

# Legal Issues in Gamete and Embryo Cryopreservation: An Overview

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## Abstract

This article provides an overview of existing and developing law surrounding IVF embryos and those who handle them. It discusses what law and legal theories of liability may apply to embryology labs, and gamete and embryo banks in the context of embryo loss, abandonment, shipping and implantation. It explores how often intertwined theories of law have been applied to this unique field, including contract, informed consent, health, tort and Constitutional law. Recent so-called “Personhood” initiatives are reviewed for their impact on ART practice. The article also explores how legal principles related to patient choice, autonomy, informed consent, and the various rights and responsibilities of providers and patients have been applied to this area of medicine which is unique both because it involves at least two patients and due to the singular nature and reproductive potential of ex-utero and cryopreserved embryos and gametes. Through an examination of largely US judicial and statutory perspectives and trends, the article assesses the complexities of the impact of the law on, and attempts to offers guidance to, those involved in this continually evolving and challenging field of medicine.

## Keywords

- ▶ embryos
- ▶ reproductive tissue
- ▶ cryopreservation
- ▶ personhood
- ▶ pre-embryo
- ▶ informed consent

Rapidly changing medical practices and advances often outpace legal frameworks, as the status of the law regarding remarkable advances in in vitro fertilization (IVF) and assisted reproductive treatment (ART) can attest. Both new uses of cryopreservation and recent cryostorage and shipping incidents involving tanks and labs in the United States underscore the continuing and emerging legal challenges surrounding the characterization, cryostorage, transport, and disposition of reproductive tissue. Fertility preservation techniques and purposes have expanded to routinely include egg freezing for both age-related purposes (sometimes referred to as “elective” or “social” freezing) and imminent disease-related conditions (the most commonly recognized of which is “oncofertility”); “freeze-all” cycles are increasing; elective single embryo transfer (“eSET”) has become a standard of care reinforced through professional guidelines and insurance-

approved protocols; and since 2017, at least five states have passed laws mandating insurance coverage of fertility preservation procedures for patients potentially facing iatrogenic infertility.<sup>1</sup> IVF programs with long-held embryos continue to wrestle with dispositional issues, including whether and when embryos may be discarded pursuant to prior instructions or considered “abandoned” and potentially discarded. Shipping reproductive tissue, including donor gametes for treatment and embryos for both treatment and long-term cryostorage, has also become a routine part of ART practices.

This article provides an overview of existing and developing law largely within the United States on a selected number of embryo-related issues for the twin purposes of shedding light on current statutory and judicial perspectives and to help provide guidance for present and anticipated future medical advances.

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## A Rose by Any Other Name? The Critical Role of Language in ART Law and Medicine

In law, language can be outcome determinative, and clarifying ART-related terms and definitions is a foundational step to both understanding and advancing legal frameworks in this arena. Consider the term “mother”: once a simple, easily understood word applicable only to a limited number of women (biological, adoptive, or step-mothers). It must now include genetic, gestational, and intended mothers. Similarly, the emergence of IVF and cryopreservation technologies has ushered in a new reality of ex-utero, or preimplantation IVF embryos, triggering a host of legal issues and challenges for both law and policy makers.

Longstanding laws predating IVF and addressing the status of pregnant women and fetuses have often conflated in utero fetuses with more recently possible ex-utero embryos. Indeed, editions of Black’s Medical Dictionary that pre-date IVF include “embryo” in the definition of a fetus, and in the 1970s in the wake of *Roe v. Wade*,<sup>2</sup> multiple fetal-tampering laws passed to criminalize late-term abortions often included an embryo in the definition of a fetus.<sup>3</sup> Unanticipated consequences of such laws included a manslaughter conviction of the chief resident of obstetrician-gynecologist at Boston Medical Center, later overturned, after he performed a legal, late-term abortion and was accused by a nurse of intentionally depriving the fetus of oxygen at delivery.<sup>4</sup> Another example includes a case brought by an IVF center and the American Civil Liberties Union claiming the center could not decipher what procedures were allowed and which procedures were prohibited by a statute that predated IVF, but could be interpreted to apply to some of the center’s practices.<sup>5</sup>

Much of the more recent law involving embryos throughout the United States has recognized the critical distinction between an in utero, developing, fetus, and an ex-utero embryo allowed to develop from fertilization only until the point it is either cryopreserved or implanted, with multiple courts employing the term “pre-embryo” for the latter.<sup>3</sup> While the scientific community has long debated the accuracy and utility of the term,<sup>6</sup> from a legal perspective having a distinct word for an ex utero, IVF-created human embryo at this early stage of development is quite helpful. Most courts have recognized and made such a distinction—often relying on expert scientific testimony—and utilizing terms such as “pre-embryo” or “zygote” and the like.

For purposes of this article, the term “embryo” or “preimplantation embryo” will be used for ex utero or preimplantation IVF human embryos. Similarly, “gamete” refers to oocytes or sperm, and “reproductive tissue” to cryopreserved gametes or preimplantation embryos collectively.

### Legally Speaking: What Is an “Embryo”?

A second, both foundational and fundamental, issue is how the law characterizes these preimplantation embryos. This

becomes especially important in the context of control or ownership of various reproductive tissues and financial damages in the event they are fought over in a divorce, damaged, mistakenly switched with another patient’s, lost, or otherwise rendered unusable. There is no singular answer to that critical question: both the context and jurisdiction (state or country) are often significant factors in that determination. The resulting ambiguity perplexes efforts to predict legal frameworks in the myriad of contexts that arise around reproductive tissue.

Courts have characterized preimplantation embryos created during a marriage in a variety of legal ways, ranging from the seminal case of *Davis v. Davis* in which the court concluded embryos are “sui generis” (defined as “a class of its own”) and “neither property nor persons but deserving of special respect” because of their potential for life,<sup>6</sup> to joint marital property of a special and indivisible character,<sup>7</sup> to simply property (the latter a Canadian case involving a donor embryo).<sup>8</sup> Some former spouses have argued that their preimplantation embryos should legally be deemed children and that they should be awarded “custody” as the better parent.<sup>9</sup> This type of argument has failed but continues to be made, often backed by antiabortion interest groups who see these so-called personhood arguments consistent with their long-term goal of outlawing abortion.<sup>10</sup>

Generally, the legal concept of “property” can connote the right of the owner to partition, use, dispose, or gift. That characterization, however, greatly oversimplifies judicial approaches to preimplantation embryos. In one early case, a federal district court ruled in favor of patients in a dispute with the clinic holding their embryos, characterizing them as the patients’ personal property.<sup>11</sup> That type of dispute does not require addressing the more complex reproductive rights and nuanced constitutional issues that are raised in divorce litigation involving disputed use, or other litigation involving valuation of lost or damaged reproductive tissue. It is important to note that even courts such as *Davis* which consider embryos in a unique category and deserving of “special respect” have ruled they can be discarded.<sup>12</sup>

Even when courts consider embryos to be some form of property in the context of divorce proceedings, it is clear that balancing the rights of two progenitors extends beyond a right of “ownership” of reproductive tissue, to the constitutionally recognized right to procreate or not to procreate, and the corollary right to become or not become a parent. Thus, in over 20 cases across the United States, divorce courts have struggled with legal theories of contract, property, contemporaneous mutual consent, and a balancing of constitutional rights. The nuances, and often inconsistent and overlapping theories, while beyond the scope of this article, illustrate the difficulty in categorizing and providing a legal framework for reproductive tissue.<sup>12</sup>

For ART care providers dealing with gametes and embryos, these questions of legal status can have a dramatic impact on the responsibilities and vulnerabilities of handling reproductive tissue.

## A Legal Perspective on Patient Choice, Autonomy, Informed Consent, and Rights and Responsibilities Regarding Embryos and Gametes

By its nature, human reproduction involves at least two individuals, and is singularly intended to result in a new human life. Those two distinctive aspects can have a tremendous impact in addressing legal rights and responsibilities involved in ART family building and the cryopreserved embryos they create. With the exception of organ transplants and bone marrow transfusions, the authors can think of virtually no other area of medicine where two (or more) patients are inextricably tied to a single medical procedure or its aftermath and in no other instance where the potential to create a new life is the intended goal, with cryopreservation extending the time frame indefinitely.

While very recent announcements suggest we are moving closer to future advances that may bring the possibility of creating either sperm or eggs from an embryonic stem cell from any individual,<sup>13</sup> thereby eliminating a second patient, and artificial wombs may one day remove the role of pregnancy from these debates,<sup>14</sup> current challenges including issues of autonomy, informed consent, and unique rights and responsibilities are likely to remain for quite some time. As such, an understanding of how the law treats progenitors, non-progenitor-intended parents, and gamete donors, and how it distinguishes between informed consent and contract law, is both timely and essential.

### Issues of Autonomy

The right to autonomy is a fundamental principle in both medicine and ethics, and at the core of all medical decision-making in the United States.<sup>15</sup> In the medical context, bodily autonomy, also known as self-determination, means that patients have the right and ability to make their own choices and decisions about their medical care and treatment. This right comes with the assumptions that patients are competent to make the requested decision, and are typically honored so long as the patient's wishes are within the bounds of the law. In the ethical context, autonomy is the "personal rule of the self that is free from both controlling interferences by others and from personal limitations that prevent meaningful choice."<sup>16</sup> In this framework, individuals act intentionally, with understanding, and free of controlling influences.

Despite these well-recognized, litigated rights, in the context of cryopreserved embryos courts often struggle with the specific interest of people using reproductive technologies to control their reproductive tissue. In contrast to a typical decision involving an individual's autonomy, court cases concerning embryos customarily impact more than one individual's autonomy, and courts are often asked to prioritize one individual's autonomy over another's. In most, but not all, cases, courts have sided with one progenitor's identified right not to procreate over a former partner's right to procreate, with varying legal bases of these decisions including constitutional, informed consent, and contract law.

## The Space between Informed Consent and Contract Law

Informed consent is another fundamental principle of both medicine and ethics. According to the American Medical Association (AMA), informed consent is the patient's right to receive information and question-recommended treatments so that they may make thoughtful choices about care,<sup>17</sup> and requires that a medical professional assess a patient's ability to understand the relevant information and the implications of their elections. Both legally and medically, documentation of informed consent should be obtained, and in legal disputes it is critical evidence and can be outcome determinative.

However, in the context of cryopreservation and cryostorage of embryos and gametes, informed consent may have significant limitations. Whether or not consent can ever really be obtained when a couple is counseled as a single decision maker is a current topic of discussion.<sup>12</sup> Other issues include a person's right to change his or her mind (and change his or her mind over time) and whether cryostorage and future disposition of reproductive tissue are issues of consent or contract law. Additionally, all of these issues can have significant public policy implications.

A primary issue with consent for cryopreservation is a person's natural inclination for his or her views to evolve. Typically, consent for a medical procedure is obtained temporal to its execution, such as with heart surgery or amputation, or an IVF procedure itself. However, by its very nature, decisions regarding embryo and gamete cryostorage and later usage are current decisions, no matter how well informed, that will only materialize in the future. Across the United States, cases continue to be brought asking a court to negate couples' previously agreed upon IVF-related decisions, including use, destruction, or donation of embryos and gametes.

A second issue related to informed consent is the legal characterization of dispositional documents: Are they informed consent documents as typically used in medical practice or legal contracts? Unlike an informed consent document, a contract is a legally binding agreement, between two parties, enforceable under the law of contracts so long as the contract is entered into in accordance with applicable law and its enforcement would not be deemed against public policy. For example, a contract to enter into slavery or prostitution would be considered against public policy and thus unenforceable, while a contract that left no negotiating power for one party and all such power with the other might be deemed unenforceable as a contract "of adhesion."<sup>18</sup> These distinctions can be outcome determinative: one court rejected an ex-wife's arguments that an embryo disposition agreement was instead an informed consent document from which she could withdraw her consent despite her husband's reliance on it, or that it was a contract of adhesion, as she was a sophisticated patient whom the court found could understand the document's contract terms.<sup>19</sup> There is a trend developing within the United States to have separate informed consent documents for the IVF procedure itself and a contract (agreement), intended to be interpreted under applicable contract law,

as to future use, cryostorage, and disposition of any resulting cryopreserved gametes or embryos.

As discussed later, SART has endorsed this position, and model forms (under further revision as this article goes to press) utilize this format. A number of court cases also suggest that judges may be more comfortable enforcing prior decisions made in the form of a legal contract, provided they meet state law requirements for such a contract, are not deemed “contracts of adhesion” (legally so one sided that the weaker party is found to have had no ability to negotiate any of its terms),<sup>18</sup> and are not deemed void as against public policy.<sup>20,21</sup> In a few states, such as California, there are specific statutory requirements that both necessitate such a contract and what must be in it,<sup>22</sup> and failure to follow the law may expose medical professionals to both civil and criminal penalties.<sup>23</sup>

On the other hand, as discussed later, extreme legislative efforts to personify embryos as recently occurred in Arizona may undercut the ability of programs or professional organizations to craft clear, enforceable dispositional documentation.

### Issues of Sex

Legal issues also arise due to the biological differences between male and female progenitors, as well as sex-stereotype expectations. Sperm retrieval is typically a relatively simple, and frequently a nonmedical, process and cryopreserving men’s sperm has been widely available for decades. By contrast, egg retrieval obviously requires a medical procedure and medical personnel, and—until egg freezing was no longer considered experimental—standard of care for any fertility cryopreservation involved fertilization and freezing any resulting embryos.<sup>24</sup> By its nature, female fertility has been historically tied to a male partner (or a sperm donor).

Reflecting these biological realities, couples experiencing infertility or in need of fertility preservation have been routinely counseled together, consented together, and asked to elect future dispositional options for their embryos together, all resulting in each progenitor’s future fertility being inextricably intertwined with their partner. Currently offered dispositional options may include use by one partner following the death or a divorce, donation for procreation either anonymously or to a known recipient, donation for research or clinical training, and discard.

Historically, other options such as “hold for future decision making” or “for a court to determine” have been criticized as simply “kicking the can down the road,” leaving both patients and clinics without any certainty. SART has weighed in, creating and updating two sets of forms for their member clinics: (1) model informed consents for the IVF procedures and (2) legal agreements or contracts designed to clearly address disposition of frozen embryos under contract law, including a clear “default” provision to discard embryos in certain circumstances, including if other choices are not available. Despite these efforts, court cases continue to arise and the varying language and treatment approaches by individual fertility clinics continue to vex law and policy

makers as they sort through these options.<sup>25</sup> This article does not address the various legal approaches courts have taken in resolving embryo disputes (which have been described variously as contract, contemporaneous consent, constitutional rights balancing, relative weight of progenitor versus nonprogenitor, and multiple combinations of these), but rather considers how clinics and labs can attempt to minimize such disputes in their protocols, subject to any applicable local laws in their jurisdictions.

In the future, advances in egg freezing may impact protocols and embryo dispositional agreements and implicate patient autonomy issues. At least from a legal perspective, egg freezing has the potential to equalize male and female patient autonomy. A woman who does not fertilize her eggs with her spouse’s or current partner’s sperm may avoid the future vulnerability to a former spouse that is reflected in many of these embryo disputes. The outcome for frozen eggs might be very different. While divorce lawyers may suggest eggs could be considered “marital property” and offer creative arguments for awarding them to the husband if, for example, he paid the associated medical expenses, it is difficult to imagine a court would actually award a woman’s eggs to her ex-husband. In a very recent 2018 case from Canada, however, a court awarded a couple’s one remaining embryo (formed through both donor egg and donor sperm) to the wife but required her to pay her ex-husband half of the equivalent cost of the donated egg and sperm.<sup>8</sup>

Medical realities, however, may conflict with any legal advantages of egg freezing. Since clinics and labs may have variable levels of expertise with egg freezing and thawing, and preimplantation testing is not yet as commonly available or as predictive for gametes as it is for embryos, women may face difficult choices in balancing potentially improved medical outcomes against improved legal protections. These issues point out the critical and challenging role of patient counseling and informed consent in this area.

### Unique Responsibilities

A final legal distinction worth noting is the unique position IVF clinics, labs, banks, and the various professionals who work in them may find themselves in due to the unique nature and promise of cryopreserved reproductive tissue. Whether a lab or a cryostorage facility is considered a medical provider providing part of a patient’s medical care, and thus subject to medical malpractice law, or a commercial entity subject to tort or contract law, are largely unresolved legal questions and may turn on the facts of any given case.

The majority of commercial law is based on the premise that injured parties can be made whole through a reallocation of resources—as is typically seen in breach of contract cases, where money is awarded to compensate a party for loss or damage. From refunding the cost of a movie ticket when a projector fails to a multi-million-dollar settlement for a supplier’s failure to deliver goods, monetary compensation is utilized to return an injured party to its preinjury self.

However, as has been seen time and time again in the case of reproductive tissue, traditional notions of commercial

fairness often do not squarely apply. Due to the complex technical aspects of freezing and cryostorage, IVF patients now regularly engage not only with medical professionals but increasingly with commercial enterprises for these services, creating unique responsibilities on the part of the clinics, hospitals, and other medical facilities. The extent to which a medical facility might be liable for issues related to off-site storage is unclear, and may depend on a number of factors, including any relationship between the medical facility and storage center, whether the patients were given a choice to move—or where to move—their reproductive tissue, and the nature of the alleged liability and damages.

Given the extreme emotional, social, religious, and cultural perspectives surrounding embryos and gametes, potential damages can create extreme liability for those charged with keeping them safe. Even for a healthy and fertile patient, the loss of an embryo or gamete can be psychologically fraught and emotionally challenging. In cases of oncofertility and other patients with limited remaining reproductive capacity, the loss or damage of an embryo or gamete may result in the forfeiture of their chance to have a genetically related child.

This reality places any fertility-based commercial business far afield of traditional service providers. A typical service provider or commercial business can rely on the long-established principles of financial compensation to make the damaged party whole. Here, the unique nature of reproductive tissue, the circumstances surrounding cryopreservation, the emotional components involved with retrieval, cryostorage and implantation, and the varying social, religious, and cultural beliefs around conception, fertilization, and life means that providers of each of these services often navigate uncharted waters. As discussed later, progress in providing legal frameworks is being made, but significant complexities remain.

### **Handling Embryos: Legal Perspectives on Cryostorage, Shipping, Abandonment, Misplacement, and Loss**

Given their unique potential for life and the strongly held competing views over such fundamental issues of reproductive choice and abortion that have always surrounded legal disputes and characterization of IVF embryos, it is not surprising that handling embryos is so fraught with legal uncertainties. This section examines existing laws and recent litigation, including theories of law and measures of damages, addressing how physicians, embryologists, laboratory personnel, cryostorage facilities, and shipping companies may all be vulnerable in their handling of preimplantation IVF embryos.

#### **Control (or Ownership?)**

In the United States, most embryo-related law has developed either in court cases as noted earlier or in a few legislative efforts. Much of the U.S. law surrounding preimplantation embryos is state specific, and relatively respectful of patient autonomy in determining dispositional decision making.

Two state laws stand in stark contrast to that approach. Louisiana, long an outlier due to its French-influenced legal structure, defines an IVF embryo as a “biological human being which is not the property of the physician who acts as an agent of the facility clinic which employs him or the donors of the sperm or ovum,”<sup>26</sup> but rather as a “juridical person”<sup>27</sup> entitled to numerous protections and restrictions. The law continues that embryos “cannot be owned by the in vitro fertilization patients who owe it a high duty of care and prudent administration.”<sup>27</sup> The Louisiana law authorizes patients to surrender parental rights to their physician who then becomes the custodian of the embryo to make it available, solely to a married couple, so long as the married couple “is willing and able to receive the in vitro fertilized ovum ... constructive fulfillment of the statutory provisions for adoption in [Louisiana] shall occur when a married couple executes a notarial act of adoption of the in vitro fertilized ovum and birth occurs.”<sup>28</sup> The Louisiana law places enormous legal responsibility on physicians and clinics, while limiting patients’ choices. Anecdotal reports have long suggested that Louisiana patients ship their cryopreserved embryos out of state. However, despite this law, a lower court in Louisiana rejected a medical malpractice basis for embryos mislabeled in a tank incident on the theory that errors in storing embryos by embryologists did not constitute medical treatment (the case was rejected on appeal on class action grounds).<sup>29</sup>

Efforts to personify embryos have also taken the form of characterizing embryo donation for procreation as “embryo adoption,” a term largely rejected by the legal community as well as ASRM as there is no born child, and protocols do not follow established adoption law, including required revocation periods following birth.<sup>12,30</sup> Aside from Louisiana, almost no state recognizes “embryo adoption” as a legal concept (Georgia allows for a standard adoption procedure following the birth of a child born from embryo donation<sup>31</sup>). Yet, the term continues to be used in legislative initiatives and public debates, raising concerns, similar to those emanating from the few divorce and embryo loss disputes where one party has characterized their claim as a “wrongful death” action, that it is part of a larger effort to personify embryos, and impact abortion-related debates.

A new Arizona law goes further. In July, 2018, in response to a divorcing couple’s lawsuit over their preimplantation embryos, Arizona enacted a law that requires a divorce court to award custody of any embryos to the progenitor who intended to help them “develop to birth,” *regardless* of any agreements reached between the parties or between the parties and the clinic.<sup>32</sup> The law does not take into account any prior expressions of intent or agreement of the patients, who wants to actually parent, whether that person would be the preferable parent, or anything other than which party would better enable the embryos to become children.

It has been suggested this law may be vulnerable to constitutional challenge.<sup>33</sup> While passed in response to concerns for an ex-wife and cancer survivor who did not receive the couple’s embryos during a divorce because of the couple’s cryopreservation documentation, in which they had

agreed only to use with mutual consent, the law might instead support *any* healthy husband receiving the embryos over a cancer survivor, with the ability to have them placed into one or more women—including a subsequent spouse or multiple gestational surrogates, or donate them to another individual. The law raises concerns not only for Arizona patients in Arizona clinics, who can no longer rely on any executed consent or dispositional forms, but also for any Arizona patients who may find a divorce in their future since an Arizona divorce court would likely have jurisdiction over their residents' stored embryos regardless of the state in which they had stored them. The law also places Arizona IVF physicians and clinics in a unique, and untenable, position as any standard of care dispositional agreements are now wholly at odds with the law, and raise genuine questions as to how clinics in that state should proceed.

Regardless of the motivation, enacted laws such as these exponentially complicate cryopreservation and disposition options for both patients and providers.

### Disposition Limits, Choices, and “Abandonment”

Storing reproductive tissue creates the potential not only for failures on the part of the clinic, lab, cryostorage facility, or transportation carriers but also the possibility that patients will not claim their embryos or gametes in a timely manner, or that applicable laws prohibit them from doing so after a set period of time established by law. The destruction and discard of embryos and gametes has garnered widespread international interest, with some countries imposing mandatory time limits requiring discard such as Sweden (5 years<sup>34</sup>) and the United Kingdom (10 years<sup>35</sup>), while others—including the United States—do not set limits, enabling patients and clinics (or individual states in some instances) to set their own rules, and triggering concerns over if, when, and how reproductive tissue may be discarded.

A brief overview of global trends and several specific country examples are discussed later; however, a comprehensive international review of practices and policies is beyond the scope of this article. For a summary of worldwide ART practices, policies, and activities, the most recent, 2016, surveillance report of the International Federation for Fertility Societies (IFFS) provides an aggregate source of information on global ART practices.<sup>36</sup>

Globally, most countries do not impose a limit on the storage of embryos. Of those that do, Belgium, China, Denmark, Norway, Romania, South Korea, Sweden, Switzerland, Turkey, Australia, Greece, Barbados, Mali, and Chile reported a limit of 5 years, with Belgium and South Korea allowing for a 5-year extension.<sup>36</sup> Estonia limits embryo cryopreservation to 7 years and Austria, Hungary, Singapore, South Africa, Taiwan, the United Kingdom (extended from the original 5-year limit), Ecuador, and Hong Kong report a limit of 10 years.<sup>36</sup>

Storage limits may also be imposed relative to the age of a female partner or life circumstance. In the United Kingdom, for example, the cryopreserved embryos may be stored for a maximum of 10 years but is not permitted beyond the female patient reaching the age of 55 years.<sup>37</sup> In Japan, embryos may

remain cryopreserved for as long as the couple is married and the female partner is within reproductive age. Spain permits embryo storage until the age of 59 years for the female partner.<sup>36</sup>

In the United States, there is no time limit placed on embryo storage by law or by professional guidelines. ASRM's Ethics Committee has addressed the issue of “abandonment,” recognizing implied abandonment for progenitors who cannot be contacted despite diligent efforts by a clinic or cryostorage facility, and essentially informed abandonment, for progenitors with dispositional control who have affirmatively indicated to the clinic or facility that their wish is to dispose of the gametes or embryos.<sup>38</sup> For the former category, ASRM advises that from an ethical perspective, programs without a contradictory protocol may dispose of embryos (removing them from cryostorage and thawing without transfer) if at least 5 years has passed since contact with the progenitors, a diligent effort has been made to contact them, and no written instructions concerning disposition exist.<sup>38</sup> The committee report also acknowledges that state law will prevail over voluntary guidance and that “legal uncertainty” remains, which may result in some programs being comfortable deciding to discard and others not, and expressly states that given that “legal uncertainty,” it is not providing legal advice on the subject.

Some states have enacted contraindicating laws and regulations. As discussed previously, Louisiana has a statutory requirement which gives an embryo a status equal to that of a living child, making the intentional destruction of frozen embryos illegal and punishable under the law.<sup>39</sup> As noted earlier, the law goes further, determining that progenitors who have abandoned their embryos have renounced their rights, and that their frozen embryos should be donated to a married couple for implantation and made available for adoption.<sup>40</sup> Similarly, Kentucky also disallows destruction of embryos, as applied to public medical facilities including IVF clinics.<sup>41</sup>

A few states have adopted laws, consistent with current professional guidelines, that prohibit using abandoned embryos for procreation or research. In Maryland, the 2006 Stem-Cell Research Act stated that using embryos for research without a progenitor's consent is statutorily prohibited, preventing abandoned embryos from being used for research.<sup>42</sup> The legislature concluded that “it would be unjust and unethical to either donate abandoned embryos for infertility treatments or allow couples to adopt abandoned embryos without the consent of the progenitors. The best solution is to statutorily mandate cryopreservation banks to dispose of the abandoned material after 5 years without contact from the progenitors, unless the progenitors have a written agreement stating otherwise.”<sup>43</sup> The legislative framework in California also prohibits the donation of an embryo for research or adoption without consent of the progenitors.<sup>44</sup>

Globally, countries have also taken a variety of approaches to address abandonment. In the United Kingdom, unclaimed embryos must be destroyed within 10 years after creation, absent instruction from progenitors to discard before that

time (or the woman reaches age 55 before that time).<sup>37</sup> In Canada, there is no federal law mandating the destruction of stored frozen embryos,<sup>45</sup> creating confusion when written instructions created in accordance with the *Assisted Human Reproduction Act* do not provide adequate guidance regarding the use or discard of frozen embryos.<sup>46</sup> For example, “the instructions may only address anticipated “own use,” and may not include instructions for use by others or instructions for eventual discard (when “own use” or “use by others” is not an option).”<sup>46</sup> As in the United States, a second problem in Canada, and around the world, is that even when there are consent forms or contracts with clear instructions about use and discard, absent laws requiring discard, clinics and cryostorage facilities are often unwilling to act when the embryo providers cannot be contacted to affirm or withdraw their original consent.<sup>47,48</sup>

It is important to recognize that long-stored embryos are not necessarily “abandoned” by the patients who created and stored them. The term, in the authors’ opinions, is too frequently and inaccurately used to describe embryos that have clearly recorded patient’s directives, which have never been followed. While ASRM offers guidance for addressing when some long-held embryos may be deemed “abandoned” and suggests protocols for some of them, the Ethics Committee report on this point also notes that state law governs, and its guidance should apply where program protocols are not already in place.

If, in fact, long-stored embryos have accompanying consents or legal agreements that clearly state what couples want to be done with their embryos (e.g., discard if they fail to maintain payments or contact), failure to follow such directives can potentially cause legal exposure for a program as much as unauthorized discard might. While programs may be understandably reluctant to actually discard embryos, it is not difficult to imagine a disgruntled former patient who finds himself or herself, for example, facing an unexpected child support claim from a former spouse, suing a program that released embryos to the ex-partner which they thought had been discarded per clear instructions. If nothing else, ex-spouses’ legal attempts to gain control over such embryos may well embroil an IVF program in their litigation.

Programs may find some protection in having documentation consistent with SART model forms that recommend prominently including a “default” provision which authorizes a program to discard the patient’s embryos if their other selected options are not available, or under other clearly stated circumstances.<sup>19</sup>

In an effort to avoid long-term cryostorage responsibilities and vulnerabilities, a number of IVF programs have also started to turn to long-term cryostorage facilities. Protocols may include requesting or requiring patients to agree to ship their embryos off-site after a certain amount of time, and sometimes to specifically designated long-term cryostorage facilities. Shipping may shift some liability away from IVF clinics, but also introduces other risks from multiple shipping processes, as well as uncertainty to the various obligations owed by those who handle embryos. It is difficult to

know what standards will apply to long-term cryostorage facilities; to the extent that they provide no medical services they may prove to be outside the legal purview of health law and malpractice liability, but subject to breach of contract and other theories as nonmedical service providers. For clinics and their internal labs, the process of shipping reproductive tissues is also not without risk, and such protocols can trigger other liability issues, as discussed in the following section.

### Liability for Mishandling Embryos

A critical legal context for reproductive tissue arises when things go wrong in the clinic, the lab, in transit, or in transferring embryos into the wrong patient. This group of cases triggers legal disputes that involve numerous, and at times overlapping, areas of the law. How to compensate a patient for a mix-up with, or loss of, reproductive tissue will likely depend on the type—and relative replaceability—of the tissue, the patient’s personal circumstances, and the impact of the wrong.

The related legal harm typically falls into one of four categories: (1) a patient being implanted with the wrong embryo (and another patient having their embryo wrongfully implanted in an incorrect individual); (2) a patient implanted with an embryo made from either the wrong sperm or eggs (and the use of another patient’s gametes for that purpose without their knowledge or consent); (3) errors in either preimplantation genetic testing (PGT) or in the reporting of such testing, which can encompass both diagnosis (PGT-M) of genetically affected, unhealthy IVF embryos and screening (PGT-A) of IVF embryos for aneuploidy (a similar claim may arise from testing of the involved adults, i.e., intended parents or potential donors for their “carrier” status) that results in the implantation of an unhealthy embryo; and (4) the loss or destruction of embryos or gametes—either within a clinic’s laboratory or cryostorage facility, or in transit between facilities.<sup>49</sup> Each type of legal harm can give rise to different legal theories of liability, and at times, the same action can result in a myriad of theories of liability and therefore damages.

Significant financial damages for patient harm have arisen when patient embryos or gametes are erroneously lost or destroyed by IVF clinics or damaged or lost while in transit. Wrongly transferred embryos may result in heart-breaking parentage and custody claims of born children, as well as damage claims against clinics. Unlike claims for the wrong genetic makeup or a failure to correctly screen or diagnose a genetic condition (discussed later), claims for lost or damaged embryos and gametes most often result in a breach of contract or negligence claim, with variable compensation outcomes for the patients.<sup>50</sup> In one recent example, a pending lawsuit was filed after a UPS employee mistakenly opened a shipper of frozen embryos during transport, resulting in the embryos being thawed and rendered unusable.<sup>50</sup> The plaintiffs sued UPS for negligence.

Almost every embryologist will have at least one story of shipping gone awry, and as most embryologists are aware, both federal “common carrier” law<sup>51</sup> and contractual terms

set by carriers such as UPS and Federal Express may limit their financial liability, leaving labs and IVF programs as the entities with “deeper pockets” in multidefendant cases. In two high-profile incidents, cryogenic tank failures occurred in two unrelated programs on the same weekend in March 2018. Both the Pacific Fertility Center in San Francisco and the University Hospitals Fertility Center in Cleveland separately reported a tank malfunction. The San Francisco incident reportedly impacted hundreds of eggs and embryos. The Cleveland incident reportedly resulted in the destruction of more than 4,000 eggs and embryos. Both cases have resulted in multiple patient lawsuits, and allegations of substantial financial damages. In Ohio, the cases contain a wide variety of allegations, including a failure to provide promised services—in one case a “wrongful death” lawsuit alleging the embryos were essentially children, and in one case, allegations that the fertility clinic violated the federal Magnuson-Moss Warranty Act for consumer product.<sup>52</sup>

The damages awarded in these types of cases are likely to depend on the relative replaceability of the reproductive tissues. When donor tissue is readily replaceable, damages are likely to be limited to the costs of replacement and any related injury. However, due to the rise in oncofertility treatment options and increased insurance coverage for fertility preservation, these patients’ embryos and gametes may now be routinely retrieved and stored, becoming the only remaining chance for them to have a genetically related child. For example, in 2001 Julie Norton and her husband cryopreserved embryos prior to Norton’s treatment for colon cancer, understanding that the treatments would likely impair her fertility.<sup>53</sup> Unfortunately, the Brigham and Women’s hospital erroneously destroyed all 13 of the couple’s stored embryos. Upon discovering the error, the Nortons filed a lawsuit against the hospital and three employees, including the clinic director and two lab managers, for negligence, breach of contract, and infliction of emotional distress, asking for \$5 million in damages and improved hospital policies.<sup>53</sup> Public press statements and news reports of the case reflect the hospital’s acceptance of responsibility for the error, which resulted from an initial erroneous belief that the embryos were among those marked for discard,<sup>53</sup> and it is believed the case was settled; however, there are no publicly available records as to the final outcome. It should be noted that settlements, together with nondisclosure agreements, are anecdotally reported to be the most common way these types of claims are resolved; as such, there are relatively few officially reported case outcomes or damages awards that can be identified.

In contrast to contract and negligence claims, the implantation of otherwise healthy embryos with the wrong genetic makeup typically results in a tort or malpractice claim, as well as potentially a parentage-custody dispute.<sup>54–56</sup> Historically, “wrongful life” and “wrongful birth” claims (and less frequently “wrongful conception” claims) have involved serious genetic defects, not a healthy child born with a different genetic makeup—that is, different eggs, sperm, or embryos than a couple had intended and planned for, which makes these actions misaligned with the traditional judicial

standards necessary for monetary damages. Furthermore, given U.S. courts’ historical reluctance to quantify the value of a life, most have rejected claims for the costs of rearing a healthy child as damages, as well as claims brought for “wrongful life” on behalf of a child themselves.<sup>57</sup>

Patients have also sought damages for emotional distress, but courts again have been reluctant to grant damages absent physical damages.<sup>58</sup> An embryo mix-up at a New York clinic resulted in one patient being implanted with two embryos—her own and that of another patient that was intended to be discarded.<sup>59,60</sup> When the error was discovered, the pregnant patient initially refused to respond to the clinic’s overtures, or, after birth, relinquish custody of the child genetically related to another patient couple. The resulting litigation involved efforts to have a visitation agreement, and a court ordered a “twin” study to examine any harm to separating the children. Ultimately the case resulted in the child being placed with his genetic parents and a denial of any parentage or visitation rights to the other couple. Both couples separately sued the clinic.<sup>59,61</sup>

For those long in the field, the multiple lawsuits arising out of the clinic at UC Irvine against it, Dr. Ricardo Asch, and his colleagues in the 1990s, will be remembered for the number of patients whose gametes and embryos were intentionally misused for other patients without their knowledge and consent, the multiple lawsuits brought for custody and parentage claims that were denied as the children had been raised by others for over 14 years, and the total reportedly over \$4 million dollar settlement entered into by UC Irvine.<sup>60</sup> More recently, a fascinating 2017 case out of Singapore identified a new tort theory, “loss of genetic affinity,” in recognizing a mix-up that resulted in a couple giving birth to a healthy child with the wife’s egg but donor sperm instead of her husband’s as they had intended.<sup>62</sup>

Claims brought against medical professionals for the implantation of abnormal embryos due to testing errors have typically been unsuccessful, at least under “wrongful birth” or “wrongful conception” tort claims, but this may be changing. In cases where there has been a failure in either “carrier screening” or PGT errors, patients have asserted those, as well as, at times, “wrongful life” claims on behalf of a child suffering from birth defects. These theories usually fail due to a lack of the typical direct causation needed for such a claim.<sup>63</sup> In the majority of the U.S. cases, courts have not found a causal connection between a professional defendant’s negligence and a child’s condition, as defense counsel have succeeded in arguing that any genetic condition was literally “caused” by the genetic contributor him- or herself.<sup>64</sup> Thus, for example, in *Paretta v. RMA NY*, the court found a failure to identify and communicate an egg donor’s positive cystic fibrosis (CF) status did not *literally* cause the child in question to be born with CF, rather the donor’s genetic condition did. However, such distinctions did not preclude potential claims for negligence or punitive damages against the providers.<sup>63</sup> It remains to be seen how the law in this area will evolve, as more and more sophisticated genetic testing comes online, some of which will inevitably result in testing or reporting errors.



An additional aspect of these types of cases, which may not be discovered for many years, involves a state's statute of limitations. In a few cases to date involving carrier testing, those statutes have been extended and have not precluded successful recovery. These cases may have some predictive value in how courts will view errors in PGT, and potential liability issues for professionals. In at least a few instances, courts have allowed cases to proceed based on professionals' failure to accurately either identify or transmit genetic information to would-be-parents years before the affected child was conceived and born, rejecting claims they were outside the applicable statute of limitations. Instead, the courts "tolled" (essentially paused) the statute of limitations to allow the claims to move forward.<sup>65,66</sup>

In *Molloy v. Meier*, a Minnesota court noted that a failure to test a woman's first child for Fragile X, while reassuring her that comprehensive testing had been done, led her to have another child, who was born with Fragile X. In rejecting the argument that the case was brought beyond the statute of limitations, the court acknowledged that liability for genetic testing might extend for years, causing a concurring judge to write, "[i]f the legislature does not act to somehow limit liability in cases like the one here, it is difficult to see where the next generation of geneticists willing to practice in Minnesota will come from."<sup>65</sup>

Similarly, a 2018 case involved a physician mistakenly recording a negative CF finding for a patient who was instead positive for CF. The patient's first child was born unaffected, but her second child was born with CF, which led to the discovery of the earlier error. The court concluded the statute of limitations started, not when the mistake was made—which would have been outside the statute of limitations and precluded the lawsuit—but during the mother's last preconception appointment prior to deciding to get pregnant, under a legal theory of "continuous course of treatment" (decision stayed as of press time).<sup>66</sup>

This discussion highlights the variety of unique issues for reproductive tissue when things go wrong in the clinic, the lab, in transit, or implantation. Legal theories and remedies are varied and decisions often pieced together from overlapping areas of the law. The complexities here demonstrate the need for more *sui generis* laws and regulations, as well as a better understanding by practitioners and service users of the legal aspects of their activities.

## A Legal Crystal Ball? Looking to the Future of Reproductive Tissue Cryopreservation

Embryo cryopreservation—and the challenges it raises—are here to stay. While improvements in egg freezing and personal circumstances may influence patients' decisions to freeze gametes over embryos, multiple factors point to a continuing increase in the number of cryopreserved embryos: expanded fertility preservation options, freeze-all cycles, increased usage of PGT, insurance coverage for established embryo protocols that emphasize single embryo transfer, standard-of-care for elective single-embryo transfer, and the growing number of states enacting mandated

coverage for fertility preservation for some patients. With clinics, labs, transport companies or common carriers, long-term cryostorage facilities, and patients all dealing with cryopreserved embryos and the legal issues they engender, for the foreseeable future, there is a concomitant need to understand the attendant responsibilities and liability for handling them.

Decades of lawsuits involving cryopreserved preimplantation embryos in the United States have provided some clarity, if not consistency, around the legal status of cryopreserved embryos and legal theories applied to resolve issues surrounding them. Providing clear, enforceable instructions in documents that conform to applicable contract law and are consistent with public policy and professional guidelines may go farthest in most jurisdictions in avoiding disputed claims to embryos. Some guidance and limits exist for IVF clinics and labs: SART recommended model consent and dispositional forms, which now include default provisions in which patients authorize their clinics to discard embryos at some future point in time, and utilization of long-term cryostorage facilities may reduce liability. On the other hand, legislative efforts to personify preimplantation IVF embryos through so-called personhood, and in application "anti-IVF," legislation and in lawsuits alleging "wrongful death" of destroyed or lost embryos, will muddy those waters with adverse legal effects for both patients and providers.

For professionals working in IVF clinics, labs, or long-term cryostorage facilities, updated protocols and documentation consistent with applicable law and public policy are essential. Additionally, efforts to follow, and update as appropriate, evolving standards of care together with thorough, careful protocols for storing, transporting, and discarding embryos are all critical. All such efforts should include respecting individual patient autonomy, especially as technical advances improve the success rates associated with egg freezing and at the same time expand genetic testing parameters. Even if and when comparable success rates are established for gametes and embryos, the current variable standards and outcomes for preimplantation testing of embryos and gametes may continue to "tip the scales" to freeze embryos. And while long-term cryostorage facilities may literally off-load some of the burden of maintaining cryopreserved reproductive tissue, when and how reproductive tissue is transported raises its own legal vulnerabilities for a myriad of providers and patients. Loss of, or damage to, reproductive tissue will continue to be a concern for all involved in this field, and how that tissue is characterized and whether or not it is replaceable will all factor into its valuation for damages if liability is established under one or more theories of law. Finally, the emergence, and rapid expansion, of genetic testing capabilities has expanded the role of reproductive genetics in ART across the spectrum of ART treatment, and the legal system is responding through expanding theories of liability and statutes of limitation.

It is hoped that this review of "embryo law" issues is helpful to those in the field who must grapple not only with medical and scientific advances but the impact of the law on their professional endeavors.

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