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SYMPOSIUM TRANSCRIPTIONS

KEYNOTE ADDRESS

PREPARING THE GROUNDWORK FOR A Responsible Debate on Stem Cell Research and Human Cloning

O. CARTER SNEAD*

Many thanks to the New England Law Review for inviting me to provide the keynote presentation for its annual symposium, "Stem Cell Research and Human Cloning: Where Do We Draw the Line?" It is quite a timely and important subject. Being a lawyer, it should not be surprising that I will begin my remarks today with a caveat. My comments at this event are entirely my own and are not intended to reflect the views of the President's Council on Bioethics or any of its members.

The debate over both cloning and stem cell research has been intense and polarizing. It played a significant role in the recently completed presidential campaign, mentioned by both candidates on the stump, at both parties' conventions, and was even taken up directly during one of the presidential debates. The topic has been discussed and debated almost continuously by the members of the legal, scientific, medical, and public

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policy commentariat. I believe that it is a heartening tribute to our national polity that such a complex moral, ethical, and scientific issue has become a central focus of our political discourse. But, as you have no doubt noticed, the content of the discourse itself has been sometimes quite impoverished and unsatisfying. No one camp in this debate is solely to blame for these difficulties—partisans on all sides bear some measure of responsibility for the current state of the public discourse. In the interests of improving the quality of public deliberation and discussion on this matter, I will use the balance of this keynote address to provide a few modest suggestions for how the public debate might be improved. I will begin my remarks with a few general observations applicable to both domains under consideration today, stem cell research and cloning. Then I will focus on each separately; first, directing my comments to stem cell research, and then turning to the distinct (though obviously closely-related) matter of cloning.

The first step in moving towards a more responsible public debate on both stem cell research and cloning is to define with clarity the overarching subject under consideration, namely, the governance of science. In our country, science is an enterprise that we hold in the highest esteem. But science is not unbounded; it is subject to extensive regulation and governance. These regulations are positive as well as negative-aiming to promote scientific progress as well as to impose certain limitations in an effort to avoid various types of harms. Thus, the central question for policy-makers and the public in this context is what values and principles should be brought to bear as we essay to govern ourselves in this area. It would be helpful for discussants in the present debates to acknowledge and affirm that these principles and values are identified and articulated through the political process. This is as it should be. Public policy relating to bioethics generally, and to stem cell research and cloning specifically, quite properly present political questions that should be argued in political fora, in political terms. They are first and foremost human questions about the relationship between our strong desire to pursue scientific research with the ultimate aim of alleviating human suffering, and our obligation to respect moral and ethical boundaries. For this reason, I believe that the oft-repeated criticism that "cloning and stem cell research should not be 'politicized," without more, is not sound. To the contrary, the political domain is precisely the proper place for this debate. But, of course, it is important to stress that the political domain has rules, chief among them is that truth should never be compromised in the service of advancing political ideology. Of this, more later.

In short, I would submit to you that the current debate on both stem cell research and human cloning would benefit greatly if all participants, from the outset, approached these matters as they would any other issue of great political import—by clearly defining which values they seek to promote and defend in this context (that is, clearly stating their argument), and by responding directly to their opponents' account of the goods and values at stake (that is, clearly responding to their opponents' argument on its terms).

For this reason, discussants would do well to acknowledge the central question in dispute, namely, what is owed to human embryos, and how does this obligation stand in relation to other human goods such as the alleviation of human suffering and the promotion of scientific freedom? This is the moral, ethical, and legal question presented by human embryonic stem cell research, in which the derivation of such stem cells requires the disaggregation and thus destruction of living human embryos. This is likewise the central question raised by one application of cloningso-called "therapeutic cloning," in which the process of somatic cell nuclear transfer (SCNT) is used to create cloned human embryos, which are then disaggregated for the purpose of deriving stem cell lines. By my lights, the discussants in the public debate on this matter do not engage this central question in all its richness. Too often, proponents of embryonic stem cell research and therapeutic cloning fail to address directly the question of the moral standing of embryos, and the necessary cost associated with research that requires the destruction of embryonic human life. Rather, they often try to short circuit the discussion either by ignoring this crucial question, or by labeling the concern for the well-being of human embryos as simply a "religious" view not requiring a response from those who are not similarly religious. In point of fact, the most prominent arguments for opposing research that requires the destruction of embryos are not framed by reference to religious authority (though, for whatever reason, these arguments seem to be embraced more readily by religious people). The most prominent argument for maximal respect for embryonic life is framed in secular terms-based on the biological and ontological status of the human embryo itself. While there is certainly not time to fully explore that argument here, it is rooted in the fact of the seamless continuity of human development across biological stages-from zygote, to embryo, to fetus, to newborn. More importantly, perhaps, the argument turns on the absence of a meaningful point of developmental discontinuity that might justify disparate treatment before or after that moment (i.e., before which instrumentalization and destruction for research is justifiable, and after which the organism is entitled to maximal respect and protection). This argument is developed in the Personal Statements of Professors Robert George and Alfonso Gomez-Lobo in the President's Council on Bioethics 2002 Report, "Human Cloning and Human Dignity: An Ethical Inquiry."1 Proponents of embryonic stem cell research and cloning for

^{1.} See generally Robert George & Alfonso Gomez-Lobo, Statement of Professor George

biomedical research would contribute to a more robust and responsible debate if they would engage these arguments in a direct manner.

Similarly, those who would limit embryonic stem cell research and cloning in the name of respect for embryonic human life could improve the debate by forthrightly addressing the real-world ramifications of limiting this avenue of scientific inquiry. Opponents of such research should acknowledge that limitations on these practices might slow or even halt the progress of science and delay indefinitely the development of cures for injuries and dreaded diseases.

Finally, before moving on to a more specific discussion of the subjects under consideration at this symposium, I would like to point to two general principles (which I will elaborate on below) that should govern the public debate on these matters. First, all sides should use fair, accurate, and clear terminology. Moral arguments cannot and should not be won simply through terminological manipulation or semantic games. Second, and last, all sides in the debate have a duty to fully understand and fairly characterize the present and proposed policies bearing on stem cell research and cloning. This applies to their own policies, as well as the policies of their political opponents. Of this, more later.

Turning specifically to stem cell research, I think it would behoove all discussants in this particular debate to acknowledge at the outset that there are different types of stem cell research, each carrying with it its own promise and moral perils.

First, it is important to establish that stem cells come from different sources—embryonic and non-embryonic. Obviously, stem cells derived from non-embryonic sources, such as bone marrow, umbilical cord blood, and so forth, do not raise the ethical concerns that arise from research that requires the destruction of living human embryos. As such, it is crucial for discussants to specify and clarify which type of stem cell research is under consideration. It is exceedingly rare to find any individual in the public debate that "opposes stem cell research." Invariably, the lines of dispute are drawn according to the type of stem cells at issue.

Second, I think it is important for all parties to the stem cell debate to understand and appreciate the historical nature of the debate thus far and how it has unfolded over the past thirty years.

The debate over the government's role vis-à-vis research on in-vitro embryos has been raging since the 1970s. There have been various moments in the past thirty years where one branch of the federal government has sought to support this research with federal dollars, while

⁽Joined by Dr. Gomez-Lobo), in PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY (July 2002), available at http://www.bioethics.gov/reports/cloningreport/index.html.

another branch resisted such a move. In fact, the positions of the federal legislative and executive branches have switched at least twice in the past thirty years on this particular question. For the past decade or so, intentionally or unintentionally, the result of this stalemate has been a sort of judicious silence on the part of the federal government, whereby the research is not prohibited, but it is also not supported by federal funds.

It is within this trajectory of the debate that the current $policy^2$ should be located and understood. Understanding the historical context of the present policy on the funding of embryonic stem cell research is the first step in defending it or critiquing it.

The policy itself is actually quite subtle and complicated, and has not been well described or understood by either its supporters or critics. The policy is based on a fundamental, bright-line principle, namely, that because embryos are human beings at the earliest stages of development, they should not be instrumentalized or destroyed in service of the benefit of others, even if those benefits are very great. Thus, the policy itself seeks to advance the scientific research on stem cells to the maximal extent possible without transgressing this bright line. Concretely, this means that federal funding is authorized only for that species of stem cell research that does not itself require, or otherwise create incentives for the destruction of human embryonic life. In practice, this means that research on stem cells derived from nonembryonic sources is subject to unlimited funding, as is research on those embryonic stem cell lines derived before the announcement of the policy (i.e., research where the embryo-destructive act has already taken place). For the fiscal year 2003 the National Institutes of Health (NIH) authorized \$25 million for research involving these lines. and allocated tens of millions of dollars for the development of research infrastructure, training programs, and the like.

Thus, discussants in the stem cell research debate should not characterize the present policy as a ban. It is a policy about federal funding. Nothing is proscribed (evidenced by California's recent decision to fund embryonic stem cell and cloning research to the tune of \$3 billion,³ as well as the efforts of Harvard's Doug Melton, who has created his own human embryonic stem cell lines for use in research⁴). Additionally, the present policy should not be attacked or defended as a "compromise"—at least not

^{2.} Address to the Nation on Stem Cell Research, 2 PUB. PAPERS 953 (Aug. 9, 2001), *available at* http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html.

Paul Elias, California's \$3 Billion Stem Cell Proposition Passes, S.F. CHRON., Nov. 3, 2004, available at http://www.sfgate.com/cgi-bin/article.cgi?f=/news/archive/2004/ 11/03/politics0459EST0073.dtl.

^{4.} See William J. Cromie, Melton Derives New Stem Cell Lines, HARV. NEWS OFFICE, Mar. 4, 2004, available at http://www.news.harvard.edu/gazette/2004/03.04/01stemcells.html.

in the conventional sense. It is a policy that is governed by a bright-line principle. It is not a policy that is based on a utilitarian calculus that the worth of human embryos outweighs the current promise of the research using the approved lines. Thus, the policy should not be attacked or defended by virtue of how much it promotes or impedes scientific progress. It is a policy grounded in inviolable respect for the embryo, regardless of the consequences to the research. And it should be critiqued or defended as such.

On a related note, it is absolutely crucial for all parties to the debate over stem cell research to be very judicious in describing the likely fruits of the research in question. They should be careful not to overstate or understate the promise of this avenue of research. Some proponents of embryonic stem cell research have been guilty of inflating the promise of this research, promising cures for every manner of disease or debilitating injury. A recent example has been the oft-repeated invocation of former President Ronald Reagan for the proposition that stem cell research holds great promise for the treatment of Alzheimer's disease. According to the nation's leading researchers in that particular field, this is not so. Alzheimer's expert, Dr. Dennis Selkoe of Harvard (himself a vigorous supporter of embryonic stem cell research) recently told the President's Council on Bioethics that there was only a "very small possibility" that stem cell research would be useful in treating the disease.⁵

By the same token, many opponents of embryonic stem cell research are insistent that it holds no promise, and that only adult stem cell research will prove efficacious in developing regenerative therapies. This too seems to me to be an incomplete account, and is more of a speculative prediction than a statement of certain fact.

I would counsel discussants on all sides of this debate to acknowledge that we simply do not know which type of stem cell research is the most promising. Embryonic stem cells are extraordinarily plastic and can, in principle, become any tissue in the body. Therein lies their great virtue. But it is also the case that this plasticity presents unique problems for directing and controlling the development of such cells, with the formation of teratomas (a type of tumor) presenting a significant concern. Adult stem cells, it has been argued, are less plastic (although recent developments have challenged this notion), but have proven useful in actual human clinical trials—something that embryonic stem cell researchers have not yet

^{5.} Session 2: Aging, Dementia and the Person: Clinical, Neurological and Existential Perspectives on Alzheimer/Dementia: Meeting of the President's Council on Bioethics (Jun. 24, 2004) (statements of Dennis J. Selkoe, Professor of Neurologic Diseases, Harvard Medical School and Director of the Center for Neurologic Diseases, Brigham and Women's Hospital, and David Shenk, author), available at http://www.bioethics.gov/transcripts/june04/session2.html.

accomplished. The future is unclear, and it is most accurate to say that both avenues seem to promise a great deal. But, as I mentioned above, it is important to always bear in mind that the promise of the research does not in itself settle the moral question of what is owed to human embryos.

In addition to being intellectually honest about unknown facts, it is equally important that parties to the stem cell debate be vigilant about learning and describing known, demonstrable facts. A case in point-the number of embryonic stem cell lines approved for federal funding. Opponents and defenders of the current policy routinely misstate this easily verifiable fact, claiming that there are only twelve lines, sixteen lines, or twenty-two lines. In point of fact, there are seventy-eight embryonic stem cell lines that are eligible for federal funding. However, before such lines are available for research, the researcher must engage in a two-step process: the line must be "characterized" (a scientific process) and the relevant intellectual property agreements must be negotiated with the owner of the line in question (a legal process). In the summer of 2002, only one eligible line was available for research, while in the summer of 2003, twelve were available. As of October 2004, twenty-two were available and the number will presumably continue to grow. It also bears mentioning that the number of stem cell lines is not the same as the number of stem cell preparations that are shipped to scientists for research. In fact, over 500 preparations have been shipped to researchers so far, with 3,500 more available for delivery.

I will now turn to the separate but obviously related matter of human cloning. Cloning, that is the use of somatic cell nuclear transfer to produce a cloned human embryo, is closely tied to embryonic stem cell research. This is because one of its applications—cloning for biomedical research (so-called "therapeutic cloning")—is aimed at the creation of embryos from which stem cells can be derived for the sake of study and ultimately for the development of therapies. However, it is also different in kind. Cloning is not simply "a form of stem cell research," as it is sometimes described in the media and by proponents of therapeutic cloning. Rather, it is a means of producing the subjects of stem cell research, namely, human embryos. It also marks a new innovation in mankind's ability to control the genetic makeup of its progeny. There will be more on these matters later. Suffice it to say, for present purposes, that discussants in the cloning debate would do well to distinguish between cloning and stem cell research, while recognizing the obviously deep connections between the two.

This leads me to revisit my earlier point regarding the importance of using clear and precise terminology. To conflate "cloning" with "stem cell research" more generally is confusing and if intentionally done, intellectually dishonest. Such conflation can (and is perhaps intended to) confuse supporters of conventional embryonic stem cell research into believing that they should, as a logical matter, support therapeutic cloning. But, as stated before, therapeutic cloning is distinct from conventional embryonic stem cell research in important ways. President Clinton himself recognized one of these crucial distinctions between creating embryos solely for the sake of research and conducting research on embryos created with a reproductive intent, but which are now destined for destruction (socalled "spare" embryos). President Clinton rejected the 1994 NIH Human Embryo Panel's recommendation to federally fund research in which embryos are created solely for the sake of research on the grounds that this pure instrumentalization of nascent human life was an ethical line that the country was not ready to cross.

Proponents of therapeutic cloning would do a great service to the public discourse on this matter by being very clear about what SCNT is and what it does. In short, the product of somatic cell nuclear transfer is a cloned human embryo. The purpose of therapeutic cloning is to create embryos that will be disaggregated (and thus destroyed) for the sake of acquiring their stem cells for research. However, in the public debate thus far, advocates of this practice have sought to obscure this fact. Indeed, in one of the bills introduced in the U.S. Senate, the product of SCNT was referred to as an "unfertilized blastocyst." I defy you to find any embryology textbook that uses this term. It simply does not exist. It is a neologistic expression that communicates the notion that the product of SCNT is not a human embryo, but something incomplete-a part and not an integrated whole. By referring to the origin of the embryo, and by using a less common term for embryo, the users of such terminology seek to persuade the public that there is no moral issue. Nothing to see here. No embryo. Move along. This is irresponsible in the extreme.

Just as it is crucial to use accurate terminology, it is likewise crucial for the health of the public debate on cloning for discussants to fully understand the policies that have been proposed at the national and state levels. It would be useful for discussants to acknowledge that there are currently no federal laws of any kind on the subject of cloning. Except for a few oral pronouncements of the FDA (not since repeated or revisited), there is no federal bar to cloning—either for producing children or for biomedical research.

Being clear about the nature and substance of proposed legislation means being clear about the impact of such laws, if enacted. It is therefore necessary for the sake of intellectual honesty that the opponents of all forms of cloning be clear that their proposals would limit the production of particular embryos for stem cell research, and thus impede or even arrest the scientific pursuit of regenerative therapies using embryonic stem cells.

Similarly, those proponents of legislation that would ban only cloning for producing children, while permitting (or even encouraging) cloning for biomedical research, must be very clear about what this sort of law will require. Not only would it sanction the creation of embryos solely for research (which, as discussed above, raises novel ethical concerns), but also it would in fact require, on pain of criminal penalty, that an entire class of embryos (those produced by SCNT) be destroyed. Every bill that has been proposed to ban cloning to produce children uses the same mechanism to produce this result: they all make it a crime to transfer a cloned embryo into a woman's uterus to initiate a pregnancy that will result in the birth of a living child. What this means in practice is that all embryos created by SCNT must be destroyed, as transfer to a woman's uterus for gestation is the only possible means of preserving their lives. Proponents of these sorts of laws should be forthright in acknowledging this innovation in the law. If adopted at the federal level, it would move the United States from a national policy that has never sponsored research requiring the destruction of embryos to a national policy that requires, as a matter of law, that certain embryos be destroyed.

I believe that the public debate over cloning could be improved by further discussion and elaboration of the grounds for opposing cloning for biomedical research, which are not rooted in respect for embryonic human life. There are a number of public figures that are strongly in favor of abortion rights, who vigorously support conventional human embryonic stem cell research, but who nevertheless oppose cloning for biomedical research. Some of these public figures may be addressing the symposium today. They oppose this application of SCNT because they believe that it opens the door for genetic modification more generally, and that may lead to the perfection of the techniques of cloning for producing children. Many feminists strongly object to SCNT because such experiments require a massive number of human ova, which must be extracted from women via a non-trivial and painful process. Such feminists (rightly in my view) worry that this research presents a great potential for exploitation of women and commodification of their body parts. This concern is particularly grave for women in poverty, who might feel coerced to sell their ova. The debate over cloning in Europe is in some ways richer than it is in the United States because there is a critical mass of these voices in the public square. In the United States these arguments are rarely heard and not well understood. As a result, our public discourse on this subject is less complex and full than it might be.

Finally, the public debate over cloning would be improved greatly by a more robust discussion of the ethical arguments (pro and con) relating to cloning to produce children. Currently, there is the appearance of consensus on this question—most everyone opposes the practice for reasons of safety. This may, however, prove to be an evanescent concern. But there are other, richer ethical grounds to be debated and discussed on this matter. For example, there are concerns regarding identity and individuality, the conversion of procreation into a process of manufacture, the prospects of a new eugenics, and finally, the potential disruption of the relations among the generations in families. These are all arguments against cloning to produce children that are unrelated to safety. There are also arguments in favor of cloning to produce children that have not been fully explored and debated. There are possible arguments that this application of SCNT might be a legitimate means to treat infertility, or to allow same-sex couples to conceive biologically-related children. There are even arguments that have not been fully aired in public about the possible virtues of trying to reproduce a person of great value through the process of cloning. I am by no means endorsing or supporting any of these aforementioned arguments, but I raise them to illustrate the point that they have not been fully debated and discussed publicly.

I thank you for your attention today, and I commend you in advance for taking up these very important ethical questions in a serious fashion. I hope that my remarks today will be useful as this symposium unfolds, and that we can, working together, truly lay the groundwork for a responsible debate on stem cell research and cloning.