

Empire State Stem Cell Board
Funding Committee
Minutes

February 15, 2008

The Empire State Stem Cell Board Funding Committee held a meeting on Friday, February 15, 2008 at the Department of Health's Offices at 90 Church Street in New York City. Commissioner Richard F. Daines, M.D., presided as Chairperson.

Funding Committee Members Present:

Dr. Richard F. Daines, Chairperson
Mr. Kenneth Adams
Dr. Bradford Berk
Dr. Richard Dutton
Mr. Robin Elliott
Dr. Hilda Hutcherson
Dr. Michael Stocker
Dr. Harold Varmus

Funding Committee Nominee Present:

Dr. Bruce Holm

Ethics Committee Member Present:

Dr. Robert Klitzman

Department of Health Staff Present:

Dr. David Anders
Ms. Bonnie Brautigam
Mr. Thomas Conway
Ms. Judy Doeschate
Mr. Mike Heeran
Ms. Lalitha Iyer
Ms. Marti McHugh
Dr. Tia Powell
Dr. Lawrence Sturman
Ms. Mary Szesnat
Dr. Ann Willey

Observers Present:

Mr. Ramon Bonachea
Dr. Michelle Cissell
Ms. Sunita D'Souza
Dr. Kevin Eggan
Mr. Joseph Feldman
Mr. Robert Feldman
Ms. Sarah Fielding
Dr. Ihor Lemischka
Mr. Mark Leinung
Ms. Sarah Lewis
Ms. Crystal Mainiero
Mr. Michael Manganiello
Ms. Kathleen McAnulty
Ms. Elizabeth Misa
Dr. Janet Paluh
Ms. Katalin Polgar
Mr. Badri Roysam
Mr. Jeff Shapiro
Ms. Ester Warshaver
Ms. Jo Wiederhorn

Opening and Introductions

Chairman Daines called the meeting of the Funding Committee to order and welcomed members, staff and the public. He noted Dr. Bruce Holm had been nominated by Speaker Silver to serve on the Funding Committee and had been asked to participate in the discussions of the Funding Committee.

Dr. Daines reported that Dr. Rudolf Jaenisch, a pioneering stem cell investigator had accepted Wadsworth Center's invitation to deliver the 2008 Brown-Hazen Award Lectures on April 3rd and 4th in Albany and invited everyone to attend the lectures.

Dr. Daines also advised Committee members that Governor Spitzer had included second-year funding of \$50 million in his budget for the 2008-2009 fiscal year, as well as the balance of unspent funds from the \$100 million first year appropriation.

Dr. Daines then asked Committee members and staff to briefly introduce themselves for the benefit of the public attending the open session and those tuning in to the webcast.

Approval of Minutes of the January 7, 2008 Meeting of the Funding Committee

Following the introductions, Dr. Daines directed Committee members to the draft minutes under tab 1 of the agenda book and asked for a motion to approve the minutes for the regular and executive session meetings of the Funding Committee for January 7, 2008. Dr. Stocker so moved; Mr. Adams seconded the motion. The motion passed unanimously.

Department Update on Grant Awards and RFAs

Dr. Sturman provided an update on the status of the contracts for the institutional development grant awards and on the Requests for Applications (RFAs) approved by the Funding Committee.

Intellectual Property – Additional Policy Considerations

Dr. Daines reminded Committee members that they had approved some changes to intellectual property policies applicable to grants funded through the Empire State Stem Cell Trust Fund, but had also expressed an interest in considering requirements for a potential return on the State's investment from commercial products developed with state funds and access to the resulting health care treatments developed with state funds. Dr. Daines turned the floor over to Dr. Willey to provide the Committee with information on these issues.

Dr. Willey first provided a brief overview of the intellectual property policies contained in Appendix A-2 which will be annexed to all contracts grantees will be required to execute. Dr. Willey then provided an overview of the intellectual property policies of other state stem cell funding programs. She advised members that of all of the states funding stem cell research, only California has developed extensive, explicit policies governing the return of investment to the state and access to therapies developed using state funds. Dr. Willey explained that California has adopted different policies for not-for-profits and for-profit entities, but has not yet funded research conducted by for-profit entities. She advised members that the policies require extensive recordkeeping for the activities supported with state funds and the revenues generated from successful commercialization of the resulting discoveries.

The California formula for not-for-profits first requires the calculation of the net revenues received by the institution from the invention, which is then prorated based upon the investment of state funds in the underlying research. The institution is then entitled to keep a threshold amount of approximately a half million dollars of the institution's net revenue after expenses and paying the inventors' share of revenue. The institution is then expected to pay 25 % of the remainder back to the state. For for-profits, the percentage of the prorated state share of the net revenues paid to the State is 17% of the amount above the threshold. Dr. Willey noted that the net revenues will be a higher percentage of the entire revenues generated by the invention because for-profits do not tend to share invention

revenues with their inventor employees. Dr. Willey explained that California also has “blockbuster” provisions that would allow the state to recover higher amounts, which could be as much as six times the total amount of the original grant plus 1% of all royalties for the life of the patent, if certain thresholds and conditions are met. All funded entities must also make any resulting therapeutic product available at the predetermined MediCal rate. She also explained that the institutions are expected to police their partners in assuring a return on the investment. Dr. Willey noted that these provisions are viewed as a real disincentive for funded entities to pursue translational research and the development of any kind of commercialized product involving stem cells.

Strategic Planning Updates and Allocation of Resources

Dr. Daines noted that Committee members had been provided with a preliminary draft of the strategic plan to solicit their input on the goals and initiatives being proposed by the Strategic Planning Coordinating Committee. He then turned the floor over to Dr. Sturman and Dr. Stocker, Chair of the Strategic Planning Coordinating Committee, to seek the Committee’s input on some of the critical questions that need to be answered in the development of the strategic plan.

Dr. Stocker provided a brief overview of the activities of the Strategic Planning Oversight Committee. He noted that the document distributed to the Committee members was a draft outline of the plan that was intended to solicit their input and comments on the proposed goals and initiatives. He stated the Committee would be provided with a substantially more developed document by March 28th. Dr. Stocker noted that the document provides ranges for the different funding categories because of the difficulty of projecting the exact amounts that will be awarded for different funding initiatives over the next five years. He noted that he expects the strategic plan will be reviewed and revised on an annual basis. Dr. Stocker also provided Committee members with a draft revised mission statement and asked Committee members to make suggestions regarding either draft statement. Dr. Stocker then turned the floor over to Dr. Sturman.

Dr. Sturman brought forth a few issues for the Committee’s consideration. First, he suggested the Committee may want to develop some mechanism for funding career faculty awards for young investigators to encourage them to engage in stem cell research for many years. He noted that California has created five-year “new faculty awards” to develop the next generation of stem cell researchers. California has devoted \$80 million to these types of awards in the first two rounds. Dr. Sturman asked members if this is something they thought should be included in the strategic plan.

Several Committee members expressed support for the development of career awards as part of the strategic plan and asked for more details on California’s approach. Dr. Sturman noted that the California awards provide support of between \$300,000 and \$400,000 per year and could be used for salary, mentoring and other support for research. The Committee discussed whether there would be flexibility in the direction the researcher

could choose over the span of the award. Dr. Sturman noted that the California model expects researchers to be engaged in regenerative medicine research to build a stable environment. Members discussed some of the advantages and disadvantages of providing flexibility or potentially reducing the length of the awards to three years. Dr. Sturman verified that the Committee supported including some type of career awards of three to five years duration in the strategic plan.

Dr. Sturman then directed members to the papers he handed out and raised the question of whether the strategic plan should include a focus on funding targeted or mission-directed research. He suggested the Committee may want to look at targeting funds in some important areas that need to be researched, such as what defines an embryonic stem cell or a pluripotent stem cell, how do the lines differ from one another, understanding the paths for differentiation, and developing reproducible cell lines essential for therapy. He noted that the draft plan does not sub-divide research allocations in any way and asked members whether they thought the plan should direct funding towards research the Committee might judge to be avenues of high rewards that are not being pursued very vigorously in New York State at this point, or whether they should wait for opportunities as they arise.

Several members expressed a preference for allowing flexibility in the funding opportunities stated in the plan because the field is so dynamic and evolving that it is hard to predict where the research will take us in two to three years. It was noted that just because the strategic plan does not target certain avenues of research that does not mean that the Board will not choose to fund targeted research as opportunities arise.

Mr. Adams observed that with the amount of money allotted, the Board cannot do everything that California is doing and should not follow California's model in many regards. He expressed disapproval of California's complex model for obtaining a return on the State's investment. Mr. Adams also expressed a preference for the new streamlined mission statement that was circulated because it focuses the Board's energies. He stated that he hoped that even if after ten years and \$600 million no "blockbuster" discoveries are made in New York State, the State's investment will have contributed substantially to developing a strong research infrastructure that should make New York a much more attractive place for great science and the institutions that support it. He suggested that the Board should look to leverage other people's money to increase support for research in New York State and that the Board could play a role in improving the coordination of efforts of other agencies and programs supporting science and related activities. He asserted that we need to make sure that five or ten years from now, New York should have more companies involved in stem cell research than indicated in the articles distributed by Dr. Sturman. Dr. Stocker suggested that the best approach to defining the impact of this program might be to get good benchmarks to determine where we are with regard to the research environment and then to measure it in the future. Mr. Adams agreed, and noted that while the science is the priority, the Board should expect to be asked about the long-term benefits of the State's investment in the future.

Dr. Sturman commented that the conversation was the introduction to the third issue he wanted to raise with the Committee. He referred members to the list of companies in the 'Nature' article he provided to members and noted how few of them are operating in New York State. He asked whether the strategic plan should include some way of promoting linkages between academia and industry. Members expressed an interest in encouraging industry in New York State, but suggested that other mechanisms not within the control of the Board may have a larger impact on whether stem cell-related companies move to, stay or develop in New York State, e.g. "angel" venture capital, tax advantages, economic development incentives. Members also questioned whether the Committee should devote energies to looking at economic development responsibilities that are within the purview of other agencies. Mr. Adams suggested that someone connected with NYSTEM should be discussing with the State Development Corporation and NYSTAR their initiatives and figuring out how this program may benefit from their initiatives.

Dr. Daines stated that the Department has had conversations with NYSTAR and agencies interested in economic development to discuss coordination of efforts and will continue to have those dialogues.

Ethics Committee Report

Dr. Daines advised Committee members that the Ethics Committee expressed a desire to increase communication between the Funding and Ethics Committees. To assist with that process, each Funding Committee agenda will have a section to report on the activities of the Ethics Committee, and each agenda for the Ethics Committee will have a report on the Funding Committee's activities. In addition, when the Ethics Committee makes specific recommendations to the Funding Committee, it hopes to have two additional members of the Ethics Committee present at the Funding Committee meeting to promote a full dialogue on those recommendations. He noted that members of the Ethics Committee had expressed some level of disappointment with the Funding Committee's decision regarding the Committee's first set of recommendations, but felt that both Committees would benefit from this kind of increased communication. Dr. Daines then provided an overview of the Ethics Committee discussions regarding the Open Meetings Law, Embryonic Stem Cell Research Oversight committees, and other issues the Ethics Committee intends to explore further.

Dr. Daines advised the Committee that the primary recommendation of the Ethics Committee to the Funding Committee related to the funding proposals that would be considered in Executive Session. These proposals grew out of a collaborative effort between members of both Committees. Dr. Daines noted that Dr. Klitzman had taken a seat at the table and Dr. Gorovitz was on the phone to provide information regarding the genesis of these two proposals and to summarize the discussion in the Ethics Committee meeting that led to their further development. Drs. Klitzman and Gorovitz then presented the Committee with that information on the two proposals. One proposal would provide funding for summer internships in stem cell research for undergraduate students, and the other would

provide funding to promote the development and implementation of curriculum for undergraduate courses in stem cell research. Drs. Klitzman and Gorovitz responded to questions from members of the Funding Committee and thanked the Committee for the opportunity to speak in support of these two proposals.

Executive Session – Consideration of New Initiatives

Dr. Daines advised the Funding Committee that New York State procurement laws require the details of pending RFAs to be kept confidential, and therefore, the discussion of the RFAs being considered for issuance need to be discussed in executive session. Dr. Daines asked for a motion to adjourn the public session and go into executive session to discuss the proposed RFAs. Dr. Varmus so moved; Dr. Stocker seconded the motion. The motion passed unanimously.

Approved: March 28, 2008