March 30, 2016

RE: AB 2531 - Oppose

Dear Member of the Assembly 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 retrieval 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. In the case of egg harvesting, investigators are not studying, or seeking to understand, the effects of the procedures on women. Their aim is to acquire eggs for further research. Egg providers are thus quite different from research subjects.

   This issue was addressed by David Magnus and Mildred K. Cho of the Stanford Center for Biomedical Ethics and Department of Pediatrics at Stanford University in *Science*.¹ They wrote of women who provide eggs for research purposes, “There is nothing experimental being tested on these women. The only research aspect of their experience is use of their tissues.” Magnus and Cho also suggest:
We may need a new category to deal with this unusual class of participants who expose themselves to substantial risk only for the benefit of others, where the risk is incurred not in the actual research but in the procurement of materials for the research. When the oocytes that are donated are anonymized, current U.S. regulations no longer recognize these donors as research subjects. However, the donors are also not patients. We recommend the use of the term “research donors” as distinct from “research subjects” to signify their dissimilar roles.

2. **The health risks of egg harvesting are significant and understudied. Existing data are notoriously inadequate, especially regarding long-term outcomes.**

Although egg harvesting is frequent in the context of fertility treatment, this unfortunately does not mean it has been shown to be safe.

Egg harvesting and retrieval expose 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. Several well-known short-term consequences of the stimulatory drugs become very serious in an uncertain (because inadequately studied) percentage of women. The best documented of these potential harms, 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% or higher. Findings from the Human Fertilization and Embryology Authority (HFEA) reported 30,000 cases of OHSS between 1991 and 2007, with symptoms ranging from chest pains and shortness of breath to kidney failure. A recent HFEA confidential inquiry into maternal deaths in the UK showed that OHSS was now one of the biggest causes of maternal mortality. Risks are highest among women with polycystic ovaries and women under 30. Many IVF providers are now implementing mild- or no-stimulation for their patients in order to minimize OHSS and increase safety for women.

Many experts remain concerned about the long-term risks of these drugs, especially their potential impact on infertility and various cancers. Follow-up research on egg providers, which could establish the frequency and severity of these adverse outcomes, and best protocols for avoiding them, is widely recognized to be grossly inadequate. An Institute of Medicine report, *Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research* (2006), concluded that one of the striking facts about ovarian stimulation is just how little is known about long-term health outcomes for women.

3. **The inadequacy of data about the risks of egg harvesting makes meaningfully informed consent difficult or impossible. AB 2531 “seeks to support the requirements in law upholding the principle of voluntary and informed consent,” but this may not be achievable.**

Given the acknowledged inadequacy of evidence about short-term and long-term health risks of egg harvesting and retrieval, women cannot make a meaningfully informed decision about undergoing egg retrieval.

Unfortunately, fertility clinics have taken few steps to collect and study data about the health outcomes of women who undergo egg harvesting and retrieval, and have not responded to repeated requests to do so by women’s health organizations including Our Bodies Ourselves. In a recent commentary, Timothy Johnson, M.D., chair of obstetrics and gynecology, University of Michigan,
Ann Arbor, and Judy Norsigian, co-founder and past executive director of Our Bodies Ourselves, write:

Although one independent voluntary national registry in the U.S., the Infertility Family Research Registry (IFRR) based at Dartmouth-Hitchcock Medical Center in New Hampshire, offers such an opportunity, very few large fertility centers are even willing to put out the brochures and placard for this registry.\(^6\)

4. **There is no published information about the outcomes for women in the one state (New York) that explicitly permits payment beyond reimbursement for eggs for research.**

AB 2531 states that concerns that expanding the market for human eggs would encourage women to undergo risks that they would not otherwise take, and thus be exploited, “have not borne out in states where compensation is allowed.” But it provides no evidence or analysis to support this assertion, and we have not been able to locate any. Concerns remain that low-income women may feel particular pressure to risk their health in order to pay living expenses, tuition costs, child care, and the like.

5. **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.**

This is a puzzling statement, since information about egg providers is neither reported to nor regulated by the CDC. Fertility clinics 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 providers, about the number of eggs retrieved from them, or about the number or severity of adverse reactions they experience.

6. **Existing California law permits women who provide eggs for research to be reimbursed for their expenses, while disallowing compensation beyond that.**

There appears to be misunderstanding of this point by some of AB 2531’s supporters. For example, the press statement from Assembly member Burke 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.”\(^7\) Limiting reimbursement to expenses is what makes providing eggs altruistic. Payment beyond that constitutes a market in eggs.

7. **Payment for eggs for research conflicts with national and state recommendations, including provisions in the California constitution.**

Proposition 71, the initiative that authorized the California Institute for Regenerative Medicine, and is part of the state of California’s Constitution, prohibits compensation beyond reimbursements to women 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 scientists not funded by CIRM. SB 1260 also recognized that the situation of egg suppliers differs from that of subjects in clinical trials, and so it provided other protections for these egg suppliers, contained in California Health and Safety Code Section 125330-125355. In 2009, the California legislature again recognized the risks of egg harvesting and retrieval by passing AB 1317, authored by Senator (then
Assemblyman) 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.”

For these reasons, we strongly urge you to oppose AB 2531. We would welcome the opportunity to discuss our concerns.

Sincerely,
Marcy Darnovsky, Ph.D.
Executive Director

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2 Ibid.


