A Good Attempt, Close to Perfect: Puerto Rico’s First ART Regulations

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This March, the Commonwealth of Puerto Rico (PR)’s Legislature was in session discussing the draft for the first proposed regulations on Assisted Reproductive Technology (ART) in its history. These proposals arose as a result of the increase of ART procedures in PR since 1985, when Dr. Pedro Beauchamp, the first Puerto Rican specialist certified by the American Reproductive Endocrinology and Infertility Board, performed the first in vitro fertilization (IVF) technique on the island.\(^1\) ART procedures have become an alternative for the 15% of women of reproductive age that suffer from infertility diseases in PR, resulting in over 400 fertilization IV cycles annually; an amazing number for an island with only 5 reproductive clinical centers.\(^2\)

Although the ART procedures are performed by medical specialists trained in the field who comply with the standards of care that American Society for Reproductive Medicine (ASRM) imposes, recent reported cases provoked the making of draft regulations to deal with the lack of current law in PR regarding such practices.\(^3\) Despite the efforts to deal with these current issues, the proposed regulations contain some loopholes that would require further discussion and amendment through special legislation topics such as posthumous procreation, alternatives to stem cell research, Preimplantation Gender Diagnosis (PGD) to cover screening for non-medical reasons, and the requirements for performing such techniques.\(^4\)

As a part of the draft’s revisions, the proposed article 303, entitled ‘Parentage through Assisted Procreation,’ acknowledges the legal effects derived from posthumous procreation, ‘if the fecundation occurs within the next year of the donor’s death.’\(^5\) Although some states, such as Virginia and Louisiana, have required that the conception of a child be achieved within ten months of the donor’s (father) death, the imposition of a time limit for conception has received criticisms from some commentators due to its severity and strictness.\(^6\) As an example, Virginia’s regulations regarding time limits for post-mortem procreation and its legal effects state the following:

> ‘Any child resulting from the insemination of a wife's ovum using her husband's sperm, with his consent, is the child of the

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\(^1\) Israel Rodríguez Sánchez, *Sí a la Reproducción Asistida*, EL NUEVO DÍA NEWSPAPER, Mar. 15, 2007 (Dr. Pedro Beauchamp, FACOG, FACS, REI, has been a member of the American Society of Reproductive Medicine (ASRM) since 1980 and founder-partner of the Society of Assisted Reproductive Technology (SART)).


\(^3\) Id.; See also Sánchez, supra note 1 (In March 2005, the first surrogate case of a child born in PR from her grandmother was reported, resulting in the filing of a legal petition to register as a daughter of her genetic parents due to the lack of regulations in PR to resolve the legal parentage of the child.)


husband and wife notwithstanding that, during the ten-month period immediately preceding the birth, either party died.’

Criticism arose due to the fact that a woman is not necessarily able to become pregnant immediately after her spouse’s death. The strictness imposed by the legislation about the time limits required has also been critiqued as a failure to understand the ‘unique circumstances’ that a woman could have after the spouse’s death. However, it must be considered that, under cryopreservation techniques, sperm motility could be maintained for over a decade. Therefore, the proposed time limits that the PR Civil Code Amendments intend to establish should provide a major extension of time for posthumous procreation considering the reality of the woman who suffered the death of her spouse or loved one and the expected viability of the gametes.

Other aspects to be considered under these proposed regulations are those concerning divorced couples or cases in which one member of the couple withdrew consent. The option of donating embryos or genetic material under cryopreservation techniques for cell stem research and other treatment services purposes should also be included. The proposed article 292 of the draft provides only the alternatives to return the cryopreserved ovules and sperm to the woman and man, respectively. The ability to withdraw consent is undermined by the draft’s language stating that embryos would be returned to the person interested in completing the ART or who is infertile. Indeed, the Human Fertilization and Embryology Act (HFEA), states that through ‘effective consent,’ the use of any embryo must specify as one or more purposes the ‘use for the purposes of any project of research and may specify conditions subject to which the embryo may be so used.’ This alternative should be included in the regulation, and with the informed consent of the parties, provide to them an alternative that could benefit the medical progress on the island.

Concerning Preimplantation Gender Diagnosis (PGD), this draft does not provide a specific regulation that restricts PGD for non-medical reasons or promoting the use of sperm sorting for those persons interested in ‘family balancing.’ Article 286 states that ART techniques could be used, among other purposes, ‘to prevent and treat genetic diseases.’ It must be clear that PGD is not a procedure to ‘prevent or treat’ genetic diseases; it is more than that. This technique may be used to detect prenatal genetic sex linked diseases as hemophilia A and B, Lesch-Nyhan syndrome, Duchenne-Becker muscular dystrophy, and Hunter syndrome. It may also be used for tissue matching to save the life of an existing child or for sex selection. However, the lack of...
specificity and complete information about what is and what is not authorized could provoke several ethical dilemmas in the future, such as discrimination against the use of embryos with genetic abnormalities, if it is not revised.\textsuperscript{16}

Finally, Article 286 imposes requirements for the performance of the ART procedures regarding clinical and sanitary conditions.\textsuperscript{17} ART techniques must be developed using the highest standard of care due to their risky and invasive nature. The proposed regulations must be amended using as a template the provisions contained in HFEA respecting the operations of fertility clinics.\textsuperscript{18} HFEA has, among others provisions, the requirement of licensing for all clinics that provide assisted reproduction and establishes a constant surveillance of the performance of the procedures in these clinics.\textsuperscript{19} Therefore, the requirements for the development of ART and the medical institutions used for these purposes must be strictly and clearly specified through special legislation for the best interest of all the parties involved.

This first draft proposing new regulations on ART’s techniques in PR is a good attempt trying to resolve issues that have been arising for more than 20 years, without any statute to deal with them, but they must not view ART as only involving issues of IVF procedures, surrogacy and posthumous procreation. They must consider, also, the availability of therapeutic cloning, stem cell research, and issues concerning the access to fertility enhancing services for same sex couples and people with low income.\textsuperscript{20} A good attempt is not enough to safeguard PR and its citizens. ART is a medical field in constant evolution, and in order to avoid possible future issues such as discrimination and the unsafe implementation of these techniques, these proposed rules need additional thought and amendment.

\begin{footnotes}
\item \textsuperscript{16} \textit{Id.}
\item \textsuperscript{17} Joint and Permanent Commission, \textit{supra} note 13.
\item \textsuperscript{18} See HFEA, \textit{supra} note 10, §8.
\item \textsuperscript{19} \textit{Id.}
\item \textsuperscript{20} Sandra Morales Blanes, \textit{Rechazo a las Uniones Gay}, EL NUEVO DÍA NEWSPAPER, April 23, 2007 (A proposed article allowing same sex couples to adopt the child of one of couple’s member is included as part of the Civil Code’s Amendments. This proposed article has received opposition from the majority of the island population and religious groups).
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