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Abstract

The regulation of assisted reproductive technologies is a contested area. Some jurisdictions, such as the UK and a number of Australian states, have comprehensive regulation of most aspects of assisted reproductive technologies; others, such as the USA, have taken a more piecemeal approach and rely on professional guidelines and the general regulation of medical practice to govern this area. It will be argued that such a laissez-faire approach is inadequate for regulating the complex area of assisted reproductive technologies. Two key examples, reducing multiple births and registers of donors and offspring, will be considered to illustrate the effects of the regulatory structure of assisted reproductive technologies in the USA on practice. It will be concluded that the regulatory structure in the USA fails to provide an adequate mechanism for ensuring the ethical and safe conduct of ART services, and that more comprehensive regulation is required.

KEYWORDS: American Society for Reproductive Medicine (ASRM), assisted reproductive technologies, infertility treatment, legislation, policy, regulation

Introduction

The regulation of assisted reproductive technologies is a contested area. Some jurisdictions, such as the UK and a number of Australian states, have comprehensive regulation of most aspects of assisted reproductive technologies; others, such as the USA, have taken a more piecemeal approach and rely on professional guidelines and the general regulation of medical practice to govern this area (Ory et al., 2013). In this paper, we argue that such a laissez-faire approach is inadequate for regulating the complex area of assisted reproductive technologies, and conclude that more comprehensive regulation is required. The aim of this paper is to give a perspective on regulation of assisted reproductive technologies in the USA and compare it with other jurisdictions with very different regulatory systems and approaches to government intervention, drawing heavily on examples from the UK. The purpose here is not to argue that the solutions and approaches to regulation adopted in other countries, particularly the UK, could be applicable to the USA. We recognize that the American socio-political context in which assisted reproductive technologies operate, attitudes towards government intervention, particularly at federal level, and the funding structure of US health care means that national legislation on assisted reproductive technologies, such as exists in the UK, is highly unlikely to be either practical or ideologically acceptable to most stakeholders in the USA. Our purpose is merely to open up the discussion by using examples of radically different regulatory systems, with a view to finding compromises between regulatory oversight and the autonomy and privacy of practitioners and users that would be acceptable in the USA. Regulatory structures and provisions are not set in stone, and the lively debate in the UK over the Government's plans to abolish the Human Fertilisation and Embryology Authority (HFEA), with strong arguments on either side (Johnson, 2013), show that these matters are never completely resolved even by comprehensive legislation.

Background

In the USA, forms of assisted reproductive technology regulation exist at federal and state level. At federal level, assisted reproductive technologies are overseen by the Fertility Clinic Success Rate and Certification Act 1992, Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services. Medical practice is also regulated at individual state level. This can include specific regulations on assisted reproductive technologies (in the main relating to insurance coverage). Considerable inter-state variation, however, exists; some states have limited or non-existent regulation and others have more comprehensive oversight. Because of the relative lack of legal regulation at both these levels, professional guidelines and good practice protocols play an important role in overseeing assisted reproductive technology practice. The American Society of Reproductive Medicine (ASRM) and its affiliate, the Society for Assisted Reproductive Technology (SART), offer professional self-regulation through guidelines and codes of conduct for fertility clinics and their staff. Key among these are the ASRM Ethics Committee Reports and Practice Committee opinions (ASRM and SART Practice Committee, 2013; ASRM Ethics Committee, 2004). The ASRM has consistently asserted that, owing to the existence of this framework assisted reproductive technologies are sufficiently well regulated and there is little need for further intervention (Adamson, 2005; Rebar and DeCherney, 2004). Following a meeting to review the oversight of assisted reproductive technologies, the ASRM produced a report in May 2010 re-stating this position that assisted reproductive technologies are, 'one of most highly regulated of all medical practices in the United States' (ASRM, 2010). We do not necessarily quarrel with that view in this paper, as our purpose is not to examine or compare different regulatory regimes of other areas of medical practice in the USA. The aim is to highlight important omissions in the regulatory structures that govern assisted reproductive technologies in the USA, and to argue that the oversight of assisted reproductive technologies is much less extensive and rigorous than the ASRM claims. Before considering the specifics of US regulation, it is useful to consider what is meant by 'sufficiently well-regulated'. We argue that assisted reproductive technologies are sufficiently well regulated if regulations, which are designed to promote the safe and ethical conduct of these practices, are present and enforceable in some meaningful way and have broad support of all the relevant stakeholders.

Limitations of regulation

At the federal level, the sole statute regulating assisted conception, the Wyden Law (the colloquial term for the Fertility Clinic Success Rate and Certification Act) is limited in scope. It is primarily designed to make publicly available accurate information about fertility clinic success rates by requiring annual data reporting to the CDC. It has been commented, however, that this publically available outcome data can be misleading, and a small number of clinics have reported data in such a way as to give an inflated picture of their pregnancy rates. For example, the analysis by Kushnir et al. (2013) of SART and CDC reporting data showed that some centres were excluding cycles started in women over the age of 38

years. By doing this, these clinics reported significantly better pregnancy rates than average and were able to increase their market share by 19.9%. Kushnir et al. (2013) conclude that future data collection and reporting need to be more patient-centred so that success rates of clinics can be more accurately and fairly compared. The HFEA, for example, organized a public consultation on how clinic success rates should be reported, to allow patients to make the most informed choices when selecting a clinic (HFEA, 2008). The outcomes of this are reflected on the HFEA's website where information is presented in an accessible way to help people understand the meaning of the statistics used in making clinic comparisons and aid them in making treatment choices (HFEA, 2014). In the USA, such comprehensive data do not exist on clinics, not all of them file reports to CDC, and each year about 12% of them fail to do so. In 2009, 43 clinics did not report (Centers for Disease Control and Prevention, 2011), in 2010, 31 clinics failed to reported (Centers for Disease Control and Prevention, 2012) and, in 2011 (the latest figures available), 30 clinics failed to report (Centers for Disease Control and Prevention, 2013). Data from clinics are also collected by SART on a voluntary basis, and these are shared with the CDC. Not all clinics report to SART either; of those that did, 113 (28.1%) did not report a complete data set (Kushnir et al., 2013). Further, it is unclear if every practising fertility clinic is known to the CDC and therefore included in these figures, as they state: 'We will continue to make every effort to include in future reports all clinics and practitioners providing ART (assisted reproductive technologies) services.' (CDC Website, commonly asked questions reference). Furthermore, the CDC request any customer who is aware of a fertility clinic that is operating but not included in their list of assisted reproductive technology centres to notify them. In addition to this lack of reporting, the data that the CDC requires clinics to collect are more limited than data provided by clinics in the UK to the HFEA and in Australia and New Zealand to the Australian and New Zealand Assisted Reproduction Database (Macaldowie et al., 2012), for example. A key area in which data collected by the CDC are limited is information on the use of donor gametes. The CDC only collect data on the use of donor eggs and do not collect data on donor sperm (i.e. how many treatments are conducted with donor sperm and success rates): 'Some ART procedures use a woman's own eggs, and others use donated eggs or embryos. Although sperm used to create an embryo may also be either from a woman's partner or from a sperm donor, information in the report is presented according to the egg source.' (CDC, Web Tutorial) The CDC only collect data on the age of egg donors and on the use of donor eggs, covering areas such as: are older women undergoing assisted reproductive technologies more likely to use donor eggs or embryos? Do percentages of transfers that result in live births differ by age for women who used assisted reproductive technologies with donor eggs compared with women who used assisted reproductive technologies with their own eggs? How successful is assisted reproductive technology when donor eggs are used? (CDC, Web Tutorial). National records of the numbers of gamete donors, to whom they donated, and medical information are not, however, required by the CDC. This makes it impossible to track gamete donor trends in the USA or determine how many times an individual donor might be used.

The Wyden Law also provides States with a model embryology laboratory certification process. It is not mandatory to implement such a model, and embryology laboratories are not

required to have this type of certification because the procedures they perform are not deemed to be diagnostic and therefore do not fall within the remit of the Clinical Laboratory Improvement Act under which compliance is mandatory. The FDA's role in overseeing assisted reproductive technologies also has significant limitations. The FDA has jurisdiction over setting standards for screening and testing donors of all forms of human tissue and tissue-based products under Regulation 21 code of Federal Regulations (CFR) Part 1271 (Food and Drug Administration, 2004). These regulations were primarily designed to prevent communicable diseases. The storage and use of reproductive tissue, however, raise distinctive issues that are not covered by these regulations. For instance, they do not incorporate guidance on genetic testing of prospective donors, and this has resulted in wide variation in the practices of sperm donor banks. This was highlighted 14 years ago (Conrad et al., 1996); more recently, Sims et al. (2010) found that routine testing for *genetic* diseases varied substantially between sperm banks, with different conditions being screened for and a wide range of tests used. Isley and Callum (2013) found similar variability of practice in their study, which included information from 13 out of 26 sperm banks in the USA. This study reported that, although these banks voluntarily followed the testing guidelines from at least one professional organization (such as the ASRM and the American Association of Tissue Banks), the lack of consistency between banks is still an issue. Similar inconsistencies in practice have been observed in the screening of oocyte donors. Lewis et al. (1999) investigated compliance with ASRM guidelines by 159 oocyte donation programmes, and concluded that, although: 'most programmes follow recommendations made by the . . . ASRM for screening of gamete donors . . . a significant percentage do not use well-established testing.' A 2011 study of 16 oocyte donation agencies and 28 assisted reproductive technologies clinics (out of 59 agencies and 205 clinics invited to take part) concluded that these programmes inconsistently applied genetic screening guidelines from the American College of Obstetricians and Gynecologists, the American College of Medical Genetics, and ASRM (Lim et al., 2011). These wide variations in practice have resulted in unacceptable variations in practice and insufficiently robust genetic screening of donor gametes (Heled, 2010). Furthermore, reproductive tissue is not included in all of the 21 CFR Part 1271 regulations (Food and Drug Administration, 2004). Only small sections of the Good Tissue Practice regulations, for example, apply to most reproductive establishments (Keel and Schalue, 2010). The FDA itself points out that it is unclear if all facilities that handle reproductive tissue comply with accepted industry standards:

> *Facilities handling reproductive tissue. . . . represent the greatest area of uncertainty. . . . There is currently no single reliable source of information on fertility center or semen bank adherence to AATB [American Association of Tissue Banks] standards or ASRM guidelines*. (Food and Drug Administration, 2004).

In summary, weaknesses in the federal regulatory structure of assisted reproductive technologies have resulted in inconsistencies in practice and areas that are insufficiently regulated.

Individual states also have the power to pass legislation governing assisted reproductive technologies; however, many states have not legislated in this area. A report published by the National Conference of State Legislatures in 2007 (that has not subsequently been updated) indicates that legislation on embryo and gamete disposition (covering key areas such as legal parenthood of children conceived from donated gametes and consent procedures for use and storage of gametes) has only been enacted in 16 states (The National Conference of State Legislatures, 2007b). Laws relating to health insurance coverage for infertility treatments also vary between states (Martin et al., 2011. The National Conference of State Legislatures, 2012). On the regulation of techniques related to standard IVF, such as cloning and embryonic stem cell research, only 15 states have legislation relating to human cloning, and, within these laws what is covered and prohibited varies (The National Conference of State Legislatures, 2008). More states have legislation governing the use of embryonic stem cells in research, but approaches differ greatly from state to state: some states, such as California and Illinois, allow this kind of research and have guidelines for consent processes and reviews procedures for projects; others, such as South Dakota, prohibit research on embryos (The National Conference of State Legislatures, 2007a). Thirteen states do not have any legislation on assisted reproductive technologies provision, and many only have limited legislative cover (Table 1). Naomi Cahn in her book *Test tube families: why the fertility market needs legal regulation* (Cahn, 2009) discusses some of the problems with piecemeal state legislation in this area, such as conflicting state laws that govern surrogacy, lack of clear legal regulation in some states over who is the legal parent of children produced from gamete, embryo donation, or both, which creates particular uncertainty for same-sex couples and single women over who has parental rights. This evidence suggests that state oversight of assisted reproductive technologies is incomplete and patchy, leaving the population in some areas with little state level regulation of key areas of assisted reproductive technologies. One argument to be made is that local areas should be able to legislate for local need and in accordance with local values; therefore, this state-wide variation is not, in itself, problematic. Assisted reproductive technologies, however, are medical treatments that operate across state and national borders, and people will travel out of state if better treatment options are available. About 16% of assisted reproductive technologies cycles in the USA in 2009 were performed on out-of-state residents (Sunderam et al., 2012). This is an issue that affects all countries, and is just as much a problem within Europe. Individuals can always travel to different jurisdictions to access treatments that are not available locally (either due to resources or regulatory prohibition) and, therefore, to a degree, even national legislation can become piecemeal in a global context (Gürtin and Inhorn, 2011). In a country the size of the USA, however, national consistency would be a desirable end. The final area of oversight of assisted reproductive technologies is through professional regulation. A major plank in this regulation, the ASRM and SART professional codes and guidelines, are essentially voluntarily recommending, rather than enforcing, good practice. Membership of SART guarantees certain standards of practice (following ASRM guidelines, reporting to the CDC, accredited embryology laboratories and staff training standards, for example), but if membership is rescinded owing to non-compliance, clinics may still operate. As mentioned previously, not all clinics report to the CDC. Therefore, a clinic's failure to submit an annual report to CDC does not seem to adversely affect its ability to continue to offer services.

TABLE 1 ABOUT HERE

Consequences of regulatory structure: examples from practice

To illustrate the limitations of the regulatory model in the USA, we will take two examples from practice, reducing multiple births and registers of gamete donors and offspring, to show how the piecemeal and voluntary regulatory structure of assisted reproductive technologies in the USA provides an inadequate mechanism for ensuring the ethical and safe conduct of assisted reproductive technology services.

Multiple births

It is widely acknowledged that multiple pregnancies represent the most significant health problem associated with assisted reproductive technology for both mothers and babies (Rebar and DeCherney, 2004). This is a phenomenon largely attributable to the number of embryos transferred in a single IVF cycle. The ASRM first issued guidelines proposing limits on the numbers of transferred embryos in 1999 (ASRM, 1999), recommending the transfer of no more than three embryos for women aged under 35 years, no more than four for women aged 35–40 years, and no more than five for women aged over 40 years. Following several revisions, the most recent guidance issued in 2013 (ASRM, 2013) recommends that, for women aged under 35 years, consideration should be given to transferring one embryo and no more than two (although the effects of this latest guidance will not be apparent for a number of years). The practice of member clinics is also monitored by SART, and an onsite inspection would be triggered if unwarranted deviation from the national mean of multiple births is evident.

The ASRM argues that an 80% decrease in the number of triplet births between 1999 and 2007 demonstrates the success of this ‘self-policing’ (ASRM, 2010). Writing over 14 years ago, Jones and Schnorr (2001) argued that: ‘It seems clear that the voluntary guideline system in the United States has not solved the problem of multiple gestations,’ and we see little evidence that the situation has improved significantly since then. In 2006, transfer of three or more embryos was still common practice in the USA (Centers for Disease Control and Prevention, 2009). In a detailed analysis of the 2009 surveillance data conducted by the CDC in 2012, Sunderam et al. (2012) conclude that more than one embryo was transferred in most IVF cycles for all age groups. The national average for embryos transferred was 2.1 among women aged 35 years and under and 2.5 for women aged 35–40 years. As a result, about 32% of assisted reproductive technologies infants born in 2009 were pre-term, compared with about 8% of pre-term births in the general US population, and 47% were born in multiple-birth deliveries, compared with 3% in the general US population. The twin rate was 43.7%, compared with 3.3% in the general US population, and the rate of triplets and higher-order multiples was 3.6%, about 25 times higher than the general US population rate. Babies born from assisted reproductive technologies contributed to 34.4% of all triplets or higher order multiple births in the population, but only 1.4% of all infants born in the USA were

conceived using ART. The authors conclude: ‘More than one embryo was transferred per procedure in most states and territories for all age groups, influencing the overall multiple birth rates in the United States’ (Sunderam et al., 2012). One study found that at least one-half of the clinicians surveyed would deviate from ASRM embryo transfer number guidelines in certain situations (Jungheim et al., 2010) Hence, it is clear that not all clinics are following the ASRM guidelines, and single embryo transfer (SET) is still not a common treatment option.

Reductions in the number of embryos transferred have been much slower in the USA compared with European countries, where external constraints and regulation have been more stringent (Gleicher et al., 2007). In the UK, for example, policies on the number of embryos that should be transferred were introduced in the form of national, legally enforceable rules (although in a specific case whether the HFEA can make such a reduction a condition of the clinic’s licence has been challenged on procedural grounds (England and Wales High Court, 2013)). In 2001, the HFEA, introduced a two-embryo transfer policy for women under the age of 40 years, and only allowed three embryos to be transferred in exceptional circumstances. In 2004, this policy was revised so that a maximum of two embryos could be transferred to women under the age of 40 years, and a maximum of three embryos could be transferred in women aged 40 years and over. These policies have had an important effect on the triplet rate. By 2007, the triplet rate was 1 in 4975 births, compared with its peak of 1 in 2130 births in 1998 (HEFA, 2013c). In 2009, the HFEA implemented a policy that required clinics to have a ‘multiple pregnancy minimisation strategy’ to increase the numbers of SET, and clinics have to meet targets for reducing their numbers of multiple births. Following the introduction of this policy, the numbers of elective SET have risen: in 2008, 4.8% of embryo transfers were elective SET, whereas, in 2011, 16.8% were elective SET. Consequently, the multiple pregnancy rate has fallen from 26.6% in 2008 to 20.1% in 2011 (HFEA, 2013a). Belgium also introduced a legal restriction on the numbers of embryos that could be transferred in 2003 (alongside reimbursement of laboratory costs), and this has resulted in a reduction in the multiple pregnancy rate from 27 to 11% (De Neubourg et al., 2013). Concerns have also been expressed over these type of policies (Gleicher, 2011), namely that they could adversely affect pregnancy rates. The most recent figures published by the HFEA, however, do not support this, and the pregnancy rate increased from 2008–2009, and remained steady in the early part of 2010 (HFEA, 2013a).

Centrally imposed elective SET levels are not the only way of reducing the multiple birth rate. Chambers et al. (2013) compared the UK’s regulatory structure with Australia that has a multiple birth rate less than one-half that of the UK at 8%, and argue that a higher level of public funding for assisted reproductive technologies in Australia (meaning that patients are more likely to accept elective SET), a lighter regulatory touch and lack of clinic league tables has driven up the elective SET rate (to 70% of cycles compared with 31% in the UK). Chambers et al. (2013) have commented that the financial context of infertility treatment has a substantial effect on the acceptability of elective SET to patients, ‘presumably because more affordable treatment reduces the financial incentive to achieve pregnancy in the shortest number of treatment cycles.’ In the USA, with the variability of insurance coverage for

infertility treatment, the resulting high cost may encourage particular practices, such as transferring more embryos (Hamilton and McManus, 2012). These authors found that insurance mandates (i.e. insurance coverage) for infertility treatment not only increased access but also led to the transferring fewer embryos. Hence, in the USA, such centrally imposed regulation might be an appropriate option in light of the funding structure of treatment with varying insurance coverage for assisted reproductive technologies.

Donor registries

A further example of difficulties raised by the absence of comprehensive legislation in the USA is the lack of any national registry of those who have used assisted reproductive technologies with donor gametes, embryos, or both, and those born from these techniques. As discussed above, the CDC does not require such information to be collected or collated nationally. A nationally mandated donor registry would enable the collection and storage of information on the donor, such as how many times they had donated, family medical history, recipients of the donation and details of the outcome of the donation. The ASRM and SART have objected to the establishment of both state and national donor registries in the USA (ASRM Office of Public Affairs, 2012), and criticised a bill proposed in New York, AB 9039/SB 6272 that would limit to 10 the number of offspring any one donor can conceive and create a donor registry in the state. The ASRM argued that scientific evidence does not support the limit of 10, and referenced existing professional guidelines, while maintaining that a single state-based registry would not only be ineffective, but also intrusive (ASRM Office of Public Affairs, 2012). Despite objections, a number of arguments exist for a national registry. First, such a registry would also allow research into ARTs to track long-term trends and follow up that can be used to increase the safety of the procedures (Basu, 2004; Cahn, 2008; D'Orazio, 2006; Sylvester and Burt, 2007). Second, the establishment of donor registries could be used to formulate appropriate limits on the use of donors, as currently without adequate records of how many times a donor is used it is not possible to provide scientific evidence to establish any evidence-based limits and develop robust guidelines for practice (Sawyer, 2009). Finally, a national registry could facilitate information exchange. If a system was introduced where donors were required to agree to the disclosure of their identity to any offspring (as it has been introduced, in part, in Washington (Washington, 2011), then accurate records would be available to facilitate the linking of donors and donor offspring. Although such legislation is unlikely to be retrospective, in the UK those who donated before anonymity was abolished in 2005 can voluntarily apply to the HFEA to re-register as non-anonymous donors. This allows any offspring who might want to find out the identity of their donor to access this information if their donor has taken up this option. This reregistration would not be possible without the national records kept by the HFEA. This presupposes that non-anonymity is deemed to be a desirable way of organising gamete donation. There has been great debate over this, and it is argued that it is unethical to practice gamete donation under conditions of anonymity (Allen, 2012; Tobin, 2012). Therefore, for some commentators, the existence of a national register could facilitate a more ethical approach to gamete donation. The Practice Committee of the ASRM and SART (2013) have recently issued recommendations for clinics and sperm banks to establish

permanent records of donor recruitment and follow-up evaluations. Although this would provide some much needed information on donor use and allow some linkage in the event of reported adverse outcomes for donors or offspring, this proposal falls short of establishing a national registry and achieving the benefits that would accrue from this.

Discussion

Although the ASRM claim that assisted reproductive technologies are adequately regulated, there is clearly room for greater non-voluntary regulation of this area. A number of objections, however, could be made to these suggestions for increased regulation. First, it has been debated whether such extended legislation, particularly at federal level, would be constitutional. Jones and Schnorr (2001) say that there seems to be a constitutional requirement that such legislation be enacted at state level. Heled (2010), however, argues that federal legislation is not *prima facie* ruled out by constitutional requirements. Whether legislation on assisted reproductive technologies at federal level would fall foul of the constitution would depend on the detail and scope of the proposals. The Supreme Court recognizes that the federal government can set national health and safety standards (Heled, 2010), and therefore such a possibility of greater federal regulation of assisted reproductive technologies cannot be automatically ruled out. Second, the legal and political framework in the USA puts a high premium on privacy (Spar, 2005), and establishing a national registry that could track gamete donors and their use could be seen as an infringement of individuals' reproductive privacy (Cohen, 2012). As Spar (2005) notes, state legislation has traditionally exerted authority over reproduction in areas such as contraception and abortion, although there is greater distrust of federal level intervention. However, national data are already collected by federal bodies, the CDC for example. We would argue that, in the case of assisted reproductive technologies, there is value in establishing such a register, and privacy concerns could be addressed by ensuring that the information was adequately safeguarded. It is worth noting that, despite being in existence for a number of years, there has never been any suggestion that the security of data held in such registers in the UK or in Australian states has ever been compromised. Finally, the cost of such increased regulation might be seen as a barrier. In the UK, the HFEA is funded by a combination of government (Department of Health) funding, about £1.3m per annum, and fees levied on the clinics (HFEA, 2012/13). Currently, clinics are charged £75 for each cycle of IVF they perform and £37.50 for donor insemination with a discount for elective SET (clinics are charged £75 for the first elective SET, after which no charge is made for all subsequent transfers (subject to a small number of exceptions). For every frozen embryo transfer that is not an elective SET, clinics are charged £75 (HFEA, 2013b). Most of the HFEA's costs are met by clinics paying this levy. In 2012–2013, fee income to the HFEA was £3,978,594, with a £778,476 grant from the Department of Health (HFEA, 2012/13). It is important to note that most fertility treatment in the UK is carried out privately (40.3% of IVF treatment was funded by the National Health Service and 59.7% funded privately; with only 17.9% of donor insemination cycles funded by the National Health Service (HFEA, 2013a)) and the cost per cycle is passed on to the consumer either as a specific item on the bill or as part of the general treatment fee. Therefore, in certain respects, the assisted reproductive technology treatment context in the UK and the

USA are not as dissimilar as they are for other forms of medicine where, with certain exceptions, the bulk is publically funded in the UK. Any increase in regulation in the USA would incur some financial cost (both to the clinics and to the federal government), raising the cost of treatment, and there would need to be some federal commitment to providing funds to support such a national endeavour. We would argue, however, that this cost would be a small one, and the benefits of a well regulated and safe provision of assisted reproductive technologies would outweigh this.

Conclusion

In this paper we have argued that existing regulations do not sufficiently regulate assisted reproductive technologies in the USA, as enforceable measures to promote the safe and ethical practice of assisted reproductive technologies is lacking. There have been suggestions within US-fertility circles for how increased regulation might be achieved. Howard W. Jones Jr., a revered figure both in the USA and internationally, together with John Schnorr, argued that one solution would be to create an agency at 'arms length' from government – modelled on the then Voluntary Licensing Authority in the UK – the precursor to the HFEA. Such a body could, in their view, accomplish more effective regulation without government interference (Jones and Schnorr, 2001). They suggested that the National Advisory Board for Ethics in Reproduction, established in 1991 by the American College of Obstetricians and Gynaecologists and the American Fertility Society, could have taken on this role. When this was mooted in the mid-1990s, however, support from practitioners and politically for such a body to be established was lacking and for the NABER to take on this role (Kalfoglou, 2000). The ASRM considered and then dismissed the suggestion to introduce a: 'medical practice act requiring specialists in ART to follow ASRM guidelines,' on the grounds that the area is already sufficiently regulated (ASRM, 2010). While we recognise that a body like the HFEA or prescriptive national legislation would find little favour in the USA, some form of greater regulation is needed. Greater regulation could ensure that clinics follow ASRM guidelines, comply with federal reporting and certification requirements, and would go some way to ensuring uniformity of practice and maintenance of minimum standards. Greater regulation would also enable better data reporting, ensuring that success rates are more accurately reported and reflect the differences between different patient groups, and a national registry would aid information and data exchange. Any regulatory structure, however, needs to have teeth, and if it is left as a voluntary measure there will always be those who do not comply.

Table 1 State regulation of assisted reproductive technologies in the USA

State	Gamete donation disposition[17]	Human cloning[16]	Stem cell research [20]	Insurance [19]
Alabama				
Alaska				

Arizona		√	√	
Arkansas		√	√	√
California	√	√	√	√
Colorado	√			
Connecticut	√	√	√	√
Delaware				
Florida	√		√	
Georgia				
Hawaii				√
Idaho				
Illinois			√	√
Indiana		√	√	
Iowa		√	√	
Kansas				
Kentucky			√	
Louisiana	√		√	√
Maine			√	
Maryland	√	√	√	√
Massachusetts	√	√	√	√
Michigan		√	√	
Minnesota			√	√
Mississippi				
Missouri		√	√	
Montana			√	√
Nebraska			√	
Nevada				
New Hampshire			√	
New Jersey	√	√	√	√
New Mexico			√	
New York	√		√	√
North Carolina				
North Dakota	√	√	√	
Ohio			√	√
Oklahoma	√		√	
Oregon				
Pennsylvania			√	
Rhode Island		√	√	√
South Carolina				
South Dakota		√	√	
Tennessee			√	
Texas	√		√	√
Utah			√	
Vermont				
Virginia	√	√	√	
Washington	√			
West Virginia				√
Wisconsin				

Wyoming	√		√	

Source: The National Conference of State Legislatures (NCSL). The data used for this table are taken from the NCSL and, in some cases, have not been updated recently. Hence, these data should be seen as illustrative and not as providing a comprehensive overview of all the legislation in this area across US states. For further details see Appendix S1.

References

Adamson, D., 2005. Regulation of Assisted reproductive technologies in the United States. Fam. Law Q. 39, 727–744.

Allen, S., 2012. Donor conception, secrecy and the search for information. J. Law Med. 19, 631–650.

ASRM, 1999. Guidelines on the Number of Embryos Transferred, Birmingham, AL.

ASRM, 2010.Oversight of Assisted Reproductive Technology. http://www.asrm.org/uploadedFiles/Content/About_Us/Media_and_Public_Affairs/OversiteOfART%20(2).pdf (accessed 10.08.10.).

ASRM, 2013. Criteria for number of embryos to transfer: a committee opinion. Fertil. Steril. 99, 44–46.

ASRM and SART Practice Committee, 2013. Recommendations for gamete and embryo donation: a committee opinion. Fertil. Steril.99, 47–62.

ASRM Ethics Committee, 2004. Informing offspring of their conception by gamete donation. Fertil. Steril. 81, 527–531.

ASRM Office of Public Affairs, 2012. ASRM and SART exert pressure to hinder legislation on several states. ASRM Bull. 14.

Basu, S., 2004. Commentary: genetic privacy: resolving the conflict between the donor and the child. Curr. Sci. 86, 1363–1365.

Cahn, N., 2008. Necessary subjects: the need for a mandatory national donor gamete registry. DePaul J Health Care Law; GWU Legal Studies Research Paper No. 402; GWU Law School Public Law Research Paper No. 402. Available at SSRN. http://ssrn.com/abstract=1120389.

Cahn, N., 2009. Test Tube Families: Why the Fertility Market Needs Legal Regulation, New York University Press.

Centers for Disease Control and Prevention, n.d.b. Tutorial for using the ART Report. http://www.cdc.gov/art/UsingARTreport.htm.

Centers for Disease Control and Prevention, n.d.a. Commonly asked questions about the US ART reporting system. http://www.cdc.gov/art/ART2010/faq.htm.

Centers for Disease Control and Prevention, 2009. Assisted Reproductive Technology: Success Rates: National Summary and Fertility Clinic Reports 2007. Centers for Disease Control and Prevention, Atlanta. http://www.cdc.gov/art/ARTReports.htm

Centers for Disease Control and Prevention, 2011. Assisted Reproductive Technology: Success Rates: National Summary and Fertility Clinic Reports 2009, Centers for Disease Control and Prevention, Atlanta. http://www.cdc.gov/art/ART2009/appixc_nonreport.htm (accessed 08.13.).

Centers for Disease Control and Prevention, 2012. Assisted Reproductive Technology: Success Rates: National Summary and Fertility Clinic Reports 2010, Centers for Disease Control and Prevention, Atlanta. http://www.cdc.gov/art/ARTReports.htm#5.
Centers for Disease Control and Prevention, 2013. Assisted Reproductive Technology: Success Rates: National Summary and Fertility Clinic Reports 2011, Centers for Disease Control and Prevention, Atlanta. http://www.cdc.gov/art/ARTReports.htm#5.
Chambers, G., Wang, Y.A., Chapman, M.G., Hoang, V.P., Sullivan, E.A., Abdalla, H.I., Ledger, W., 2013. What can we learn from a decade of promoting safe embryo transfer practices: a comparative analysis of policies and outcomes from in the UK and Australia 2001–10. Hum. Reprod. 28, 1679–1686.
Cohen, I.G., 2012. Rethinking sperm-donor anonymity: of changed selves, non-identity, and one-night stands. Georgetown Law J. 100, 431–447.
Conrad, E.A., Fire, B., Hecht, B.R., Pergament, E., 1996. Current practices of commercial cryobanks in screening prospective donors for genetic disease and reproductive risk. Int. J. Fertil. Menopausal Stud. 41, 298–303.
De Neubourg, D., Bogaerts, K., Wyns, C., Albert, A., Camus, M., Candeur, M., Degueldre, M., Delbaere, A., Delvigne, A., De Sutter, P., Dhont, M., Dubois, M., Englert, Y., Gillain, N., Gordts, S., Hautecoeur, W., Lesaffre, E., Lejeune, B., Leroy, F., Ombelet, W., Perrier D'Hauterive, S., Vandekerckhove, F., Van der Elst, J., D'Hooghe, T., 2013. The history of Belgian assisted reproduction technology cycle registration and control: a case study in reducing the incidence of multiple pregnancy. Hum. Reprod. 28, 2709–2719.
D'Orazio, P., 2006. Half of the family tree: a call for access to a full genetic history for children born by artificial insemination. Health Biomed. Law 2, 249–276.
England and Wales High Court, 2013. Assisted Reproduction and Gynaecology Centre and Anor V Human Fertilisation and Embryology Authority. 3087 (Admin). http://www.bailii.org/ew/cases/EWHC/Admin/2013/3087.html (accessed 11.13.).
Food and Drug Administration, 2004. Eligibility determination for donors of human cells, tissues, and cellular and tissue-based products; final rule and notice. 21 CFR parts 210, 211, 820,1271. p. 29817. http://www.fda.gov/ohrms/dockets/98fr/04-11245.htm.
Gleicher, N., 2011. Eliminating multiple pregnancies: an appropriate target for government intervention? Reprod. Biomed. Online 23, 404–406.
Gleicher, N., Weghofer, A., Barad, D., 2007. Update on the comparison of assisted reproduction outcomes between Europe and the USA: the 2002 data. Fertil. Steril. 87, 1301–1305.
Gürtin, Z.B., Inhorn, M.C., 2011. Introduction: travelling for conception and the global assisted reproduction market. Reprod. Biomed. Online 23, 535–537.
Hamilton, B.H., McManus, B., 2012. The effects of insurance mandates on choices and outcomes in infertility treatment markets. Health Econ. 21, 994–1016.
Heled, Y., 2010. The regulation of genetic aspects of donated reproductive tissue – the need for federal regulation, Columbia Sc. Tech. Law Rev. XI, 244–308.
HFEA, 2008. Consultation presenting clinic performance and outcome data. http://www.hfea.gov.uk/512.html.
HFEA, 2012/13. Annual Report and Accounts 2012/13, HFEA, London.

HFEA, 2013a. Fertility trends and figures 2011 – annual report. http://www.hfea.gov.uk/docs/HFEA_Fertility_Trends_and_Figures_2011_-_Annual_Register_Report.pdf.
HFEA, 2013b. Fees. http://www.hfea.gov.uk/1899.html (accessed 10.13.).
HFEA, 2013c. Embryo transfer and multiple births. http://www.hfea.gov.uk/2587.html#3045 (accessed 11.13.).
HFEA, 2014. Understanding fertility success rates. http://www.hfea.gov.uk/fertility-clinics-success-rates.html#clinicwebsites.
Isley, L., Callum, P., 2013. Genetic evaluation procedures at sperm banks in the United States. Fertil. Steril. 99, 1587–1591.
Johnson, M., 2013. HFEA reprieved – for the moment! Reprod. Biomed. Online 26, 303–304.
Jones, H., Schnorr, J., 2001. Multiple pregnancies: a call for action. Fertil. Steril. 75, 11–13.
Jungheim, E., Ryan, G.L., Levens, E.D., Cunningham, A.F., Macones, G.A., Carson, K.R., Beltsos, A.N., Odem, R.R., 2010. Embryo transfer practices in the United States: a survey of clinics registered with the Society for Assisted Reproductive Technology. Fertil. Steril. 94, 1432–1436.
Kalfoglou, A., 2000. Looking back, looking forward: the legacy of the National Advisory board of the ethics of reproduction. Women's Health Issues 10, 92–104.
Keel, B., Schalue, K., 2010. Reproductive laboratory regulations, certifications and reporting systems. In: Carrell, D., Peterson, C.M. (Eds.), Reproductive Endocrinology and Infertility Integrating Modern Clinical and Laboratory Practice, Springer, New York, pp. 55–70.
Kushnir, V., Vidali, A., Barad, D., Gleicher, N., 2013. The status of public reporting of clinical outcomes in assisted reproductive technology. Fertil. Steril. 100, 736–741.
Lewis, G., Saller, D.N., Kouides, R., Garza, J., 1999. Survey of genetic screening for oocyte donors. Fertil. Steril. 71, 278–281.
Lim, R.M., Callum, P., Ruberto, C., Zinberg, R.E., 2011. Genetic screening practices at oocyte donation programs. Fertil. Steril. 96 (3 Suppl.), S218 NB P-376.
Macaldowie, A., Wang, Y.A., Chambers, G.M., Sullivan, E.A., 2012. Assisted reproductive technology in Australia and New Zealand 2010. Assisted Reproduction Series No. 16. Australian Institute of Health and Welfare. http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=10737423255.
Martin, R., Bromer, J., Sakkas, D., Patrizio, P., 2011. Insurance coverage and in vitro fertilization outcomes: a U.S. perspective. Fertil. Steril. 95, 964–969.
Ory, S.J., Devroey, P., Banker, M., Brinsden, P., Buster, J., Fiadjoe, M., Horton, M., Nygren, K., Pai, H., Le Roux, P., Sullivan, E. International Federation of Fertility Societies, 2013. Surveillance, 2013. http://c.ymcdn.com/sites/www.iffs-reproduction.org/resource/resmgr/iffs_surveillance_09-19-13.pdf (accessed 31.10.13.).
Rebar, R., DeCherney, A., 2004. Assisted reproductive technology in the united states. N. Engl. J. Med. 350, 1603–1604.
Sawyer, N., 2009. Who's keeping count? The need for regulation is a relative matter. Fertil. Steril. 92, 1811–1817.

Sims, C., Callum, P., Ray, M., Iger, F., Falk, R., 2010. Genetic testing of sperm donors: survey of current practice. Fertil. Steril. 94, 126–129.
Spar, D., 2005. Reproductive tourism and the regulatory map. N. Engl. J. Med. 352, 531–533.
Sunderam, S., Kissin, D., Flowers, L., Anderson, J., Folger, S., Jamison, D., Barfield, W., 2012. Assisted Reproductive Technology Surveillance – United States 2009. MMWR Morb. Mortal. Wkly Rep. 61(SS7), 1–23.
http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6107a1.htm (accessed 07.13.).
Sylvester, T., Burt, R., 2007. The Case Against Sperm Donor Anonymity, Yale Law School, New Haven, CT.
The National Conference of State Legislatures, 2007a. Stem cell research, updated July 2007. http://www.ncsl.org/default.aspx?tabid=14413 (accessed 27.10.).
The National Conference of State Legislatures, 2007b. Embryo and Gamete disposition Laws, updated July 2007. http://www.ncsl.org/default.aspx?tabid=14379 (accessed 27.10.).
The National Conference of State Legislatures, 2008. Human Cloning Laws, updated January 2008. http://www.ncsl.org/default.aspx?tabid=14284 (accessed 27.09.10.).
The National Conference of State Legislatures, 2012. State laws related to insurance coverage for infertility treatment, updated March 2012. http://www.ncsl.org/issues-research/health/insurancecoverage-for-infertility-laws.aspx (accessed 04.14.).
Tobin, J., 2012. Donor-conceived individuals and access to information about their genetic origins: the relevance and role of rights. J. Law Med. 19, 742–757.
Washington, 2011. Section 53 chapter 26.26 RCW (Revised Code Washington). http://apps.leg.wa.gov/documents/billdocs/2011-12/Pdf/Bills/House%20Bills/1267.pdf.

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Supplementary Material (to be made available online)

Table S1: Embryo and gamete disposition laws in the USA

Updated July 2007

State	*Statutes*
California	California Penal Code §367g prohibits the use spermatoza, ova, or embryos in assisted reproduction technology in a manner other than stated on the written consent form of the provider of the spermatoza, ova or embryos. The statute also requires signed written consent to implant embryos or gametes. The use of sperm donated to a licensed tissue bank is excluded. California Health and Safety Codes §125315 requires healthcare providers to give infertility patients the necessary information to make an informed and voluntary choice about the disposition of any human embryos remaining after fertility treatment. Patients must receive a form that sets forth advance directives for the disposition of frozen embryos. Patients must be offered several options, including storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research. The State Department of Health Services must establish and maintain a registry of embryos that would provide researchers with access to embryos for research purposes. The law specifies requirements for obtaining informed consent from an individual considering donating embryos for research. California Probate Code §249.5 to 249.8 states that a child conceived and born after the death of a parent shall be deemed to have been born in the lifetime of the deceased parent as long as the deceased parent consented to the use of the genetic material or the child was *in utero* within 2 years of the decedent's death. If the child meets one of these qualifications, he or she will be entitled to death benefits from that parent. 2006 Cal. Stats., Chap. 483 requires a physician and surgeon, before obtaining informed consent from an individual for assisted oocyte production or other method of retrieving eggs from the ovaries for research or medical treatments, to provide the individual with a standardized written summary of health and consumer issues, and to obtain written and oral informed consent. It prohibits human oocytes or embryos from being acquired, sold, offered for sale, or otherwise transferred for valuable consideration for medical research or therapies. 2006 Cal. Stats., Chap. 806 requires a person who causes conception through assisted reproduction to submit to the jurisdiction of the courts of California. It permits a person who enters an assisted reproduction agreement to bring an action to establish a parent and child relationship. It permits the court to enter an order or judgement based on that action before the birth of the child and to consider a parent's criminal record before the felony conviction in making a finding that a parent is unfit to have future custody or control.
Colorado	Colorado Rev. Stat. §19-4-106 relates to parentage issues. The law clarifies the status of eggs, spermatoza, or embryos in case of marriage dissolution. In addition, the law states that the consent of a former spouse to assisted reproduction may be withdrawn by that individual in a record at any time before placement of eggs, sperm, or embryos. The law also clarifies that if a spouse dies before placement of eggs, sperm, or embryos, the deceased spouse is not a parent of the resulting child unless the deceased spouse consented in a record that if assisted reproduction were to occur after death, the deceased spouse would be a parent of the child.
Connecticut	Connecticut General Statutes §19a- 32d to 32g requires a healthcare provider delivering fertility treatment to provide information to patients about disposition of embryonic stem cells or embryos after treatment. Patients must be given the option to donate embryos to research, donate embryos to another couple, store embryos, or otherwise dispose of embryos or embryonic stem cells. Written consent to donate embryos, embryonic stem cells, eggs or sperm to research is required.
Florida	Fla. Stat. Ann. §742.14-742.17 requires written agreement that provides for the disposition of a couple's eggs, sperm, and pre-embryos in the event of a divorce, the death of a spouse, or any other unforeseen circumstance. Fla. Stat. Ann. §63.212 relates to pre-planned adoption agreements, which includes the use of 'fertility techniques', which are defined as artificial embryonation, artificial insemination, whether *in vivo* or *in vitro*, egg donation, or embryo adoption.

Louisiana	La. Rev. Stat. Ann. §9:391.1 declares that any child conceived after the death of a decedent, who specifically authorized in writing his surviving spouse to use his gametes, shall be deemed the legitimate child of such decedent, provided that the child was born to the surviving spouse, using the gametes of the decedent, within 2 years of the death of the decedent. Any heir of the decedent whose interest in the succession of the decedent will be reduced by the birth of a child conceived shall have 1 year from the birth of such child within which to bring an action to disavow paternity. La. Rev. Stat. Ann. §9:126 states that an in-vitro fertilized human ovum is a biological human being that is not the property of the physician; the physician acts as an agent of fertilization, the facility which employs him, or the donors of the sperm and ovum. If the IVF patients express their identity, then their rights as parents as provided under the Louisiana Civil Code will be preserved. If the IVF patients fail to express their identity, then the physician shall be deemed to be temporary guardian of the in-vitro fertilized human ovum until adoptive implantation can occur. A court in the parish where the in-vitro fertilized ovum is located may appoint a curator, upon motion of the IVF patients, their heirs, or physicians who caused IVF to be performed, to protect the in-vitro fertilized human ovum's rights. La. Rev. Stat. Ann. §9:130 An in-vitro fertilized human ovum is a juridical person that cannot be owned by the patients undergoing IVF who owe it a high duty of care and prudent administration. If the IVF patients renounce, by notarial act, their parental rights for in-utero implantation, then the in-vitro fertilized human ovum shall be available for adoptive implantation in accordance with written procedures of the facility where it is housed or stored. The IVF patients may renounce their parental rights in favour of another married couple, but only if the other couple is willing and able to receive the in-vitro fertilized ovum. No compensation shall be paid or received by either couple to renounce parental rights. Constructive fulfilment of the statutory provisions for adoption in this state shall occur when a married couple executes a notarial act of adoption of the in-vitro fertilized ovum and birth occurs. La. Rev. Stat. Ann. §9:133 Inheritance rights will not flow to the in-vitro fertilized ovum as a juridical person, unless the in-vitro fertilized ovum develops into an unborn child that is born in a live birth, or at any other time when rights attach to an unborn child in accordance with law. As a juridical person, the embryo or child born as a result of IVF and in-vitro fertilized ovum donation to another couple does not retain its inheritance rights from the IVF patients.
Maryland	Md. Ann. Code art. 70, §83A, s 5-2B-10 Provides individuals with information on embryo adoption. Md. Ann. Code Business and Economic Development §5-2B-10 requires healthcare providers delivering fertility treatment to provide patients with the option to store, discard, donate embryos to research, donate embryos for adoption, or donate embryos to the fertility clinic for clinical purposes. Written consent is required for donation to research, and unused oocytes (eggs) may not be donated to state-funded research.
Massachusetts	Mass. Gen. Laws Chapter 111L states that a physician who provides a patient with IVF treatment must provide the patient with information sufficient to allow that patient to make an informed and voluntary choice regarding the disposition of any pre-implantation embryos or gametes remaining following the treatment. The physician must present the patient with the options of storing, donating to another person, donating for research purposes, or otherwise disposing of, or destroying, any unused pre-implantation embryos.
New Jersey	N.J. Stat. Ann. §26:2 Z-2 A person shall be presented with the option of storing any unused embryos, donating them to another person, donating the remaining embryos for research purposes, or other means of disposition.
New York	10 NYCRR 52-8.7 Embryos shall not be created for donation by fertilizing donor oocytes with donor semen, except at the request of a specific patient who intends to use such embryos for her own treatment. Embryos shall not be created using semen or oocytes of client-depositors or directed donors who are blood relatives of the other gamete provider to a degree that their sexual contact would constitute incest under New York State law.

	10 NYCRR 52-8.8 (a) Reproductive tissue banks shall obtain written informed consent from the donor for participation in the donation program, after the director or a designee has provided information to the donor on the procedures for collection, storage and use of semen, oocytes or embryos, and the risks of any drugs, surgical procedures, or anaesthesia administered. The rules include criteria for informed consent.
North Dakota	N.D. Cent. Code §14-20-64 Defines the effect of dissolution of marriage or withdrawal of consent regarding embryo donation. N.D. Cent. Code §14-18-03; 14-18-07 clarifies legal parentage of a child conceived after invalidity or annulment of marriage or death of spouse.
Ohio	Ohio Rev. Code Ann. 3111.97 Defines parental rights in embryo donation and adoption.
Oklahoma	Okla. Stat. tit. 10, §554 Any child or children born as a result of a heterologous oocyte donation shall be considered for all legal intents and purposes, the same as a naturally conceived legitimate child of the husband and wife which consent to and receive an oocyte pursuant to the use of the technique of heterologous oocyte donation. Okla. Stat. tit. 10, §555 An oocyte donor shall have no right, obligation or interest with respect to a child born as a result of a heterologous oocyte donation from such donor. A child born as a result of a heterologous oocyte donation shall have no right, obligation or interest with respect to the person who donated the oocyte, which resulted in the birth of the child. Okla. Stat. tit. 10, §556 authorizes human embryo donations and transfers. The law requires certain techniques to be used by physicians. It requires written consents and confidentiality. This statute relates to children; authorizes human embryo donations and transfers; requires performance of certain techniques by physicians; prohibits certain activities; requires written consents; specifies certain procedures; requires confidentiality; specifies legal status of certain persons; provides that certain donations and transfers are not trafficking in children; specifies conditions; provides for codification; and declares an emergency.
Texas	Tex. Family Code Ann. §160.001, et seq. creates the Uniform Parentage Act and describes various aspects of determination of maternity and paternity as well as parentage. The law requires a man and woman to sign consent to assisted conception. If the father does not sign, however, it does not necessarily mean that he is not the legal father.
Virginia	Va. Code §20-158(3)(B) clarifies legal parentage of a child conceived after death of or divorce from a spouse.
Washington	Wash. Rev. Code §26.26 creates the Uniform Parentage Act and clarifies legal interpretation of parentage of a child of assisted reproduction, including in the event of divorce or death.
Wyoming	Wyo. Stat. §14-2-401, et seq. creates the Wyoming Uniform Parentage Act. The law defines 'assisted reproduction' and includes intrauterine insemination, donation of eggs, donation of embryos, IVF and transfer of embryos, and intracytoplasmic sperm injection in the definition.

Table S2: Human cloning laws

Updated January 2008

State	*Statute citation*	*Summary*	*Prohibits reproductive cloning*	*Prohibits therapeutic cloning*	*Expiration*
Arizona	HB 2221 (2005)	Bans the use of public monies for reproductive or therapeutic cloning.	Prohibits use of public monies	Prohibits use of public monies	
Arkansas	§20-16-1001 to 1004	Prohibits therapeutic and reproductive cloning; may not ship, transfer or receive the product of human cloning; human cloning is punishable as a Class C felony and by a fine of not less than $250,000 or twice the amount of pecuniary gain that is received by the person or entity, whichever is greater.	Yes	Yes	
California	Business And Professions §16004-5 Health & Safety §24185, §24187, §24189, §12115-7	Prohibits reproductive cloning; permits cloning for research; provides for the revocation of licenses issued to businesses for violations relating to human cloning; prohibits the purchase or sale of ovum, zygote, embryo, or fetus for the purpose of cloning human beings; establishes civil penalties	Yes	No	
Connecticut	2005 SB (Senate Bill) 934	Prohibits reproductive cloning, permits cloning for research; punishable by not more than $100,000 or imprisonment for not more than 10 years, or both.	Yes	No	
Indiana	2005 Senate Enrolled Act No. 268	Prohibits reproductive and therapeutic cloning; allows for the revocation of a hospital's license involved in cloning; specifies that public funds may not be used for cloning; prohibits the sale of a human	Yes	Yes	

		ovum, zygote, embryo or fetus.			
Iowa	707B.1 to 4	Prohibits human cloning for any purpose; prohibits transfer or receipt of a cloned human embryo for any purpose, or of any oocyte, human embryo, fetus, or human somatic cell, for the purpose of human cloning; human cloning punishable as Class C felony; shipping or receiving punishable as aggravated misdemeanour; if violation of the law results in pecuniary gain, then the individual is liable for twice the amount of gross gain; a violation is grounds for revoking licensure or denying or revoking certification for a trade or occupation.	Yes	Yes	
Maryland	2006 SB 144	Prohibits reproductive cloning; prohibits donation of oocytes for state-funded stem cell research but specifies that the law should not be construed to prohibit therapeutic cloning; prohibits purchase, sale, transfer or obtaining unused material created for IVF that is donated to research; prohibits giving valuable consideration to another person to encourage the creation of IVF materials solely for the purpose of research; punishable by up to 3 years in prison; a maximum fine of $50,000 or both.	Yes	No	
Massachusetts	2005 SB 2039	Prohibits reproductive cloning; permits cloning for research; prohibits a person from purchasing, selling, transferring, or	Yes	No	

		obtaining human embryonic, gametic or cadaveric tissue for reproductive cloning; punishable by imprisonment in jail or correctional facility for not less than 5 years or more than 10 years or by imprisonment in state prison for not more than 10 years or by a fine of up to 1 million dollars; in addition a person who performs reproductive cloning and derives financial profit may be ordered to pay profits to Commonwealth.			
Michigan	§§333.2687-2688, §§333.16274-16275, 333.20197, 333.26401-26403, 750.430a	Prohibits human cloning for any purpose and prohibits the use of state funds for human cloning; establishes civil and criminal penalties.	Yes	Yes	
Missouri	§1.217	Bans use of state funds for human cloning research that seeks to develop embryos into newborn children.	Prohibits the use of state funds	No	
New Jersey	§2C:11A-1, §26:2Z-2	Permits cloning for research; prohibits reproductive cloning, which is punishable as a crime in the first degree; prohibits sale or purchase, but not donation, or embryonic or fetal tissue, which is punishable as a crime in the third degree and a fine of up to $50,000.	Yes	No	
North Dakota	§12.1-39	Prohibits reproductive and therapeutic cloning; transfer or receipt of the product of human cloning; transfer or receipt, in whole or in part, any oocyte, human embryo, human fetus, or human somatic cell, for the purpose of human cloning; cloning or attempt to clone punishable as a class C	Yes	Yes	

		felony; shipping or receiving violations punishable as class A misdemeanour.			
Rhode Island	§23-16.4-1 to 4-4	Prohibits human cloning for the purpose of initiating a pregnancy; for a corporation, firm, clinic, hospital, laboratory, or research facility, punishable by a civil penalty punishable by fine of not more than $1,000,000, or in the event of pecuniary gain, twice the amount of gross gain, whichever is greater; for an individual or an employee of the firm, clinic, hospital, laboratory, or research facility acting without the authorization of the firm, clinic, hospital, or research facility, punishable by a civil penalty punishable by fine of not more than $250,000, or in the event of pecuniary gain, twice the amount of gross gain, whichever is greater.	Yes	No	July 7, 2010
South Dakota	§34-14-27	Prohibits reproductive and therapeutic cloning; transfer or receipt of the product of human cloning; transfer or receipt, in whole or in part, any oocyte, human embryo, human fetus, or human somatic cell, for the purpose of human cloning; cloning or attempt to clone is punishable as a felony and a civil penalty of two thousand dollars or twice the amount of gross gain, or any intermediate.	Yes	Yes	
Virginia	§32.1-162.32-2	Prohibits reproductive cloning; may prohibit therapeutic cloning but it is unclear because	Yes	Unclear	

		human being is not defined in the definition of human cloning; human cloning defined as the creation of, or attempt to, create a human being by transferring the nucleus from a human cell from whatever source into an oocyte from which the nucleus has been removed; also prohibits the implantation or attempted implantation of the product of somatic cell nuclear transfer into an uterine environment so as to initiate a pregnancy; the possession of the product of human cloning; and the shipping or receiving of the product of a somatic cell nuclear transfer in commerce for the purpose of implantation of such product into an uterine environment so as to initiate a pregnancy. The law establishes civil penalty not to exceed $50,000 for each incident.			

Table S3: Stem cell research

Updated January 2008

State/Jurisdiction Statute Section	*Specifically permits research on the fetus or embryo*	*Restricts research on the aborted fetus or embryo*	*Consent provisions to conduct research on thefetus or embryo*	*Restricts research on the fetus or embryo resulting from sources other than abortion*	*Restrictions of purchase or sale of human tissue for research*
Arizona §§36-2302, 2303	No	Yes, prohibits research on aborted living/non-living embryo or fetus.	No	Yes, prohibits the use of public monies for cloning for research.	No
Arkansas §§20-17-802, 20-16-1001 to 1004	No	Yes, prohibits research on an aborted live fetus.	Yes, consent to conduct research on an aborted fetus born dead.	Yes, prohibits research on cloned embryos.	Yes, prohibits sale of fetus or fetal tissue.
California Health and Safety 2004 Proposition 71 §§123440, 24185, 12115-7, 125300-320	Yes, permits research on adult and embryonic stem cells from any source.	Yes, prohibits research on an aborted live fetus.	Yes, consent to donate IVF embryo to research.	Prohibits sale of embryos and oocytes; prohibits payment in excess of the amount of reimbursement of expenses to be made to any research subject to encourage her to produce human oocytes for the purposes of medical research.	Yes, prohibits sale for the purpose of reproductive cloning or for stem cell research.
Connecticut §§4-28e; 19a-32d et seq.	Yes, on embryos before gastrulation (a process during embryonic development).	No	Yes, consent to donate IVF embryo to research.	No	Yes, prohibits payment for embryos, embryonic stem cells unfertilized eggs or sperm donated following IVF treatment..
Florida §390.0111	No	Yes, prohibits on aborted live fetus.	No	No	No
Illinois 720 ILCS 510/6, 510/12.1 Executive Order 6 (2005);410 ILCS 110/1 et seq.	Yes, permits research on embryonic stem cells, embryonic germ cells and adult stem cells from any source.	Yes, prohibits research on aborted living and non-living fetus.	Yes, written consent to perform research on cells or tissues from a dead fetus other than from an abortion.	Yes, prohibits research on the fetus or fertilized embryo; prohibits funding under E.O. 6 (2005) of research on fetuses from induced abortions and the creation of embryos through the combination of gametes	Yes, prohibits sale of fetus and fetal tissue; prohibits purchase or sale of embryonic or fetal cadaveric tissue for research but permits reimbursement for removal, storage and

				solely for the purpose of research.	transportation for research.
Indiana §35-46-5-1, 16-18-2-5.5	Yes, permits fetal stem cell research on placenta, cord blood, amniotic fluid or fetal tissue.	Yes, prohibits research on aborted living and non-living embryo or fetus.	Yes, consent required for fetal stem cell research.	Yes, prohibits research on cloned embryos.	Yes, prohibits sale of human ovum, zygote, embryo or fetus.
Iowa §§707C.4	Yes, ensures that Iowa patients have access to stem cell therapies and cures; Iowa researchers may conduct stem cell research.	No	No	No	Yes, prohibits transfer or receipt of the product of human reproductive cloning.
Kentucky §436.026	No	No	No	No	Yes, prohibits sale of fetus and fetal tissue.
Louisiana §14: 87.2	No	No	No	Yes, prohibits research on the fetus, embryo *in utero*, and in-vitro fertilized embryo.	No
Maine 22§1593	No	No	No	Yes, prohibits research on fetus or embryo born or extracted alive; only applies to in-vitro fertilized embryos after implantation.	Yes, prohibits sale of fetus and fetal tissue.
Maryland 83A§5-2B-01 et seq.	Yes, permits research on adult and embryonic stem cells.	No	Yes, written consent to donate unused IVF material to research.	Yes, prohibits donation of unused oocytes for state-funded stem cell research; cloning of an organism beyond the embryonic stage is prohibited.	Yes, prohibits valuable consideration for the donation or production of IVF material.
Massachusetts 112§12J, 2005 SB 2039	Yes, on embryos that have not experienced more than 14 days of development (not including days frozen).	Yes, prohibits research on embryo and live fetus.	Yes, written consent to perform research on a dead fetus and informed consent to donate egg, sperm, or unused preimplantation embryos created for IVF.	Yes, prohibits research on live embryo or fetus; also prohibits creation of fertilized embryo solely for research.	Yes, prohibits sale of neonate, embryo or fetus for illegal purposes; prohibits sale of embryos, gametes or cadaveric tissue for research.
Michigan	No	Yes, live embryo/	Yes, written consent of	Yes, prohibits research on a	No

§§333.2687-2688, §§333.16274-16275, 333.20197, 333.26401-26403, 750.430a		fetus	mother to donate dead embryo, fetus or neonate to research.	live embryo or fetus, or cloned embryo.	
Minnesota §§145.421, 422	No	No	No	Yes, prohibits research on a live embryo or fetus up to 265 days after fertilization.	Yes, permits the sale and purchase of cell culture lines from non-living human conceptus.
Missouri §§188.036, 037	No	Yes, prohibits research on a fetus alive before abortion.	No	No	Yes, prohibits receipt of valuable consideration for aborted fetal organs or tissue.
Montana §50-20-108(3)	No	Yes, prohibits research on a live fetus.	No	No	No
Nebraska §§28-342, 346, 71-7606	No	Yes, prohibits research on aborted live fetus or the use of state funds for research on fetal tissue obtained from an abortion.	No	Yes, limits the use of state funds for embryonic stem cell research; restrictions only apply to state healthcare cash funds provided by tobacco settlement dollars.	Yes, prohibits sale, distribution or donation of viable aborted child.
New Hampshire §§168-B:1, 15	No	No	No	Yes, prohibits the maintenance of a unfrozen fertilized pre-embryo past 14 days.	Yes
New Jersey C.26:2Z-1 et seq.; C.2C:11A-1	Yes	No	Yes	No	No
New Mexico §24-9A-1, 3, 5	No	No	No	Yes, prohibits research on a fetus or embryo born or extracted alive, only applies to in-vitro fertilized embryos after implantation.	Yes, prohibits abortion for the purpose of selling the fetus to researchers.
New York Public Health Law Article 2, Title 5A	Yes, permits research on adult and embryonic stem cells from any source.	No	No		
North Dakota §14-02.2-01, 2; 2003 HB 1424	No	Yes, prohibits research on a living or non-living embryo	Yes, requires consent to conduct research on a non-living fetus or	Yes, prohibits research on a fetus born or extracted alive; cloned embryos.	Yes, prohibits the sale of a fetus to be used for illegal purposes.

		or fetus.	embryo other than from an abortion.		
Ohio §2919.14	No	Yes, prohibits research on a living/non-living embryo or fetus.	No	No	Yes, prohibits sale of fetus or fetal remains from an abortion.
Oklahoma 63 §1-735	No	Yes, prohibits research on a fetus/embryo	No	No	Yes, prohibits sale of fetus or fetal remains.
Pennsylvania 18 §§3203, 3216	No	Yes, prohibits research on a live embryo or fetus.	Consideration may not be given to mothers consenting to research; in cases involving abortion, consent must be provided after decision to abort.	No	Yes, consideration may not be given to mothers consenting to research or other transferring tissue except for expenses involved in actual retrieval and , storage, etc.
Rhode Island §11-54-1	No	No	Yes	Yes, prohibits research on a fetus or embryo born or extracted alive; only applies to in-vitro fertilized embryos after implantation.	Yes, prohibits sale of neonate, embryo or fetus for illegal purposes.
South Dakota §§34-14-16, 17, 20; 34-23A-17	No	Yes, prohibits research on a living or non-living embryo or fetus.	No	Yes, prohibits research on an embryo outside of a woman's body; research on cells or tissues derived from an embryo outside a woman's body.	Yes, prohibits sale of embryo.
Tennessee §39-15-208	No	No	Yes, consent required to conduct research on an aborted fetus.	No	Yes, prohibits sale of aborted fetus.
Texas Penal Code §48.02	No	No	No	No	Prohibits sale of fetus and fetal tissue.
Utah §§76-7-301, 310	No	No	No	Yes, prohibits research on a live fetus, fertilized embryo after implantation.	Yes, prohibits sale of fetus or fetal tissue; also prohibits sale of live unborn children, which is not defined, but are referred to in abortion statute.

Virginia §32.1-162.32-2	No	No	No	May prohibit research on a cloned embryo or fetus.	Yes, prohibits shipping or receiving of the product of human cloning for commerce.
Wyoming §35-6-115	No	No	No	No	Yes, prohibits sale, distribution or donation of live or viable aborted child, defined to include embryos, for experimentation.

Table S4: State laws related to insurance coverage for infertility treatment

Updated June 2014

Since the 1980s, **15 states—Arkansas, California, Connecticut, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Montana, New Jersey, New York, Ohio, Rhode Island, Texas and West Virginia—**have passed laws that require insurers to either cover or offer coverage for infertility diagnosis and treatment. **Thirteen states** have laws that require insurance companies to cover infertility treatment. **Louisiana** and **New York** prohibit the exclusion of coverage for a medical condition otherwise covered solely because the condition results in infertility. **Two states—California and Texas—**have laws that require insurance companies to offer coverage for infertility treatment. **Utah** requires insurers providing coverage for maternity benefits to also provide an indemnity benefit for adoption or infertility treatments. While most states with laws requiring insurance companies to offer or provide coverage for infertility treatment include coverage for in vitro fertilization, **California, Louisiana,** and **New York** have laws that specifically exclude coverage for the procedure.

State	Summary of Statutes
Alabama	
Alaska	
American Samoa	
Arizona	
Arkansas	**Ark. Stat. Ann. § 23-79-510** specifies that the Arkansas Comprehensive Health Insurance Pool shall not include coverage for any expense or charge for in vitro fertilization, artificial insemination or any other artificial means used to cause pregnancy. **Ark. Stat. Ann. § 23-85-137 and § 23-86-118 (1987, 2011)** require accident and health insurance companies to cover in vitro fertilization. Services and procedures must be performed at a facility licensed or certified by the Department of Health and conform to the guidelines and minimum standards of the American College of Obstetricians and Gynecologists and the American Society for Reproductive Medicine. (2011 SB 213)
California	**Cal. Health & Safety Code § 1374.55** and **Cal. Insurance Code § 10119.6** require specified group health care service plan contracts and health insurance policies to offer coverage for the treatment of infertility, except in vitro fertilization. The law requires every plan to communicate the availability of coverage to group contractholders. The law defines infertility, treatment for infertility and in vitro fertilization. The law clarifies that religious employers are not required to offer coverage for forms of treatment that are inconsistent with the organization's religious and ethical principles. The law was amended by **2013 Cal. Stats., Chap. 644** (AB 460) to specify that treatment of infertility shall be offered and, if purchased, provided without discrimination on the basis of age, ancestry, color, disability, domestic partner status, gender, gender expression, gender identity, genetic information, marital status, national origin, race, religion, sex, or sexual orientation.
Colorado	
Connecticut	**Conn. Gen. Stat. § 38a-509 and § 38a-536 (1989, 2005)** require that health insurance organizations provide coverage for medically necessary expenses in the diagnosis and treatment of infertility, including in vitro fertilization procedures. Infertility, in this case, refers to an otherwise healthy individual who is unable to conceive or produce conception

	or to sustain a successful pregnancy during a one-year period. Amended in 2005 to provide an exemption for coverage that is contrary to the religious beliefs of an employer or individual.
Delaware	
District of Columbia	
Florida	
Georgia	
Guam	
Hawaii	**Hawaii Rev. Stat. § 431:10A-116.5 and § 432.1-604 (1989, 2003)** require all accident and health insurance policies that provide pregnancy-related benefits to also include a one-time only benefit for outpatient expenses arising from in vitro fertilization procedures. In order to qualify for in vitro fertilization procedures, the couple must have a history of infertility for at least five years or prove that the infertility is a result of a specified medical condition.
Idaho	
Illinois	**Ill. Rev. Stat. ch. 215, § 5/356m (1991, 1996)** requires certain insurance policies that provide pregnancy-related benefits to provide coverage for the diagnosis and treatment of infertility. Coverage includes in vitro fertilization, uterine embryo lavage, embryo transfer, artificial insemination, gamete sperm artificial intrafallopian tube transfer, zygote intrafallopian tube transfer and low tubal ovum transfer. Coverage is limited to four completed oocyte retrievals, except if a live birth follows a completed oocyte retrieval, then two more completed oocyte retrievals are covered. (1996 Ill. Laws, P.A. 89-669)
Indiana	
Iowa	
Kansas	
Kentucky	
Louisiana	**La. Rev. Stat. Ann. § 22:1036** prohibits the exclusion of coverage for the diagnosis and treatment of a medical condition otherwise covered by the policy, contract, or plan, solely because the condition results in infertility. The law does not require insurers to cover fertility drugs, in vitro fertilization or other assisted reproductive techniques, reversal of a tubal litigation, a vasectomy, or any other method of sterilization. (2001 La. Acts, P.A. 1045)
Maine	
Maryland	**Md. Insurance Code Ann. § 15-810 (2000)** amends the original 1985 law and prohibits certain health insurers that provide pregnancy-related benefits from excluding benefits for all outpatient expenses arising from in vitro fertilization procedures performed. The law clarifies the conditions under which services must be provided, including a history of infertility of at least a 2-year period and infertility associated with one of several listed medical conditions. An insurer may limit coverage to three in vitro fertilization attempts per live birth, not to exceed a maximum lifetime benefit of $100,000. The law clarifies

	that an insurer or employer may exclude the coverage if it conflicts with the religious beliefs and practices of a religious organization, on request of the religious organization. Regulations that became effective in 1994 exempt businesses with 50 or fewer employees from having to provide the IVF coverage. (2000 Md. Laws, Chap. 283; H.B. 350) **Md. Health General Code Ann. § 19-701 (2000)** includes family planning or infertility services in the definition of health care services.
Massachusetts	**Mass. Gen. Laws Ann. ch. 175, § 47H, ch. 176A, § 8K, ch. 176B, § 4J, ch. 176G, § 4 and 211 Code of Massachusetts Regulations 37.00 (1987, 2010)** require general insurance policies, non-profit hospital service corporations, medical service corporations and health maintenance organizations that provide pregnancy-related benefits to also provide coverage for the diagnosis and treatment of infertility, including in vitro fertilization. This law was amended in 2010 to change the definition of "infertility" to be a condition of an individual who is unable to conceive or produce conception during a period of one year if the female is under the age of 35, or during a period of six months if the female is over the age of 35. If a person conceives but cannot carry that pregnancy to live birth, the period of time she attempted to conceive prior to achieving that pregnancy shall be included in the calculation of the one year or six month period. (SB 2585)
Michigan	
Minnesota	**Minn. Stat. Ann. § 256B.0625** specifies that medical assistance shall not provide coverage for fertility drugs when specifically used to enhance fertility.
Mississippi	
Missouri	
Montana	**Mont. Code Ann. § 33-22-1521 (1987)** revises certain requirements of Montana's Comprehensive Health Association, the state's high-risk pool, and clarifies that covered expenses do not include charges for artificial insemination or treatment for infertility. (SB 310) **Mont. Code Ann. § 33-31-102 et seq. (1987)** requires health maintenance organizations to provide basic health services on a prepaid basis, which include infertility services. Other insurers are exempt from having to provide the coverage.
Nebraska	
Nevada	
New Hampshire	
New Jersey	**N.J. Stat. Ann. § 17:48-6x, § 17:48A-7w, § 17:48E-35.22 and § 17B:27-46.1x** (2001) require health insurers to provide coverage for medically necessary expenses incurred in diagnosis and treatment of infertility, including medications, surgery, in vitro fertilization, embryo transfer, artificial insemination, gamete intrafallopian transfer, zygote intrafallopian transfer, intracytoplasmic sperm injection and four completed egg retrievals per lifetime of the covered person. The law includes some restrictions as well as a religious exemption for employers that provide health coverage to fewer than 50

	employees. (SB 1076)
New Mexico	
New York	**N.Y. Insurance Law § 3216 (13), § 3221 (6) and § 4303(1990, 2002, 2011)** prohibit individual and group health insurance policies from excluding coverage for hospital care, surgical care and medical care for diagnosis and treatment of correctable medical conditions otherwise covered by the policy solely because the medical condition results in infertility. The laws were amended in 2002 to require certain insurers to cover infertility treatment for women between the ages of 21 and 44 years. The laws exclude coverage for in vitro fertilization, gamete intrafallopian tube transfers and zygote intrafallopian tube transfers. The laws were amended again in 2011 by **N.Y. laws, Chap. 598** to require every policy that provides coverage for prescription fertility drugs and requires or permits prescription drugs to be purchased through a network participating mail order or other non-retail pharmacy to provide the same coverage for prescription fertility drugs that are purchased from a network participating non-mail order retail pharmacy provided that the network participating non-mail order retail pharmacy agrees in advance to the same reimbursement amount and the same terms and conditions that the insurer has established for a network participating mail order or other non-retail pharmacy. The policy is prohibited from imposing additional fees, co-payments, co-insurance, deductibles or other conditions on any insured person who elects to purchase prescription fertility drugs through a non-mail order retail pharmacy. (2011 AB 8900) **N.Y. Public Health Law § 2807-v (2002)** creates a grant program to improve access to infertility services, treatments and procedures from the tobacco control and insurance initiatives pool.
North Carolina	
North Dakota	
Ohio	**Ohio Rev. Code Ann. § 1751.01 (A)(1)(h) (1991)** requires health maintenance organizations (HMOs) to provide basic health care services, which are defined to include infertility services, when medically necessary.
Oklahoma	
Oregon	
Pennsylvania	
Puerto Rico	
Rhode Island	**R.I. Gen. Laws § 27-18-30, § 27-19-23, § 27-20-20 and § 27-41-33 (1989, 2007)**require any contract, plan or policy of health insurance (individual and group), nonprofit hospital service, nonprofit medical service and health maintenance organization to provide coverage for medically necessary expenses for the diagnosis and treatment of infertility. The law clarifies that the co-payments for infertility services not exceed 20 percent. Infertility is defined as the condition of an otherwise healthy married individual who is unable to conceive or produce conception during a period of one year. Rhode Island includes IVF coverage. Amended in 2007 to increase the age of coverage for infertility

	from forty (40) to forty-two (42) and redefines infertility to mean a woman who is unable to sustain pregnancy during a period of one year. (2007 R.I. Pub. Laws, Chap. 411, SB 453)
South Carolina	
South Dakota	
Tennessee	
Texas	**Tex. Insurance Code Ann. § 1366.001 et seq. (1987, 2003)** requires that all health insurers offer and make available coverage for services and benefits for expenses incurred or prepaid for outpatient expenses that may arise from in vitro fertilization procedures. In order to qualify for in vitro fertilization services, the couple must have a history of infertility for at least five years or have specified medical conditions resulting in infertility. The law includes exemptions for religious employers.
U.S. Virgin Islands	
Utah	**2014 Utah Laws, Chap. 353** (HB 347) amended **§ 31A-22-610.1**, which requires insurers that provide coverage for maternity benefits to also provide an adoption indemnity benefit of $4,000 for a child placed for adoption with the insured within 90 days of the child's birth. The law was amended to allow an enrollee to obtain infertility treatments rather than seek reimbursement for an adoption. If the policy offers optional maternity benefits, then it must also offer coverage for these indemnity benefits under certain circumstances.
Vermont	
Virginia	
Washington	
West Virginia	**W. Va. Code § 33-25A-2 (1995)** amends the 1997 law and requires health insurers to cover basic health care services, which include infertility services. Applies to health maintenance organizations (HMOs) only.
Wisconsin	
Wyoming	

Note: List may not be comprehensive, but is representative of state laws that exist. NCSL appreciates additions and corrections.