

**Empire State Stem Cell Board**  
**Full Board Meeting Minutes**  
**June 11, 2009**

The Empire State Stem Cell Board held a meeting on Thursday, June 11, 2009, in Meeting Room 2, at the Empire State Plaza, Albany, New York. Commissioner Richard F. Daines, M.D., presided as Chairperson.

**Funding Committee Members Present:**

Dr. Richard F. Daines, Chairperson	Dr. David Hohn
Mr. Kenneth Adams	Dr. Hilda Hutcherson
Dr. Richard Dutton	Dr. Michael Stocker
Mr. Robin Elliott	Ms. Madelyn Wils
Dr. Gerald Fischbach	

**Funding Committee Members Absent:**

Dr. Bradford Berk	Dr. Bruce Holm
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**Ethics Committee Members Present:**

Dr. Samuel Gorovitz	Rev. H. Hugh Maynard-Reid
Dr. Robert Klitzman	Dr. Samuel Packer
Dr. Vivian Lee	Mr. Robert Swidler

**Ethics Committee Members Attending by Telephone:**

Ms. Brooke Ellison	Ms. Nancy Neveloff-Dubler
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**Ethics Committee Members Absent:**

Fr. Thomas Berg

**Department of Health Staff Present:**

Mr. Martin Algaze	Ms. Amy Nickson
Dr. David Anders	Ms. Beth Roxland
Ms. Bonnie Brautigam	Ms. Lokia Rucker
Dr. Kathy Chou	Dr. Stewart Sell
Mr. Thomas Conway	Ms. Phyllis Silver
Ms. Judy Doesschate	Dr. Lawrence Sturman
Ms. Gail Gardener	Ms. Linda Tripoli
Dr. Matthew Kohn	Ms. Carlene VanPatten
Ms. Jerroo Kotval	Dr. Ann Willey
Ms. Marti McHugh	Ms. Kathy Zdeb

**Special Guest Present:**

Dr. John Gearhart

**Observers Present:**

Ms. Caron Crummey  
Mr. Michael Mangeniello  
Ms. Caroline Marshall  
Mr. David McKeon  
Ms. Barbara Meara

Dr. Scott Noggle  
Ms. Kelly Ryan  
Ms. Susan Solomon  
Mr. Steven Taylor

**Motion to Amend the Agenda**

Dr. Daines asked for a motion to amend the agenda for the Board to consider the adoption of a statement on the payment of gamete donors as its first item of business. Dr. Packer so moved and Dr. Stocker seconded the motion. The motion passed unanimously.

**Approval of Statement of the Board on the Payment of Oocyte Donors**

Dr. Daines directed members to a draft statement entitled "ESSCB Statement on Payments to Oocyte Donors" that had been distributed. He advised members that staff had prepared the draft statement in anticipation of inquiries regarding the resolution the Funding Committee adopted earlier in the day. He noted that members of the Ethics Committee had also expressed an interest in creating a document to educate the public on their findings and the rationale for their recommendations to the Funding Committee. Dr. Daines provided members with time to read the document and then opened the floor for comments and recommended changes to the document.

The Board recommended several edits to increase the accuracy and clarity of the document including: 1. replacing "insurmountable impediments" regarding oocyte procurement to "experience in other jurisdictions indicates that lack of reasonable compensation to women who donate their oocytes to stem cell research has created a significant impediment to such donation;" 2. adding a reference to both the short and long term risks of oocyte donation; 3. deleting the words "more than adequately" before "protects against this possibility of undue influence...;" 4. adding a reference to the American Society for Reproductive Medicine's (ASRM's) \$10,000 limit on payments; 5. inserting "(human eggs)" following the first use of "oocytes;" 6. deleting the phrase "at large" after "benefits to society;" and 7. deleting "cryopreserved oocytes."

Several members recommended that an introductory paragraph be added that clearly summarizes the Board's action and the rationale for the decision. It was noted that the summary contained in the resolution itself could be modified slightly and serve as the introductory paragraph. Dr. Lee also suggested that the introduction and the document should emphasize the substantial safeguards that are in place to protect women and that there is no ethical basis for differentiating between the compensation of women donating oocytes and other participants in research. Dr. Stocker suggested the statement should also clarify that the resolution does not refer to reproductive cloning.

Mr. Elliott commented that Fr. Berg's concern that the payments would be more attractive to women who are poor, minority or college students deserved more attention. He noted that one person's paternalism is another person's protection and that while the

Board favors free, informed choice, the statement should provide guidance on where and how these payments are advertised and encourage equal opportunities for all types of potential donors.

Dr. Daines noted that the discussion on the proposed Board statement was not an opportunity to change the standards in the resolution itself. He also reminded the Board that the proposed payments and the process for procuring oocytes would need to be cleared by Embryonic Stem Cell Research Oversight (ESCRO) committees, Institutional Review Boards (IRBs) and NYSTEM's contracting process.

Mr. Elliott inquired how the Board would respond to a hostile question suggesting that the Board did nothing to prevent the possibility that the people who donate oocytes are those with the least choices. Dr. Stocker pointed out that the system for oocyte donations for reproductive purposes has been in place for a long time. Ms. Roxland also noted that the Ethics Committee envisioned that exploitation would be protected against by the ESCRO and IRB reviews and individual research protocols. Dr. Gorovitz recommended that Mr. Elliott's concern should be addressed by adding an expression of the Board's confidence that the protective procedures implemented through ESCROs and IRBs will adequately protect against problems such as exploitation or inequitable access to opportunities to donate. Mr. Swidler suggested the Board should also require funded researchers to provide data to the Board on the donors who have been paid, how much they have been paid and their demographics. He also recommended that the Board explicitly require ESCRO committees to review marketing proposals.

Mr. Swidler noted that Fr. Berg's position should be included in the document. Dr. Hohn suggested that Fr. Berg's dissent could be addressed by having the opening paragraph note that after extensive deliberation and the solicitation of different points of view, the Board arrived at near total consensus with the decision with a single dissent. Members agreed that the process and a notation regarding Fr. Berg's dissent should appear near the beginning of the statement.

Ms. Roxland then advised members that she had drafted an additional statement to address the issue of any compensation being an allowable expense under NYSTEM contracts. Members agreed with the statement with one minor edit. In response to questions, Dr. Daines clarified that the statement and the resolution were expected to be posted on the NYSTEM website.

Dr. Daines then asked for a motion to approve the statement with the changes noted. Dr. Klitzman so moved and Dr. Gorovitz seconded the motion. The motion passed unanimously.

### **Approval of Minutes for the June 27, 2008, Full Board Meeting**

Dr. Daines directed members to the draft minutes for the June 27, 2008, meeting of the full Board included in their agenda books and asked for a motion to approve the minutes. Dr. Hohn so moved and Mr. Adams seconded the motion. The motion passed unanimously.

## **Program Updates**

Dr. Sturman reported on the status of all awards approved as of the date of the meeting. He reported that 24 of the 25 contractors awarded Institutional Development Grants have submitted reimbursement vouchers totaling \$10.1 million and that NYSTEM staff has begun to review progress reports and conduct on-site visits to audit the awards. Dr. Sturman reminded members that the 2009 Grantees Conference for scientists to report on the research funded through these grants was scheduled for the following day at the Desmond Hotel in Albany, New York.

Dr. Sturman reported that planning activities and progress reports are underway for the 18 recipients of the consortia planning grants. He advised members that NYSTEM staff has scheduled a forum for September 8<sup>th</sup> in New York City where awardees will have an opportunity to present information on their planning efforts.

Dr. Sturman reported that of the nine Shared Equipment/Facilities awards made totaling \$32.4 million, three have been submitted to the Office of the State Comptroller, five have been forwarded to the Department for processing and one contract is awaiting additional information.

Dr. Sturman stated that staff continues to work to execute the contracts for the 98 awards made for the targeted and investigator initiated research projects. He also stated that 69 of the awardees have returned the required proof of ESCRO, IRB and other approvals, allowing 57 contracts to be forwarded to the Department for processing.

Dr. Sturman advised members that the Undergraduate Curriculum Development Request for Applications (RFA) was released March 18<sup>th</sup> and six applications were received as of May 20<sup>th</sup>; the Summer Undergraduate Research Experience RFA was released April 8<sup>th</sup> and five applications were received as of June 1<sup>st</sup>; the Requests for Proposals (RFPs) for the Assessment of the Economic and Other Benefits of the NYSTEM Program was published on April 6<sup>th</sup> and proposals are due June 23<sup>rd</sup>; and staff continue to work on processing the RFP for Scientific Symposia for 2010-2014 and the RFAs for Recurring Innovative Investigator Initiated Research, Targeted Human Embryonic Stem Cell Research, Fellow-to-Faculty and Shared Facilities.

Dr. Sturman reported that the Board's comments relative to the National Institutes of Health's (NIH) Draft Guidelines for Human Stem Cell Research were submitted to the NIH and a copy of the letter has been posted to the NYSTEM website.

Dr. Sturman reported that the Interstate Alliance on Stem Cell Research (IASCR) met on May 5<sup>th</sup> and 6<sup>th</sup> and that Ms. Roxland and Dr. Willey attended this meeting. He stated that the purpose of the meeting was to hear NIH's perspective on the proposed NIH guidelines for use of federal funds in human embryonic stem cell (hESC) research and to facilitate communication among the various state stem cell research funding programs and minimize discrepant policies across the programs to the extent practicable.

**Presentation: “Natural and Experimental Chimeras” by Dr. John Gearhart**

Dr. Daines advised members that Dr. John Gearhart would be presenting information on the issue of chimeras. Dr. Daines advised members that Dr. Gearhart is the Director for the University of Pennsylvania’s Institute for Regenerative Medicine and the James W. Effron University Professor at the University of Pennsylvania. Dr. Daines also noted that Dr. Gearhart may be best known for his work in leading a research team that identified and isolated hESCs. Dr. Daines then turned the floor over to Dr. Gearhart.

Dr. Gearhart opened his presentation by expressing his appreciation for all the work the Board is doing to provide organization, oversight and support to the stem cell community and doing it well. He emphasized the importance of educating the public about science because the public is the patron of most research funding and commended the Board for having public discussions and working to ensure the public understands what the Board is doing.

He stated he would be talking about primary chimeras, secondary chimeras and interspecies chimeras. He advised members that the topic of chimeras impacts stem cell biology in many ways and that chimeras have been around a long time. The earliest human chimeras were detected from pronounced pigmentation patterns in individuals and through blood bank donations that revealed individuals with two or four different sets of the human leukocyte antigen (HLA) patterns. He noted that everyone in the room was probably a chimera because people have cells in their bodies that come from different sources. He then provided several examples of naturally-occurring human chimeras.

The first examples were two women who were tested for reasons unrelated to questions of parentage and both were told they were not the mother of their children. In each case it was determined that the woman had ovaries that had been derived from two different embryos and the germ cells in their ovaries were from two different embryos. Dr. Gearhart explained that in the early stages an embryo can be manipulated such that two four-cell embryos come together and aggregate, which results in a chimera. This can also occur naturally when the cells of twin embryos merge *in utero*. Dr. Gearhart also noted that human chimeras can be formed from embryos of different sexes which can present as intersex with issues such as undescended testes.

Dr. Gearhart also explained that some fetal cells cross the placenta into the mother during pregnancy and vice versa, and that this results in small pockets of cells of different genetic types being found in a wide range of tissues in both the mother and the fetus. He said it is possible to tell how many times a woman has been pregnant by looking at the different chimeric components in a woman. Dr. Gearhart said this is referred to as “microchimerism.” He advised members that researchers have found evidence of “good” microchimerism, such as when the fetal cells have repaired a damaged thyroid, as well as “bad” microchimerism that has resulted in auto-immunity in women, such as systemic sclerosis and systemic lupus erythematosus. Dr. Gearhart explained that these are all types of primary human chimeras. He also cited examples of secondary human chimeras that are the result blood transfusions, organ and bone marrow transplants and surgeries involving animal parts, e.g. replacing a heart valve with a pig’s heart valve.

Dr. Gearhart showed photographs of chimeras that were the result of two or more fertilization events, including chimeras in which the coat or skin was banded with different colors, a mouse that was created from two embryos – one of which had a fluorescence gene and a “geep” - formed from the combination of a goat embryo and a sheep embryo. He also showed a video of how a chimera could be created by picking up a blastocyst on the end of a pipette and injecting it with stem cells. He explained that any gene can be manipulated in embryonic stem cells and that this is a very powerful tool for manipulating a germ line and correcting genetic mutations.

Dr. Gearhart noted embryologists and biologists have been grafting cells from one animal to another and creating chimeras looking for clues in developmental biology for over a century. He advised members that when interspecies grafts are used, they raise questions about how good or reliable the information is compared to experiments using human cells and tissues. He stated there has been a concerted effort to produce animal models using human tissues that will accept grafts of human cells. As an example, he noted that sheep with a human liver or a human circulatory system can be a valuable tool to help scientists understand how different human grafts work. He noted that these types of developments raise questions about how much chimeras should be “humanized.”

Dr. Gearhart advised members that the National Academy of Science (NAS) and International Society for Stem Cell Research (ISSCR) guidelines address three issues with respect to research involving pluripotent stem cells and chimera. He said the greatest concern is related to embryonic chimeras, where human cells are injected at the blastocyst stage. In such cases, scientists are not sure where the human cells may wind up. He said most of the guidelines will not permit scientists to do this and then implant the chimera into a uterus.

The second type of restriction prohibits scientists from breeding chimeric human-animals. He said the fear is that some of these cells will form human eggs or sperm and result in the production of a human embryo inside of a mouse or other animal. He noted that although researchers may not be purposely involving the germ line when they use other cells, such as neuro stem cells, those animals should not be mated.

The final area of concern is when derivatives of human stem cells may wind up in the brains of animals. He said the concern is that higher human cognitive abilities might be transferred to the animal and that this will reduce the dignity of humans. Variables to be considered with respect to research involving the possible humanizing of an animal brain include: 1. the stage of development when the cells are introduced; 2. the proportion of human cells introduced; 3. the site of the graft; and 4. the relatedness of the host to the human. He said that putting brain cells in a very closely related primate raises special concerns because people fear those cells could affect the functioning of some higher cognitive abilities in these non-human primates. He noted that there is no animal with the number of connections and the architecture of the human brain, but that many ethical review boards want to look at this issue to determine what should be permitted.

Dr. Gearhart stated that one of the principal reasons for doing this type of research is to gather animal-based data for the federal Food and Drug Administration (FDA) to judge whether the kinds of cells proposed to be used in clinical trials are safe, whether

they will stay where they're supposed to stay, whether they will do what they are supposed to do and whether they work. He said the only place you can test the efficacy and safety of human stem cells is *in vivo*; it cannot be done in a laboratory dish.

Dr. Gearhart stated that one of the major questions with stem cell research is whether scientists should wait months, years or decades after performing a graft or conducting other stages of research before concluding it is safe. He said the FDA has stayed clear of this issue and relies on the scientists to provide them with their best animal data. He noted that everyone continues to struggle with this question.

Dr. Gearhart noted there are very legitimate reasons to use animals in research, but the experiment and its potential impact on the animals must be scientifically justified. He showed a video of an experiment that involved the destruction of the lower motor neurons of a mouse that was then infused with human neural stem cells. He advised members that every animal they performed this experiment on had a recovery of motor functions. He said there are a number of hypotheses about how this is happening, but that the human cells clearly created connections between descending motor neurons and muscles. Dr. Gearhart emphasized that these kinds of experiments are needed and very important in helping understand what is happening when a graft is performed. He then provided other examples to demonstrate the importance of using animal models to gain information about how human stem cells will behave when grafted.

Dr. Gearhart advised members that opposing views and concerns with humanizing animals include concerns about animal welfare, respecting the boundaries of species and respect for human dignity. He noted that there is also the “yuck” factor; the visceral reaction to the research and the images it creates. He suggested the Board will need to consider all of these factors while also understanding that some interspecies experiments are necessary to determine the safety and efficacy of human stem cell therapies.

Dr. Gearhart then provided clarification regarding the terms that should be used for various combinations that are often referred to as chimeras. He reminded members that chimeras are animals composed of cells derived from two or more zygotes. He contrasted this with a “mosaic,” which is an animal with two or more apparent cell populations, but formed from a single zygote. He noted that all women are mosaics because they have two x chromosomes (one from the mother and one from the father), but in each cell in the body, one or the other of the x chromosomes becomes inactive. In sum, a mosaic is the result of one fertilization event with different genetic events occurring in the cells.

Dr. Gearhart explained that a “hybrid” is the offspring of parents from different species through crossbreeding, such as a mule. A “clone” is an animal derived from a single individual. He noted that he had been among the people who started to coin the term “therapeutic cloning” and expressed his regrets for doing so. He urged members not to use that term for any purpose.

He advised members that the term “transgenic” applies to an organism whose genome has been altered by the transfer of gene sequences from another species or the

same species. He showed examples of transgenic mice and pigs that had a fluorescence gene inserted into them so the scientists could track the lineage of the offspring. Finally, he said the term “cybrid” is the appropriate term to be used when you recombine the nucleus of one cell with the cytoplasm of another.

Dr. Gearhart ended his presentation by noting that ethics boards and IRBs will need to address additional difficult ethical issues as the research progresses towards clinical applications. He said clinical trials raise questions about what kinds of cells can be used, what kinds of patients can participate in clinical trials, and what activities should be permitted. He advised members that recent studies also suggest that physicians will be able to supply certain molecules to tissues to repair or regenerate tissues and get them to function the way we want them to. He noted that this raises questions about how this technology can be used for other purposes, such as enhancing athletic and mental abilities. He noted this kind of technology could affect major changes in the human body that will not be traceable and that it will be a challenge to figure out how to oversee this to make sure it is done appropriately. Dr. Gearhart then offered to answer any questions members might have.

In response to questions asking him to elaborate on his last point, Dr. Gearhart noted that the work done on hESCs provided the foundation for the development of induced pluripotent cells (iPS) by helping scientists understand what genes were critical for pluripotency. He said scientists can use the four genes that have been identified as being critical to pluripotency to convert any cell back to something like a hESC. He noted that more recently researchers have gone beyond the genes and can do the same thing with proteins and small molecules. He stated that he thought these developments, along with the work done by Dr. Doug Melton that converted exocrine pancreatic cells directly into an endocrine pancreatic cell by introducing two genes into the pancreatic cells in an animal, suggests that scientists will be able to figure out how to affect the function of a cell by changing the extracellular matrix and substrates around it. He emphasized that all cell functions are contextual and that if you change the context and instructions, it will change the function of that cell. He also emphasized that because this is research, the forms these changes will take are uncertain.

In response to a question about what policies, guidelines and regulations he would develop on chimeras, Dr. Gearhart recommended the Board discuss these issues with their funded scientists to understand their vision of what they want to do and understand their needs and thoughts about what should be taken into consideration in these very difficult decisions. He also noted that the Board should address safety concerns and be mindful of the public’s sensitivities about these issues.

Dr. Gearhart responded to a question about the extent to which the Institutional Animal Care and Use Committee (IACUC) considers the ethical implications of animal-human research, by noting that the charge of the IACUC is not aimed at the research itself, but at the welfare of animals. He said their goal is to minimize the use of animals and any pain.

In response to another question, Dr. Gearhart acknowledged that transgenic, hybrids, clones and cybrids, as well as chimeras, all also raise significant questions and

concerns about human-animal experimentation. He noted that the issues with interspecies research need to be understood in the context of what the scientists are trying to accomplish. For example, when testing brain neurons that relate to higher cognitive functions, some people argue that they need to replace one quarter of the animal's brain architecture because if just a few neurons are introduced and interspersed among the animal neurons they will take on more of the properties and functions of animal neurons. He said he supports this kind of research because it is necessary to test things in the proper context, but that he also recognizes that this raises concerns about how much an animal should be humanized to test something in them.

Mr. Swidler noted that he was familiar with the debate on the potential for genetic enhancement or genetic therapies that would make people smarter, faster or better looking and asked Dr. Gearhart if he was talking about similar issues with regard to "cellular enhancements." Dr. Gearhart responded saying he sees these issues as being addressed by the overarching term "regenerative medicine," which is a continuum from molecules and cells to tissues, organelles and the rebuilding of parts of organs. Dr. Gearhart advised members that he sees the most important aspect of stem cell biology being the knowledge base that is developed from this research rather than all of the cell-based interventions people anticipate. He said stem cell research is helping scientists understand how cells do things and that scientists will figure out which genes are the important ones through stem cells. He said that whether changes are made through a cell or a molecule, the purpose for most of this is to develop strategies that can be used to rebuild, repair and renew the body. He noted that this gets into the real area of ethics and quality of life issues and what types of therapies and interventions are acceptable.

Dr. Daines noted that the Board could continue this dialogue for a much longer time and thanked Dr. Gearhart for his very informative presentation.

### **Draft Annual Report: Discussion and Adoption**

Dr. Daines then asked the Board to turn to the draft annual report that was included in their binders. He noted the annual report required the Board's approval before it would be finalized, formatted and posted on the NYSTEM website. He then turned the floor over to Dr. Sturman discuss the report.

Dr. Sturman advised members that the report had been revised to reflect the comments the Board had provided on an earlier draft. He noted that additional project abstracts would be added and that the photographs and images at the end of the report would be interspersed throughout the report. He then solicited comments from members on specific areas of the report.

Members offered many suggestions and guidance that resulted in agreement to revise the report to: 1. combine several charts regarding the geographical breakdown of awards and provide a comparative context, such as funding received from the NIH; 2. clarify early in the report that the time frame for the report is April 1, 2008, through March 31, 2009; 3. correct a reference to the limitation on hESC research to clarify that research would not be permitted "after formation of the primitive streak;" 4. clarify the

labeling on the chart showing “uncommitted funds;” 5. rearrange some descriptions in the section on the highlights of research in New York State to eliminate the inference that some of the previously mentioned research was not “translational;” 6. modify labels on two of the charts to simplify and clarify the research classifications; and 7. provide quotes from researchers so that the relevance and significance of this funding is more easily understood.

Mr. Swidler then moved to approve the Empire State Stem Cell Board Annual Report for 2008-09 with the modifications discussed. Dr. Packer seconded the motion. The motion passed unanimously.

### **Intellectual Property and Economic Development Workgroup Report and Discussion**

Dr. Daines noted that because of the timing, the discussion on educational programs and priorities would need to be postponed until another meeting. He then turned the floor over to Dr. Sturman and Mr. Adams to present a summary of the work and findings of the Intellectual Property and Economic Development Workgroup.

Dr. Sturman noted that members had been provided with copies of the workgroup’s draft report which included the meeting agendas, a list of attendees, a brief summary of what occurred at the meetings and several portions of a white paper prepared by Dr. Jerroo Kotval and Dr. Kathy Chou. He noted that the document had not yet been reviewed by the people who attended the meetings and that they would be provided with an opportunity to supplement the report. He then turned the floor over to Mr. Adams.

Mr. Adams provided a brief summary of the workgroup report and noted that it remains a work in progress. He thanked NYSTEM staff for their excellent work on the project and expressed his appreciation to all of the researchers, guest speakers and individuals who participated in the meetings. Mr. Adams stated that it appears that New York is well placed in its translational and intellectual property climate, especially compared with other research-intensive states. He noted that NYSTEM’s investment is focused on basic research and discovery and this research will by extension produce economic results beneficial to New York, but that the Board should not have a policy that ties that research to any particular specific fiscal or economic development outcomes.

Mr. Adams observed that New York's intellectual property policies are generally conducive to encouraging this research and translational applications. He recommended that any statewide policy modifications should be congruent with federal, international and interstate policies to maximize the potential for additional research dollars to flow into New York State and to encourage top notch researchers and business application specialists to locate here. He noted that the assessment of the overall culture for life sciences and translational development is beyond the scope of the workgroup, but that members looked forward to participating in that larger discussion with the relevant government policymakers.

Mr. Adams asked everyone who attended the meetings to review the draft report and their own notes and submit any additional comments, thoughts, observations or edits to Marti McHugh by the end of June. He said he wanted the final report to represent the common ground of all recommendations so that New York has the best climate for economic development to benefit from these research investments and so that NYSTEM's policies are supportive of this research. He said the final report will be shared with the Board and discussed at a future meeting. Mr. Adams noted that New York City Economic Development Corporation (NYCEDC) staff made a terrific presentation at the last meeting of the workgroup and then turned the floor over to Ms. Wils to provide information on a concept that came out of the workgroup.

Ms. Wils said she found the two workgroup sessions incredibly informative and appreciated the diverse points of view presented during the workgroup sessions, but felt that the workgroup had only gotten to the tip of the iceberg on these issues. She noted that some recurring themes became clear by the end of the second meeting. She also noted that the NYCEDC team has investigated what New York City needs to do to draw talent to New York City given the fact that it already has great talent in the education system, but that people tend to go elsewhere after they graduate. She then referred members to a proposal she had distributed. The document proposed that NYCEDC would work in conjunction with NYSTEM staff and the workgroup to develop an RFA for a study that would examine how a larger talent pool for stem cell research might be created in New York State. She noted that they might identify some very short term solutions about how to help with the talent pool and other longer term solutions relating to capital investments. One issue the group had been discussing is the ways they might help tenured faculty who are interested in transferring to New York, but would have to start the tenure track all over again. Ms. Wils stated that she would like to put together a scope of a study project that could be presented to the Funding Committee in the fall.

Dr. Daines commented that one of the themes that came through during the workgroup meetings was that any attempt by the State to make a claim on royalty or patent income is more likely to strangle the research than to result in a lot of benefit to New York State. He noted that New York was fortunate in not being bound as some other states and programs in this area. He said that there seem to be points of leverage and bottlenecks that can be addressed and open up this line of research and other funding sources. He stated he would be in favor of getting some good advice about smart entry points for state money that could relieve the bottlenecks and don't drive the most promising research elsewhere.

Dr. Sturman stated that he agreed with the first two hypotheses in the proposal and emphasized the benefits of recruiting more investigators who are successful competitors for NIH funding. He said he thought the proposal was an attractive idea.

Dr. Klitzman suggested that many faculty members do not think about patenting their work or know where to start in developing revenues from their work. He suggested that a course on academic-industry partnerships and other opportunities for faculty or researchers to network with industry and venture capitalists would help further economic development in New York State. Dr. Sturman noted that the draft workgroup report

included a reference to the “state as educators” and provided some examples of programs, workshops or courses for scientists and entrepreneurs to develop an understanding of how to bring together essential pieces like science marketing and securing funding.

Dr. Klitzman suggested that the last paragraph on page 7 of the draft report relating to “distributive justice” should be revised to make it clear that distributive justice is an aspirational goal that the Board wants to encourage, rather than mandate. Dr. Sturman clarified that the report was an overview of what was discussed at the meetings, but not final recommendations or conclusions. He said that they are briefly covered in the report because they were raised in the workgroup sessions, but that the statements in the workgroup report were not intended to finally resolve the issue. Mr. Swidler recommended that the report be revised to clarify that several participants commented on the importance of distributive justice.

Dr. Stocker noted that one of the workgroup participants had commented that some researchers are interested in commercialization and other researchers are not – they just want to do basic research. He stated there was discussion about whether there should be a preference in funding mechanisms for researchers and institutions that have a track record of commercialization since the intent of this funding is to get to cures and therapies. He said this raised interesting questions the Board should consider.

Dr. Stocker also commented that New York State seems to lose the opportunity for economic development when venture capital and angel investments are sought for preclinical development. He noted that it is important to have an academic center as a partner because that's where the intellectual property comes from, but that not-for-profit academic institutions are limited in how much they can use their facilities for activities that generate income. He noted that there really isn't good space for those kinds of activities, especially downstate. He said moving to the next level requires cooperation from academic institutions, but also requires the institution to let go a certain amount so that the project can get private money for commercialization.

Mr. Adams underscored Commissioner Daines' point that sometimes you can accomplish more with less. He said that New York's commitment to the research rather than economic development or a specific return on investment may enable New York to accomplish more. He suggested the workgroup might want to make a list of the things New York is *not* doing that are good and underscore that we're doing more for the environment and the culture by doing less.

Mr. Adams expressed his support for Ms. Wils' proposal and noted the study she proposed was intended to look at the unique obstacles in New York that might be preventing the State from attracting as many great researchers as we would like to see in New York. He noted that the workgroup heard that those obstacles are different in different parts of the State and that suggests a regional analysis is required. He noted that he would also like to see the study examine how government agencies could better coordinate activities better and develop policies that leverage what NYSTEM and the Board are doing. He noted that other states have lead economic development agencies

that are leveraging their investments in the life sciences and suggested that this should be part of the study.

Ms. Wils concluded, noting that she had also provided some information regarding other states and Governor Paterson's innovation economy matching grants program and expressed an interest in hearing about how that program is operating and the results.

### **Discussion of Future Agendas**

Dr. Daines opened the floor up for suggestions regarding future agendas and asked Ms. Roxland what issues she thought should be addressed at future Ethics Committee meetings. Ms. Roxland stated that she thought that chimeras should be on the next agenda, but stated she was interested in hearing what Board members thought.

Dr. Hohn suggested the issue of harmonizing state policies to prevent state rules from acting as a barrier for collaboration among researchers in different states. Mr. Elliott suggested public-private initiatives to draw on the resources of nonprofit organizations should be discussed. Dr. Klitzman suggested the Board look at the anticipated revisions to the federal FDA's regulations governing clinical trials.

Dr. Sturman noted that new RFAs will be developed based upon the Board's discussions. Dr. Daines noted that educational programs would be on a future agenda as well since it was removed from the day's agenda.

### **Adjourn**

Dr. Daines then asked for a motion to adjourn the meeting of the full Board. Dr. Stocker so moved. Dr. Packer seconded the motion. The motion passed unanimously.

*s/ Judy L. Doesschate, Esq.  
Executive Secretary to the  
Empire State Stem Cell Board  
Approved: December 11, 2009*