PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Pub lic Health Council was held on Wednesday, April 25, 2007, 10:00 a.m., at the Department of Public Health, 250 Washington St., Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair John Auerbach, Commissioner, Department of Public Health, Ms. Helen R. Caulton-Harris, Dr. Muriel R. Gillick, Mr. Paul J. Lanzikos, Dr. Philip C. Nasca, Ms. Lucilia Prates Ramos, Mr . José Rafael Rivera, Mr. Albert Sherman, Dr. Michael Wong, Dr. Alan C. Woodward, and Dr. Barry S. Zuckerman. Absent was Dr. Michèle David. Also in attendance was Attorney Donna Levin, General Counsel, Department of Public Health.

Chairperson Auerbach announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance . The new Commissioner of Public Health introduced himself and the new members of the Council as follows:

"I am happy to introduce myself to you. I am John Auerbach, and I am the new Commissioner of Public Health for the Commonwealth of Massachusetts. I am the Chairperson of the newly reconstituted Public Health Council, and with me you will see many of the members of that newly reconstituted Council. As those who are here may know, the previous Council has been disbanded, and a new Council has been created, that is larger and that represents a wide variety of different areas of expertise, and you will hear in a minute from the new Council Members, their introductions of themselves and what they do, and you will have a sense of the diversity and the expertise that is represented among the new Council Members."

Chairperson Auerbach said further, "The new Council Members were appointed by Governor Deval Patrick, and they each will have a six year term. The Members of the Council were selected, in part, because there are specific requirements for certain types of affiliation and expertise but also because the Governor, in consultation and cooperation with the Legislature, wanted to ensure that the Public Health Council was able to operate with the highest degree of standards and integrity, as it deals with some of the most challenging health and public health issues in the Commonwealth. It was in the interest of the Governor and the Legislature to ensure that the Council had people who made decisions, often very important decisions, using public health principles, using evidence - based approaches, using science as their guiding principle as to what is in the best interest of the health of the residents of the Commonwealth of Massachusetts…"

The present Council Member introduced themselves as follows:

1. Dr. Barry S. Zuckerman, Professor and Chair of Pediatrics at Bost on University School of Medicine and Boston Medical Center

2. Lucilia Prates Ramos, Director, Massachusetts Medicare Patrol (SMP) Program. "It is a program that outreaches and educates limited English proficient populations across the state around Medicare issues and how to become active health care consumers to prevent health care errors, fraud and abuses.

3. Paul J. Lanzikos, Executive Director of North Shore Elder Services in Danvers. He noted that his appointment is based on the recommendation of the Secretary of Elder Affairs.

4. José Rafael Rivera, Substance Abuse Specialist for the Central Massachusetts Center for Healthy Communities and Member of the Board of Directors for MACHW, the Massachusetts Association for Community Health Workers.

5. Dr. Michael Wong, physician at Beth Israel Deaconess Medical Center and Community Health Center. He noted that he does a lot of work with HIV.

6. Albert Sherman, Vice Chancellor, University of Massachusetts Medical Campus in Worcester and a registered pharmacist. Mr. Sherman noted that he is the only hold-over member from the previous Public Health Council.

7. Dr. Alan C. Woodward, President of Emerson Hospital Emergency Physicians. Dr. Woodward noted, "I have been a practicing Emergency Physician since 1981 in Massachusetts. I have been involved in a host of public health and patient advocacy initiatives, first as President of the Mass. College of Emergency Physicians, also as a District President, and two years ago, served as President of the Massachusetts Medical Society, and was very much involved in the development of Chapter 141, our Patient Bill of Rights, and several other public health initiatives, and establishing a Public Health Committee at the Mass. Medical Society as a standing committee, and some of its subsidiaries that work on a host of different public health matters.

8. Helen R. Caulton-Harris, Director, Division of Health and Human Services, City of Springfield. Ms. Harris said, "I have direct oversight for the Department of Health and Human Services, administrative oversight for Elder Affairs, Veterans, the Library, and the Animal Control Shelter and a Job Training Program."

9. Philip C. Nasca, Ph.D., Professor of Epidemiology at the School of Public Health and the Health Sciences at the University of Massachusetts Amherst, and also Associate Dean for Research in the School of Nursing.

10. Dr. Muriel R. Gillick stated, "…I am a physician, specializing in geriatrics and palliative care for Harvard Vanguard Medical Associates. I was previously Physician in Chief at Hebrew Rehab Center, and Director of the Geriatric Fellowship Program at Harvard Medical School, and my scholarly interests are in ethical issues near the end of life."

In the closing of introductions, Chairperson Auerbach stated, "In addition to the expertise that people have in Health and Sciences, we are also very pleased that the Council Members represent a great deal of diversity with regard to the sections of the state that they come from, how there has been attention to have all regions of the state represented by different individuals and institutions. There was also a good deal of attention to representating the racial and ethnic diversity of the Commonwealth and about forty percent of the members have been appointed by the Governor are people of color, and we are proud of that, as well."

State Representative Peter Koutoujian on 105 CMR 960.000:

State Representative Peter Koutoujian from Waltham. He said in part, "I am Chairman of the House Committee on Public Health and I am pleased to be in support of the proposed changes to 105 CMR 960.000…I was at the last meeting when the regulation about which we speak was first proposed and discussed, and it concerned me a great deal, that we were going to create – instead of tearing down walls to greater research and greater benefits to the people, we were going to build walls. We were going to put up hurdles. We were going to create obstacles, and I think that this is not only unfair to scientists, it undermines an industry with a potential to revitalize the Massachusetts economy, as well as to save countless lives and alleviate suffering in countless more lives."

State Rep. Koutoujian continued, "The proposed regulations respect scientists as the committed professionals they are rather than treating them as unethical entrepreneurs. I have always held the highest regard for the ethics of the scientists and for those that would like to suggest that they are not ethical, they are sadly mistaken because I know many scientists, and I know this industry, and I know how careful they are with regard to their ethics, and how thoughtful they are with regard to these issues. 105 CMR 960.000, as it currently stands, places state authorities and life scientists in opposition rather than encouraging collaboration, and I believe that we have to create an arena in which we actively foster research in therapies and life sciences, and regenerative medicine. Further, we must create a certainty to our regulatory environment, instead of an uncertainty, in order to create more contribution by these scientists, and particularly when we add criminal penalties to the mix. This really goes beyond the pale, as far as I am concerned, with regard to how much we trust the people that we are trusting with our lives right now."

State Rep. Koutoujian said further, "We are all excited about the potential of stem cell research to provide the treatments for many conditions, such as diabetes, asthma, Parkinson's Disease and spinal cord injuries. I still remember having our first stem cell debate, where young diabetics, 13 and 15 years olds, who stood and spoke and thinking

how powerful, mature and poised this young girl was and then another child and another just as poised and mature. I realized it was because they had to be much more adult in their younger ages, and that they had to grow up, and that they carried the weight of not only their own, but their parents' worry for them, too, which was very apparent in their relationships…"

State Rep. Koutoujian noted that a woman at the hearing noted that she had a dream that one day she would hold a photo of herself in her wheelchair and her daughters would ask her, 'Mommy, why were you in a wheelchair?' And she would reply, 'that is something we used to have, called spinal injuries, and that is something that I had a long time ago.' State Rep. Koutoujian mentioned a 26 year old daughter of a good friend who died of Metachromatic Leukodystrophy. "This is the type of suffering that I think we can stop", he said.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Attorney Melissa J. Lopes, Deputy General Counsel, Office of the General Counsel.

STAFF PRESENTATION: "STEM CELL RESEARCH" BY DR. DAVID SCADDEN, M.D., DIRECTOR, MASSACHUSETTS GENERAL HOSPITAL, CENTER FOR REGENERATIVE MEDICINE:

Dr. Scadden made the presentation to the Council on stem cell research. He said in part, "…I will be telling you about my view of the prospects for stem cell based medicine, and there are really four major areas where this field is likely to have an impact. The one that is the most commonly appreciated is that of cell therapy, of potentially using the cells as a replacement part, if you will, which is something we already know because stem cell science is not brand new. It is something that has been around for about forty years, and it has been practiced in the area of treatment for blood in cancer, with the use of adult stem cells and bone marrow transplant for a number of decades. This model is the one that is typically used when people think about how stem cells of different types may be used for different diseases, but it is only one of the ways in which this therapy will ultimately be useful."

Dr. Scadden continued, "a second one is a very big opportunity, that we hope Massachusetts will be leading in, is the idea of being able to take advantage of the fact that there are stem cells in many of our tissues, and to be able to essentially manipulate those with medicine, to use drugs as a way to enhance the ability of stem cells to induce tissue generation. The third is the use of stem cell model in the treatment of cancer….Finally, and a very important area and perhaps the most important in terms of developing truly novel approaches, is that of trying to model different diseases that are degenerative diseases for which we currently have very little therapy, and to develop novel treatments for these. This requires the use of embryonic stem cells, and it is the one that is actually, in many ways, at the focal point of a lot of the controversy today."

He said in part, "…A stem cell is absolutely required for the maintenance of life. If we didn't have stem cells, we would last about two to three weeks. Stem cells are required not just for the formation of all of our tissues, but also for the maintenance, and these cells are unique in several properties. First, they don't do much themselves. They don't have the capacity, like a liver cell does, of making lots of new protein, or a blood cell does, of carrying oxygen. They are pretty much couch potatoes, but they do produce all of the offspring cells that make up all of the mature cells of each tissue type. So, they have this capacity to undergo a differentiated process. I am not fooling myself that that works. This process of specialization or differentiation occurs from these cells; but, when they have a possibility of dividing, they can either have some of their cells go off making all of these specialized cells, they also have the opportunity to remake themselves. They essentially become a self-propagating, self-perpetuating, everlasting source of cells to replace what might be a damaged mature cell. Some of our cells only last a matter of hours – certain blood cells will only stay in the blood stream for seven hours. Just to replace the amount of blood that gets destroyed every day, we have to make ten billion new blood cells, and that is regardless of whether you have got a committee meeting or not, and that is all dependent on stem cell function."

Dr. Scadden continued, "Different kinds of stem cells come from different places in our development. Very early on, after the egg is fertilized, the first few cell divisions, if one of those cells is to break off, it has the capacity to form an entire organism. It has the capacity to make both those things that make up the placenta, the extra embryonic tissue, as well as all of the tissues that make up the organism. Once more cell divisions occur and the size of the entity goes to about a hundred to two hundred cells, this is only occurring in the first five to seven days after fertilization. This is before the fertilized egg actually implants in the wall of the womb. A so-called blastocyst is formed and a region of that blastocyst is the inner cell mass that is ultimately the region where the embryo will form, and, if you isolate those cells, you can grow them in a Petri dish, and those will go on to become what is called an embryonic stem cell line or a free embryo. They have the capacity of forming every cell type. In the human being, it has not formally been shown; but in every other animal where it has been tested, they have the capacity to form every cell type. These cells then represent an enormously powerful source of being able to provide cells or most tissue types, any tissue type that you are interested in studying or potentially replacing."

He stated further, "…Once the organism begins to take on more complexity, which can happen as early as ten to fourteen days, the cells lose that broad range of capacity and they become much more restricted. They become what is called multi-potential – they become things like a blood stem cell. It can make all the different types of blood cells but it can only make blood cells. It won't make a brain cell. Brain cells will make many different types of neurons, but they will only make brain cells. Thus we have the difference between the adult stem cell and the embryonic stem cell. The embryonic stem cell is the one that can form all cell types…"

Dr. Scadden noted some alternative methods of obtaining the embryonic stem cell for research (in brief) that would not require embryo destruction (disruption of blastocyst – ending development):

- Parthenogenesis – an egg stimulated in a particular way that its cell division is modified so that it goes on to start to form the early cell types – the early structure of an embryo and some of those cells can then be cultured in a way that you can create embryonic stem cells (tested in non-primate models; non-humans);
- Use of fertilized eggs that would have been discarded in the course of in vitro fertilization;
- Use of stalled or so-called dead embryos. They are not dead just stalled in development. The efficiency with which embryonic stem cell lines can be generated from these is at least ten fold lower than what you could use from a viable embryo;
- Single cell isolation – This is a technique that is used now for genetic diagnosis, where once the cells are starting to divide, you get a cluster that looks something like a blackberry under a microscope (submicroscopic). You can take an individual cell and do a genetic analysis on that cell.
- Altered nuclear transfer (tried on mice) an unfertilized egg with the nucleus removed - end up with cytoplasm. Allows for possibility of reprogramming cells to forget they are a certain kind of cell (a skin cell for instance) and become a primitive cell that can be programmed to become another kind of cell.
- One laboratory reported a potential option - cells in amniotic fluid have a range of capabilities that make them resemble embryonic stem cells.

Dr. Scadden spoke about the way we are already using stem cell medicine, which we call cell therapy: in bone marrow transplants, skin grafts (skin cells generate new skin) bone stem cells regenerate new bone; and stem cells as a way of delivering protein.

Dr. Scadden talked about injecting a dye (containing human blood cells) in the bloodstream of a mouse. The cells were matured and then isolated to become a blood vessel. The cells then sub assembled and attached themselves to the post vasculature of the mouse. "This notion of being able to create de novo blood vessels would be very powerful in a setting with insufficient blood supply," he said.

The use of mesenchymal stem cells is being studied. One of the ways is the injection of cells into individuals who have had a heart attack and the cells have impacted the heart function. The cells don't become part of the heart – they are just delivering something that changes the response to injury.

Dr. Scadden mentioned studies around brain stem cells, blood stem cells, bone forming cells used in conjunction with hormones to treat osteoporosis which modified stem cells; drug-based therapies to augment already existing stem cell approaches to diseases like lymphoma and leukemia, the use of umbilical cord blood cells and focusing on cancer stem cells to understand the cause of tumor spread and tumor growth. "The hypothesis is that maybe the resident stem cell is what allows for recurrence of tumors, and if we focus on what is different about these cells, and target them, then maybe there may be a cure. We are now starting to develop drugs with a focus on these cancer stem cells, and that I think will be a very important consequence of cell biology", he said.

During his presentation, Dr. Scadden noted that the basic strategy for findings cures for diseases like ALS and Parkinson's is to create cell lines that have the genetic abnormalities that are associated with the diseases. This would allow for testing of drugs on the stem cell lines for a possible cure or better medication. He said however, "At the moment, the only proven way we have of being able to get disease-specific embryonic stem cells is the idea of the process that is used in fertility clinics, and right now there have disease-specific cell lines that have been generated because there have been some cells in a fertility clinic, early embryos, that have been discarded because of their genetic abnormality. One of the questions is, if there was a couple, who had a known genetic disorder, and they wanted to contribute to this kind of research, could you actually do the process of in vitro fertilization with the sole intent of trying to get a creation of an embryonic stem cell line, and that is really the crux of the business of the DPH today, and the Commission today."

In closing, Dr. Scadden said, "What I have tried to do is tell you what are the ways in which I think this therapy can result in a wide range of different opportunities for us in terms of developing new treatments for people, that might be pharmacy-based, that might be cell-based. They might be understanding new ways of treating an old disease, like cancer, and that really depends on a wide range of different techniques, the aggregate of a lot of different kinds of expertise, and something that I think Massachusetts currently has a real leadership role in, but the question is - Is our current advantage something that can become durable leadership, and is this something that we can partner with you in trying to accomplish?"

Chairperson Auerbach noted for the record, "We are going to err on the side of not having Council Members participate in the discussion of the specific regulation that is being proposed if they work for or are employed by an institution that is involved in stem cell research because we feel like there is a potential for a conflict of interest." However, the Chair further noted that all members could participate in the questions and answer segment of the meeting with Dr. Scadden just not on the regulation segment of the meeting on 105 CMR 960.000.

Discussion followed from which the following information is obtained:

- Amniotic fluid stem cells
  - Some can be grown
  - Function like mesenchymal stem cells – they can become other tissues

- Federal funding rules

  - No restriction on working on cell lines from any source
  - Restriction is on the use of the federal funding
    - Can be used for any application related to adult stem cells
    - Can only be used on human embryonic stem cells that were derived before 7:00 p.m. on August 9, 2001 (problem is quality of old cells not the same as the quality of recently derived cells)

- Private funds from foundations can be used or state funds for stem cell research
- Harvard University has a Stem Cell Institute funded by private donors
- Untapped talent at universities that cannot raise private funds for stem cell research
- Young people are discouraged from entering the line of work of stem cell research because of the funding issues and the potential for crossing the law
- There is difficulty for scientists to work with their colleagues in other states due to the different state laws
- It was noted that an institution that wants to conduct stem cell research in Massachusetts must register with the state and have an Institutional Review Board and Escrow Committee for oversight in place

During discussion, Chair Auerbach asked Dr. Scadden his best guess about when we will see significant breakthroughs in terms of regenerative medicine due to stem cell research. Dr. Scadden replied, "I want to emphasize that stem cell therapies exist now. Today, there are stem cell therapies going on in this city, and they are evolving, and I think we will see that kind of incremental advance extend beyond the reach of what diseases are treated. In addition, there are new therapies that are emerging, that are drug-based therapies, that will target stem cells in adult tissues and that will be, I would think, within the next five years."

Dr. Scadden said further during discussion, "The idea of cancer stem cell model having impact on medical therapy, I think that is also probably in the five year window. The use of the embryonic stem cell, I don't know if it will ever get into the clinic. I think we will use it as a tool to understand a lot more about adult stem cells. We use it as a tool to develop understanding about disease and possibly to drug development. We hope it will become a source of cells that might be implemente d as an insulin producing cell to replace the missing eyelet cell in a person with diabetes that will still be a fairly long interval. I think we are measuring that more in a decade or more, but I think the research is clearly incremental, and we do alrea dy have impact on stem cell work that has been done in Massachusetts, that is being applied around the nation. I think that it will continue to gradually open those doors. A big ah ha moment with embryonic stem cells, I think, is very unpredictable. We are hoping that it is within a decade, but it may be more."

PROPOSED REGULATION: INFORMATIONAL BRIEFING ON AMENDMENTS TO 105 CMR 960.000, BIOTECHNOLOGY:

Attorney Melissa Lopes, Deputy General Counsel, presented the informational briefing on 105 CMR 960.000, Biotechnology to the Council. Atty. Lopes stated, "On August 29, 2006, the Department promulgated 105 CMR 960.000 which interprets and implements MGL Ch. 111L, Biotechnology, as enacted under Ch. 27 of the Act of 2005…Section 1 of the Act added a new chapter to the general laws (c.111L, Biotechnology). Chapter 111L addresses several matters related to the biotechnology industry in Massachusetts, including the registration of institutions conducting human embryonic stem cell research; research methods that are permitted, and those that are prohibited, informed consent protection for individuals undergoing infertility treatment, and for those donating genetic materials in embryos for research, the protection of employees of research institutions performing human embryonic stem cell research, the establishment of a public institutional review board at the University of Massachusetts Medical School in Worcester, Massachusetts, the establishment of a public bank for the purpose of collecting and storing umbilical cord blood and placental tissue in Massachusetts, the establishment of a Biomedical Research Advisory Council, which you have heard a little bit about, otherwise referred to as the BRAC."

Atty. Lopes continued, "Ch. 111L sets forth the Massachusetts General Court's finding that the extraordinary biomedical scientists working within institutions of higher education, research institutes, hospitals, biotechnology companies, pharmaceutical companies, can contribute significantly to the welfare of mankind by performing outstanding research in these fields, and that it shall be a policy of the Commonwealth to foster research and therapies in regenerative medicine, and that it shall be the policy of the Commonwealth to prohibit reproductive cloning."

Atty. Lopes further said, "Section 10 of Mass. General Laws, Chapter 111L sets up procedures for the promulgation of regulations pursuant to the Chapter. In accordance

with these procedures, the Department provided 90 days notice prior to public hearings on these regulations, held two public hearings, one on May 11 in Boston and one on May 12th in Worcester, and held a public comment period until May 26, 2007. No oral or written testimony was received at the public hearings…Two letters were received during the public comment period. One was from Partners Healthcare with signatories to the letter including Harvard University, Beth Israel Deaconess Medical Center, Massachusetts General Hospital, Brigham and Women's Hospital, McLean Hospital, Joslin Diabetes Center, Children's Hospital, Boston, and the Dana Farber Cancer Institute. The other letter was from the Dana Farber Cancer Institute with signatories to the letter including Harvard University, Children's Hospital, Boston, Beth Israel Deaconess Medical Center, and the Dana Farber Cancer Institute. The substance of both letters was largely the same and centered on the Department's interpretation of Section 8B of MGLc.111L, which provides in relevant part that no person shall knowingly create an embryo, by the method of fertilization, with the sole intent of donating the embryo for research. The Department's interpretation of Section 8B can be found in Sections 960.005A and 960.006C-3 of the Regulations. With the exception of these sections, the remainder of the regulations promulgated last August track the statutory language."

Atty. Lopes noted, "Both letters of testimony stated that the Department exceeded its legislative authority to promulgate 105 CMR 960.005A and 960.006C-3 under Chapter 111L. The letters also expressed, as their fundamental concern, that these two sections will pass a cloud of doubt on research that would otherwise be conducted in this Commonwealth. The Department presented 105 CMR 960.000 to the former Public Health Council on August 29, 2006 with these two sections included. That Public Health Council unanimously approved the regulations as drafted."

Atty. Lopes continued, "Because this cloud of doubt remains, it has been discussed in meetings of the BRAC and has also been echoed by others within the research community. In considering this issue, the BRAC reviewed laws in other states and the National Academy of Sciences Guidelines published in 2005. These guidelines state that 'embryos may be used in properly overseen research, as a valid scientific pursuit'. Laws in other countries and in several states of the USA including California do not prohibit the creation of embryos solely for research. After consideration of these findings, the Department has determined that Sections 960.005A and 960.006C-3 have created an uncertain regulatory environment for researchers performing this research in the Commonwealth. To allay this uncertainty, and to clarify that Massachusetts does foster stem cell research within the Commonwealth, the Department is proposing to rescind the language in these two sections, 960.005A and 960.006C-3. Additionally, in Section 960.006C-3, we are adding the word "knowingly" to further track the statutory language."

In conclusion, Atty. Lopes stated, "The purpose of this proposed amendment will return us to the original statutory language in Section 8B and also hopefully, make clear that the Massachusetts does not stand in the way, or further impede this type of research."

Atty. Lopes noted that these amendments will be released for public hearings and a public comment period. The notice of the hearings will be published 90 days prior to a hearing rather than the conventional 21 days notice. In addition, notice is required in several newspapers, a medical journal published in Massachusetts and a biotechnology newsletter or journal. Notice will be further sent to the Joint Committee on State Administration and Regulatory Oversight and the Joint Committee on Economic and Emerging Technologies of the General Court. These committees may review the regulations and hold their own hearings on the proposed regulations. The BRAC will also review these proposed regulations. Atty. Lopes noted that due to these extensive reviews of the regulations, there may be a significant lapse of time before the final regulations are returned to the Public Health Council for review and final action.

Chair Auerbach summarized the stem cell situation:

"My understanding is that the Legislature, in May of 2005, passed stem cell research, which delegated a responsibility to the Department, to provide additional oversight into how that research could be conducted. That responsibility fell to the Council, which then passed regulations, which included some language which was different from the language that was in the legislation itself. A relatively brief portion of the regulation that was passed by the Public Health Council was different than the language that was in the legislation, and that portion, which speaks specifically to the use of embryos for research, and I will read that sentence, "No person shall knowingly create embryos or preimplantation embryos by the method of fertilization with the sole intent of using the embryo for research." That sentence did not appear in the legislation that was passed, but was added by the Council and that created a fear, a concern, among researchers, that additional obstacles to doing the research now existed, as a result of the Council regulation. The proposal is that the additional language, which went beyond the Legislature's intent, be deleted, so that the remaining regulation is entirely consistent with what was passed by the Legislature."

For the record, Chair Auerbach noted the Council Members who may have a conflict of interest or a potential conflict of interest who would not participate in discussion of this regulation. Those Members are: Drs. Gillick, Wong and Zuckerman; and Mr. Sherman. Dr. Zuckerman was not present (He left the meeting at approximately 11:45 a.m., during discussion on the staff presentation).

Discussion continued. It was noted how other states have handled the stem cell research issue. The states that explicitly have legislation banning stem cell research (six of them) are: Arkansas, Indiana, Louisiana, Michigan, North Dakota and South Dakota. There are seven states that allow stem cell research: California, Connecticut, Illinois, New Jersey, Maryland, Massachusetts, and Missouri. About 37 states do not have any statutes that promote or prohibit stem cell research.

Chair Auerbach added, "It is the intent of the Department to comply with the law that says that we should be relying upon the expertise represented by the Biomedical Research Advisory Council (BRAC), to help to identify rather specific aspects of the research that we may need to comment on, or pass judgment on, and that that can occur outside of the regulatory process; and we, as a Department, as I said, will be compliant with that, and do look forward to continuing to meet and talk about some of those aspects of the work, where clarity, with regard to the Department taking positions on certain specific aspects of research that may exceed either the regulation or the law, we will be doing that and look forward to Dr. Scadden and Dr. Fineberg's help in terms of identifying those and determining how best to address any areas of uncertainty. "

Chair Auerbach added in closing, "What our perspective is at the Department, is that a regulation is a particularly cumbersome way of providing guidance to a rapidly developing and changing area of science and it is not our intent to come back frequently to the Council to amend this regulation because there are lengthy periods of public comment that are involved every time we change a single word in the regulations. It is our intent to have the regulations reflect the language that was in the legislation and then to have many of those fine points, that may be scientific points that reflect the changing area of research, dealt with through guidance by the BRAC, outside of the regulatory process. It is just a much more practical way of addressing this issue."

The proposed regulations state in part: (new language underlined and deleted language is ~~stricken.~~):

960.005: Creation of Human Embryos for Research

~~A) No person shall knowingly create embryos or pre implantation embryos by the method of fertilization with the sole intent of using the embryo for research.~~

A) No person shall knowingly create an embryo or pre-implantation embryo by the method of fertilization with the sole intent of donating the embryo for research.

B) Pre-implantation embryos may be created by somatic cell nuclear transfer, parthenogenesis or other asexual means for research purposes.

960.006: Purchase, Sale, Transfer, Receipt and Donation of Embryos, Human Gametes or Cadaveric Tissue

(A) No person shall knowingly and for valuable consideration, purchase, sell, transfer or otherwise obtain embryos, human gametes or cadaveric tissue for research purposes.

(B) Persons may bank or donate their gametes for personal future use and may donate their gametes to another person or may donate their gametes for research.

(C) Persons from whose cells a pre-implantation embryo has originated or will originate may donate such pre-implantation embryo or cells to another person for research:

(1) In the absence of valuable consideration;
(2) After the fulfillment of the requirements of informed consent;
(3) Provided that the pre-implantation embryo, if created by the method of fertilization, was not knowingly created with the sole intent of donating ~~or using~~ the resultant embryo for research; and
(4) Provided that the recipient of the pre-implantation embryo shall use the extant or resultant pre-implantation embryo in biomedical research and shall not transfer the pre-implantation embryo to a uterus or uterine-like environment or nurture the pre-implantation embryo beyond 14 days of development.

960.007: Prohibition on Human Reproductive Cloning

(A) Human reproductive cloning is prohibited. No person shall knowingly attempt, engage in, or assist in human reproductive cloning.

(B) No person shall knowingly purchase, sell, ~~or~~ transfer or otherwise obtain human embryonic, gametic or cadaveric tissue for the purpose of human reproductive cloning.

960.008: In Vitro Fertilization for Reproductive Purposes

(A) The provisions of these regulations do not prohibit the use of in vitro fertilization for reproductive purposes.

(B) A physician or other health care provider who provides a patient with in vitro fertilization therapy shall provide the patient with timely, relevant and appropriate information sufficient to allow that patient to make an informed and voluntary choice regarding the disposition of any pre-implantation embryos or gametes remaining following treatment.

960.009: Penalties

A) A person who is found to have knowingly violated sections 960.005 (A) ~~or (B)~~ or 960.006 (A) shall be punished by imprisonment in a jail or house of correction for not less than 1 year nor more than 2 years or by imprisonment in the state prison for not more than 5 years or by a fine of not more than $100,000.

B) A person who is found to have knowingly violated section 960.007 shall be punished by imprisonment in a jail or house of correction for not less than 5 years nor more than 10 years or by imprisonment in the state p rison for not more than 10 years or by a fine of not more than $1,000,000. In addition to such penalty, and at the discretion of the court, a person who is found to have knowingly violated this section and derives a personal financial profit from such vio lation may be ordered to pay all or part of any such profits to the Commonwealth as damages.

C) Complaints regarding violators shall be referred to the Office of the Attorney General.

No Vote/Information Only (supporting material is attached and made a part of this record as Exhibit No. 14, 882).

The meeting adjourned at approximately 12:15 p.m.

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John Auerbach, Chairperson

LMH/lmh