California State Senate Committee on Health
State Capitol Room 2191
Sacramento, CA 95814

May 31, 2016

RE: AB 2531 - Oppose

Dear Senate Health Committee:

I am writing to express strong opposition to AB 2531, which would repeal SB 1260 (Health & Safety Code 125330-125355).

My organization, the Center for Genetics and Society, is one of a number of public interest, women’s health and reproductive rights, and responsible research organizations with deep concerns about expanding payments for eggs to women who provide them for research. We worked closely on SB1260 in 2006 with then-Senator Deborah Ortiz, who is widely respected as a champion of women’s health and medical research, to find the appropriate balance between supporting medical research and protecting women’s health. SB 1260 was approved by near-unanimous votes in both the California Senate and Assembly. AB 2531 would seriously disrupt the balance it achieves by authorizing payments beyond reimbursement for women who undergo egg retrieval so that their eggs can be used for research.

We believe that AB 2531 threatens women’s health and well-being. We oppose paying women to supply eggs for research, beyond reimbursement for their expenses, for the following reasons:

1. It is not appropriate to treat women providing eggs for research “in the same manner as other research subjects,” as AB 2531 seeks to do. Women providing eggs are not research subjects, and egg harvesting is very different from a clinical trial.

In clinical trials, investigators study the reactions and health outcomes of subjects who take a drug, use a device, or undergo a procedure. Research using human eggs does not seek to address women’s health, but rather uses eggs for fertility, stem cell, genetic modification, and other research. Women thus serve the role of providing the raw materials of pre-clinical research, rather than participating in human subject research.

Professors David Magnus and Mildred K. Cho of the Stanford Center for Biomedical Ethics and Department of Pediatrics at Stanford University addressed this issue in an article published in Science.¹ “There is nothing experimental being tested on these women. The only research aspect of their experience is use of their tissues.” As a result, as Magnus and Cho pointed out, the rules for human subject research do not adequately protect women who provide eggs for research.
2. The health risks of egg retrieval are substantial, but there is insufficient research to be able to provide true informed consent.

The experience of women undergoing egg harvesting for fertility treatment shows that the process imposes risks on women. Egg harvesting exposes women to multiple synthetic hormones, usually over a period of several weeks.

Lupron™ (leuprolide acetate) is commonly used to suppress ovarian function, though it is not approved by the FDA for this purpose. Many adverse effects have been reported, some of them long lasting. Following the suppression of ovarian functions, other drugs are administered to stimulate the ovaries to produce many times the normal number of eggs per cycle. The stimulatory drugs cause several well-known short-term consequences, and very serious effects in an uncertain (because inadequately studied) percentage of women. The best-documented of the effects, Ovarian Hyper-Stimulation Syndrome (OHSS), can cause organ damage, ovarian rupture, renal failure, and in rare instances death. Reports estimating the incidence of OHSS, either in mild, moderate, or severe forms, vary from 0.3% to 10%^2 or higher.

The inadequacy of data about the short-term and long-term risks of egg retrieval makes meaningful informed consent difficult or impossible. AB 2531 “seeks to support the requirements in law upholding the principle of voluntary and informed consent.” Existing law requires disclosure of “foreseeable risks” yet lack of data translates into few “foreseeable risks” and many unanswerable questions. More studies are urgently needed. A registry to follow the health outcomes of egg providers should be a priority of the American Society for Reproductive Medicine.\(^3\)

3. Payment beyond reimbursement for eggs for research conflicts with recommendations by the National Academy of Sciences, and with policies that apply to CIRM-funded researchers and are part of the California Constitution.

Proposition 71, the initiative which authorized the California Institute for Regenerative Medicine (CIRM), and which is part of the state of California’s Constitution, prohibits compensating women beyond expenses for providing eggs for research conducted by CIRM-funded scientists. The regulations implementing this provision have been affirmed by CIRM’s Standards Working Group.

SB 1260, which became California law in 2006, extended the prohibition on paying women to provide eggs for research (beyond reimbursement for their expenses) to non-CIRM funded research. SB 1260 also recognized that women who provide eggs for research are situated differently from research subjects and provided other protections. The protections are now contained in California Health and Safety Code Section 125330-125355. In 2009, the California legislature again recognized the substantial risks of egg harvesting and retrieval by passing AB 1317, authored by Senator (then Assembly Member) Marty Block, which requires a warning label on advertisements for recruiting human egg providers.

In addition, the 2010 guidelines of the U.S. National Academy of Science recommend that “[n]o payments, cash or in kind, should be provided for donating oocytes for research purposes.”\(^4\)

We are also concerned about several misunderstandings with regard to current policies and practices related to egg retrieval:

- AB 2531 states that concerns about encouraging women to undergo risks that they would not otherwise take “have not borne out in states where compensation is allowed.” However, there is
no published information about the outcomes for egg providers in the sole state (New York) that explicitly permits payments beyond reimbursement for eggs for research.

- AB 2531 states that “all women undergoing ovarian stimulation and oocyte retrieval have another layer of regulation as all cycles are reported to the federal Centers for Disease Control and Prevention.” This is not the case. Fertility clinics do report the number of IVF cycles that use third-party eggs and the number of resulting live births to the CDC, but they report no information at all about the women who undergo egg harvesting and retrieval as paid or altruistic providers, about the number of eggs retrieved from them, or about the number or severity of adverse reactions they experience.

- The press statement from Assembly Member Burke’s office about the introduction of AB 2531 quotes the Chair of the California Hepatitis C Task Force saying, “Impeding the altruistic donation by denying an appropriate and reasonable compensation for expenses to the donor constitutes an unreasonable disincentive to participate.” This seems to reflect a misunderstanding of current California law, which permits women who provide eggs for research to be compensated for their expenses.

We strongly urge you to oppose AB 2531, and would welcome the opportunity to discuss our concerns.

Sincerely,

Marcy Darnovsky, Ph.D.
Executive Director

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2 Ibid.

