The American Society for Reproductive Medicine

Administrative Office
1209 Montgomery Highway
Birmingham, Alabama 35216-2809
tel (205)978-5000 • fax (205)978-5005 • email: asrm@asrm.org
www.asrm.org • www.reproductivefacts.org • www.asrmcongress.org

J. Benjamin Younger
Office of Public Affairs
409 12th Street S.W., Suite 602
Washington, D.C. 20024-2155
tel (202)863-4985 • fax (202)484-4039

May 30, 2019

The Honorable Richard Pan
Chair, Senate Health Committee
State Capitol Room 5114
Sacramento, CA 95814

RE: Assembly Bill 922 (Burke) ASRM Position: Support/Sponsor

Dear Senator Pan:

The American Society for Reproductive Medicine is an organization of national fertility experts, with 7,700 members including obstetrician/gynecologists, urologists, reproductive endocrinologists, embryologists, mental health professionals, internists, nurses, practice administrators, laboratory technicians, research scientists, and veterinarians. Our affiliated organization, the Society for Assisted Reproductive Technology (SART) represents fertility clinics. We are sponsors of AB 922 (Burke). The bill is expected to be heard next in the Senate Health Committee.

AB 922 is intended to reverse California's ban on compensation for women providing oocytes for research. AB 922 creates a fair balance between research participant compensation while extending existing protections under state and federal law ensuring participants are protected.

In the United States and California there is a fundamental principle that all research participants deserve just compensation for their contribution to research that entails some risk and much time, trouble and inconvenience. While all other research participants are compensated for their time, trouble, and inconvenience, California earmarked a difference over a decade ago by prohibiting compensation to women for their participation in oocyte retrieval for research. This difference is unjustifiable and creates an unfounded assumption that a woman cannot make an informed decision for herself.

As a result, lack of compensation deters participants, and stalls research. Women considering ovarian stimulation and oocyte (human egg) retrieval are capable of informed decision making as to the risks of compensated participation in research, just as they do now for fertility and other research. Fairness requires research participants be compensated just as those providing sperm for research. Allowing compensation for fertility purposes while banning it for research serves a false value, subordinating research to fertility.

By reversing the ban on compensation for research, AB 922 attracts and keeps medical technology and funding in California, allowing us to assume a position of leadership among the 47 states and other countries that allow compensation, maintaining California's status as a top state for cutting edge research. Failure to reverse the ban means research can still occur in 47 other states and other countries that allow compensation, and means a loss to participants of the comprehensive protections they would have in California but also a loss to women's health in areas including fertility, contraception and cancer treatment when research cannot be done in California.

Societal Need for, and Duty to, Research Participants

ASRM sponsored AB 922 to provide equitable treatment for women who participate in research, and allows them to be treated as any other research participant when they undergo ovarian stimulation and oocyte retrieval for tissues necessary in a wide range of important research. Generally, society benefits from compensated participation in research whether in clinical trials for new drugs, new models of cancer treatment or tissue donation such as sperm, lung and intestinal biopsies for study. To encourage research participation, there is a basic principle, recognized in the social contract, that there should be some reward for inconvenience and discomfort undertaken for the public good.

Existing Protections for Research Participants

Opponents fixate on the spectral potential that persons will participate purely for financial gain, disregarding health risks. There are already in place, however, federal and state legal protections for all research participants to avoid undue influence or coercion. The following are some of the legal protections afforded to research participants under both state and federal law and extended protections that will be provided under AB 922:

1. Human subject research panels and Institutional Review Boards (IRB) oversee and approve any research in which humans participate. They have the authority to set participant compensation by balancing the need for participation against the risk of undue influence.
2. Institutional Review Boards must analyze a whole host of elements including whether this research truly requires human participation, whether the research is prohibited, whether the materials and processes used guarantee informed consent and whether the compensation (in excess of reimbursements for expenses) rewards participation without creating undue inducement.
3. IRBs perform ongoing assessment of the population responding to the study, and evaluates whether compensation levels need adjustment. For other research, such as stem cell, additional layers of protections are required by Stem Cell Research Organizations.
4. Federal regulations of the Office of Human Subject Protections require that a range of specific questions be addressed to ensure fair treatment.
5. The *California Research Participants' Bill of Rights* compliments federal requirements and provides additional protections for all research participants. The *California Research Participants' Bill of Rights* will require research participants to be informed of their rights in both oral and written form in a language that they understand. Additional rights include, but are not limited to: receive information about the nature and purpose of the medical research, an explanation of the procedures that will be followed, information about reasonably foreseeable risks, benefits, alternative procedures, an opportunity to ask questions, and that consent to participate may be withdrawn at any time. Research participants must understand the material facts reasonably necessary to make a determination to participate and voluntarily provide their informed consent confirmed in writing.

These protections for research participants are in addition to the basic protection afforded to them as patients of the involved physician. Participation in research does not alter the underlying physician/patient relationship and the physician's existing duty of care to the participant under state law.

Roots of the Current Ban on Compensation

In the early to mid- 2000's, the public dialogue on embryonic stem cell research was at its zenith. After the federal government banned federal funding of new stem cell lines, California leaders took the lead by passing Proposition 71 (2004). Proposition 71 authorized the sale of $3 billion in California bonds to fund stem cell research. It restricted the use of bond funds for research where tissue donors were compensated above expenses.

Groups opposed to compensation persuaded the drafters that female family members of patients with diseases which could benefit from stem cell research would willingly participate, which we now know does not occur. Some opponents of embryonic stem cell research supported a ban on compensation to discourage the research altogether.

The ban on compensation in Proposition 71 is limited to research funded by the California Institute of Regenerative Medicine (CIRM). However, as there could be stem cell research funding available outside of the bonds authorized by Proposition 71, the compensation opponents insisted adding a ban in California law for compensation to oocyte donors for *all* research, even though no evidence of abuse or problems existed. They seized on a sensational 2005 case from South Korea as proof that California researchers could not be trusted to obey existing law protecting research participants. It was in that climate that Senate Bill 1260 (Ortiz/Runner - 2006) passed, banning compensation for all oocyte donors to research.

With this backdrop and without clinical support, the opposition prevailed with claims that ovarian stimulation is carcinogenic. This argument to is analogous to, and as valid as the post hoc ergo propter hoc claims that abortion causes breast cancer, or as Dr. Andrew Wakefield famously claimed that vaccines cause autism.

Effect of the Ban

The research ban harms reproductive health research in California. Reproductive health research will flourish when women are treated as all other research participants and are compensated for their time, trouble, and inconvenience. To be clear, this is not payment for human eggs. Compensation is not dependent on the number of oocytes obtained; it will be made even when no oocytes can be obtained.

The evidence shows the detrimental impact of compensation bans. In Massachusetts, one of three states banning compensation, (California and South Dakota are the others) women do not participate without compensation. Harvard spent $100,000 on outreach, yielding only one woman both qualified and willing to be a donor. Frustrated researchers surveyed those who responded to the outreach, and who were screened and qualified, but did not ultimately participate. Half of the women cited lack of fair compensation as the primary reason for non-participation.

The irony is that researchers in Oregon have demonstrated that a relatively small number of oocytes and embryos may suffice for research, when opponents fear large volumes are needed. A recent scientific paper suggests that Human Embryonic Stem Cell research is most efficient when fewer oocytes are retrieved and oocyte quality improves. (This looks to be true for fertility as well.) In other words, in the absence of a research ban on compensation theoretically designed to protect women, and scientists were able to compensate donors, the scientists demonstrated how patient safety and research effectiveness go hand in hand. This research could not have been done in California.

Examples of Research Impeded By the Ban That Would Benefit From A Reversal

In the 30+ years we have practiced in vitro fertilization (IVF), embryo cryopreservation has advanced to the point where it is highly successful and frequently results in a pregnancy. Despite this success, oocyte (human egg) freezing has proved more challenging. Oocyte freezing is essential for fertility preservation, critical for young women whose cancer treatment will likely leave them sterile. More research needs to be done to improve the chances of a successful pregnancy using cryopreserved oocytes. Those changes matter greatly to the woman weighing her options for cancer treatment.

Oncologists report patients delay care, or choose less effective care, such as surgery and radiation but without chemotherapy, in efforts to preserve her fertility. Additional research to increase the success of fertility preservation will allow women to focus solely on the best cancer treatment, with the assurance that their oocytes were effectively preserved.

Because cancer in younger women is typically more aggressive, cancer patients of reproductive age will not have the two to five weeks necessary for fertility preservation before beginning chemotherapy. For these women, knowing the effect of different chemotherapy agents on oocyte quality is vital to future fertility. Researchers are cued up to do this research once sufficient participants can be engaged. That will not occur without compensation, not in California.

As another example, a better understanding of embryo quality will provide intended parents the confidence in implanting fewer embryos when undergoing IVF. A high priority of ASRM is to reduce the number of multiple births from IVF. Although we have made great strides, research is needed to develop more reliable embryo evaluation. When intended parents have emotionally and financially struggled through years of infertility and IVF, they need a high degree of confidence they will be able to achieve a pregnancy with fewer implanted embryos. A better understanding of embryo quality so that there are fewer multiple births is a goal worth pursuing. It can only be achieved through research with compensated participants.

Excess Oocytes and Embryos from Fertility Treatments

Included in AB 922 is the ability to use excess oocytes and embryos obtained and created for fertility, using different standards than used for women participating solely for research. In these instances, excess tissue is derived from women compensated for the purposes of fertility to help another woman or couple, create a child. These provisions were included in AB 922 to be able to use this excess tissue that already exists and would otherwise be destroyed. Recognizing that women compensated for fertility were not induced by any aspect of research participation, including compensation for research, the California Institute of Regenerative Medicine (CIRM) agency promulgated regulations where these tissues could be used by CIRM funded researchers, when certain conditions were met.

Conditions included that the tissues were obtained for fertility, shall not compromise or interfere with the fertility potential of the intended woman, that fertility decisions were made prior to any consideration of research and that the infertile woman is the one who makes the determination that she does not want or need the excess tissues. Under these conditions, the amount of compensation for fertility is irrelevant there was no original intent or inducement for research. AB 922 mirrors those regulations for non-CIRM research in this bill. Passage of AB 922 would allow these valuable, existing tissues to be used for research instead of discarded. Donating to research is consistent with the desires of the overwhelming majority of parents.

Conclusion

AB 922 brings fairness to the field of medical research compensation by removing the anomalous prohibition of compensation for women participating in oocyte (human egg) donation for medical research. All other research participants can be compensated for their time, trouble, and inconvenience involved in participating in research. Women are compensated when they undergo the exact same procedure, with the same exact physicians, for the purposes of fertility. We believe women are capable of deciding for themselves in either circumstance. We sponsored AB 922 to ensure that women are treated equally, and will be helped when reproductive endocrinologists and other researchers have tissues needed to make medical breakthroughs.

When AB 922 passes and is signed by the Governor, barriers will fall for women participating in research that could result in improvements to reproductive health, including infertility and cancer care. This research will benefit untold numbers of women. With the protections in place for all research participants and additional protections added by AB 922 for those providing oocytes, women, even with compensation as a consideration, will prove capable of making participation decisions for themselves.

Questions & Contacts

If you or your staff has any questions, please contact me at 916.441.2430. We thank you for your consideration on this bill supporting California as a leader in science, technology and health research. We respectfully ask for your "AYE" vote in the Senate Health Committee.

Sincerely,

Shannon Smith-Crowley
Legislative Advocate

cc: Assemblymember Autumn Burke
Senate Health Committee, Members and Consultants