Assisted Reproductive Technology in Spain: Considering Women's Interests

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It might come as a surprise to many that Spain, a country with a strong Catholic tradition that officially banned contraceptive technologies until 1978, has some of the most liberal regulations in assisted reproduction in the world. *Law No. 35/1988* was one of the first and most detailed acts of legislation undertaken on the subject of assisted-conception procedures. Indeed, not only did the law permit research on nonviable embryos, it made assisted reproductive technologies available to any woman, whether married or not, through the national healthcare system.[1]

That such liberal laws on assisted reproduction were enacted in Spain is less shocking when one realizes that the Socialist government of Felipe González was in power at that time. As with the recent debate on stem cell research under another Socialist administration, that of José Luis Rodríguez Zapatero,[2] the debate on assisted reproductive technology (ART) in Spain was framed as a dispute between science and religion and resulted in a high-decibel argument between what has been called "las dos Españas."[3]

Today, 25 years after the first "test-tube baby" was born in Spain, more than 12,000 are the result of ART. The initial controversies surrounding these technologies have now withered. When they arise, they usually focus on the moral status of the embryo or on the safety of new techniques such as preimplantation genetic diagnosis (PGD).

Less attention has been paid, however, to the effects of ART regulations on the well-being of women. Of course, the degree to which women's interests are taken into account in these regulations varies from country to country. In this paper, I examine the new Spanish law on ART and explore its impact on women's welfare. My goal is to evaluate some of the new provisions to see whether women's interests are advanced and, if so, how. Spain is a particularly interesting case study because the status of women has changed significantly during the past three decades, with levels of educational, political, and economic attainment among the best in the European Union.

Regulating Assisted Reproductive Technologies in Spain

As would be expected, advances in the science and technology of ART have not been disregarded by the Spanish public or by the different administrations. In fact, it has been a response to those changes that instigated regulatory revisions in this area.

First Regulatory Effort

In April 1986, and under the Socialist government of Felipe Gonzalez, Marcelo Palacios, president of a special commission set up by the Spanish Cortes

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(the National Legislature) to study human in vitro fertilization (IVF) and donor insemination, issued the commission's report.[4] Following this report, *Law 35* received the Royal Assent[5] on November 22, 1988.[6] It was one of the first laws worldwide to regulate ART. The law covered artificial insemination, IVF, and gamete intrafallopian transfer. It laid down general principles for the application of these technologies that emphasized informed consent, full disclosure of risks, patient data collection and confidentiality, fertilization of ova for the sole purpose of procreation, and minimization of surplus embryos.

Research on viable embryos was allowed only where benefits to the particular embryo were expected. Research on nonviable embryos was permitted. The law also stipulated that surplus frozen embryos should be stored in authorized banks for upto 5 years. It permitted sperm and embryo freezing but prohibited ova freezing because of concerns about the safety of the technique. It specified conditions applicable to gamete donors, persons undergoing fertility treatment, and the status of resultant children.

As mentioned earlier, the law made these services available through the national health system to any woman. It also decreed the establishment of the National Commission for Human Assisted Reproduction that would be in charge of regulating infertility services. The Commission, however, was not established until 1997.

Changing Politics, Changing Legislation

Because of scientific and technological advances related to reproductive technologies, the promises of stem cell research, and especially because of the difficulties in deciding what to do with the increased number of surplus embryos in storage for more than 5 years, *Law 35* was modified in 2003 by the center-right government led by Jose María Aznar.[7] Following recommendations by the National Commission for Human Assisted Reproduction, *Law 45/2003* was passed as an attempt to address these issues. Trying to limit the number of surplus embryos, and thus the problems about what to do when they were not needed for procreation, the law limited the number of oocytes to be fertilized to three per cycle. It allowed for exceptions for medical reasons.

The new law also eliminated the limit of 5 years for the storage of frozen embryos and extended it to the reproductive life of the woman. If a woman had not had all of her surplus embryos transferred, then the couple, or woman, could donate them for reproductive purposes only. However, for embryos frozen before the establishment of *Law 45/2003*, the new law permitted couples, or the woman, to choose between keeping the embryos frozen until they could be transferred to the woman, donating them to other women for reproductive purposes, giving the embryos for research, or allowing their thawing and destruction. *Law 45/2003* thus created a distinction between embryos frozen before and after the passing of the law. Although those frozen before the law could be used for research purposes, those frozen after it could only be used for reproduction.

The New Law on ART

Discontent with several of the provisions of the 2003 law led the new socialist government of Mr. Zapatero to propose new regulations for ART. *Law*

14/2006—Human Assisted Reproduction Techniques came into effect in May 2006.[8] It superseded *Law 35* of 1988, which in turn had been amended by *Law 45/2003*.

The new law regulates the use of ART and facilitates the use of these techniques by people with fertility problems. It also establishes procedures for their utilization in the prevention and treatment of genetic diseases and sets up requirements for gamete and embryo use. Similarly, following the European Constitution, it maintains the prohibition against reproductive cloning.

The law also proscribes payments to gamete and embryo donors, except to compensate them for time, effort, and discomfort. Compensation, however, cannot be such as to be an economic incentive. Gamete and embryo donation are anonymous, although children can obtain general information about the donors. In exceptional cases, however, when the life or health of the child might require it, the law allows the disclosing of donors' identity. Additionally, rather than simply enumerating the reproductive techniques that can be used, the new law takes into account the fact that new successful technologies might be developed and allows for their introduction when evidence exists of their efficacy and safety.

Some Important Changes

The most significant changes of this law include new registration requirements, the authorization to use embryos for research purposes when the embryo donors consent, the elimination of a prohibition on fertilizing more than three oocytes per cycle, and the admissibility to use PGD to provide therapies for third parties.

Recognizing the fact that information about these technologies might not meet infertile people's needs, the new law establishes additional registry requirements. It maintains the gamete and embryo donor registry set up by *Law 35/1988*. This registry will have information about the number of children born from particular donors, the identity of the people using donated gametes or embryos, as well as the location of both donors and recipients when donation and use takes place. But the new law creates a registry of centers of assisted reproduction activity. To help infertile couples in their decisions, this new registry will record data about the types of technologies used, success rates, and other factors that indicate the quality of the centers. Such data will be made public once a year. The registry will also document the number of embryos stored in each center.

Although, as mentioned before, the law of 2003 allowed embryo research, it limited such research to embryos frozen prior to the law. The new law eliminates this restriction and allows any excess embryo to be eligible for research. Informed consent by the couple, or in some cases the woman, continues to be a requirement. The new law, however, specifically indicates that consent to donate embryos for research purposes must include detailed information about research goals and possible consequences. It must also state that the donors will relinquish all rights to any profit derived from the investigations with embryos.

The elimination of restrictions on the number of oocytes that may be fertilized per cycle is the result of requests by infertile couples, organizations, and infertility professionals. Presumably, the removal of this restriction will increase the possibility of success of ART as well as reduce the need to repeat the procedures required for oocyte procurement. Embryos not used by the couple or woman can be stored for their future use, for donation to other couples, or for

research purposes. The new law, however, maintains the prohibition on implanting more than three embryos per reproductive cycle.

Finally, *Law 45/2003* permitted the use of PGD in order to detect embryos at risk of severe genetic diseases for which treatment was unavailable. The new law, though, extends the use of this technique to include the selection of embryos that are compatible with a third party in need of medical treatment. The use of PGD in this case requires approval from health authorities after a favorable review by the National Commission of Human Assisted Reproduction. Such review must include an assessment of the clinical, therapeutic, and social characteristics of the particular case.

The New Law and Women's Interests

It is not uncommon for laws, regulations, or guidelines on reproductive technologies to neglect women's interest.[9] In part this is so because reproductive technologies have begotten various legal, social, and ethical problems. These techniques, for example, allowed us to produce human embryos in vitro for the first time, and thus questions about the moral status of extracorporeal embryos emerged. Similarly, these techniques introduced third parties by making possible the donation of gametes and embryos. This brought about concerns related to the disclosure to children. Thus, the interests of children, trepidation about embryos, and fears about effects on the family have often taken precedent over concerns for women's interests in laws and regulations.

Respecting Women's Autonomy: Adequate Information

A measure of whether laws and regulations on reproductive technologies adequately protect women's well-being can be found in their ability to promote respect for women's autonomy. As with other medical procedures, such respect is usually translated into requirements for informed consent. Laws regulating reproductive techniques do defend the importance of obtaining informed consent from patients and donors. Nonetheless, this defense means little to the ethical requirement of free informed consent if measures are not put in place to ensure that the conditions for such consent exist. For example, adequate knowledge about the real chances of having a child through ART is relevant when making decisions to undergo treatment. If laws fail to address satisfactorily problems related to obtaining adequate information about success rates, then they fall short of protecting women's rights to free informed consent.

Unfortunately, this has been the case in Spain. Thus, although *Law 35/1988* and *Law 45/2003* emphasized the need for informed consent, they failed to promote and enforce mechanisms that would assure that women could easily attain meaningful information on success rates. Even though infertility clinics might advertise success rates higher than by natural conception[10] and as high as 70%,[11] this might mean little for the real chances that a particular woman would have a live birth.

Moreover, because IVF consists of a series of treatment phases, a woman may drop out of any stage because the treatment failed.[12] Therefore, when estimating success rates, using embryo-transfer cycles as the denominator will increase the success rate, whereas using all started treatments will decrease it. Similarly, when

doctors use clinical pregnancies as the measure of success, then they count as success of the treatment chemical pregnancies (changes in the woman's hormonal levels), ectopic pregnancies, miscarriages, and preterm births.[13]

Furthermore, because definitions of "success" are unclear, IVF success rates appearing in the media can be misleading. Such statistics do not specify the numerator and denominator of the rate. They fail to reveal, for example, if the denominator is the number of ovarian stimulations that the doctors have performed, the quantity of eggs retrieved, the number of eggs fertilized, or the total of implanted embryos. Likewise, the statistics published in the media fail to disclose client characteristics, although success rates vary significantly depending on the underlying cause of infertility, the age of the woman, and the technologies used.[14]

Because patients and clinics might define "success" in ART treatment differently, prospective patients cannot adequately assess their likelihood of having a child through the use of these techniques. Without clearly defined and universally employed definitions of "success," meaningful evaluation and decisionmaking are impossible. The introduction of additional registry requirements by the new law might address these problems.

Of course, whether the new law ultimately promotes adequate conditions for informed consent depends considerably on enforcement measures. It is discouraging, for example, that in 2002 and 2003 only 36 out of 185 clinics and 44 out of 187 clinics, respectively, reported data to the European IVF monitoring program.[15] In any case, the new law at least requires that data from all certified infertility centers about the types of technologies used, success rates, and other factors that indicate the quality of the centers be registered. As mentioned before, it also calls for such data to be made public yearly.

If mechanisms are put into place to collect standardized and meaningful information about success rates at different clinics, efficacy of the various techniques, as well as success by infertility etiology, this would go a long way toward fostering women's ability to give free, informed consent. Furthermore, access to this data must be widely available if it is going to reach those who might need it. Thus, strategies to make this information public must take into account, for instance, different backgrounds, socioeconomic status, and educational attainment, as these factors influence the degree to which people might be able to access and understand necessary information.

Respecting Women's Autonomy: Donor's Consent

But respect for women's autonomy is also recognized in the new law when it requires informed consent for the donation of embryos for research purposes. Significantly, the consent must include detailed information about research objectives, its stages, whether the research will include basic science or clinical applications, as well as the possible consequences that could follow from it. Moreover, if embryos are going to be used for a research purpose not specified in the original consent form, such consent must be obtained before the research can proceed.

This requirement acknowledges women's labor in the production of oocytes as well as their agency in deciding what to do with the reproductive product of such labor. Rather than seeing extracorporeal embryos as completely independent

of women's bodies and desires, the law recognized women's interests in making decisions about what to do with them.

Considering Women's Well-Being

Another aspect of the law that affects women in a considerable way is the prohibition on transferring more than three embryos at a time. As mentioned earlier, this ban was already established by *Law 45/2003* as a way to reduce the number of multiple births. Given that the principal complication associated with assisted reproductive technology is multiple pregnancies, it is laudable that the new law maintains the prohibition. In fact, the incidence of multiple births has risen at an extraordinary pace over the past two decades. IVF is responsible for as much as one half of all multiple pregnancies in various parts of the world.[16] Fortunately, the rates of multiple births have been declining steadily in the past few years. This trend is in part the result of legislative measures in many European countries that dictate the maximum number of embryos permitted for transfer as well as the recommendations of several professional societies.[17]

In spite of the trend toward the transfer of fewer embryos, the new law decided to maintain the limit of three. Presumably, this was a way to balance the possible increase in birth rates with the increase in multiple pregnancy risks. However, growing evidence suggests that delivery rates can be preserved after implementing protocols that reduce the number of embryos transferred per patient.[18] A report from the U.S. Center for Disease Control, for instance, showed that, in women younger than 35 years of age using their own freshly fertilized embryos, a single embryo transfer resulted in live-birth rates of 45%. There was a small difference in live-birth rates among patients with single versus double elective embryo transfers. Nevertheless, transferring two embryos posed a multiple-birth risk of approximately 38% for this group.[19] When three or more embryos were transferred, there was a significant risk for higher-order multiple births (8%–10%), but no increase in the overall pregnancy rate.[20]

Although a significant debate still exists about whether requiring single embryo transfers for most patients is appropriate, considerable agreement exists that the transfer of only two embryos should be encouraged as a way to reduce higher-order multiple pregnancies.[21] Even in the United States, where the number of embryos transferred and the rate of multiple births are higher, recommendations for a 2-embryo transfer policy are forthcoming.[22] Similarly, some European countries have established new regulations that prohibit transferring more than two eggs or embryos during a single cycle in women under 40 years of age, with no exceptions. They allow up to three in women over this age.[23]

As compared with singleton pregnancies, multiple births are associated with increased health risks for both mothers and infants. For mothers, there are increased risks of hypertensive disorders, anemia, miscarriage, urinary tract infections, glucose intolerance, antepartum hemorrhage, preterm labor placental abruption and placenta previa, preterm labor and delivery, the need for cesarean section and its attendant risks, and death.[24] Major risks for infants include those of prematurity, low birth weight, congenital anomalies, and death. Infants from multiple pregnancies also suffer an increased risk of health and developmental problems.[25] Because women bear a disproportionate burden for the care of children, multiple births can significantly affect their well-being.

Moreover, health risks associated with multiple births also contribute to healthcare costs due to the need for obstetric and neonatal intensive care and the effects of babies' disabilities.[26] But costs incurred during infancy and childhood are also higher from multiple gestations compared with singleton pregnancies.[27] This is so because multiple birth children have special needs, require ongoing pediatric care and other therapies and might need special education.[28] Because Spain has a national healthcare system, such an increase in costs needs to be taken into account. Obviously, ARTs have great opportunity costs, and, thus, public money used for these technologies or for their health consequences cannot be used for other purposes.

Given the evidence about success rates with the transferring of fewer than three embryos and given the significant adverse health effects for women and their children, the new law might have better served women's interests by recommending single embryo transfers for patients under 35 with excellent prognosis. For older patients who still have a favorable prognosis, recommendations for not more than two embryos transferred would also reduce the incidence of triplets. Of course, the law could still provide for the possibility of exceptions, as it does, for example, for the use of PGD.

Conclusion

Laws regulating ART affect a variety of social institutions: business practices, medical licensing, donor banks, and so on. But they also have considerable effect on infertile people in general and women in particular. Rarely are ART laws evaluated so as to see whether they promote women's interests. Although women are the only ones who undergo IVF and other infertility treatments, concern about them is usually absent from evaluations of their regulatory mechanisms. Because women are the ones who bear and give birth to children, the implementation and use of any ART law or regulation of reproductive technology will surely affect them. Therefore, an analysis of how these laws might influence women seems necessary. In this essay I have shown how some of the provisions of the new Spanish law on assisted reproduction techniques foster or hinder women's interests.

Notes

1. Jefatura del Estado. Ley 35/1988, de 22 de Noviembre, Sobre Técnicas de Reproducción Asistida. Madrid: *BOE*, 282, November 24, 1988: 33373–8.
2. Zapatero apoya una investigación con células madre ''con rigor'' y sin ''frenos artificiales.'' *EL PAIS.es*. 2006 Mar 27; available at http://www.elpais.es/articulo/elpporsoc/20060327elpepusoc_3/Tes/sociedad/Zapatero/apoya/investigacion/celulas/madre/rigor/frenos/artificiales (last accessed 28 Jul 2008).
3. Rodriguez del Pozo P, Fins JJ. Iberian influences on Pan-American bioethics: Bringing Don Quixote to our shores. *Cambridge Quarterly of Health Care Ethics* 2006;15(3):225–38; Gracia Guillén D. Spanish bioethics comes into maturity: Personal reflections. *Cambridge Quarterly of Healthcare Ethics* 2009:18(3):219–227 (this issue).
4. Comisión Especial de Estudio de la Fecundación ''In Vitro'' y la Inseminación Artificial Humanas. *Informe.* Madrid: Gabinete de Publicaciones; 1987.
5. The granting of Royal Assent is the formal procedure by which the sitting constitutional monarch, in this case King Juan Carlos I, completes the legislative process of lawmaking by formally assenting to a legislative act.

6. See note 1, Jefatura de Estado, 1988.
7. Jefatura del Estado. Ley 45/2003, de 21 de Noviembre, Por la que se Modifica La Ley 35/1988, De 22 de Noviembre, Sobre Técnicas de Reproducción Asistida. Madrid: *BOE*, 280, November 22, 2003: 41458–63.
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21. See note 16, El-Toukhy et al. 2006; Nakhuda GS, Sauer MV. Addressing the growing problem of multiple gestations created by assisted reproductive therapies. *Seminars in Perinatology* 2005;29(5):355–62.
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28. See notes 26, Ombelet et al. 2005; see note 27, Collins 2007.