genetic manipulation extends the belief that all children should be wanted — a principle justifying abortion — to embrace the belief that children, to be acceptable, should, in their genetic traits, satisfy our wants for their identities. Eugenics exemplifies the modern project — to control the future, including the imposition of our design on our children, while our autonomy remains uncontrolled. A casualty of this project is, Kass says, the awe and respect for life arising from "the unique, never-to-be-repeated character of each human life."

When parents stop saying (in Kass' words) "yes to the emergence of new life in its novelty," when they stop saying yes to whatever the child turns out to be, then the meaning of having a child, and the parent-child relation, will be profoundly altered, with consequences that are unforeseeable but cannot be benign. When parents can preselect their child's genetic constitution, procreation will become manufacture, children will become artifacts, identity and individuality will become confused, and parents will become despots.

It is, Kass says, "moral myopia" to think that all values must yield to the goals of better health and desirable traits. A cost of such yielding can be the reduction of man to the status of just another man-made thing.

But such warnings may be overwhelmed by what Kass calls "the technological imperative" — whatever science can do, will be done. That imperative seems irresistible because today's moral vocabulary is so impoverished that society can hardly even formulate good intentions. Part of that vocabulary is dedicated utilitarianism that weighs only tangible harms and benefits: If something reduces an individual's suffering or improves an individual's well-being, it should be done. ANDi is an intimation that nuclear explosions are not the only way science can end the human story. Biology might do that more gradually than physics can, but no less decisively, and even more repugnantly.

George Will's column is syndicated by the Washington Post Writers Group.

AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE
Formerly The American Fertility Society

June 18, 2001

The Honorable Bobby Scott
Subcommittee on Crime
Committee on the Judiciary
U.S. House of Representatives
Washington DC 20515

Dear Representative Scott:

Thank you for the opportunity to present our views on Human Cloning. The American Society for Reproductive Medicine, (ASRM) a professional society of more than 9,000 physicians, scientists and health care professionals has been on record as opposed to human reproductive cloning since the announcement of the cloning of sheep in 1997.

At this time the scientific perils are too great, and our knowledge too slim for anyone to seriously consider cloning a human being. Therefore we support passage of HR 2172, The Cloning Prohibition Act of 2001 as introduced by Representative Greenwood.

HR 2172 takes the necessary steps to prohibit attempts at human reproductive cloning, while protecting related areas of science and medicine.

HR 2172 would make illegal any attempt to initiate a pregnancy using a cloned human embryo. This focus is careful, precise and correct. It would prohibit the act that most scientists, and indeed most citizens, feel should be prohibited - the creating of a human child using somatic cell nuclear transfer techniques without harming other important areas of medical research. The potential for benefit using somatic cell cloning techniques is immense. Therapeutic cloning from somatic cells may hold the key for repairing or creating new tissues or organs that could alleviate a myriad of medical conditions: diabetes, heart disease, spinal cord injury, Parkinson's, to name just a few. At this time the ability to create "customized tissues" using a patient's own DNA to avoid rejection problems appears promising.

Unfortunately, there are no guarantees in medicine, particularly in medical research. We cannot at present guarantee you that the creation of replacement tissues using embryonic stem cells, either from sexually (such as in vitro fertilization or IVF) or asexually (such as cloning) produced embryos will result in cures. It is scientifically uncertain whether adult stem cells will be an adequate substitute for embryonic stem cells. Based on our present knowledge, we feel that adult stem cells will not prove to be an alternative for embryonic tissues. Until we can know more, it would be unethical for us NOT to pursue research using embryonic stem cells, even if these cells are created using cloning techniques.

HR 2172 makes is explicitly clear that other related research and medical treatments will not be banned or restricted. For those of us who care for infertility patients, this provision is very important. Infertility is just

OFFICE OF GOVERNMENT AND MEDIA RELATIONS • 409 12TH STREET SW, SUITE 203 • WASHINGTON, DC 20024
TEL 202/863-4985 • FAX 202/484-4039 • URL www.asrm.org

one area of medicine where we are developing cutting edge techniques such as cytoplasmic transfer and germ cell nuclear transfer to help our patients. We would hate to see research into these procedures cut short by legislation that mistakenly treats them as the equivalent of reproductive cloning.

Unfortunately, HR 1644 takes its prohibitions too far. Rather than simply prohibiting the creation of a human child using cloning techniques, it prohibits any use of the technology at all. Thus, before we could even explore the potential good of some of these techniques, they would be outlawed.

An overly broad prohibition, such as proposed in HR 1644 would put the United States at a competitive disadvantage. Many other countries have made decisions to allow therapeutic cloning while prohibiting reproductive cloning. If the U.S. does not allow therapeutic cloning, our burgeoning biotech industry will suffer, as American competitors are able to develop these techniques first. More importantly, American patients will not be able to avail themselves of the benefits of therapeutic cloning.

The legal enforcement of a cloning prohibition will present challenges, regardless of whether the ban is complete (as in HR 1644) or more focused as in HR 2172). We do not accept the argument that prohibiting all human cloning technology eliminates these challenges.

Every day in infertility clinics across the country, eggs are being fertilized and embryos created in order to help our patients have children. Someone interested in cloning could someday adapt some of the laboratory techniques we use. We are very concerned that the provisions in HR 1644 would have a chilling effect on research into new infertility therapies since it may prove difficult to discern if an embryo has been created via sexual or asexual methods.

The ASRM opposes any attempt at human reproductive cloning. We support innovations in medical treatments that will save lives, alleviate suffering and build families. Accordingly, we urge you and your colleagues to support HR 2172, which prohibits reproductive cloning but protects research, and reject HR 1644 which offers no advantage over HR 2172 in terms of stopping cloning, but does, by prohibiting cloning related research, consign millions of Americans to further suffering.

Thank you for allowing us to convey our views. Please feel free to call on us if we can provide additional assistance or information on these very complicated and important issues.

Sincerely,

Michael R. Soules, MD
President

FASEB

Federation of American Societies for Experimental Biology

—— Quality Life Through Research ——

Member Societies

The American Physiological Society

American Society for Biochemistry and Molecular Biology

American Society for Pharmacology and Experimental Therapeutics

American Society for Investigative Pathology

American Society for Nutritional Sciences

The American Association of Immunologists

Biophysical Society

American Association of Anatomists

The Protein Society

The American Society for Bone and Mineral Research

American Society for Clinical Investigation

The Endocrine Society

The American Society of Human Genetics

Society for Developmental Biology

Associate Members

American Peptide Society

Association of Biomolecular Resource Facilities

Society for the Study of Reproduction

Teratology Society

Radiation Research Society

Society for Gynecologic Investigation

Environmental Mutagen Society

President and Board Chairman

Mary J.C. Hendrix, Ph.D.
Kate Daum Professor and Head
Department of Anatomy and Cell Biology
Deputy Director, Cancer Center
University of Iowa College of Medicine
51 Newton Road, 1-100 BSB
Iowa City, IA 52242-1109
Tel.: 319-335-7755
Fax: 319-335-7770
e-mail: mary-hendrix@uiowa.edu

Office of Public Affairs
9650 Rockville Pike
Bethesda, Maryland 20814-3998
Telephone 301-571-0657
FAX 301-571-0686
WWW: http www.faseb.org opa

June 18, 2001

The Honorable Robert C. Scott
Ranking Member House Judiciary Committee and Investigations
Subcommittee on Crime
B-336 Rayburn House Office Building
Washington, D.C. 20515

Dear Representative Scott:

As you prepare for your June 19 hearings, we wanted to alert you that the Federation of American Societies for Experimental Biology (FASEB) has already established a moratorium on cloning human beings in the U.S.

FASEB is comprised of 21 societies with more than 60,000 members, making it the largest coalition of biomedical research associations in the United States. The mission of FASEB is to enhance the ability of biomedical and life scientists to improve, through their research, the health, well-being and productivity of all people.

FASEB adopted a voluntary moratorium on human cloning in September of 1997. The moratorium defined human cloning as "the duplication of an existing or previously existing human being by transferring the nucleus of a differentiated, somatic cell into an enucleated human oocyte, and implanting the resulting product for intrauterine gestation and subsequent birth." The moratorium was subsequently adopted by other major organizations (ASRM, AAMC, AMA) whose members comprise the vast majority of physicians and scientists who would be able to accomplish such an act.

If you or the Subcommittee have any questions about the science or FASEB's moratorium on cloning human beings, we hope you will contact us.

Yours on behalf of the FASEB Member Societies,

Mary J.C. Hendrix

Mary J.C. Hendrix, Ph.D.
President

UNITED STATES CATHOLIC CONFERENCE
NEWS
Department of Communications
3211 4th Street, N.E. Washington, DC 20017-1194

DATE: June 7, 2001

FROM: William Ryan

O -202-541-3200
H -202-686-1824

FOR IMMEDIATE RELEASE

AMERICANS OVERWHELMINGLY OPPOSE HUMAN CLONING

WASHINGTON - A new poll commissioned by the National Conference of Catholic Bishops confirms that Americans overwhelmingly oppose human cloning -- whether it is used to provide born children for infertile couples or to produce human embryos for medical research.

The questions on cloning were included in a multi-issue survey conducted by International Communications Research (ICR), a national polling firm headquartered in Media, Pennsylvania. A weighted sample of over a thousand American adults was surveyed by telephone between June 1 and June 5 to obtain the results.

"Previous polls showed overwhelming opposition to human cloning," said Richard Doerflinger, Associate Director for Policy Development at the NCCB Secretariat for Pro-Life Activities. "But they did not test for public sentiment on what some call 'therapeutic cloning' -- that is, making human embryos to be destroyed for medical research. This new poll shows that Americans are as opposed to that practice as they are to 'reproductive cloning,' trying to create liveborn children for infertile couples."

These results became available as the House Judiciary Subcommittee on Crime is about to hold hearings on legislation to ban human cloning. The Catholic bishops' conference endorsed the Brownback/Weldon "Human Cloning Prohibition Act of 2001" (S. 790, H.R. 1644). This legislation would ban use of somatic cell nuclear transfer -- the technique used to

more.....

create "Dolly" the sheep -- to create a living organism of the human species, whether for reproductive or experimental purposes. It would not affect use of cloning techniques to produce DNA, cells other than human embryos, tissues, organs, or plants and animals.

"This survey indicates that the American people strongly support the goals of the Brownback/Weldon bill," said Mr. Doerflinger. "We hope Congress will act swiftly to approve this legislation and prevent irresponsible attempts at human cloning."

The survey results were as follows:

Should scientists be allowed to use human cloning to try to create children for infertile couples?

Yes	12.4%
No	84.6%
Don't Know	2.6%
Refused	0.4%

Should scientists be allowed to use human cloning to create a supply of human embryos to be destroyed in medical research?

Yes	9.8%
No	86.0%
Don't Know	3.8%
Refused	0.5%

The survey of 1013 adult Americans has a margin of error of plus or minus 3%.

#####

01-098
CNS, RNS, CRUX, SEC

DON'T THROW THE BATH WATER OUT WITH THE BABY

by Patricia Backlar, R. Alta Charo, James F. Childress, David R. Cox, Carol W. Greider, Steven H. Holtzman, Bette O. Kramer, and Lawrence H. Miike

---

The authors are members of the National Bioethics Advisory Commission, but the views here are their own. The views of other individual members vary, and the Commission has neither endorsed nor opposed the cloning bills now in Congress.

Most Americans agree that it is unsafe and unwise at this time for anyone to try to create a child by reproductive cloning. It would be dangerous to mother and prospective child, and its larger societal implications are still under debate. By contrast, there is wide support for new medical treatments that may come from stem cell research.

Two congressional committees are now considering legislation, H.R. 1644, that would not only ban reproductive cloning, but would also put a halt to potentially life-saving stem cell research that uses cloning technology in a way wholly unrelated to making babies. Even worse, the legislation would make it nearly impossible to take advantage of research already going on in places such as England, by blocking importation of cell-based therapies that might result from such work. H.R. 1644 goes beyond just denying federal funding to research cloning; it proposes to outlaw this research entirely. This is a threat and an insult to the millions of Americans who already or soon will suffer from illnesses ranging from Alzheimer's to heart disease to diabetes.

The rationale for this legislation is that stem cell research using cloned blastocysts will inevitably lead to creating cloned children. But courts have already decided in cases concerning frozen embryos that no one has a constitutional right to insist that every embryo be used to initiate pregnancy. Preventing the creation of children through cloning, therefore, should be as simple as prohibiting anyone from transferring a cloned blastocyst into a woman's body. This would make reproductive cloning impossible.

Non-reproductive uses of cloning, for example, to derive human stem cells, should not be prohibited. Revolutionary new therapies such as regenerating damaged heart or brain or skin tissue will depend upon exploring every aspect of stem cell research. Other research on stem cells derived from discarded embryos and aborted fetuses is essential, and has garnered support even from staunch abortion opponents such as Sen. Orrin Hatch and Sen. Strom Thurmond. But H.R. 1644 would shut down the avenue of stem cell research that many believe is most likely to result in these new regenerative medicines.

In 1997, the National Bioethics Advisory Commission recommended a moratorium on reproductive cloning, at least until it had been shown to be safe, and in 1999 it called for federal support for research using adult stem cells and embryonic stem cells derived from excess embryos and fetal cadavers. It made no recommendations concerning private sector efforts to use cloning for non-reproductive research purposes. Some people have suggested that H.R. 1644, which would ban non-reproductive cloning, is consistent with the Commission's recommendations. We wish to make it clear that our support of the Commission's recommendations was based on our belief that properly regulated non-reproductive research uses of cloning should be explored and, if shown to be medically promising, given federal support.

Enlightened public discourse around these highly charged, emotional issues requires clarity about the true issue at

stake. If the real debate is about creating children through reproductive cloning, then that should be the sole focus of the legislation. If it is about embryo research, then attention should be paid to the far more prevalent practice of producing embryos through in vitro fertilization. And if it is about fetal life, then it should be about abortion practices. Children with juvenile diabetes, veterans with spinal cord injuries, and grandparents with Parkinson's and Alzheimer's disease should not become collateral damage in our culture wars.

Patricia Backlar is Research Associate Professor of Bioethics, Portland State University
R. Alta Charo is Professor of Law and Bioethics, University of Wisconsin
James F. Childress is the Kyle Professor of Religious Studies, University of Virginia
David R. Cox is the Scientific Director of Perlegen Sciences, Inc.
Carol W. Greider is Professor of Molecular Biology and Genetics, Johns Hopkins University
Steven H. Holtzman is the Chief Business Officer of Millennium Pharmaceuticals, Inc.
Bette O. Kramer is the Founding President of the Richmond Bioethics Consortium
Lawrence H. Miike is the former Director of the Hawaii State Department of Health

Contact Information:

R. Alta Charo
racharo@facstaff.wisc.edu
(through June 26)
608-233-1193

Steven Holtzman
holtzman@mpi.com
617- 679-7219

---

r. alta charo, j.d.
professor of law & medical ethics

racharo@facstaff.wisc.edu
http://www.law.wisc.edu/faculty/charoalt.htm

608-262-5015 (tel)
608-262-5485 (fax)

university of wisconsin law school
7111 law building
975 bascom mall
madison, wisconsin 53706 usa

"Injustice anywhere is a threat to justice everywhere. We are caught in an inescapable network of mutuality, tied in a single garment of destiny. Whatever affects one directly, affects all indirectly." Martin Luther King, 1963.

[NOTE: Additional material submitted for the Hearing Record is not reprinted here but is on file with the House Judiciary Committee. The material referred to is listed below.]

Cloning Human Beings, Volume I, Report and Recommendations of the National Bioethics Advisory Commission, Rockville, MD, June 1997

Ethical Issues in Human Stem Cell Research, Volume I, Report and Recommendations of the National Bioethics Advisory Commission, Rockville, MD, September, 1999

○