Chapter Two

Policy, Politics in Assisted Reproduction

In 1978 Britain became the first country to achieve a human birth through in vitro fertilization (IVF). Four years later the British government appointed a committee: “to examine the social, ethical and legal implications of recent, and potential developments in the field of human assisted reproduction.”

After considerable study and debate the Committee, chaired by philosopher Mary Warnock, issued a voluminous set of legislative recommendations. But contrary to the Committee’s expectations, another five years passed before the Government brought its Embryology Bill to Parliament (1989). The measure became law the following year. Subsequently, only minor changes were made until 2008 when Parliament substantially overhauled the regulations.

By a lucky coincidence I was on sabbatical in London in the fall of 1989 just as the Government announced its plan to present its Bill to Parliament so I was able to witness debate on the Bill. The following account is drawn in part from firsthand experience but largely from published commentaries on the legislation and its influence on other local, national, and transnational efforts to regulate the rapidly growing assisted reproduction industry.

The British regulatory scheme prompted the formation of numerous national and international policy panels and has often been invoked as a prototype for regulation of assisted reproductive technologies (ART). British political controversy and experience under regulation reveal many of the hurdles that other countries experience (and occasionally overcome) as they grapple with regulatory oversight of assisted reproduction. For that controversy incorporated virtually all of the moral and social issues that were to surface in other countries. Of course, no other country's experience is wholly comparable. National traditions and institutional structures vary. Particular political alignments influence the comparative weight of affected interest groups. But as technological developments traverse national boundaries and the capacity to provide a full panoply of reproductive innovations expands across the globe, the comparative weight of local institutions diminishes and transnational issues become more prominent. Globalizing influences-- including capital mobility, free trade, cheap transportation, and rapid internet communication-- weaken the ability of national governments to control the industry.

Nonetheless, the complexities of the British legislative process are relevant to other efforts to rein in the burgeoning assisted reproductive technology industry. First, I describe and evaluate British controversy that led to the first comprehensive regulation of assisted reproduction; next I examine the contrasting experience of the U.S. and note the regulatory experiences of other countries, particularly

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1 M.G. Warnock. 1985, vi.

2 For a detailed chronology of regulatory changes over the years since passage of the original legislation see http://www.hfea.gov.uk/134.html
within the European Union. Then I turn to transnational issues including: political and social structures in which the industry is embedded, exclusion of centrally affected groups from policymaking bodies, and manipulation of the language of reproduction by special interests that have the power to shape the parameters of regulatory oversight and control the industry. Finally, I suggest correctives to more adequately meet the needs of infertile people and others whose fertility is at risk.

**Framing debate: British controversy**

Many knowledgeable Britons considered the Warnock Committee’s call for regulation ill-timed. For some it was too early, for others already too late.³ Some thought consensus about regulation would have been more easily achieved had the committee convened four years earlier before the ascendency of the religious right and invited public comment before issuing any report.⁴ Others, including some utilitarians, argued that since no public consensus on major issues had emerged yet, regulatory recommendations would only enshrine in law the inconsistencies of public sentiment, so it would be better to wait until a set of socially approved recommendations emerged which would be surer to promote social utility—to them, the key ethical consideration. Both groups, though, agreed that it was consensus that mattered. Mary Warnock, chair of the committee that drafted the report, also a philosopher, countered the utilitarian contention. She argued that Parliament could rely on the public’s felt responses and intuitive revulsion to specific technological innovations. The principled consistency utilitarians seek, she insisted, only promotes “insensitivity to the kind of inhibitions and scruples which are at the center of morality.”⁵ Her supporters emphasized the most “disgusting” case scenarios: implantation of human embryos in animals and the creation of chimeras. Swift legislation, they insisted, was imperative to squelch such practices.

Earlier commissions charged with drafting legislation on moral issues had bypassed the search for substantive consensus and followed a procedural route, distinguishing between the public realm where morality is enforced by law and a private sphere within which individuals are left free to act on their own preferences.⁶ The Warnock Committee elected to incorporate a fuller set of substantive values. Debate on the Embryology Bill demonstrated to all who were not already persuaded that the anticipated consensus had failed to materialize. The parliamentary process opened up deep cleavages in British opinion. The Warnock Commission itself, contributed to the polarization of opinion.

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³ For over a decade before establishment of the Warnock Commission articles had been circulating in scientific journals that raised ethical and social questions about the new techniques. Initial moral objections to IVF focused on fears that laboratory manipulation of embryos might lead to serious developmental abnormalities and innovative forms of surrogacy.


Ensuing debate showed that neither side fully recognized either the multiple sites of power at the source of conflict or the irreconcilability of moral ideologies at work within the regulatory controversy—one supported by the apparatus of Government and the medical profession and another mounted by the religious right. Nor did they recognize other interests that lacked access and voice. In the end, both those who argued for delay and those who sought immediate action were partially vindicated and partially discredited. Warnock, herself, eventually admitted that the notion of a consensus morality is an untenable myth.

The parliamentary process opened up deep cleavages in British opinion. From the time the committee reported until their recommendations were introduced to Parliament, conflict intensified and stiffened around antagonistic moral ideologies. The Report’s framing and ordering of moral and scientific issues added to the divisions. It identified ‘the value of human life’ as the most significant issue, focused on a traditional patriarchal construction of family, assumed that the aim of embryo research was solely the alleviation of infertility, took little account of health risks to women undergoing IVF, and neglected newer technological developments which were growing in prominence. During debate, older unresolved moral controversies, such as abortion and donor insemination, became intertwined with newer problems, including genetic screening and pre-implantation diagnosis that call for different responses.

The leading medical organizations interested in pursuing embryo research grasped the initiative. Medical researchers courted members of Parliament, escorted them around their labs, and lectured them on the vital importance of their research. They organized collectively and established a voluntary body incorporating their own guidelines that implemented informally certain recommendations of the Warnock Report, namely the licensing of clinics and the collection of data relating to embryo research and laboratory fertilization. Through these measures the medical profession sought to protect a controversial area of scientific activity by displaying a semblance of control and establishing a prototype for the statutory licensing authority to be established by legislation. These factors are closely interrelated.

The voluntary body took under its purview newly emerging practices that were generating moral and social controversy because they involved significant medical risk: the number of ova or embryos transferred in a single IVF cycle, the donation of ova by known donors, and multi-fetal pregnancy reduction following the use of fertility enhancing drugs. Though this body had no legal authority or powers of enforcement beyond the withdrawal of a clinic's license, many presumed that peer pressure would suffice to insure compliance with its guidelines. But the allure of commercial success proved more powerful than the disapproval of peers. Clinics resented this quasi-legitimate body’s intrusion into their ‘clinical judgment’ and sought to divert public discussion from social and political issues requiring collective management to clinical freedom to manage individual cases without outside interference. They claimed that restriction on the number of embryos transferred would reduce the chances of individual women to achieve pregnancy. However, widespread awareness of the economic rewards sown by private clinics led others to wonder whose interests were being served under the banner of unrestricted freedom of clinical judgment.

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7 Warnock, op. cit., note 1, p. xvi.

8 Some enthusiastically supported all embryo research within fourteen days after fertilization. Others opposed all research, a third group was willing to permit research only for the benefit of a specific embryo, and still others sought to limit research to embryos fertilized in the course of treatment.

9 Ian Craft, director of Humana's fertility unit, was particularly vocal in this debate, which revealed that some
Despite such objections, the medical profession succeeded in putting its own institutional stamp on IVF technology well before the establishment of formal oversight. Its members were also able to influence the practice and expectations of researchers and these influences would endure. The organizational structures and procedures of the informal body provided a model for the statutory body that would have expanded enforcement powers.\textsuperscript{10} On the eve of legislation the informal authority renamed itself the Interim Licensing Authority (ILA), a move which further secured its identity as the regulative body described in the Warnock Report and the Embryology Bill. Since all members of the ILA, both medical and lay, had been selected by the sponsoring medical bodies, their continuing influence was assured.\textsuperscript{11} Clearly, the ILA was a key participant in the pro-research lobby pressuring Parliament. Their tactics, however, were in part reactive.

The intensely adversarial character of the debate had already been established long before the medical profession organized its lobbying campaign. While the Government waited for consensus to emerge before presenting its Bill to Parliament, opponents of the Warnock Committee's recommendations seized the initiative. Within a year after the Report, they introduced into Parliament the ‘Infant Life (Protection) Act’ linking the embryo research issue to abortion.\textsuperscript{12} Unlike earlier objections to IVF that focused on fears that laboratory manipulation might cause developmental abnormalities in embryos, backers of the new Bill claimed that embryo research violated the moral status of the early embryo irrespective of its subsequent development. They sought to ban all embryo research, permit IVF only after securing permission of government authorities, and require that all ova recovered during a cycle be transferred back to the woman undergoing treatment (despite risk to her and her fetus(es)). The large body of support for this Bill demonstrated the effectiveness of a new political strategy which broadened the base of the “new right”, a politically unaligned lobby composed of traditionalists and neo-conservative groups.\textsuperscript{13} By extending anti-abortion rhetoric to embryo research and appealing to the sanctity of human life from conception, the new right restructured the agenda for all subsequent debate and firmly fixed the status of the embryo as the prime moral issue. Through this strategy they forged the crucial link connecting moral priorities with the explosive issue of abortion.

The anti-research Bill won majority support in the House of Commons and failed to become law only because of technical limitations governing private member bills.\textsuperscript{14} Fortified by the near success of their Bill, organizations that opposed some of the Warnock Report recommendations (including the Catholic Church) continued to wage a militant, tightly organized and well-funded campaign to halt

\begin{itemize}
  \item The powers of the statutory body established by the legislation range over an area that encompasses the VLA.
  \item Price, \textit{op. cit.} note 7.
  \item A private member bill does not have the endorsement of the majority party.
\end{itemize}
embryo research, limit possession of an embryo to use by a specific woman, and recriminalize many abortions.\textsuperscript{15} So when the Government finally brought its own Bill to Parliament opponents were ready and waiting.

The framers of the Embryology Act also failed to anticipate technological advances during the years intervening between the Warnock Report and parliamentary consideration of their recommendations. They had not anticipated advancement in embryo retrieval techniques and genetic research. Shortly after the Government's Bill was presented to Parliament the first gene was successfully isolated. This achievement led researchers to shift emphasis from concern about childlessness to control of genetic anomalies. During debate supporters argued that if research on embryos were forbidden, families at risk for birth of disabled children would be denied a future benefit. In response, opponents emphasized the eugenic implications of techniques to diagnose genetic anomalies prenatally (PGD) and destroy affected embryos. Both the anti-abortion and disability rights lobbies condemned PGD. Feminists, both within and outside Parliament, questioned the tendency of this technology to reduce the complexity of decision-making to so few options. Despite such objections, supporters of the Bill were successful in turning embryo research into a principal argument favoring IVF. All objections were brushed aside as mere pretexts to advance the cause of the anti-abortion, anti-research lobby. So the Bill passed without significant revision and the Human Fertilisation and Embryology Authority (HFEA) came into being.

\textbf{Reflections on the British legislative debate}

Feminist reaction to the Warnock Report proposals and subsequent parliamentary debate casts in bold relief the partiality that dominated so many of the Committee's recommendations. Rosalind Petchesky captured succinctly the sense of outrage about the legislation which shaped the response of many feminists:

The Warnock Report may be read as an ideological document that lays down the terms of a neo-liberal, utilitarian "fertility contract".... imbedded in this very approach are fundamental assumptions about morality and family that undercut feminist understandings with respect to reproductive decisions, the position of women and alternative household arrangements....The lopsided preference given embryonic life over the lives of women patients...demonstrated a willful disregard of patient interests.\textsuperscript{16}

Priority was given to an ideological construction of family life that protected the fiction of a "natural family". Debate increasingly focused on what one commentator called “an over-individualized notion of the embryo” that ignores the site of its origins and the necessary conditions for its subsequent nurture and development.\textsuperscript{17} The narrow focus on embryonic life conflated two distinct uses of “human,” the descriptive and evaluative, dissolving distinction between the biological and social dimensions of embryonic life. It also reduced the carrying women to near invisibility. Once the status of the embryo as an autonomous entity became the debate's central focus, moral distinction between embryo research and abortion issues was dissolved. Those who favored abortion rights but had reservations about embryo

\textsuperscript{15} Since 1967 abortion up to 28 weeks was legally available with the consent of two physicians.

\textsuperscript{16} R.P. Petchesky, 1984, xv-xvi.

\textsuperscript{17} Yoxen, 175, \textit{op.cit.} note 8.
research could no longer be perceived as offering an alternative moral position. They were summarily dismissed as logically inconsistent. Only after the heat of debate subsided was it possible to recognize such maneuvers as “linguistic engineering” in the service of genetic engineering.\(^{18}\)

A recent commentator notes that “the social meaning of infertility often works both sides of the table, with those who support the growth of ART and those who oppose it invoking the same set of societal and cultural norms.”\(^{19}\) This observation has particular bearing on the PGD controversy. Most objectionable in British debate was the polarity of options on offer. Moral justification of limitations on patient access to PGD requires a more fine-grained approach to regulation that takes into account the circumstances of parents and their capacity to assimilate a disabled child into their family. Objective universal measures can’t fix boundaries between a “serious” genetic condition and a “trivial” one. An institutional body with generalized authority to examine people's reasons for requesting either pre- or post-implantation diagnosis would be preempting the decision-making authority of those who have ongoing responsibility for the consequences of such decisions. Moreover, unless that body also had the power and means to significantly expand social resources available to these families, they would be unjustly imposing burdens on people who lack the resources to bear them.

In intervening years the HFEA has worked to fill obvious gaps in the law and sought out the views of a broader spectrum of the public. They have conducted numerous surveys and sought opinions of diverse groups on issues such as sex selection and donation of ovarian tissue. However, wide disparity between the results of surveys by the HFEA and other associations demonstrates the difficulty of finding a representative public opinion in such a sensitive area.\(^{20}\) The HFEA has been criticized on several grounds: responding reactively to each uproar in the media rather than adopting a more proactive stance; rapidly moving from one development to another, and focusing on sensational issues at the frontier of science, thereby playing into the impression that the mundane aspects of ART procedures are morally unproblematic and require no further scrutiny; and moving technological development forward rapidly while using its presence as a regulatory authority to reassure the public. On the other hand, the Authority's accessibility to the public and its openness in communicating information about its activities has contributed to general acceptability of the regulatory framework and international interest in adapting its outlines to conditions in other countries. Still, the rapid pace of technological and clinical innovation raises serious questions about the adaptability of any regulatory structure as specific and detailed as the HFEA.

Despite subsequent technological developments and changing public attitudes, many original provisions of the 1990 Act remained in effect until 2008 when the Act was amended. The new legislation replaces the more conspicuously outdated regulations and speaks to many key objections to the original Act. The more obviously patriarchal provisions have been removed and provisions that discriminated against couples in same sex relationships and single mothers were modified. The 2008 Act takes into account a broad range of situations that became prominent in intervening years, such as sperm and egg

\(^{18}\) R. M. Morgan and D. Lee. 1991, 75.

\(^{19}\) M. Ryan. Test case for evolving methodologies in feminist bioethics. Signs 2009: 34, 808.

donation to third parties. Hopefully, other countries that follow the British prototype will emulate the HFEA's efforts to increase democratic participation in regulatory processes.

British legislative experience has brought to the fore issues that virtually any jurisdiction considering comprehensive regulation of assisted reproduction would need to consider. Admittedly, some moral concerns affect other European countries more deeply than Britain, such as the prospect of state sanctioned genetic intervention which refueled French and German anxieties about eugenics. Yet many concerns that surfaced in Britain are generalizable. The three distinct interests in evidence during British legislative debate: researchers, an anti-research/anti-abortion lobby, and government, are likely to surface virtually anywhere, though their relative strengths will vary. Some claimed that the British Government had little interest in how matters were resolved as long as closure was achieved, but subsequent events showed that the state does have distinctive interests to preserve. Though constructions of family vary, any government has an interest in maintaining stable patterns of family arrangements if only to prevent the burdens of child care from falling preponderantly on state agencies or overwhelming their court system with competing claims to parental rights. No democratic state is likely to push for comprehensive legislation if it can achieve its ends in less cumbersome ways. It is more apt to legislate in some areas (where the threat to prevailing family norms is more immediate) than in others (where reproductive innovations are more readily adaptable to existing norms).

I move now to consider a reaction to regulatory initiatives that falls at the opposite end of the spectrum from the kind of comprehensive scheme favored in Britain.

**The market model of choice: The U.S. approach**

Throughout continuing controversy about abortion and embryo research, ART practice in the U.S. has proliferated without any systematic oversight of procedures that manipulate gametes and embryos, techniques practiced on patients, or publically sponsored embryology and genetic research. The little ART regulation that does exist consists of a patchwork combining vaguely worded federal statutes, state medical licensing, laboratory accreditation, the voluntary practice guidelines of professional societies, and local institutional review boards. Some bioethicists refer to this uncoordinated patchwork as the Wild West of medicine. Efforts of professional groups and federal authorities to bring a semblance of order to the industry have yielded little success. In this section I chronicle and critique successive efforts to establish coordinated oversight of the U.S. ART industry.

In the same year as the first IVF birth in Britain, the U.S. government convened an Ethics Advisory Board to examine ethical issues raised by research on early embryos. Responses varied considerably. Two orientations predominated. Conservatives questioned any interventions that tampered with nature’s way of doing things or traditional social practices. Liberals leaned toward a laissez faire attitude. Some stressed the reproductive freedom of individual patients and the autonomy of researchers and clinicians. Others emphasized the importance of expanding knowledge about reproductive processes now and deferring moral assessment until the impact of new techniques became evident.

Conservative critics exerted a powerful influence over government policy and public sentiment. They feared that technological developments would yield too much power and control.

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21 Some anti-research MPs raised the specter of Nazism in their speeches, but opponents seldom took them seriously.
to researchers and special interests.\textsuperscript{22} They were instrumental in dissolving the Ethics Advisory Board and they continued to block efforts to create a permanent committee to produce legislation to federally fund research on the early embryo. As a consequence, private fertility services proliferated without the standards of safety and effectiveness that federal funding would have provided. When George W. Bush was elected in 2000, he established another Bioethics Council that gave conservatives even greater influence over mainstream bioethics. He issued a directive limiting federal funding for embryo research to cell lines that had already been created. Some were subsequently found to be contaminated; others were not viable.

As pressure from irate consumer groups escalated, tensions between academic medicine and commercial practitioners intensified. Congressional committees uncovered mounting instances of egregious clinical practices that exploited the vulnerability of infertile patients. Faced with increasing incursions by profit-driven venture capital enterprises, the American College of Obstetricians and Gynecologists (ACOG) and the group that was soon to become the American Society of Reproductive Medicine (ASRM), took steps to demonstrate their respectability and ward off mandatory regulation. In 1991 they established a voluntary professional group to address ethical issues in ART practice that superficially resembled the British medical organization that preceded the statutory licensing body. But, unlike that organization, it had no authoritative policy document to ground its recommendations and in 1998 it abruptly shut its doors.

Meanwhile, in response to numerous consumer complaints about false and misleading clinic advertising Congress finally passed the Fertility Clinic Success Rate and Certification Act in 1992. It required each medical center that performs ART procedures to report standardized data on every ART procedure initiated to the Federal Centers for Disease Control (CDC) annually. State-specific data on individual clinic success rates are posted on the internet including the names of clinics that fail to report (26 clinics in 2009).\textsuperscript{23} But since the Act does not specify penalties for non-compliance, no action can be taken against non-reporting clinics. However, the Act also brought under surveillance laboratories that handle embryos, the only reproductive endocrinology procedure subject to enforceable national regulation. The ASRM influenced the wording of this legislation to deny laboratory inspectors authority over any activity remotely linked to the clinical practices of physicians. The law categorizes the selection, screening and matching of egg donors and recipients as a ‘medical service’ beyond the reach of regulation.

In the wake of further fertility clinic scandals, the ASRM reconsidered its former opposition to compulsory regulation of the fertility industry and endorsed creation of an independent licensing authority to oversee and validate clinical and laboratory practices.\textsuperscript{24} Though that proposal fizzled too, later furor over increased health care costs due to the high rate of multiple births led them to revive the licensing

\textsuperscript{22} Some feminists who were critical of the newfound powers of the medical establishment initially shared this view but drew away as conservative perspectives hardened and a number of former liberals came onboard. For critique of the resulting neoliberal perspective from a mainstream bioethicist's viewpoint see R. Macklin, "The new conservatives in bioethics," Hastings Cent Rep 2006; 36, 34-43.

\textsuperscript{23} Their most recent report for 2009 is available at: http://www.cdc.gov/art/ART2009/PDF/ART_2009_Full.pdf

\textsuperscript{24} Note H. Jones. The Time Has Come. Fertility and Sterility 1996; 6.
authority proposal. In 2006 they strengthened their earlier recommendations on the maximum number of embryos that should be transferred during an IVF cycle.25

Then another scandal reignited turmoil. In late 2009 a divorced, unemployed 33 year old California woman who already had six children under the age of eight and a history of psychiatric illness disclosed that she had given birth to octuplets. During the ensuing media furor the woman made numerous television appearances and reportedly secured a multi-million dollar advance on a book contract. Eventually, the ASRM expelled the physician who performed the procedure. He is still able to practice but some private insurance companies that cover IVF treatment withhold reimbursement from treating physicians who are not members of the ASRM.26 After a thorough investigation of the physician’s medical practices, The California Medical Board filed a complaint accusing the physician of negligence and violation of professional guidelines. In addition to these general tort violations, the licensing board also accused the physician of giving his patient elevated levels of hormones during treatment, poor record keeping and failure to recognize that the patient’s conduct placed her offspring at risk of potential harm27 (Mohajer). At the close of an 18 month investigation, the California Medical Board moved to revoke the physician’s license to practice medicine. The frenzy fomented further doubts about the industry’s ability to self-regulate and motivated criticism of the CDC’s voluntary reporting standards. Critics argued that their method of computing success rates was misleading and inadvertently encouraged clinics to increase their competitive edge and enhance their revenue by performing multiple embryo transfers.28

Meanwhile, several states called for mandatory regulation to limit the number of embryos transferred during a single fertility treatment. Others have called for a federal solution to prevent a 'mishmash of policies' allowing patients to shop for treatment from state to state.29 But the fertility industry is claiming that reproductive technology is already too highly regulated. They are lobbying instead for increased insurance coverage of ART procedures.30 Despite the inadequacy of this proposal, it is not in itself a bad idea. It would reduce incentives to perform multiple embryo transfers, thereby reducing medical costs for the care of premature infants (a common side effect of multiple births).31

25 Available at: http://www.medicalnewstoday.com

26 It's been reported that this physician subsequently transferred seven embryos to another woman during a single IVF cycle.


28 A more comprehensive analysis of the shortcomings of the current CDC reporting system is available on the CDC website, op.cit. note 23.


31 In the face of increasing multiple birth rates and improved success of singleton births, the HFEA has rolled out a new multiple birth policy that strongly encourages single embryo transfer (SET) and reduces the annual percentage of multiple births to a target of 10% from the 24% limit in 2009. Several other European countries have already
In 2008 the new Obama administration authorized a new Presidential Commission for the Study of Bioethical Issues. Obama also extended the authority of the National Institutes of Health (NIH) to restore federal funding for embryo research that uses embryos left over after IVF treatment providing that women from whom they are recovered grant consent. Since NIH has the authority to monitor consent procedures and the conduct of research, their approval would provide a nationwide standard for all human embryonic stem cell (hESC) research that would extend to privately funded projects that are currently subject only to standards imposed by the researcher’s home institution. A U.S. district court judge promptly issued a preliminary injunction against the NIH, halting federal funding of hESC research. Plaintiffs, including right-wing religious groups, argued that NIH policy violates a provision in Congressional appropriations bills that prohibits use of public funds for research that destroys embryos. The provision at issue (the Dickey-Wicker amendment), passed every year since 1996, has always been interpreted to allow research funding for use of hESC lines so long as the project itself does not destroy embryos. In September 2010, an appeals court temporarily lifted the injunction pending a hearing on the merits of the case and possible Congressional legislation clarifying their interpretation. After considering arguments for and against the injunction with respect to the statutory language of the Dickey-Wicker amendment, the U.S. Appeals Court of the D.C. circuit overturned the injunction against the NIH.

Beyond Britain and the United States: Transnational issues

On superficial review regulatory experiences in the UK and U.S. would appear to have little in common but closer study reveals significant commonalities. Researchers and clinicians behaved comparably in both settings. They tried to ward off legislation they saw as intruding on their own domain. They used rhetoric stressing the march of medical progress and their struggle against diseases that plague humankind. When the threat of legislation intensified, they tried to demonstrate their capacity for voluntary self-regulation by devising codes of conduct. When that move failed to placate their opposition, they established oversight bodies consisting largely of their own members. They exerted every effort to retain effective control over their own practices.

But why the broad disparities between regulatory outcomes in the UK and the U.S.? Timing is, no doubt, a notable factor. British regulation was initiated long before IVF regulation became a public

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issue in the U.S. Though the religious right had already gained a footing in the U.K., their influence over healthcare policy was far less than in the U.S. The Roman Catholic hierarchy and conservative evangelical groups have had considerably more political influence over public policy formation in the U.S. Polarized debates about abortion and the moral status of embryos obscure broader concerns about assisted reproduction. Acrimonious disputes about pregnancy termination often block regulatory efforts.36 Different national traditions also play a role. Britain has a long tradition of social solidarity. Individualism is more pronounced in the U.S. In Britain the central government regulates health care but in the U.S. regulation is largely the responsibility of individual states and the medical board of each state.

Meanwhile, European efforts to marshal a consensus among EU countries have met with little success. Initially, Europeanists pressed for the formation of a trans-European consensus to ward off transnational travel by individuals and researchers to evade regulation in their home country. International bodies called attention to specific issues where agreement could most reasonably be reached. However, British debate proceeded with little acknowledgment of the implications of British experience for other countries. Scientists and biotechnology companies in countries that ban or severely limit embryo and/or genetic research pursue opportunities to work in countries with more permissive policies.37 Consequently, practitioners in countries with stricter policies are caught in a dilemma. Should they make use of research findings that employ embryos or human subjects deemed unethical in their own country? Offer their patients access to new or improved therapies developed through research proscribed at home? Or recommend that they travel to other countries for treatment?38

Two decades after European-wide regulation was initially proposed, local political alignments still have considerable influence over policy. Where the Roman Catholic Church is politically powerful, regulations are more stringent and few ART clinics exist. Among European countries, Italy has had some of the most restrictive ART regulation.39 Many, including Germany, Norway, Austria, and Denmark, do not permit ovum donation; and Austria, Norway, France, and Sweden prohibit the use of anonymous donor sperm. Recent amendments to the UK law extend ART access to same-sex couples, but most European countries limit access to couples in stable heterosexual relationships. Austria and Italy explicitly exclude single women and lesbians. But Spain, the Czech Republic, Ukraine, and Romania have very permissive policies. Reproductive tourism is a growth industry in these countries attracting women from countries across Europe where regulation is tighter.


37 A decade ago the U.S. National Bioethics Advisory Commission (NBAC) expressed concern that if there were less than a complete ban on human cloning, the U.S. could become a relatively unregulated ‘offshore island’ attracting scientists from countries with more restrictive policies. See E. Eiseman. 2003. NBAC: Contributing to Public Policy. Santa Monica, CA: Rand.

38 I consider the last issue in more detail in a subsequent chapter. See also A. Donchin, “Reproductive tourism and the quest for global gender justice.” Bioethics 2010; 24; 323-332.

39 LP: Many of the most restrictive elements of the relevant legislation in Italy have very recently been overturned on constitutional grounds (2013).
Comprehensive international data that quantify ART procedures are difficult to come by.\textsuperscript{40} Available data are often unreliable because ART terminology varies considerably within and among countries.\textsuperscript{41} But uniform reporting standards would only tell part of the story about the effects of the institutionalization of ART services. Much as a particular configuration of British interests influenced the structures of discourse about changing reproductive practices and their institutionalization, so other countries circumscribe discourse about reproduction within their own institutional structures, thereby controlling access to medical assistance and selection of gametes and embryos. So institutionalization has a far more extensive effects than the specific regulatory measures adopted. It also influences the structures of discourse surrounding reproduction and public acceptability of changing reproductive practices.

Thus the process and outcome of regulation raise pervasive questions, not only for consumers of ART but for entire societies. The cultural experiences of specific social groups influence responses to reproductive interventions. As public reaction to the original British legislation illustrates, pressure to force a national consensus under government auspices is likely to overlook the interests of those who lack substantial political influence. As institutionalization shifts the focus of reproductive decision-making from individual consumers of ART services to the medical and legal institutions that determine access, people who lack representation are further disadvantaged. Power imbalances are magnified by conflicts between commercial and patient interests, third parties, potential children, and disabled people. As gatekeepers, however, practitioners play a central role. They control access to assisted conception, determine the boundaries of acceptable risk, and make judgments that often extend well beyond their technical expertise, such as embryo selection to circumvent the transmission of genetic anomalies.

Roman Catholics and Christian fundamentalists are not the only groups to voice serious reservations about recent developments in reproductive medicine, embryology and genetics. Feminists, environmentalists, and public health professionals all question the tendency to incorporate high-technology infertility intervention into standard medical practice. However, the latter groups rarely have an effective lobby. They are seldom well organized, often have no more than token representation on regulatory commissions (since officials tend not to recognize them as ‘key’ interest groups), and are unlikely to have sufficient funding to mount a forceful campaign that can resist both the medical lobby and the influence of fundamentalist religious groups.

However, in the absence of comprehensive oversight, patients lack assurance that even their immediate interests will be well served. They are no match for the authority of their physicians who often prioritize institutional interests. As Debora Spar observes: “the people who purchase fertility services don’t see themselves as participating in a commercial relationship.”\textsuperscript{42} Hence even after years of

\textsuperscript{41} The International Federation of Fertility Societies (IFFS) has released the 5th edition of its triennial global survey of the assisted reproduction industry. Though the new edition includes data from 105 clinics, the quality of the information varies considerably. See http://www.iffs-reproduction.org/documents/IFFS_Surveillance_2010.pdf. In 2009 the International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised their glossary of ART terminology to insure my uniform reporting standards. The new glossary is available at: http://www.who.int/reproductivehealth/publications/infertility/art_terminology2.pdf.

\textsuperscript{42} Spar 2006, 49.
frustrating treatment they rarely explore alternative options. Given the pronatalist atmosphere surrounding ART and the mystique and authority of physicians, patient consent to treatment may be more a reflection of social norms and hierarchies of social stratification than autonomous personal choice. Some critics view prevailing consent procedures as a subtle form of social control. Many factors may compromise consent including the force of patriarchal institutions, gender-specific stereotypes, and other surrounding social conditions. As Onora O’Neill observes:

Genuine, legitimizing consent is unfortunately often undermined by some of the institutions and practices which most readily secure an appearance of consent. The more relations with others are ones of structural dependence, the more the weak have to depend on trusting that the (relatively) strong will not exercise the advantages which proximity and superior status give them.

In conclusion, I outline some considerations that would contribute to a more just regime of reproductive regulation.

Toward Reproductive Justice

What conditions would a morally adequate approach to reproductive regulation need to satisfy? First, patients would understand their options comprehensively. Presently, people seeking treatment may not know which if any of the available medical interventions are likely to help them or whether a particular practitioner has the requisite expertise to provide assistance appropriate to their condition. Many now turn to the internet, but those resources are often sponsored by special interests such as leading hyperovulatory drug manufacturers. Reports of IVF success rates are more reliable now than they have been, but often are manipulated to draw more patients into particular clinics; it appears that some clinics have had no live births. Even when regulatory bodies impose uniform standards on clinics, they can be diluted by close alliances between medical organizations and government authorities.

Second, more effort would be put into identifying and controlling the environmental and iatrogenic causes of infertility. Across the globe women’s wellbeing is threatened by multiple factors including early or late childbearing and substandard care during pregnancy and childbirth. In some developing regions the infertility rate is as much as three times higher than in developed countries due to inadequate healthcare, unsafe abortions, undiagnosed or untreated pelvic infections, and botched delivery. If fertility were not compromised in developed countries the disparity would be far greater. Delayed childbearing, damage to reproductive organs from hormonal contraceptives and intra-uterine devices, and environmental and workplace toxins all contribute to the toll on fertility in developed regions of the globe. Everywhere the fertility of poor women and women of color is at risk from nutritional deficiencies, exposure to hazardous work situations, and damaging medical and environmental conditions. The fertility of women who defer pregnancy until advanced childbearing age is also affected by greater exposure to environmental and iatrogenic factors. Their ova are also more susceptible to mutations associated with Down syndrome. Mounting evidence indicates that sperm are also adversely affected by

43 Ryan 2010.

44 O’Neill. 2000, 166.

45 When cesarean section is not available, prolonged labor may lead to obstetrical fistula. In developing countries, fistula victims are often abandoned by their husbands and rejected by their communities. UNFPA estimates that the world population of fistula sufferers exceeds two million. See WHO-Department of Making Pregnancy Safer Obstetric Fistula 2006 report http://whqlibdoc.who.int/publications/2006/9241593679_eng.pdf.
environmental contaminants. Reduction of environmental pollutants and establishment of screening programs for the more common infectious agents could be accomplished at far less cost than treatment to alleviate the consequences of diminished fertility.

Third, a more adequate response to reproductive innovations would be attentive to gender-specific social structures that perpetuate traditional expectations that women bear children. Where legislatures perpetuate such expectations or distort them to serve other ideological agendas, women often fare no better under regulation than under market control. An adequate response would also take into account the subjectivity of individual women (those who forego treatment as well as those undergoing it) and the framework that shapes their options. It would address the presently pervasive tendency to objectify the patient under treatment and erase her individuality. It would end preoccupation with the early embryo as an independently existing entity and recognize the continually changing relationship between woman and fetus as pregnancy progresses.

Women's groups in both developed and developing countries are now forming participatory alliances to more accurately identify the reproductive needs of specific groups of women. These alliances are seeking a new politics with a social agenda that is responsive to transnational consolidation of the reproductive industry. They link women's concerns more closely to international human rights programs and more extensive reproductive rights agendas. They seek to build a reproductive justice movement that situates reproductive health and rights within a framework that stresses intersections with racism, sexism, xenophobia, heterosexism, and class oppression. Along with a number of feminist theorists, they are urging comprehensive reconfiguration of basic moral conceptions embedded in ART practices.

Among key concerns of these groups is the rhetoric of reproductive medicine that perpetuates the dogma that women cannot lead worthwhile lives without bearing children. They also challenge the individualistic vocabulary that pervades legislative debate, disregards human dependency needs, and devalues social and political connection. They call for a perspective toward reproductive choice that includes surrounding social conditions, political context, and institutional structures that shape reproductive options.

Implementation of their agenda would require structural changes among institutions that control access to ART, both nationally and transnationally, as well as the transformation of policymaking processes to take into account, not only the benefits of changing reproductive practices, but also the burdens borne by those whose wellbeing is adversely affected by prevailing practices. I turn now to more comprehensive consideration of the interests of consumers of ART, who are principally women.

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