Journal of Assisted Reproduction and Genetics (2019) 36:1041–1048
https://doi.org/10.1007/s10815-019-01478-x

REVIEW

Cryostorage failures: a medicolegal review

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Received: 28 March 2019 / Accepted: 3 May 2019 / Published online: 24 May 2019

Abstract

Purpose To heighten awareness of the potential legal and financial burdens faced by those providing cryopreservation storage services of embryos and gametes in light of recent lawsuits involving inadvertent thawing of specimens.

Methods Case law review of US legal databases and courthouse dockets with a focus on lawsuits against reproductive endocrinologists and cryostorage facilities offering cryopreservation. Emphasis was placed on court decisions, awarded damages, and legal and media coverage related to cryostorage failure events.

Results Lawsuits pertaining to two notable ongoing cases of cryostorage failure that occurred at fertility clinics in the US in 2018 were reviewed. Media coverage of these events and plaintiff and defense attorney strategies were evaluated. Legal documents from previous, similar cryostorage failures were also reviewed. Common claims in cryostorage system failures include breach of contract and negligent handling of property. Facilities offering cryostorage services are vulnerable to significant burden, legally and financially, if they are to experience a storage system failure.

Conclusion Providing cryostorage services is not without significant financial risk. Inadvertent thawing of specimens can lead to high damage awards against cryostorage facilities and those individuals linked to a cryostorage failure event. Because monetary damages can surpass insurance policy limits, those providing cryostorage services should be aware of plaintiff attorney strategies, common legal defenses, and basic asset protection principles to safeguard themselves if ever faced with these situations. Facilities should also carry out regular maintenance and safety checks on equipment and alarm structures to deter such events.

Keywords Medical negligence · Liability · Cryostorage · Cryopreservation · Embryo

Introduction

Two recent, ongoing high-profile cases related to failure of fertility clinic storage systems emphasize the need for reproductive endocrinologists and laboratory personnel to familiarize themselves with legal and financial risks associated with providing cryopreservation services. Incidents like these can lead to direct damage from litigation and indirect damage in the form of a tarnished reputation, both of which can be devastating to a medical business and the individuals involved. Inadvertent thawing of cryopreservation specimens is an unfortunate event that could potentially happen to any in vitro fertilization (IVF) facility providing cryopreservation services. The purpose of this medical-legal review is not to find fault with those facilities currently involved in lawsuits but to provide awareness as to the potential legal and financial consequences of providing cryopreservation services, review plaintiff and defense legal strategies, discuss asset protection measures for reproductive endocrinologists, and emphasize the importance of quality assurance measures to help deter the risk of inadvertent thawing of cryopreserved specimens.

Materials and methods

Nexis Uni, formerly known as LexisNexis Academic, was used to review legal filings from previous cases of cryostorage failure. LexisNexis is a legal search engine largely comprising documents pertaining to state and federal cases that have been appealed. Also included in the search engine results are law

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Table 1 Search results

Search terms	Type of publication						
	Cases (*n*)	Newspaper articles	Web-based publications	Magazines and journals	Law reviews and journals	Legal news articles	Newswires and press releases
Egg storage failure	2415	37,471	7651	3804	3538	674	10,124
Embryo storage failure	163	4824	970	640	1973	223	3185
Sperm storage failure	380	4406	941	513	1452	50	1535
Gamete storage failure	25	133	31	40	1034	3	156
Embryo loss	1830	203	33	67	9019	223	151
In vitro fertilization	754	15,599	4126	1653	4855	92	15,599
In vitro fertilization storage failure	76	1630	289	215	1257	92	941
Cryopreservation	107	1294	624	241	802	1	4101
Cryopreservation failure	107	101	40	26	802	1	274

reviews and media coverage of events, which may include references to cases in lower courts. LexisNexis results are detailed as in Table 1. County and district courthouse dockets were also queried for filings related to lawsuits that have not been appealed. Specifically, cases filed in Cuyahoga County, Ohio, San Francisco County, California, and the US District Court, Northern District of California, were queried. Local and national media coverage was used to provide details of the various events discussed. PubMed was used to retrieve background information on legal considerations relevant to physicians, and specifically reproductive endocrinologists. Publications by the American College of Obstetrician and Gynecologists (ACOG) and American Society for Reproductive Medicine (ASRM) were used to help formulate specific recommendations applicable to physicians practicing in obstetrics and gynecology, especially reproductive endocrinology and infertility.

Results

Information from two recent high-profile cases of cryostorage failure was obtained from court documents and news media coverage. Lawsuits from previous cryostorage failures at other fertility clinics were similarly obtained. In each instance, specific information collected included causes of action, details of the events surrounding system failure, and damages sought and awarded. For each episode, the event of cryostorage failure incited a series of lawsuits, in some instances upwards of 60 individual claims. Some of these individual lawsuits were consolidated into class action claims. From the database results shown in Table 1, eight references were directly utilized. In addition, 11 legal cases were referenced directly from county and district court dockets. Typical legal claims made include, but are not limited to, breach of contract and negligent handling of property. While information on specific damages requested by and awarded to plaintiffs is not widely available, evidence from select cases indicates the value to be in the range of millions of dollars.

Discussion

Recent ongoing cryofailure lawsuits

In March 2018, University Hospitals Medical Center in Ohio experienced cryogenic storage failure resulting in the estimated loss of over 4000 embryos and eggs, affecting roughly 950 patients. Court documents describe how, at the time of the incident, tanks were being manually refilled due to maintenance on the clinic's automatic liquid nitrogen refilling tank. Unfortunately, the storage tank's system alarm, designed to alert staff of any rise in temperature, was turned off at this time [1]. A full description of events surrounding this episode is still emerging. As of this writing, over 50 lawsuits have been filed related to this incident, with some having already been consolidated and others seeking class action status [2, 3]. As seen in a sample of these cases, *Ash v University Hospitals Health System Inc.* [4], *Brickel v University Hospitals Ahuja Medical Center* [5], and *Babel v University Hospitals Health System Inc.* [6], each suit asserts similar allegations that personnel at the University Hospitals failed to adequately regulate, monitor, and respond to the rising temperature of their storage tanks.

Around the same time of the above incident, Pacific Fertility Center in California experienced an event in which insufficient liquid nitrogen levels, alleged in lawsuits and media reports to be possibly related to a faulty seal on the storage tank, led to the loss of thousands of embryos and gametes. As with the event at University Hospitals, a formal set of details has yet to be

established. Over 400 individuals are claimed to be affected by this event. It is alleged that personnel at Pacific Fertility failed to maintain acceptable electronic tank monitoring maintenance, leading to the loss of embryos and gametes. To date, a series of lawsuits has been filed against Pacific Fertility Center in the US District Court of Northern California, with 20 different suits having reached the Superior Court of California, San Francisco County [7] (see *S.M. v Pacific Fertility Center* [8], *A.B. v Pacific Fertility Center* [9], and *Bauer v Pacific Fertility Center* [10]). A specific dollar amount requested has not been laid out here, but plaintiff court pleadings seeking class action status claim damages are in excess of $5,000,000 [9].

Legal claims

Specific claims filed against both practices include:

(1) Breach of contract, in which the clinics had established an expressed, written agreement with each plaintiff for the collection of gametes and/or development of embryos, which were to be stored and preserved in a suitable state as to be used for future implantation through IVF when deemed appropriate
(2) Negligent handling of property, in which the clinics allegedly failed to use appropriate care in handling and preserving embryos and gametes, as well as failed to establish appropriate guidelines for monitoring and maintaining storage equipment

Additionally, claims of negligent infliction of emotional distress have been made. One couple's lawsuit against University Hospital Cleveland, see *Penniman v University Hospitals Health System Inc.* [11, 12], seeks for each embryo to be classified and granted the legal rights of a person, in which case the possibility of wrongful death claims could be made. This claim could exponentially increase the sum total of damages awarded in lost embryo cases, regardless of a state's tort reform status. In general, states with tort reform place caps on noneconomic damages that can be awarded, such as those for pain and suffering. However, there are typically no caps on economic damages, such as medical bills, lost wages, and lost future wages. Classifying each embryo as a person, and in turn allowing for wrongful death claims, would allow economic damage claims in the form of projected lost future wages to be made for each embryo.

A further development in the ongoing case against University Hospitals Health System involves a separate set of plaintiffs filing suit against not only the hospital system and physicians but also the manufacturer of the tank alarm system, which is alleged to have failed to notify staff of rising tank temperatures (see *Petite v University Hospitals Health System Inc* [13, 14]).

Prior cryostorage failure lawsuits

Incidents involving storage tank malfunctions are not a new phenomenon. Previously, similar episodes occurred at the South Florida Institute for Reproductive Medicine [15] and at Northwestern Memorial Hospital. In the aftermath of the event at Northwestern Memorial Hospital, approximately 65 lawsuits were filed [16]. While financial information is not available for each case, it has been reported that one individual case was settled for $1 million [17].

Despite this specific initial cryostorage incident at Northwestern Memorial Hospital occurring in 2013, individual claims against the hospital and hospital foundation have not all been resolved at this point. Complicating matters for the hospital and personnel involved in this case was a move by the hospital's insurance provider to absolve itself from its duty to provide compensation for settlements in the legal proceedings. The insurance provider in this case asserted that claims made by affected individuals are exempt from the hospital's policy in that the policy does not cover claims related to "personal property in the care, custody or control of the insured" [18]. For now, an appellate court has issued a stay on the issue of whether the insurance policy covers the inadvertent thawing of specimens, meaning the court's decision on this matter will be postponed until all individual claims made in the trial courts have been settled and a comprehensive set of facts established. Once this is finalized, the court will then decide whether the policy exclusions should apply.

Fundamentals of medical legal claims

Successful medical legal claims are based on establishing four key elements:

(1) A medical provider's duty to the patient
(2) A deviation in the standard of care
(3) Injury suffered by the patient
(4) A causation between the deviation in the standard of care and the injury

When a plaintiff attorney is able to establish each of these four elements, physicians can be at risk for significant financial burden from awarded damages, especially when a court awards damages in excess of a physician's insurance policy limits, meaning the physician could be responsible for payment of damages above what is covered by their policy. Rather than necessitating proof beyond a reasonable doubt, as in criminal proceedings, medical lawsuit claims need proof only as a "more likely than not" standard, known as the "preponderance of evidence standard" [19].

Insurance providers carry the fundamental obligations of representing, defending, and acting in the best interest of their client, in addition to covering financial damage claims up to

the agreed upon policy limit, known as the duty to indemnify. Insurers must also act in "good faith and fair dealing" with their endeavors. If any of these factors are conceded, insurance companies may become responsible for financial liability in excess of policy limits [19]. Given these set forth expectations, significant trust is often placed in the insurance provider to determine whether a settlement should be accepted.

Asset protection in the face of litigation

Deciding on when to settle within a policy limit can be one of the most prudent forms of asset protection physicians can take. When potential damages could surpass a physician's insurance coverage limit, it may be in the physician's best interest to settle within their policy limit, if given the opportunity by the plaintiff attorney. Episodes have occurred where a physician accepted a plaintiff attorney's settlement offer within the physician's policy limit, but the insurance provider elected to proceed forward with the case at trial. In these situations, where an agreement with the physician has been made within the policy limit, precedent has been set such that physicians are not to be held responsible for damages beyond what their policy covers if the insurer continues with the case to trial (see *Bramlett v Medical Protective Company* [20, 21]). However, without written, documented proof by the physician informing their attorney and insurance provider of their desire to accept a settlement offer, it can be contested that the physician agreed to proceed with going to trial.

At the same time, insurers may include a "hammer" clause in available policies. Clauses of this type stipulate that if a physician is advised by the insurer to accept a settlement but does not accept, the physician will be personally and directly responsible for damages in excess of the settlement advised by the insurer [22].

To preempt any such dispute between physicians and their insurance provider, if there is concern of a perceived conflict of interest, it may be beneficial for physicians to have their own personal attorney acting in their best interests, rather than relying on an attorney attempting to balance the interest of the physician and insurance company. Physicians can further protect themselves by ensuring their policy includes a "right to consent to settlement," meaning the insured (i.e., the physician) is able to authorize and approve a settlement of a malpractice claim. Incorporating this into a policy assures that any claim settlement accepted by the insurance company is only considered valid if approved by the physician policyholder [22].

Reproductive endocrinologists must also be clear on specific coverages of their malpractice and general liability insurance. Insurance coverage commonly comes with policy limits specific to a per-claim limit and an aggregate limit. A per-claim limit is the total amount a physician is covered for with respect to each separate claim made. Meanwhile, the aggregate limit is the maximum an insurer will cover for all claims filed during the coverage period [22]. With regard to medical claims made, most malpractice insurers will cover cases made directly against the physician, such as patient injury during a surgical procedure or a missed diagnosis. Unless explicitly stated in the policy, malpractice insurance might not cover mishaps in embryology labs. For reproductive endocrinologists, this means they may need a separate insurance policy for the lab associated with their fertility clinic. This additional policy should explicitly state it is providing coverage for stored embryos, sperm, and eggs, so as to avoid any ambiguity in the contract if a claim were to be made.

Personal assets in the form of 401(k)s, IRAs, Roth IRAs, and life insurance policies are generally spared from third party creditors when physicians must pay damages in excess of their policy limits [19]. Other assets, such as an individual's primary residence or Social Security payments, may also be protected, but protection will vary greatly from state to state. To further defend their personal assets, reproductive endocrinologists should consider establishing their embryology labs and associated surgical centers as a limited liability company (LLC) or a professional limited liability company (PLLC), depending on local state rules and regulations. An LLC or PLLC may help exempt physicians from personal liability for claims made against the company and, in general, allows members' personal assets to be protected. This exemption only stands as long as there is no intermingling of personal and company funds; otherwise, the creditors can pursue legal actions in the form of "piercing the corporate veil." This means the company will no longer be seen as its own entity, and if sued, each partner or shareholder can be held personally liable [23]. Some states have homestead laws which help protect citizens residing in that state from creditors going after their homes as long as mortgage payments are met and taxes are paid [24]. Other strategies including establishing a trust, dividing assets with a spouse, or transferring income-producing possessions, commonly real estate investments, to a family limited partnership are all options that may be available [22]. However, transferring assets to family members can be problematic when there is discord among family members, such as in a divorce. Physicians should work closely with legal experts in their specific state to establish the best asset protection strategy given the local laws. Any changes in asset protection or allocation must be executed before a claim is filed and before an event that may result in a claim has happened, as no changes in asset protection can be made once either of these events has occurred.

Potential defenses to cryostorage failure lawsuits

Upwards of 4000 cycles with the intent of embryo banking and nearly 9000 cycles with the intent of oocyte banking were carried out in 2016, the most recent data available from the Society for Assisted Reproductive Technology (SART) [25].

While only representing a sampling of the patient population, some surveys indicate that, on average, embryos are stored for 5 years. Though, in one-third of respondents, no endpoint for how long they plan to keep their cryopreserved embryos in storage was indicated. The absolute number of stored embryos is not comprehensively tracked by SART, but it is believed that up to 4–5 million embryos are in storage facilities in the USA, with between 1 and 7% considered "abandoned" [26, 27]. In the above cases of cryostorage failure, one potential defense available is that some of the thawed embryos could be classified as abandoned.

Broadly speaking, as defined by ASRM, embryo abandonment occurs "when an individual or couple with dispositional control cannot be contacted" or "when an individual or couple with dispositional control over stored embryos may simply affirmatively indicate to the program or facility that they do not wish to have anything further to do with the embryos." Ethically, ASRM asserts it reasonable to determine embryos to be abandoned and storage facilities able to properly dispose of them if the responsible party has left no written instructions regarding disposing of embryos and it is has been more than 5 years since last contact with the responsible party despite meticulous attempts to contact the individual(s) [28].

Even with ASRM's ethical guidelines, there exists legal ambiguity regarding criteria for abandonment and ability to dispose of abandoned embryos. For example, ASRM notes that handling of embryos in the event of a patient failing to pay storage fees should be addressed before initiating the cryopreservation process; however, no formal guideline is given as to the duration of nonpayment at which point an embryo is considered abandoned. Because uncertainties like this can occur, standard procedure for some clinics may be to keep embryos in storage indefinitely [28, 29].

The American Bar Association (ABA) details their own set of guidelines for embryo abandonment, outlining that an embryo is considered abandoned if 5 years have passed since initial embryo storage, in the absence of another agreed upon storage duration, and due effort has been made through certified mail to contact the responsible parties, with no response after 90 days. Ideally, according to the ABA, the stipulation is made that responsible parties must be informed of the facility's criteria for embryo abandonment prior to the initiation of cryopreservation at the facility. These guidelines go on to say that, as long as there exists no malintent, facilities that adhere to these provisions are protected from any civil or criminal liability related to disposing of the embryos in question [30].

To preempt situations where proper action may be ambiguous, the issue of embryo storage should be addressed upfront, in written form, ideally at the onset of infertility treatment or at the time of cryopreservation. Specific topics to address should include the individual's or couple's wishes with respect to embryo handling in the event of patient death, partner divorce or separation, failure to pay storage fees, and inability of partners to agree on handling, as well as in the event of patients being lost to follow-up. The written consent should also be clear in outlining the specific criteria defining embryo abandonment and emphasize the necessity of patients keeping the facility up to date with their current contact information.

A thorough informed consent process is another key aspect of protecting a clinic's ability to defend itself in court. In response to allegations made against University Hospitals Health System in Ohio, the defendants assert that the plaintiffs were "fully advised of the material risks, benefits and alternatives available for treatment, and thereafter voluntarily assumed and consented to those risks" [31]. Medical facilities and physicians may attempt to limit their liability by drafting an exculpatory clause within the contracts given to patients. An exculpatory clause is a statement in a contract that attempts to absolve the drafting party of any liability. Even if an agreement is signed and properly executed by a patient, courts typically do not uphold such exculpatory clauses, as it is considered against public policy and a threat to the protection of patients and their rights. Courts are aware of a patient's lack of bargaining power when entering into these contracts with medical providers [32].

It is not unreasonable for concerned parties to still include exculpatory clauses in their contracts. These clauses may protect medical facilities and physicians from liabilities that arise that are not caused by negligence, such as the inevitable risks arising from a procedure. For these clauses to be upheld in court, the language must be clear, specific, and unequivocal [33]. The clause must specifically state the situations in which the facility or physician is not liable. This is illustrated in *Frisina v Women and Infants Hospital Rhode Island* where the plaintiffs sued the hospital for misplacing frozen embryos. The exculpatory clause included the statement "it is possible that a laboratory accident in the Hospital may result in loss or damage to one or more of said frozen embryos." The court denied the hospital's motion for summary judgment and held that "this language does not appear to cover those situations where loss or destruction arises because the Hospital has acted negligently or without due care" [33].

Cryostorage recommendations

In the instances at University Hospitals Medical Center and Pacific Fertility Center, the fertility clinics disclosed the errors to affected patients, consistent with ASRM guidelines [34]. That two comparable incidents of cryostorage failure occurred in such close temporal proximity highlights the need for clinics to employ measures to safeguard against similar, future incidents.

In the USA, three federal organizations oversee assisted reproductive technology: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS). The CDC, in affiliation with SART, records and

releases assisted reproductive technology procedure data and outcome statistics, as outlined in the Fertility Clinic Success Rate and Certification Act of 1992. The FDA regulates medications, devices, and biological products used by reproductive endocrinologists, along with regulating handling of reproductive specimens. The CMS operates through the Clinical Laboratory Improvement Act to maintain consistency, safety, and accuracy of laboratory-based testing [35]. Varying by practice type, organizations like the College of American Pathologists or the hospital Joint Commission will inspect and certify the overall safety and organization of embryology labs. In addition, ASRM publishes guidelines on minimum standards for maintaining an embryology lab with appropriately qualified personnel [36]. At the time of this publication, ASRM is in the process of preparing recommendations for practitioners and patients regarding cryopreservation [37].

Some unfavorable outcomes in cryopreservation can be considered unavoidable, for example, in the event of a natural disaster or fire, and should be clearly detailed during the informed consent process [38, 39]. Reemphasizing certain aspects of day-to-day and short-term monitoring and safety measures of embryology labs may preempt future episodes of avoidable cryosystem failure.

In general, cryostorage system failures most often occur as a result of either equipment malfunction or lapses in the liquid nitrogen supply chain. To preempt any interruption in the supply of liquid nitrogen, facilities should maintain extra quantities such that they will comfortably be able to maintain storage tank levels in the event a delivery is delayed [40]. Many places now have automatic liquid nitrogen filling systems, which if malfunctioning, could result in overfilling, underfilling, or complete failure to fill storage tanks. Because of this risk, it is reasonable for tanks to be set to refill daily during regular business hours, so staff will reliably be present in the event issues arise.

A facility that manually fills its storage tanks should maintain logs of the amount of liquid nitrogen added to each tank, so any tanks requiring unexpected amounts can be identified and potential leaks resolved. Regardless of whether a clinic uses automatic or manual refilling systems, dewars should be inspected for external clues of potential problems as indicators of possible tank failure. This strategy of tank surveillance is aimed at early detection of a failing tank. It includes daily assessment for evidence of liquid nitrogen leakage, as indicated by formation of ice or frost, on the tanks and associated hoses, as well as inspection for evidence of evaporation, condensation, or unusual sounds coming from the system [41]. An official log should be kept of all actions and observations related to storage tanks. Ideally, there should be a spare storage tank to which samples can be transferred in the event of malfunction; however, this may be impractical for smaller facilities [38]. Clinics should also consider separating a patient's samples into different storage tanks to avoid complete loss if a tank were to fail.

Facilities should utilize a continuous automatic alarm system to detect any fluctuations in tank temperatures and/or liquid nitrogen volume levels or weights. Additionally, there should be a formal "on-call" schedule of lab personnel responsible for responding to alerts outside of business hours [42]. When triggered, the alarm should have the capacity to notify multiple points of contact, in the event of a lapse in communication with the primary contact person.

With respect to equipment maintenance, guidelines from ASRM advise that "equipment should be maintained and calibrated on a daily, monthly, and annual basis as appropriate to the type of equipment" and "if the laboratory preforms cryopreservation, there should be a system in place for the detection of low levels of liquid nitrogen" [43]. While there is currently no universal guideline for specific maintenance intervals of cryostorage tanks, manufacturers recommend regular verification to assess components, such as liquid nitrogen levels and supply and alarm functioning [44, 45]. Specific recommendations may vary between manufacturers, and those providing these services should be familiar with the manufacturer's guidelines for their specific laboratory equipment. ASRM recommends facilities maintain copies of specimen handling protocols and manufacturers' equipment manuals in the laboratory [43, 46]. Laboratory personnel should follow their facility's standard operating procedures and protocols, as failing to do so could serve as a point of contention should a mishap occur and litigation ensue. Plaintiff attorneys will often seek a facility's protocol manual in an attempt to demonstrate internal breach of standard operating procedure by an employee.

Many tank manufacturers offer warranties for their products. Most warranties generally cover the vacuum component for 5 years but may also include standard parts and labor, depending on the company [44, 47–49]. Warranties are typically restricted to defects or malfunction in the manufacturing of the pieces and are void if damage stems from negligence, abuse, misuse, corrosion, fire, heat, or effects of normal wear [47, 49]. Warranties may also become void if a different company from the original manufacturer performs maintenance or repair. It is recommended that facilities become familiar with the warranty terms of their purchase and utilize maintenance services offered through the manufacturer to avoid improper care of their equipment.

Conclusion

Recent notable cases of cryopreservation failure at facilities offering embryo and gamete preservation services stress the importance of clinics and physicians offering these services to be aware of the possible legal outcomes of providing cryopreservation services. Liability exposure from cryostorage failure can easily exceed the financial assets of a cryostorage

facility or reproductive endocrinologist. The above analysis and discussion are not meant to assign blame but to serve as a resource for reproductive endocrinologists in aiding them to familiarize themselves with relevant legal strategies and asset protection measures, as well as facility recommendations in an effort to avert future, similar events of unintended specimen thawing. In all, these two events have brought increased awareness to cryostorage system quality management practices and will undoubtedly bring about innovative approaches to management and surveillance of cryopreserved specimen.

Acknowledgments The authors thank Goldie Tabor for her assistance in preparing the manuscript.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

References

1. Reynolds M. Parents want embryos deemed people after clinic meltdown. 2018. https://www.courthousenews.com/would-be-parents-want-embryos-deemed-people-after-clinic-meltdown. Accessed November 17, 2018.
2. *Ash v University Hosptials Health System Inc.*, 18-CV-894343, 2018 CP Cuyahoga County Ct. 1426973.
3. *Brickel v University Hospitals Ahuja Medical Center*, 18-CV-894332, 2018 CP Cuyahoga County Ct. 1543850.
4. *Ash v University Hosptials Health System Inc.*, 18-CV-894343, 2018 CP Cuyahoga County Ct. 1323564.
5. *Brickel v University Hospitals Ahuja Medical Center*, 18-CV-894332, 2018 CP Cuyahoga County Ct. 1323322.
6. *Babel v University Hospitals Health System Inc.*, 18-CV-906199, 2018 CP Cuyahoga County Ct. 1536926.
7. The Superior Court of California: County of San Francisco. Civil Case Information Search. 2018. https://webapps.sftc.org/ci/CaseInfo.dll?&SessionID=378CBA1E192AFEBB8E6858530545BCDCCDE85FD8. Accessed November 21, 2018.
8. *S.M. v Pacific Fertility Center*, 3:18-CV01586, N.D. Cal. 2018.
9. *A.B. v Pacific Fertility Center*. 3:18-CV-2298, N.D. Cal. 2018.
10. *Bauer v Pacific Fertility Center*, 3:18-CV-01634, N.D. Cal. 2018.
11. *Penniman v University Hospitals Health System Inc.*, 18-CV-895503, 2018 CP Cuyahoga County Ct. 1342806.
12. Jacobo J. Couple argues that lost frozen embryo was a person, lawsuit states. 2018. https://abcnews.go.com/US/couple-argues-lost-frozen-embryo-person-lawsuit-states/story?id=56994691. Accessed November 30, 2018.
13. *Petite v University Hospitals Health System, Inc.*, 19-P-000089, 2019 CP Geauga County.
14. Orvos J. New lawsuits filed in IVF storage tank failure case. 2019. http://www.contemporaryobgyn.net/ivf/new-lawsuits-filed-ivf-storage-tank-failure-case. Accessed January 28, 2019.
15. *Kurchner v State Farm Fire and Casualty Co.*, 858 So. 2d 1220; Fla App. Lexis 17096, 2003.
16. *Doe No. 1 v Northwestern Memorial Hospital*, 2014 IL app (1st). Lexis 140212.
17. First settlement in sperm loss cases at northwestern. 2015. https://www.pfaffgill.com/blog/2015/06/first-settlement-in-sperm-loss-cases-at-northwestern.shtml. Accessed November 24, 2018.
18. *Sentry Ins., Co v Cont'l Cas. Co.*, 74 N.E.3d 1110 (Ill. App. Ct. 2017).
19. Walden PA, Zeybek B, Phelps JY. Understanding the legal essentials of a bowel injury lawsuit in minimally invasive gynecologic surgery. J Minim Invasive Gynecol. 2017;25(1):30–7.
20. *Bramlett v Medical Protective Company*. 3-10-CV-2048-D (ND Tex, Dallas 2013).
21. Thornton RG. Settling a claim within policy limits. Baylor Univ Med Proc. 2002;15(3):336–7.
22. The American Congress of Obstetricians and Gynecologists. Professional liability and risk management: an essential guide for obstetricians-gynecologists. 3rd Washington, DC: ACOG, 2014.
23. Macey J, Mitts J. Finding order in the morass - the three real justifications for piercing the corporate veil. 2014. https://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=4647&context=clr. Accessed January 28, 2019.
24. Shrock K. Asset protection 101: more than malpractice. AAOS Now. 2015.
25. The Society for Assisted Reproductive Technology (SART). SART national summary report 2016. 2016. https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?reportingYear=2016. Accessed November 11, 2018.
26. Lomax GP, Trounson AO. Correcting misperceptions about cryopreserved embryos and stem cell research. Nat Biotechnol. 2013;31(4):288–90.
27. Snow D, Cattapan A, Baylis F. Contesting estimates of cryopreserved embryos in the United States. Nat Biotechnol. 2015;33(9):909.
28. Ethics Committee of the American Society for Reproductive Medicine. Disposition of abandoned embryos: a committee opinion. Fertil Steril. 2013;99(7):1848–9.
29. Sauer M, Crockin S, Braverman A, Daar J. Dilemmas in embryo disposition. ASRM Ethics Webinar Ser. 2016; https://www.asrm.org/news-and-publications/ethics-committee-documents/ethics/ethics-webinars/webinars/ethics-webinar-dilemmas-in-embryo-disposition/. Accessed December 12, 2018.
30. American Bar Association. American Bar Association. Model act governing assisted reproductive technology. 2008. https://www.americanbar.org/content/dam/aba/publishing/family_law_quarterly/family_flq_artmodelact.pdf. Accessed November 11, 2018.
31. *Doe v University Hospitals Health System Inc.*, 18-CV-897272, 2018. CP Cuyahoga County Ct. 1426988.
32. Bernholz R, Herman G. Legal implications of human in vitro fertilization for the practicing physician in North Carolina. Campbell Law Rev. 1984;6(1).
33. *Frisina v Women and Infants Hospital Rhode Island*. 95–4037 (2002), C.A. No. 95–4037 C.A. No. 95–4469 C.A. No. 95–5827 (Sup. Ct. R.I. 2002).
34. Ethics Committee of the American Society for Reproductive Medicine. Disclosure of medical errors involving gametes and embryos: an Ethics Committee opinion Ethics Committee of the American Society for Reproductive Medicine. Fertil Steril. 2016;106(1):59–63.
35. American Society for Reproductive Medicine. Oversight of assisted reproductive technology. 2010. https://www.asrm.org/globalassets/asrm/asrm-content/about-us/pdfs/oversiteofart.pdf. Accessed December 12, 2018.
36. Practice Committee of the American Society for Reproductive Medicine, Practice Committee of the Society for Assisted Reproductive Technology. Revised minimum standards for practices offering assisted reproductive technologies: a committee opinion. Fertil Steril. 2014;102(3):682–6.
37. American Society for Reproductive Medicine. ASRM statement on second report of storage tank failure. 2018. https://www.asrm.org/news-and-publications/news-and-research/press-releases-and-bulletins/asrm-statement-on-second-report-of-storage-tank-failure/. Accessed December 20, 2018.

38. Tomlinson M. Risk management in cryopreservation associated with assisted reproduction. Cryo Lett. 2008;29(2):165–74.
39. Practice Committee of the American Society for Reproductive Medicine. Recommendations for development of an emergency plan for in vitro fertilization programs: a committee opinion. Fertil Steril. 2016;105(5):e11–3.
40. Tomlinson M. Managing risk associated with cryopreservation. Hum Reprod. 2005;20(7):1751–6.
41. Schiewe MC, Freeman M, Whitney JB, VerMilyea MD, Jones A, Aguirre M, et al. Comprehensive assessment of cryogenic storage risk and quality management concerns: best practice guidelines for ART labs. J Assist Reprod Genet. 2019;39(1):5–14.
42. Tomlinson M, Morroll D. Risks associated with cryopreservation: a survey of assisted conception units in the UK and Ireland. Hum Fertil. 2008;11(1):33–42.
43. The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology. Revised guidelines for human embryology and andrology laboratories. Fertil Steril. 2008;90:S45–59.
44. Chart Inc. Chart cryogenic freezer with MVE TEC 3000 controllers: technical manual. 2018. http://files.chartindustries.com/13289499_K_TEC3000_Tech_Manual_2.pdf. Accessed December 20, 2018.
45. Chart Inc. MVE Vario series with MVE vario pro controller: technical manual. 2018. http://files.chartindustries.com/14930250_D_Vario_Pro_TM_2.pdf. Accessed December 20, 2018.
46. Practice Committee of the American Society for Reproductive Medicine, Practice Committee of the Society for Assisted Reproductive Technology and PC of the S of RB and T. Recommended practices for the management of embryology, andrology, and endocrinology laboratories: a committee opinion. Fertil Steril. 2014;102:960–3.
47. Cryosafe. Cryosafe: owners manual. 2003. https://www.cryosafe.com/docs/default-source/manuals/all-aluminum-series-manual.pdf?sfvrsn=4e967afb_2. Accessed January 3, 2019.
48. CryoService. MVE series – liquid or vapour storage. 2019. http://www.cryoservice.co.uk/MVE-series.aspx?FP. Accessed January 3, 2019.
49. Taylor-Wharton. Instruction manual: XL-100, XL-160, XL-180, XL-230 and XL-240. 2018. http://twcryo.com/wp-content/uploads/2018/06/INSTRUCTION-MANUAL-L-Series-L100-160-180-230-240_PN7950-8091.pdf. Accessed January 3, 2019.