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May 1, 2008

Commissioner Richard Daines, M.D.
Chair, Empire State Stem Cell Board
Nelson Rockefeller Empire State Plaza
Albany, New York 12237

Re: The Ethics of Embryonic Stem Cell Research

Dear Dr. Daines,

The ethics of scientific research aimed at deriving and studying new lines of embryonic stem cells has become a public policy issue in both the national and state political arenas. At the national level the issue arises in recent, unsuccessful attempts in Congress to reverse federal policy that precludes federal funding for scientific research involving the creation or study of embryonic stem cell lines derived after August 2001. At the state level, the issue is arising in the deliberations of New York's Empire State Stem Cell Board which was created legislatively in 2007 to provide state funding for stem cell research. In this letter, the Committee on Bioethical Issues of the Association of the Bar of the City of New York strongly urges you and the other members of the Empire State Stem Cell Board to support, immediately and forcefully, the derivation of embryonic stem cell lines from early stage embryos or from somatic cell nuclear transfer ("SCNT") and the use of those derived embryonic stem cells for bio-medical research.

For the reasons set out in this letter, the Committee believes that scientific research involving the creation and study of new embryonic stem cell lines is both ethical and important. The availability of alternative scientific approaches to producing cells with similar properties does not change the underlying ethics of conducting scientific research using very early stage embryonic tissue or using SCNT. The Committee believes that there should be no ethical or legal barrier to supporting this scientific research with New York State funds.

In the remainder of this letter we summarize some relevant scientific background, review current federal and state policy, discuss why we reach our ethical conclusions and, finally, present our specific recommendations to the Empire State Stem Cell Board.

I. Scientific Background

Embryonic stem cell research is at one cutting edge of current biological and biomedical research.[i] Embryonic stem cells are the precursors of all human tissue and appear to have enormous potential for helping researchers learn how specialized tissue cells are formed and, over time, how injured or diseased tissue can be replaced or repaired.

The primary ethical controversy regarding embryonic stem cells arises because they are typically obtained from very early stage embryos that are created in a laboratory, usually at an in vitro fertilization ("IVF") clinic, and have been frozen for storage. When those embryos are no longer needed for commencing a pregnancy, they typically would be discarded if not used (with the donors' full consent) for scientific research. Research that involves removing an embryonic stem cell often destroys the embryo which would have been destroyed in any event. It is that destruction that is controversial to some.

An alternative route to producing embryonic stem cells that has been demonstrated in animal models involves cloning an adult cell by transplanting the nucleus of that cell, which contains the cell's principal genetic material, into an egg cell whose nucleus has been removed. That process is called "somatic cell nuclear transfer" ("SCNT"). The resulting single cell "clone" resembles a fertilized egg cell. It can be grown to the early embryo stage at which point an embryonic stem cell can be removed and cultured. The ethical concern about using cloning to produce embryonic stem cells also concerns the destruction of early stage embryos but, in addition, is based upon a fear that this research could facilitate reproductive cloning.

Once a single embryonic stem cell is removed, it can reproduce in a laboratory culture through many cycles of cell division. This enables scientists to grow an essentially unlimited number of offspring cells – which are genetically and functionally identical embryonic stem cells. In short, from one destroyed very early stage embryo, a "line" of embryonic stem cells can be derived and grown to create a very large number of identical cells that can be used for research or for medical treatment. This ability to propagate continuously without change is one of the unique hallmarks of embryonic stem cells.

A second distinguishing feature of embryonic stem cells is their ability to develop into essentially all of the specialized cells that make up a mature organism. An embryonic stem cell can, upon cell division, produce one progeny cell that is specialized: for example a nerve cell, a muscle cell, a skin cell, or almost any other type of cell found in a mature human. A cell with this property is described as "pluripotent." While stem cells found in adults can transform themselves into certain categories of specialized cells, for example into blood cells, they are not pluripotent, meaning that adult stem cells have lost this ability to transform themselves into all other types of specialized cells.

Human embryonic stem cells were first isolated and grown in culture in 1998 using knowledge gained from similar research with animal models. Animal model research has progressed to offer tantalizing hints of the amazing properties of embryonic stem cells. For example, researchers have learned to transform animal embryonic stem cells into specialized cells including nerve cells, heart muscle cells, insulin-secreting cells and many others. In principle, these derived, specialized cells can be transplanted back into living organisms and can integrate themselves into the organism to repair or replace damaged tissue. For example, in principle, new healthy heart muscle cells could be integrated into a damaged heart, new nerve cells could help repair damaged nerve tissue and new insulin-secreting cells could replace pancreatic tissue damaged by diabetes. While this research, even in animal models, is in early stages, it suggests at a minimum that scientists will acquire powerful new tools to study basic biomedical science and medicine. There is also the ultimate prospect, by no means assured, of useful new therapies to previously untreatable diseases and injuries.

Very recent, stunning scientific advances demonstrate an entirely new way to create stem cells that appear to have the most important properties of embryonic stem cells. Normal specialized adult cells, for example a cell scraped from an adult's skin, can be genetically "reprogrammed" to make cells that mimic the remarkable pluripotency of embryonic stem cells. This new science has led some commentators to suggest that the ethical debate over embryonic stem cell research should now be moot. These commentators argue that there is no longer any need to extract stem cells from embryonic tissue because similar ("pluripotent") stem cells can be obtained through cellular reprogramming which does not require any embryonic tissue. For the reasons explained below, the Committee disagrees with this mootness argument.

II. Public Policy

A. Federal policy

Currently, federal regulations prohibit federal funding to be used to derive new stem cell cultures or to conduct research using human embryonic stem cells that were created after August 2001, the date the federal policy took effect.[ii] Federal funding is available for research on a small number of human embryonic stem cell cultures grown from cells extracted before the ban took effect. There are, however, no federal regulations or laws that ban privately sponsored research to create new embryonic stem cell lines or research on any embryonic stem cell line created after the ban or that limit state or local governments from sponsoring that research.

B. State policy

Some states have enacted laws concerning stem cell research.[iii] While a few states have banned or limited stem cell research,[iv] other states with active research communities recently have enacted laws explicitly permitting it. For example, California, Connecticut, Illinois, Maryland, Massachusetts, New Jersey, New York, and Wisconsin have laws that reflect a state policy of encouraging biomedical research that involves deriving and studying new lines of embryonic stem cells and have provided state funds or other inducements to support the research.[v]

In 2007 New York State created a fund to support stem cell and related research in the State through grants of state funds. The grants will be awarded and administered by the Empire State Stem Cell Board (the "Board"). The Board, appointed by the Governor, issued its first Request for Proposals in September 2007 and has awarded its first round of grants.[vi]

III. The Ethical Debate

Nearly all human embryonic stem cell cultures produced to date have come from very early stage embryos that were stored frozen at IVF clinics and were no longer needed by the patients who often donated their eggs or sperm. If not used for scientific research, such as the extraction of a single embryonic stem cell to begin the growth of a new cell line, those "excess" embryos are typically discarded by the IVF clinics that produced them.

The core of the ethical debate over embryonic stem cells is the question of the ethical status of those very early stage embryos. Is it "one of us," deserving the rights and moral respect of any other person?[vii] Or is it more akin to human tissue stored in a laboratory -- such as blood – that is routinely used in biomedical research? If it is "one of us," then it would be unethical to create and destroy a person solely to derive cells for research or for the treatment of others. If it is stored human tissue, then there is widespread precedent for making it available for research.

The biological facts are largely agreed, but are used by disputants on both sides of the ethical issue. Stem cells are extracted from embryos that have been frozen about 5 or 6 days after conception is achieved in a laboratory. At that stage, the embryo is a tiny, fluid filled ball – approximately the size of the period at the end of this sentence. The cells comprising the ball are arranged in two layers. The outer layer is made up of cells that would form a placenta. The inner layer consists of undifferentiated embryonic stem cells. At the stage when an embryonic stem cell is extracted, this inner layer is a round hollow mass of about 100 cells – without any organs, shape or functions that most people would recognize as human.

From a practical, tangible perspective, there is nothing about the appearance or function of this early stage embryo that suggests that it should be treated ethically or legally as a separate human being. It has no organs, no nervous system or brain and no recognizably human form. In

the laboratory dish where this tissue has been frozen, it has no ability to develop into a functioning human being unless and until it is implanted into a woman's uterus.

There are a number of arguments that are marshaled to support the "humanness" of this early stage embryonic tissue. First, there is the undisputed fact that the early stage embryo has the potential, if implanted in a mother's uterus, to grow into a baby. Second, is the also undisputed fact that the development of an embryo from the moment of conception to birth is essentially a continuous process. Third, it is pointed out that the early stage embryo is genetically unique – a "being" genetically distinct from all other members of the human species. Each of these is discussed below.

The potential of an early stage embryo for development into a fully formed human baby persuades some that this tiny cell mass (and even its single cell precursor) is "one of us." But what that potential is, is not well understood. Nearly all human cells carry the full set of the genes that are expressed to form an adult human being. Presumably, the embryonic stem cells also contain a complex set of biochemical triggers that are cocked and timed to carry out an amazingly intricate and little understood process of cell division, specialization and cooperation that somehow results in a baby. But we don't know if other cells also carry those complex triggers and timers and if one day we will learn how to reset or otherwise activate them. The recent advances in "reprogramming" normal specialized adult cells into pluripotent precursor cells suggest that this could be achieved in the not too distant future. In any event, whatever those triggers are that provide the potential for a very early stage embryo to undertake spontaneous organized growth, they hardly seem sufficient to make this tiny cell mass deserving of special ethical status or legal rights.

For example, if scientists one day learn to reprogram specialized adult cells to enable a new organism to be re-generated from one of those cells, would all adult cells be entitled to special legal protection and ethical respect? Would living cells in hair clippings, saliva or blood samples be entitled to specialized protection? The implausibility of an affirmative answer to those questions suggests that most people would not place special legal or ethical significance on the potential of a cell or cell mass to be transformed into an individual.

Consider also the possibility of creating a very early stage embryo where the potential for development to a baby has been disabled in some fashion. Should there really be a significant ethical distinction – permitting us to use these "disabled" embryos to create stem cells but not to use otherwise identical embryos that have not been "disabled?"[viii] Would that be true if the disability was reversible?

In at least one important respect, the very early stage embryo that has been created and stored in a laboratory has already been disabled; it has no chance of developing to term unless it is successfully implanted into a mother's uterus. As it exists in a laboratory, the embryo can not be grown to term (at least not with current technology) and, once thawed, can be kept "alive" only briefly. Creating a baby from that unfrozen *in vitro* embryo is certainly not a natural or spontaneous progression.

In sum, the potential of a single cell or of a small mass of undifferentiated cells in a laboratory dish to develop into a functioning human being if implanted into a mother's uterus is not a sufficient basis to give that cell or those cells full ethical status as human beings.

Another biological fact that is discussed in the bioethical literature is the essentially continuous nature of the biological development and growth of a human from a one cell fertilized egg to adulthood. From this fact, some argue that the only logical boundary for

ascribing legal and ethical rights is the creation of that one cell embryo, notwithstanding the wide acceptance of other milestones, such as implantation or the first appearance of the "primitive streak," the precursor of the spine.[ix] The law assigns rights in many contexts by drawing legal boundaries across continuous phenomena. For example, there is no clear, consistent or precise biological boundary between a child and an adult. But that does not prevent distinct legal rights and ethical status being ascribed on the basis of an age (usually 18 or 21) designated in law and custom. Abortion law also draws legally salient distinctions across the continuous prenatal growth of a fetus. In short there are many areas of law and ethics where important lines are drawn across continuous phenomena.

An extreme example of this argument is set out in a recent book written by Robert George, a Princeton University professor of philosophy and a member of the President's Council on Bioethics, and Christopher Tollefsen, a professor of philosophy at the University of South Carolina, entitled Embryo. The authors argue that "embryo science tells us … that human embryos are human beings… and that in the vast majority of cases, those human beings begin at conception."[x] They argue that since human beings are essentially "animal organisms having a rational nature," then early stage embryos , because they are human animal embryos, are human beings. Finally they argue that "all human beings deserve full moral respect," even those that never attain the stage of "personhood" i.e. that stage where attributes such as rational thought distinguishes humans from other animals.

It should be noted that the implications of this sweeping, absolutist position are stunning. Professors George and Tollesen explicitly propose that all human embryonic stem cell research (even privately funded research) should be prohibited. They also propose that *in vitro* fertilization as it is now practiced in the United States should be prohibited.[xi] The logic of their

position would also require a prohibition on all forms of abortion at any stage, and on any form of birth control that acts after conception. It is also logically inconsistent with many common practices of end of life medical care including voluntary refusal of life sustaining treatment and brain death.[xii]

There are sound logical and ethical reasons why society has never seriously considered the extreme position advocated by professors George and Tollefsen. First most people will be puzzled and not convinced by the authors' approach of seeking , finding and applying only absolute principles to resolve complex ethical issues. For example, the authors reject any attempt to make ethical distinctions between a mature human being and an early stage fetus, arguing that any such distinction depends upon mere "attributes" of a person rather than the authors' "animalistic" concept of personhood. The authors state that because different people could have different views of what "attributes" should be important (e. g. first appearance of a "primitive streak", or implantation, or some stage of fetal development) then any such attribute based distinction is "absurd, for it results in obvious contradiction."[xiii] Moreover, the authors argue that any conclusion based on such mere "attributes" would have to be made "by those with enough power to impose their decisions upon others."[xiv] This happens "where the scientific establishment and the powers of the state collude to make research upon embryonic human beings legally permissible..."[xv]

But, surely it can not be "absurd" to make any ethical distinction between an early stage fetus and a functioning human being just because different people might hold different views on exactly how best to place the ethical boundaries in any particular case. Most people will also disagree with the authors' narrow, absolutist views, but the possibility of disagreement alone does not make those views "absurd." And there is clearly nothing *per se* wrong about drawing

ethical distinctions between early stage embryos and more fully developed human beings. Because it may be ethically objectionable to draw ethical distinctions on the basis of some attributes (for example race) surely does not mean it is always equally wrong to draw distinctions on the basis of every other attribute. Also, why is it problematic that the resolution of an ethical issue will ultimately depend upon "the power of the state?" How else do we resolve legal and ethical issues in a democracy? How else do George and Tollefsen intend to enact their extreme ethical views without invoking the "power of the state" (perhaps in "collusion" with philosophers and political scientists such as themselves)?

More generally, the formulaic and absolutist argument of George and Tollefsen makes no mention of competing ethical principles or interests. Nowhere do they mention or acknowledge that any future for any early stage *in vitro* embryo they seek to protect will require a woman agreeing to have it implanted in her womb and to carry it to term. Without that mother, there is nothing either the authors or modern science can do to "save" any of those embryos. Should not the wishes and rights of those mothers figure somewhere in the ethical analysis? Isn't it "absurd" (to use the authors phrase) for the authors to speak abstractly about those embryos "right to life" unless and until there is a woman who has agreed to become the embryo's birth mother?

The third general objection against embryonic stem cell research is based upon the genetic uniqueness of the early stage embryo. But this is not a persuasive basis for ascribing special ethical status to an early stage embyro. Identical twins are not genetically unique, but that fact is not relevant to their ethical value or status. Indeed, at the stage when embryonic stem cells are extracted, an embryo can still transform into twins , so it is not yet possible to associate it consistently with any distinct human person. Also we know that some genes of any human can

mutate over time changing his or her precise genetic makeup. This, too, would seem to be wholly irrelevant to ethical status. What we value in all human beings has very little to do with any concept of genetic uniqueness as compared to other people.

There is essentially no precedent for the legal protection of a very early stage human embryo. We do not treat early stage embryos as people with full legal rights in any legal context. On the contrary, embryos are routinely created in in-vitro fertilization clinics and are stored frozen until a small fraction of those created is unfrozen as needed for implantation. Embryos remaining after fertilization efforts have achieved the desired result or have been abandoned are discarded without any particular legal or ethical qualms.

The novelty of according special ethical or legal status to early stage embryos can be illustrated by the implications of that status. Even very early first trimester abortions would become legally and ethically problematic. Some popular forms of birth control could be asserted to be homicide. IVF clinics would have to drastically change their operations – if they could operate at all. Spontaneous miscarriages, which are estimated to happen naturally to about 80% of all fertilized human eggs,[xvi] would be treated as an unprecedented infant mortality epidemic and a massive public health problem. The fact that all of this seems far-fetched argues strongly against establishing a new precedent in the context of stem cell research by ascribing some special ethical or legal status to early state embryos.

It is also important to include in the ethical analysis the potential for good that can come from embryonic stem cell research. Most would acknowledge that if a cure for diabetes or Parkinson's disease could be achieved tomorrow through the use of embryonic stem cells, there would be no public patience with delaying that cure. If the health or lives of actual patients were at stake, the ethical or religious qualms of a minority would be swiftly brushed aside at

least as those qualms would prevent others without such qualms from receiving treatment This should tell us something about the strength of those concerns.

There is, of course, no certainty that cures for any diseases will come from scientific research on embryonic stem cells. But it is certain that this research is a promising path to learn fundamental biological and medical truths. In itself, that is a very substantial and powerful public good. Any governmental or ethical barriers asserted to prevent or hinder us from acquiring that knowledge should be viewed with extreme skepticism.

While it could turn out that other scientific approaches, for example genetic "reprogramming" of adult cells, may have more clinical potential for curing disease, "reprogramming" could also prove to be a dead end or another entirely new scientific avenue could emerge to achieve the clinical potential of embryonic stem cells. The history of science suggests that predictions at this stage of knowledge are very uncertain; the most likely outcome is one that will be a complete surprise. This should tell us that it would be a mistake to foreclose any promising path to scientific advances unless there is a sufficient ethical reason without regard to the promise or lack of promise of scientific alternatives.[xvii] There is no such sufficient ethical reason to abandon or to disable embryonic stem cell research.

Research that attempts to derive embryonic stem cells using cloning (via SCNT) is sometimes referred to as "therapeutic cloning" to distinguish it from reproductive cloning research. There appears to be wide agreement that it would be unethical to attempt to use cloning for human reproduction. The clinical uncertainty concerning risks to the baby would, at this stage of knowledge, be unacceptable to many. Thus, we start with the assumption that human reproductive cloning for now should be banned. The principal ethical objection to research that seeks to use SCNT to produce embryonic stem cells (other than those objections

discussed above) is that the research will inevitably contribute to the knowledge that could be used for reproductive cloning.

While that statement is certainly true, it is neither an ethical nor a legal reason to prohibit or constrain therapeutic cloning research. First, the knowledge will come, albeit perhaps more slowly, no matter what bans apply in the United States or in any state. The knowledge will come from animal work and from research abroad done in countries with more liberal research standards. Second, if there is agreement that human reproduction cloning should be banned, it is, of course, perfectly feasible to have and enforce that ban whether or not the scientific knowledge exists to reproductively clone a human baby. Trying to impede scientific knowledge is neither a necessary nor a practical way to prevent human reproductive cloning. Therapeutic cloning research does not, at this point, involve destroying a viable human embryo since at this stage of scientific knowledge cloned human embryos can not be developed to term.[xviii] But, as the world saw so vividly with Dolly the sheep, reproductive cloning technology does exist for large mammals. It is, therefore, reasonable to anticipate that the technical knowledge to reproductively clone human beings will exist in the reasonably near future. At that point, the ethical argument against therapeutic cloning could include some of those that are discussed above regarding deriving human embryonic stem cells from very early stage human embryos created at IVF clinics.

Any discussion of the ethics and public policy regarding embryonic stem cell research and reproductive cloning should also consider the practical effect of withholding government funding from important areas of research. It is reasonable to expect that the research will go ahead –either with private funding or within other countries and regions. If New York decides not to fund embryonic stem cell research, some scientists may either move to where they can

pursue the research or choose other areas of research, in either event undermining New York's (and the United States') historic preeminence in biomedical science. An additional consequence is that our state and federal authorities will no longer have the same ability to shape the regulation of embryonic stem cell research.

For example, there are a host of regulatory and other issues that will need to be considered in connection with research on embryonic stem cells. What standards for informed consent should be applied? What review process is appropriate for embryonic stem cell research proposals? What limitations, if any, should apply to research that involves inserting nonhuman genes into human stem cells or their specialized progeny? Should payment to donors of tissue for this research be permitted? Government funding provides a basis for governmental bodies to provide thoughtful, uniform answers to those questions. But a government that declines to fund an area of research is less likely to engage the difficult and controversial process of providing ethical guidelines.

Non-governmental entities can fill the void by drafting suggested codes. Two such codes addressing embryonic stem cell research have been prepared by prestigious nongovernmental bodies. The National Academies of Sciences in April 2005 published its Guidelines for Human Embryonic Stem Cell Research ("NAS Guidelines"). Those Guidelines were amended in 2007. With some modifications they were adopted by California to govern research funded by its state grants. Another widely recognized set of guidelines was issued by the International Society of Stem Cell Research in December 2006. Both of these codes deal with issues such as the appropriate informed consent that must be received from egg or sperm donors, the prior review of embryonic stem cell research proposals by an institutional oversight committee (an Embryonic Stem Cell Research Oversight ("ESCRO") committee) and the use of

SCNT to derive new stem cell lines. The lack of uniform federal rules in this area will result in many states, probably including New York, adopting variants of one or both of these codes. If New York State refuses to fund embryonic stem cell research, it will lose one opportunity to lend its voice to that process. It is likely that the result would be that each major medical center or company in the state that chooses to pursue this research with private funds will have to set its own rules, contributing inevitably to the proliferation of differing rules. This will give rise to a whole set of questions about how research material from one institution can be shared or used with other institutions that have slightly different ethical guidelines.

All of these considerations convince this Committee that there are no persuasive ethical reasons why New York State funds should not be available to support embryonic stem cell research, including research that involves creating new cell lines from early stage embryos or from SCNT. A public policy choice to refuse to fund that research on ethical grounds would unreasonably and unnecessarily disadvantage New York State.

IV. New York Should Now Fully Embrace Embryonic Stem Cell Research.

Former Governor Spitzer made financial support of stem cell research an important public policy priority in New York State. In April, 2007 the state legislature passed and then Governor Spitzer signed, a major initiative to fund stem cell research in New York State. A new section 265 of the New York Public Health Law created within the Department of Health an "Empire State Stem Cell Board" empowered "to make grants to ...research and development activities that will advance scientific discoveries in fields related to stem cell biology." N.Y. Pub. H. Law sec. 265-a.1. Section 99-p of the State Finance Law established an Empire State Stem

Cell Trust Fund from which the grants are made. The State has committed $100 million to that Fund for its 2007-2008 fiscal year and plans call for a total of about $600 million over ten years.

The statute authorizing the Empire State Stem Cell Board provides for two committees – a 13 member Funding Committee and a 13 member Ethics Committee – whose members together constitute the Empire State Stem Cell Board. The Funding Committee is empowered to solicit research grant proposals, review those proposals and make recommendations to the Commissioner of Health for grant awards. The Ethics Committee is empowered to make recommendations to the Funding Committee regarding "relevant ethical and regulatory issues." N.Y.Pub. H. L. sec. 265-c.2.d.

The Board had its first meeting on October 22, 2007 and issued its first request for proposals for funding soon after. Proposals were due by January 4, 2008 and the first grants were announced in early January. Funded contracts are anticipated to start by April 1, 2008. The October 2007 RFP also provided that proposals would have to conform to any ethical guidelines adopted prior to December 31, 2007 by the Commissioner on recommendation of the Ethics and Funding Committees.

The Ethics Committee held its first meeting on November 30, 2007 to consider ethical guidelines that would apply to this first RFP. At the meeting several Committee members stated that they needed more time to consider whether or not grant funding should be available for research in New York State aimed at deriving new stem cell lines. After a confused motion and vote, that limitation on funding was construed to be the Committee's recommendation.[xix]

That recommended limitation was considered and rejected by the Funding Committee at its December 13, 2007 meeting. Funding Committee members noted at the meeting that even a temporary New York State ban on funding research to derive new embryonic stem cell lines

would be "enormously influential and important" and would send an "unfortunate signal to the scientific community." Ironically, the ban would have adopted as New York policy (albeit perhaps temporarily) the same type of substantive funding restriction applied since 2001 by the federal government which restriction was largely responsible for motivating New York State to provide state funds to support embryonic stem cell research.

The Funding Committee should be commended for rejecting the temporary funding ban proposed by the Ethics Committee. There is no sound, persuasive ethical reason why New York State funds should not be immediately available to support research that seeks to create new lines of embryonic stem cells from early stage embryos that would otherwise be discarded by IVF clinics. The Ethics Committee's proposed ban was probably intended by many Committee members as no more than a temporary measure intended to give the Committee more time to consider and discuss the relevant ethical issues. But even a temporary ban is not warranted and could have substantially impaired the purpose of the legislature and the executive in creating the fund.

The ethical issues have been widely, deeply and publicly debated for at least five years. Members of the Ethics Committee should be, or become, familiar with those issues and be expected to act promptly – one way or the other. If members feel that they need time to consider and discuss the ethical issues, that could certainly be done without imposing a temporary ban on funding the very research that the legislation was created to promote.

The temporary funding ban recommended by the Ethics Committee raised a host of technical questions that arose in regard to the federal funding ban. For example, could a grant recipient continue with pre-existing research to derive new embryonic stem cell lines, and if so, how would it appropriately segregate grant funds? When, exactly, would the New York State

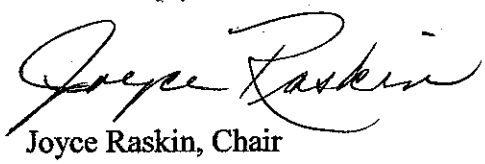
ban take effect? Could grant funds be used support research on stem cell lines created before the ban, or on lines created with private funding or in other states that permit state funding to be used to derive new embryonic stem cell lines? None of those matters was adequately considered by the Ethics Committee.

Most importantly, even a temporary ban sends a very unfortunate signal to New York State scientists who are considering expensive, multiyear research commitments for their laboratories and need stability and certainty regarding ethical rules that will apply to their work. No scientist is likely to commit his or her time, scarce laboratory resources and students to a complicated, ongoing research project when there is a significant chance that the work will have to be suspended or abandoned because of a shifting political battle over "ethics."

Conclusion

The Committee on Bioethical Issues of the Association of the Bar of the City of New York strongly supports the efforts of the Empire State Cell Board, and particularly of its Funding Committee, to clearly and unequivocally endorse, as ethically sound, scientific research that seeks to derive new embryonic stem cell lines from early stage embryos.

Sincerely yours,



Joyce Raskin, Chair

Cc Members of the Empire State Stem Cell Board

Endnotes

[i] A very useful but somewhat dated summary of scientific developments in stem cell research with extensive citation to the research literature is contained in Chapter 4 of a January, 2004 report by the President's Council on Bioethics entitled "Monitoring Stem Cell Research." The report is available on the Council's website at www.bioethics.gov/reports/stemcell.

[ii] See, generally, The President's Council on Bioethics, "Monitoring Stem Cell Research" (June 2004) (especially Chapter 2: "Current Federal Law and Policy").

[iii] For state laws, rules and policies regarding stem cell research and related matters, see National Conference of State Legislatures, *Stem Cell Research*, available at www.ncsl.org/programs/health/genetics/embfet.htm (last visited March 6, 2008) and Interstate Alliance on Stem Cell Research, *State Stem Cell Programs*, available at www.iascr.org/states.shtml (last visited March 6, 2008).

[iv] According to the National Conference of State Legislatures, Arkansas, California, Connecticut, Indiana, Iowa, Maryland, Massachusetts, Michigan, Rhode Island, New Jersey, North Dakota, South Dakota, and Virginia have banned human reproductive cloning. Arkansas, Indiana, Iowa, Michigan, North Dakota and South Dakota also prohibit cloning for research purposes, sometimes referred to as therapeutic cloning. See National Conference of State Legislatures, *State Human Cloning Laws*, available at www.ncsl.org/programs/health/genetics/ rt-shcl.htm (last visited March 6, 2008).

[v] The California Stem Cell Research and Cures Initiative (Proposition 71); Conn. Gen. Stat. §19a-32d through §19a-32g and 4-28e(c)(3) (2005); 410 Ill. Comp. Stat. §110 (2007); Md. Code, art. 83A, § 5-2B (2006); Mass. Gen. L. ch. 111L (2005); N.J. Rev. Stat. § 26: 2Z-1 et seq.; N.Y. Pub. Health L. art. 2, tit. 5-A (2007); Wisc. Exec. Order 147 (2006).

[vi] See press release, dated January 7, 2008, available at http://www.ny.gov/governor/press/0107081.html.

[vii] The phrase "one of us" is used by the President's Council on Bioethics in its report entitled "Human Cloning and Human Dignity", for example at pages 121 and 153, which is available at www.bioethics.gov.

[viii] For a further discussion of the ethics of creating "non-viable embryos" or "non-viable embryo-like artifacts" see the President's Council on Bioethics, "Monitoring Stem Cell Research" (Jan. 2004) at 89-903 available at www.bioethics.gov.

[ix] See, for example, the American College of Obstetricians and Gynecologists Committee on Ethics' Opinion Number 347 released in Novermber 2006 entitled Using Preimplantation Embryos for Research which permits research on preimplantation embryos younger than 14 days, the stage at which the primitive streak forms. See also the President's Council on Bioethics. "Monitoring Stem Cell Research" (Jan. 2004) at 78-84 available at www.bioethics.gov.

[x] George and Tollefesen, *Embryo* (Doubleday 2008) at 7.

[xi] *Id. at 216.* The authors propose that IVF should be legally regulated in the United States 'to ensure that couples create no more embryos that they could reasonably expect to bring to term." This would be a significant departure from current practice and would, at a minimum, make IVF significantly more expensive and burdensome to the patients and providers.

[xii] Professors George and Tollefsen argue that their position is not inconsistent with brain death "because the irreversible collapse of the brain destroys the capacity for self-directed integral functioning of human beings who have matured to the stage at which the brain performs the key role in integrating the organism. What is left is no

longer a unitary organism at all." But anyone who has seen a brain dead person whose heart is still beating, who is still breathing, metabolizing food, maintaining body temperature, growing hair and finger nails and other functions will instantly appreciate that its level of function and integration is vastly more advanced than that of a very early stage embryo.

[xiii] *Id.* at 131.

[xiv] *Id.* at 131-2.

[xv] *Id.*

[xvi] See President's Council on Bioethics, "Monitoring Stem Cell Research" (Jan. 2004) at 88.

[xvii] Researchers at the University of Wisconsin who developed the reprogramming technique have warned against abandoning embryonic stem cell research. See Leshner, Alan and Thomson, James, "Standing in the Way of Stem Cell Research," Washington Post, December 3, 2007 ("We simply cannot invest all our hopes in a single approach. Federal funding is essential for both adult and embryonic stem cell research, even as promising alternatives are beginning to emerge.").

[xviii] The widely reported 2007 claims of Korean scientists to have produced a cloned human embryo and to have extracted stem cells from them turned out to have been a stunning scientific fraud.

[xix] See minutes of meeting of Ethics Committee of Empire State Stem Cell Board, held on November 30, 2007, available at http://www.nystem.com/ethics/ecm_11_30_2007.html.