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Office of the General Counsel
Mass. Department of Public Health
250 Washington Street
Boston, MA 02108-4619

September 21, 2007

Re: Comments on Proposed Amendments to 105 CMR 960.000, Draft April 30, 2007

Dear Sir/Madam:

It is difficult to support or oppose the proposed amendments to 105 CMR 960.000 drafted on April 30, 2007, given the confusing nature of the claims regarding what the current underlying statute and regulations are purported to do and not do, and what the proposed amendments to those regulations are purported to do.

As indicated in the April 25, 2007 minutes of the Department of Public Health's Public Health Council, which on that date discussed the proposed amendments now subject to public comment, Dr. David Scadden of the Center for Regenerative Medicine identified what he referred to as "the crux of the business at the DPH today." According to Dr. Scadden, the question at issue with respect to the proposed regulatory amendments is whether "you could actually do the process of in vitro fertilization with the sole intent of trying to get a creation of an embryonic stem cell line"? Minutes at 7.

According to a legal reading of the plain language of MGL c. 111L, such a process should be considered already statutorily prohibited. The statute, on which 105 CMR 960.000 is based, states at section 8(b) that "[n]o person shall knowingly create an embryo by the method of fertilization with the sole intent of donating the embryo for research."

The plain meaning of the statutory reference to "person" necessarily includes all persons, even if they happen to be scientists, doctors, technicians or any other individuals, and regardless of whether they were working within or outside of Massachusetts. The substantive scope of the word "person" is not limited along occupational or geographical lines.

In addition, the plain meaning of the statutory reference in 8(b) to “donating” already covers, and thus prohibits, even the scenario addressed by former Governor Mitt Romney in a 2005 communication with the state legislature, whereby “a laboratory could obtain donated eggs and donated sperm to create a virtually unlimited supply of human embryos for experimentation.” See Letter from Governor Mitt Romney to the Massachusetts Senate and House of Representatives Proposing Amendments to Senate Bill 2039 at 2 (May 12, 2005). Then-Governor Romney proposed a clarifying statutory amendment prohibiting the “use” of embryos created solely for research by scientists through fertilization, to close, as he put it, the supposed “opening left by Section 8(b).” *Id.* The substance of that proposed statutory amendment, an amendment ultimately rejected by the state legislature, is reflected in the current regulations.

However, the dictionary meaning of “donate” includes the terms “give,” “transfer,” and “contribute,” thus obviating the need for further clarification. See Merriam-Webster Online at <http://www.m-w.com/dictionary/donate>. A scientist, doctor, technician or any other individual involved in directly creating an embryo for research purposes necessarily must give, transfer or contribute the embryo, therefore not keeping it, when the research requiring access to an embryo results in the embryo’s destruction. The laboratory creator’s act of offering the embryo for destruction removes the embryo from anyone’s possession and prevents the embryo’s return. Since the word “donating” is defined by direct reference to “giving,” “transferring,” and “contributing,” it is not an implicit meaning of the statute, but rather an explicit one, that controls. Therefore the statute, when its plain meaning is considered, already prohibits scientists or anyone else from researching on an embryo created by the combining of egg and sperm, if the creation was done solely to provide an embryo for research that takes the embryo’s life.

Thus, the proposed regulatory amendments do not and cannot change the statutory prohibition that prevents researchers, after obtaining gametes (either their own or others’), from using the process of in vitro fertilization for the purpose of creating embryos to be handed over for destructive research. By using exactly the same references to “person” and “donating” as found in the statute, the proposed regulatory amendments would have exactly the same effect.

Furthermore, the rejection by the state legislature of the proposed statutory amendment to section 8(b) offered by then-Governor Romney cannot be interpreted as an indication of any legislative intent to allow what the statute on its face clearly prohibits. In any event, “legislative history” cannot override the plain meaning of the statute.

Also, one can reasonably conclude that the legislature rejected the statutory amendment offered by then-Governor Romney not because the legislature deemed it beyond the statute's intended scope, but because it was found by legislators to be unnecessary in light of the statute's actual language. If the statute reflects on its face a legislative intent to prevent the destruction of embryos created by in vitro fertilization solely for research purposes, then that intent will govern any application of the statute or its implementing regulations, notwithstanding the failure of then-Governor Romney's proposed statutory amendment or the successful enactment of the proposed regulatory amendments.

Finally, research guidelines promulgated by other jurisdictions or by the ethics organs of the embryonic stem cell research industry nationally do not and cannot override express statutory language applicable to practices in Massachusetts. If there is any "cloud" that inhibits researchers from doing in Massachusetts what is allowed elsewhere, as claimed by testimony submitted to the Department of Public Health concerning the current regulations (see April 25, 2007 Minutes at 10 (referring to remarks of Melissa Lopes discussing the May 23, 2006 Comments on the original regulations submitted by Dana-Farber, and by Beth Israel Deaconess Medical Center et al.)), then that cloud must be directly attributed to the language found in section 8(b) of chapter 111L of the Massachusetts General Laws.

Sincerely,

A handwritten signature in cursive script that reads "Daniel Avila".

Daniel Avila, Esq.

Associate Director of Policy & Research