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Reproductive Tourism and the Role of the European Union

Elizabeth Ferrari Morris

I. INTRODUCTION

As reproductive technologies have developed and become more widespread internationally, an increasing number of infertile couples have continued to seek reproductive therapy, including in vitro fertilization, either with their own cells or through cell donation, with the hope that they can start families. However, these new technologies have caused European governments to respond in different ways, ranging from an outright ban based on moral and ethical objections to no restrictions on access to reproductive assistance. As a result, European countries have erected regulatory structures that often change drastically and rarely parallel one another.¹

Since there is no central regulation of access to reproductive technology, the evolving legal status of cell donation has created a phenomenon called "reproductive tourism." Reproductive tourism refers to the practice of citizens leaving their home country for another in hopes of receiving treatment that has been banned in their home country, typically for safety or moral reasons.² Although reproductive tourism has long been an issue in Europe, there has been

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¹ For example, Italy was one of the last European countries to put any sort of regulation into place, yet the government implemented one of the most stringent regulations for infertile couples. See, for example, Rachel Anne Fenton, Catholic Doctrine versus Women's Rights: The New Italian Law on Assisted Reproduction, 14 Med L. Rev 73 (2006).

an even greater influx in recent years as the regulations of countries within the European Union have begun to diverge even more.  

As a general matter, national regulation of reproduction is not particularly troubling. With such a spread of regulatory schemes, though, the question arises whether European citizens would benefit if countries submitted to centralized regulation by the EU. Currently, the EU only regulates the specific guidelines concerning the quality of cells to be used for transplantation and the ethical rules for compensating donors. Since this regulation is so narrow, countries are free to generate their own policy concerning which citizens can actually access this technology. Consequently, a country’s ability to deny citizens reproductive therapies could result in unequal application of the EU’s public health directives because countries with reproductive technologies compete for patients, resulting in unequal access to quality care. Accordingly, this inequality raises the question whether the EU should define the reproductive policy of its Member States.

As such, this Development will focus on the role that the EU can and should play in administering the reproductive technology needs of its Member States. First, this Development will delve into the specific problems that have arisen from lack of central regulation. The discussion will then turn to current EU regulation practices of donated cell material and how these initiatives are insufficient to confront the public health problems produced by reproductive tourism. Finally, the argument concludes by discussing how the EU can administer cell donations more effectively and in a manner that is more consistent with its other bioethical practices without infringing on the ethical concerns of the individual Member States. Overall, this Development will show that, although individual policymaking has historically been left to the discretion of the Member States, the unique challenges of ensuring public health norms for all Europeans require more integrated harmonization of scientific practices in individual countries. However, this harmonization does not necessarily need to offend Member States’ ethics because countries would still decide whether or not to offer cell donation as a reproductive option. Rather, instead of ignoring reproductive tourism, a Directive from the EU would acknowledge that a

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3 See, for example, Fenton, 14 Med L Rev at 74 (cited in note 1) (stating that, with stricter Italian laws preventing couples from reproducing, more citizens must seek treatment abroad).


5 Although the reproductive technologies in question range from basic artificial insemination to surrogate motherhood, this Development’s discussion of “reproductive technologies” refers to any alternative treatment that is sought by an individual or a couple to become pregnant, either with their own cells or donor cells. In particular, the argument will focus on the particular problem of cell donation, but the arguments presented here are applicable to the wider range of reproductive therapies that exist.
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market has developed for cell donation. By regulating this market, the EU would instill greater confidence in patient safety.

II. REPRODUCTIVE TOURISM AND THE CURRENT POLITICAL ATMOSPHERE

Reproductive or infertility tourism usually refers to "the movement of citizens to another state or jurisdiction to obtain specific types of medical assistance in reproduction that they cannot receive at home." Reproductive tourism occurs for a variety of reasons. People may have to seek out cell donations and in vitro treatment elsewhere because these treatments are unavailable, due to general lack of medical expertise in cell donation, laws that have banned cell donation because it is adjudged to be unsafe, long waiting lists in the home country, or lower costs abroad.

Reproductive tourism is not a new phenomenon in the EU. Ever since biotechnology began introducing new ways for couples to become pregnant, countries have reacted very differently to regulating both the procedures themselves and the groups of people who could secure such treatment. Although there is obvious variation between laws, the countries’ approaches have been classified in four ways. First, some countries are “designing by non-decision.” Often seen as having the most liberal regimes, these countries actually have such severe fragmentation of ethical viewpoints that compromise for an appropriate system cannot be reached, and as a result there is little to no regulation. Second, other moderate countries are considered “designed by experts” because similarity of moral ideas has essentially encouraged national legislatures to depend upon the dominant medical beliefs of the time. The third approach is to “design by mobilization and consultation,” which essentially entails legislative groups who agree that restrictive regulations are necessary.

6 Pennings, 19 Human Reproduction at 2690 (cited in note 2).
8 In fact, some commentators have noted how reproductive tourism is becoming an increasingly global phenomenon. See id at 146. The problem has been especially heightened in Europe, though, given the array of legislation that continues to arise both to keep pace with the advances in science and to address ethical concerns. Id at 146–47.
10 Id at 250–51.
Finally, “design by party politics” evolved in countries where, although beliefs did not appear to be similar, legislative compromises emerged because of a shared belief for the need for state responsibility and a general leaning towards restrictive policy preferences.

Not surprisingly, these different legislative atmospheres have created varied reproductive regulatory structures within each Member State. Some countries, like Belgium, have policies which essentially reflect a design that only creates authorizations for practice and little else.\(^1\) As such, “governance is largely private, [and] market forces play an important role. . . .\(^2\) By contrast, other countries, like Germany, Norway, and Switzerland, have created regimes that strictly limit access to reproductive therapies while simultaneously prohibiting many techniques, including egg donation, pre-implantation diagnostics, and embryo donation.\(^3\) Not surprisingly, Germany has often had concerns with citizens leaving for Belgium to seek reproductive assistance.\(^4\)

Although there have always been divergent approaches to regulating reproductive therapy and other biotechnologies amongst the Member States, the legal status of the procedures seemed stable. The EU only intervened in what appeared to be extreme situations. For example, when Germany required mandatory gynecological exams on women returning to the country from Belgium, the EU effectively stopped this practice in 1991.\(^5\) On the whole, however, the EU has abstained from direct legislation that would require countries to have particular procedures or to require access to reproductive therapies. These moral and ethical judgments have traditionally been left to countries, and the EU has remained steadfast in this position.\(^6\)

The EU’s silence on this issue has recently begun to take a toll on the relative stability of reproductive tourism in Europe. Since there is no central structure with established guidelines for moderating access to reproductive technologies, countries have been free to change their governing regimes in rapid and sometimes unpredictable ways. The most recent example of a major political shift occurred in Italy. Long considered to be one of the most liberal countries for its lack of regulations, the source of Italy’s lax laws was the country’s severe fragmentation in beliefs regarding regulating assisted reproduction. The result was a widely unregulated industry due to an interrupted

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\(^1\) Id at 231.
\(^2\) Id at 232.
\(^3\) Id at 229.
\(^4\) Pennings, 19 Human Reproduction at 2691 (cited in note 2).
\(^5\) Id.
design process.\textsuperscript{17} Although this flux was well-known throughout Europe and many laws had been proposed in Italy to ban or to encumber access to reproductive therapies, including cell donation, few anticipated that Italy would actively regulate access to reproductive technology. However, in 2004, the Italian government essentially reversed its permissive position and passed legislation that severely limited access to new reproductive methods, even in the face of strong disapproval from its secular and female public.\textsuperscript{18} Not only did Italy reduce the number of assisted reproductive technologies available to its citizens, it also drastically reduced the number of people who could receive these technologies by limiting them to heterosexual, committed couples.\textsuperscript{19} This change will undoubtedly force increasing numbers of people to leave Italy to seek out alternative treatment.\textsuperscript{20}

The situation in Italy reveals the reality of the delicate balance that exists within European countries. As countries attempt to parse out and to adapt to the scientific realities of reproductive therapies, the state of reproductive tourism will be thrown into an unmanageable state of flux. As one country creates more stringent standards, another will be forced to absorb the surge of patients. To date, the Member States of the EU have only dealt with reproductive technologies on a national level and have not taken steps to address the larger problems created by reproductive tourism. In addition, most problems of regulation have arisen between the Western European and Scandinavian countries. Some concern has been raised that, as Central European states become more involved in the reproductive market, the variety of regulatory schemes will only multiply.\textsuperscript{21} Therefore, as reproductive regimes in the countries increasingly become unstable, the time is ripe for the EU to moderate the situation and to prevent long-term public health concerns that are linked with unregulated reproductive tourism.

\textsuperscript{17} Rothmayr, et al, \textit{Comparing Policy Design} at 234 (cited in note 9).
\textsuperscript{18} Fenton, 14 Med L Rev at 75–77 (cited in note 1) (discussing the disparity between the secular public that disapproved of the change and the strong support from the Roman Catholic church); \textit{Italian Lawmakers Enact Rules That Limit Reproductive Rights}, NY Times A16 (Dec 12, 2003).
\textsuperscript{19} Fenton, 14 Med L Rev at 73 (cited in note 1).
\textsuperscript{20} Id at 74.
\textsuperscript{21} Hervey and McHale, \textit{Health Law and the European Union} at 146 (cited in note 7).
III. PRESENT REGULATION: DIRECTIVE 2004/23/EC ON TISSUES AND CELLS

The EU has not completely overlooked regulating cell donation and in vitro fertilization. The increase in variations in national reproductive policies has generated considerable discussion about the role that the EU should play in creating a stable set of reproductive regulations for all of the Member States. In fact, the general rise of bioscience in many arenas, including genetically modified food, has created more support for the EU to play a larger role in regulation.22

Accordingly, in 2004, the EU passed Directive 2004/23/EC on Tissues and Cells (“Directive”). The Directive does not focus solely on reproductive technology; however, the implications of the Directive effect a minimum standard of safety and health protocols that Member States must follow when using donor cells, including using donor cells for reproduction.23 The essential objective of the Directive is to “lay[ ] down standards of quality and safety for human tissues and cells intended for human applications, in order to ensure a high level of protection of human health.”24 That is, it establishes standards for each level of the donation process, including the recruiting of donors, the storage and distribution of donor cells, and the privacy rights of donors.25 The Directive does not purport to control the regulation of a patient using his or her own cells. It only focuses on donations in order to “safeguard public health and to prevent the transmission of infectious diseases by these tissues and cells,” advising that in order to do so, “all safety measures need to be taken during their donation, procurement, testing, processing, preservation, storage, distribution, and use.”26

The Directive focuses more explicitly on acceptable scientific levels of safety instead of ethical considerations governing reproductive technologies. This approach is not surprising, given the EU’s general trend of relying on scientific studies to establish guidelines27 and leaving moral and ethical

22 See, for example, Gabriele Abels, Experts, Citizens, and Eurocrats—Towards a Policy Shift in the Governance of Biopolitics in the EU, 6 European Integration Online Papers (Mar 12, 2002), available online at <http://eiop.or.at./eiop/pdf/2002-019.pdf> (visited Nov 17, 2007) (noting the transition in European politics from civil governance to policy formulation).
23 Council Directive 2004/23/EC at 48 (cited in note 4) (“This Directive should apply to tissues and cells including haematopoietic peripheral blood, umbilical-cord (blood) and bone-marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells.”).
24 Id at 51.
25 See generally id.
26 Id at 48.
determinations to Member States. The Directive reinforces this position by making continual declarations to Member States to set stricter standards if appropriate because the Directive intends to protect the "human rights and dignity of the human being with regard to the application of biology and medicine . . . [and] [n]either the Charter nor the Convention makes express provision for harmonization or prevents Member States from introducing more stringent requirements in their legislation."

Although the Directive takes admirable steps in establishing a safety standard, its own language conflicts with its stated objective. On its surface, it appears that the EU sets the affirmative safety and quality levels for cell donation while leaving questions of implementation and ethics to the Member States. Unfortunately, even though the Directive is an admirable effort, the EU’s desire to leave ethical questions to countries has left gaps in the safety guidelines regulating cell donation. For example, the Directive strongly encourages voluntary, nonpaid cell donation because such processes produce safer, higher quality cells, but it does not mandate such measures. In addition, there is no real reporting mechanism that allows the EU to moderate the safety of cell donation procedures. Rather, the Member States are left to develop their own penalties for noncompliance with the EU’s Directive. Consequently, even though the EU has set up these particular guidelines, Member States have been left with so much discretion in their implementation that the level of care can vary widely amongst the countries, leaving open the potential for public health standards to dip below the EU’s recommended—and more stringent—guidelines. This problem appears to be coming to fruition. In 2006, the EU released a study that indicated that one country, Romania, was already moving away from the voluntary, unpaid donative standard, and donors of reproductive cells were remunerated. This study strongly suggests that countries, in order to

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29 Id at 49 ("Voluntary and unpaid tissue and cell donations are a factor which may contribute to high safety standards for tissue and cells and therefore to the protection of human health.").
30 Id.
31 Id, art 27.
address the market demands of reproductive tourism, can be swayed to defy Directive guidelines in order to entice reproductive tourists into their countries for treatment. This problem will only be inflamed as countries continue to change their laws, which are becoming increasingly divergent from one another.

Essentially, the EU remains powerless to act for two primary reasons. First, since the penalty regime does not have specific guidelines, and since the unpaid donor standard is permissive, the EU cannot enforce standards against the Member States because none exist. Second, even if the EU had standards to enforce, it remains in a defensive position because Member States retain the right to regulate their own activities. The EU can only gain information by requesting reports from the Member States or by asking the Member States to conduct their own studies.34

As a more general matter, the EU has administered and regulated biotechnologies before. Regulating reproductive technologies would therefore be consistent with the administrative role it already plays in other contexts. Because the EU is not new to biopolitics and governing biotechnologies, it could apply expertise it has already gained from generating other regulatory structures. For example, one useful governing approach that has emerged for analyzing EU biotechnology regulations is to view EU governance as framing biotechnologies within a market framework. Casting the discussion of biotechnology as one of markets makes it easier to engage controversial topics by setting a more neutral tone.35 Discussions about markets are preferable because they “seek[ ] to make general statements across national boundaries, offering a ‘universalizing discourse’ which brings rationality and coherence to a complex and uncertain issue.”36 Second, discussing biotechnologies in a market framework realistically structures the particular problem that the EU is trying to regulate while avoiding stickier ethical issues.

Thinking about reproductive tourism within a market arrangement governed by the EU is helpful in establishing consistent safety protocols for cell donation. Even though reproductive tourism is a clear example of a market created by differing biotechnology laws, the Member States and the EU overlook the market created by these laws and focus only on the ethical

34 See, for example, Health & Consumer Protection Directorate-General, Report on the Regulation of Reproductive Cell Donation (cited in note 32).
36 Id at 78. It is also important to note, however, that Irwin does not mean to overlook that certain issues will be emphasized over others in this sort of regime; however, he does at least note that “economic significance of public attitudes is given great emphasis.” Id.
questions that arise. Acknowledging that reproductive tourism is a market helps frame the discussion and focus directly on the public health concerns that arise from a competitive free market in donor cells. By creating a neutral platform that concentrates on how the market affects patient and cell donation conditions, the EU can determine where public health defects exist and craft laws that address specific problems. Otherwise, patient safety standards will almost certainly suffer. For example, reproductive tourism has been criticized as creating disparities between the rich and poor, because wealthier couples or individuals can afford to travel abroad to seek out medical care.\(^\text{37}\) As a result, as the market for reproductive technologies emerges, there will be an increased market temptation not only to continue to cater to the wealthy, but also to create lower priced medical options for poorer patients. However, it is unclear how countries could afford to provide lower cost medical services.\(^\text{38}\) Countries might also be increasingly tempted to continue to dodge the Directive's requests for voluntary donations.

### IV. Creating Consistent Bioethical Regulation in the European Union

When faced with the challenges of administering guidelines for cell donation, the problems of reproductive tourism indicate that the EU should adapt its Directive to confront the present and impending problems of reproductive tourism. In particular, the EU should take a more central role in the administration of cell donation to ensure that countries are not tempted by the market demands to reduce public safety standards. The EU can adapt its present standard by mandating the use of voluntary donations and by assessing penalties itself, without relying on the Member States to pass these guidelines themselves. By expanding its central administrative role, the EU can account for the full picture of reproductive tourism by widening its bioethical standard to mandate safer, voluntary cell donation and by becoming the administrative body that develops penalties for noncompliant states. By doing so, the EU would help create a more stable environment for reproductive tourism because patients can be assured that a country engages in safe practices that are consistent with EU guidelines. If Member States must assess penalties on their own, however, patients do not have the same guarantee that practices are safe, and the EU does not have a reliable method for ensuring that countries are compliant.


\(^{38}\) Id at 271.
Expanded EU regulation would not necessarily impinge on the individual ethical concerns of Member States. Member States could still decide which practices would be allowed and even who would have access to cell donation and in vitro fertilization. If a country decided to offer a technology, though, the Member State would have to submit to stricter regulation by the EU itself so that the quality of medical care would remain consistent between the countries. Accordingly, countries like Italy could maintain their ethical position and not feel compromised by stricter EU enforcement. Essentially, a new, EU-centric regulation would not be focused on eliminating reproductive tourism. Rather, it would acknowledge instead of ignore the problems of reproductive tourism and create a safer atmosphere for helping patients seek treatment without violating the ethical concerns of their home countries.

In addition, bringing regulation of cell donation under EU administration is a logical move because the EU has emerged and established itself as an administrator of biotechnology regulation in other fields. For example, in developing regulations for genetically modified foods and organisms ("GMOs"), the EU has effectively dealt with balancing countries’ ethical concerns with public safety concerns. The EU could certainly apply these techniques to developing effective reproductive regulations.

Admittedly, the development of GMO regulation has been a system of trial and error; however, the GMO debate has highlighted the importance of three characteristics for effective EU regulation that are directly applicable to the problems presented by reproductive tourism. First, the Commission is beginning to rely more heavily on a science-based model of regulation. It is encouraging a stronger dialogue between experts and policymakers to create a tighter connection with science and society. This growing dependence on science has brought the emergence of two additional but closely related factors: the development of bioethics and the need for social support for technological innovation. Bioethics has emerged primarily in strategic decisionmaking and policy creation. Similarly, social support has also played a major role both in creating a common ground for establishing a baseline of regulation and for more sensitive governance of GMOs. In particular, GMOs became an important area of policymaking so the European Community could win the trust of the public to regulate bioethics more safely and effectively.


40 Id at 7–8. For a similar discussion on somewhat similar three strands of biotechnology regulation, see Irwin, *The Global Context for Risk Governance* at 72–80 (cited in note 35).

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Seen within this context, the gaps in the regulation of reproductive tourism become clearer. Although the Directive on Tissues and Cells is inclined towards a science-based model of regulation, it directly overlooks the second and third factors of bioethics and public discourse. Because the EU has been concentrated almost exclusively on creating a baseline of safe scientific techniques with little to no mention of the bioethics involved with such regulation, the door has been opened for countries to compete with one another directly for patients, thus creating the market system that threatens the actual viability of the Directive itself.

Although it would seem that establishment of supranational bioethics would impinge on a Member State’s ability to allow or to ban a procedure, bioethics for reproductive tourism need not be so broad. Even though these discussions on the supranational level would raise difficult questions, they are necessary to the very credibility of the larger EU governance structure, as the Directive deviations in Romania intimate. Some commentators have even noted that such discourse is necessary because the commodification of parenting (in this case, through reproductive tourism) removes parenting from the private sphere into the public sphere through the large dependence on commercial and third party processes.\(^42\)

The EU need not go so far as these commentators theorize, though. The need for bioethics can emerge from disagreement over a variety of ethical issues, ranging from arguments concerning who should have access to procedures to whether the procedures themselves should even be allowed.\(^43\) Therefore, these ethical questions do not necessarily need to center on whether the therapies themselves should be allowed or who should have access to them. Member States can retain their position as the appropriate platform for making these decisions. The concern of the EU is more logically contained in what is ethically acceptable in the procedures themselves. Although the Directive on Tissues and Cells has directly established strict standards for the acquisition of cells, their storage, and donor information, it only alludes to how voluntary cell collection should occur and offers no guidelines on how penalties should be enforced. The lack of bioethical standards creates the weaknesses inherent in the Directive, leaving countries with the ability to exploit these gaps in regulating their own bioethical industries. Accordingly, strengthening these guidelines should be the

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EU’s first step toward creating a consistent market for reproductive tourism and holding countries accountable for the health and safety of its cell donations and its patients.

Overall, the EU’s unique position to review the problems presented by reproductive tourism as a coherent whole cannot be overlooked. Although individual countries have the right to legislate what is ethically appropriate for their citizens, the EU also has an ethical obligation to ensure adequate public health standards for European citizens. It is naïve to think that the ethical considerations of a country can be completely divorced from the ethical concerns of the EU. However, as reproductive tourism continues to grow as an unregulated market, the more accountable the EU will need to become for maintaining acceptable health standards of donors, donor cells, and patients. Evaluating the conditions of the market, setting stringent safety standards, and establishing penalties for violating these standards are not only consistent with the role of the EU, but are necessary to stay in harmony with the EU’s goals to ensure the quality and safety of cells.44

V. CONCLUSION

Reproductive tourism has become an unmistakable part of the European landscape. The different policies between the countries will only become increasingly divergent as rising health costs and public health risks spread throughout Europe. Since the EU has emerged both as a supranational market regulator and the principal body for setting scientific standards, regulating reproductive tourism would be consistent with the present role that the EU occupies and would not need to interfere with countries’ ethical concerns.

Although the EU has traditionally refrained from inserting itself into the ethics of Member States, regulation of reproductive tourism does not supplant the individual characteristics of the Member States. The instability inherent within the regimes of each country is pushing the Member States towards a potential public health problem, and action by the EU is necessary to prevent more dire consequences. Francis Fukuyama has acknowledged elsewhere that although national governing bodies usually fix regulatory issues, that should not preclude more affirmative action by bodies like the EU:

Regulation seldom starts at the international level; nation states have to develop rules for their own societies before they can even begin to think about creating an international regulatory system . . . but there is absolutely

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no reason to rule out the possibility that it will emerge at this early stage in the game.45

Within this vein, this Development does not mean to suggest that the EU should regulate the particular ethical standards of each individual country. Rather, the EU should focus on how to regulate cell donation and in vitro procedures that countries have chosen to adopt. Even as countries struggle to assemble a sensible national policy, the EU can develop its own standards that reflect public health worries and that could ostensibly offer additional guidance to countries attempting to grasp how to manage national ethical concerns.

As long as countries diverge over what procedures are morally or ethically reasonable, citizens of Member States will continue to seek out countries that can meet their personal needs and desires to begin a family. By failing to acknowledge that these differing laws have created a market, the EU cannot effectively govern safe cell donation because countries will always have an incentive to evade the more permissive aspects of the Directive of Tissues and Cells. The EU has traditionally filled the role of market regulator and biotechnological expert well. By combining these two roles, the EU can effectively govern safe cell donation and create consistent practices that treat patients—and the laws and practices of the Member States—more equitably than the current, unregulated regime.

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