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May 18, 2006

Nancy E. Forbes
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Re: Meaning of Valuable Consideration in Chapter 111L as it Pertains to the Donation of Gametes by Women for Research

Dear Ms. Forbes,

This letter is in response to your letter dated February 22, 2006 seeking guidance on the meaning of the phrase “valuable consideration” as set forth in §2 of M.G.L. c. 111L. Specifically, you have requested a ruling as to what constitutes a permissible form of reimbursement to donors in connection with the donation of their gametes for research. This letter constitutes an Advisory Ruling pursuant to M.G.L. c. 30A, §8, and is based upon the facts detailed in your letter.

Facts

In your letter, you state that you have a client who would like to use somatic cell nuclear transfer (“SCNT”) to derive human stem cells from donated human eggs, and intends to conduct this research in Massachusetts. The SCNT methodology requires that your client (and other researchers) obtain donated eggs from women willing to undergo various medical procedures to suppress and stimulate their ovaries to produce such eggs. Specifically, donors must undergo preliminary physical and psychological examinations, multiple administrations of hormone therapy, subsequent medical procedures to harvest eggs, as well as time spent in recovery. To manage this process, your client proposes to establish an egg donation program whereby medical expenses related to the egg donation process, such as the cost of hormone therapy, laboratory tests, medical appointments, and time-limited egg donor accident insurance to cover medical care and treatment of

complications arising directly from the egg donation process will, in most cases, be covered outright, i.e. paid directly by your client to the clinic involved in the actual egg donation procedure.¹ Donors would be reimbursed solely for the following out-of-pocket expenses actually incurred incident to their egg donation process:

- (i) travel expenses,
- (ii) lost wages,
- (iii) temporary lodging,
- (iv) health insurance expenses, and
- (v) childcare expenses.

Donors will be provided with material that sets forth what qualifies as a reimbursable cost with the condition that reimbursement will vary depending upon the specific circumstances of each donor. Additionally, donors will be asked to certify to childcare, travel, health insurance and other reimbursable expenses actually incurred and to attest to the lost wages resulting from the time needed to complete the egg donation process, including, where applicable, time recovering from complications. This information would be requested in a reimbursement form that each donor would be asked to complete and which you attached to your letter. Because your client recognizes that reimbursement will vary depending upon whether and where the donor works, the donor's place of residence, and if the donor has children, your client proposes to evaluate each donor on a case-by-case basis in determining the extent to which the donor has incurred reimbursable costs. You further state that your client's Institutional Review Board will review and approve this process for reimbursement of egg donors and the reimbursement form, consistent with the informed consent requirements of Chapter 111L.

Issues

1. Whether costs associated with travel, housing, child care, medical care, health insurance and actual lost wages are "reasonable costs" consistent with the definition of "valuable consideration" in §2 of Chapter 111L .
2. Whether your client's proposed egg donation program represents a permissible form of reimbursement under Chapter 111L.

¹ In the event that an egg donor were to experience complications that neither the egg donor's regular health insurance policy nor the time-limited egg donor accident insurance policy covers, the client would consider on a case by case basis, in consultation with its IRB and/or Ethics Advisory Board, the option of reimbursing the donor for the medical care required to treat such complications.

3. Whether donations under your client's proposed egg donation program constitute a valid donation to research consistent with §8(c) of Chapter 111L.

Discussion

M.G.L. c. 111L, § 8(c) provides, in relevant part, that:

No person shall knowingly and for valuable consideration purchase, sell, transfer or otherwise obtain human embryos, gametes or cadaveric tissue for research purposes. Nothing in this section shall prohibit a person from...donating their gametes for research.

The term "valuable consideration" is defined by M.G.L. c. 111L, § 2 as:

any consideration beyond reimbursement for *reasonable costs* incurred in connection with the donation, removal, processing, disposal, preservation, quality control, storage, transplantation or implantation of gametes, embryonic or cadaveric tissue. (emphasis added)

What is clear from the statutory definition of valuable consideration is the Legislature's intent to omit "reasonable costs" from the calculus of "valuable consideration." What remains open to interpretation is what constitutes "reasonable costs" under the statutory definition of "valuable consideration" and to whom such costs may be reimbursed. To determine whether your client's proposed egg donation program is permissible under Chapter 111L, an analysis of these terms within the context of the statute and its history must be undertaken.

Chapter 111L does not define the term "reasonable costs." Further, Chapter 111L does not provide an exclusive or exhaustive list of costs deemed to be "reasonable costs." We may infer from this silence that the Legislature did not intend to strictly limit out-of-pocket costs for which §8(c) donors may be reimbursed, as long as they are reasonable.

You state that your client plans to reimburse potential egg donors for their medical expenses, health insurance expenses, travel expenses, lost wages, temporary housing and childcare expenses actually incurred during the donation process. At issue is the reasonableness of such a reimbursement plan under Chapter

111L. Section 1(c) of Chapter 111L states that “it shall be the policy of the commonwealth to actively foster research and therapies...by permitting research and clinical applications involving somatic cell nuclear transfer, placental and umbilical cord cells and human adult stem cells and other methods to create embryonic stem cells.”² Such research cannot flourish without willing donors.³ To ensure that willing donors exist, donors must be treated with respect and account must be made for the time and expense they incur as a result of their decision to donate. The ethics committee of the American Society for Reproductive Medicine cites that egg donors spend approximately “56 hours in the medical setting, undergoing interviews, counseling, and medical procedures...”⁴ related to the egg donation process. During this process, donors may incur lost wages, travel expenses and childcare expenses in addition to medical expenses. Because donating eggs is such a “time-consuming, uncomfortable, and potentially risky endeavor”⁵, it is reasonable to reimburse donors for their out-of-pocket costs incident to donation in an environment fostering stem-cell research. This is not to suggest that potential donors should receive financial incentives to donate or be paid according to the number or quality of the eggs produced in the donation process. Nor can donors be compensated for undertaking the potential risk and experiencing the discomfort involved in this research. However, by sanctioning reimbursement to donors for reasonable costs, the Legislature assured that donors who incur a number of expenses during the donation process would not be financially disadvantaged by their decision to donate.

The legislative history of Chapter 111L provides further insight into the meaning of “reasonable cost” and “valuable consideration.” Earlier versions of the bill that ultimately became Chapter 111L, namely Senate Bills 2028 and 2032, contained a defined term indicative of the drafters’ intent with respect to valuable consideration. These earlier bills equated valuable consideration with “financial inducement,” a term that specifically excluded: “(i) reimbursement for reasonable costs incurred in connection with a donation; and (ii) reasonable compensation to a donor from whom an oocyte or somatic cell is recovered for the time,

² Mass. Gen. Laws. Ann. Ch. 111L, §1(c).

³ According to Robert Steinbrook, M.D., a national correspondent for the New England Journal of Medicine, “without willing donors, there will be less research on human embryonic stem cells. Robert Steinbrook, M.D., *Egg Donation and Human Embryonic Stem Cell Research*, 354 NEW ENGLAND JOURNAL OF MEDICINE 324 (2006).

⁴ Ethics Committee of the American Society for Reproductive Medicine. *Financial incentives in the recruitment of oocyte donors*. 74 FERTIL STERIL 219 (2004)

⁵ Steinbrook, Robert. *Egg Donation and Human Embryonic Stem-Cell Research*. New England Journal of Medicine. Vol 354: 324-326 January 26, 2006.

burden and risk of such recovery and the preparation for it.”⁶ The use of the term “financial inducement” highlights the drafters’ concern with the potential for abuse in the egg retrieval process if donors received financial inducements to undergo the treatments necessary for donation. Governor Romney, in a letter to the House and Senate dated May 12, 2005, also expressed concern that financial remuneration to donors might lead to “the exploitation of women.”⁷

Despite these concerns, neither the Legislature nor the Governor determined that out-of-pocket costs incident to the donation process constitute “financial inducements.” The Legislature excluded such costs from its definition of “financial inducement” and the Governor suggested that donors may receive “reimbursement for out-of-pocket expenses actually paid by the donor in connection with the egg donation.”⁸ In doing so, the Governor also suggested that transportation and medical services costs might qualify as reimbursable costs.⁹ The “financial inducement” language was not incorporated into the final version of the bill, Senate Bill 2039, nor was Governor Romney’s suggested language. Nevertheless, this history lends some context to the interpretation of what constitutes a “reasonable cost.” Because the drafters were concerned solely with compensation in the form of financial inducements to act, one can assume that compensation that does not constitute a financial inducement falls under the ambit of “reasonable costs.”

Your client’s proposed reimbursement scheme would not constitute a “financial inducement.” A donor might be induced to donate if the compensation for donating were to represent a financial windfall unavailable to her if she chose not to donate. One cannot say that a donor who receives reimbursement for medical expenses (or direct payment to providers of these medical services), travel expenses, lost wages, temporary housing, health insurance (i.e. co-pays or deductibles) and childcare expenses actually incurred during the donation process receives a financial windfall. These are expenses taken on by the donor as a result of her decision to donate. In referencing health insurance in your letter, you did not specify whether your intent was to reimburse potential donors for yearly premium expenses or co-pays and deductibles. To clarify for the purposes of this opinion, donors may only be reimbursed for deductible and co-pay expenses, not for yearly premiums charged for a regular health insurance policy. However, your client may purchase,

⁶ SB 2028 and SB 2032 (Mass. 2005).

⁷ Letter from Governor Mitt Romney, Governor, Commonwealth of Massachusetts to the Honorable Senate and House of Representatives (May 12, 2005).

⁸ *Id.*

⁹ *Id.*

or reimburse the donor or clinic involved in the actual egg donation procedure for the purchase of time-limited egg donor accident insurance designed to cover the medical care and treatment of complications arising directly from the egg donation process. Your client may also reimburse the donor for deductible and co-pay expenses incurred under this time-limited insurance. In the event that complications arising directly from the egg donation process are not covered by insurance, your client may also, if it chooses, reimburse the donor for the costs of medical care required to treat such complications. Reimbursements for out-of-pocket medical, travel and other costs incident to the donation process simply assures that potential donors will not suffer a financial loss because of their decision to donate. If a financial inducement is exploitative of potential donors, so too is the imposition of a financial burden in addition to the time, risk and discomfort a potential donor necessarily donates along with her gametes.

An interpretation of §8(c) that allows donors to be reimbursed for medical expenses, travel expenses, actual lost wages, temporary housing, health insurance and childcare expenses in the stem cell research context is consistent with the treatment of donors in other states prohibiting payment for research donations. The California Institute for Regenerative Medicine (“CIRM”), which was established in early 2005 with the passage of the California stem-cell initiative, recently proposed regulations clarifying the parameters of “valuable consideration.” CIRM’s proposed regulations, like Chapter 111L, §8(c), expressly prohibit donors of gametes, embryos, somatic cells or human tissue from receiving valuable consideration.¹⁰ However, CIRM’s proposed regulations exclude what CIRM terms “permissible expenses” from valuable consideration.¹¹ The proposed regulations define permissible expenses as: “necessary and reasonable costs directly incurred as a result of donation or participation in research activities.”¹² The definition goes on to provide a non-exclusive list of reimbursable costs, such as: “...travel, housing, child care, medical care, health insurance and actual lost wages.”¹³

Summary

Costs associated with travel, housing, childcare, medical care, health insurance (if limited to co-pays and deductibles and the purchase of time-limited accident insurance coverage for complications arising directly from the egg donation process) and actual lost wages are “reasonable costs” consistent with the definition of

¹⁰ 17 Cal. Code. Regs. §§100.000-100.012 (proposed February 10, 2006).

¹¹ *Id.* at 100.007(e)(2).

¹² *Id.* at 100.001(b).

¹³ *Id.*

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“valuable consideration” in §2 of Chapter 111L. The egg donation program proposed by your client, as described in your letter, represents a permissible form of reimbursement under Chapter 111L and donations under this program will constitute valid donations to research consistent with §8(c) of Chapter 111L.

Please note that this opinion is based on and limited to the facts described herein and in your letter dated February 22, 2006. This opinion does not cover any material changes to the information set forth above.

FOR THE DEPARTMENT OF PUBLIC HEALTH

Melissa J. Lopes
Deputy General Counsel