

**Empire State Stem Cell Board
Ethics Committee Meeting Minutes
May 21, 2013**

The Ethics Committee of the Empire State Stem Cell Board held a meeting on Tuesday, May 21, 2013, at the offices of the Department of Health, 90 Church Street, New York, New York. Janet Cohn presided as Chair-designee.

Ethics Committee Members Present:

Ms. Jann Armantrout
Ms. Nancy Dubler
Ms. Brooke Ellison*
Dr. Samuel Gorovitz
Dr. Robert Klitzman

Rev. Maynard Hugh-Reid
Dr. Inmaculada de Melo-Martin
Dr. Samuel Packer
Dr. Allen Spiegel, Vice-Chair
Dr. Camille Wicher

Funding Committee Members Present:

Mr. Robin Elliott
Dr. Richard Gronostajski
Dr. Mario Loomis*
Dr. Samuel Packer
Dr. Allen Spiegel, Vice-Chair
Dr. Melissa Wasserstein
(*participated by videoconference)

Department of Health Staff Present:

Ms. Janet Cohn
Dr. Kathy Chou
Dr. Matthew Kohn
Dr. Jill Taylor
Ms. Mary Thatcher

Guest Presenter:

Dr. Ann Willey

Observers Present:

Ms. Julia Gelman
Mr. John Gee

Welcome and Introductions

Ms. Cohn called the meeting to order and welcomed board members, staff, and the public. She stated that Dr. Shah would not be attending that day and reminded Board members that, pursuant to Public Health Law 206(8), he had delegated the authority to Ms. Cohn to act in his position when he was absent from meetings.

Ms. Cohn introduced the two new members of the Ethics Committee, Dr. Camille Wicher, Vice-President of Clinical Operations, Corporate Ethics and Research Subject Protection at Roswell Park Institute; and Dr. Inmaculada de Melo-Martin, Associate Professor in the

Division of Medical Ethics at Weill Cornell Medical College. She then asked board members and staff to introduce themselves.

Approval of Minutes for the May 22, 2012, Ethics Committee Meeting

Ms. Cohn asked for a motion to approve the minutes from the May 22, 2012 Ethics Committee meeting. After a brief discussion, Dr. Gorovitz so moved, Dr. Packer seconded, and the motion passed.

Discussion and Possible Recommendation of Revisions to Appendix A-2 to NYSTEM Contracts

Ms. Cohn asked Dr. Kohn to describe the proposed changes to Appendix A-2. He explained that these were recommended by staff based on another year's experience with NYSTEM contracts and pointed out that they were not substantive changes. Rather, they reflected an effort to clarify the Board's language and/or intent.

Dr. Kohn explained that the changes staff were recommending included removal of the acronym HSC, since it is not a standard abbreviation; removing redundant language contained in E(1)(e) and elsewhere; dividing Section E(1)(c) into two separate categories because each represents a different cell type; removing the "E" from ESCRO (Embryonic Stem Cell Research Oversight), as those bodies oversee more than embryonic stem cell research and for greater consistency with the guidelines of the International Society for Stem Cell Research (ISSCR); and expanding the exemption from SCRO review to include research involving Induced Pluripotent and other types of stem cells discovered after the ISSCR and the National Academy of Science drafted their guidelines, upon which NYSTEM's were modeled.

Ms. Cohn then asked for a motion to recommend the changes to the Funding Committee, which would have an opportunity to consider them later that day. Dr. Gorovitz first suggested that a definition of "march-in rights" be included in a footnote, which Ms. Brautigam agreed to do. Dr. Ellison pointed out that the changes would generally bring NYSTEM more into alignment with the standards of the ISSCR.

Dr. Klitzman moved that the changes be recommended and Dr. Packer seconded the motion. It passed unanimously.

Presentation and Discussion: *AMP v. Myriad Genetics*

Ms. Cohn introduced the two speakers who would discuss the case of *AMP v. Myriad Genetics*, which had just been argued in the United States Supreme Court.

First, the Committee heard from Dr. Ann Willey. Dr. Willey worked in the Wadsworth Center of the Department of Health for more than 25 years, is currently an Adjunct Faculty

member of both the School of Public Health in Albany and the Albany Law School and an expert in Patent Law.

Next, the Committee heard from Ms. Nancy Dubler, a founding member of the Empire State Stem Cell Board Ethics Committee, a Harvard-trained attorney and the founder of the Bioethics Consultation Service at the Montefiore Medical Center, where she served as Director for 30 years.

Dr. Willey provided an account of the legal background to *AMP v. Myriad*. She reminded members that the purpose of the Patent Law was to strike a balance between encouraging and rewarding innovation and making those discoveries available for further development by others. The basis for the challenge to Myriad's patent was its "subject matter." In this case, plaintiffs challenged Myriad's ability to patent a gene, something that already existed in nature that the "inventors" had not created or improved upon. In this case the challenged patent was of two genes -- BRCA1 and BRCA2 -- which have a strong correlation with an increased risk for breast cancer and ovarian cancer. After receiving its patents, Myriad exercised its rights exclusively, making the test for the presence of the genes prohibitively expensive for many women.

Relying on Supreme Court precedent, the federal appellate court upheld the patent in most respects. Dr. Willey pointed out that historically the Supreme Court deferred to the Patent and Trademark Office and has left it to Congress to overturn its decisions. The final outcome here, however, could not be predicted.

Ms. Dubler focused her remarks on the origins of patent law in our Constitution, the development of the nation's values, and the decline of the notion put forth by John Locke that private property was to serve the public good. In this case, she stressed, private property had been exploited in such a way as to deprive most consumers of its benefits, benefits that could affect their health and life. A lengthy discussion ensued, which was recorded and is preserved in NYSTEM archives.

Adjourn

Dr. Klitzman moved to adjourn the Ethics Committee meeting and Reverend Maynard-Reid seconded. The motion passed and the meeting was adjourned.

*s/ Janet Cohn
Executive Secretary to the
Empire State Stem Cell Board
Approved: October 31, 2014*