Date of Hearing: April 19, 2022

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
AB 1896 (Quirk) – As Amended April 6, 2022

SUBJECT: Gamete banks.

SUMMARY: Requires a licensed gamete bank to provide specified information to individuals obtaining donor gametes to conceive a child, including information on the risk of consanguineous relationships between half-siblings or closely related individuals that result in children; how genetic disease and disease risk factors from a sperm donor can be inherited by a donor-conceived child; how genetic disease and disease risk factors from a sperm donor can be inherited by a donor-conceived child; and, how large donor-sibling groups could occur as a result of a lack of tracking or limits on sperm donation use. Requires the Department of Public Health (DPH) to develop the information and guidance with stakeholders. Specifically, **this bill**:

1) Requires a gamete bank licensed in this state to do both of the following on and after January 1, 2024:

    a) Provide the following information in writing to individuals obtaining donor gametes in order to conceive a child:
        i) Information on the risk of consanguineous relationships between half-siblings or closely related individuals that result in children;
        ii) Information about how genetic disease and disease risk factors from a sperm donor can be inherited by a donor-conceived child;
        iii) Information on how large donor-sibling groups could occur as a result of a lack of tracking or limits on sperm donation use; and,
        iv) Information on ways to mitigate the potential genetic, psychological, and social risks faced by donor-conceived children and adults, such as education on the benefits of parent transparency with donor-conceived children about their method of conception and materials for age-appropriate disclosure to donor-conceived children, if available.

    b) Inform prospective gamete donors of the potential of genetic technologies to reveal the relatedness of the donor to children conceived through the donor's gametes, even if the donor has chosen to remain anonymous at the time of donation and thereafter. Requires a gamete bank to make a good faith effort to provide this information to donors who submitted their donations out-of-state when importing sperm from an out-of-state, but not international, gamete bank.

2) Requires the information and guidance required in 1) above to be developed by DPH in consultation with stakeholders, including, but not limited to, a donor-conceived person demonstrably involved in the representation of donor-conceived people, a mental health professional with experience counseling recipient parents and donor-conceived people, and a representative of a sperm bank operating in the state.

3) Requires DPH to provide the information and guidance developed under 1) to the public on its internet website.

4) Permits DPH to suspend or revoke the license of a gamete bank that violates the above requirements.

5) Specifies the intent of the Legislature to protect the health and mental well-being of persons conceived through sperm donations and their offspring.

6) Finds and declares all of the following:
   a) Advances and access in genetic sequencing technologies and direct-to-consumer genetic testing are eliminating gamete donor anonymity;
   b) Sperm donors could face potential psychosocial harm upon discovery of an unexpectedly high number of biological children and may suffer from being contacted by a large number of genetically related but unfamiliar individuals; and,
   c) There is an increased probability that genetic disease risk factors and adult-onset genetic disorders are inherited by an unusually large number of individuals when sperm donations from an affected individual are used without restrictions. In the absence of unbiased, genomewide genetic screening of sperm donors, that risk cannot be adequately mitigated.

EXISTING FEDERAL LAW:

1) Establishes procedures to prevent the introduction, transmission, and spread of communicable diseases by human cells, tissues, and cellular and tissue-based products (HCT/Ps).

2) Defines HCT/Ps as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient, including semen or other reproductive tissue.

3) Requires a donor-eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, for all donors of cells and tissues used in HCT/Ps, and prohibits the implantation, transplantation, infusion, or transfer of HCT/Ps until the donor has been determined to be eligible, with specified exemptions.

4) Requires, before the completion of a donor-eligibility determination:
   a) Screening a donor's medical records for specified risk factors for, and clinical evidence of, relevant communicable disease agents and diseases;
   b) Keeping semen from anonymous donors quarantined for at least six months after the date of donation. Defines quarantine as the storage or identification of an HCT/P, to prevent improper release, in a physically separate area clearly identified for such use, or through other procedures, such as automated designation; and,
   c) Retesting of anonymous semen donors by collecting a new specimen from the donor and testing it for evidence of infection due to human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), syphilis, and human T lymphotropic virus (HTLV).

5) Exempts from specified donor eligibility requirements and HCT/P-use prohibitions:
   a) Cells and tissue for autologous use;
   b) Reproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use; and,

c) Cryopreserved cells or tissue for reproductive use, as specified.

6) Authorizes the Food and Drug Administration (FDA) to regulate establishments that engage in the manufacture of HCT/Ps, including any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of HCT/Ps.

7) Establishes under federal law, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which sets standards for privacy of individually identifiable health information and security standards for the protection of electronic protected health information, including, through regulations, that a HIPAA covered entity may not condition the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except under specified circumstances. Provides that if HIPAA's provisions conflict with state law, the provision that is most protective of patient privacy prevails.

EXISTING STATE LAW:

1) Establishes DPH to license and regulate gamete banks.

2) Requires a licensed gamete bank, for gametes collected on or after January 1, 2020, to collect certain identifying information and medical information from a gamete donor, including the donor's full name, date of birth, and address.

3) Requires a gamete bank to obtain a declaration from the gamete donor stating whether the donor agrees to disclose the donor's identity to a child that results from the donation, upon the child turning 18 years of age and requesting the information.

4) Defines the following:
   a) Donor as an individual, living or deceased, from whom tissue is removed;
   b) Gamete bank as a tissue bank that collects, processes, stores, or distributes gametes including a facility that provides professional reproductive services, other than those facilities exempt from tissue bank licensure;
   c) Person as an individual, corporation, business trust, estate trust, partnership, association, state or local government, or subdivision or agency thereof, or any other legal entity;
   d) Tissue as a human cell, group of cells, including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body, but shall not include an organ when recovered for transplantation or research purposes; and,
   e) Identifying information as the full name of the donor, the donor's date of birth, and the permanent and, if different, current address at the time of donation.

5) Prohibits, under the state Confidentiality of Medical Information Act, a provider of health care, a health care service plan, a contractor, a corporation and its subsidiaries and affiliates, or any business that offers software or hardware to consumers, including a mobile application or other related device, as defined, from intentionally sharing, selling, using for marketing, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. States that

a violation of these provisions that results in economic loss or personal injury to a patient is a crime.

FISCAL EFFECT: Unknown. This bill has not yet been analyzed by a fiscal Committee.

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, discussions around assistive reproductive technologies have left out the impacts on those who have the least say in the matter, but are most impacted: donor-conceived people (DCP). A lack of regulation and data collection has resulted in sperm banks using donations to produce dozens, even upwards of 100 children. Such large donor-sibling groups greatly increase the social, psychological, and genetic harms and risks on DCP. An unusually large number of half-siblings close in socioeconomic background, age, and location – influential determinants of partner selection among U.S. adults – may lead to unwitting intimate relationships between half-siblings or closely related individuals. Children born of such relationships are at greatly elevated risk of genetic disease. Unrestricted use of donor sperm also raises the odds of a genetic disease or disease risk factor being passed on to an unusually large number of DCP conceived from one donor. When DCP find out that they may be one of an unknown number of half-siblings, often through genetic tests like 23andMe, they report facing significant psychosocial burdens and mental health impacts. In a survey of over 480 donor-conceived individuals, 92% of respondents favor a limit on the number of families established from a single sperm donor and 71% reported experiencing negative emotions associated with their method of conception. Advances in direct-to-consumer genetic testing are also breaking down the barriers of anonymity. Sperm donors, who at the time of donation may have wanted to remain anonymous, face personal pressures and difficulty when contacted by a large number of biological children who desire to feel connected. Parents of DCP may fear the stigma they or their children may face as a result of the use of sperm donations and may also not know how or when to communicate with their children, making parent education a critical step to reducing risks. AB 1896 requires sperm banks to provide educational materials to recipients of sperm donations and to donors to explain the genetic, social, and psychological burdens faced, and best practices to mitigate these harms and risks. This bill also requires DPH to develop such information with input from stakeholders and subject matter experts.

2) **BACKGROUND.**

   a) **Federal regulations.** Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient is regulated as a human cell, tissue, and cellular and tissue-based product or HCT/P. The Center for Biologics Evaluation and Research (CBER) regulates HCT/P. Examples of such tissues are bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes and semen. Federal regulations also require tissue establishments to screen and test donors, to prepare and follow written procedures for the prevention of the spread of communicable disease, and to maintain records. The FDA also broadened the scope of products subject to regulation and to include more comprehensive requirements to prevent the introduction, transmission and spread of communicable disease. The rule also requires tissue establishments to register and list their HCT/Ps with the FDA. Additionally, tissue establishments must evaluate donors, through screening and testing, to reduce the transmission of infectious diseases through

tissue transplantation. There are also quarantine requirements and retesting before the use of anonymous donation.

b) Guidelines Regarding Gamete and Embryo Donation: Currently, there are two organizations to which physicians who practice reproductive medicine generally belong. One is the American Society for Reproductive Medicine (ASRM) and the other is the Society for Reproductive Technology, an affiliate of ASRM. According to ASRM, the use of sperm, oocyte, and embryo donation services has increased over the past several decades. The availability of donor gametes provides individuals and couples who otherwise may not be able to conceive with an opportunity to build a family. To optimize safety and outcomes, the FDA, American Association of Tissue Banks, US Centers for Disease Control and Prevention (CDC), and ASRM have developed their own guidance for the screening of donor tissue and recipients. The ASRM guidance also incorporates prenatal optimization, psychoeducational counseling of donors and recipients, and genetic risk assessment. This guidance for the screening and testing of gamete and embryo donors applies to all potential donors in the United States.
In California, DPH licenses gamete banks, defined as a tissue bank that collects, processes, stores, or distributes gametes including a facility that provides professional reproductive services, other than those facilities exempt from tissue bank licensure. Current law requires a gamete bank to collect and retain from a gamete donor the donor's identifying information and medical information at the time of the donation. A gamete bank that receives gametes from a donor collected by another bank to collect and retain the name, address, telephone number, and email address of the gamete bank for which the gametes were received. The ASRM guidance includes guidance for indications, screening and selection of sperm, oocyte donation, embryo donation, management of sperm/oocyte donors, screening and testing of recipients and their partners, and genetic screening and counseling.

c) State requirements. A gamete bank licensed in this state that collects gametes from a donor is required to: i) provide the donor with information in a record about the donor's choice regarding identity disclosure; ii) obtain a declaration from the donor regarding identity disclosure; and, iii) maintain identifying information and medical information about each gamete donor. A gamete bank is also required to give a donor the choice to sign an attested declaration that does either of the following: i) states that the donor agrees to disclose the donor's identity to a child conceived by assisted reproduction with the donor's gametes, on request, once the child attains 18 years of age; or ii) states that the donor does not presently to disclose the donor's identity to the child but permits a withdrawal of this declaration at any time and replace it with a declaration to disclose.

A gamete bank, upon request of a child conceived by assisted reproduction using donor gametes and who is 18 years of age, is required to provide the child with identifying information of the donor who provided the gametes unless the donor signed and did not withdraw a declaration for nondisclosure. A gamete bank is required to make a good faith effort to notify the donor of their ability to withdraw a prior nondisclosure declaration and agree to release the donor's information. Additionally, a gamete bank that received gametes from another game bank is required to disclose the name, address, telephone number, and email address of the gamete bank from which the gametes were received. Upon request of a child who is 18 years of age or by the guardian or parent of a child, a gamete bank must provide access to nonidentifying medical information provided by the

donor.

There are no requirements in state law that address the genetic risks of consanguinity between related donor conceived people and any other related information that consumers may find useful.

3) **SUPPORT.** In support, the California Catholic Conference states that this bill seeks to prevent the unfortunate incidences of genetic yet unknown half-siblings feeling drawn to each other, experiencing romantic attraction, and creating families together. The emotional and relational impact for these families cannot be understated.

4) **PREVIOUS LEGISLATION.**

   a) AB 785 (Bloom), Chapter 539, Statutes of 2019, updates existing law to streamline the transition of donor information from one bank to another by requiring gamete banks receiving donors' gametes to maintain the contact information of the gamete bank from which the samples were received and to include oocyte and embryo donors. These updates will ensure families and donor-conceived individuals have access to their donor's medical history when gamete samples are transferred from one gamete bank to another, while complying with FDA regulations.

   b) AB 2684 (Bloom), Chapter 876, Statutes of 2018, updates and revises the Uniform Parentage Act relating to establishing a parent and child relationship to, among other things, refer instead to genetic testing and parentage. AB 2684 also revises the presumptions and procedures for establishing and challenging parentage based on a genetic or nongenetic relationship with a child, including to modify the procedures for genetic testing for parentage. AB 2684 also modifies the procedures and requirements under which a voluntary declaration of parentage may be established and challenged.

   c) AB 2356 (Skinner), Chapter 699, Statutes of 2012, permits the recipient of sperm donated by her sexually intimate partner for reproductive use to waive a second or repeat testing of that donor for HIV, HBV and HCV, syphilis, and HTLV, if the recipient is informed of existing donor testing requirements and signs a written waiver. AB 2356 also exempts physicians or tissue banks that provide insemination or assisted reproductive technology services from liability and disciplinary actions, as specified.

5) **CORRECTION AMENDMENTS**. The committee recommends the following amendments:

   (c) A gamete bank licensed in this state shall do both of the following on and after January 1, 2024:

   (1) Provide the following information in writing to individuals obtaining donor gametes in order to conceive a child:
   (A) Information on the risk of consanguineous relationships between half-siblings or closely related individuals that result in children.
   (B) Information about how genetic disease and disease risk factors from a ~~sperm donors~~ ***gamete donors*** can be inherited by a donor-conceived child.
   (C) Information on how large donor-sibling groups could occur as a result of a lack of tracking or limits on sperm donation use

REGISTERED SUPPORT / OPPOSITION:

Support

California Catholic Conference
U.S. Donor Conceived Council, Inc.

Opposition

None on file.

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