

Empire State Stem Cell Board
Minutes

October 22, 2007
9AM – 11:45 AM and 3:15 PM to 3:30 PM

The inaugural meeting of the Empire State Stem Cell Board was held on Monday, October 22, 2007, at the New York Academy of Sciences Conference Center, 7 World Trade Center, New York, New York. Commissioner Richard F. Daines, M.D., presided as Chairperson.

Board Members Present:

Dr. Richard F. Daines, Chairperson
Mr. Kenneth Adams
Fr. Thomas Vincent Berg
Dr. Bradford Berk
Dr. Richard Dutton
Mr. Robin Elliott
Ms. Brooke Ellison
Dr. Gerald Fischbach
Dr. Samuel Gorovitz
Dr. David Hohn
Dr. Hilda Hutcherson
Dr. Robert Klitzman
Rev. H. Hugh Maynard-Reid
Dr. Michael Stocker
Dr. Daniel Sulmasy
Mr. Robert Swidler
Dr. Harold Varmus

Department of Health Staff Present:

Dr. David Anders
Ms. Bonnie Brautigam
Mr. Thomas Conway
Ms. Judy Doeschate
Dr. Carmen Mannella
Ms. Diane Mathis
Ms. Marti McHugh
Ms. Amy Nickson
Dr. Tia Powell
Ms. Beth Roxland
Ms. Wendy Saunders
Dr. Lawrence Sturman
Ms. Mary Szesnat
Dr. Jill Taylor

Ms. Joann Wells
Dr. Ann Willey
Ms. Katherine Zdeb

Special Guests Present:

Lt. Gov. David Paterson
Dr. Jonathan Moreno

Observers Present:

Mr. Robert Cohen
Ms. Jean Ellison
Mr. Edward Ellison
Mr. Robert Feldman
Ms. Janet Felleman
Mr. Ross Frommer
Mr. Matthew Haiken
Ms. Amy Happ
Ms. Julia Rubin
Mr. Mark Leinung
Mr. Jack Linville
Ms. Crystal Mainiero
Mr. Michael Manganiello
Ms. Kathleen McNulty
Ms. Elizabeth Misa
Ms. Taylor Palumbo
Ms. Kelly Ryan
Ms. Susan Solomon

OPENING COMMENTS AND INTRODCUTIONS

Chairman Daines called the meeting to order and welcomed Board members, presenters, support staff, and other guests to the first regular meeting of the newly created Empire State Stem Cell Board. He commented that New York State is at the beginning of an endeavor that could potentially become the greatest scientific endeavor in the history of New York State; one that holds great promise for saving lives and improving health, and also for strengthening and revitalizing the state's biomedical research industry. He noted that with an investment of over \$600 million spread over 11 years, New York will now be positioned to be a leader in stem cell research. Dr. Daines thanked Governor Eliot Spitzer and Lieutenant Governor David Paterson and other state leaders for their visionary effort that resulted in the enactment of this initiative, as well as members of the medical, scientific, voluntary health, and patient advocacy communities, who urged the state to embrace this promising field of science.

Dr. Daines noted that the Board members who have agreed to serve include many of New York's preeminent leaders in the fields of science, public health, economics, and ethics. He

asked Board members to briefly introduce themselves. Following their introductions, he thanked Board members for their commitment to serving on the Board and for taking on the challenge of determining how best to invest in research to advance stem cell science.

Dr. Daines then introduced Department staff who will be assisting the Board in fulfilling their responsibilities: Dr. Lawrence Sturman, Director of Wadsworth Center, who will serve as the Executive Director of the Empire State Stem Cell Board; Judy Doesschate, Esq., who will serve as Director of Board Operations; Dr. David Anders, a research scientist, who led a Wadsworth Center group to interview stem cell scientists across the state; Bonnie Brautigam, who will administer the Board's funding programs; Dr. Ann Willey, Director of Wadsworth's Office of Policy and Planning; Dr. Tia Powell, who is the Executive Director of the New York State Task Force on Life and the Law and will serve as a special assistant to the Commissioner on this project; Ms. Wendy Saunders, who is Chief of Staff; and Mr. Tom Conway, who is General Counsel for the Department of Health.

Dr. Daines previewed the agenda and noted that Lieutenant Governor David Paterson, who has been a longstanding advocate of stem cell research and headed the Governor's effort to establish this initiative, will be speaking later in the day.

Dr. Daines then turned the floor over to Ms. Doesschate to review the Board's organization and responsibilities and present the proposed bylaws to the Board.

BOARD ORGANIZATION:

Overview of ESSCB Statute, Public Officers Law, and Related Provisions

Ms. Doesschate advised members that the Department of Health provides all new boards with a brief orientation regarding their responsibilities under the various laws that govern board activities. She then provided an overview of Chapter 58 of the Laws of 2007 that created the Empire State Stem Cell Board (ESSCB); the Code of Ethics contained in the Public Officers Law §74; General Construction Law §41; and the Open Meetings Law. She reviewed the specific responsibilities of the Funding and Ethics Committees, informed members of their right to be defended for non-criminal acts related to their service on the Board, advised them of their obligations to avoid even the appearance of impropriety in their service on the Board, addressed quorum and voting issues, and reminded them to file an oath of office, if they have not already done so.

Ms. Doesschate advised the Board that in accordance with Governor Spitzer's Executive Order No. 3, all meetings of the ESSCB will be webcast and will be available on the Department of Health (DOH) and NYSYSTEM websites. They will also be archived and continue to be accessible 30 days after each meeting. Ms. Doesschate noted that Board documents are subject to the Freedom of Information Law, but may be subject to various confidentiality requirements. She encouraged Board members to refer any requests for access to records to her or DOH's Records Access Officer to ensure that disclosures do not violate any statutes or personal privacy protections that might apply.

Ms. Doesschate encouraged Board members to give the Office of Counsel or her a call whenever they might have questions regarding their responsibilities under the law.

Adoption of Empire State Stem Cell Board Bylaws

Ms. Doesschate provided an overview of the proposed bylaws. She noted that many of the statutory provisions highlighted earlier in her presentation were incorporated into the proposed bylaws. Ms. Doesschate advised members that the purpose of incorporating Robert's Rules of Order into the bylaws is to provide a structure for the meetings, to help the Board conduct its business, and to ensure members are clear about matters being considered for formal action by the Board.

Ms. Doesschate called the Board's attention to Article VII of the proposed bylaws, which establishes standards for independent peer review and merit-based peer review application guidelines. She pointed out that these are unique to the ESSCB's bylaws and required by the ESSCB statute. She advised the Board that the proposed guidelines include basic principles used in many peer review processes, including scientific qualifications for reviewers and protections against conflicts of interest, while ensuring that the Funding Committee has some flexibility to tailor the level and type of review to the specific types of activities to be funded. She noted the Funding Committee can provide additional guidance when specific funding proposals are considered, and that reviewers will be required to apply the criteria established by the Funding Committee in its solicitations. Ms. Doesschate also stated that, consistent with the statute, Article X of the bylaws requires the merit-based peer review guidelines to be adopted by a majority of the Funding Committee. Following that, it would be appropriate to have the entire Board adopt the bylaws.

Mr. Adams moved that the Funding Committee approve the independent scientific peer review and application guidelines contained in Article VII of the proposed bylaws. Dr. Varmus seconded the motion.

During the ensuing discussion of the proposed bylaws, several members expressed concern that the flexible language contained in section 4 of Article VII could be construed as allowing the Funding Committee to routinely dispense with peer review of applications. After further discussion of various circumstances in which it might be appropriate for the Funding Committee to rely on other objective criteria and/or prior peer-review of research, Dr. Varmus moved that section 4 of Article VII be amended to insert "under exceptional circumstances," after the phrase, "notwithstanding the foregoing." Dr. Hohn seconded the motion. Chairman Daines then polled the members of the Funding Committee on the proposed amendment. The motion passed unanimously.

Dr. Daines then polled the members of the Funding Committee on the main motion to approve Article VII, as amended. The motion passed unanimously.

Dr. Klitzman moved to approve the proposed bylaws, as amended. The motion was seconded by Dr. Stocker. The motion passed unanimously.

Adoption of Guidelines for Observers

Ms. Doesschate explained that proposed guidelines for observers follows a template used successfully by the Department for many other boards and councils, modified slightly to reflect the Board's title and structure.

Dr. Klitzman moved to approve the proposed Guidelines for Observers. Reverend Maynard-Reid seconded the motion. The motion passed unanimously

STEM CELL RESEARCH IN NEW YORK STATE: A SNAPSHOT

Chairman Daines introduced Dr. Anders, who presented information gathered by a team of Wadsworth Center staff, who interviewed stem cell researchers across New York State. Dr. Anders pointed out that members were provided with a copy of the full report which includes a directory of the 162 stem cell scientists, representing 21 different institutions, who were interviewed. (see http://www.stemcell.ny.gov/publications_stem_cell_research_in_nys.html.) Dr. Anders provided breakdowns regarding research topics, types of cells used, funding sources, and patents of the scientists funded. Based upon the results of the survey, the team concluded that there is a large, robust community of stem cell scientists in the state, as judged by their publication record, their external funding record, their diverse interests and expertise. Dr. Anders noted that of the 39 investigators engaged in human embryonic stem cell research, 24 reported using only NIH-approved (“registry”) hESC lines.

Dr. Anders also presented information regarding the types of funding mechanisms interviewees thought should be pursued. Investigator-initiated large grants, investigator-initiated innovative research grants, multi-investigator grants, postdoctoral training grants, and grants to target recruitment of senior investigators were most commonly mentioned by the scientists surveyed. There was also considerable enthusiasm for short-term funding for “sabbaticals” in which investigators could visit another laboratory to acquire specific training in stem cell research or a related field. He noted the collected data also provided evidence of the need for traineeships, with only 58% of all principal investigators currently having graduate students working on stem cells. He said there was little support for institutional training grants in which graduate students or postdoctoral fellows are supported to work in assigned labs en masse. He stated there was a very strong consensus among the scientists that the available funding should be used to enhance support for human embryonic stem cell research, but should not be restricted to human embryonic stem cell research. He noted that researchers almost universally felt it would be useful to organize annual conferences and/or workshops to bring researchers from around the state together to exchange ideas.

Dr. Anders responded to questions from Board members. In doing so, he agreed that some investigators felt that access to materials had impeded their research, and clarified that researchers favored using the appropriated sums to fund research and provide support to laboratories, rather than building facilities. Several Board members expressed the view that they would like to see the available funds used to catalyze the development of a coherent research community in New York through workshops and conferences.

Dr. Daines thanked Dr. Anders for his presentation and noted that some of the questions raised by Board members provided an appropriate segue into the next agenda topic.

STRATEGIC PLAN OPTIONS AND DISCUSSION

Dr. Daines informed Board members that a description of some of the most commonly used mechanisms for funding research was provided in their agenda books as background for

members who may not be familiar with grant funding processes. He noted that an initial \$100 million in funding is available for distribution in the current state fiscal year, and that an additional \$50 million has been committed for each of the following ten years. He advised the Board, that its primary task is to find an effective, productive way to begin using these funds as early as this year. Board members were also provided with a copy of the strategic plan for the California Institute for Regenerative Medicine. Dr. Daines noted the Board could follow that Institute's approach of contracting out the strategic planning process, or could undertake strategic planning in collaboration with Wadsworth Center staff. Dr. Daines asked Board members for their thoughts on how they would like to proceed with making decisions on the kinds of research activities they want to fund, and on the strategic planning process.

Board members provided their views on the benefits and drawbacks of engaging in a strategic planning process, the elements of a strategic plan, and the processes they could employ in developing a strategic plan. During the discussion a consensus evolved that the Board should engage in a strategic planning process; that the process needs to be driven, directed, and finally passed by the Board; that the Board may use a combination of internal staff and external consultants; that the strategic plan should have an educational and reasonable expectation setting aspect, as well as a technical plan for the experts; that it should address the economic and academic development aspects of stem cell research, as well as the strictly scientific and research and development aspects; that it should identify New York's natural niches and uniqueness and consider potential opportunities to link up with other states in the Northeast engaged in similar activities; that the plan must have a vision, mission, goals, and values; that stakeholders need to be consulted and re-consulted at multiple stages during the project; and that it would be good to develop the plan within the next six months to begin to guide the Board in the 2008-2009 fiscal year. Several Board members also expressed the view that the strategic plan should not be as detailed or directed as the one developed in California, and it shouldn't become the principal product of the Board. The Board also agreed that it should move quickly to begin funding worthy projects this year, which may be in advance of the final formal strategic planning.

Board members also acknowledged that the strategic planning process requires a great deal of legwork to gather information on what has been done, what has worked, and what hasn't worked. Some Board members also suggested the Board form a subcommittee to lead the strategic planning process. Dr. Berk suggested that the Department contact the administration of academic health centers that have engaged in strategic planning, because they are likely to have a large amount of the data that is needed for a strategic plan. Mr. Adams commented that if the Board plans to engage a consultant, it should be done at the beginning of the process, rather than later on. Dr. Daines concluded the discussion by summarizing the consensus of the Board, and asking Dr. Sturman to consult with any and all members of the Board, identify resources, investigate viable options, and report back to the Board.

FUNDING COMMITTEE EXECUTIVE SESSION

Dr. Daines noted that the next item on the agenda was the Funding Committee's consideration of a Request for Proposals (RFP) for peer review services. He stated that the State Finance Law requires the details of an RFP to be kept confidential until it is approved and published, and since the Funding Committee will next be discussing the terms of a proposed RFP, that needs to occur in executive session.

Dr. Daines requested a motion for the Funding Committee to move into executive session. Dr. Stocker so moved; and Dr. Fischbach seconded the motion. The motion was voted upon by the members of the Funding Committee and was passed unanimously.

COMMENTS OF LT. GOV. DAVID PATERSON

The full Board reconvened at 3:15 P.M.; following a meeting of the Ethics Committee held in the afternoon. Dr. Daines introduced Lt. Gov. David Paterson, noting it was logical for Governor Spitzer to designate him as his representative for this stem cell initiative because the Lt. Gov. has been a long-term champion of stem cell research. Dr. Daines welcomed Lt. Gov. Paterson and turned the floor over to him.

Lt. Gov. Paterson said he came to offer encouragement to the members of the Board, and to express his and Governor Spitzer's appreciation for their participation on the Board. He said that the State committed one hundred million dollars in the first year, and fifty million dollars per year each year for the next ten years, to send a signal to medical facilities and researchers that this is a serious commitment that will be sustained. He stated that the expectation is that funding will reach over a billion dollars at its peak and encouraged the Board to begin funding immediately, within ethical parameters, to help return New York to a position of leadership in medical and scientific research. The Lt. Gov. also expressed his gratitude to Commissioner Daines for responding swiftly to the administration's lofty goals for this initiative. He concluded by thanking the Board members for joining the administration in this endeavor and thanking them for their hard work and commitment to the task.

Approved: May 13, 2008