

Human Cloning and Human Dignity: An Ethical Inquiry

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The President's Council on Bioethics
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Chapter Eight

Policy Recommendations

The Council's formation of its policy recommendations is shaped by the following considerations:

First, our recognition of both the scientific and technological and the human and ethical contexts of human cloning, considered in Chapters One through Four.

Second, our awareness that human cloning is but a small part of a large and growing field of biomedical science and technology based on the convergence of developmental biology and genetics; and our awareness that this field offers relief for human disease and suffering while impinging also upon human procreation and family life, regard for nascent human life, and the relations between science and society.

Third, our ethical assessments of cloning-to-produce-children and cloning-for-biomedical-research, as presented in Chapters Five and Six.

Fourth, our ethical and prudential assessment of the strengths and weaknesses, benefits and harms, of the various policy options, as presented in [Chapter Seven](#), including a serious effort to judge – in the face of unavoidable ignorance about what the future may bring – what will likely be gained and what will likely be lost should we pursue one path rather than another.

Fifth, our assessment of recent congressional efforts to develop national legislation on human cloning, and the reasons for their failures to date.

Sixth, our respect for the strongly held moral views of those with whom we do not agree, both on the Council and in the larger society.

Seventh, our desire to seek a wise and prudent course of action that does justice to our deepest moral concerns while preserving our nation's thriving biomedical science and technology.

I. The Council's Points of Departure in Formulating Policy Recommendations

(a) The Council regards the country's public policy decision about human cloning as a matter of great moment. It is important not only for its effect on the prospects of human cloning but also for what it will say about our democratic society's ability to govern the course of technological innovation and use in the name of things we as a nation hold dear.

(b) The Council is unanimous in opposing cloning-to-produce-children. We hold that the likely harms and injustices to prospective cloned offspring and the women involved, as well as to their families and the broader society, are sufficiently great and sufficiently likely as to justify governmental action to prevent cloning-to-produce-children.

(c) Two general approaches have thus far been proposed by those seeking to prevent cloning-to-produce-children. The first would stop the process at the first step by banning the creation of any cloned embryos. The second would stop the process at the initiation of a pregnancy by banning the transfer of a cloned embryo into a woman's uterus (or other gestational environment). If the question of cloning-to-produce-children were considered in isolation, the first and stricter ban would be most prudent: if it were illegal to produce cloned embryos, they would be less likely to be created and hence less likely to be available for attempts at pregnancy. But such a comprehensive ban would preclude cloning-for-biomedical-research, research favored by most scientists and patient advocacy groups, but about which the public is deeply divided.

(d) Regarding the ethics of cloning-for-biomedical-research, the Council is of many minds. Among Members who *approve* the practice – all of whom strongly endorse the worthiness and importance of the research and its enormous potential for medical therapies – a few approve it unconditionally and with enthusiasm, but more approve it with moral concern. Among the latter are a few Members who, though approving it in principle, are reluctant at this time to approve it in practice, for one or more of the following prudential reasons: the current lack of sufficient scientific evidence to sustain claims of the *unique* value of *cloned* embryos for the desired researches; the absence of proper regulatory institutions and mechanisms to enforce regulations, held by these Members to be a *prerequisite* for allowing the research to go forward; and an unwillingness to alienate large numbers of our fellow citizens who oppose this research on moral grounds.

Among Members who *disapprove* of cloning-for-biomedical-research, most oppose it permanently because they think it is immoral to create human embryos for purposes that are foreign to the embryos' own well-being and that necessarily require their destruction. Others oppose such cloning permanently because they hold that society (and not only the embryos) will suffer irreversible moral harm by crossing the boundary that allows nascent human life routinely to be treated as a natural resource. Some Members oppose permitting the practice because they fear that it will greatly increase the likelihood that cloning-to-produce-children will occur or because they think that a law banning only the transfer of a cloned embryo into a woman's uterus would be unenforceable. Some Members oppose the practice also because they think that the scientific case for proceeding has not yet met the burden of showing why this research is *necessary* and of sufficient importance to justify crossing the moral barrier of creating nascent human life for the purpose of experimentation.

(e) Were we to indicate where we stand on the ethical and prudential assessments of the two forms of human cloning, *each considered independently*, we would line up as follows:

	<u>Permit Now</u> <u>(with Regulation)/u></u>	<u>Moratorium</u>	<u>Ban</u>
To produce children	0	0	17
For biomedical research	7ⁱ	3	7

Where we stand on the *public policy options* – in which both cloning-to-produce-children and cloning-for-biomedical-research are *necessarily considered together* – we shall indicate below, in our recommendations.

(f) The Council notes that research on stem cells, both embryonic and adult, is still in its very early stages. Work with both embryonic and non-embryonic stem cells has led to some very promising results,² and it is impossible to predict which avenues of research will prove most successful in providing basic knowledge of disease processes and tools for regenerative medicine. It is likely that different diseases or research problems will require different approaches. The Council also notes that the possible benefits of cloning-for-biomedical-research are, at the present time, uncertain and undemonstrated. There is little evidence from animal experimentation to indicate, one way or the other, whether work with embryonic stem cells derived from *cloned* embryos offers *unique* benefits not otherwise available. Only further research can answer these questions. These uncertainties about the future should cut in two directions. They should temper claims of medical miracles just around the corner, placing a high demand for cautious accumulation of evidence. They should also temper assertions that biomedical researchers can pursue their goals without using human embryos because other approaches that are morally nonproblematic will surely prove successful.

(g) The Council notes, with special emphasis, that proposals to engage in cloning-for-biomedical-research necessarily endorse the creation of (cloned) human embryos *solely for the purpose of such research*. Public policy that specifically promoted this research would thus *explicitly and officially approve* crossing a moral boundary.³

(h) The Council also notes that, at the present time, human embryo research proceeds unregulated in commercial biotechnology companies and with local oversight in university – based laboratories (under the governance of institutional review boards [IRBs], whose oversight is generally stringent). In addition, federally funded research on human embryonic stem cell lines is now proceeding, under guidelines established by the National Institutes of Health pursuant to President Bush's decision of August 9, 2001. Any legislative action on human cloning, including cloning-for-biomedical-research, would not directly affect this other valuable research, including all research on embryonic stem cells derived from IVF embryos. In addition, a ban on cloning-for-biomedical-research would leave undisturbed the freedom that scientists (in the private sector) now have to create embryos solely for research by means of IVF, a practice that lacks official sanction and that has drawn public criticism but that is nonetheless legal (except in those few states that have banned this practice).

(i) Finally, in viewing congressional efforts in 1998 and in 2001-2002 to enact a legislative ban on human cloning, the Council notes the failure to enact a ban on cloning-to-produce-children—a ban that nearly everyone supports – because of irreconcilable differences between the supporters of cloning-for-biomedical-research and the opponents of any research that destroys (cloned) human embryos. Failure to prohibit cloning-to-produce-children, especially after protracted debate on the issue, amounts tacitly to public willingness to allow this practice to remain legal. We are accordingly interested in seeking a policy proposal that would, among other things, overcome this impasse.

Below are the two alternative proposals to which Council Members have given their support.

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II. First Proposal

Ban on Cloning-to-Produce-Children, Moratorium on Cloning-for-Biomedical-Research (Policy Option 6 of [Chapter Seven](#)).

Call for a federal review of current and projected practices of human embryo research, preimplantation genetic diagnosis, genetic modification of human embryos and gametes, and related matters, with a view to recommending and shaping ethically sound policies for the entire field.

We recommend a congressionally enacted ban on all attempts at cloning-to-produce-children and a four-year national moratorium (a temporary ban) on human cloning-for-biomedical-research.⁴ These measures would apply everywhere in the United States and would govern the conduct of all researchers, physicians, institutions, or companies, whether or not they accept public funding. We also recommend that, during this moratorium, the federal government undertake a thoroughgoing review of present and projected practices of human embryo research, preimplantation genetic diagnosis, genetic modification of human embryos and gametes, and related matters, with a view to proposing, before the moratorium expires, an ethically acceptable public policy to govern these scientifically and medically promising but morally challenging activities. Several reasons converge to make this our recommended course of action at the present time. Members of the Council who support this recommendation do so for different reasons; some individual Members do not endorse all the concurring arguments given below.

A. Strengths of the Proposal

1. Bans Cloning-to-Produce-Children

The strong ethical verdict against cloning-to-produce-children, unanimous in this Council (and in Congress) and widely supported by the American people, is hereby translated into clear and strong legal proscription. The nation's moral conviction is expressed with force of law through the people's representatives. To be sure, such a ban (like any proscription) could be violated, but it could not be violated with impunity. By reflecting the pervasive moral judgment of the community, this ban would also serve as a source of moral instruction and a sign that we can exercise some control over the direction and use of biotechnology. Moreover, were we at this time to settle for a mere moratorium on cloning-to-produce-children, we might lose what may be our society's best chance to get a permanent ban on this practice before it occurs and to

declare our opposition to the idea of designing and manufacturing our children. We would lose this precious opportunity to demonstrate that we are able to practice democratic self-rule regarding biotechnology and that we can establish firm guidelines for the moral practice of science and technology.

2. Provides a Highly Effective Means of Preventing Cloning-to-Produce-Children

The proposal's ban on all efforts to produce cloned children is a primary goal. The moratorium on cloning-for-biomedical-research (while desired by many for its own sake) would also provide an additional safeguard against cloning-to-produce-children during the next four years, beyond what would be available in a proposal that banned only the implantation of cloned embryos but left cloning-for-biomedical-research unregulated. By stopping all human cloning for four years, this proposal would prevent the creation of cloned embryos, thus decreasing the chances that anyone will be able to attempt to produce a cloned child. The moratorium would also permit time to explore other effective safeguards against this possibility that might be put in place should the moratorium not be reenacted after four years.

3. Calls for and Provides Time for Further Democratic Deliberation

A true national discourse on cloning-for-biomedical-research has not yet taken place. Certainly it has begun. But no consensus has been reached, no clear majority has appeared, and only in rare cases have the various parties to the debate acknowledged (as we have attempted to do in this report) that their opponents are also defending important and shared values. The matters at stake are too significant to be settled now – either by proceeding with the research with minimal delay or by banning the research outright – when the nation is so divided and when the implications of proceeding or not proceeding are as yet unclear. Under these circumstances, the proper attitude is modesty, caution, and moderation, expressed in a temporary ban to be revisited when time and democratic argumentation have clarified the matter. By allowing the debate and deliberation to continue, a moratorium would offer the following specific benefits:

(a) Seeking consensus on crossing a major moral boundary. To decide to create nascent human life expressly for the purpose of experimentation and use is to cross a significant moral boundary. It goes beyond permitting the use of extra embryos, created for reproductive purposes, that are stored in IVF clinics and otherwise destined for destruction. Yet the meaning and moral propriety of crossing such a boundary are today hotly contested. Many people believe that even the earliest stages of a new human life should be protected against such use and destruction and would oppose such a practice at any time. Many others favor permitting the practice, but only under conditions of strict governmental regulation that would guard against abuses and reflect measured respect for the embryonic life that is being sacrificed. Our society needs more time to explore the full moral significance of taking such a step, to debate the moral and practical issues involved, and to seek a national consensus – about *all* research on early human embryonic (and fetal) life (not just that formed through cloning techniques).

(b) Gaining needed scientific evidence. The moratorium on all human cloning will allow time for scientists to produce hard evidence from cloning research in animals and animal disease models – evidence not available today. Such evidence, if available, would support their present claims regarding the value of cloning-for-biomedical-research, both for understanding normal and disease processes and for finding new treatments. The moratorium will also provide time

to see whether cloning research will be indispensable for these goals or whether there are equally fruitful but morally nonproblematic alternatives to cloning, (such as, for example, work with adult stem cells or multipotent adult progenitor cells or work that would solve the transplant rejection problem for tissues derived from ordinary embryonic stem cell lines).

(c) Promoting fuller and focused public debate, leading to a better-informed decision. For people who believe that the human embryo must not be violated, and who would therefore advocate a permanent ban on cloning-for-biomedical-research, this moratorium offers a partial step in what they deem to be the right direction, and an opportunity to make further progress through moral persuasion and political action. By preventing cloning-for-biomedical-research for a while, this proposal takes seriously their warnings of possible harms from allowing such research. But it also calls on them to make those warnings more concrete and convincing, by arguing their case in the proper context of embryo research in general and not just that of cloning. Meanwhile, those who now do (or later might) support cloning-for-biomedical-research would also find benefits in this moratorium. It would allow them the opportunity to make their full case and win over new supporters, to prepare the ground properly (using new scientific evidence) for agreement on the merits of research when the time to decide comes, and to devise safeguards against likely abuse and misuse. The public decision made after the moratorium expires would be better informed and more fully considered as a result of such debate.

(d) Preserving a decent respect for the deep moral concerns of our fellow citizens. A large number of Americans, perhaps even a majority, hold that it is deeply immoral to create what they regard as new human life for the purposes of experimental research that involves the destruction of that life. We should be very reluctant to ride roughshod over these views and to practice contempt for our fellow citizens, especially for the sake of promised benefits that are at this point highly uncertain and speculative, and especially when the *necessity* of this approach to the treatment of disease has not been demonstrated and when the public debate has been so brief. A moratorium will enable us to respect and assess these moral concerns while we look to science to provide alternatives that do not require crossing this moral boundary. Should the community decide, after the ongoing deliberation made possible by the moratorium, to cross it, no group would have grounds to complain that its views had been treated with contempt. Also, we could have in the meantime established new boundaries and devised effective regulations that could give genuine assurance that additional and more problematic practices would be forestalled or avoided altogether.

4. Provides Time and Incentive to Develop Adequate Regulation Regarding Human Cloning

Because of the widespread concern to prevent cloning-to-produce-children, those who support cloning-for-biomedical-research bear the burden of devising and instituting adequate oversight and regulatory mechanisms that would effectively reduce the risk that embryos cloned for research might be used in efforts to produce cloned children. In addition, regulatory guidelines and mechanisms, devised and installed in advance, are called for regarding cloning-for-biomedical-research itself. Because everyone has a stake in how nascent human life is treated, serious efforts are necessary to protect the public interest. *Cloning-for-biomedical-research, if and when it is to be allowed, must be preceded by the formulation of proper rules and the institution of effective safeguards.* Devising effective regulatory instruments takes time, and a moratorium could afford regulation proponents that time. Equally important, in the absence of a moratorium, *few proponents of the research would have much incentive to help institute an effective regulatory system.* And a governmental policy simply to withhold federal

funding pending the development of a regulatory regimen would have no effect on the conduct of this research in the private sector. The following matters, at a minimum, would need to be considered by any serious program of regulation:

(a) *Comprehensive scope.* Regulations that would cover all cloning research, whether done with public or private funds, whether done in universities, private research institutes, assisted reproduction clinics, or biotech companies.

(b) *Protections for egg donors.* Regulations governing the safety and consent of the oocyte donors, with safeguards against improper inducements and exploitation of poor or otherwise vulnerable women.

(c) *Transparency and accountability.* Regulations permitting full public knowledge and scrutiny of what is being done with cloned embryos produced for research purposes.⁵

(d) *Equal access to benefits.* Guidelines to promote equal access to the medical benefits that flow from such research.

The very process of proposing such regulations would clarify the moral and prudential judgments involved in deciding whether and how to proceed with this research, as well as how cloning-for-biomedical research relates to other areas of embryological, reproductive, and genetic experimentation.

5. Calls for and Provides Time for a Comprehensive Review of the Entire Domain of Related Biotechnologies

A moratorium on cloning-for-biomedical-research would enable us to consider this activity in the larger context of research and technology in the areas of developmental biology and genetics. The practices of human embryo research and preimplantation genetic diagnosis are largely unregulated by the federal government, or regulated in a haphazard, uncoordinated way. These practices, along with those of assisted reproduction, are largely unstudied: we lack comprehensive knowledge about what is being done, with what success, at what risk, under what ethical guidelines, respecting which moral boundaries, subject to what oversight and regulation, and with what sanctions for misconduct or abuse. If we are to have wise public policy regarding these scientifically and medically promising but morally challenging activities, we need careful study and sustained public moral discourse on this general subject, and not only on specific narrowly defined pieces of the field. To achieve this goal, the moratorium here proposed should be accompanied by a concerted review of the entire field, with the aim of establishing permanent institutions to advise and shape federal policy in this arena.

The President's Council on Bioethics stands ready to undertake the preliminary steps of such a process and to provide advice on further steps. As part of our ongoing inquiry, we intend to continue to study various models of oversight and regulation of biomedical research and technology, both professional and governmental, that are used in the United States and abroad. As the necessary efforts will likely lead beyond the authority, scope, and perhaps also the duration of this advisory Council,⁶ we shall be especially interested in recommendations for devising a more permanent national agency or institution, with broad oversight, advisory, and decision-making authority,⁷ that could emerge before the expiration of the four-year moratorium here proposed. Such a body could provide much-needed understanding and national guidance on these vitally important subjects. Progress toward creating such a body

would ratify and perpetuate the deliberative goals of the moratorium.

6. Provides Time to Garner Long-Term Respect and Support for Biomedical Research and to Reaffirm the Social Contract between Science and Society

A moratorium, rather than a lasting ban, signals a high regard for the value of biomedical research and an enduring concern for patients and families whose suffering such research may help alleviate. By providing time to consider whether and how regulations might govern research in this morally troubling area, the moratorium invites the scientific, medical, and industrial communities into the activities of devising boundaries that they themselves would willingly respect. Such responsible behavior of biomedical researchers would go a long way to protect them against a public backlash should some less responsible scientists or technologists engage in practices repugnant to community standards or should some of their experiments result in great harm to some human subjects. It would reaffirm the principle that science can progress while upholding the community's moral norms. It would reassure researchers that any public moral restrictions on their activities will be rare, strictly limited, and carefully drawn. It would reassure the community that there is to be no slippery slope toward significant interference with the progress of beneficial biomedical research, the treatment of human diseases, or the moral uses of biomedical technologies. Friction between scientists and the wider community, aggravated by precipitate decision, would be reduced. The community's moral support for science and biomedical technology would be reaffirmed, and, as a result, the long-term interests of patients, families, and the entire society could be better served.

B. Some Specifics for the Legislation

Drafting the legislation that would give effect to this proposal lies beyond the scope and competence of the Council. Yet the following considerations would seem to be indispensable for a well-drafted and effective statute.

1. Broad Coverage

The ban and moratorium should cover everyone, corporations as well as individuals, private as well as public institutions.

2. Narrowly Drafted

The statute should be very narrowly drafted, making sure that only the human cloning actions in question are proscribed, and indicating explicitly other research and assisted-reproduction practices that will not be in any way affected by the ban or moratorium.

3. Temporary

Regarding the moratorium on cloning-for-biomedical-research, in the event that Congress takes no further action after four years, the moratorium should lapse.

C. Conclusion

The proposal we recommend is, admittedly, a compromise, requiring some give on both sides of the national debate if it is to be enacted. But it is by no means merely a compromise. On the contrary, it is perfectly warranted by the state of public opinion and justified by the supreme

value in our democracy of informed and deliberate decision in matters of great moment. If enacted, it would establish a permanent ban on cloning-to-produce-children, a practice that the nation overwhelmingly opposes. And it would not prematurely settle the equally important question of cloning-for-biomedical-research.

As already noted, this proposal accurately reflects the state of the public discussion of human cloning. There is broad agreement that cloning-to-produce-children should be banned, but there is deep disagreement and uncertainty regarding whether and how to proceed with cloning-for-biomedical-research. Such uncertainty calls for more discussion, more data, and more time – things a moratorium would provide. In proposing the combination of a ban on cloning-to-produce-children and a moratorium on cloning-for-biomedical-research, we do not imply that we hold one form of cloning to be worse than the other, but rather that the state of the public debate is such that a clearly-agreed-upon course of action presents itself in the one case, but more time and deliberation are called for in the other. Even some of us who see merit in proceeding with cloning-for-biomedical-research worry that cloning-for-biomedical-research may turn out to be morally worse than cloning-to-produce-children, at least in magnitude, especially should it lead to a routinized practice of embryo cultivation and the growth of nascent human life for body parts. But given the present state of the public discussion and the dearth of scientific evidence, the Council has not reached consensus on how to formulate a permanent policy on this matter at this moment, and the American people are apparently divided on the subject.

The proposal we have offered is not just an acknowledgement of the current lack of consensus. It is intended to advance the discussion toward an informed decision by forcing both sides to argue for their positions clearly and openly. A moratorium means that neither side would be free to cling to the status quo and avoid presenting its full case for public discussion.

On the one hand, the moratorium would permit and require the research community to provide the public with more information about the desirability and necessity of the research, and to indicate how it can go forward within proper limits and respectful of communal norms. It will also provide time and incentive for researchers to seek out and invest in alternative technological approaches that are morally nonproblematic. It may well be that when Congress revisits the issue after the moratorium expires, the facts on the ground may show no unique or compelling need for cloning-for-biomedical-research, and morally nonproblematic alternatives may have been discovered. Yet the ban on cloning-to-produce-children would remain in place regardless of what happens on the research front.

On the other hand, the moratorium would permit and require the community concerned about defending the inviolability of embryonic human life to continue the moral argument in the hope of persuading the broader society to desist. That argument, we point out, has to be about embryo research in general, and not just about cloned embryos in particular. With cloning-to-produce-children prohibited and hence off the table, the debate could focus honestly and fully on this central question.

We acknowledge the concerns raised by opponents of this proposal, who worry that even a four-year moratorium on cloning-for-biomedical-research cuts off urgently needed investigation, and that prominent scientists may be tempted to leave the United States for countries without such restrictions on cloning research. These are understandable worries, but we believe they are misplaced and are not sufficient to force an immediate decision on this subject.

First, the promise of this research is for now purely speculative, and no significant evidence from animal research has presented itself that might demonstrate that this (to many people) morally disquieting or objectionable practice is in fact *necessary* for the goals that researchers aim to serve, or that adult stem cells cannot provide equally good models for studying inherited diseases, or that other routes are not more effective in addressing the transplant rejection problem.

Second, there is more to this matter than scientific and medical progress. We ask proponents to recognize the moral hazards that such research would be unleashing. Treating nascent human life as a natural resource (or even, more respectfully, as a *human* resource to which we ought to feel indebted) is morally troubling, and there is a clear and present danger that it could lead us down a path where our reverence for life may be imperiled. We would therefore ask proponents of this research and the public-at-large to keep these moral concerns in mind as we try to develop a sound public policy for the whole area of embryo research. We think that the moratorium provides needed time to do this right.

Finally, while it is possible that a few scientists will leave the country if a moratorium is enacted, the vast majority will not. We have examples at the state and national levels (for instance, Michigan and Germany) where highly restrictive laws banning all human cloning have been enacted yet where the biotechnology industry is thriving. We have confidence that this robust field will continue to grow, including the area of stem cell research from sources other than cloned embryos (Indeed, several other countries, including France, Italy, Norway, South Korea, and Canada, permit work on embryonic stem cells but do not allow cloning-for-biomedical-research). Moreover, succumbing to the threat that some researchers might leave would not be a worthy way of making such a crucial moral decision. A scientist, like any other citizen, may choose to leave the United States for many different reasons. But there is no reason to assume that good scientists will not be able to work with and within the moral boundaries of the communities of which they are members and whose blessings and support they enjoy.

We believe that a permanent ban on cloning-to-produce-children coupled with a four-year moratorium on cloning-for-biomedical-research would be the best way for our society to express its firm position on the former, and to engage in a properly informed and open democratic deliberation on the latter. Moreover, combined with a systematic review at the federal level of the general field of embryo, reproductive, and genetic research and technology, this proposal would enable our society to think more comprehensively about how we should deal not just with human cloning but also with other vitally important areas of biotechnology. Ethical principles and boundaries need to be established; regulatory mechanisms need to be considered and devised; and ways must be found to give guidance to biomedical researchers and technological innovators so that beneficial research may proceed while upholding the moral and social norms of the community. The decision before us is of great moment and importance. Creating cloned embryos for any purpose requires crossing a major moral boundary, with grave risks and likely harms, and once we cross it there will be no turning back. Our society should take the time to do it right and to make a judgment that is well-informed and morally sound, respectful of strongly held views, and representative of the priorities and principles of the American people. We believe this proposal offers the best means of achieving these goals.

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III. Second Proposal

Ban on Cloning-to-Produce-Children, with Regulation of the Use of Cloned Embryos for Biomedical Research (Policy Option 3 of [Chapter Seven](#)).

We recommend a congressionally enacted ban on all attempts at cloning-to-produce-children while preserving the freedom of cloning-for-biomedical-research. We recommend the establishment of a system of oversight and regulation that would permit cloning-for-biomedical-research to proceed promptly, but only under carefully prescribed limits. These measures would apply everywhere in the United States and would govern the conduct of all researchers, physicians, institutions, or companies, whether or not they accept public funding. In addition, we recommend that the federal government undertake a thoroughgoing review of present and projected practices of human embryo research. Several reasons converge to make this our recommended course of action at the present time. Members of the Council who support this recommendation do so for different reasons; some individual Members do not endorse all the concurring arguments given below.

A. Strengths of the Proposal 1. Bans Cloning-to-Produce-Children

The strong ethical verdict against cloning-to-produce-children, unanimous in this Council (and in Congress) and widely supported by the American people, is hereby translated into clear and strong legal proscription. The nation's moral conviction is expressed with force of law through the people's representatives. To be sure, such a ban (like any proscription) could be violated, but it could not be violated with impunity. By reflecting the pervasive moral judgment of the community, this ban would also serve as a source of moral instruction and a sign that we can exercise some control over the direction and use of biotechnology. Moreover, were we at this time to settle for a mere moratorium on cloning-to-produce-children, we might lose what may be our society's best chance to get a permanent ban on this practice before it occurs and to declare our opposition to the idea of designing and manufacturing our children. We would lose this precious opportunity to demonstrate that we are able to practice democratic self-rule regarding biotechnology and that we can establish firm guidelines for the moral practice of science and technology.⁸

2. Provides an Effective Means of Preventing Cloning-to-Produce-Children

Statutory prohibition on the transfer of a cloned human embryo to a woman's uterus, backed by heavy penalties, would provide a sufficient deterrent for anyone contemplating cloning-to-produce-children. Cloned embryos created for research could, it is true, possibly get into the hands of those who would attempt to use them to produce cloned children. But the regulatory mechanisms and guidelines governing cloning-for-biomedical-research, provided for by this proposal (see below), will greatly minimize the likelihood of such an occurrence. And anyone who attempted to clone a child could not claim the credit for any successes without incurring prosecution. Even if slightly less foolproof than a ban that also blocked the creation of cloned embryos, this is a sufficiently effective means for preventing cloning-to-produce-children.

3. Approves Cloning-for-Biomedical-Research and Permits It to Proceed without Substantial Delay

Here is the major benefit to be obtained from this proposal (benefits foreclosed by the First Proposal). This proposal would provide clear congressional endorsement of the importance of

proceeding with cloning-for-biomedical-research. This potentially very valuable research, promising for all the reasons enumerated in [Chapter Six](#), Part III ("The Moral Case for Cloning-for-Biomedical-Research") could now go forward without substantial delay using *human* cloned embryos and the stem cells and tissues derived therefrom. Uncertainty about the potential of this research can only be overcome by doing the research. It will be critically important to compare directly the advantages and disadvantages of adult stem cells, embryonic stem cells from IVF blastocysts, and embryonic stem cells from cloned blastocysts side by side in the same laboratory. Regardless of how much time we allow, no amount of experimentation with animal models could provide the essential and urgently needed understanding of *human* diseases. Moreover, the special and possibly unique benefits of stem cell research using *cloned* embryos (see [Chapter Six](#), Part III) cannot be obtained using embryos produced by in vitro fertilization. The possible benefits to potentially millions of patients are so great that we think they should be pursued as soon as possible (under proper guidelines and regulations; see next point). While not disturbing the current policy on embryo research (which permits federal funding for research only on certain designated stem cell lines), this proposal explicitly eschews federal legal bans on new approaches to the revolutionary possibilities of regenerative medicine.

4. Establishes Necessary Protections against Possible Misuses and Abuses, Thus Paying the Respect Owed to Embryos Sacrificed in the Research

Unlike those human cloning bills, recently considered by Congress, that would permit cloning-for-biomedical-research, this proposal takes seriously the special respect owed to nascent human life as well as the moral hazards involved in this research, and it proposes concrete steps to prevent or minimize them. While such regulation will not satisfy those who believe that all such research is morally wrong, it will give concrete expression to our view that human embryos are never merely a *natural* resource, and that the special respect owed to them as *human* resources must be reflected in limits on what we may do with them. In addition, such regulation may succeed in assuaging everyone's worst fears about where this research might lead.⁹

Because of our concern to prevent cloning-to-produce-children, we call for adequate oversight and regulatory mechanisms to effectively reduce the risk that embryos cloned for research might be used in efforts to produce cloned children. In addition, we welcome regulatory guidelines and mechanisms, devised in advance, regarding cloning-for-biomedical-research itself. We agree that everyone has a stake in how nascent human life is treated, and that therefore serious efforts are necessary to protect the public interest. And although we want now to approve cloning-for-bio-medical-research, we agree that it shall not go forward in the absence of appropriate regulations and effective mechanisms for enforcing them.

Although this is not the place to draft legislation, the regulatory mechanisms we favor would be based on the following principles:

(a) Prevent cloned embryos from being used to initiate pregnancies. To do this, regulations must register, inventory, and track the fate of individual cloned embryos; prohibit the shipping or sale of cloned embryos (but not stem cells or other tissues or products derived from these embryos).

(b) Provide enforceable ethical guidelines for the use of cloned embryos for research. To do this, regulations must license and conduct prior review of all research involving cloned human

embryos; set a definite time limit and developmental stage beyond which a cloned human embryo may not be grown, either in vitro or in vivo (we suggest fourteen days, or the formation of the primitive streak); prohibit the transfer of a cloned human embryo into the womb (or other gestational environment) of a human being or an animal (or into an artificial equivalent of the same) for research purposes; and provide strong penalties to deter unlicensed or impermissible research.

(c) Protect the adult participants in this research. To do this, regulations must establish clear regulations for the protection of any human egg donors; set rules for financial compensation for egg donation; and establish other relevant measures designed to protect against the exploitation of women.

(d) Promote equal access to the medical benefits that flow from this research. To do this, guidelines must be developed that will keep down costs of medical therapies made available through this research, which would have been explicitly sanctioned by the community to serve the health needs of all.

5. Who Should Regulate This?

Whether done by an existing agency or a new one devised for this purpose, the regulatory authority should include scientists, physicians, and representatives of the biotechnology and pharmaceutical industries, but also lawyers, ethicists, humanists, clergy, and members of the public. In its composition and in its activities, every effort should be made to avoid even the appearance of conflict of interest, to prevent capture by special interests, and to ensure that the public's moral concerns are fully addressed in the devising of the regulations. A special Cloning Research Review Board, appointed by the President, might be one way to ensure high visibility and accountability.

6. Calls for a Comprehensive Review of the Entire Domain of Embryo Research

The ethical and policy issues regarding cloning-for-biomedical-research deserve to be considered in the context of all human embryo research. Regulatory mechanisms for cloning-for-biomedical research should be part of a larger regulatory program governing all research involving human embryos. To achieve this goal, we recommend that the federal government undertake a thorough-going review of present and projected practices of human embryo research, with the aim of establishing appropriate institutions to advise and shape federal policy in this arena.

B. Some Specifics for the Legislation

Drafting the legislation that would give effect to this proposal lies beyond the scope and competence of the Council. Yet the following considerations would seem to be indispensable for a well-drafted and effective statute.

1. Broad Coverage

The ban on cloning-to-produce-children, as well as the regulations devised for cloning-for-biomedical-research, should cover everyone, corporations as well as individuals, private as well as public institutions.

2. *Narrowly Drafted*

The statute should be very narrowly drafted, making sure that only the human cloning actions in question are proscribed and indicating explicitly other research and assisted-reproduction practices that will not be in any way affected by the ban or regulations.

C. Conclusion

This recommendation is above all grounded in the importance of not needlessly foreclosing or delaying a promising avenue of medical research. Permitting cloning-for-biomedical-research now, while governing it through a prudent and sensible regulatory regime, is the most appropriate way to allow this important research to proceed while ensuring that abuses are prevented. Combined with a firm ban on the transfer of cloned embryos into a woman's uterus, as we have recommended, such a policy would provide the balance of freedom and protection, medical progress and respect for moral standards, always sought in a free society. Most important, it would leave open and endorse an important new avenue of research that might help alleviate the suffering of millions of our fellow citizens.

We respect and recognize the concerns of many in the public and in this Council regarding cloning-for-biomedical-research, especially about the need for further deliberation and the necessary safeguards to prevent cloning-to-produce-children. But we do not believe that our proposal forecloses continued deliberation. On the contrary, the public process of designing a system to regulate cloning-for-biomedical-research is likely to generate public discussion about the difficult ethical issues posed by embryo research in general.

First, the ban we propose on cloning-to-produce-children would be a strong deterrent against a practice that the nation overwhelmingly opposes. By stopping, with the force of law, the transfer of cloned embryos into a uterus, this ban would effectively prevent the cloning of children. Like any law, the ban we propose could be violated, but so too could a more comprehensive ban on all cloning of embryos. Moreover, we believe that the sort of regulatory mechanisms we have proposed here would provide sufficient protection against the implantation of cloned embryos. Research scientists and fertility specialists are not out to break the law or violate the moral norms of their communities. They can in general be relied upon to abide by the ban we have proposed, and those who violate it can be penalized.

Second, we believe that the regulatory system we have proposed would address those concerns specific to cloning-for-biomedical-research itself. We do not discount these concerns. The moral seriousness of working with nascent human life and the larger public concern about where this research may lead make it imperative, even as a matter of enlightened self-interest, for the research community to welcome and participate in the regulation of this research. Because the issues at stake are not just those of safety and efficacy, but moral and social ones as well, the participation of other citizens in these decisions is entirely appropriate. Cooperation with the broader community in this matter of public moral concern can only advance the relations between science and technology and the broader society.

Third, we do not believe that cloning-for-biomedical-research is the place to settle the more general question of research on human embryos. That is why we have proposed that the federal government review in a systematic way the general field of embryo research, with an eye to devising a possible set of general policies or institutions. In the meantime, it seems inappropriate to halt promising embryo research in one arena (cloned embryos) while it

proceeds essentially unregulated in others. A sensible system of regulation will allow this important research to continue safely, while the nation considers a possible general policy on all embryo research.

Last, in answer to the specific concern that our proposal may put the government in the position of mandating the destruction of human embryos, we point out that those who would be producing the cloned embryos for research would have absolutely no intention of keeping them alive beyond the limits needed for the research. Hence there would be no occasion when governmental interference might be called for to compel unwilling researchers to destroy the cloned embryos. Strictly speaking, it would be the researchers, not government officials, who would be responsible for the destruction of the embryos; the government would not be requiring anything that was not already implicit in the research activity itself. True, the government, by enacting this legislation, would be accepting the use of cloned embryos for research, but it would be doing so fully mindful of the moral cost, for very good reason and under strict guidelines.

We therefore believe that the legitimate concerns about human cloning expressed throughout this report are sufficiently addressed by a ban on cloning-to-produce-children and the regulation of cloning-for-biomedical-research. And we believe that the nation should affirm and support the responsible effort to find treatments and cures that might help ameliorate or thwart diseases and disabilities that shorten life, limit activity (often severely), and cause great suffering for the afflicted and their families. Finding a way to support such valuable research while preserving moral standards is the challenge that confronts the federal government and the American public in the matter of cloning. We believe our approach offers the best means of achieving that goal.

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IV. Recommendation

After extensive deliberation, Members of the Council have coalesced around the two policy proposals, as follows:

The following ten Members of the Council form a majority in support of the First Proposal: Rebecca S. Dresser, Francis Fukuyama, Robert P. George, Mary Ann Glendon, Alfonso Gómez-Lobo, William B. Hurlbut, Leon R. Kass, Charles Krauthammer, Paul McHugh, Gilbert C. Meilaender.

The following seven Members of the Council form a minority in support of the Second Proposal: Elizabeth H. Blackburn, Daniel W. Foster, Michael S. Gazzaniga, William F. May, Janet D. Rowley, Michael J. Sandel, James Q. Wilson.

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- i. This group includes some Members who would make the permission to proceed contingent upon the *prior* institution of strict regulations and a mechanism for enforcing them, and some Members who would allow the regulations to be developed as the research proceeds. [Back to Text](#)
 - ii. The embryonic stem cells in these studies were obtained from *non-cloned* human embryos, produced by IVF. [Back to Text](#)
 - iii. The National Bioethics Advisory Commission recommended that federal agencies not fund research involving the

derivation or use of human embryonic stem cells from embryos *made solely for research purposes or using SCNT*. (NBAC, *Ethical Issues in Human Stem Cell Research*, Vol. I, 1999, Recommendations 3 and 4, pp. 71-72.) [Back to Text](#)

- iv. Operationally, the legislation could address separately the two uses of cloning and define the prohibited acts as follows. Cloning I: the creation of a cloned human embryo by somatic cell nuclear transfer. Cloning II: the creation of a cloned human embryo, produced by somatic cell nuclear transfer, followed by transfer into a woman's (or animal's) uterus or into an artificial womb. It could then declare that: (1) Cloning I shall be unlawful for four years from the date of the enactment of this legislation. (2) Cloning II is hereby declared unlawful. [Back to Text](#)
- v. Careful consideration should be given to the following matters: licensing requirements to engage in such research; accurate inventory and reporting of the numbers, uses, and fates of all cloned embryos; decisions about whether to permit the buying and selling of cloned human embryos; rules governing commerce or traffic in cloned human embryos, should it be allowed; patent law questions regarding cloned human embryos, blastocysts, and later stages of cloned human organisms; age and stage of embryonic development beyond which it would be impermissible to maintain and experiment upon cloned embryos; rules regarding the permissibility of growing cloned human embryos in animal hosts or artificial substitutes for a human or animal uterus; regulations concerning cloned human-animal chimeras (for example, human nuclei placed in animal oocytes); guidelines specifying the kinds of experiments that may be performed on the cloned embryos; guidelines regarding production levels and storage of cloned embryos; and, finally, effective institutional mechanisms—designed to prevent easy capture by cloning researchers or biotech companies—for monitoring cloning activities, enforcing the rules, and penalizing violators. [Back to Text](#)
- vi. The President's Council on Bioethics is currently chartered through November 2003. [Back to Text](#)
- vii. In thinking about this process we think it will be helpful to consult the work of the Canadian Royal Commission on New Reproductive Technologies. The process by which that Commission arrived at its final conclusions, and its manner of presenting those conclusions (carefully taking into account voluminous public testimony and dissenting opinions) strike us as providing an excellent model worthy of study and, to the extent appropriate, emulation. The scope, principles, structure, and functions of the proposed Assisted Human Reproduction Agency of Canada seem to us worthy of special attention. [Back to Text](#)
- viii. On this point and some others to follow, this policy proposal is identical to the First Proposal. To indicate this fact, the earlier argument will sometimes be repeated in this Second Proposal verbatim. We do so for symmetry and balance, and to allow each proposal to be read as a self-contained unit, without relying on the other. [Back to Text](#)
- ix. See Position Number One of "The Moral Case for Cloning-for-Biomedical-Research" in [Chapter Six](#) and the discussion of Policy Option 3 in [Chapter Seven](#) for the details of the moral hazards and how specific regulations can deal with them. [Back to Text](#)