Chapter- IV

Laws in Different Countries on Assisted Reproductive Technology

4.1 Introduction

Although infertility is a global health issue that affects millions of people worldwide there is ambivalence and anxiety about the commercial use of ART and particularly gestational surrogacy. While most industrialized nations ban commercial surrogacy other nations such as Brazil, Israel, and the United Kingdom have established regulatory mechanism or partial ban to control access to it. The surrogacy market is unregulated by the United States government, leaving it up individual states to develop regulatory policies. The legal restrictions placed on surrogacy in most of Europe and Asia has enabled California to be the global destination of choice for reproductive tourists.\(^1\) In the United Kingdom, the influential 1984 Warnock Report argued that “it is inconsistent with human dignity that a woman should use her uterus for financial profit and treat it as an incubator for someone else’s child.” The British government subsequently prohibited commercial surrogacy under the 1985 Surrogacy Arrangement Act but focused primarily on the role of third parties: technically, brokering a surrogacy arrangement was illegal, but entering into one was not. In many parts of the world, such criticism rapidly made its way into law. Germany and France, for example, banned any form of surrogacy contract, arguing (in the French case) that “the human body, its elements and its products may not be the subject of a contractual agreement.” In Australia, the Government of Victoria agreed in 1984 that commercial surrogacy was “completely unacceptable as part of an IVF programme” and accordingly passed legislation banning surrogacy contracts, agencies, and advertisement. In most part, of the Canada, noncommercial surrogacy was quietly allowed, but the law explicitly treated the birth mother in such cases as the child’s legal parent, regardless of either her genetic link to the child or any outstanding contract with an intended parent.\(^2\) This chapter provides a detail analysis of the laws and policies of different countries in the world regarding the use of ART.


4.2 ART in United Kingdom

The United Kingdom was the first country in the world to ART with the first child born through in vitro fertilization (IVF). To control such practices, the government has developed policies to regulate reproduction techniques and protect their users, unlike the United States where such regulation is minimal. As a part of these policies, in 1990 the U.K. enacted ‘The Human Fertilization and Embryology Act’ (HFEA) with the intent to enforce the regulations related to assisted reproductive technologies and to control research on human embryos. The Act grants, among other provisions, the authority of the agency charged with overseeing HFEA to keep under its own review information about embryos and to advise people who are using ART or to whom posses a license to operate a fertility clinic. Moreover, this Act provides that licensed fertility clinic managers who provide or receive economic remuneration or other benefit to obtain gametes or embryos may be punished by imprisonment. In December 2006, the government revised these regulations and reorganized the agency that has oversees HFEA, creating new proposals in response to social changes and scientific developments that have been occurring in the U.K. over in recent decades. The 1990 Act setup the powerful Human Fertilization and Embryology Authority. Some activities are only permitted under a licence from this Authority. These cover: treatment, research and storage. The Human Fertilization and Embryology Authority (HFEA) is responsible for licensing fertility clinics and regulating the use of donor gametes, assisted fertilization, pre-implantation genetic diagnosis, the storage of gametes and reproductive tissue, and research using human embryos. The HFEA limits the number of embryos transferred per reproductive cycle to 1-2 embryos for women under the age of 40. A maximum of three embryos can be transferred to women over 40. The HFEA also prohibits commercial egg and sperm donation.3

As a part of the revisions, the U.K. banned the use of sex selection for “family balancing” and facilitated access to certain assisted reproductive methods, such as in vitro fertilization (IVF), to single women and lesbian couples.4 The U.K. also proposed a ban on the use of genetically modified sperm, eggs, or embryos for

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reproductive purposes. However, the law permits the use of reproductive assisted methods and genetic modification intended to prevent the genetic transmission of certain gender-based diseases, such as hemophilia or forms of muscular dystrophy. These policies and regulations promulgated by the U.K. have established controls on certain contentious ART practices. In the United States, there are no similar rules.

The United Kingdom’s laws on ART include the Surrogacy Arrangement Act (1985), the Human Embryology & Fertilization Act (1990), and the Human Reproductive Cloning Act. These laws prohibit reproductive cloning, the transfer of a non-human embryo to a woman or a human embryo into an animal, allowing embryos to develop outside of the human body for fourteen days, germ line modification, non-medical sex selection, and commercial surrogacy arrangements. The broad objectives of the Human Fertilization and Embryology Act 1990 Act are as follows:

(a) To provide a statutory framework for the supervision and control of human embryo research.
(b) To allow for the licensing of certain forms of what are termed ‘assisted conception’ practices.
(c) To effect changes to the Abortion Act 1967

The research licence allows for the creation and use of in-vitro embryos for certain embryos for certain specific projects. Paragraph 3 of schedule 2 to the Act sets out the type of projects for which these licences may be granted:

(a) The promotion of advances in the treatment of infertility.
(b) Increasing knowledge about the cause of congenital disease.
(c) Increasing knowledge about the cause of miscarriage.
(d) Developing more effective contraception techniques.
(e) Developing methods of detecting the presence or absence of gene or chromosome abnormalities before the implantation of an embryo.

The Human Fertilization and Embryology Act 1990 provide a nearly comprehensive scheme for regulating assisted reproduction and research on human embryos outside the human body. It provides for formal administrative oversight

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7 “Review of the Human Fertilization and Embryology Act, Proposals for revised legislation (including
through the statutory authority, bringing a degree of centralization, but also includes a conscience clause, ensuring that professionals may not be forced to participate in any of the activities governed by the Act. This web of regulation is interesting both for the model it provides for the governance of health care ethics and for the specific provisions governing clinical practice and research. This section considers the impact of the Act on treatment services.

The Act works by outlawing certain activities unless they are carried out under the auspices of a licence from the authority. Section 3 sets out a wide-ranging prohibition on creating, keeping, or using human embryos. Section 3A prohibits the use in fertility services of eggs taken from embryos or fetuses. Section 4 prohibits the storage and use of human gametes. A special exemption has been granted in relation to the storage of the gamete only for the purpose of research, including developing pharmaceutical and contraceptive products, and teaching. Although the 1990 Act covers most type of infertility treatment, some techniques do not come within it. There is no prohibition on artificial insemination where the sperm is provided by the women’s partner. Thus this can be offered without the licence. The technique of gamete intra-falopian transfer (GIFT) is not regulating by the Act because it does not involve an embryo being created outside the women’s body. Instead, sperm and egg are inserted so that fertilization takes place in the fallopian tube. However, some GIFT treatments will fall within the Act because it involves using stored or donated sperm (which come within the scope of the prohibitions). Self-insemination is not covered, provided that sperm are not stored, because it is only services offered to the public that fall within the definition of the treatment services.

In general, the offences under the Act are punishable by up to two years imprisonment and an unlimited fine. However, some breaches of these provisions carry much heavier sentences. Those who place non-human embryos or gametes into a women, place human embryo or foetus, or mix human gametes with non-human ones are liable to a sentence of imprisonment of up to ten years and an unlimited fine or both. Prosecutions cannot be brought without the consent of the Director of Public Prostitutions.

The power to relax these prohibitions on dealings with human embryos or gametes in treatment services on defined premises. Only activities on those premises are covered, and only when carried out under the supervision of the persons named. The power of the Authority to issue licences is limited by the Act. Licences may not authorize keeping an embryo beyond the appearance of the primitive streak, placing a human embryo in an animal, or replacing the nucleus of an embryo (intended to prevent cloning). In addition to these provisions specifying what may not be authorized, the Act also sets out the type of activities which can be licensed. These are, however, broadly phrased, and include in relation to treatment ‘using gametes’ and ‘placing an embryo in a woman’. Further guidance on the exercise of the licencing powers may be given in regulations, but no such regulations have been issued at present. The emerging science of genetic manipulation raises the possibility of overcoming a genetic defect by removing or inserting genes. The Human Fertilization and Embryology Act 1990 prohibit the licensing of this sort of therapy on human embryos, although the Act allows for regulations permitting it in the future. We can divide activities in the areas of ART and research into three categories:

i. Activities Prohibited by the HFE Act

The HFEA Act renders certain activities unlawful and does not permit the HFEA to license them. They include the following:

(1) An embryo cannot be stored for more than fourteen days after the mixing of the gamete (at which time the primitive streak will have appeared). This means that although research can take place on embryos up until the fourteen days, the HFEA has no power to authorize the storage of an embryo beyond that time.

(2) It is unlawful to place an embryo which is not a ‘permitted’ embryo in a woman. The definition of a ‘permitted embryo’ allow the HFEA to issue regulations which would allow embryos to be created using animal gametes.

(3) It is unlawful to place a human embryo in a non-human animal.

(4) The use of eggs taken from embryos in fertility treatment is forbidden.

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Keeping or using an embryo under any circumstances in which regulations prohibit its keeping or use is unlawful. It is unlawful to alter the genetic structure of any cell while it forms part of an embryo.

ii. Activities only Permitted if Performed under a Licence

The HFEA Act also outlaws certain activities, although it enables the HFEA to provide a licence for them which render them lawful.

(1) The storage of an embryo is only lawful if carried out under a licence issued by the HFEA.

(2) The storage and use of gamete can only be lawfully carried out under a licence issued by the HFEA. This includes, since the HFEA Act 2008, those offering courier services delivering sperm to women’s home. In 2009 two men were prosecuted after setting up an internet site that offered 450 pound for a ‘door to door’ service for sperm delivery.

iii. Activities which do not Require a Licence

These are of course other activities involving assisted reproduction which do not require a licence. This is the process which does not involve the creation of an embryo outside the human body or the storage of any gametes. ‘Do it yourself insemination’ using fresh sperm and a turkey baster (or similar instrument) is not subject to regulation. It would of course be difficult to police a law which made it illegal for someone to give someone else their fresh sperm.

The Paramountcy of Consent

A key principle in the HFEA Act is that gamete or embryos may not be used without the consent of the provider(s). So, if a couple have had embryos frozen these can only be stored with the couple’s consent. If they ask for the embryo to be destroyed then it would be unlawful for the clinic not to do so. However, there is a maximum limit of ten years on the storage of embryos and gametes. An embryo can be stored for up to fifty-five years if the couple in question is infertile or likely to be infertile.  

4.3 ART in United States

The fertility industry remains largely unregulated in the United States. Where regulation of these technologies has occurred, however, it has had real-life consequences for thousands of people and ripple effects on multiple areas of the law,

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from adoption to abortion, from health insurance to inheritance. While some states have passed laws that indirectly affect the practices of fertility clinics, legislatures and courts have focused more on the ramifications of these procedures. Since its 1981 introduction in the United States, through the year 2002, almost 300,000 babies have been born in this country as a result of reported ART procedures (IVF accounts for ninety-nine percent of these ART births). In 2002, approximately one in every one hundred babies born in the United States was conceived using ART (the live birth rate of an IVF cycle in 2002 was twenty-eight percent). According to the Center for Disease Control’s (CDC) most recent reports, a total of 89,533 fresh embryo cycles using non-donor eggs occurred in 2004 and 92,389 occurred in 2005. The live birth rate decreases with the age of the intended mother. In 2005, the live birth rate for women under thirty-five was 43.1%; for women forty-one to forty-two it was 17.6%.  

In the United States, the federal government has been comparatively mute: there are no federal laws regarding the use of ART. Instead, most issues of surrogacy have been determined by state courts and legislatures, many responding directly to the specific cases brought before them. Initially, for example, the Michigan court that reviewed Noble Keane’s business concluded that commercial surrogacy was directly akin to commercial adoption and thus illegal: “The state’s interest,” held the court, “is to prevent commercialism from affecting a mother’s decision to execute a consent to the adoption of her child.” Court in Kentucky, however, soon found otherwise, ruling in a 1986 case that surrogacy did not constitute baby-selling as long as the contract was entered into before conception. Thus what was illegal in Michigan became legal in Kentucky. New Jersey, meanwhile, echoed Michigan; in the famous Baby M case, the state supreme court invalidated the surrogacy agreement between the Stern and Mary Beth Whitehead, holding that “this is the sale of a child, or, at the very least, the sale of a mother’s right to her child.”  

As traditional surrogacy gave way to gestational arrangements, some state courts and legislatures continued to rule against commercial surrogacy agreement,

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13 Supra 2 at 84.
defining them—often with reference to adoption law—as illegitimate payment for a child. Other state courts, most notably those in California, explicitly permitted gestational surrogacy and began to carve out an extended set of rights for parents who contracted with a gestational carrier. In the 1990 case of *Johnson v. Calvert*, for example, a surrogate carrying the contracting couple’s genetic child filed for custody of the baby. Because the surrogate in this case was black and not wealthy and the contracting couple was white and well off, the ensuing legal debate ignited a storm of related controversy. (The intended mother was actually Filipino, a fact that was frequently overlooked.) Even protracted opposition, however, did not impress the courts. Instead, both the trial court and the California Supreme Court found for the contracting parents in the *Johnson case*, arguing that, although both “mothers” in this case presented proof of maternity, “she who intended to procreate the child—that is, she who intended to bring about the birth of a child that she intended to rise as her own—is the natural mother.” In California, therefore, the court explicitly tied “intent” to motherhood, using surrogacy arrangements as a way to determine parenthood when genetic links and labor did not coincide in the same woman.

One of the first known cases of cross-border surrogacy occurred in 1987, when Alejandra Munoz, a nineteen-year-old Mexican woman, crossed illegally into the United State to be impregnated with the sperm of her cousin’s husband. She was followed in due course by several British parents, including gay and single men, who began in the mid-1990s to hire U.S. surrogates to bear their babies.

In contrast with the U.K., the U.S. has developed a profitable market in ART without regulations that limit its commercialization. For that reason, some have considered the United States as the “Wild West” of ART, due to its minimal regulation to control ART technologies. Some fertility experts and bioethicists stated that commercialization is increasing, and that these embryos are treated as “commodities.” Commercialization has affected the quality of the services in assisted reproduction and promoted a market in which “shared risk,” “refunds” and “warranties” are part of marketing campaigns to achieve a pregnancy. The American Society for Reproductive Medicine (ASRM) characterizes these kinds of reproductive programs as exploitative, misleading and contrary to professional norms. ASRM

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14 (1993) 5 CAL 484.
15 Supra note 2 at 85.
16 Id at 86.
thinks that a lot of people using these programs are desperate to have a child, do not receive sufficient information about the best plan to select according to their needs, and may be induced to buy the most expensive form of IVF service.\textsuperscript{17}

Federal government surveillance of this issue is limited mostly to the collection of data regarding the use of assisted reproduction in the United States. Although some states have enacted statues on specific reproductive technologies, such surrogacy, such laws are limited to dealing with specific issues and are not enough to oversee this business. Some states and the federal government have started to work on new proposals concerning ART procedures and have recognized this issue as an important one. States such as Arkansas, Illinois, Hawaii, and New Jersey regulate certain aspects of ART, for example, by requiring that in vitro fertilization procedures be performed at medical facilities that conform to the standards provided by ASRM or the American College of Obstetricians and Gynecologists (ACOG). Also, the U.S. has from time to time established commissions to study certain aspects of ART, such as bioethical issues raised by the procedures. Yet these efforts are not enough. The only federal legislation passed pertaining to ART is the \textit{Fertility Clinic Success Rate and Certification Act of 1992} establishing the reporting of pregnancy success rates to the Centers for Disease Control and Prevention for publication. Regulation of ART varies at the state level. Seven states have legislation that prohibits human cloning for both reproductive and research purposes, while eight states ban reproductive cloning. Other states prohibit commercial surrogacy or regulate surrogacy agreements. Several states require private insurance coverage of ART and regulate the donation of sperm, eggs, and embryos. Only Pennsylvania extensively regulates and monitors ART clinics and activities.\textsuperscript{18}

California has also allowed the surrogacy agreements, which has no statute directly dealing with surrogacy. Courts generally rely on Uniform Parentage Act to deal with various surrogacy agreements. California Supreme Court in \textit{Johnson v. Calvert}\textsuperscript{19}, held that gestational surrogate has no parental rights to a child born to her since a gestational surrogacy contract is legal and enforceable and the intended mother is the natural mother under the Californian law. In the above case the intended mother donated the egg and a surrogate mother gave birth, in such a case the Court held that the person who intended to procreate should be considered as the natural mother. In another case decided by the U.S. Court in the year 1998 - \textit{Buzzanca v.}
Chapter IV  Laws in Different Countries on Assisted Reproductive Technology

Buzzanca\textsuperscript{20}, the Court considered the issue of traditional surrogacy agreements. That was a case where the surrogate mother has been artificially inseminated i.e. a surrogate mother was impregnated by using her ova and anonymous sperm, meaning thereby the intended parents had a genetic link to the child. Court held that when a married couple uses non-genetically related embryo and sperm implanted into a surrogate intended to procreate a child, they are lawful parents of the child. In another U.S case decided in 1998, In Re Marrijo Moschetta awarded legal parent rights to the intended father and surrogate mother. In another U.S case considered by the New Jersy Supreme Court, In Re Baby M\textsuperscript{21} gave custody to the natural father of the child, but rights of the adopted mother was denied. Surrogate mother who conceived the child via artificial insemination was granted visitation rights.

The federal government’s failure to regulate this industry has left it up to individual states to regulate. Consequently there is a patchwork of laws and contradictory legislation in the United States. Some states, such as Arizona and the District of Columbia, ban all commercial surrogacy contracts, while other ban payments but allow for services (Florida, Nevada, New York, New Hemisphere, Virginia, Washington), while other like California have become interstate and international destinations of choice for couples wishing to purchase reproductive services and hire surrogates.

4.4 ART in China

ART is very interesting in China because it not only relates to reproductive policy but also involves the family, one of the most important concepts for social organization. Whereas in many western countries, ART policy discussion takes place in a relatively unrestricted context, in China, reproduction is tightly controlled. It is an extremely important process related to two socially and politically significant issues: the one-child policy and China’s household registration system (houkou) which relies heavily on parentage to determine a child’s residency. In addition, whereas in many democratic nations, the public opinion has a direct influence on legislative decisions, in China, policy can be decided by only a handful of people behind closed doors.\textsuperscript{22} China’s reproductive policies from 1970 onwards incorporated what he translated as

\textsuperscript{20} 1961 CAL. App 1410 (1998),
\textsuperscript{21} 537 A.2d 1227 (NJ.02/03/1988),
\textsuperscript{22} Congcong Guo, “Conceiving Conception: The Bioethics of Assisted Reproductive Policy in China” (March 2011) at 9 available at \url{http://www.wcfia.harvard.edu/sites/default/files/UGthesis_eguo.pdf} visited on 19/01/2013 at 11:21 A.M.
“eugenic” (yousheng) ideals to punish those who deviate from the norm – the mentally disabled or physically deformed – by preventing them from freely engaging in reproductive practices. To put it another way, China has historically sacrificed individual reproductive freedom for public health on the basis of genetic considerations.  

Many of the most visible public controversies around assisted reproduction have arisen because of conflicts related to the family. In May 2001, Mrs. Zheng’s husband was imprisoned for murder, and in August of that year, he was sentenced to death. Mrs. Zheng wanted to have a child with her husband so she requested permission for use of ART with semen from her jailed husband, first asking the city court, then the High Court of her province. Her request was first rejected, and then circumvented on appeal so that Mrs. Zheng did not receive permission before her husband was executed in January 2002. Her request was widely discussed around China as a case questioning the morality of single-parenting. In another case, a woman and her parents-in-law pleaded for artificial insemination by husband (AIH) following a car accident that left the husband in a coma. She was eventually granted permission. In these cases, traditional conceptions of the meaning of the family and of reproduction were violated mainly because newly naturalized means of reproduction had been made possible by ART.  

Yet, ART is not perfect, and bioethicists have voiced concerns over conflicts that may arise due to the procedures. One involves the discontinuation of the blood line in cases where the child is not genetically related to both parents. While some bioethicists simply see this ethical issue as arising from people’s lack of understanding about the technology and traditional views of parenthood, others believe the continuation of the blood line is important because it underpins other traditional practices in China.  

On February 20, 2001, the Ministry of Health issued Orders 14 and 15 the Human Assisted Reproductive Technology Administrative Guidelines and the Human Sperm Bank Administrative Guidelines. On May 14 of the same year, the Education and Technology Department of the Ministry of Health issued Orders 143, the Human Assisted Reproductive Technology Guidelines and the Human Sperm Bank Standards and the Practical Principles and Ethical Standards for Human Assisted Reproductive  

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23 Id at 23  
24 Id at 61  
25 Id at 62
In March 2002, the MOH held multiple meetings with experts in different fields to reexamine China’s ART policy, taking account of regulations in other countries. At these meetings, the state encouraged experts to evaluate what sorts of technology regulations, standards, and ethical principles would best meet China’s practical needs and to consider adapting parts of foreign regulations to include them in a set of revised Chinese ART regulations. In an official policy document, the government stated that through these revisions, it hoped to create guidelines that would provide the right technologies “in accordance with society’s ethical, moral, and legal needs to respect life and to protect future generations from harm.” The edited draft seriously expanded the scope of government control by providing more detailed ethical and technological requirements, including standards for multiple embryo implantations and embryo reduction, access to ART, and prohibitions on embryo and sperm commercialization. On October 2003, the Ministry of Health issued the final draft of the revised *Human ART Regulations, Human Sperm Bank Regulations*, and *Human ART and Sperm Bank Ethical Guidelines and Principles*, replacing the earlier provisions.\(^{26}\)

The last set of regulations issued by the MOH contains a comprehensive space, facilities and equipment requirements as well as quality standards and specific prohibitions for ART clinics. It also lists background and training needed for medical personnel in offering ART. Two separate parts which have similar provisions address IVF and artificial insemination, respectively. The first section details requirements for the clinics, including the types of rooms and the equipment required in them. Given a large amount of space and high technological capabilities are required, the regulations imply that only large hospitals can legally operate ART clinics. Because clinical operations and laboratory work must take place in the same building, only a hospital with significant research and clinical resources can operate an ART clinic. Each ART institution must also establish a working Reproductive Medical Ethics Committee.

The second section of the regulations concerns clinic management - those hospitals must carefully check the identity cards of potential couples for proof of a marriage certificate; couples must also qualify for pregnancy under national

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\(^{26}\) Id at 73
population and family planning laws. Even foreigners must present passports and marriage certificates before they are allowed to undergo the procedure. In addition, physicians may not transfer more than three embryos per IVF cycle and for women under 35, physicians may not transfer more than two embryos in the first cycle. The third section of the policy provides specifications for couples who can undergo certain procedures, including which couples qualify for IVF treatment.

Physicians can perform a pre-implantation genetic examination if a couple is highly likely to produce a child that might have “single-gene related genetic diseases, chromosomal abnormalities, sex-linked genetic diseases, and reproductive abnormalities.” Under these circumstances, a woman is also eligible for an egg donation. Egg donation is also an option if the woman cannot produce eggs or if the woman is carrier of a serious genetic disease. There are additional specifications for women who wish to donate their eggs. To prevent the commercialization of gamete donation, only women who have leftover eggs after undergoing assisted reproductive treatment can be egg donors. Certain people are also prohibited from IVF procedures, including individuals “suffering from severe mental disorders, acute urogenital infections, or sexually transmitted diseases.”

The regulations fourth section lists quality standards for ART clinics, measured by their success rates for procedures. These rates are high even compared to international standards. In this area, one provision reads, “multiple pregnancies fetal reduction must be used to avoid twinning and to promote the strict prohibition of the birth of triplets or more than three children in a birth.”

The final section provides a list of guiding principles for all medical personnel. These guidelines mandate that all personnel must strictly adhere to national population and family planning laws and regulations. Medical personnel must comply with informed consent and voluntary informed choice procedures and respect a patient’s right to privacy. It prohibits non-medical use of sex selection, surrogate technology, embryo donation, and genetic manipulation, and bars single women from ART. The last few provisions forbid the use of ART for human cloning, chimeras, or unspecified research purposes.

In addition to these guidelines, the Department of Medical Technology and Education of the Ministry of Health also issued a set of “ethical guiding principles” regarding ART. These principles were to provide “a safe, effective, and rational implementation of human assisted reproductive technology, the protection of
personal, family, and health of future generations and interests, and to safeguard the social welfare.” Seven overriding principles govern these areas: benefit to patients, informed consent, protection of future generations, benefit for social welfare, confidentiality, prevention of commercialization, and ethical oversight. The largest numbers of restrictions relate to informed consent, the protection of future generations and the benefits for social welfare. With regard to the protection of future generations, medical personnel have a duty to stop ART implementation if “there is evidence that the implementation of human assisted reproductive technology will have serious physical, psychological, and social damage to future generations.” The MOH explicitly gives medical personnel the responsibility for implementing these ethical principles in assisted reproduction. Thus, while the government broadly defines what “bioethics” entails, hospitals need to ensure that these principles are rigorously carried out.\(^{27}\)

Currently, marriage is a strict requirement for couples who hope to use ART not only in China but also in Egypt, Hong Kong, Iran, Jordan, Korea, Morocco, Saudi Arabia, Singapore, Taiwan, Tunisia, and Turkey. In all other countries, only a stable relationship is required. This list can further be separated into two categories: countries with a strong Islamic tradition and East-Asian states with a strong Confucian tradition (Korea, Hong Kong, Singapore, and Taiwan). This evidence only reinforces a conclusion about Chinese assisted reproductive policy: cultural norms can be as influential as religious convictions in bioethics, and in the process of coproduction, different bioethical understandings can contribute to different policy outcomes.\(^{28}\)

In March 1988, the Beijing Review announced the birth of the China’s first “test-tube baby,” born to a 39-year-old peasant woman. The media presented the official announcement as a technological success story, a symbol of science and medicine ushering in a modern China. This healthy little girl, 3900 grams in weight and 53cms in height, was born at Beijing Medical University at 8:56am. Zou, a peasant from a rural southern province and now a first time father at 42, clapped his hands and wiped away his joyful tears when he saw his daughter. The twelve members of his family had already arrived in Beijing several days earlier to wait for this happy moment. Professor Lizhu Zhang, the famous scientist and head of the in-

\(^{27}\) Id at 77.
\(^{28}\) Id at 93.
vitro research program, took the baby in her arms and happily said, “I am a grandmother again.”

4.5 ART in Turkey

In 2010, Turkey became the first country to regulate against the cross-border reproductive travel of its citizens seeking third-party reproductive assistance (i.e. donor gametes or surrogacy). The use of donor eggs, donor spermatozoa and surrogacy arrangements have been prohibited in Turkey since the establishment of a legal structure to regulate assisted reproductive treatment in 1987; however, until recently Turkish men and women retained the option to travel abroad to access these treatments. However, such cross-border reproductive care (CBRC) arrangements are set to cease as a result of recent amendments to Turkey’s assisted reproduction regulation.

Introduced on 6 March 2010, ‘Legislation Concerning Assisted Reproduction Treatment Practices and Centres’ sets out the latest version of Turkey’s assisted reproduction regulations. It asserts a number of new restrictions that will significantly affect the practice of assisted reproduction in Turkey, including limitations regarding the licensing of private IVF centres, specifications on gamete and embryo storage and restrictions on the number of embryos that can be transferred to a patient (only one for women aged under 35 in their first and second cycle of IVF, and a maximum of two embryos for women in their third or subsequent cycles or over 35 years of age.

Turkey’s first tüp bebek (literally ‘tube baby’), Ece Çokar, was born on 18 April 1989, 11 years after the birth of Louise Brown heralded a new era in assisted reproduction. Her parents were one of 10 couples recruited to undergo IVF treatment at Ege University Hospital, under the care of doctors who had received their training mostly in Germany. Despite relatively early successes for the next decade resources and infrastructure for IVF in Turkey remained limited, with little public knowledge of or demand for the technique. Now, there is a dramatically different picture. In the past decade, the assisted reproduction sector in Turkey has boomed into a successful, popular and lucrative industry with an elevated social profile, comprising one of the most rapidly growing IVF markets in the developing world. Thus, unlike in some of

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29 Id at 95.
31 Official Gazette no. 27513.
32 Star Gazette, 30 December 2006.
its other global incarnations, IVF in Turkey is not shrouded in secrecy, angst and shame, but rather pursued as the weapon of choice in the ‘battle’ against infertility, transforming involuntary childlessness from an intractable personal tragedy to a solvable medical problem. Currently there are 118 fertility clinics operating in Turkey. A number of fertility clinics exist within public or university hospitals, but the great majorities are based in private hospitals or operate as independent centres. Many are located in densely populated urban cities, such as Istanbul, Ankara and Izmir, although in recent years clinics have also opened in the country’s farthest corners. A range of socio-cultural and economic factors can be referenced to explain this transformation. In particular the introduction of (partial) funding for IVF by the state and social security institutions in 2005 and 2006 has been instrumental in broadening access and providing opportunities for the sector’s market expansion. Figures from the Ministry of Health attest to an accelerated growth during this period, with the number of licensed fertility clinics rising almost 50%, from 66 in 2005 to 91 in 2007. Reliable data on the number and outcome of assisted reproduction cycles in Turkey are not available, despite mandatory reporting of such figures by clinics to the Ministry of Health since 1996. Estimates based on the consumption of gonadotrophin ampoules suggest that there are around 40,000 cycles of IVF performed each year, with demand far exceeding the supply available. According to reports based on figures from the pharmaceutical industry, total annual IVF expenditure in Turkey is in excess of US$300 million, ranking Turkey as ‘The world’s 7th biggest IVF market’ (behind Israel, France, Spain, UK, USA and Germany) . The Ministry of Health is responsible for licensing, registering, regulating and overseeing all forms of assisted reproduction practice. A framework for regulating assisted reproduction was introduced in 1987 as a piece of pre-emptive legislation preceding the birth of Turkey’s first IVF baby by 2 years. This initial legislation, entitled ‘By-law on Centres for Assisted Procreation’, was superseded by the ‘By-Law Concerning Treatment Centres for Assisted Procreation’ on 19 November 1996. This comprehensive piece of legislation detailing definitions, prohibitions and all necessary requirements (including building and physical environment specifications, equipment,
materials and personnel) for assisted reproductive practice was subsequently updated a further four times – twice in January 1998, once in March 2001 and once in July 2005– to reflect advances and technological developments but retained essentially the same character. Then, in March 2010 a new version of the regulations, the ‘Legislation Concerning Assisted Reproduction Treatment Practices and Centres’, was introduced. This latest version instigates some significant changes to the way assisted reproduction is practiced in Turkey.

Although assisted reproduction practice in Turkey can be seen as advanced and liberal in some respects, for example in the use of PGD, it also has a conservative hetero normative character. From the very outset of Turkey’s assisted reproduction regulation, any treatment involving third-party reproductive assistance, namely the use of donor eggs, donor spermatozoa or surrogates, has been prohibited. Indeed, the legislation provides the following definition for ‘Assisted Reproduction Treatments’:

“Procedures, accepted as treatment methods by modern medicine, which involve assisting the fertilization of the prospective mother’s egg with her husband’s sperm in various ways, enabling them to fertilize outside of the body when necessary, and transferring the gametes or the embryo back to the prospective mother’s genital organs”.

The exclusivity of treatment provision to married couples using their own gametes is reiterated at the start of Section 5 Prohibitions:

“The use of the eggs and sperm or the embryo of applicants undergoing ART for any other purpose, or in the treatment of other applicants, or the use of those [spermatozoa, eggs or embryos] obtained from anyone other than the applicants in the treatment of the applicants, or the storage, use, transfer, and sale [of spermatozoa, eggs or embryos] for any sort of purpose falling outside the definitions of this legislation, are prohibited”.

Apart from this statement, until the amendments of 2010, neither the assisted reproduction legislation nor any other item in Turkish law specifically addressed the use of donor spermatozoa, donor eggs or surrogacy, nor made any provisions for penalties or consequences for engaging in such activities. However, the 2010 version of the legislation, alongside a range of other restrictions to assisted-reproductive-technology practice, also contains three new items specifically related to this matter. Following item 18.4 which outlines the prohibitions on all third-party reproductive
assistance, item 18.5 sets out the legal ramifications that will result if third-party assisted reproduction is practiced by a Turkish clinic:

“In the event of a discovery at any stage of a pregnancy achieved against any of these prohibitions [on third-party reproductive assistance], the [assisted reproduction practice] certificates of the involved persons will be nullified, the centre will be closed indefinitely, and all personnel will be indefinitely barred from working at ART centers”.

Furthermore, items 18.6 and 18.7 stipulate penalties for CBRC involving third-party assisted reproduction: “If it is discovered that any centre and/or any centre personnel has participated in acts of referring or sending patients to domestic or international ART centers, encouraging patients or acting as intermediary, in a way that is in contravention with the legislation, such centers will be closed down for 3 months in the first instance, and indefinitely in the event of such acts being repeated. Those who are not centre personnel but are discovered to have acted as intermediaries in such cases will have their certificates, if such exist, nullified by the Ministry. In the event of a discovery at any stage of practices contravening the particulars outlined in the items 18.4, 18.5 and 18.6, the person who has conducted this procedure, the persons who have referred patients or acted as intermediaries, the impregnated person, and the donor will be reported to the state prosecutor”.

The above prohibitions effectively limit the scope of assisted reproductive technology to aiding the reproduction of married heterosexual couples (presumed to be) suffering a medical impediment to conception and they preclude any form of third-party reproductive assistance, not only within national borders but also with international relevance. Although Turkey is a secular country committed to secularism in medical ethics its pattern of assisted reproduction regulation, described above, can be thought of as distinctly ‘Sunni Muslim in character’.

4.6 ART in Italy

Legislation on the regulation of ART in Italy has been delayed due to its controversial subject matter. The National Committee for Bio-ethics (CNB) has been considering reproductive technologies since 1991, but only issued its recommendations on 17 June 1994. Due to the large variety of ethical theories and opinions held by the members, the committee’s recommendations were not
unanimous, although the members found common ground on several points.\textsuperscript{36} The new Italian law is hugely important because it has been influenced to a large extent by Catholic doctrine and, as such, is an example of how moral and ethical issues may be determined by peculiarly national cultural perspectives, identity and heritage.\textsuperscript{37}

In Italy, ART is regulated under the \textit{Medically Assisted Procreation Law} (2004). This law prohibits research and reproductive cloning, the manipulation of embryos, the use of donated eggs or sperm for ART, and the cryopreservation of embryos (with the exception of severe injury/illness preventing embryo transfer). A maximum of three eggs can be fertilized and transferred per reproductive cycle. Sex-selection is only permitted through sperm sorting for sex-lined genetic diseases. All forms of surrogacy are prohibited. The use of pre-implantation genetic diagnosis for the selection of embryos is generally prohibited, but has been allowed through the courts on a case-by-case basis. Genetic testing for non-medical purposes is prohibited. The use of ART is restricted to stable heterosexual couples who live together, are of reproductive age, are over the age of 18, have documented infertility, and have been first provided the opportunity for adoption.

The Italian parliament passed the first national law on medically assisted procreation (commonly known as Law 40) in February 2004, after a lengthy parliamentary and public debate. This is the first Italian organic law on the use of ARTs.\textsuperscript{38} In its very first article, Law 40 states that assisted procreation is allowed with the unique goal of solving reproductive problems arising as a result of human sterility or infertility, in case any other possible types of therapy has failed. The law explicitly guarantees the rights of all the involved subjects, including the foetus. This first article is particularly important because it presents the two main principles the law has been grounded on. First, ARTs are primarily medical therapeutic acts directed at safeguarding the health of sterile couples. Assistance is not available for people who do not prove their disease and the failure of other healing therapies: thus, single women and homosexual couples are excluded from the treatments. Second, the foetus is characterized as a carrier of rights: even if the jurists are still debating on the


meaning of this particular sentence about the rights of the foetus, it nevertheless gives evidence to the new intensity with which the law guarantees the juridical protection of the foetus.

Access to treatments is allowed only to couples composed of heterosexual adults, married or living together, of reproductive age, who have been formally declared medically infertile or sterile, and who are both alive. Before starting any treatment, these couples must sign a written consent, which can be withdrawn by either of the partners up until the moment of fertilization of the egg but not thereafter. This document states that the patients accept the treatments and what follows, namely they declare that they will be the legal parents of the hypothetical offspring.

Cryopreservation of embryos and donation of gametes and embryos are banned as well as the destruction of fertilized eggs, while pre-implantation genetic diagnosis (PGD) has been possible since March 2008, after the new guidelines mentioned above were issued. Other techniques, like inseminations, In-Vitro Fertilization (IVF) and Intracytoplasmatic Sperm Injection (ICSI) are admitted if they imply the use of reproductive material of the couple. In other words, assisted procreation is open to heterosexual couples with certified medical problems of infertility, which do not require the use of donated gametes. The law limits the number of eggs that can be fertilized to three and each one of them must be transferred into the womb of the woman who produced it.

Further, homosexual couples, single women and healthy post-menopausal women are excluded from assisted procreation, given that, following the principles of biological reproduction; treatments are only available for people who would be potentially fertile, if not affected by medical problems. On the other hand, the law states that each woman who gives birth to a child is given the possibility not to recognize this child as hers despite the biological tie established through the pregnancy and the act of delivery in this case the anonymity of the mother is applied and the child is declared adoptable. Moreover, a non-married father has to declare his paternity although he does not have to prove his biological relation to the child. Only if the court is called to invest somebody with the role of parent for a child who has not been recognized by any one at its birth, the procedure can include a genetic test in order to identify the biological parents. In all the other cases the relationship of descent is confirmed through a voluntary declaration. Thus the relationship of descent is confirmed through an act of will.
4.7 ART in Japan

The great importance placed on family lineage also intensifies pressure to produce genetic offspring. The focus on heredity also means that some couples may be disinclined to adopt, preferring to carry on their family line. More so than in other parts of the world, Japanese couples seeking infertility treatment wish to have children with biological links. The first IVF baby was born in Japan in 1983.  The number of infants born as a result of assisted reproductive technology (ART) has increased every year ever since. In 2007, the total number of infants born as a result of ART was reported to be 19,595, close to 2% of all births. Japan is having a large number of registered ART facilities, 606 in total. Among these, only five facilities perform more than 700 cycles of both IVF-ET and ICSI per year. Only a few facilities, all of which are private clinics, perform more than 3,000 cycles of ART per year. In Japan, the practice of ART is not governed by legislation. It is voluntarily regulated by physicians, mainly according to the bulletins of the Japan Society of Obstetrics and Gynecology and the Society of Reproductive Medicine. This regulation has had some degree of success. For example, the multiple pregnancy rates fell to 10.7% in 2007 after the Society of Obstetrics and Gynecology recommended single ET for women under the age of 35 undergoing their first ET. It was also recommended to transfer a maximum of three embryos, even for women who have undergone two or more ETs or for those over age 40. On the other hand, since 1998, there have been cases in which members of the societies have performed IVF using oocytes donated by siblings or third parties, against regulations. Further, there have been some cases in which sisters have acted as gestational surrogates. Many couples go abroad to receive donated oocytes. In 2008, one couple come to India to obtain a gestational surrogate, but divorced before the infant was born. According to Japanese law, the child did not qualify for Japanese nationality, and so has no nationality. Thus, assisted reproduction has been prevalent and has contributed to Japanese society. However, legislation has not caught up with the advances and prevalence of this technology.  

Techniques (June 2001). This law prohibits reproductive cloning, germline modification, and the transfer of human/animal hybrid embryos to either a human or animal. Research cloning is permitted in Japan. Other ART activities are regulated by voluntary guidelines produced by the Japan Society of Obstetrics and Gynecology.41

Japan has taken a different legal stand in respect of surrogacy. Supreme Court of Japan, on March 23, 2007, denied parenthood to genetic parents since the twin babies were born to a surrogate mother at United States. Interpreting the Civil Code of Japan, the Supreme Court, held a mother who physically gives birth to a child is the legal mother. There is no provision in the Code to recognize the genetic mother as the legal mother. There exists no specific laws in Japan concerning parent-child relationship for artificial insemination, and the mother and child relationship will be based on the fact of delivery. The issue of Citizenship status of such an infant is also a burning problem in Japan. The Japan Supreme Court rejected the Japanese commissioning parents bid to register their twins born to a U.S surrogate mother in Japan, on the ground that the law presumes the woman, who gives birth to a child as its mother.

4.8 ART in Australia

The NHMRC Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research (2007) deal with the ethical aspects of research and clinical practice of assisted reproductive technology.42 The document is divided into three parts. Part A provides background and introductory material. Part B provides ethical guidelines for the clinical practice of ART and Part C provides ethical guidelines for research. Part C of the guidelines is consistent with the Prohibition of Human Cloning for Reproduction Act 2002 and the Research Involving Human Embryos Act 2002. The guidelines are primarily intended for ART practitioners, researchers, infertility clinic administrators, Human Research Ethics Committees and governments. The Research Involving Human Embryos Act 2002 requires that research on certain human embryos may only be conducted under a licence issued by the NHMRC Embryo Licensing Committee. The Licensing Committee must be satisfied that the research proposal has been assessed and

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41 Supra note 3.
approved by Human Research Ethics Committee acting in compliance with the National Statement on Ethical Conduct in Human Research (2007) and the ART guidelines.

The RIHE Act distinguishes between embryos intended for transfer to a woman to achieve a pregnancy and embryos that have been deemed to be no longer needed in an ART program. The Prohibition of Human Cloning for Reproduction Act 2002 and Research Involving Human Embryos Act 2002 permit research on excess ART embryos, including those that are unsuitable for implantation, and embryos created by means other than by fertilization of a human egg and human sperm. Consent from the donor must also be sought prior to use of excess ART embryos for research. For any licensable activity the number of excess ART embryos, other embryos or human eggs should be restricted to that likely to be necessary to achieve the goals of the activity. Research proposals involving human embryos must not include any practices prohibited by the legislation. Many aspects of clinical practice in ART raise ethical issues. The ART Guidelines cover activities including:

- posthumous use of gametes
- surrogacy
- donor conception
- sex selection; and
- Pre-implantation Genetic Diagnosis (PGD).

The Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2007 underpin the regulation of ART practice within Australia. Accreditation of ART treatment centres by the Reproductive Technology Accreditation Committee (RTAC) is the basis of a nationally consistent approach for overseeing ART clinical practice. RTAC accreditation requires ART treatment centres to comply with government laws and guidelines concerning the practice of ART. The ART Guidelines are included in this requirement. RTAC was established by the Fertility Society of Australia.

The Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2007 are consistent with the Research Involving Human Embryos Act 2002 (RIHE Act) and the Prohibition of Human Cloning for Reproduction Act 2002 (PHCR Act). The Guidelines are also prescribed in the regulations under the RIHE Act. The NHMRC Licensing Committee oversees the RIHE Act and the PHCR Act. An independent committee was established by the
Australian Government to review this legislation on cloning and research involving human embryos in Australia and was chaired by the Justice Peter Heerey QC. The review of this legislation commenced in late December 2010 and the independent committee released its report in July 2011. The Australian Government is currently considering the recommendations in the Heerey Report. There are important links between the human embryo research legislation and the ART Guidelines. Accordingly NHMRC is preparing for a review of the guidelines, subject to the response from Government to the Heerey Report.

The ART Guidelines restrict the use of PGD for sex selection in Australia. These Guidelines reflect the sentiment of the community that admission to life should not be conditional upon a child being of a particular sex. Therefore, sex selection (by whatever means) should not be undertaken except to reduce the risk of transmission of a serious genetic condition.

4.9 ART in Belgium

Belgium’s key laws pertaining to ART are the Law on Research into Embryos In Vitro 2002 and the Law on Medically Assisted Reproduction and the Disposition of Supernumerary Embryos and Gametes 2007. These laws prohibit reproductive cloning, the creation of embryos for research purposes, non-medical sex selection or treatment for eugenic purposes, and the creation of chimeras or hybrid embryos.

As of 2003, ART is completely covered by Belgium’s national health plan. This insurance provides up to 6 cycles of ART for women under the age of 42. Women over 42 years are ineligible for coverage. This coverage comes with strict limits on the number of embryos transferred per cycle, limiting the number of embryos transferred to a maximum of 2 for women under the age of 36 and a maximum of three for women under the age of 40.

4.10 ART in Canada

In Canada reproductive and genetic technologies (RGTs) are of great interest to the Canadian public and the federal government is moving ahead with its work on this complex issue. Same sex marriage has been legalized in Canada and unmarried same sex cohabitants are legally recognized for many purposes. Family law has

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43 Supra note 3.
become largely gender neutral, partly due to the increased recognition of same sex relationships, but also reflecting the influence of the fathers’ rights lobby. Sexuality and procreation have increasingly become uncoupled both technologically and socially, and “baby making of all sorts, including the hi-tech and clinical kind, has increasingly occurred outside heterosexual marriage.”\(^\text{45}\)

The first federal Canadian initiative was *The Processing and Distribution of Semen for Assisted Conception Regulations* which falls under the Food and Drugs Act and came into effect in June 1996, and was amended in March 2000. The voluntary moratorium is still in effect in Canada and calls upon the medical and research communities in Canada to refrain from applying nine RGTs identified as raising serious ethical and social problems, including cloning of human embryos.

Canada’s *Assisted Human Reproduction Act* (2004) created the Assisted Human Reproduction Agency of Canada (AHRA) responsible for administering and enforcing the AHR act and its regulations. This Act prohibits reproductive and research cloning, the creation of IVF embryos for purposes other than reproduction or reproduction research, non-medical sex selection, germline modification, the creation of a chimera or hybrid embryo, commercial surrogacy, and the commercial trading of human eggs, sperm and embryos. This Act also establishes a series of principles related to ART including the provision that the health and well-being of children born through the application of assisted human reproductive technologies must be given priority in all decisions respecting their use and that the health and well-being of women must be protected in the application of these technologies. These principles also discourage discrimination against persons seeking to use ART on the basis of their sexual orientation or marital status and they discourage the use of ART for commercial ends due to its exploitative nature.

In Budget 2012, the Government of Canada announced that it would wind down Assisted Human Reproduction Canada (AHRC), in response to the 2010 ruling of the Supreme Court of Canada that significantly reduced the federal role in assisted human reproduction (AHR). Health Canada has taken over responsibility for the remaining federal functions in AHR, such as compliance and enforcement, and outreach, effective October 1, 2012. As a result, all federal functions have been transferred to the Health Products and Food Branch (HPFB) of Health Canada. This

includes the policy and regulatory development function that previously resided with the Assisted Human Reproduction Implementation Office (AHRIO). AHRIO was wound down at the same time as AHRC.\footnote{Available at \url{http://www.ahrc-pac.gc.ca/v2/index-eng.php} visited on 8 December 2012.}

Assisted reproductive technologies (ART) are a policy concern in Canada due to the continued prevalence of infertility and the recent rise in the number of multiple pregnancies. The issue of access, funding, and the regulation of ART’s \textit{in-vitro} fertilization (IVF) in particular has generated considerable debate.\footnote{Available at \url{http://www.cadth.ca/products/environmental-scanning/health-technology-update/issue-10-september-2008/assisted-reproductive} visited on 8 December 2012.}

In 2004, the federal government enacted legislation to regulate assisted reproduction. The Assisted Human Reproduction Act, which governs the clinical and research activities of medically assisted human reproduction, identifies activities that either are prohibited or are subject to regulation. In 2006, Assisted Human Reproduction Canada was established to implement and enforce the Act’s principles. The constitutional validity of the Act has come under attack from several provinces. In 2008, the Quebec Court of Appeal challenged several provisions of the Act, contesting that they are not matters of criminal justice and do not put the public’s health at risk and, therefore, should be governed by provincial legislation.\footnote{Ibid}

\textbf{4.11 ART in France}

In France medically assisted procreation (ART) entails clinical and biological procedures enabling in vitro conception, embryo transfer, and artificial insemination, as well as any technique having an equivalent effect enabling procreation outside the natural process. The regulation of ART in France is through the comprehensive set of laws: No. 94-548 of July 1, 1994 on personal data processing for health research purposes; No. 94-653 of July 29, 1994 on respect for the human body; No. 94-654 of July 29, 1994 on donation and use of human body parts and derivatives, ART and antenatal diagnosis.\footnote{Beverly J. Wunderlin, “The Regulation of Medically Assisted Procreation in Europe and Related Nations and the Influence of National Identity, Social Cultural, and Demographic Differences”, available at \url{http://digital.library.unt.edu/ark:/67531/metadc3192/m2/1/high_res_d/dissertation.pdf} visited on 19 December 2012.} The three laws are incorporated into the Civil Code, the Public Health Code, and the Penal Code. For example 1995 amends the Public Health Code in regard to ART activities. Additionally on the National Commission on Medicine, Reproductive Biology and Prenatal Diagnosis amend the Public Health Code. A more
current Order of January 12, 1999 pertains to the rules of good clinical and biological practice in the field of medically assisted procreation.

French bioethics law restricts access to ART to heterosexual couples of child-bearing age, both of whom are alive at the time of insemination or embryo transfer, and are either married or in a relationship that approximates to matrimony for a minimum of two years. If one member of the couple dies, frozen gametes or embryos must be donated to an infertile couple by the surviving person or destroyed. Gamete donation includes the provision by a third party of spermatozoa and oocytes for the purpose of ART. An embryo may not be conceived with gametes that are not derived from at least one of the two members of the couple. Donors must be members of a couple that has procreated. Written consent must be obtained from the donor and his or her spouse. The French view this relationship to be a fertile couple donating to an infertile couple in support of family life.

France’s key laws include the Bioethics Law No. 2004-800 (2004) and the Law on the Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation, and Prenatal Diagnosis, No. 94-654 (1994). The Bioethics Law created the French Biomedicine Agency, responsible for licensing and regulating ART centers. These laws prohibit reproductive and research cloning, the creation of embryos for research purposes, germline modification, and non-medical sex selection, surrogacy is also prohibited. In France, pre-implantation genetic diagnosis is allowed only when a parent or close relative has a serious genetic disease and also for HLA tissue matching. France’s national health plan provides complete coverage for ART to heterosexual couples who are of reproductive age and are married or have lived together for two years.

### 4.12 ART in Germany

ART practices are strictly regulated in Germany. The basis for ART regulation in Germany is the Embryo Protection Law of December 1990, which took effect January 1, 1991. The thirteen sections of this law are part of the criminal law. The purpose of the law is to prevent the misuse of reproductive technologies.

The improper use of reproductive technologies holds a penalty of up to three years imprisonment or a fine. This includes the transfer of an unfertilized egg cell

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from one woman to a different woman or carrying out actions to enable either surrogacy or embryo donation. Sex selection is also prohibited unless circumstances such as sex-linked hereditary disease exist. A physician who violates the sex selection prohibition may receive up to one year in prison or a fine.

In Germany ART is only permissible within the context of a heterosexual relationship that is either a marriage or approximates matrimony. Sperm donation is allowed but oocyte or embryo donation is prohibited. The only exception is the “spare embryo” or unplanned incident whereby the unintentional surplus embryo cannot be implanted in the womb of the woman to whom the embryo originated. In this situation the “spare embryo” may be implanted in another woman, and this woman will be considered the mother of the offspring. The donation is considered preferable to the destruction of the embryo. The 1990 law prohibits cloning. The creation of an embryo genetically identical to another embryo, fetus or individual living or dead is an offense. Implantation of an embryo created in this way is a crime.

Germany’s key laws and guidelines pertaining to ART include the Federal Embryo Protection Law 1990, the Adoption Brokerage Law 2006, and the Guideline of the German Federal Medical Chamber 2006. These laws prohibit research and reproductive cloning, gamete donation, the creation of hybrid embryos, the cryopreservation of fertilized eggs, sex-selection (with the exception of sperm sorting for the prevention of a few sex-lined genetic disorders), pre-implantation genetic diagnosis, and all forms of surrogacy. Only three eggs can be fertilized and transferred in one reproductive cycle.

4.13 ART in Netherlands

The Netherlands’s key laws on ART are the Act Containing Rules Relating to the Use of Gamete and Embryos (Embryos Act) (July 1, 2002) and the Commercial Surrogacy Act (November 1, 1993). The Embryos Act prohibits the creation of embryos for research purposes, allowing an embryo to develop outside the human body for longer than 14 days, reproductive cloning, germline modification, the creation of human/animal hybrid embryos, non-medical sex selection, and commercial donation of gametes or embryos for reproductive or research purposes. The Commercial Surrogacy Act prohibits commercial and professionally arranged surrogacy. In the Netherlands, pre-implantation genetic diagnosis is permitted only for serious genetic disease at one facility, although the government has recently allowed
testing for certain hereditary cancers and is considering offering testing for a wider range of conditions in the future.

4.14 ART in Spain

In Spain, key laws pertaining to ART are the *Law on Assisted Human Reproduction Techniques, No. 14/2006* (May 27, 2006) and the *Biomedicine Law 14/2007* (July 3, 2007). The National Commission on Human Reproductive Assistance is Spain’s ART advisory committee. The above laws prohibit reproductive cloning, the transfer of more than three embryos per reproductive cycle, the creation of embryos for purposes other than reproduction, germline modification, non-medical sex selection, and the use of pre-implantation genetic diagnosis for non-medical purposes. Surrogacy is not recognized in Spain. The commercial donation of gametes is allowed for assisted reproduction and research, although only 6 children can be born from the same donor.

Spanish law does not limit access to infertility treatment based upon marital status. Single women may receive treatment if over age 18 years and judged to have full legal capacity. There are no other age restrictions. Posthumous conception by artificial insemination of sperm of the deceased spouse or partner is allowed if the consent of the deceased was granted within six months of the date of death in a will or alternative document. Sperm and ovum donation is allowed. Embryo donation is prohibited. Surrogate motherhood is not legally restricted but delivery decides maternity, i.e., the birth mother is the legal parent. Donation is treated as anonymous.

4.15 ART in Sweden

ART is strictly regulated in Sweden. Artificial insemination was the first to require that information on the sperm donor be recorded in the hospital’s special register and made available to the offspring upon maturity when requested. The Swedish In-Vitro Fertilization Act of 1988 is currently the basis for ART practice. This law was passed June 8, 1988 and entered into force January 1, 1989. In vitro fertilization is available to couples within the context of marriage or a conjugal relationship that approximates heterosexual marriage. The couples own sperm and ovum must be used. Ovum fertilized outside the body must be implanted only in the womb of the woman from whom it came. Surrogacy is prohibited in Sweden. Neither ovum nor embryo donation is allowed. No national statutory age limit exists; but the

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52 Supra note 3.
various county councils have established upper age limits between 35 and 37 years of age. Swedish Law prohibits the cloning of embryos and oocytes.

In Sweden, key laws regulating ART are the Act on Ethics Review of Research Involving Humans, Law No. 460 (2003), and the Genetic Integrity Act, Law No. 351 (2006). Sweden provides financial coverage for ART to couples who are married or are in a stable relationship. Reproductive cloning, surrogacy, germline modification, and the use of pre-implantation genetic diagnosis for social purposes are prohibited. Pre-implantation genetic diagnosis is permitted for disease and for HLA matching (only after approval by the Board of Health and Welfare). Sweden allows only one embryo (two in older women) to be transferred per reproductive cycle. Embryos can be cryopreserved for up to five years.\(^{53}\)

### 4.16 ART in Switzerland

Switzerland’s key laws regulating ART include the Federal Law on Medically Assisted Reproduction (1998), the Federal Act on Research Involving Embryonic Stem Cells (2003), and the Federal Law on Medically Assisted Reproduction (2004). Prohibited practices include reproductive and research cloning, egg and embryo donation for ART, creating an embryo for research purposes, creating a hybrid embryo, germline modification, pre-implantation genetic diagnosis, nonmedical sex-selection, and surrogacy. Switzerland limits the number of embryos transferred per reproductive cycle to three and requires cryopreserved gametes and embryos to be destroyed after five years.

### 4.17 ART in Israel

Israel’s reproductive care policy appears to reflect Jewish religious, cultural, and social norms regarding fertility. Parenthood is considered a basic human right based on biblical and other Jewish religious sources. The personal desire for parenthood, and specifically motherhood, has been engrained in Jewish culture and has been strengthened by the historical persecution of Jews in the Diaspora and particularly by the genocide perpetrated against Jews in the Holocaust. The continuing loss of life in Arab-Israeli wars and terrorist acts, combined with constant threats to the State’s existence by hostile powers in the region, have also been linked to Israelis’ attitudes regarding procreation. Israel’s pro-natalist approach is supported by legislation regulating in vitro fertilization (IVF), ova extraction, the use of semen in

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\(^{53}\) Ibid
IVF fertilization, ova donation and allocation, and surrogacy agreements. The regulation of assisted reproductive technology (ART) in Israel appears to support reproductive choice while respecting certain religious and cultural considerations. A person’s right to procreate has been recognized in Supreme Court rulings, especially in the leading case of *Nachmani v. Nachmani*\(^\text{54}\), where the Court held that in the special circumstances of that case the right of a woman to motherhood was superior to her husband’s right not to be a father.

The recognition of the importance of parenthood and the superior right to motherhood, however, has not resulted in recognition of a woman’s full autonomy over her reproductive status. By law, a woman does not have a general right to choose to terminate her pregnancy. An interruption of pregnancy may be permitted under certain circumstances by special committees for the interruption of pregnancies established by hospitals or the Ministry of Health. Such circumstances include the age of the woman; the pregnancy deriving from rape, incest, or an out-of-wedlock relationship; and fetal disabilities and physical or mental danger to the mother posed by continuation of the pregnancy.

Israel has one of the highest birth and fertility rates among industrialized countries. Although the average age of women giving birth for the first time has consistently increased in the past ten years, modern technologies such as in vitro fertilization (IVF) and the use of assisted reproductive technology (ART), along with a pro-natalist state policy fully or partially subsidizing such treatments, have made it possible for an increased number of women, including unmarried or infertile women and those wishing to delay procreation to facilitate career development, to give birth.

Israel maintains a system of national health care. In accordance with the National Health Insurance Law, 5754-1994, Israeli residents are entitled to medical services that are provided by Health Funds that are approved by the Ministry of Health. The Health Funds must provide services that are included in “a basket of basic health services,” which includes specific reproductive health services and products. The scope of technologies and medications to be included in the basket of basic health services, within the budget allocation, is determined on a yearly basis by a public committee appointed for that purpose by the Minister of Health. Insured patients are entitled to be provided with oral contraceptives. In addition, they are entitled to

\(^{54}\) 35 TEXAS INTL L. J. 1 (2000)
prenatal care; interruption of pregnancy for medical reasons, as well as for nonmedical reasons in the case of girls under nineteen years of age; fetal organ system exams; epidurals during birth; exams for identification of fetal disabilities, including amniocentesis, etc.

Israeli residents are also entitled to genetic counseling, including blood tests and genetic evaluation. Such evaluation is provided to carriers of genetic or chromosomal interference or of especially severe genetic diseases, to couples with a high probability of giving birth to a child with especially serious chromosomal disabilities, and to women who have undergone repeated miscarriages. Entitlement to prenatal genetic evaluation is limited to two pregnancies resulting in birth. Israeli women are also permitted to undergo extraction of ova for freezing for future implantation for any reason. The procedure and the freezing of the ova are fully covered when done for medical reasons, and the maximum amount of coverage for other reasons is to be determined by the Ministry of Health.\footnote{Reproduction and Abortion: Law and Policy, Law Library of Congress, Israel’, available at http://www.loc.gov/law/help/israel_2012-007460_IL_FINAL.pdf visited on 12 December 2012.}

\textbf{4.18 ART in Austria}

The regulation of ART in Austria is through the 1992 Reproductive Medicine Law and the 1998 Ordinance on reports about activities and experiences with medically assisted reproduction. Effective January 1, 2000 a fund for the financing of in vitro fertilizations was established through passage of legislation: IVF-Fonds-Gesetz.\footnote{Supra note 48.}

The 1992 Reproductive Medicine Law amended the General Civil Code, the Marriage Law, and the Rules of Jurisdiction. The filiations of children born is covered in Section 156(a): “If the mother’s husband has consented, in the form of a court protocol or act authenticated by a notary, to Medically Assisted Procreation using the sperm of a third person, the legitimacy of the child born as the result of the use of the sperm of a third person may not be contested.” Section 163(1) establishes paternity in the case of a child born out of wedlock in ART practice, i.e., “the man whose sperm has been used shall be presumed to be the father of the child.” The Marriage Law was amended to state: “A marriage partner shall not have grounds for divorce if the other partner refuses ART or ART”.

\textsuperscript{56} Supra note 48.
The Federal Law of 1992 states under Section 2(1): “ART shall only be permissible within the context of marriage or a relationship that approximates to matrimony.” It further stresses the need to explore all alternatives before relying on ART practice. Although the sperm of a third party may be used when necessary, the “oocytes and viable cells may only be used in the woman from whom they are obtained”. Under Section 9 (3) “The use of a mixture of sperm from different persons shall not be permitted for the purposes of ART.”

4.19 ART in Bulgaria

The regulation of ART in Bulgaria is limited to artificial insemination. The July 17, 1990 order of the Ministry of Health and Social Welfare amends Order No. 12 of May 30, 1987 on artificial insemination of women. The order mandates the testing of donor sperm and limits the number of fertilizations. Additional donated sperm may be stored in the sperm bank to be used for insemination of foreign citizens or for research purposes. Bulgarian law limits sperm donation to persons of Bulgarian nationality between 18 and 40 years of age. Posthumous conception, i.e., the insemination of widows with the sperm of deceased spouses is not done. Bulgaria does not specify an upper age limit for people seeking infertility treatment. Access to infertility treatment is not limited according to the marital status of the couples seeking assistance. Although most ART practices are not against the law, the quality of reproductive medicine is impacted by funding limitations.

4.20 ART in Czech Republic

The only legislative text is the 1982 Order of the Health Ministry pertaining to homologous and heterologous artificial insemination. The Czech Gynecological and Obstetrics Society’s assisted procreation section is responsible for the founding of ART principles. A Code of Ethics has been prepared by the Association of Medically Assisted Procreation Centers. The Ministry of Health of the Czech Republic and others suggested contacting Dr. Mardesic because he administers the largest infertility treatment center in the Czech Republic.

The practice of sperm and egg donation is legal and practiced. The use of donated gametes is restricted to married couples. Surrogate motherhood is not possible. The donation of gametes is anonymous. The Czech Society for Assisted Reproduction and Sterility is responsible for updating and evaluating the minimum standards.
4.21 ART in Denmark

The regulation of ART in Denmark is through Law No. 460 of June 1997 on artificial fertilization in connection with medical treatment, diagnosis, and research. ART legislation was adopted by the Danish Folketing at the third hearing on May 27, 1997, according to Maja-Lisa Axen (personal communication, December 16, 1999). ART practices are required to have the objective of uniting a genetically unchanged oocyte with a genetically unchanged spermatozoon. Artificial fertilization is only made available to couples within the context of marriage or a conjugal relationship that approximates heterosexual marriage. ART practice is prohibited where the proposed birth mother is over 45 years of age.

Artificial insemination and the reporting of in-vitro fertilization treatments and pre-implantation diagnosis were made in pursuance of Law. Among other things the destruction of sperm stored for the purpose of causing the donor’s partner to become pregnant is mandated in the event of the donor’s death. It is also prohibited to contribute in any manner to the sale of unfertilized or fertilized oocyte. Fertilized oocyte may be kept alive no longer than fourteen days outside a woman’s uterus. The transplantation of ovaries for the purpose of remedying sterility or infertility is prohibited. Human oocytes (fertilized or unfertilized) may be frozen for up to two years. Upon the death of the woman or man, or in the event of their separation or divorce, or at the end of the two year period the frozen oocytes must be destroyed.

A Scientific Ethical Committee System and the Handling of Biomedical Research Projects (1992) addresses cloning. Research on cloning, i.e., production of genetically identical individuals, is forbidden.

4.22 ART in Ireland

The Republic of Ireland has not adopted specific legislation to address ART practices. “General Medical Council Guidelines” issued by the Irish Medical Council (1999) is a guide to ethical conduct, procedures, and fitness to practice. The guidelines stand as the basis for the regulation of treatment. Infertility treatment is provided to married couples. The guidelines state: “There is no objection to the preservation of sperm or ova to be used subsequently on behalf of those from whom they were originally taken”.

Physicians are advised to provide extensive counseling to couples and donors when considering third-party donation. Failure to provide such counseling could result in disciplinary proceedings. Techniques such as in-vitro fertilization should
only be used after thorough investigation has ruled out alternatives. “Any fertilized ovum must be used for normal implantation and must not be deliberately destroyed”.

4.23 ART in Russia

The regulation of ART in Russia is through the Act on Artificial Fertilization Act, 1996. Thorsteinsdottir says the Regulation is the same as the Act plus more rules. The Regulation gives the decision to approve ART practices to the physician. If the physician has concerns about the social conditions of the couple, an opinion is requested from child welfare authorities. A committee appointed by the Minister of Health and Social Security composed of a lawyer, a physician, and a social worker who serve for four years review any complaints and issue a decision, which is final.57

The Regulation suggests that the couple reside together for three continuous years. There is an upper age limit of 42 years for women or 45 years if gametes are in storage. The upper age limit for men is 50 years. Posthumous conception is not allowed. Surrogate motherhood is prohibited. Sperm and oocyte or ovum donation are allowed. Embryos may be created using in-vitro fertilization and placed in storage. The embryo can only be implanted in the womb of the woman the oocyte came from or the wife of the man who contributed the sperm. If the marriage or relationship ends or a spouse dies, the embryo is destroyed.

4.24 ART in New Zealand

The National Ethics Committee on Assisted Human Reproduction (NECAHR) was established by and accountable to the Minister of Health under section 46 of the Health and Disability Services Act of 1993. The objectives or role of the committee is to review proposals to ensure ethical aspects are considered; to ensure rights of patients, donors, and offspring are protected; to develop protocols and guidelines to assist regional ethics committees; and to provide the Minister of Health and National Advisory Committee on Health and Disability Service Ethics with advice on ART issues.

New Zealand has federal regulatory legislation on ART pending. According to Jenny Hawes, an analyst for the Ministry of Health, the government recently agreed to develop new legislation out of the two bills under consideration.58 The new law was being drafted in late 2001. The two competing bills before the Health Select

57 Ibid
58 Ibid
Committee were the Human Assisted Reproductive Technology Bill introduced in 1996 and the Assisted Human Reproductive Technology Bill introduced in 1998.

4.25 ART in Norway

The regulation of ART in Norway is through the Act relating to the Application of Biotechnology in Medicine Act, 1994.\(^{59}\) Both Norwegian and English versions of the Act were provided by the Health and Social Affairs. The Royal Ministry of Health and Social Affairs advised that administration of the Act is delegated to the Norwegian Board of Health. The Norwegian government has appointed an independent advisory board known as The Norwegian Biotechnology Advisory Board to review problems and suggest ethical guidelines.

ART treatment services are made available to couples within the context of marriage or a conjugal relationship that approximates heterosexual marriage. It is suggested that an upper age limit of 38 years is preferable for the birth mother; but no statutory limit exist. Posthumous conception is prohibited. Sperm donation is allowed. The sperm donor remains anonymous. Ovum and embryo donation are not allowed. Surrogate motherhood is prohibited. Sex selection is prohibited except for reasons of a sex-linked hereditary disease. Embryo cloning is prohibited.

4.26 Conclusion

It is absolutely understandable that different countries will reach different regulatory conclusions regarding assisted reproductive technology, based on a variety of factors including cultural attitudes, traditions, religious views and the majority’s moral position. The legislation adopted and regulatory structures implemented vary in regard to the priorities emphasized. The concerns of some nations are health risk based whereas others view the morality of this approach to be in question. A division exists over the importance granted to individual privacy versus social consciousness. These factors along with economic circumstances influence actions taken, as well as, inaction. The level of economic development and the stability of the health care structure are closely related issues.

\(^{59}\) Available at http://www.ub.uio.no/ujur/ulovdata/lov-20031205-100-eng.pdf visited on 8 November 2012.