Perspective

Federalism and bioethics

Women's health and the regulation of oocyte donation

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ABSTRACT. **The absence of comprehensive federal oversight of human biotechnologies in the United States continues to stimulate academic discourse on the relative merits of European-style regulatory agencies as compared to the current, decentralized approach. Many American bioethicists support the latter, maintaining that the key features of federalism—policy experimentation and moral pluralism—allows for the efficient regulation of these complex and contentious issues. This paper examines state-level regulation of oocyte donation to assess claims regarding the superiority of this decentralized regulatory approach. Further, this paper introduces an additional element to this examination of state law, which concerns the degree to which the health and safety of key participants is addressed at the state level. This inquiry assesses one facet of fertility medicine and biomedical research law, oocyte donation, an analysis that can be used to inform the broader discourse regarding the regulation of human biotechnologies and bioethical issues by the states.**

Key words: Oocyte donation, bioethics, fertility medicine, assisted reproductive technologies, biomedical research law, human embryonic stem cell (ESC) research, federalism

The expansion of the fertility industry over the past three decades and growing demand for new applications of human embryonic stem cell (ESC) research has stimulated considerable debate and legal conflict in the United States. Despite significant apprehension regarding the ethical and normative implications of these new technologies, there is no comprehensive regulation of either fertility medicine or biomedical research at the federal level. This absence of oversight generates criticism from different locations, including feminist scholarship, religious institutions, and nonprofit organizations committed to social justice and healthcare equity, with some describing the U.S. system as the "wild west" of biomedicine.[1] Although concerns have been raised by clinicians and researchers over donor health and safety, and broader issues raised about the impact of these technologies on society, there has been no movement towards establishing national standards or a singular regulatory agency, which is common in many nations.

In the current system, the states have begun to legislate various aspects of biomedicine, with many scholars in support of this regulatory approach.[2] This support is, in part, based upon established theories of federalism that privilege state action, allowing for policy experimentation and regulatory pluralism. Further, this regulatory approach can lead to policy diffusion in cases of successful new policy development as well as greater government responsiveness to diverse constituent preferences.[3] Bioethicists in support of keeping this power with the states argue that it will lead to the development of diverse and pluralistic policies over a range of bioethical issues. Given the intense conflict surrounding these practices and the

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improbability of comprehensive federal action, state-level action appears to be the most effective solution for the time being.[4] While theoretically sound, these claims have yet to be fully examined—currently, the full extent of policy experimentation and implementation of pluralistic regulations among the states is unclear.[5] Additionally, the centrality of federalism in much of the discourse on the regulation of human biotechnologies obscures full evaluation of the problems that may arise for the various participants in research and clinical practice. Systematic inquiry into the treatment of participants' health and well-being at the hands of the state should be a critical element of any inquiry that addresses the broader question of who should regulate.

This paper utilizes one particular case—oocyte donation—to evaluate the claim that state-level regulation is the ideal approach to ensure sufficient action on complex and divisive biomedical issues. Oocyte donation serves as a valuable test case, in part because this practice is essential for both fertility medicine and biomedical research. Furthermore, as donated oocytes are critical for both clinical and research aims, competing ethical, legal, and moral interests from diverse constituents are at stake. A content analysis of state law is used to discern the presence of federalism's classic virtues, policy experimentation and moral pluralism, as well as the degree to which participant safety and well-being is sufficiently addressed. This inquiry, addressing one facet of fertility medicine and biomedical research, provides evidence that decentralization has not led to experimentation, diffusion, and pluralism in the regulation of oocyte donation by the states. More importantly, this investigation illustrates the failure of the states to sufficiently protect the participant's that are central to this process. This latter finding suggests the need for greater oversight of human biotechnologies within the United States, particularly for those encountering the greatest degree of risk.

Oocyte procurement and use

Oocyte donation is an ideal case to examine state-level regulation of bioethical issues. Donated oocytes are critical for fertility medicine and biomedical research; specifically, it is the different uses of this material that bring a number of diverse parties into the political discourse regarding the ethics of this practice. The different perspectives and preferences among those involved in this process illustrate the competing interests that could be addressed through public policy by the states.

Medical and psychological risks

Oocyte donation is a complex and time-intensive process with numerous risks to donors' health, generating ethical and legal dilemmas distinct from that of sperm donation or altruistic organ donation. Oocyte retrieval first requires a series of self-administered hormone injections followed by a medically invasive extraction procedure that can lead to physical or emotional issues as well as complications for donors' future fertility. Some of the known short- and long-term medical risks include (but are not limited to) mild adverse reactions to the hormone treatments such as nausea, bloating, and headaches to more severe problems including ovarian hyper-stimulation syndrome.[6]

Significant harm from hormone injections is rare, although some scholars maintain that the limited amount of data available renders these findings inaccurate.[7] Additionally, evidence suggests that some donors experience post-donation psychological distress stemming from concerns for their own future fertility, not knowing if a live birth was achieved, or general regret for participating in this process.[8] Long term estimates of the presence and depth of the psychological and emotional problems associated with oocyte donation are needed; as the population of egg donors expands, more conclusive findings may emerge.

The American Society for Reproductive Medicine (ASRM), the industry's professional association, has established a number of recommendations to protect donors, based upon the risks of this practice. These include guidelines for the recruitment, screening (medical and psychological), and securing of informed consent from potential donors as well as limits on compensation, repetitive donation, and donor age.[9] These guidelines are voluntary yet adherence is necessary for membership in ASRM. Failure to uphold these established standards may detrimentally impact physicians' medical practice and standing in the field.

Coupled with potential medical and psychological risks, donor compensation generates broader concerns

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regarding donors' health and well-being, particularly in the absence of comprehensive oversight. The demand for this material, combined with the complexity of oocyte retrieval, results in a wide range of payment offers for donors. The ASRM states that remuneration over $5,000 requires justification and total payment in excess of $10,000 is not appropriate.[10] Investigation of donor recruitment indicates that compensation offers extend well above the recommended limits established by ASRM's Ethics Committee. One study found payments that range from $25,000 to $50,000, although the author notes that this most likely understates the range of payments due to reports of advertisements offering $100,000.[11] Additional research finds evidence of compensation that exceeds ASRM recommendations, although the full extent of noncompliance is unclear given the absence of enforceable reporting requirements.[12]

A second issue concerning the ethics of the current market for oocytes is the targeted advertising by fertility programs, intended parents, and third-party egg brokers. Advertisements abound in college newspapers that highlight payment for oocytes in excess of the recommended limit as well as increased compensation based upon other factors.[13] ASRM advises that recruitment and payment of donors based upon unique traits, abilities, and previous donations is problematic and morally troubling for the donor as well as potential offspring.[14] Studies indicate, however, that many advertisements highlight specific traits that are in demand, some of which result in higher rates of compensation. Egg donors tend to be taller, thinner, and more Nordic looking than the female population in the United States, and many fertility clinic websites advertise "premium fees" for donors with particular attributes or characteristics that are in demand.[15] Finally, some fertility clinics advertise higher payments for those who have successfully donated before, despite the ASRM recommended limit on cycles per donor.[16]

This environment generates concern for undue influence over donors' decision-making to enter into this arrangement without the full consideration of the risks present. The risks and benefits of any medical procedure are communicated to patients by treating physicians to ensure their informed consent. As applied to oocyte donation, donors are ideally informed of the purpose, duration, and invasiveness of the extraction procedure and medications, as well as the associated medical and psychological risks prior to making the decision to donate.[17] ASRM guidelines require full disclosure of the potential medical, psychological, and legal problems that may emerge as a result of donation. Donors are also to be informed of opportunities for non-identifying or identifying information disclosure to future offspring as well as the potential for legal changes that may void such agreements. Finally, clinics are to maintain registries with donors' medical, psychosocial, and all other forms of screening information received.[18]

In the absence of systematic oversight, however, it is impossible to ensure that donors are receiving complete and accurate information from medical professionals that are simultaneously treating those in need of this material for *in vitro* fertilization.[19] Scholars have questioned the integrity of informed consent given the financial vulnerability of those most commonly targeted—young college students—for participation.[20] One study finds that pre-donation, most donors (80 percent) were aware of some medical risks associated with the process while a majority of women (62 percent) viewed the potential for such health and safety risks as minimal or virtually nonexistent. The same study finds that among the 80 donors interviewed, almost 20 percent donated solely because of financial need and approximately 60 percent of the sample identified remuneration as very significant in the decision to donate.[21] The vulnerability of potential donors relative to physicians and intended parents raises substantial concerns regarding the absence of strict oversight over the informed consent process, with some questioning the utility of this method altogether.[22]

The medical and psychological risks present in oocyte donation, the potentially coercive payment offers, and the vulnerability of those most often targeted by intended parents and egg brokers illustrate the specific interests and needs of donors regarding their health and safety. Young, healthy women are bearing the sole weight of these risks for the desires of intended parents and the profitability of this multi-billion dollar industry.[23] Many feminist scholars emphasize the pressing need to limit this coercion and exploitation in oocyte donation, to ensure sufficient protections are in place to prevent or mitigate these risks. The focus on donor health and well-being is critical, yet often ignored in the scholarship of exploitation in fertility medicine are the risks and

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potential sources of conflict intended parents encounter while seeking and utilizing donated oocytes.

Use of donated oocytes in assisted reproduction

Intended parents drive much of the demand for oocytes, which has increased dramatically in recent years. Today, increased acceptance of assisted reproduction and its use by single individuals and same-sex couples contributes to a greater number of patients pursuing treatment. Additionally, as men and women increasingly delay marriage and childbirth, there is a consequent rise in age-related infertility.[24] In the private market, intended parents have open access to treatment and the freedom to recruit their ideal donor.

While intended parents often prefer minimal regulation to maintain this open access, the current system produces numerous problems in the process to obtain and use donated oocytes. In the absence of insurance mandates, or sufficient coverage, many are unable to afford the high cost of this material and the consequent treatment. For those unable to pay these costs, the free-market is inherently restrictive, keeping all but the wealthiest from this reproductive option. In response to the high costs, fertility loan companies are increasingly partnering with fertility clinics and programs to offer specialized fertility lending agreements. Some companies are placing loan counselors on site, advertising through medical programs' websites or working directly with physicians to promote these lending arrangements.[25] Further, some medical professionals are investing in lending companies that are promoted to their patients, creating a potential conflict of interest within the patient-physician relationship. Although the extension of quick credit increases accessibility of treatment, this practice compromises the relationship between these two parties. Given the vulnerability of those suffering from infertility, patients may be encouraged to utilize donated oocytes regardless of the expense even when the prospects for success are moderate to low.

Without legal clarity regarding the rights and responsibilities of intended parents and donors in these arrangements, new dimensions of conflict may form. Disputes may arise between intended parents regarding the use of donated gametes, either before or after fertility treatment in instances of death, divorce, or withdrawn consent of one partner. Additionally, problems may arise in disposition following fertility treatment. There are numerous methods for gamete and embryo disposition, yet certain options are more contentious than others, particularly the donation of unused materials to another couple or for use in ESC.

Finally, legal uncertainty and conflicts can emerge following the transfer of this material to the intended parents. Is the donor's right to privacy more important than the child's right to know the donor? Does the donor retain any legal standing to sue if this material is used for purposes beyond the originally agreed upon use? Does a donor ever have grounds to sue for custody of a child born with her genetic material? The legal complexities that arise in the use of donated oocytes in assisted reproduction, as well as their use following treatment, introduce numerous dimensions of conflict and uncertainty.

Use of donated oocytes in ESC research

Biomedical research, and in particular embryonic stem cell (ESC) research, remains a controversial practice that is, in part, rooted to the polarizing debate over abortion. As the primary focus of federal regulations has been the use of public funding for this research rather than a system of comprehensive oversight, much of the current embryo research is conducted in the private sector.[26] Although numerous political and legal issues emerge as a result, one issue of practical significance facing researchers in the United States is the need for donated oocytes and embryos.[27] The moral controversy surrounding this research has left many in vitro fertilization participants reticent to donate excess embryos for stem cell research; the difficult and risky process to obtain oocytes further restricts the conduct of this research.[28] While ESC research raises numerous ethical and legal issues outside the scope of this project, the shortage of oocytes and their critical importance to this line of biomedical research may inform the development of state policy on oocyte donation and its use.

The procurement and use of donated oocytes in fertility treatment raises troubling legal and ethical issues for intended parents that are largely a product of the market-based system. Donors and intended parents have distinct motivations and objectives for their involvement in this process, in turn leading to divergent interests and needs. Both parties are vulnerable during and after their participation, particularly in the absence of federal standards to ensure their safety, well-being,

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and ethical treatment. Finally, the critical need for donated oocytes to conduct ESC research raises additional ethical and political issues in the use of oocytes for this specific purpose. In light of the perils and uncertainty facing the aforementioned parties and the many political conflicts surrounding donation and this material's use, the following section considers the breadth and scope of state regulation.

State regulation: Medicine, ethics, politics

The ethical, medical, and legal dimensions of oocyte donation generate numerous avenues for policy development. Specific policies applicable to oocyte donation and use serve as the unit of analysis for the investigation, which examines the presence and extent of experimentation and pluralism in state-level policymaking. While it is difficult to quantify and measure these concepts, policies that address the ethical, medical, and legal interests of key participants directly involved in this practice are regarded as empirical evidence of policy diversity and experimentation.

To assess the extent to which policies address the needs and interests of oocyte donors and intended parents, a content analysis of all state legislation concerning oocyte donation is conducted. The frequency with which these interests and needs are met through public policy is documented, and the issues most commonly addressed by policymakers as well as those not addressed in state law are identified. Further, this inquiry into state policy considers the nature of the health and safety protections established for participants and the extent to which the primary risks to donors' health and safety have been addressed.

The data utilized for this analysis comes from two sources, the *National Council of State Legislatures* (NCSL) and a Lexis-Nexis key word search of state statutes. The NCSL provides a listing of "Embryo and Gamete Disposition Laws," "Embryonic and Fetal Research Laws," and "Human Cloning Laws," which was used to identify applicable state regulations.[29] Additionally, searches in Lexis-Nexis with the keywords "oocyte donation," "gamete donation," and "gamete disposition," was used to identify all pertinent legislation not included in the NCSL listings.

A total of 55 laws from 36 states were identified from state statutes, economic development codes, and family or domestic relations codes. (Although some of the laws included in this analysis were initially brought to state legislatures by executive orders from the governor's office, this review does not include such orders.) This analysis includes legislation that impacts the recruitment of oocyte donors, informed consent, compensation, the process of procurement, and the disposition of donated oocytes (see Table 1). Excluded from this analysis are policies that do not specifically address gamete donors or the use of this donated material, such as the funding of research activities (beyond compensation for gametes) and the use of genetic testing or gender selection in assisted reproduction.

The most common issue addressed by state law deals with legal parentage in assisted reproduction, although a few states are responsive to other aspects of this process. A significant minority of states have not regulated any aspects of oocyte donation and their use, while California, Massachusetts, Maryland, and New York remain the most active in this respect. While it is beyond the scope of this paper, further inquiry into the role of these states as innovators may contribute to a greater understanding of policy development in this issue area and human biotechnology policy more generally. Specifically, examination of how a cutting-edge and potentially risky policy experiment reaches the legislative agenda and is passed into law in one state may uncover the arguments and strategies successful brokers used to push this policy proposal. In the analysis below, policies are categorized based upon the specific party addressed; the final category consists of parentage acts, which attend to the rights and legal responsibilities of both oocyte donors and intended parents.

Statutory protections for oocyte donors

There is some variation among bioethicists regarding the policies or practices that are expected to sufficiently protect oocyte donors. Some argue for complete prohibition on compensation or strict enforcement of payment limits, separate medical staff for the donor and intended mother, greater protection from legal responsibility for offspring, and the right to privacy for donors. Others argue for broader changes to the

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Table 1. State laws on donation and use of oocytes.[a]

Donor informed consent laws	*Donor compensation/ recruitment laws*	*Donor protection from parental responsibility*	*Informed consent for oocyte disposition*	*Information requirement for oocyte disposition*	*Limits on the use or disposition of oocytes*	*Parental rights in ART*[b] *(married couples only)*
Arizona	Arizona	Alabama	California	Connecticut	California	Alaska
California	California[c]	Arkansas	Florida	Massachusetts	Louisiana	Arizona
Connecticut	Connecticut	Colorado	Maryland	New Jersey	Maryland	California
Illinois	Indiana	Connecticut	Massachusetts			Illinois
New York	Louisiana	Delaware	North Dakota			Kansas
	Maryland	Florida				Louisiana
	Massachusetts	Idaho				Massachusetts
	New York	Minnesota				Missouri
		New Mexico				Montana
		North Dakota				Nevada
		Oklahoma				New Hampshire
		Texas				New Jersey
		Utah				New York
		Virginia				N. Carolina
		Washington				Ohio
		Wyoming				Oregon
						Tennessee
						Wisconsin

[a] As of December 2012.

[b] Assisted reproductive technologies.

[c] California has laws regarding donor compensation and the recruitment of oocyte donors.

industry or the complete elimination of this practice, given the concerns about coercion and exploitation.[30]

Table 2 presents state-level policies that are specifically tailored to the needs of oocyte donors. Five states have taken action on informed consent, mandating specific requirements for donor consent agreements. The Arizona statute provides the most in-depth explanation of the protocol, outlining five points that must be addressed prior to asking consent. This includes the communication of complete information on the known and potential risks of the hormone treatments, the purpose and longevity of each medical component in the donation process, and the potential impact for donors' future fertility.[31] Despite Arizona's more comprehensive informed consent policy, there is little variation among the states regarding the content, purpose, and source of this information. The variation that is present in informed consent policies concerns the intended use of this material. Specifically, two out of the five laws require informed consent for all types of oocyte donation, while three specify that this requirement only pertains to those donating to biomedical research.

The recruitment of oocyte donors is often viewed as a coercive and exploitative process, particularly following stories about excessive payment for "designer eggs."[32] California, the only state responsive to this issue, requires all recruitment materials to provide information on the medical and psychological risks of donation. Additionally, all advertisements must include a disclaimer that advertised rates of payment may not be the *actual* payment received, a provision of the law

Table 2. Oocyte donor protections across the states.

	Informed consent			*Prohibits compensation*			*Allows compensation*	
State	*ART*	*ESC*	*Both*	*ART*	*ESC*	*Both*	*ESC*	*Ad regulation*
AZ			X		X			
CA		X			X			X
CT		X			X			
IL		X						
IN					X			
LA				X				
MA					X			
MD					X			
NY			X				X	

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Table 3. Intended parents' rights and protections.

	Disposition of unused oocytes from ART			
	Informed consent			
State	*Death or divorce*	*Donate to ESC*	*Information required*	*Prohibitions on gamete use*
CA		X		X
CT			X	
FL	X			
LA				X
MA		X	X	
MD		X		X
ND	X			
NJ			X	

addressing the higher payments often given to women with specific and in demand characteristics or features.[33] This 2009 policy illustrates experimentation by the California legislature; it has yet to be seen if other states will follow suit.

Seven states prohibit compensation for oocyte donation, with each state specifying the extent of the prohibition. Louisiana, the only state that restricts compensation for oocytes used in assisted reproduction, also has a ban on all ESC research (see Table 3). Thus, a ban on compensation for oocytes used in research is unnecessary. The remaining five states have prohibited compensation for oocytes donated for research purposes without addressing compensation for oocytes donated for use in assisted reproduction. Arizona's law is specific, prohibiting compensation for oocytes donated to research, while remuneration for sperm or embryos used in research is not addressed. The remaining four states prohibit compensation for oocytes and all other gametic materials used for research including sperm, embryos, and zygotes. California laws allow reimbursement for direct expenses incurred (primarily out-of-pocket expenses such as travel to and from the medical facility) through oocyte donation for research purposes, but California is the only state law that allows for this type of remuneration.[34]

New York explicitly allows for compensation for oocytes donated for research beyond direct expenses incurred, although this policy is not a product of the state legislature. The New York Empire State Stem Cell (ESSC) Board's Funding Committee, in collaboration with the New York Stem Cell Science Program (NYSTEM) a state agency that oversees stem cell research in New York—allows NYSTEM funds to be used to compensate oocyte donors commensurate with the remuneration recommended by the American Society for Reproductive Medicine. Remuneration beyond expenses incurred includes compensation for the time, discomfort, and inconvenience of donation, in effect increasing payments by thousands of dollars. The ESSC funding committee has stated that the risks associated with the donation process remain the same regardless of the purpose or use of the material. Further, the organization argues that prohibition on reasonable remuneration for oocyte donation for research is "unnecessarily paternalistic," as long as sufficient safeguards for donors are implemented and followed. [35]

New York's policy is distinct from the other state laws on oocyte donor compensation for research not only in its provisions but in the intentional discussion of the risks facing donors and the potential coercive influence of excessive remuneration, a critique most often observed in academic analyses. Overall, state regulations governing compensation for oocyte donation—and to a certain extent, those concerning informed consent—are primarily focused on the intended use of this material rather than the mitigation of risk, medical or otherwise. New York's ESSC committee decision (which is not a state law and pertains only to NYSTEM-funded research) is a rare example of a policy that frames the issue almost solely in terms of women's health and safety rather than the intended use of the material. While this policy clearly facilitates the ability of researchers to obtain gametes for ESC research, it acknowledges and is responsive to concerns regarding undue influence, coercion, and exploitation.

Several states have legalized stem cell research, others provide public funding for this research, and a few have established state-funded stem cell research

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centers similar to that of New York, yet no state has established any such regulations to ensure the ethical treatment of oocyte donors. In 2013, California legislators passed Assembly Bill 926, which would provide compensation for oocyte donation for research purposes commensurate with ASRM standards applied in oocyte donation for fertility medicine; however, the governor vetoed this legislative effort.[36] Thus, New York's policy remains the primary example of a donor-centered approach to regulating compensation and treatment of oocyte donors in research settings.

This inquiry into state regulation has uncovered two examples of policy experimentation, one from the California state legislature and the second from a New York state agency. California's disclosure requirement is the first effort by a state to protect women from false or misleading information in oocyte donation advertisements. The policy from New York's ESSC establishes harmonization in the remuneration of female gamete donors, regardless of the material's intended use. In general, there is evidence that the states have responded to some of the concerns for oocyte donors raised by scholars and members of the policymaking community. A majority of the policies, however, pertain only to those women donating their oocytes for research purposes, indicating that donor safety and well-being may not be the primary focus of the legislation. In particular, the prohibitions on compensation for oocyte donation for research suggests that these policies may be designed to limit the availability of this material for biomedical research rather than protect donors from the coercive pressure of compensation. While there are some differences in the precise content of these policies, in general, they offer no substantive protections for women donating their oocytes for assisted reproduction, as addressed by both feminist bioethicists and the ASRM.

Most significant in this analysis is the relative absence of regulation by most states, which carries significant implications for oocyte donors' health and safety. Theoretically, one of the chief virtues of federalism is the presumption that state action is more efficient and responsive on these complex and divisive issue areas than national legislation. Although it is unclear why limited action has taken place within the states, the complete absence of regulation in most states and the limited number of issues attended to by the nine states that have acted (listed in Table 2) suggests that the safety and ethical treatment of female participants is not a major concern. While there is some evidence of policy experimentation by a few states and limited pluralism or diversity in state laws establishing certain protections, it appears that state officials have not prioritized oocyte donor safety and well-being in policy development.

Statutory protections for intended parents

Intended parents, also central participants in oocyte donation, encounter a unique set of risks based upon their particular points of vulnerability within the industry. The regulations most responsive to the interests of this group are centered on clarifying the legal use and disposition of gametes before and after fertility treatment, as presented in Table 3.

The most common issue addressed is the use and ownership of gametes before and after fertility treatment. Five states have informed consent requirements for intended parents regarding the use or disposition of gametes following treatment. The primary difference between informed consent requirements for intended parents in these regulations pertains to the intended use of the donated material. Two states, Florida and North Dakota, require informed consent for the disposition of donated oocytes prior to treatment in cases of divorce or death. Additionally, North Dakota allows either parent to withdraw their consent to fertilize and implant donated oocytes at any time during the process.[37] California, Massachusetts, and Maryland require informed consent from intended parents for the donation of unused oocytes from fertility treatment for ESC research. These state regulations, however, do not address the use of donated oocytes in fertility treatment or ownership in instances of death or divorce.

Connecticut, Massachusetts, and New Jersey require that intended parents receive information regarding the disposition of unused, donated gametes following treatment. These statutes are similar, with requirements to inform intended parents of the options to store, dispose, or donate—for research or to other assisted reproductive technology participants—unused materi-

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als. Finally, California, Maryland, and Louisiana have introduced specific constraints on the use and disposition of donated oocytes. California prohibits the use of donated oocytes for any purpose not identified through informed consent, which is secured prior to donation.[38] Maryland prohibits the donation of unused gametes for state-funded stem cell research, although oocytes can be donated directly to research centers or to privately funded projects.[39] Louisiana has established the most significant restrictions on the use of donated oocytes, prohibiting (and criminalizing) their use for anything but assisted reproduction.[40]

For intended parents, the absence of federal oversight of the fertility industry introduces many legal complexities and potential problems in the use of donated oocytes. The primary issue addressed by state officials is the use and disposition of donated oocytes, with a handful of states enacting specific restrictions on the use of this donated material. Although there is some diversity in the content of regulation, there is no real evidence of policy experimentation among the states. Concerns over patient and future children's privacy, access to information about oocyte donors, and requirements regarding the selection and screening of donors are just some of the significant legal issues yet to be addressed by the states. Table 3 shows that only eight states (California, Connecticut, Florida, Louisiana, Massachusetts, Maryland, North Dakota, and New Jersey) have addressed the issues associated with the use and disposition of gametes, leaving intended parents everywhere else in legal limbo when the aforementioned disputes arise.

Legal parentage: Donors and intended parents

Thus far, state policies have been categorized on the basis of population or type of participant targeted by the legislation. For a variety of reasons, uniform parentage acts are placed in a separate category. First, their ubiquity among the states stands in stark contrast to laws regulating oocyte donation. The preponderance of these acts is, in part, a product of the model legislation created by the National Conference of Commissioners on Uniform State Laws designed to reconcile inconsistencies in family law among the states. Second, despite some variation in content, many of these acts address the rights and responsibilities of both oocyte donors and intended parents. Finally, the evolution and diffusion of these laws among the states over time is distinct from laws pertaining to oocyte donation.

In 1973 the National Conference of Commissioners on Uniform State Laws created a legislative model, the Uniform Parentage Act (UPA), to clarify parent-child relations—including the determination of legal parentage and paternity in custody and child support disputes—for the equitable administration of family law. Insofar as assisted reproduction is concerned, the first round of states to adopt this legislation only clarified the legal rights for donors and intended parents in artificial insemination, the only reproductive technology available at the time. Many states continue to operate under the 1973 UPA, assigning legal parentage and clarifying rights and responsibilities when donated sperm is used in assisted reproduction.[41] Since the development of egg donation, which allows for *in vitro* fertilization, surrogacy, and other forms of biomedical intervention, the UPA has been updated to extend these protections to those cases involving donated oocytes. Since 2002, sixteen states have adopted the most recent version of the UPA, providing legal protection from parental rights and responsibilities for all gamete donors, while eleven states still utilize the 1973 version (see Table 4). Thus, only sixteen states protect oocyte donors from parental responsibilities and specify the donors and intended parents' legal rights when contractual disputes emerge.

As shown in table 4, seven states have addressed parental rights in assisted reproduction cases involving donated gametes. Specifically, these statutes establish that a child born through *in vitro* fertilization to a married couple is their legitimate child. Although unstated, it is assumed that gamete donors are protected from parental responsibilities, yet this protection is only conferred when the gestational mother is married. In these states, the rights associated with legal parenthood do not extend to single men and women, unmarried couples, and same-sex couples unable to marry, rendering their legal status and rights (as well as that of gamete donors) uncertain when legal disputes emerge.[42]

This review of policies designed to clarify the legal rights and responsibilities of intended parents and donors regarding children born with donated gametes again does not provide evidence of much policy

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Table 4. Protection from and establishment of parental rights in assisted reproduction.

All gamete donors (2002 UPA)	*Sperm donors* (1973 UPA)	*Intended parents* (if married)	*No statute clarifying parental rights*
Alabama	California	Alaska	Georgia
Arkansas[a]	Illinois	Arizona	Hawaii
Colorado	Kansas	Louisiana	Indiana
Connecticut	Missouri	Massachusetts	Iowa
Delaware	Montana	New York	Kentucky
Florida	Nevada	North Carolina	Maine
Idaho	New Hampshire	Tennessee	Maryland
Minnesota	New Jersey		Michigan
North Dakota	Ohio		Mississippi
New Mexico	Oregon		Nebraska
Oklahoma[a]	Wisconsin		Pennsylvania
Texas			Rhode Island
Utah			South Carolina
Virginia			South Dakota
Washington			Vermont
Wyoming			West Virginia

[a]State law extends greater legal protection to female gamete donors rather than male gamete donors.

experimentation by the states. Specifically, the prevalence of such laws is largely a product of a federal mandate requiring the states to clarify legal parentage, coupled with the Uniform Law Commission's provision of model legislation for the states. There is some diversity among the states regarding parental rights, although much of this difference is explained by the failure of states to update the law following technological innovations in fertility medicine.

Additionally, many of these regulations fail to address numerous concerns that may arise in disputes between intended parents and oocyte donors including the right to privacy (oocyte donor and/or child born with donated gametes), the right to information, and the use of donated material following treatment. Seven states (Alaska, Arizona, Louisiana, Massachusetts, New York, North Carolina, and Tennessee) have established indirect protections of parental rights for married couples utilizing donated gametes. In these states, however, the rights and obligations of gamete donors in relation to the intended parents or child is unclear; to wit, do oocyte donors have any legal responsibilities for the child or can they sue for custody or breaches of contract?[43] Finally, sixteen states (see Table 4) have no legal directives regarding the parental rights of gamete donors or intended parents.

This examination of policies concerning legal parentage and parental rights and obligations suggests that keeping regulatory power with the states leaves oocyte donors and intended parents in a precarious legal position. Despite the federal government's requirement for states to clarify legal parentage and a nonprofit, research organization's assistance in policy development, legal directives to prevent these disputes in assisted reproduction remains out of reach for many, depending on location.

Regulating oocyte donation

In the U.S., many bioethicists continue to advocate for state-level regulation of human biotechnologies, maintaining that the basic features of federalism allow for policy experimentation and respect for diverse policy preferences as well as government responsiveness.

The most commonly voiced concerns for oocyte donors center on the problems that emerge in the absence of industry oversight, specifically coercion and exploitation. A handful of states have devised policies to address aspects of these broader concerns, and California in particular is a leader in these efforts.[44] The majority of policies dealing with compensation and informed consent, however, pertain only to the donation of materials for research purposes. While there is some diversity among the states, the primary focus of much of this state regulation concerns stem cell research. California and New York stand out for their unique policies regarding the regulation of donor recruitment advertisements and allowance of compensation for oocytes used in research, although the diffusion of these policies to other states has not yet occurred. The issue most frequently addressed is

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protection from legal responsibility for the child. This form of regulation, shielding donors from the responsibilities of parenthood, as well confers many legal rights to intended parents using donor gametes in assisted reproduction.

While there is evidence of limited experimentation and moral pluralism in public policies governing the treatment of oocyte donors, there is little evidence to suggest that such a circumscribed approach is the best way to ensure sufficient protections for their health and well-being. State law, more often than not, confers protections to those donating for research rather than reproduction—or both. This suggests that keeping regulatory power over oocyte donation with the states allows other political priorities and agendas to exert influence over policy development. Specifically, the interests and needs of donors appear to have been usurped by the political goal of limiting stem cell research. Although this approach preserves the power of the states, the creation of sufficient protections for oocyte donors in this system remains unlikely.

Intended parents encounter a number of risks and issues in the attainment, use, and disposal of donated oocytes for assisted reproduction. State regulations pertaining to this population, however, focus primarily on the disposition of donated gametes, particularly for stem cell research. While two states have devised measures to deal with gamete disposition following death and divorce, the majority of state laws concern the donation of this material for research. This focus on stem cell research is significant as ancillary or additional protections for those participating in assisted reproduction are largely absent. As is the case with protections for oocyte donors, secondary political conflicts appear to be the dominant focus of state legislation rather than the needs of intended parents.

Policies that clarify issues of legal parentage in assisted reproduction are the most common form of state regulation governing the use of donated oocytes. There is little diversity in these acts as the Uniform Commission on Laws provides model legislation for the states. The primary differences among the states exist in the adoption of the model legislation and subsequent update of this legislation. This passive posture has not led to greater innovation or policy development regarding legal parentage among the states, and a majority of states do not have sufficient legal protections for oocyte donors from parental responsibilities or obligations. Intended parents have been conferred greater legal protections in assisted reproduction since its development, although many gaps remain, particularly for individuals, unmarried couples, and same-sex couples.[45]

Discussion

Focusing on the case of oocyte donation, this review has challenged the claim that state regulation is the most efficient and effective approach for the regulation of human biotechnologies on two counts. First, the presence of moral pluralism or diversity in state policymaking, argued to be one of the key benefits of federalism, is found in rather limited supply. Although there are differences in the issues addressed and protections conferred in state regulation, the variation is minimal as compared to the potential problems facing both oocyte donors and intended parents.

Second, while affording state regulatory authority over human biotechnologies fits with the political culture of the U.S., in practice it has proven insufficient in providing adequate protections—medical and legal—for the participants involved. In one sense, the virtues of federalism are appealing in light of the ethical, legal, and social controversies raised in fertility treatment and biomedical research, and continued inaction by the federal government. If the federal government continues its stance of nonintervention, the states are free to engage in lawmaking to meet the needs of their constituents and attempt innovative policy experiments. Within the context of oocyte donation, however, allowing the states to act has resulted in laws that do not address the immediate or long-term health and safety risks that donors experience, or the legal issues that intended parents face. Further, many of these policies in effect limit stem cell research by restricting the availability of oocytes.

This review of state law governing oocyte donation also raises concerns regarding the ability of the states to adequately protect citizens in a sensitive area of biomedicine and illustrates the need for further evaluation of human biotechnology regulation at the state level. With regard to oocyte donation, there is a noticeable absence of federalism's key virtues in state-level public policy, as well as inadequate protections for this industry's most vulnerable populations. More gener-

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ally, this examination raises broader concerns regarding the absence of federal oversight and the market-based economy for assisted reproduction and biomedical research. The inability of the industry to successfully self-regulate, as seen in the recruitment and compensation of oocyte donors, coupled with a lack of comprehensive federal oversight, opens the door for increasingly egregious ethical violations in human biotechnologies.[46]

Fertility medicine is often characterized as a means for women to assert greater control over reproduction, yet it is clear that women's experiences with oocyte donation can vary tremendously based upon their social location within the system.[47] These experiences, with their accompanying potential for exploitation and coercion, raise questions of substantive interest that merit future investigation. One avenue for follow-up research is the examination of interest group involvement, especially by feminist activists and organization, in the debates over oocyte regulation. Traditionally, the feminist movement in the United States has focused on reproductive rights, namely the protection of access to contraception and abortion. However, the increasing activism on issues such as oocyte donation and other assisted reproductive technologies among social justice organizations, including the Council for Responsible Genetics and the Center for Genetics and Society, may produce avenues for increased collaboration with feminist organizations.

In the years ahead, the development and use of newly emerging biotechnologies will continue to grow, and the range and depth of bioethical issues will follow in complexity and sophistication. The current absence of comprehensive regulation and oversight of fertility medicine and ESC research carries significant implications for the adequate protection of participants, including providers of reproductive materials and labor, intended parents, and future children. Further, this research illustrates a troubling feature of federalism in which controversial yet prescient issues fail to receive the necessary attention, leaving legal, ethical, and moral uncertainty in its wake.

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