I think the people of the United States of America deserve a judge who will say that an individual who shoots someone, perhaps for smiling or laughing, is an individual who deserves a serious sentence.

Here is yet another example of lenient sentencing, Commonwealth vs. Burgos. During a raid on the defendant's house, police seized more than 2 pounds of cocaine, along with evidence that the house was a distribution center—2 pounds of cocaine. The street value of 2 pounds of cocaine is astronomical.

The defendant, Mouin Burgos, was convicted. Judge Massiah-Jackson sentenced the defendant only to 1 year's probation. Then-District Attorney Ron Castille criticized Judge Massiah-Jackson's sentence as ''defying logic'' and being ''totally bizarre.'' He commented:

> This judge just sits in her ivory tower . . .. She ought to walk along the streets some night and get a dose of what is really going on out there. She should have sentenced these people to what they deserve.

Well, earlier this afternoon I had the privilege of relating the fact that virtually the entire law enforcement community of Pennsylvania has noticed this predisposition to be antagonistic to law enforcement.

The Executive Committee of the Pennsylvania District Attorneys' Association voted unanimously to voice their objection to the appointment of this individual to the Federal bench. The Fraternal Order of Police, both locally and nationally, has expressed its opposition to this nominee. And frankly, the Democrat district attorney in Philadelphia sent a letter saying this is the worst judge that she had ever seen. The letter also states her opinion that whoever is appointed to the Federal district court for that district should be a black woman—that they need to have a black woman on the bench there—but also stating that Judge Massiah-Jackson cannot be the one.

It takes real courage for a district attorney to say that about a judge who will stay in her current role if the Senate heeds the warning of the district attorney. And the district attorney will have to continue to send prosecutors into that court and be involved in that legal environment. But not only did District Attorney Abraham from Philadelphia, who is a Democrat, make such a contention, District Attorney Morganelli also made the same kind of statements, saying that we really have no business confirming an individual whose record is so replete with this kind of abuse.

These points are points that I believe are easily understood. It takes a substantial amount of effort to obscure these points. But these points are understood—and they are painfully understood by those who are closest to this situation and involved in the courts on a daily basis: the police officers and prosecutors. Obviously, we would not expect defense attorneys to be here objecting to this nominee.

This nominee lacks the fundamental commitment to the judicial system, to respect it, and to respect the participants of it. She has demonstrated that on many occasions. And profanity in the courtroom is important. It reflects a disregard for the court. But when it is profanity directed to officers of the court, it is a disregard for the system itself. And I do not think it is appropriate to minimize that. It makes a difference to me. I think it makes a difference to the American people whether or not we have judges who respect the institution over which they preside.

I raise the issues about the antagonism to the police. It is pretty clear that when you warn the community to be careful of the police, to ''watch out,'' that you reveal a disrespect for this system that we do not need to institutionalize on the Federal bench. And when you use virtually every contrivance that you could possibly imagine, and even then when the appellate court says there is no basis in law, no basis in rule that would support the kind of leniency that you find in some of these cases, I think it is pretty clear that we have an individual whose predisposition is so favorable to the violators of the law that those who would enforce the law and the need for the culture to enforce the law are at a serious disadvantage in a courtroom like that.

It is clear to me—very clear to me—that this is a nominee whose resume does not merit reward, whose recommendation by the President should be withdrawn rather than confirmed.

During the closing hours of the session last year, prior to the break for the year-end recess, the Judiciary Committee was meeting. There was a debate over whether to send this nominee to the floor. And among those who are now saying that we have to have more meetings and more time in the committee were those who carried me to one of the anterooms off the committee room, and begged me, ''Let's send this to the floor so it can be debated on the floor.'' I said, ''I don't think this is appropriate to send to the floor.'' And they said, ''You don't have to support her on the floor, but do not stop the committee from acting to send her to the floor at this time.''

Frankly, the rules of the committee would have made it possible for me at that time to have stopped this individual from coming to the floor. It just strikes me as ironic that those who prevailed on me to send this nominee to the floor, and to allow her to come to the floor, are now arguing that somehow those of us who want to vote on this candidate on the floor or a withdrawal by the President are doing an injustice—that somehow by accommodating them and providing a basis which would allow the candidate to make it to the floor, that we were now wanting to act on that candidate and somehow wanting to act inappropriately.

I think all of that is just so much process—whether you had the committee hearings, and how many you had. The key to this whole situation is, what kind of information do you have? And do you have the capacity to make a good judgment about whether or not to confirm a nominee of the President of the United States?

This nominee who disrespects the system, disrespects the participants, disrespects law enforcement, this nominee who has done virtually everything within her power to make it easy on those who have violated the law and tough on those who would enforce the law, does not merit our confirmation. The President ought to withdraw her nomination, and, absent that, the Senate should vote to reject this nomination for the Federal bench.

I yield the floor.

The PRESIDING OFFICER. The Senator from California.

Mrs. FEINSTEIN. Mr. President, I ask unanimous consent to depart from the regular order and enter a period of morning business.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mrs. FEINSTEIN. Mr. President, I ask to be recognized to speak in morning business.

The PRESIDING OFFICER. Without objection, it is so ordered.

HUMAN CLONING PROHIBITION ACT

Mrs. FEINSTEIN. Mr. President, I will follow on the comments of the distinguished Senator from Massachusetts, since the Senate is scheduled tomorrow to vote on a cloture motion, whether to move Senate bill 1601, a bill that prohibits the cloning of human beings. I will clarify where we are and what the issues really are.

Let me be clear at the outset: I support a ban on the cloning of human beings. There is widespread agreement that the cloning of a human being should be prohibited. That agreement, I believe, exists in the Congress. It clearly exists in the scientific community. It exists in the medical community, in the religious community, and it exists in virtually every patient and health group that I know of.

I submit, Mr. President, that the cloning of human beings is scientifically unsafe; it is dangerous; it is morally unacceptable; and it is ethically flawed. We should enact a ban. We should pass a law that establishes the illegality of human cloning and sets forth appropriate penalties.

The argument I make today is not the ban, but how the bill before the Senate tomorrow, the Bond-Frist bill, would affect scientific research. I introduced identical bills with Senator KENNEDY, Senate bills 1602 and 1611 which would protect research that someday, we believe, is likely to provide cures for many of the most dreaded diseases.

Some examples are treatments for damaged nerve cells, for spinal cord injuries, blood cell therapies for leukemia and sickle cell anemia, liver cell transplants for liver damage, cartilage cells for reconstruction of joints damaged by arthritis or injuries, the creation of stem cells to treat burn victims, and the creation of cells to treat some 5,000 different genetic diseases.

The bill that the leadership is trying to rush through the Senate, Senate bills 1599 and 1601, would make it a crime with up to 10 years in prison to conduct that kind of research—research that someday will save lives and suffering.

Those bills, because they don't have clear scientific terms, they don't have definitions of critical words which are part of somatic cell nuclear transfer technology, would submit scientists to prison terms for treatments using this technique. These penalties would have a serious, chilling effect on promising scientific research.

Somatic cell nuclear transfer—and I am a newcomer to this so I have had a crash course, and I still have an awful lot to learn—this transfer process is its own science. It has a lexicon all of its own. Scientists tell us that the traditional definitions of reproductive health—the traditional definitions of reproductive health—do not fit somatic cell nuclear transfer. There is the rub.

S. 1601 uses these terms but doesn't define them. The bill doesn't define somatic cell, for example. Now, what I know a somatic cell to be is a cell in your body. You can take a cell from a mammary gland. In Dolly's case, the cell was taken from the udder.

Additionally, the bill does not define embryo or preimplantation embryo. It does not define oocyte. Without clear, scientifically accurate definitions, we don't know what we are talking about and scientists will be reluctant to conduct research that might save lives and alleviate human suffering.

That is the bottom line of asking for a delay, of asking that the Senate's proper procedures be employed so that the scientific community can come forward, provide their definitions, explain them, we can debate them and clearly understand what we are doing.

My father used to tell me that the first tenet of medicine is ''Do no harm.'' We can do great harm by proceeding without a full understanding of what this is all about.

According to the Biotechnology Industry Association, Senate bill 1601 would go beyond the issue of human cloning and would outlaw research to create stem cells. It would make it a crime for doctors to use a currently effective treatment for mitochondrial disease. The Biotechnology Industry Association says, ''In this treatment, women who have this disease have an extreme and tragic form of infertility. The disease is a disease of the mitochondria an essential element of any egg. The treatment for this disease involves the use of a fertilized nucleus which is transferred through the use of somatic cell nuclear transfer to an egg from which the nucleus has been removed. The new egg is a fresh, endocyst egg. The current Bond bill would make it a crime to provide this treatment even though the nucleus which is transferred is the product of fertilization and not cloning.''

So there is no need to rush. The bill we are asked to vote on is one week old—one week. It was introduced February 3, brought to the full Senate 48 hours later, on February 5. Now we are asked to vote on whether to continue consideration and have a vote of the bill. It has not been referred to committee. There have been no hearings. It has not gone through the normal deliberative process.

We should not be ramrodding a bill with this potential for harm through the Senate. It is one of the most profound issues of our time. This is a difficult area of science. It involves terminology and technologies few Americans have ever studied, let alone fully understand, terminology and technologies that few Senators understand. It poses very serious and fundamental moral, ethical and scientific questions.

We need not rush a bill to the floor without committee consideration. That is the other point. The scientific community has imposed a voluntary moratorium. The Food and Drug Administration has said they will assert jurisdiction. Many organizations have written urging caution.

Let me go into some of them right now. Let me begin with the American Cancer Society, in a letter dated February 9, and I ask unanimous consent this letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

AMERICAN CANCER SOCIETY,
February 9, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR FEINSTEIN: The American Cancer Society has called for your commitment for a renewed war on cancer through a national investment in biomedical research and cancer prevention and control programs. The sustained downturn in cancer mortality and incidence—for the first time ever—is evidence that our investment in this war is beginning to make a difference.

The current opportunities in cancer research, including our understanding of the molecular nature of the disease, are bringing us closer to the answers we need to prevent and cure cancer. Congress and the Administration are calling for unprecedented increases in funding for biomedical and cancer research which will allow us to exploit scientific knowledge and bring answers more quickly to the American people.

The American Cancer Society urges you to oppose S. 1601, legislation that would prohibit the use of somatic cell nuclear transfer. The American Cancer Society agrees with the public that human cloning should not proceed at this time. However, the legislation as drafted would have the perhaps unintended effect of restricting critical, legal scientific research. The ability to create therapeutically valuable stem cell lines from oocytes, therefore promoting genetic reprogramming of cells to prevent and cure cancer exemplifies the type of research that could be hindered with overly restrictive regulations. The current language in S. 1601 could hamper or punish scientists who contribute to our growing knowledge about cancer.

We urge you to carefully consider all aspects of this legislation to ensure the continued support for all legal and ethical modalities of cancer research.

Sincerely,
DAVID S. ROSENTHAL, MD,
President.

Mrs. FEINSTEIN. Let me quote one part:

The American Cancer Society urges you to oppose S. 1601, legislation that would prohibit the use of somatic cell nuclear transfer. . . . The legislation as drafted would have the unintended effect of restricting critical legal scientific research. The ability to create therapeutically valuable stem cell lines from oocytes, therefore promoting genetic reprogramming of cells to prevent and cure cancer exemplifies the type of research that could be hindered with overly restrictive regulations. The current language in S. 1601 could hamper or punish scientists who contribute to our growing knowledge about cancer.''

The American Heart Association—I ask unanimous consent their letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

AMERICAN HEART ASSOCIATION, OFFICE OF COMMUNICATIONS AND ADVOCACY,
Washington, DC, February 9, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR FEINSTEIN: On Tuesday, February 10th, the Senate is expected to initiate a cloture vote regarding a motion to consider S. 1601, the *Prohibition on Cloning of Human Beings Act of 1998.* The American Heart Association urges you to vote *against* the cloture petition.

The American Heart Association wishes to make it clear that we do not support any legislation allowing the cloning of a human being. However, we fear that this legislation may place biomedical research at risk and might negatively impact the use of cloning techniques on human cells, genes and tissue critical to identifying cures for a host of diseases, including cardiovascular diseases. The American Heart Association is concerned that a rush to passage of S. 1601 may inadvertently threaten to restrict critical biomedical research, which promises to have great impact on disease prevention and treatment for the American people.

For example, we are concerned that this legislation may effectively ban research using the generation of stem cells for treating heart attack victims, as well as blood vessel endothelial cells for treating atherosclerosis.

The American Heart Association urges the Senate to engage in a more deliberate debate on this important issue. Please vote ''no'' on cloture for S. 1601 and allow a more extensive debate on these complex issues.

Sincerely,
MARTHA N. HILL, RN, PH.D.,
President.

Mrs. FEINSTEIN. ''The American Heart Association urges the Senate to engage in a more deliberate debate on this important issue.''

The Cystic Fibrosis Foundation, I ask unanimous consent their letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

CYSTIC FIBROSIS FOUNDATION,
February 9, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR FEINSTEIN: The current frenzied atmosphere on Capitol Hill surrounding the issue of human cloning instills great fear in the scientific community. On behalf of cystic fibrosis (CF) scientists, researchers, caregivers, and most importantly patients, the Cystic Fibrosis Foundation (CFF) asks all members of Congress to take the time to study the potentially harmful ramifications of prohibitive human cloning legislation. As America's governing body, Congress has an unequivocal responsibility to hold public hearings on this issue in order to fully understand the scope of this debate. The CFF agrees that the cloning of a complete human being should not be done. However, we have grave concerns over current legislation that is crafted in such a way to restrict the advancement of lifesaving biomedical research.

A voluntary moratorium on human cloning should suffice to prevent scientists from attempting to clone a complete human being in the laboratory. Nevertheless, if it is decided that legislation must be drafted, extreme care should be taken not to restrict the capacity to pursue cutting edge technologies which hold great promise. For example, the strategy that may ultimately be needed to achieve a cure for CF through gene therapy techniques is called somatic cell/stem cell gene transfer therapy.

Enactment of the Bond/Frist Cloning Prohibition Act in its current form and other existing pieces of legislation would prevent the use of this kind of technology. This would be a critical set-back in our ability to develop new therapies to treat individuals with CF and other life-threatening diseases. To consider the passage of legislation without appropriate debate from the scientific community, as well as a public airing of the consequences on future biomedical research, will do irreparable damage.

For the 30,000 children and young adults with CF in this country, the message is clear. Do not allow hasty and capricious action to impede our ability to impact on this disease. It is equally important to note that until essential scientific debate has reached completion, the cloning of a complete human being cannot occur, as the regulatory safeguards of the FDA already in place prevent such an act.

Your attention to this critical matter is appreciated.

Sincerely yours,
ROBERT J. BEALL, PH.D.,
President and CEO.

Mrs. FEINSTEIN. They say, ''To consider the passage of legislation without appropriate debate from the scientific community, as well as a public airing of the consequences on future biomedical research, will do irreparable damage.''

The American Association for Cancer Research, I ask unanimous consent that letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

AMERICAN ASSOCIATION
FOR CANCER RESEARCH, INC.,
Philadelphia, PA, February 4, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR FEINSTEIN: Medical research, conducted in the United States over the last 20 years, has opened up tremendous opportunities to make progress against many devastating diseases. The scientific community does not desire to make human beings, or modify or genetically mark any portion of our population. However, to deny the application of molecular biology, made possible through the use of cloning technologies, to patients who could be benefitted would be a great injustice.

A litany of beneficial applications of cloning technology was enumerated in this weeks TIME Magazine. Several of these applications are at the core of cutting-edge cancer research, and there are many more potential benefits that are unknown at this time. These applications, as well as any future progress, would be eliminated by broad legislation setting back progress and potential in our conquest to develop effective approaches to the prevention, detection, and treatment of cancer.

The American Association for Cancer Research (AACR), with over 14,000 members, is the largest professional organization of basic and clinical cancer researchers in the world. Founded in 1907, its mission is to prevent, treat, and cure cancer through research, scientific programs, and education. To accomplish these important goals it is essential that scientists vigorously pursue all promising lines of investigations against cancer.

The AACR feels strongly that an ethical and just compromise can be reached that will protect the public and the scientific community from the irresponsible application of cloning technology while permitting meaningful and ethical research to move forward. The medical and cancer research community feels that the present rush to enact legislation without proper consideration or deliberation is a serious mistake, and the unfortunate result would be irresponsible legislation.

As scientists we clearly see the tremendous advantages of cloning technology as well as its potential problems, which we, also, have reason to fear if it is applied in an unreasonable manner.

The AACR, therefore, appeals to all Members of Congress to establish and honor a moratorium of at least 45 days on enacting any legislation until definitions and implications of legislation can be determined in a more reasonable and thoughtful manner, and in an open and public process. This would be a service to humanity, science, and millions of individuals who are now suffering, or will suffer in the future, from catastrophic and crippling diseases such as cancer. We appeal to all members of Congress to give this important moral and scientific issue very careful consideration and deliberation. Clearly a rush to judgment on this complex issue could be a major setback for cancer and medical research.

Sincerely,
DONALD S. COFFEY, PH.D.,
President.

Mrs. FEINSTEIN. They say, ''The medical and cancer research community feels that the present rush to enact legislation without proper consideration or deliberation is a serious mistake and the unfortunate result would be irresponsible legislation.''

The Juvenile Diabetes Foundation International, the Diabetes Research Foundation, I ask unanimous consent that letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

JUVENILE DIABETES FOUNDATION
INTERNATIONAL,
THE DIABETES RESEARCH FOUNDATION,
February 9, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR FEINSTEIN: On behalf of the Juvenile Diabetes Foundation International (JDFI), we urge you to vote ''no'' on a motion to invoke cloture and proceed to consider S. 1601, a bill to ban human cloning. This vote is scheduled to come before the Senate on Tuesday, February 10.

We want to be clear: there is *no* acceptable moral or ethical justification for making a replica of another human being. As currently drafted, however, S. 1601 threatens to restrict future promising stem cell research which could lead to improved treatments or even a cure for diabetes and many other serious, chronic illnesses.

Diabetes affects approximately 16 million Americans and is a leading chronic disease in children. In addition to its severe human impact, diabetes costs about $137 billion per year in direct and indirect expenses. Therefore, it is critical that any federal policies affecting medical research are crafted so that they do not unnecessarily restrict the potential for promising future advances in diabetes research.

In the case of type 1, or juvenile, diabetes, the beta cells of the pancreas which produce insulin are destroyed. Promising stem cell research could make it possible to produce pancreatic beta cells that could then be transplanted into a person with diabetes. As a consequence, a person with type 1 diabetes would be free of the up to eight daily blood tests and up to six daily insulin injections that so significantly reduce the quality of life. More importantly, this type of cell transplantation could eliminate the horrible complications of the disease which include: kidney failure; blindness; amputation; increased risk of heart disease and stroke; and premature death.

For these reasons, JDFI urges you to vote ''no'' on the cloture motion for S. 1601, thereby allowing the Senate to conduct a more thorough debate on this issue. We need to better understand the impact that legislation in this area could have on research critical to improving the lives of people with devastating illness. In order to ensure medical progress and the attainment of future opportunities, we urge you to proceed cautiously.

Sincerely,
ROBERT LEVINE, MD,
Chairman, Government Relations Committee.
JAMES E. MULVIHILL, DMD,
President and CEO, Juvenile Diabetes Foundation International.

Mrs. FEINSTEIN. They say, ''We urge you to proceed cautiously.''

Resolve, the National Infertility Organization says, ''go slow.''

I ask unanimous consent that letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

RESOLVE,
Somerville, MA, January 30, 1998.

The Hon. Senator DIANNE FEINSTEIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR FEINSTEIN: RESOLVE expresses its strong support for the cloning bill being co-sponsored by you and Senator Edward M. Kennedy. This bill, consistent with RESOLVE's position, includes an important provision specifying that research using somatic cell nuclear transfer technology should not be banned while recommending a moratorium on the cloning of a human being until further review.

RESOLVE is pleased to note that the proposed legislation does not ban embryo research. Embryo research has been instrumental in the development of procedures that allow many couples to overcome the difficulties they experience as they strive to build families. The emotional and physical consequences of this struggle can be overwhelming. In vitro fertilization is an amazing technology which would not have been possible without the knowledge gained through embryo research. This effective treatment has brought about the birth of thousands of much-wanted babies. Continued embryo research has the potential to further the understanding of the causes of infertility, including the tragedy of miscarriage, as well as provide information which can lead to new breakthroughs.

As a national organization which provides support, advocacy and education to those experiencing infertility, RESOLVE is contacted by thousands of people from all walks of life who are struggling with this disease. The stories about their struggles can be heart-wrenching. The success stories about the joy and overwhelming appreciation of the children that are brought into this world are enormously heart-warming.

Avenues for further research to help couples must not be halted. RESOLVE joins with many other organizations across the country in expressing its opposition to any attempts to ban embryo research. We applaud your efforts to develop carefully-constructed legislation which will not impact the potential for medical advances that will help the many couples struggling to build much-wanted families.

Sincerely,

DIANE D. ARONSON,
Executive Director.

Mrs. FEINSTEIN. The National Coalition for Osteoporosis and Related Bone Diseases says, ''Congress needs to be extremely cautious in drafting legislation too quickly on this very complex issue.''

It is signed by several doctors. I ask unanimous consent this letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

THE NATIONAL COALITION FOR OSTEOPOROSIS AND RELATED BONE DISEASES,
Washington, DC, February 5, 1998.

The Hon. DIANNE FEINSTEIN,
U.S. Senate,
Washington, DC

DEAR SENATOR FEINSTEIN: As representatives of the Osteoporosis and Related Bone Diseases National Coalition, which consists of scientists and patients, we are writing to urge you to vote against human cloning legislation which would ban some types of promising stem cell research.

We support a ban on cloning a human being. We see no ethical or medical justification for anyone in the public or private sector, whether in a research or clinical setting, to create a human child using somatic cell nuclear transfer technology. However, we are concerned that legislation which would expedite a ban on cloning would also effectively eliminate research on ''customized'' stem cell research which one day could lead to cures for many diseases.

Congress needs to be extremely cautious in drafting legislation too quickly on this very complex issue. We are concerned that Congress will not take the time to analyze the effects on stem cell research already underway or consider the future benefits of such research. It is our hope that with input from the scientific community Congress will come to a consensus which will address the public's concern about human cloning and yet allow the scientific community to do their work.

Again, we urge you to protect stem cell research which can generate cells for the treatment of numerous diseases including osteoporosis and related bone diseases. If you need further information about the proposed legislation, please contact Bente E. Cooney, Director of Public Policy at the National Osteoporosis Foundation (202) 223–2226.

Sincerely,

BENTE E. COONEY, MSW,
Director of Public Policy, National Osteoporosis Foundation.
FRED SINGER, MD,
Chairman, The Paget Foundation.
STEPHEN CUMMINGS, MD,
Chair, ASBMR Public Affairs Committee, American Society of Bone and Mineral Research.
JOE ANTOLINI,
President of the Board, Osteogenesis Imperfecta Foundation.

Mrs. FEINSTEIN. The Alliance for Aging Research strongly supports our bill, the Feinstein-Kennedy bill. They urge a no vote on cloture. They say this is not a vote for cloning but rather for reasoned debate that draws upon the wisdom of scientists and medical experts:

Senators should also take time to hear from patients and their families who yearn for cures and treatments for life-threatening diseases. A rush to legislate in this area could have serious consequences for research that could benefit the lives of millions of Americans.

I ask unanimous consent to have that letter printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

ALLIANCE FOR AGING RESEARCH,
Washington, DC, February 9, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate
Washington, DC.

DEAR SENATOR FEINSTEIN, The Alliance for Aging Research strongly supports your efforts and those of Senator Kennedy to legislate responsibly in the area of somatic cell nuclear transfer technology. You and Senator Kennedy and others have proposed a ban on human cloning without threatening vital research efforts into cellular technologies that could produce cures and valuable therapies for Alzheimers Disease, Parkinsons, would healing, age-related blindness and many other medical problems of the elderly. The not-for-profit Alliance applauds your efforts on behalf of research, and we urge you to vote ''no'' when a motion to cut off debate on S. 1601 comes to the Senate this week.

The Alliance for Aging Research strongly opposes the cloning of a human being on moral grounds, as does every responsible health advocacy organization we know. However, the Lott-Bond-Frist bill is written so broadly as to halt cellular technology that could be a significant tool in developing therapies for scores of age-related diseases and disabilities.

The Alliance is also concerned there has not been sufficient discussion and debate to allow reasoned consideration of this highly technical and complicated issue. A ''no'' vote on cloture is not a vote for cloning, but rather for a reasoned debate that draws upon the wisdom of scientists and medical experts. Senators should also take time to hear from patients and their families who yearn for cures and treatments for life-threatening diseases. A rush to legislate in this area could have serious consequences for research that could benefit the lives of millions of Americans.

Respectfully,

DANIEL PERRY,
Executive Director.

Mrs. FEINSTEIN. The National Health Council states, ''We urge careful consideration of the issue and a vote against cloture so a more thorough debate can occur.''

I ask unanimous consent that be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

NATIONAL HEALTH COUNCIL,
Washington, DC, February 9, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR FEINSTEIN: Early this week the Senate will decide whether to begin debate on legislation to ban the cloning of a human being. The National Health Council, which represents the Nation's leading patient organizations, agrees with the American public that the cloning of a human being should be prohibited. However, we urge careful consideration of the issue and a vote against cloture, so a more thorough debate can occur within the committees of jurisdiction before consideration by the full Senate.

Current advances in medical research are, for the first time, holding true promise of curing some of the most well-known diseases: cancer, diabetes, and paralysis. In the past, scientific gains have provided patients with novel treatments, allowing us to manage disease more effectively. But cures have eluded us.

Cloning, the duplication of scientific material, such as cells or genes, has allowed scientists to more efficiently study biological processes, and has led to many recent medical advances. The technique which created the sheep Dolly was a new approach to producing duplicate material. This novel process, called somatic cell nuclear transfer, may hold the key not only to understanding the function of all human cells but also to identifying new avenues to repair damaged cells.

By gaining a greater understanding of how cells develop and differentiate we may be able to replace damaged pancreatic cells with healthy cells, therefore curing diabetes. Combined with gene therapy, cloning may also make it possible to eliminate the transmission of such inherited diseases as Huntington's Disease.

We appreciate your concerns regarding the issues relating to cloning, but it is critical

that we have a better understanding of all the implications of the various approaches aimed at banning the cloning of human beings. I am certain that you share our interest that important medical research is protected. In order to ensure medical progress and the attainment of future opportunities, we urge you to proceed cautiously.

Thank you for your consideration of this important issue.

Sincerely,

MYRL WEINBERG, CAE,
President.

Mrs. FEINSTEIN. The National Patient Advocate Foundation says, ''There is no rush to legislate.''

I ask unanimous consent their letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

NATIONAL PATIENT
ADVOCATE FOUNDATION,
Newport News, VA, February 6, 1998.

DEAR SENATOR: The National Patient Advocate Foundation urges you to vote ''no'' on the cloture vote next Tuesday, February 10, regarding the motion to proceed to consider S. 1601, the legislation to ban human cloning. A vote ''no'' is a vote to protect biomedical research. It would also call for more deliberate debate on this complicated scientific issue.

As an organization that continues to seek insurance reimbursement for cancer therapies, therapeutic devices and agents that hold promise of improved quality of life after a cancer diagnosis, life extension and improvement in preventing cancer, bio-medical research presents significant hope for improvement in preventing, detecting and treating cancer. We have been involved with this issue since early last summer when the anti-cloning discussion first emerged when the Ehler's bills was introduced. Our position then and now is the same. Though we are in full support of no cloning of human beings, we value the progress being made in biomedical research and can not support any initiative that threatens continued research in this area. Zygotes, diploid cells and somatic cell nuclear transfer are issues that are complicated and present myriad opportunities for misinterpretation without thorough discussions relative to the impact on bio-medical research that this anti-cloning legislation poses. We urge your no vote on cloture February tenth, so that this matter may be addressed in detail in hearings.

There is no need to rush to legislate. The Food and Drug Administration has full jurisdiction to ensure that no one will clone human beings at this time. We urge careful and deliberate consideration of this legislation to ban cloning. It should be carefully reviewed by key Committees, which has not occurred. S. 1601 raises serious questions about its scope and impact on critical biomedical research seeking cures for deadly and disabling diseases.

This bill is not confined to''cloning'', which is the creation of a child genetically identical to another individual.

It would halt research to develop ''customized'' stem cells which promise potential new treatments for many diseases and conditions.

It would outlaw a current medical procedure to treat infertility which uses eggs which are fertilized and contain the genetic traits of two individuals, not the clone of one individual.

Again, we urge you to vote ''no'' on Tuesday's cloture vote on S. 1601 to protect biomedical research.

Sincerely,

NANCY DAVENPORT-ENNIS,
Founding Executive Director.

Mrs. FEINSTEIN. The California Biomedical Research Association, signed by 40 or 50 major companies, urges us ''to support continuing debate about the potential negative impact of Senator TRENT LOTT's legislation.''

I ask unanimous consent that be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

CALIFORNIA BIOMEDICAL
RESEARCH ASSOCIATION,
Sacramento, CA, February 9, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate, Hart Senate Office Building, Washington, DC.

DEAR SENATOR FEINSTEIN: On behalf of the CBRA Governing Board, I am writing to encourage your ''no'' vote on the cloture vote on S. 1601 scheduled for Tuesday, February 10, 1998. The Association urges you to support continuing debate about the potential negative impacts of Senator Trent Lott's legislation.

Somatic cell transfer technology is essential to continuing research into cures for some of our greatest human health threats—Parkinson's Disease, leukemia, diabetes, Alzheimer's disease and spinal cord injuries. Unintended consequences of this bill as currently written could threaten the future health of millions of Americans.

Please feel free to contact our office if you should need further information.

Sincerely,

SUZANNE NESS,
President.

MEMBERS (PARTIAL LIST)

Allergan
Alliance Pharmaceutical
ALZA Corporation
American Association for Laboratory Animal Science: Northern, Orange County, San Diego, Southern and Palms to Pines Branches
American Cancer Society, California Division, Inc.
American Diabetes Association, California Affiliate
American Heart Association (Western States Affiliate and Greater L.A. Affiliate)
American Lung Association of California
Amgen
Bayer Corporation
Berlex Bio Sciences
BioDevices
Buck Center for Research in Aging
California Institute of Technology
California Medical Association
California State University: Long Beach, Pomona, Office of the Chancellor
California Veterinary Medical Association
Cedars-Sinai Medical Center
Charles River Laboratories
Children's Hospital Oakland Research Institute
Children's Hospital of Orange County
Chiron Corporation
City of Hope
Genentech
J. David Gladstone Institutes
Good Samaritan Hospital
Harbor UCLA Medical Center, Research and Education Institute, Inc.
Heartport
Huntington Medical Research Institutes
Isis Pharmaceuticals
Lawrence Berkeley Laboratory
Loma Linda University
NASA Ames Research Center
Palo Alto Medical Foundation
Roche Biosciences
Salk Institute for Biological Studies
San Diego State University
San Jose State University
Scripps Research Institute
Stanford University
The Parkinson's Institute
University of California: Berkeley, Davis, Irvine, Los Angeles, Riverside, San Diego, San Francisco, Santa Barbara, Santa Cruz, Office of the President
University of Southern California
Veterans Administration Medical Centers at: Loma Linda, Long Beach, Palo Alto, San Diego, San Francisco, Sepulveda, West Los Angeles.

Mrs. FEINSTEIN. The AIDS Action Council, the Allergy and Asthma Network, the Alliance for Aging Research, the Alzheimers Aid Society, the American Academy of Optometry and the American Academy of Pediatrics urges that we ''proceed with extreme caution and adhere to the ethical standards for physicians, 'first do no harm'.''

I ask unanimous consent that the letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

JANUARY 26, 1998.

Re legislation to ban cloning of human beings.

DEAR MEMBER: We are writing to express our concern about legislation pending in the Congress to ban the cloning of entire human beings.

Let us be clear. We oppose the cloning of a human being. We see no ethical or medical justification for the cloning of a human being and agree with the conclusions of the National Bioethics Advisory Commission (NBAC) that it is unacceptable at this time for anyone in the public or private sector, whether in a research or clinical setting, to create a human child using somatic cell nuclear transfer technology. We recognize that this application of the technology raises fundamental ethical and social issues. This technology is not currently safe to use in humans.

The American Society for Reproductive Medicine, the Biotechnology Industry Organization, and the Federation of American Societies of Experimental Biology have all stated that their members will not seek to clone a human being. These three associations include essentially every researcher or practitioner in the United States who has the scientific capability to clone a human being.

We agree with NBAC in its report on cloning that: ''It is notoriously difficult to draft legislation at any particular moment that can serve to both exploit and govern the rapid and unpredictable advances of science.'' Poorly crafted legislation to ban the cloning of human beings may put at risk biomedical research, such as the use of cloning techniques on human cells, genes and tissues, which is vital to finding the cures to the diseases and ailments which our organizations champion. Cancer, diabetes, allergies, asthma, HIV/AIDS, eye diseases, spinal cord injuries, Guillain-Barré syndrome, Gaucher disease, stroke, cystic fibrosis, kidney cancer, Alzheimer's disease, tuberous sclerosis, tourette syndrome, alcoholism, autoimmune diseases, osteoporosis, Parkinson's disease, infertility, diseases of aging, ataxia telangiectasia and many other types of research will benefit from the advances achieved by biomedical researchers.

We urge the Congress to proceed with extreme caution and adhere to the ethical standard for physicians, ''first do no harm.'' We believe that there are two distinct issues here, cloning of a human being and the healing which comes from biomedical research.

Congress must be sure that any legislation which it considers does no harm to biomedical research which can heal those with deadly and debilitating diseases.

Please keep patients' concerns in mind as you proceed in analyzing this very complicated issue.

Sincerely,

AIDS Action Council.
Allergy and Asthma Network/Mothers of Asthmatics, Inc.
Alliance for Aging Research.
Alzheimer Aid Society.
American Academy of Optometry.
American Academy of Pediatrics.

Mrs. FEINSTEIN. The Biotechnology Industry Organization, which represents literally hundreds of biotech organizations, says, ''We are very concerned about the rushed process to pass legislation on this complex subject and the possibilities for unintended consequences.''

I ask unanimous consent to have the letter printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

STATEMENT OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) REGARDING LEGISLATION INTRODUCED TO BAN HUMAN CLONING

The Biotechnology Industry Organization (BIO) believes that it is both unsafe and unethical to even attempt to clone a human being. BIO strongly supported the review of this issue by the National Bioethics Advisory Commission (NBAC) and the moratorium on cloning imposed by President Clinton. We believe that the FDA has clear authority and jurisdiction and will, as they have stated, prohibit any attempt to clone a human being.

BIO is concerned about the scope and impact of legislation introduced to make it a crime with a ten year prison sentence to conduct biomedical research which may or may not have any relevance to the cloning of a human being. We are very concerned about the rushed process to pass legislation on this complex subject and the possibilities for unintended consequences. The scientific and legal issues with respect to any legislation regarding biomedical research are exceedingly technical, and a hastily drafted bill could advertently and inadvertently damage biomedical research on deadly and disabling diseases.

The Senate needs to adhere to the standard for doctors, ''first, do no harm.'' Biomedical research into deadly and disabling diseases is far too important to rush to enact legislation which would unequivocally undermine promising research and therapies. The Senate should be extremely cautious before it starts sending scientists to jail when the purpose of their research meets the highest moral and ethical standards and holds such promise for relieving human suffering.

ANALYSIS OF PENDING BILLS AND THE SCIENCE AT RISK

Several bills have been introduced in the Senate regarding human cloning. They vary widely in focus and precision. The three principal bills are S. 368, S. 1599, and S. 1602 and we have analyzed each of them here.

The first bill introduced by Senator Bond last year, S. 368, is one of the better drafted bills introduced in either body. It uses reasonably accurate terms to describe the applicable science and limits Federal funding for the cloning of a human being.

The new bill introduced by Senator Bond, S. 1599, would impose a ten year prison sentence for any individual for the act of ''producing an embryo (including a preimplantation embryo)'' through the use of a specified technology, ''somatic cell nuclear transfer,'' even if the production of such an embryo is for purposes unrelated to the cloning of a human being and even if the embryo does not contain nuclear DNA which is identical to that of an existing or previously existing human being (cloning). The bill goes beyond the issue of cloning to make it a crime to use somatic cell nuclear transfer of a nucleus derived from normal sexual union of an egg and sperm, which is obviously not cloning. It would also make it a crime to conduct some research seeking to generate stem cells to treat a wide range of deadly and disabling diseases, treatments which have nothing whatever to do with human cloning.[1]

The third bill, introduced by Senator Feinstein, S. 1602, would impose heavy civil fines for any entity that would ''implant or attempt to implant the product of somatic cell nuclear transfer into a woman's uterus . . .'' This sharply focuses the bill on an attempt to clone a human being and would not imperil biomedical research.

IMPACT OF BILLS ON STEM CELL RESEARCH

The current bill introduced by Senator Bond would, because it goes well beyond the issue of human cloning, imperil promising biomedical research, including research to generate stem cells. Instead of focusing on cloning, it makes it a crime to create a zygote or embryo through the use of a new technology, somatic cell nuclear transfer, even if the use of this technology is essential for the generation of stem cells to treat disease and where there is no intention of attempts through use of this technology to clone a human being. Basically the current bill would make it a crime to conduct research if it could possibly be related to the cloning of a human being even if it is not, in fact, conducted for that purpose.

This approach in S. 1599 goes beyond the issue of human cloning and would outlaw some research to create stem cells, including stem cells for the following types of treatments: cardiac muscle cells to treat heart attack victims and degenerative heart disease;; skin cells to treat burn victims; spinal cord neuron cells for treatment of spinal cord trauma and paralysis; neural cells for treating those suffering from neurodegenerative diseases; pancreas cells to treat diabetics; blood cells to treat cancer anemia, and immunodeficiencies; neural cells to treat Parkinson's, Huntington's and Amyotrophic Lateral Sclerosis (ALS); cells for use in genetic therapy to treat 5,000 genetic diseases, including Cystic Fibrosis, Tay-Sachs Disease, schizophrenia, depression, and other diseases; blood vessel endothelial cells for treating atherosclerosis; liver cells for liver diseases including hepatitis and cirrhosis; cartilage cells for treatment of osteoarthritis; bone cells for treatment of osteoporosis; myoblast cells for the treatment of Muscular Dystrophy; respiratory epithelial cells for the treatment of Cystic Fibrosis and lung cancer; adrenal cortex cells for the treatment of Addison's disease; retinal pigment epithelial cells for age-related macular degeneration; modified cells for treatment of various genetic diseases; and other cells for use in the diagnosis, treatment and prevention of other deadly or disabling diseases or other medical conditions.

To be precise, the current bill introduced by Senator Bond, S. 1599, would make it a crime to generate stem cells, for the above uses, where somatic cell nuclear transfer technology is used. It would not ban stem cell research where the stem cell is generated without the use of somatic cell nuclear transfer. It is not possible to say how much of this promising research will or might involve the use of somatic cell nuclear transfer. As described below, the bill would clearly ban the generation of any stem cells ''customized'' to an individual where somatic cell nuclear transfer must be used.

This stem cell technology is exciting and potentially revolutionary. Scientists are developing a new approach for treating human diseases that doesn't depend on drugs like antibiotics, but on living cells that can differentiate into blood, skin, heart, or brain cells and can potentially treat various cancers, spinal cord injuries, and heart disease. For example, this stem cell research has the potential to develop and improve cancer treatments by gaining a more complete understanding of cell division and growth and the process of metastasis. This could also lead to a variety of cancer treatment advances.

The types of cells that make up most of the human body are differentiated, meaning that they have already achieved some sort of specialized function such as blood, skin, heart or brain cells. The precursor cells that led to differentiated cells come from an embryo. The cells are called stem cells because functions stem from them like the growth of a plant. Stem cells have the capacity for self-renewal, meaning that they can reproduce more of themselves, and differentiation, meaning that they can specialize into a variety of cell types with different functions. In the last decade, scientists studying mice and other laboratory animals have discovered new power approaches involving cultured stem cells. Studies of these cells obtained from a mouse's stem cells show that they are capable of differentiating, in vitro or in vivo into a wide variety of specialized cell types. Stem cells have been derived by culturing cells of non-human primates. Promising efforts to obtain human stem cells have also recently been reported.

Stem cell research has been hailed as the ''[most] tantalizing of all'' research in this field, because adults do not have many stem cells. Most adults cells are fully differentiated into their proper functions. When differentiated cells are damaged, such as damage to cardiac muscle from a heart attack, the adult cells do not have the ability to regenerate. If stem cells could be derived from human sources and induced to differentiated in vitro, they could potentially be used for transplantation and tissue repair.

Using heart attacks as an example, we might be able to replace damaged cardiac cells, with healthy stem cells, that could differentiate into cardiac muscle. Research using these stem cells could lead to the development of ''universal donor cells,'' and could be an invaluable benefit to patients. Stem cell therapy could also make it possible to store tissue reserves that would give health care providers a new and virtually endless supply of the cells listed above. The use of stem cells to create these therapies would lead to great medical advances. We have to be sure that this legislation concerning human cloning would not in any way obstruct this vital research.

BOND BILL APPLICATION TO NON-IDENTICAL NUCLEUS

The purpose of a bill to ban human cloning is supposedly to ban the cloning of an individual and the essence of this is the duplication of the DNA of one individual in another. The term ''somatic cell,'' however, is not limited in the current Bond bill to somatic cells with DNA which is the same as that of an existing or previously existing human being. If it is not limited to cases where the

[1] An identical bill has been introduced by Senator Lott as S. 1601 and this may be the bill which is called up for the Senate debate.

DNA is identical, human cloning is—by definition—not involved.

The current Bond bill goes beyond cloning because it does not define the term ''somatic cell'' or limit to cases where the DNA is identical. It only defines the term ''somatic cell nuclear transfer,'' but it does not define the term ''somatic cell.'' We need a brief glossary of terms to define what constitutes a ''somatic cell.''

''Zygote'' means a single celled egg with two sets (a diploid set) of chromosomes as normally derived by fertilization;

''Egg'' and ''oocyte'' mean the female gamete;

''Gamete'' means a mature male or female reproductive cell with one set (a haploid) set of chromosomes;

''Sperm'' means the male gamete;

''Somatic cell'' means a cell of the body, other than a cell that is a gamete, having two sets (a diploid set) or chromosomes;

So a ''somatic cell'' is any cell of the body other than a gamete, and it includes a fertilized egg. This means that the current Bond bill would make it a crime to use somatic cell nuclear transfer even in cases where the somatic cell contains a nucleus derived from sexual reproduction, which is obviously not cloning. This means that even though the nucleus is not a clone, the current Bond bill makes it a Federal crime to create it. This means that the current Bond bill goes beyond the issue of cloning.

Because of this coverage of all ''somatic cells'' the current Bond bill would make it a crime for doctors to use a currently effective treatment for mitochondrial disease. In this treatment women who have the disease have an extreme and tragic form of infertility. The disease is a disease of the mitochondria, which is an essential element of any egg. The treatment for this disease involves the use of a fertilized nucleus which is transferred through the use of somatic cell nuclear transfer to an egg from which the nucleus has been removed. The new egg is a fresh, undiseased egg. The current Bond bill would make it a crime to provide this treatment even though the nucleus which is transferred is the product of fertilization, not cloning.

CUSTOMIZED STEM CELLS

If the current Bond bill was limited to somatic cells with nuclear DNA identical to that of an existing or previously existing human being, i.e. to a cloned nucleus, it would make it a Federal crime to conduct one especially promising type of stem cell research, research into generating ''customized'' stem cells.

A researcher or doctor might want to create a human zygote with DNA identical to that of an existing or previously existing person through the use of somatic cell nuclear transfer, the act prohibited in the bill, in order to create a customized stem cell line to treat the individual from whom the DNA was extracted. By using the same DNA, the stem cell therapy would more likely be compatible with, and not be rejected by, the person for whom the therapy is created. By starting with the patient's own nuclear DNA, the therapy is, in effect, custom made for that person. It is like taking the patients blood prior to surgery so that it can be infused into the patient during surgery (avoiding the possibility of contamination by the use of blood of another person).

Because the current Bond bill makes it a crime to use the technology—somatic cell nuclear transfer—if would make it a crime to develop a therapy with the equivalent of the patient's personal monogram on it, a customized treatment based on their own nuclear DNA.

Because the bill introduced by Senator FEINSTEIN requires the implantation of an embryo, it does not curtail stem cell research, and the bill provides that the transferred nucleus must be that of an ''existing or previously existing human child or adult,'' precisely the limitation not present in the current Bond bill. None of the issues we have raised regarding the current Bond bill apply to the Feinstein bill, which is narrowly focused on the act of cloning, or attempting to clone an individual.

PROTECTING BIOMEDICAL RESEARCH

The current Bond bill and the Feinstein bill both contain clauses for the protection of biomedical research. There is a critical difference between them.

At the press conference announcing introduction of his bill Senator BOND distributed a document entitled ''Current Research Untouched by the Bond/Frist/Gregg Legislation.'' The title of this document was followed by a list of such research, including ''In Vitro Fertilization,'' ''Stem Cell Research,'' ''Gene Therapy,'' ''Cloning of Cells, Tissues, Animals and Plants,'' ''Cancer,'' ''Diabetes,'' ''Birth Defects,'' ''Arthritis,'' ''Organ Failure,'' ''Genetic Disease,'' ''Severe Skin Burns,'' ''Multiple Sclerosis,'' ''Muscular Dystrophy,'' ''Spinal Cord Injuries,'' ''Alzheimer's Disease,'' ''Parkinson's Disease,'' and ''Lou Gehrig's Disease.'' Unfortunately, the title is followed by a critical qualification, an asterisk. The asterisk qualification states, ''The current Bond bill would not prohibit any of this research, even embryo research, as long as it did not involve the use of a very specific technique (somatic cell nuclear transfer) to create a live cloned human embryo.''

In the ways described above this asterisk qualification acknowledges that the bill would, in fact, make it a crime to conduct some types of stem cell research and other research. Given the importance of the asterisk, the document's title and the list of supposedly protected research could be considered misleading. The document should more accurately have been entitled ''Only Some Research Regarding the Following Diseases Is Outlawed.''

The current Bond bill contains a Section 5 entitled ''Unrestricted Scientific Research.'' This section provides that ''Nothing in this Act (or an amendment made by this Act) shall be construed to restrict areas of scientific research that are not specifically prohibited by this Act (or amendments).'' This provision is circular. It states that the bill does what it does and does not do what it does not do. The provision does nothing to modify the prohibitions on research and does nothing to protect ''scientific research.''

In contrast the Feinstein bill includes a provision regarding ''Protected Research and Practices'' which provides that ''Nothing in this section shall be construed to restrict ares of biomedical and agriculture research or practices not expressly prohibited in this section, including research or practices that involve the use of—(1) somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; (2) mitochondrial, cytoplasmic or gene therapy; or (3) somatic cell nuclear transfer techniques to create nonhuman animals.'' This is a ''savings'' clause with meaning and content. Its reference to the cloning of ''cells'' and to ''mitochondrial'' therapy are laudatory and meaningful.

NBAC RECOMMENDATION AND CLINTON ADMINISTRATION BILL

The National Bioethics Advisory Commission (NBAC) cautioned that poorly crafted legislation to ban human cloning may put at risk biomedical research on the following types of diseases and conditions: ''regeneration and repair of disease or damaged human tissues and organs'' (NBAC report at 29); ''assisted reproduction'' (NBAC report at 29); ''leukemia, liver failure, heart and kidney disease'' (NBAC report at 30); and ''bone marrow stem cells, liver cells, or pancreatic beta-cells (which produce insulin) for transplantation'' (NBAC report at 30). The Clinton Administration proposed law, like the Feinstein bill, avoids the peril identified by NBAC and focuses only on the issue of human cloning and does not imperil biomedical research.

SUNSET AND PREEMPTION

NBAC proposed that any law include both sunset review and preemption provisions.

Regarding a sunset review provision, NBAC stated in its report: ''It is notoriously difficult to draft legislation at any particular moment that can serve to both exploit and govern the rapid and unpredictable advances of science. Some mechanism, therefore, such as a sunset provision, is absolutely needed to ensure an opportunity to re-examine any judgment made today about the implications of somatic cell nuclear transfer cloning of human beings. As scientific information accumulates and public discussion continues, a new judgment may develop and we, as a society, need to retain the flexibility to adjust our course in this manner. A sunset provision. . .ensures that the question of cloning will be revisited by the legislature in the future, when scientific and medical questions have been clarified, possible uses have been identified, and public discussion of the deeper moral concerns about this practice have matured.'' NBAC report at 101. President Clinton has proposed a five year sunset in his bill. The Feinstein bill includes a ten year sunset and the current Bond bill includes no sunset review.

BIO supports inclusion of a sunset review provision, but the most important issue is whether the terms of the prohibition in any law focuses only on the issue of human cloning. A sunset review provision will not undo the damaged which a poorly crafted, over broad law would do to biomedical research prior to the sunset date.

The Feinstein bill, but not the current Bond bill, includes a clause which preempts inconsistent state laws. NBAC strongly supported a preemption of state laws: ''The advantage to federal legislation—as opposed to state-by-state laws—lies primarily in its comprehensive coverage and clarity. . . . Besides ensuring interstate uniformity, a federal law would relieve the need to rely on the cooperation of diverse medical and scientific societies, or the actions of diverse IRBs, to achieve the policy objective. As an additional benefit, federal legislation could displace the varied state legislative efforts now ongoing, some of which suffer from ambiguous drafting that could inadvertently prohibit the important cellular and molecular cloning research described . . . in this report.'' NBAC report at 100. Numerous bills introduced in state legislatures, some of which are very poorly crafted and over broad.

BIO supports inclusion of a preemption clause. Again, the key issue is whether the prohibition in any law focuses only on the issue of human cloning and does not imperil biomedical research. A poorly drafted, over broad Federal law which preempts state laws might do even more damage.

NBAC ROLE AND COMMISSION

NBAC performed a public service with its quick and thoughtful analysis of the human cloning issue. the current Bond bill would set up an entirely new body to review the human cloning issue rather than rerefer the issue back to NBAC for further review. NBAC is well qualified and positioned to perform this function and it may be wasteful and expensive to establish another body to

perform this ongoing review. The Feinstein bill calls on NBAC to conduct the reviews.

Mrs. FEINSTEIN. Finally, there are hospitals and universities, the University of California Medical Center in San Francisco, the Reproductive Genetics Unit, also sent a letter.

I ask unanimous consent to have that printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

UNIVERSITY OF CALIFORNIA,
San Francisco, CA, February 4, 1998.

Hon. SENATOR KENNEDY,
U.S. Senate, Washington, DC.

DEAR SENATOR KENNEDY: I am writing to express my deep concern about the negative impact of impending legislation introduced by Senators Bond, Frist *et al.* (S. 1599) intended to regulate cloning of a human being. As an active researcher in the scientific field of the discovery leading to Dolly, I understand its implications for basic science and human health. Dolly's existence proves for the first time that the genetic material of an adult body cell can be completely reprogrammed by the egg, thus totally restoring the genetic potential for specializing into all possible cell types. This discovery that genetic reprogramming is possible in mammals is as important to human health as the discovery of penicillin. Basic research on genetic reprogramming will likely lead to novel transplantation therapies for numerous human disease, including heart disease, diabetes, neurodegenerative diseases (such as Parkinson disease), genetic diseases and birth defects. I believe that imprecise, hastily-written legislation against human cloning, such as S. 1599, will hinder these important research opportunities for understanding genetic reprogramming of adult cells. Excessive regulation as specified by S. 1599, including civil penalties and criminalization, in the areas of this new discovery is likely to thwart the momentum of basic research on genetic reprogramming and deter the enthusiasm and ability of researchers poised to make new contributions in applying their findings to human health problems.

In no conceivable instance would research on genetic reprogramming involve cloning of human beings. Indeed, active, credible researchers and clinicians overwhelmingly regard cloning a human being as an unethical and reprehensible act. Last year, working through the Society for Developmental Biology, I spearheaded a voluntary moratorium on cloning human beings. This moratorium unequivocally states that we have no intention to clone human beings, where this is defined as ''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.'' To date, 15 additional scientific and medical societies, including the Federation of American Societies for Experimental Biology, the American Society for Reproductive Medicine, and the Society for the Study of Reproduction, together representing more than 60,000 reproductive, developmental, cell and molecular biologists, have endorsed this moratorium. Historical precedent (with recombinant DNA technology) indicates that a voluntary moratorium can deter activities that are potentially unsafe for humans. It is evident from recent events that anyone who advocates cloning human beings for any purpose will be subjected to ostracism and discredited scientifically. Therefore, I believe that the existing voluntary moratorium against cloning human beings is an effective means of regulating the behavior of U.S. scientists and physicians.

Presently, the fields of developmental biology and human genetics are at an exciting juncture, where many novel genes are being identified through the Human Genome Project and their functions during normal development are being understood for the first time. In addition, an understanding of how these genes interact with the internal and external environment of the cell is emerging for studies such as those giving rise to Dolly. Deriving the full benefits of these new insights for human health will require a dedicated and cooperative research effort by many scientists, including those who conduct research on human cells and tissues.

In conclusion, there is a great risk that anti-cloning legislation would deprive the American people of unprecedented human health benefits. I thus urge extreme caution in any legal sanctions, such as those included in S. 1599, which would have lasting detrimental effects on our ability to alleviate human diseases, and would also undermine the competitive abilities of U.S. scientists in our field.

Respectfully yours,
ROGER A. PEDERSEN, PH.D.,
Professor and Research Director, Reproductive Genetics Unit,
Department of Obstetrics, Gynecology and Reproductive Science.

Mrs. FEINSTEIN. Let me move for a moment to think tanks. I must say, Mr. President, that one of the most interesting letters to me is one from the CATO Institute, dated February 6.

They attach to their letter a very interesting article from Science magazine which really casts major doubts on the conclusions drawn from the Dolly experiment.

The letter says that the new information indicates that there is no need to rush legislation, and it can be accorded the time and deliberation appropriate to legislate that can have a lasting impact on biological research in this country.

The article from Science magazine questions whether Dolly originated from adult cell DNA. Interesting. And it suggests that she might have resulted from the cloning of an embryonic cell. ''Scientists have cloned embryonic cells for years, and those activities have raised no public concern. The last sentence in the first paragraph of the Science news article sums up the significance of the new information. If Dolly isn't the product of DNA from a mature cell, 'it would mean that human cloning, which for most conceivable purposes would start with adult cells, is not the immediate threat some worry about.' ''

And CATO goes on and says:

With this new information in hand, there appears to be no need to rush legislation, and at a minimum there is ample time for hearings with knowledgeable and respected scientists, ethicists, theologians, and others testifying about the proposed legislation and its ramifications.

The CATO letter continues,

Many scientists, including the Director of the NIH, worry that hastily drafted and loosely drawn legislation directed against cloning will foreclose research that promises new drugs and the capacity to replace or repair nerves, skin, and muscle lost to injury or disease. The information from Science indicates that legislative haste is not necessary.

I ask unanimous consent that the CATO letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

CATO INSTITUTE,
Washington, DC, February 6, 1998.

HON. DIANNE FEINSTEIN,
Washington, DC.

DEAR SENATOR FEINSTEIN: As you are well aware, the uproar over Dolly and the perils that many people see in the possibility of human cloning have resulted in the introduction of legislation to prohibit research into human cloning. A letter and news article from this week's Science magazine (enclosed) cast doubt on the conclusions drawn from Dolly. The new information indicates that there is no need to rush legislation and that it can be accorded the time and deliberation appropriate to legislation that can have a lasting impact on biological research in this country.

Few biological results have excited as much attention as the announcement of Dolly's birth eleven months ago. Dolly was important and surprising because, it was claimed, she was produced from the DNA of an adult sheep.

Mammalian life begins with a ''totipotent'' fertilized egg that can multiply and differentiate into all the diverse types of cells—skin, nerves, bones, muscle, etc.—that make up a mature animal. As cells differentiate into specialized cells, they lose the capacity to carry out the functions of other cell types; they are no longer totipotent. A skin cell cannot produce a nerve, bone, or muscle cell, for example.

Dolly was a surprise because she was, apparently, the product of DNA from a differentiated, specialized cell from the udder of a mature sheep. The DNA was introduced into a DNA-less egg, and the egg was implanted into the uterus of a sheep where it developed into Dolly.

Dolly, at the time the experiment was announced last year, appeared to open up the possibility of human cloning. In theory, DNA could be taken from a woman or man and inserted into a DNA-less egg, and the egg, which now contained the genetic information from the donor, could be introduced into the uterus of a woman. If a child resulted from the process, she or he would be genetically identical to the woman or man from whom the DNA came.

The enclosed letter from Science questions whether Dolly originated from adult cell DNA, and it suggests that she might have resulted from the cloning of an embryonic cell. Scientists have clonsed embryonic cells for years, and those activities have raised no public concerns. The last sentence of the first paragraph of the Science news article sums up the significance of the new information. If Dolly isn't the product of DNA from a mature cell, ''it would mean that human cloning, which for most conceivable purposes would start with adult cells, is not the immediate threat some worry about.''

With this new information in hand, there appears to be no need to rush legislation. At a minimum, there is ample time for hearings with knowledgeable and respected scientists, ethicists, theologians, and others testifying about the proposed legislation and its ramifications.

Human cloning, if it is ever accomplished, will offer the promise of a child to love and cherish to couples who otherwise would be childless. Although cloning has been greeted very negatively, it is also true that negative

reactions met almost every advance in human reproduction technologies—artificial insemination, in vitro fertilization, ''fertility drugs,'' prenatal diagnoses. Those technologies became accepted when they gave healthy children to couples that otherwise would have been childless.

Many scientists, including the Director of the National Institutes of Health, worry that hastily drafted and loosely drawn legislation directed against cloning will foreclose research that promises new drugs and the capacity to replace or repair nerves, skin, and muscle lost to injury or disease. The information from Science indicates that legislative haste is not necessary.

I will be happy to talk with you or your staff and to provide additional information.

Sincerely,

MICHAEL GOUGH, Ph.D.

Mrs. FEINSTEIN. Mr. President, there are also brand new letters that I did not enter into the RECORD my last time on the floor speaking about this issue. They are from the American Society for Biochemistry and Molecular Biology, from the professor and chairman of the Department of Developmental Biology at Stanford University School of Medicine, the American Society for Cell Biology, which interestingly enough is signed by more Nobel laureates than I have ever seen signing one letter. And this is truly amazing. There are 27 Nobel laureates on this letter.

What they say, in summing up, is:

If legislation is deemed to be necessary, we respectfully urge you to be sure that it be limited to the cloning of human beings and not include language that impedes critical, ongoing, and potential new research.

And I have letters from the American Society for Cell Biology, the American Society for Human Genetics, the National Association for Biomedical Research, a telegram from the Federation of American Societies for Experimental Biology. I ask unanimous consent that these letters be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

AMERICAN SOCIETY FOR BIOCHEMISTRY AND MOLECULAR BIOLOGY,

Bethesda, MD, February 10, 1998.

Hon. CHRISTOPHER BOND,
U.S. Senate, Washington, DC.

DEAR SENATOR BOND: We are writing to express a number of concerns regarding your bill, S. 1601, the Human Cloning Prohibition Act, which would prohibit the use of ''Somatic cell nuclear transfer technology for purposes of human cloning.'' Our main concern is that harm not be done to biomedical research through your well-intentioned effort to prevent disreputable individuals or companies from attempting to clone a human being. We recognize it is not your intent to harm biomedical research. However, we respectfully point out that this would be the likely result if the bill were to become law in its current form.

Our first concern is that few of the scientific terms used in the bill are defined. The bill defines the broad term ''human somatic cell nuclear transfer technology,'' but the definition is flawed in several ways. The use of the word ''technology'', for example, implies that it is the physical tools needed to carry out human somatic cell nuclear transfer that are banned, not the process itself. The technology needed to carry out such a nuclear transfer is readily available in any modern biological laboratory dealing with reproductive biology; surely it is not your intention to ban these tools.

The definition also includes as banned the production of ''an embryo (including a preimplantation embryo)''. This inclusion would clearly interfere with work needed to develop a variety of therapies described below for burn victims, diabetes sufferers, and others suffering from more rate genetic diseases.

The bill also does not define the term ''oocyte,'' which many members of the Senate may not understand. It would be useful to define term so these senators know what is being discussed. The same could be said for the terms ''nuclear'', ''nuclear transfer,'' ''cell,'' ''somatic cell,'' and ''cloning.'' The point of this discussion of definitions is that this whole area of biology is extremely complex, and the process itself is only now beginning to be understood by people who have devoted years of study to the subject. It is thus premature to attempt to define in legislation a process that is still evolving.

Second, we are concerned by the bill's permanent prohibition of human somatic cell nuclear transfer. While no responsible member of the life sciences community is in favor of cloning humans at this time, there may come a time, after further research and study, when it will be viewed as less egregious. For example, infertile couples might appreciate the availability of human somatic cell nuclear transfer, as it might someday enable them to experience the joys and rewards of parenthood.

Third, cloning is a widely used technique in modern biology to produce large numbers of cells and other biological materials scientist need to carry out modern biomedical research. The National Institutes of Health has produced a paper called ''Cloning: Present Uses and Promises'', which discusses all of these issues in clear and useful detail.

This paper explains that human somatic cell nuclear transfer can have profound benefits for human health if research is allowed to proceed using the technique. For example, a burn victim often needs skin grafts. Current grafting techniques require taking undamaged skin from the victim and grafting it onto the patient's burned areas. Skin from other humans cannot be used because it would be rejected by the victim's immune system. However, if adult cells can be taken from the victim, treated in such a way as to return them to an embryonic state and then made to grow into skin cells, virtually unlimited quantities of the victim's own skin could be grown and used as grafts. This skin would not be rejected since it would be genetically identical to the victims' original skin.

The NIH paper also discusses the potential use of somatic cell nuclear transfer in attacking diabetes, and other, more rare genetic diseases. Of course, these therapies are not available now—but they might be in the future, if biomedical research on the uses and limits of somatic cell nuclear transfer is not permanently banned, as it would be under the provisions of your bill.

Even though your bill notes that ''Nothing in this Act . . . shall be construed to restrict areas of scientific research that are not specifically prohibited . . .'' section 2 declares that ''. . . it is right and proper to prohibit the creation of cloned human embryos that would never have the opportunity for implantation and that would therefore be created solely for research that would ultimately lead to their destruction.'' This language, plus the way your definition of ''human somatic cell nuclear transfer technology'' is phrased, makes it impossible for research to continue on these therapies using somatic cell nuclear transfer. We respectfully note that we cannot support such a broad prohibition.

A fourth matter to consider is that history is replete with examples of bad law that were primarily the products of undue haste. In our view, human cloning is not going to occur soon enough to justify taking this bill directly to the floor of the Senate without hearings at the subcommittee and committee level. Such hearings would develop the points we raise above as well as many more, and explore the consequences (both positive and negative) of the bill's provisions. There is no need at this point to short-circuit the normal hearing process, which serves our country and the Congress very well.

Finally, all of the above notwithstanding, it is not absolutely clear that the now famous sheep Dolly was cloned using an adult cell and not a fetal cell in the first pace. One prominent researcher, Dr. Norton Zinder, of Rockefeller University, believes that it has not been proven that Dolly was created using the nucleus of a somatic cell. In a recent letter to Science, he notes that so far, Dolly has not been replicated, and that it took 400 tries to create her in the first place. One success in 400 ''Is an anecdote, not a result,'' he writes. Thus, since it has not been definitely proven that an adult cell was used to clone Dolly, it is possible that Dr. Wilmut's announcement approximately a year ago was mistaken, and that a fetal cell was used by accident (the sheep from which the cell was taken was pregnant at the time, and fetal cells circulate throughout the body in such situations).

Thus, it may be that there is no danger of somatic cell nuclear transfer being used to clone a human being because it cannot be done! We simply don't know at this point. It would therefore be unfortunate if this technique, which has promise in so many other biological applications, was placed ''off limits'' to researchers before its promise and pitfalls were thoroughly explored. This is yet another reason why haste is not desirable.

Let me make it clear that the ASBMB does not support human cloning. This is why the ASBMB Public Affairs Advisory Committee supports the National Bioethics Advisory Commission's call for a 5-year moratorium. The committee adopted the following resolution in September 1997:

''The ASBMB Public Affairs Advisory Committee supports the declaration of a voluntary five-year moratorium on cloning human beings, where 'cloning human beings' is defined 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.''

Numerous life sciences organizations, such as the Society for Developmental Biology, the Federation of American Societies for Experimental Biology, the American Society for Cell Biology, and the Association of American Medical Colleges, have indicated their support for a voluntary moratorium on human cloning. We are confident that such a moratorium will be effective in preventing the act you fear from occurring. It would also allow the issue to be revisited later, after further research and deliberation.

We hope you will take all these thoughts into consideration before moving ahead with a bill that is well-intentioned but which could also do serious harm to biomedical research unless it is modified. We would be pleased to provide you with further information on these issues in the days and weeks ahead.

For your information, the American Society for Biochemistry and Molecular Biology,

founded in 1906, is a scientific and educational organization with a membership of 10,200 life scientists who teach or conduct research at most of our country's colleges and universities, nonprofit research institutions, in industry, and for the federal government. We publish the *Journal of Biological Chemistry*, one of our nation's premiere peer-reviewed journals in the life sciences. Our headquarters are on the campus of the Federation of American Societies for Experimental Biology, in Bethesda, Maryland.

Sincerely,

I. ROBERT LEHMAN,
President.

BECKMAN CENTER,
Stanford, CA, February 4, 1998.

Hon. CONNIE MACK,
U.S. Senate, Washington, DC.

DEAR SENATOR MACK: The Congress is moving rapidly, indeed precipitously, to legislate a ban on attempts to produce a human being by somatic cell nuclear transfer (SCNT) technology. The bill sponsored by Senators Bond, Frist, Gregg and others, if passed, would be the first to ban a specific line of research. I believe this is a serious mistake, one that we could regret because of its unintended implications for otherwise valuable biomedical research.

Extending the President's moratorium to the private sector would provide an interim solution to preventing any and all attempts to produce a human being by SCNT until a congressional commission determined whether and what kind of legislation would be appropriation.

I call to your attention a position statement supported by many scientific societies which recommends a course of action you should consider.

At the request of the National Bioethics Advisory Commission, the American Society for Cell Biology recommended in the Spring of 1997 a voluntary international moratorium on human nuclear transfer for the purpose of creating a new human being. This would allow scientists and the public the opportunity to determine the safety and appropriateness of such experimentation.

The ASCB continues to support such a moratorium as a constructive interim response to the concerns raised by the cloning of an adult sheep. However, recent events in the U.S. have escalated and infused new urgency into this debate, resulting in increased demands for regulatory legislation.

The ASCB urges that if legislation is needed, it should specifically be concerned with the reproduction of a human being by nuclear transfer. At the same time, any legislation should not impede or interfere with existing and potential critical research fundamental to the prevention or cure of human disease. This research often includes the cloning of human and animal cell lines and DNA, but not whole human beings.

The National Biomedical Advisory Commission did recommend a three to five year moratorium on human nuclear transfer for the purpose of creating a new human being in order to allow time to evaluate the safety of and public views about such procedures. The ASCB urges that the Commission's recommendation be the basis for any federal legislation.

Very sincerely yours,

PAUL BERG,
Nobel Laureate, Chemistry, 1980.

THE AMERICAN SOCIETY FOR
CELL BIOLOGY,
Bethesda, MD, February 9, 1998.

To the President of the United States and Members of the United States Congress:

There is a broad consensus supporting the President's National Biomedical Ethics Advisory Commission's proposal to ban the creation of a human being by somatic nuclear transplants. The Commission urged that such a ban should not deliberately or inadvertently interfere with biomedical research that is critical to the understanding and eventual prevention of human disease. To that end, we the undersigned endorse the statement on cloning from the American Society for Cell Biology. If legislation is deemed to be necessary, we respectfully urge you to ensure that it be limited to the cloning of human beings, and does not include language that impedes critical ongoing and potential new research.

Sincerely,

Sidney Altman, Sterling Professor of Biology, Professor Chemistry, Yale University, Nobel Prize in Chemistry, 1989; Kenneth J. Arrow, Joan Kenney Professor of Economics Emeritus, and Professor of Operations Research Emeritus, Stanford University, Nobel Prize in Economics, 1972; David Baltimore, President, California Institute of Technology, Nobel Prize in Physiology or Medicine, 1975; Paul Berg, Cahill Professor of Cancer Research, Department of Biochemistry, Stanford University School of Medicine, Nobel Prize in Chemistry, 1980.

J. Michael Bishop, University Professor, University of California, Director, the G.W. Hooper Research Foundation, University of California, San Francisco School of Medicine, Nobel Prize in Physiology or Medicine, 1989; Stanley Cohen, Distinguished Professor of Biochemistry, Vanderbilt University School of Medicine, Nobel Prize in Physiology or Medicine, 1986; E.J. Corey, Sheldon Emery Professor of Chemistry, Department of Chemistry & Chemical Biology, Harvard University, Nobel Prize in Chemistry, 1990; Peter Doherty, Department of Immunology, St. Jude Children's Research Hospital, Nobel Prize in Physiology or Medicine, 1996.

Gertrude B. Elion, Research Professor of Pharmacology and Medicine, Nobel Prize in Physiology or Medicine, 1988; Walter Gilbert, Carl M. Loeb University Professor, Department of Molecular and Cellular Biology, Harvard University, Nobel Prize in Chemistry, 1980; Alfred G. Gilman, Regental Professor and Chair, Department of Pharmacology, University of Texas Southwestern Medical Center, Nobel Prize in Physiology or Medicine, 1994; Donald A. Glaser, Professor of Physics and Neurobiology in the Graduate School, University of California at Berkeley, Nobel Prize in Physics, 1960.

Joseph L. Goldstein, Professor and Chairman, Department of Molecular Genetics, University of Texas Southwestern Medical Center at Dallas, Nobel Prize in Physiology or Medicine, 1985; Roger Guillemin, Distinguished Research Professor, The Salk Institute for Biological Studies, Nobel Prize in Physiology or Medicine, 1977; Dudley Herschbach, Baird Professor of Science, Harvard University, Nobel Prize in Chemistry, 1986; Edwin G. Krebs, Professor Emeritus, Department of Pharmacology, University of Washington, Nobel Prize in Physiology or Medicine, 1992.

Joshua Lederberg, Professor Emeritus, The Rockefeller University, Nobel Prize in Physiology or Medicine, 1958; Leon M. Lederman, Pritzker Professor of Science, Illinois Institute of Technology, Director Emeritus, Fermi National Accelerator Laboratory, Nobel Prize in Physics, 1988; Edward B. Lewis, Thomas Hunt Morgan Professor of Biology, Emeritus, Nobel Prize in Physiology or Medicine, 1995; Daniel Nathans, Senior Investigator, Howard Hughes Medical Institute, University Professor, The Johns Hopkins University School of Medicine, Nobel Prize in Physiology or Medicine, 1978.

Marshall Nirenberg, Laboratory Chief, Laboratory of Biochemical Genetics, The National Institutes of Health, National Heart Lung & Blood Institute, Nobel Prize in Physiology or Medicine, 1968; Douglas D. Osheroff, J.G. Jackson and C.S. Wood Professor of Physics, Stanford University, Nobel Prize in Physics, 1996; Phillip A. Sharp, Professor and Head, Department of Biology, Massachusetts Institute of Technology, Nobel Prize in Physiology or Medicine, 1993; Susumu Tonegawa, Amgen Professor of Biology and Neuroscience, Director, Center for Learning and Memory, Massachusetts Institute of Technology, Investigator, Howard Hughes Medical Institute, Nobel Prize in Physiology or Medicine, 1987.

James D. Watson, President, Cold Spring Harbor Laboratory, Nobel Prize in Physiology or Medicine, 1962; Eric F. Wieschaus, Squibb Professor of Molecular Biology, Investigator, Howard Hughes Medical Institute, Nobel Prize in Physiology or Medicine, 1995; Torsten Wiesel, President, The Rockefeller University, Nobel Prize in Physiology or Medicine, 1981.

THE AMERICAN SOCIETY FOR CELL BIOLOGY
STATEMENT ON CLONING JANUARY, 1998

At the request of the National Bioethics Advisory Commission, the American Society for Cell Biology recommended in the Spring of 1997 a voluntary international moratorium on human nuclear transfer for the purpose of creating a new human being. This would allow scientists and the public the opportunity to determine the safety and appropriateness of such experimentation.

The ASCB continues to support such a moratorium as a constructive interim response to the concerns raised by the cloning of an adult sheep. However, recent events in the U.S. have escalated and infused new urgency into this debate, resulting in increased demands for regulatory legislation.

The ASCB urges that if legislation is needed, it should specifically be concerned with the reproduction of a human being by nuclear transfer. At the same time, any legislation should not impede or interfere with existing and potential critical research fundamental to the prevention or cure of human disease. This research often includes the cloning of human and animal cell lines and DNA, but not whole human beings.

The National Bioethics Advisory Commission did recommend a three to five year moratorium on human nuclear for the purposes of creating a new human being in order to allow time to evaluate the safety of and public views about such procedures. The ASCB urges that the Commission's recommendation be the basis for any federal legislation.

THE AMERICAN SOCIETY
OF HUMAN GENETICS,
Bethesda, MD, February 5, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate, Washington, DC.

DEAR SENATOR FEINSTEIN: Senators Kit Bond (R-TN) and Bill Frist (R-TN) have introduced S. 1601, ''to prohibit the use of somatic cell nuclear transfer technology for purposes of human cloning.'' While the majority of the scientific community and the public supports a ban on human cloning, the

bill's language would effect other important areas of medical and scientific research.

As President of The American Society of Human Genetics representing over 6,000 researchers in the field human genetics, I want to go on record as opposing this bill.

Congress must make sure that any bill would not restrict or inhibit stem cell research which is being used to create a whole new type of therapy—cell therapy. Congress must also make sure that research is not restricted into the pathology of disease, gene therapy research, research into the ways genes operate in the cell and other basic biomedical research which gives hope that we can find and develop cures and therapies for deadly and disabling diseases.

Thank you for allowing us to go on record as opposing S. 1601.

Sincerely yours,

ARTHUR BEAUDET, MD,
President, ASHG.

NATIONAL ASSOCIATION FOR BIOMEDICAL RESEARCH,
Washington, DC, February 5, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate, Washington, DC.

DEAR SENATOR FEINSTEIN: The NABR membership respectfully requests that you vote ''no'' next Tuesday, February 10, when a motion to invoke cloture and proceed to consider S. 1601, a bill to ban human cloning, is scheduled to come before the Senate. There is virtually unanimous agreement that human beings should not be cloned. However, as currently drafted S. 1601 threatens to restrict research efforts far beyond those which could involve cloning human beings. The proposal is going to the floor without the customary committee consideration and recommendation. The result is a well-intentioned, but ill-defined, measure that will destroy promising new research avenues that might provide long-awaited solutions to untold human suffering. Your ''no'' vote is needed to protect responsible biomedical research and allow this legislation to receive the full deliberation it deserves.

We all fear a disastrous outcome of new cloning technologies; however, S. 1601 is not focused on outcomes. Rather, for the first time, the government would ban a specific research technique and process. To prevent a real or imagined future calamity, approval of this bill would mean the public must also forego all the beneficial fruits of ''somatic cell nuclear transfer,'' including the possible cloning of cells or tissue to cure and treat cancer, diabetes, Alzheimer's and many other illnesses. (Please see enclosed Time article for further discussion.) For this reason, Congress certainly should take the time to carefully consider S. 1601 and other proposals dealing with human cloning. Surely, the people whose healthy futures depend on more and better research must have the opportunity to understand and participate in the decisions Congress is facing. The current rush to pass imprecise, misunderstood legislation to ban human cloning is much more dangerous to the pubic than the remote chance a mad scientist might actually attempt it in the near future.

Until the moral, ethical and medical questions surrounding the possibility are fully explored and satisfactorily answered, no one should try to duplicate a human being by cloning. The nation's leading scientific, medical, pharmaceutical and biotechnology organizations agree and have already subscribed to a voluntary moratorium to this effect. In addition, the Food and Drug Administration has announced it will exercise regulatory authority over human cloning should any irresponsible individual try to ignore the mainstream scientific community. Therefore, it is not necessary to act hastily in the absence of all the facts.

Should you or your staff require additional information, please contact NABR. Thank you for your consideration of this urgent matter.

Sincerely,

FRANKIE L. TRULL,
President.

FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY,
Bethesda, MD, February 3, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate, Washington, DC.

The Federation of American Societies for Experimental Biology (FASEB) urges the Senate to proceed extremely cautiously as it considers legislation regarding human cloning. While the Federation considers the cloning of human being to be reprehensible, dangerous, and unethical, we are concerned that overly restrictive legislation could unintentionally preclude critical research of great benefit to the American people. We believe that S. 1599, currently pending consideration by the Senate, would be damaging to worthwhile research. By flatly banning all use of human somatic cell nuclear technology for any purpose, this legislation would close off key areas of research which do not involve the creation of humans. We urge that the Senate not approve this legislation in its current form as it does not balance appropriate ethical considerations with the health needs of the American people.

RALPH G. YOUNT, Ph.D.,
President.

Mrs. FEINSTEIN. And academics. I have a letter from the University of California at San Diego, from the professor of the Division of Cellular and Molecular Medicine, the Department of Pharmacology, University of California; another one from Dr. Bishop, Nobel laureate, University of California; a letter from the Whitehead Institute; another letter from the University of California from the Vice President of Health Affairs and the Vice Provost of Research; a letter from Dr. Roger Pedersen, professor and research director of the Reproductive Genetics Unit, University of California, San Francisco; and a letter from the Nobel laureate of chemistry to Senator MACK. In 1980, he won the Nobel prize.

I ask unanimous consent that these be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

UNIVERSITY OF CALIFORNIA,
San Diego, CA, February 10, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR FEINSTEIN: I am writing to urge you to continue working to protect basic biomedical research in any proposed human cloning legislation. While we all agree that ''cloning'' a complete human being is undesirable and unethical at present, it is very important that any legislation that is passed not inadvertently block important research into regenerative technology, or into the creation of artificially grown human organs for transplantation and other purposes. For example, as you know the recently proposed Bond/Frist cloning bill, S. 1599 in the Senate is far too broad and would ban many related and valuable research and medical activities. Your bill S. 1602 with Senator Edward Kennedy (D–MA) bans the implantation of the product of somatic cell nuclear transfer into a woman's womb. The language in S. 1602 appears much more reasonable and with minor modification could be recommended for support by the scientific community.

For your information, I have reproduced below a statement from the American Society for Cell Biology on cloning, which clearly delineates principles that many scientists feel are most useful in thinking about this important legislative challenge.

''The American Society for Cell Biology
Statement on Cloning, January, 1998

''At the request of the National Bioethics Advisory Commission, the American Society for Cell Biology recommended in the Spring of 1997 a voluntary international moratorium on human nuclear transfer for the purpose of creating a new human being. This would allow scientists and the public the opportunity to determine the safety and appropriateness of such experimentation.

''The ASCB continues to support such a moratorium as a constructive interim response to the concerns raised by the cloning of an adult sheep. However, recent events in the U.S. have escalated and infused new urgency into this debate, resulting in increased demands for regulatory legislation.

''The ASCB urges that if legislation is needed, it should specifically be concerned with the reproduction of a human being by nuclear transfer. At the same time, any legislation should not impede or interfere with existing and potential critical research fundamental to the prevention or cure of human disease. This research often includes the cloning of human and animal cell lines and DNA, but not whole human beings.

''The National Bioethics Advisory Commission did recommend a three to five year moratorium on human nuclear transfer for the purpose of creating a new human being in order to allow time to evaluate the safety of and public views about such procedures. The ASCB urges that the Commission's recommendation be the basis for any federal legislation.''

It is very important that our citizens and legislators think calmly and carefully about what legislation is passed in this area. We must ensure that we do not inadvertently hold back important and valuable medical research. I am sure that simple and temporary legislation, which doesn't seek to be too broad in its scope, and introduce many unintended consequences would be the best strategy. I hope that you will proceed with great caution.

Sincerely,

LAWRENCE S.B. GOLDSTEIN, Ph.D.

WHITEHEAD INSTITUTE,
Cambridge, MA, February 5, 1998.

Hon. EDWARD M. KENNEDY,
Russell Senate Office Building, Washington, DC.

DEAR SENATOR KENNEDY: I am very concerned about efforts to bring Senate Bill 1599, the Bond bill, to an immediate vote. While I agree that there should be a national ban on human cloning, it is essential that any such law protect areas of critical research that can benefit human health. The Bond bill's generic ban on the use of ''human somatic cell nuclear transfer technology,'' would, in fact, be quite damaging to medical research progress in the United States.

The Bond bill would seriously limit our ability to develop new cell-based strategies to fight cancer, diabetes, and Alzheimer's disease. It would also prevent vital research on the repair of spinal cord injuries and severe burns.

I urge you to convey to your colleagues that the Bond bill would cause us to lose ground in the battle against deadly and disabling human diseases. In contrast, Senate

Bill 1602 (the Feinstein/Kennedy bill) focuses on the implantation of the product of somatic cell nuclear transfer. By banning implantation, the Feinstein/Kennedy bill would permit life-saving research to continue and still prohibit the cloning of human beings.

All major advances in technology raise new ethical, legal, and social issues. The cloning issues are particularly complex. I appreciate your efforts to promote widespread and careful public deliberation and, at the same time to foster important advances in human health.

Sincerely,

GERALD R. FINK,
Director.

UNIVERSITY OF CALIFORNIA,
Oakland, CA, February 10, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senator, Hart Senate Office Building, Washington, DC.

DEAR SENATOR FEINSTEIN: We are writing on behalf of the University of California to urge you to vote against the upcoming cloture motion for S. 1601, the cloning bill. While we recognize the sensitivity and importance of this issue, the University is concerned that premature legislation on cloning, however well intentioned, may prove to be too inclusive, with resulting negative consequences on future advances in biomedical research.

The current opportunities in biomedical research are unparalleled. Thousands of experiments are carried out each day in the university laboratories using routine molecular and cellular research approaches involving human tissues, cells and molecules. Over the past two decades, this research has contributed to major advances in our understanding of the molecular and cellular basis of human disease. It has led to important new medical advances, including the production of human insulin, hepatitis vaccine, and sensitive diagnostics for AIDS. The scientific techniques involved in cloning research are very promising in terms of our ability to treat and manage myriad diseases and disorders, ranging from cancer to heart disease, to Parkinson's and Alzhemier's, to infertility and HIV/AIDS. These advances have saved hundreds of thousands of lives and dramatically reduced health care costs.

We urge you to vote no on the motion to invoke cloture on S. 1601, so that there is more time to consider the implications of cloning legislation. If Congress chooses to enact legislation, we urge you to make certain that any legislative language does not prohibit legitimate and worthwhile scientific research that has the potential to provide enormous health benefits. We would be happy to offer our resources as the legislative debate continues.

Thank you for considering our views.

Sincerely,

CORNELIUS L. HOPPER,
Vice President, Health Affairs.
ROBERT N. SHELTON,
Vice Provost, Research.

UNIVERSITY OF CALIFORNIA,
SAN FRANCISCO,
San Francisco, CA, February 4, 1998.

Hon. CONNIE MACK,
U.S. Senate,
Washington, DC.

DEAR SENATOR MACK: I understand that the U.S. Senate is considering several bills related to human cloning. One of these bills, introduced by Senator Bond and others, prohibits human somatic nuclear transfer to be used for the purpose of creating an embryo. Although this bill, as I understand it, protects many areas of science, the specific prohibition on somatic nuclear transfer is unwarranted and potentially detrimental to medical research.

The fundamental flaw in this legislation is the prohibition of a technology irrespective of its application. Such prohibition forecloses on any benefit from the technology, even if that benefit were in no way objectionable. Many well-intentioned people fail to understand that somatic cell nuclear transfer is not limited to cloning an organism. There are many examples of possible future applications of this technology to produce healthy tissue for therapeutic purposes, such as skin grafts for burn patients, or even to create insulin-producing cells for diabetics. There may also be applications for cancer patients who need a bone marrow transplant for whom a match cannot be found.

The Senate should instead address its attention to specific applications of this technology that are unwanted in our society, such as creating a new human being.

I hope that you will work to ensure that research on this promising technology is allowed to continue.

Sincerely,

J.M. BISHOP,
Nobel Laureate.

FEBRUARY 4, 1998.

Hon. SENATOR KENNEDY,
U.S. Senate,
Washington, DC.

DEAR SENATOR KENNEDY: I am writing to express my deep concern about the negative impact of impending legislation introduced by Senators Bond, Frist et al. (S. 1599) intended to regulate cloning of a human being. As an active researcher in the scientific field of the discovery leading to Dolly, I understand its implications for basic science and human health. Dolly's existence proves for the first time that the genetic material of an adult body cell can be completely reprogrammed by the egg, thus totally restoring the genetic potential for specializing into all possible cell types. This discovery that genetic reprogramming is possible in mammals is as important to human health as the discovery of penicillin. Basic research on genetic reprogramming will likely lead to novel transplantation therapies for numerous human diseases, including heart disease, diabetes, neurodegenerative diseases (such as Parkinson disease), genetic diseases and birth defects. I believe that imprecise, hastily-written legislation against human cloning, such as S. 1599, will hinder these important research opportunities for understanding genetic reprogramming of adult cells. Excessive regulation as specified by S. 1599, including civil penalties and criminalization, in the area of this new discovery is likely to thwart the momentum of basic research on genetic reprogramming and deter the enthusiasm and ability of researchers poised to make major new contributions in applying their findings to human health problems.

In no conceivable instance would research on genetic reprogramming involve cloning of human beings. Indeed, active, credible researchers and clinicians overwhelmingly regard cloning a human being as an unethical and reprehensible act. Last year, working through the Society for Developmental Biology, I spearheaded a voluntary moratorium on cloning human beings. This moratorium unequivocally states that we have no intention to clone human beings, where this is defined as ''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.'' To date, 15 additional scientific and medical societies, including the Federation of American Societies for Experimental Biology, the American Society for Reproductive Medicine, and the Society for the Study of Reproduction, together representing more than 60,000 reproductive, developmental, cell and molecular biologists, have endorsed this moratorium. Historical precedent (with recombinant DNA technology) indicates that a voluntary moratorium can deter activities that are potentially unsafe for humans. It is evident from recent events that anyone who advocates cloning human beings for any purpose will be subjected to ostracism and discredited scientifically. Therefore, I believe that the existing voluntary moratorium against cloning human beings is an effective means of regulating the behavior of U.S. scientists and physicians.

Presently, the fields of developmental biology and human genetics are at an exciting juncture, where many novel genes are being identified through the Human Genome Project and their functions during normal development are being understood for the first time. In addition, an understanding of how these genes interact with the internal and external environment of the cell is emerging for studies such as those giving rise to Dolly. Deriving the full benefits of these new insights for human health will require a dedicated and cooperative research effort by many scientists, including those who conduct research on human cells and tissues.

In conclusion, there is a great risk that anti-cloning legislation would deprive the American people of unprecedented human health benefits. I thus urge extreme caution in any legal sanctions, such as those included in S. 1599, which would have lasting detrimental effects on our ability to alleviate human diseases, and would also undermine the competitive abilities of U.S. scientists in our field.

Respectfully yours,

ROGER A. PEDERSEN, PH.D.,
Professor and Research Director, Reproductive Genetics Unit, Department of Obstetrics, Gynecology, and Reproductive Science.

Mrs. FEINSTEIN. There are new letters from industry groups. There is a very interesting letter from Genentech. Genentech is a huge biotech firm. Actually, biotechnology was spawned out of San Francisco and Genentech was one of the very first companies in the Nation to enter this area. They have a very cogent letter that states well their opposition. They point out, ''. . . deliberate and exercise caution and restraint in legislating this issue.''

I ask unanimous consent that the February 9 letter from the Biotechnology Industry Organization be printed in the RECORD.

There being no objection, it has been ordered to be printed in the RECORD, as follows:

REGARDING HUMAN CLONING LEGISLATION
TUESDAY CLOTURE VOTE: S. 1601, BOND/LOTT

FEBRUARY 9, 1998.

DEAR SENATOR: Tomorrow the Senate is scheduled to vote on cloture on S. 1601, the Bond/Lott human cloning bill. The Biotechnology Industry Organization (BIO) urges you to vote ''no'' on the cloture petition. BIO represents 760 biotechnology companies throughout the world engaged in research on diseases, the immune system, cell therapy, vaccines, drugs/biologics, antibiotics, and gene therapy.

The Bond/Lott bill is not ripe for consideration by the Senate. It was introduced on Wednesday of last week, no hearings have

been held on it and no mark-up in the two committees with jurisdiction have been held on it. Most important, the bill as drafted would have a dire impact on biomedical research completely unrelated to human cloning.

This is not a human cloning bill. This is a bill which bans the use of biomedical technology even if that use has nothing whatever to do with human cloning.

A ''no'' vote is a vote to protect biomedical research on deadly and disabling diseases.

There is no rush to legislate. The FDA has jurisdiction over Dr. Seed and any others. Violations of the FDA regulatory requirements carry draconian penalties. A ''no'' vote is a vote to proceed with caution to make sure that biomedical research is not harmed.

A ''no'' vote is a vote to restrict this bill to the human cloning issue.

A ''no'' vote is a vote to permit the Senate Labor and Senate Judiciary Committees, which have jurisdiction over the bills to take care to draft the legislation and confine it to the human cloning issue.

BIO believes that a human cloning experiment would be utterly unethical and unsafe. What we are writing about here is our views on the terms of the Bond/Lott bill, not the larger debate about human cloning.

Attached is a more detailed statement outlining our concerns about the Bond/Lott bill which was printed in the Congressional Record on Thursday. If you have any questions about our position, please feel free to call at 857–0244.

Sincerely,

NANCY BRADISH,
Director, Federal Government Relations.
CHARLES E. LUDLAM,
Vice President for Government Relations.

Mrs. FEINSTEIN. Mr. President, I ask unanimous consent that the January 28 letter from the Pharmaceutical Research and Manufacturers of America be printed in the RECORD.

There being no objection, the letter was ordered to be printed in the RECORD, as follows:

PHARMACEUTICAL RESEARCH AND,
MANUFACTURERS OF AMERICA,
Washington, DC, January 28, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR FEINSTEIN: I urge you to consider any legislative proposals to ban the cloning of an entire human being with great caution. The research-based pharmaceutical industry appreciates the widespread ethical and moral concerns about the possibility of creating a genetic duplicate of an existing (or previously existing) human being. We also share the view expressed by the National Bioethics Advisory Commission that such a procedure is unsafe.

For equally valid ethical, moral and safety reasons, we are concerned that some pending proposals would inadvertently harm patients with unmet needs and their families. The member companies of the Pharmaceutical Research and Manufacturers of America support the President's call for a voluntary moratorium on any cloning of an entire human being. However, the best help and heal patients, biomedical researchers need to be able to continue to clone human genes, cells and tissues. If not drafted with laser-precision, legislation to ban ''human cloning'' could—unintentionally, but heartbreakingly—stop life-saving and health-enhancing medical research.

The Food and Drug Administration has announced it will prevent any cloning of an entire human being. The FDA's assertion of regulatory authority eliminates any need for well-intended but risky haste. In your consideration of any legislative proposals, we urge you to protect patients and their families from unintended impediments to ethical, moral and safe biomedical research that does not involve any cloning of an entire human being, but does involve cloning human genes, cells or tissues.

Sincerely,

ALAN F. HOLMER,
President.

Mrs. FEINSTEIN. The California Biomedical Research Organization ''. . . urges you to support continuing debate about the potential negative impact of Senator TRENT LOTT's legislation.''

This is accompanied by, I would have to say, 30 campuses and companies. Ligand Pharmaceuticals, two letters for the RECORD. I ask unanimous consent that these letters be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

GENENTECH, INC.
San Francisco, CA, February 9, 1998.

Hon. CONNIE MACK,
Hart Senate Office Building, Washington, DC.

DEAR SENATOR MACK: I am writing with regard to legislative proposals currently pending in the Senate relating to cloning entire human beings. This vexing topic needs to be put into a larger perspective before the Senate votes on a bill, S. 1601, which was introduced only last week.

The biotechnology and research community has been very open and public about its support for the President's request for a voluntary moratorium on activities that could lead to the cloning of entire human beings. This exercise of responsibility in science is consistent with our long history of restraint in the pursuit of basic biomedical research. We do not plan or seek to clone entire human beings. In addition, we fully recognize the existence of various federal laws setting out the jurisdiction of the Food and Drug Administration which, when taken together, would bar the commercialization of cloning of entire human beings. Because of this moratorium and existing legal limitations on action, it is possible to deliberate and exercise caution and restraint in legislating this issue.

The reality of modern biomedical research is that it is difficult to predict in advance exactly how specific, even esoteric, areas of research will produce breakthroughs. As Michael Bishop (cancer researcher, Nobel laureate in medicine and my colleague from the University of California, San Francisco) spoke of this issue recently, in 1968 his work with Dr. Harold Varmus, and Professor Herb Boyer would have never been foreseen as leading to breakthroughs in recombinant DNA research and cancer genetics. Similarly, work done in the 1980s on transgenic animals by Dr. Phil Leder, of Harvard, and others, would not have easily been understood as being essential to the development of animal models that could facilitate dramatic advances in our ability to test new AIDS therapies.

It is also the case that with virtually every scientific advance there are voices that seek to delay legitimate, if misunderstood, advances in science. In the early 1970s, some government officials sought to vary virtually all recombinant DNA research out of exaggerated fears about the safety of the technology. Researchers and companies voluntarily adopted a moratorium on some research until more information was obtained. Fortunately, the calls for more radical local or federal regulation were rejected. The self-regulatory efforts by industry and the research community worked, and there were no significant safety issues to arise out of that research.

In the 1980s some critics advocated bans on transgenic animal research out of fear of science. These requests for a halt to research were often based on assertions of pseudoscience. Again, we are fortunate that Congress did not act to bar the creation of transgenic animals, which are now so commonly used in drug development, especially in AIDS research. In addition, transgenic animals may someday be used for the actual production of pharmaceutical compounds. This hope for pure protein production at a lower cost is yet to be realized, but if Congress had acted in the 1980s to end research, patients would have had that hope foreclosed.

Now Congress is faced with difficult decisions about how to react to a single experiment in sheep. Each side of the current debate has sincere motivations and convictions about its legislative approach. Senators Bond, Frist and others have bona fide concerns about cloning human beings and hope that their bill would not affect biomedical research. Yet, determining how to prohibit the act of cloning an entire human being has proven to be a daunting task. For a set of reasons outlined below, we prefer the approach taken in the bill, S. 1602, to that found in the bill currently pending, S. 1601.

Most importantly, in considering restrictions on scientific research in the private sector (as opposed to previously enacted limitations on the expenditure of federal funds), great care must be exercised. In addition to the legal rights of persons to free expression and inquiry in the private market, there is little precedent for imposing limitations on research except for reasons of safety or other narrowly crafted circumstances.

In this instance, there are multiple possibilities of promising research with somatic cells. Our hope in the research community is that this branch of research will lead to discoveries that permit us to develop new cures and treatments for serious and unmet medical needs. Some of our colleagues in academe have already begun exploring questions of how to turn on and off these somatic cells so that new biological material could be generated for transplantation and for other therapeutic purposes. At this point in the discovery process, it is not known exactly how to accomplish this therapeutic goal, but one possible way is to use the technique known as somatic nuclear cell transfer. Such research could, in some circumstances, involve conduct that would be permitted under S. 1602 and would be criminalized under S. 1. This difference (among others noted below) is the reason we prefer your bill.

There seems to be little dispute within the Congress about the current inappropriateness of using somatic nuclear cell transfer technology to create an embryo which is implanted into the uterus, with the goal being reproductive in nature. On the other hand, it is hard to understand why scientists should become criminals if they pursue legitimate new therapies for heart disease, cancer, diabetes, and other diseases, and if their research has no prospect or intent of creating an entire cloned human being.

Given our current state of knowledge, there is no reasonable prospect for creating a new human being unless an embryo is implanted into the uterus of a woman. Thus, the approach should be to adopt a bill that effectively bars what the political consensus

wants to prohibit, while simultaneously retaining the option of research that is aimed at new therapies, not at reproductive ends.

There are several other reasons to support the approach taken in S. 1602:

S. 1602 preempts inconsistent state laws. Given the rush to judgment in various states, the high likelihood for overlapping and inconsistent standards, and the clearly negative effect on interstate commerce, a federal standard is appropriate.

S. 1602, unlike S. 1601, uses a civil penalty structure that will be sufficient to deter unwanted conduct. If criminal penalties or asset forfeiture are threatened for research activities, there is likely to be a chilling effect on research in this entire area. Moreover, there are additional sanctions available under the Food, Drug and Cosmetic Act to address human cloning.

S. 1602 appropriately requires that Congress should review these limitations on research after a set period of time. This review could be facilitated if, using carefully drawn criteria, there was a balanced review of this area of research by a nonpolitical entity.

The suggestion in S. 1602 for international cooperation on this topic is welcome, as is the ratification of the authority of the jurisdiction of the Food and Drug Administration.

One final point, S. 1601 would establish a commission that could approach the bioethics questions associated with certain limited new somatic cell nuclear transfer technologies. This concept is worthy of serious consideration. As we approach scientific advances, it is important that we make sure that science reflects our basic human and ethical values.

The work done by existing entities, such as the Recombinant DNA Advisory Committee of the NIH, and the NIH-DOE Working Group on Ethical, Legal, and Social Implications of Human Genome Research, has advanced the public discussion. In this regard, the work already done by the President's Commission on the topic of cloning entire human beings has materially assisted the national debate on this topic. We leave to the political process questions of whether any such bioethics commission should be situated in the Executive Branch and who should exercise the appointment authority.

There are several caveats worth noting, however:

Past history, here and in Europe, suggests that there is a real risk that any such commission could inadvertently begin to function as a new regulatory entity and serve to delay the approval of new treatments for patients. This temptation should be avoided at all costs by explicitly limiting the role of the commission.

There is a risk that any new commission will be led by other political agendas into discussions that do not advance progress on improving human health. This temptation should also be avoided by narrowly circumscribing the commission's charter.

The composition of any commission should broadly reflect the best available thinking in science, law, and ethics. The mere prohibition on political officials serving on such a panel is not likely sufficient to prevent the politicization of the appointment process. There are, I understand, precedents that permit certain relevant professional societies to offer lists of nominees to an appointing authority. This approach would appear to mitigate the risk of an overly political appointment process.

In closing, let me thank you for having the special sensitivity and commitment to biomedical research to ask for greater deliberation and for crafting a more precise bill that seeks a uniform consensus about how to ban the cloning of entire human beings.

The issue before the Senate is: Can we simultaneously advance science and the search for cures for serious diseases while also barring the cloning of entire human beings? We believe that to foster further dialogue and deliberation can help achieve that common goal.

Sincerely,

ART LEVINSON,
President.

CALIFORNIA BIOMEDICAL
RESEARCH ASSOCIATION,
Sacramento, CA, February 9, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate, Hart Senate Office Building, Washington, DC.

DEAR SENATOR FEINSTEIN: On behalf of the CBRA Governing Board, I am writing to encourage your ''no'' vote on the cloture vote on S. 1601 scheduled for Tuesday, February 10, 1998. The Association urges you to support continuing debate about the potential negative impacts of Senator Trent Lott's legislation.

Somatic cell transfer technology is essential to continuing research into cures for some of our greatest human health threats—Parkinson's Disease, leukemia, diabetes, Alzheimer's disease and spinal coral injuries. Unintended consequences of this bill as currently written could threaten the future health of millions of Americans.

Please feel free to contact our office if you should need further information.

Sincerely,

SUZANNE NESS,
President.

MEMBERS (PARTIAL LIST)

Allergan
Alliance Pharmaceutical
ALZA Corporation
American Association for Laboratory Animal Science Northern, Orange County
San Diego, Southern and Palms to Pines Branches
American Cancer Society, California Division, Inc.
American Diabetes Association, California Affiliate
American Heart Association (Western States Affiliate and Greater L.A. Affiliate)
American Lung Association of California
Amgen
Bayer Corporation
Berlex Bio Sciences
BioDevices
Buck Center for Research in Aging
California Institute of Technology
California Medical Association
California State University: Long Beach, Pomona, Office of the Chancellor
California Veterinary Medical Association
Cedars-Sinai Medical Center
Charles River Laboratories
Children's Hospital Oakland Research Institute
Children's Hospital of Orange County
Chiron Corporation
City of Hope
Genentech
J. David Gladstone Institutes
Good Samaritan Hospital
Harbor UCLA Medical Center, Research and Education Institute, Inc.
Heartport
Huntington Medical Research Institutes
Isis Pharmaceuticals
Lawrence Berkeley Laboratory
Loma Linda University
NASA Ames Research Center
Palo Alto Medical Foundation
Roche Biosciences
Salk Institute for Biological Studies
San Diego State University
San Jose State University
Scripps Research Institute
Stanford University
The Parkinson's Institute
University of California: Berkeley, Davis, Irvine, Los Angeles, Riverside, San Diego, San Francisco, Santa Barbara, Santa Cruz, Office of the President
University of Southern California
Veterans Administration Medical Centers at: Loma Linda, Long Beach, Palo Alto, San Diego, San Francisco, Sepulveda, West Los Angeles.

LIGAND PHARMACEUTICALS,
San Diego, February 2, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate, Hart Senate Office Building, Washington, DC.

DEAR SENATOR FEINSTEIN: Ligand Pharmaceuticals Inc. of San Diego and its more than 300 employees, like other responsible members of the biomedical community, deplore the recent announcement by Dr. Richard Seed of his intention to clone a human being. We regard such an effort to be medically irresponsible and ethically abhorrent. Nevertheless, we are concerned that Congress and State legislatures, in understandable zeal to prevent Dr. Seed and anyone of a like mind from actually attempting to clone a human, will enact legislation that fails to distinguish between vital medical research and misguided human cloning. Therefore, we ask that you and other members of Congress carefully consider both the need for and the scope of any legislation addressing this issue before acting upon it.

With respect to whether legislation is needed, Ligand suggests a careful review of existing legislation to determine whether the U.S. Food and Drug Administration (FDA) already has the authority to regulate research related to and the actual cloning of a human being. Many, including the Biotechnology Industry Organization to which Ligand belongs, believes the FDA has this authority.

If legislation is deemed to be necessary, it should achieve two important ends. The first is that it should be drafted narrowly to deal with the cloning of a human being and not contain broad or even ambiguous prohibitions on cloning which would halt or disrupt vital medical research based upon widely accepted cloning techniques. Secondly, it should be preemptive of State laws governing cloning. Biomedical research is carried out, often with Federal funding, throughout the United States. This research occurs in public and private universities and in big and small companies. Much of this research is done on a collaborative basis involving entities in more than one state. Furthermore, every advance paves the way for further progress. The individual states should not, therefore, be allowed to erect a maze of law and regulation which unnecessarily regulates this area of research.

Congress, unlike the states, has ready access to the expertise of NIH, NSF, FDA and other sources of expertise that should be drawn upon before the drafting of appropriate legislation. That fact, and the interlocking nature of biomedical research, suggests that preemption is in the best interests of the country with respect to dealing with the issues raised by Dr. Seed. We believe this to be the case even though our Federal system rightly contemplates that the fifty states can exercise sovereignty in most areas, either in concert with, or in the absence of legislation at the national level.

Should you, therefore, have the opportunity to shape the debate on this important, and even emotional issue, we ask that you support hearings which address first whether new legislation is required. If a reasoned analysis of current law suggests that FDA is not able to effectively regulate, then

and only then should legislation carefully drawn based on input from the biomedical community be enacted.

Very truly yours,

WILLIAM L. RESPESS,
Senior Vice President.

LIGAND PHARMACEUTICALS,
San Diego, February 5, 1998.

Hon. DIANNE FEINSTEIN,
U.S. Senate, Hart Senate Office Building, Washington, DC.

DEAR SENATOR FEINSTEIN: I am writing on behalf of Ligand Pharmaceuticals Inc. asking that you oppose Senator Bond's Bill S. 1599 concerning human cloning. It is my understanding that this bill is to come up for a vote without hearings or mark-up. We believe that is an action that is too precipitous and could result in legislation which will adversely impact the biomedical industry.

I wrote to you on February 2, 1998 expressing opposition to the announcement by Dr. Richard Seed to engage in an effort to clone a human being. However, legislation or regulation to ban such activity must be carefully drawn so as not to inhibit legitimate research. Therefore, it is essential that hearings be held on any bill to permit testimony by scientists, representatives of the biomedical industry, and others potentially affected by such legislation to be heard on the specifics of any bill. This is not the time for a justifiable rush to judgment on Dr. Seed's announced intention to result in hastily conceived legislation which may do as much harm as good. Research on cloning and the use of cloning techniques are important to the progress of medical science. While Congress should move with deliberate speed, this is not the occasion to act outside of the usual congressional scheme of engaging in hearings before appropriate committees before taking action on matters of such import.

In my letter of February 2, 1998, I suggested that Congress first look to determine whether the FDA already has the authority to regulate in this area and, only if it is persuaded that the FDA lacks such authority, to undertake to draft legislation. I still believe that is the most appropriate process.

Very truly yours,

WILLIAM L. RESPESS,
Senior Vice President.

Mrs. FEINSTEIN. Mr. President, let me be very clear. Every letter that is coming in says: Stop, consider, proceed cautiously; this bill would be harmful; it would stop vital research. What is the rush, since the FDA has asserted jurisdiction and the scientific community has engaged in a moratorium? Why proceed like this in such haste, straight to the floor?

Only two letters have come in saying, proceed like this: One from the Christian Coalition, and the other one is from the National Right to Life Committee, two letters. The entire scientific community says, go slow, define your terms, know what you are doing.

Let me share with you what I understand this technology is. Let's say a somatic cell were taken out of my tissue. The nucleus of that cell is removed and is entered into an egg cell and fused. That cell, once fused, begins to divide and create more cells. The only way that cell can produce a human being is if it is put into a human uterus. Otherwise, it cannot produce a human being. We don't even know if it will produce a human being if it is put in a uterus. There is only one known instance in an animal, Dolly, which now Science magazine has challenged in a major way. But what we do know is that those stem cells, because of their DNA, can clone tissue.

For example, a third-degree-burn patient who may reject a skin graft may some day get a skin graft made from his or her own cells and will not reject it. My husband, Bert Feinstein, died of colon cancer and liver cancer. What a miracle if those cells could have been used to come up with a cancer treatment that would have prevented his death. That is really where we are. That is what we hope for.

There are no definitions in the bill. We don't know what they call a somatic cell. We don't know what they call an embryo. The bill does not define oocyte. But the point is, we have to know, and these terms have to be spelled out in the legislation.

The bill says, if there is this stem tissue research, it is illegal, and the scientists have a 10-year sentence.

So what we are begging, imploring, respectfully asking the distinguished majority leader is, please, let's not proceed tomorrow. Let's observe the regular order. Let's go to committee. Let Senator KENNEDY and I have an opportunity to present our bill. Let's have the majority leader, Senators BOND and FRIST, whom I respect, have an opportunity to present their bill. Let's discuss it and see what is best. Then at least we have heard everybody with knowledge.

Let me be clear. I want a bill. I want a carefully crafted bill. I want this Congress to act to ban the cloning of human beings.

I thank the Chair. I yield the floor.

Mr. GRAMS addressed the Chair.

The PRESIDING OFFICER. The Senator from Minnesota.

Mr. GRAMS. Mr. President, I ask unanimous consent to be able to speak as if in morning business for 10 minutes.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. GRAMS. Thank you very much.

FEDERAL SURPLUS PROPERTY IMPROVEMENT ACT OF 1998

Mr. GRAMS. Mr. President, I rise today to introduce the ''Federal Surplus Property Improvement Act of 1998'' and ask my colleagues for their support of this legislation.

Congressional oversight of our country's surplus personal property donation program may not be a topic of debate in the Senate, but it is of great importance to my constituents and the 70,000 recipients of surplus federal personal property in all of our states.

Members of Congress and state and local officials all have an obligation to see that the government distributes this property fairly and equitably, ensuring accountability to the taxpayers.

Too often, federal agencies forget that the owners of this property are the American people—the federal government is merely its public custodian.

As my colleagues may know, once a piece of federal personal property such as a typewriter, chair or vehicle is declared ''excess'' by a federal agency, it is offered to other federal agencies for their use. If no other agency can utilize the property, it is donated to the states or other public agencies.

The current system of disposal is based on reforms signed into law by President Ford over twenty years ago.

The reforms to the Federal Property and Administrative Services Act of 1949 enacted in 1976 were based on concerns that as surplus property distribution programs multiplied, confusion and inefficiency on the part of the federal government grew as well.

Congress realized that the various state agencies and the General Services Administration should work together to ensure a fair and equitable allocation of surplus federal property to eligible recipients.

Under this new partnership, states would have a greater role over distribution, while GSA would guide the overall system on the federal side.

Mr. President, the 1976 reforms also broadened the pool of eligible recipients to include parks and recreation, conservation, public health and public safety.

Since then, each state agency for surplus property has worked with neighboring state agencies and GSA to provide the equipment, supplies and material used to educate our children, maintain roads and streets, keep utility rates reasonable, train the workers of tomorrow, protect families from crime, and during natural disasters, treat the health of our nation's sick and needy.

Through the efforts of the state agencies for surplus property, eligible recipients have acquired impressive pieces of equipment such as trailers, forklifts, fire trucks, aircraft, boats and generators.

The original acquisition value of property distributed through the U.S. state agencies for surplus property totaled over $537 million in fiscal year 1997. Over the last few weeks, I have heard from many recipients of surplus federal property and ask unanimous consent that their letters be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

DEPARTMENT OF PUBLIC SAFETY,
STATE PATROL DIVISION,
St. Paul, MN, January 13, 1998.

Senator ROD GRAMS,
Dirksen Senate Office Building, Washington, DC.

DEAR SENATOR GRAMS: For the past several years the flight of the Minnesota State Patrol has called upon the services of the state surplus property program, a division of the Department of Administration, for various pieces of equipment needed to accomplish our mission. In more recent years my contact person at surplus property has been Mr. Gene Glaeser who now heads up that program. Any time I have needed something,