Legal Aspects of Fertility Preservation

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Introduction

Roughly a third of Americans report a connection to the world of fertility preservation [1]. For many, fertility treatment made starting a family possible. For others, advancements in assisted reproductive technologies ("ARTs") benefitted a family member or a friend. Not only are Americans turning to fertility preservation more frequently when it comes time to start a family, employers now routinely offer subsidized egg preservation as a "perk" to younger employees [2]. Yet, despite this growing popularity, many legal issues associated with fertility preservation remain unsettled—leaving clinicians with limited guidance and patients vulnerable.

To date, US legal doctrines and regulatory bodies have taken a piecemeal approach to regulating fertility preservation and, in doing so, often miss critical issues that warrant intervention. Courts consider individual cases and controversies, which limits their vision to the facts in front of them. While regulatory bodies have a more expansive line of sight, they often regulate in silos. This leaves gaps where typically unrelated areas of law—like federal drug regulation and state family law—intersect. Fertility preservation inhabits exactly such an intersection. To supplement this fragmented regulatory environment, groups like the American Society for Reproductive Medicine ("ASRM") step in. Professional organizations have a more holistic understanding of the challenges posed by ARTs, but self-regulation can only go so far.

Whether in the courtroom, the legislature, or a regulatory environment, the ever-changing scope of the term "ARTs" presents a challenge. The pace of scientific progress makes pinning down the term's definition difficult, yet laws and regulations require precise definitions. ARTs upset our very conceptualizations of life and personhood by moving the reproductive process (at least partially) ex vivo. These scientific advancements force the legal and regulatory worlds to reckon with the "continuum of distinctly identifiable processes involving in vivo (via natural conception or artificial insemination) or in vitro fertilization ("IVF")"—and different entities take different approaches when it comes to defining that continuum [3].

The current regulatory landscape of ARTs highlights this definitional challenge. For example, even within the federal government, different entities don't always follow the same definition. The Fertility Clinic Success Rate and Certification Act of 1992 ("FCSRCA"), overseen by the Department of Health and Human Services

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("HHS"), defines ARTs as follows: "all treatments or procedures which include the handling of human oocytes or embryos including in vitro fertilization, gamete intrafallopian transfer, [and] zygote intrafallopian transfer" [4]. The statute also allows the secretary of HHS to broaden this definition, subject to public notice and comment. Yet, the Centers for Disease Control and Prevention ("CDC")—the agency tasked with collecting reports on the safety of certain fertility clinics—takes a narrower view [5]. For the CDC, the definition of ARTs includes only "fertility treatments in which both eggs and embryos are handled" and expressly excludes treatments involving only sperm (e.g., intrauterine or intracervical insemination) or drugs that stimulate ovulation absent egg retrieval [6]. Disjointed definitions like these represent just one piece of the fertility preservation puzzle—a puzzle that often leaves physicians with limited guidance.

While the legal issues associated with ARTs could fill their own book, this chapter focuses on issues most relevant to fertility preservation. From accessing care in the first place to handling long-frozen embryos, patients and providers face thorny legal and regulatory issues at nearly every stage. These issues include insurance coverage, informed consent requirements, regulation of the cryopreservation process, and legal challenges associated with final disposition of reproductive material. This chapter will proceed in four parts, introducing the legal doctrines relevant at each stage of fertility preservation to give physicians some insight into the legal dimensions of patient care.

Insurance Entities as Regulators in a World of Limited Oversight

In some sense, the fertility preservation process begins before a patient even selects a provider. Insurance entities play a significant gatekeeping function in fertility preservation. Despite growing popularity, the cost of treatment puts fertility care out of reach for many Americans. For patients unable to pay out of pocket, insurance coverage dictates treatment options. The treatments insurance entities will cover vary greatly, and laws that require coverage for certain procedures differ from state to state. Only a handful of states require at least *some* form of ART coverage—but these coverage mandates are often narrow. With a narrow mandate comes additional out-of-pocket costs that can leave fertility preservation prohibitively expensive.

One might assume limited insurance coverage means limited involvement of insurance entities in the regulation of fertility preservation. And yet, insurance entities play an outsized role in regulation. Not only do these entities often dictate *who* can access treatment, but they also define *what* procedures qualify for coverage. Insurance companies may present obstacles to treatment by requiring patients undergo multiple cycles of intrauterine insemination prior to IVF, even against a treating physician's recommendation. But they may also serve an important signaling function for patients by refusing to cover expensive and unproven IVF "add-ons" [7]. In this way, insurance entities both limit access to treatment and "quality control" the procedures available to many patients. While one can easily cast gatekeeping in a negative light, insurance activity offers benefits as well—especially when one considers the fertility space's piecemeal regulatory environment.

The Piecemeal Regulatory Environment of ARTs

Many consider legislatures and federal agencies as the entities best suited to regulate ARTs [8]. Unlike courts, legislatures and administrative agencies have the purview to broadly regulate—therefore, the purview to adapt to changes in the world of medicine more quickly. They produce statutes, administrative rules, and regulations that are prospective and (in theory) better match the cadence of advancements in medical practice. Despite this "ideal" venue, legislatures are beholden to their constituents. This democratic tether imports political and social tensions underpinning issues of reproduction justice and the ever-present question of when human life legally

begins. The polarizing nature of the conversation hinders attempts to pass a comprehensive regulatory scheme for ARTs and likely contributes to fertility preservation's disjointed and inadequate public oversight [8]. Instead of a comprehensive scheme, a piecemeal framework of federal, state, and private actors regulates ARTs broadly and fertility preservation specifically.

Federal Regulation

On the federal level, the Fertility Clinic Success Rate and Certification Act of 1992 ("FCSRCA") directly and purposefully regulates ARTs. The act requires fertility clinics report their pregnancy success rates and certification information of each embryo laboratory the clinic uses to the Centers for Disease Control and Prevention ("CDC"). But while the FCSRCA outlines reporting requirements, the statute provides neither incentives nor penalties for clinics that fail to comply. The FCSRCA lacks any enforcement mechanisms, crippling its regulatory purpose by allowing the estimated 12% of clinics that fail to comply with the act's mandate to keep their doors open [8].

In addition to the FCSRCA, the FDA also plays a role in the federal regulation of ARTs—albeit a small one. In addition to outlining reporting requirements, the FCSRCA tasks the Food and Drug Administration ("FDA") with screening third-party reproductive material for infectious diseases [4]. However, the FCSRCA expressly limits the FDA's regulatory authority over fertility preservation. Thanks to strong lobbying by the fertility industry, "Congress add[ed] a carve out forbidding the agency from 'establish[ing] any standard, regulation, or requirement, which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs'" [8]. As most fertility preservation does not involve any third-party reproductive material, the act considers fertility preservation a medical procedure. For this reason, most fertility preservation falls outside of the FDA's regulatory purview.

Beyond the restrictions imposed by the FCSRCA, the FDA has minimal regulatory authority over ARTs. Statutes constrain a federal agency's regulatory authority. The FDA can only regulate "articles" whose commercial distribution engages the Commerce Clause and qualify as either *biologics* under Section 351(a) of the Public Health Services Act or as *drugs* or *devices* under the Food, Drug, and Cosmetics Act [9]. Given this limited scope, FDA authority over ARTs varies depending on the specific technology in question—and whether it qualifies as a *biologic* (e.g., semen, oocytes, and embryos), *drug*, or *device*. Certain ARTs do fall within the FDA's regulatory purview, such as "minimally manipulated" human cells, tissues, and cellular and tissue-based products ("HCT/Ps") [10]. But the agency nevertheless stays largely away from the ART world, refusing to do more than discourage research in the mitochondrial transfer, germline embryo editing, and human cloning spaces [11].

State Regulation

To supplement what many consider insufficient federal oversight, some states have enacted their own ART-specific legislation. However, ART-specific legislation varies greatly from state to state. Some focus their legislation on issues related to embryonic stem cell research, insurance coverage for infertility, and surrogacy agreements [12]. A few others go further. Utah, for example, allows provider-conceived children to access the medical records of their sperm provider when they reach majority.

In terms of state legislation, Louisiana likely offers the most "comprehensive" regulation of ART procedures. The state requires providers "possess specialized training and skill in in vitro fertilization in conformity with the standards established by the American Fertility Society or the American College of Obstetricians and Gynecologists" ("ACOG") [13]. Louisiana's legislation also requires that IVF procedures occur in a medical facility meeting ASRM or ACOG standards. While the legislation goes further than other comparable statutes, the state still offers little guidance as to the meaning of "specialized training and skill," instead importing self-regulation by professional organizations.

Though such laws could do more to guide physicians, ART-specific state legislation rests on an established regulatory backbone: state medical boards. State medical boards interpret and enforce state's laws and regulations that govern the practice of medicine and, in doing so, establish the standards of the profession [14]. Regulation occurs through physician licensing, investigating complaints, and tracking all formal actions taken against a practitioner. That said, recent years show a pronounced trend toward more lax disciplinary treatment—with state medical boards disciplining fewer and fewer doctors each year [15].

In the fertility space, specifically, numerous instances exist where state medical boards failed to revoke licenses even after egregious misconduct. For example, one doctor at the Pacific Fertility Center in California saw multiple medical malpractice suits. Claims ranged from false promises, failure to train staff, botched IVF, and performing an abortion without a patient's consent to cover up implantation of the wrong couple's embryos [16]. Yet, the California state medical board failed to act.

Third-Party Regulation

Given limited federal regulation and uncoordinated state efforts, professional groups such as ASRM and ACOG serve a particularly important regulatory function in the fertility space. As evidenced by Louisiana's ART statute, and others like it, states do integrate organizational guidelines into legislation. Therefore, organizational guidelines can have the force of law in some states. That said, many of the same problems that plague federal and state regulatory efforts exist in third-party regulation as well—namely, a lack of enforcement power.

ASRM sets forth industry standards for clinicians, fertility clinics, and sperm banks—however, these standards only apply to clinics that *opt* into the society's Reproductive Laboratory Accreditation Program ("RLAP"). RLAP aims to "make laboratory processes more fail-safe and reduce risk of errors in patient identification, specimen labeling, handling of embryos and gametes and cryo-storage conditions to protect patients" [17]. To achieve this aim, RLAP institutes standards which include ongoing competency of all testing personnel and embryologists, administrative reporting requirements, and facility inspections [17].

While ASRM's guidelines offer a much-needed supplement to federal and state regulation, the same problem exits: limited enforcement power. Fertility clinics are not required to join ASRM, and even those who opt into RLAP "routinely ignore" program requirements [8]. Individual clinicians are not obligated to follow the organization's guidelines, and ASRM does not vet new ART procedures prior to their clinical use. ASRM also lacks the ability to do more than withhold accreditation for those who violate best practices, which does little to deter bad actors. Ultimately, though third parties wield power when it comes to ART regulation—especially in light of limited federal and state regulatory schemes—many agree that a gapping regulatory hole exists in the fertility industry.

Insurance Entities as De Facto Regulators

In addition to professional organizations, another third-party actor wields tremendous influence over the provision of ARTs: insurance entities. Insurance entities serve as gatekeepers—first, by dictating *who* may access treatment and, second, by dictating *what* treatments they will cover. In doing so, insurance entities take on a quasi-regulatory role in the ART space.

Insurance Entities as Gatekeepers: Who Gets Treatment

For patients unable to afford fertility preservation out of pocket—an expense that can total tens of thousands of dollars—insurance coverage dictates who can access treatment [18]. Both public and private insurers often refuse to cover fertility preservation. Only 15 states currently have laws related to covering fertility services, including 1 state Medicaid program (though the program does not cover artificial insemination or IVF) [19]. And even between these 15 state mandates,

coverage varies greatly. Two states—California and Texas—require insurance companies *offer* coverage for infertility treatment, whereas the remaining 13 require insurance companies *cover* infertility treatment [20]. Some state mandates define infertility and those who qualify for fertility preservation broadly, while others limit their mandated coverage to "oncofertility" services.

An outlier, Colorado takes a broad approach when it comes to mandated coverage of fertility preservation. The state requires all individual and group health benefit plans issued or renewed after January 2022 cover diagnoses of infertility, treatment for infertility, and fertility preservation services. The "Colorado Building Families Act" ("the CBFA") features nondiscretionary language and broadly defines infertility to include *all* indicated needs for infertility diagnosis, treatment, and fertility preservation, irrespective of marital status or sexual orientation [21]. The bill covers three completed egg retrievals and unlimited embryo transfers [21]. It also mandates that infertility be treated as any other disease process (i.e., no additional co-pays, coinsurance requirements, or waiting periods) [21]. While increasing the availability of fertility preservation for many Coloradans, the CBFA only applies to health insurance plans regulated by the Division of Insurance ("DOI") in Colorado's Department of Regulatory Agencies [22]. In total, approximately one million Coloradans receive health insurance through DOI regulated plans and may benefit from ARTs they might not otherwise have access to.

In contrast, many states with mandated infertility coverage limit fertility preservation services to patients who receive medical treatment that may jeopardize their fertility. Delaware, for example, only mandates fertility preservation coverage for patients suffering from iatrogenic infertility [23]. The statute defines iatrogenic infertility as "an impairment of fertility due to surgery, radiation, chemotherapy, or other medical treatment" [23]. All group and blanket health plans offered by health insurers, health service corporations, or HMOs in the state must cover "standard fertility preservation" for such patients. Despite these mandates, practitioners in states like Delaware still note the critical role the preauthorization process plays in whether patients actually receive coverage [24].

Whether a state broadly defines those who qualify for fertility preservation or limits services to oncofertility, these mandates only apply to insurance plans regulated by state law. Even in states with inclusive mandates, many states exempt small businesses or religious employers from such legislation. In addition, the Employment Retirement Income Security Act of 1974 exempts self-insured employer plans from state regulation. Instead, federal law regulates these plans [25]. In 2019, 61% of covered workers were enrolled in self-funded plans exempt from state regulation [26]. While progressive state mandates broaden the reach of ARTs, many Americans see no benefit from these efforts. But regardless of variances in coverage, insurers serve a quasi-regulatory function by gatekeeping who can access fertility preservation.

Insurance Entities as Gatekeepers: What Gets Covered

In addition to gatekeeping *who* can access treatment, insurance entities also gatekeep *what* treatment options patients can realistically consider. While legislation differs from state to state, typically, *if* state mandates cover fertility preservation, they often only apply to the preservation of eggs and sperm and do not include "elective preservation," the long-term storage costs of cryopreservation, or "experimental" treatments [27]. In this sense, insurance entities also serve a quasi-regulatory function by limiting clinical practice through coverage decisions.

Many fertility treatments are not considered "medically necessary" by insurance entities and therefore do not receive coverage—but that raises the question: how do we make sense of "medical necessity?" Linda Bergthold sees the term "mainly a placeholder [] in insurance plans," with the national healthcare reform debate prompting a discussion about what "a necessary service actually is and who should decide if it is covered" [28]. Like the term ART itself, both "medical" and "necessity" defy definitional precision—which allows insurers a dangerous level of

freedom in decision-making. Generally, an insurer's calculus for medical necessity includes the following:

1. The scope as determined in the contract
2. The standards of professional practice
3. Patient safety and setting of the intervention
4. Medical service (e.g., service a medical need)
5. Cost-effectiveness of the particular treatment [28]

Given that each of the aforementioned goals intersect with each other in both subjective and variable ways, some suggest that an insurer's calculus "ultimately result[s] in a determination that best suits [their] interests" [29]. As insurance providers do not disclose their process for making individual determinations, patients "implicitly ... struggle to know what [their] plans actually cover and, critically, what they do not" [29]. With the authority to create their own definitions and criteria for medical necessity, insurance entities hold considerable influence over individual patient and provider behavior within the fertility sector [29].

Embedded in the question of medical necessity is the dichotomy of "established" versus "experimental" treatment. Insurance entities favor "established" treatments and regularly deny coverage for those deemed "experimental." Some statutes offer insurance entities guidance in how to distinguish between the two. Colorado, for example, specifically defines "standard fertility preservation" as "procedures and services that are consistent with established medical practices or professional guidelines published by ASRM or ASCO" [21]. In 2012, ASRM shifted its classification of oocyte freezing from experimental to established treatment [30]. In 2018, guidelines issued by the American Society of Clinical Oncology ("ASCO") noted that "[s]perm, oocyte, and embryo cryopreservation are considered standard practice and are widely available" and that "the field of ovarian tissue cryopreservation is advancing quickly and may evolve to become standard therapy in the future" [31]. In the same vein, ASRM's 2019 guidelines declared ovarian cryopreservation nonexperimental [32]. Evolving guidance from professional associations carries weight in how insurance entities classify fertility preservation procedures and make coverage decisions.

In this sense, insurance entities and professional organizations work together to shape clinical practice. The gatekeeping effect created through definitions of "medical necessity" and "established treatment" influences patient and physician behavior. Insurance activity may, therefore, weed out dangerous or cost-ineffective care. But the effect of insurance entities on "quality control" remains less than clear; no studies demonstrate a definitive impact. In the fertility space specifically, patients may supplement their covered care with "elective" procedures and "add-ons," which they pay for out of pocket. This may dilute the effect of coverage decisions on "quality control." While quantifying the effect might be difficult, insurance entities play a significant role in regulation nevertheless by limiting *who* can access *what* fertility procedures.

The Challenges of Informed Consent

Separate from concerns about *who* receives *what* kind of care, *consent* to care introduces its own unique legal questions in fertility preservation. Legally, informed consent requirements obligate physicians to disclose all risks that a reasonable person would find significant in making an informed treatment decision [33]. Even in the best of circumstances, informed consent presents a challenge. The informed consent process surrounding fertility preservation is especially fraught; how can clinicians effectively communicate unknowns about the likelihood of successful pregnancy to patients desperate to start families? How can patients effectively evaluate the risks and benefits of fertility "add-ons" with limited empirical backing?

Despite these challenges, informed consent remains vitally important. Minimal regulations, difficulties proving the elements of medical malpractice, and policy pressures to steer clear of "wrongful life" claims offer patients limited

recourse when things go awry. This lack of recourse hinders recovery, even when gamete banks fail to screen for genetic disorders or neglect to validate information provided by anonymous sperm providers (be it medical information, educational history, or criminal records) [34]. These acute information asymmetries leave patients vulnerable and underscore the importance of the informed consent process.

The Fraught Process of Informed Consent for Fertility Treatment

To satisfy the legal requirements of informed consent, clinicians must discuss the risks and benefits of procedures with their patients. Only after does the law consider patients able to make an "informed" decision about treatment. Courts use two competing touchstones to determine the adequacy of informed consent: (1) whether a similarly situated, competent doctor would have disclosed the risk and (2) whether a reasonable patient would have elected not to undergo the treatment as a result [35]. In the context of fertility preservation, clinicians cannot realistically disclose every possible risk of a procedure—as many of the risks are financial or legal in nature. Instead, these standards offer some guidance about what risk or alternate treatment information a clinic *must* disclose to prevent liability.

But "informed" consent presumes patients actually *understand* the information conveyed to them—which is a lofty goal. Risk is a deceptively simple framework that dictates much of our decision-making. Conceptualizing risk and making decisions based on that information require translating the uncertainty risk implies. Even if a clinician "objectively" reports a numerical risk score, a patient's understanding of that value is inherently subjective. Often, clinicians cannot provide quantified risk scores for each possible outcome in fertility treatment. And even if they could, patients desperate to start families might hear what they want to hear, regardless of the information conveyed by providers.

Concerns about patients hearing what they want to hear apply equally to conversations about the benefits of fertility preservation. Despite a provider framing successful egg retrieval and cryopreservation as the benefit of treatment, a patient might conceptualize successful pregnancy as the benefit instead. What makes these conversations even more fraught is the reality that many patients interact with fertility preservation prior to their first clinical encounter. From "egg freezing parties," where women discuss fertility preservation over martinis, to employers like Apple and Facebook offering subsidized egg retrieval, many patients came to understand the benefits of fertility preservation well before walking into a clinic [36]. In this sense, recruitment starts well before the clinical encounter and raises questions about how to conceptualize the scope of the informed consent process.

In other areas of medicine, informed consent *starts* with recruitment. In the clinical trial context, for example, the FDA considers direct advertising the beginning of informed consent and requires institutional review boards scrutinize recruitment materials to prevent undue coercion [37]. The agency demands heightened scrutiny when a study "involves subjects who are likely to be vulnerable to undue influence" which might compromise informed consent. Contrast this approach with events hosted by fertility clinics at venues like the Beverly Hills hotel. There, clinics pitch egg freezing to childless women as "the smartest thing [they] can do if they are not in a serious relationship"—and they do it over drinks [36]. Clinics try to "make the idea [of egg freezing] less intimidating" and encourage women to conceptualize fertility preservation as "not a medical issue, [but as] a social issue" [36]. It's hard to suggest these environments are not intentionally coercive, especially when clinic specialists admit that "with a glass of wine, everything sounds better" [36].

These encounters undoubtedly shape how patients understand the risks and benefits of fertility preservation and raise fundamental questions about the validity of informed consent once patients enter the more traditional clinical paradigm. But like many things in the realm of fertility preservation, the law remains unsettled in this area. While the next few years

will likely bring litigation challenging these practices, whether such encounters are appropriate prior to the establishment of a doctor-patient relationship remains an open question. Regardless, these encounters are a reality of current practice and likely influence how patients make sense of fertility preservation during informed consent. As the challenges of medical malpractice and "wrongful life" claims give patients limited recourse when things go awry, informed consent represents a vital safeguard for patients.

The Difficultly of Successful Legal Claims

When injuries do arise, a constellation of factors including financial, social, and legal hurdles prevents litigants from successfully bringing their claims to court. Law Professor David Engle notes that, "'more than nine out of ten injury victims' in the United States 'assert no legal claim at all … even in cases where it is likely that a legal duty was breached, and a claim would succeed'" [8] (p. 32). First, litigation is both time-consuming and expensive. Second, states discourage medical malpractice claims by implementing short statutes of limitation (often between 6 months and 2 years), by requiring patients first submit their claims to malpractice review panels, and by capping damage awards. Third, litigation is intrusive; patients may be understandably reticent about putting their medical histories and decisions to use fertility treatment on trial. In addition to these impediments, the doctrine of medical malpractice itself imposes challenges on litigants.

A successful medical malpractice claim requires patients show that the physician or clinic breached a duty of care owed to them and that they were harmed as a result. Traditionally, the law translates this burden into four interrelated elements that plaintiffs must prove by a preponderance of the evidence (i.e., more likely than not): duty, breach, causation, and damages. Each element presents its own challenges in the context of reproductive negligence.

Duty and Breach

The first two elements a patient must prove are (1) that the provider owed them a duty of care and (2) that the provider breached that duty of care. Duties of care exist in the context of many different relationships, from that between parents and children to motorists and pedestrians on the street. These relationships all require people exercise reasonable care to prevent harm to those around them. The duty of care in the context of the doctor-patient relationship is even more acute—which makes duty a relatively easy element to establish in a paradigmatic case. A duty of care is implied once a plaintiff establishes the existence of a doctor-patient relationship, where the doctor was responsible for the patient's health at the time of injury. If the plaintiff then shows the provider failed to exercise that duty of care (i.e., they failed to act as another doctor with a comparable skill level would in the same situation), they will also have established their second element: breach [8].

The context of fertility preservation, however, raises challenges in terms of proving both duty and breach. The introduction of third parties into the equation distances the fertility industry from the paradigmatic doctor-patient relationship. Physicians are generally held to a higher standard of care than nonprofessionals (i.e., gamete banks). The highly regulated nature of medicine produces a high standard of care. In contrast, gamete banks and other third parties involved in ARTs face far less regulation. As a result, these entities are not beholden to the same standard of care. This creates an odd asymmetry: "sperm banks are operating in the reproductive health care realm by providing services for ART procedures, but they are not being held to the same standards as the physicians they work alongside" [38]. As the literature notes, "without similar laws and regulations governing sperm banks, it is difficult to determine what, *if any*, duty or standard of care sperm banks must provide in their relationship with patients or with donors" [38].

Thus, even if courts find that the third party in question owed a duty of care in the given circumstance, proving breach is yet another hurdle plaintiffs must overcome. Courts assess breach in

relation to the relevant industry. Even in the most egregious cases, proving a gamete bank "breached its duty during [the] provider screening, selection, and matching processes [may still be difficult] because the sperm bank's standard of care when conducting these processes will likely be that which is considered reasonable within the industry" [38]. As discussed in section "Insurance Entities as Regulators in a World of Limited Oversight", the piecemeal regulatory environment of ARTs places few requirements on gamete banks. Going beyond the floor set by legislation and guidelines promulgated by professional organizations remains voluntary, meaning what is considered "reasonable" within the industry remains a fairly low standard. As such, proving breach—even in relation to blatant misrepresentations or oversights—may still prove difficult.

Causation

Once patients prove duty and breach, they must establish the third element of medical malpractice: causation. Causation entails two separate showings. A patient must prove that a provider's breach of their duty of care was both (1) the "cause in fact" and (2) the "proximate cause" of their harm. "Cause in fact" simply means that, but for the provider's breach, the patient would not have suffered the harm. "Proximate cause" requires a bit more nuance; at its core, it means showing that the breach directly caused the harm in question, rather than some other intervening event or unforeseeable circumstance. Just as in science, definitively proving causation in the courtroom is a challenge. A patient might develop an unforeseeable complication despite their provider adhering to the appropriate standard of care, or an intervening event might attenuate the provider's liability.

The fertility preservation context is no different. For example, if a lab has suboptimal thawing processes, it is difficult to confirm that step of the process was the cause of the failed fertilization or implantation attempt. These challenges make proving that a provider's breach *caused* the adverse outcome difficult—especially by the "more likely than not" standard required in civil litigation.

Damages

In addition to the difficulties of proving duty, breach, and causation, identifying a cognizable harm and calculating monetary damages also prove challenging for courts and litigants alike. When harms typically occur in the fertility space, they often fall into one of four categories:

1. Implantation of the wrong embryo in a patient
2. Mix ups in the sperm or eggs used to create an embryo
3. Errors in preimplantation genetic testing
4. Damage or destruction of reproductive material in the laboratory or at a cryopreservation facility [39]

When the harm in question deprives an individual of a successful pregnancy or the chance at biological parenthood, courts make their best guess at the sum that would make the patient "whole again." The legal fiction that a monetary award can in fact make someone "whole" underpins civil litigation in the United States. Courts have various methods to calculate damage awards, but reproductive harms are understandably difficult to quantify [39].

Patients seeking recourse for pregnancies that *did* result in children face an additional problem: asserting that a mistake or misrepresentation made by a clinic caused them harm often gets uncomfortably close to a "wrongful life" claim. Courts "generally reject [these claims] as abhorrent" and against public policy, as they "validate pejoration of genetically challenged or interracial children" [40]. These concerns invoke a form of the nonidentity problem, where "as long as the [mistake or misrepresentation] does not produce a child whose life 'is not worth living' we can't say the child has been harmed" [41].

Zelt v. Xytex proves illustrative here. In *Xytex*, a family filed suit claiming that their sperm bank misrepresented their anonymous provider's qualifications. The Zelts selected Donor #9623, described as a PhD candidate with an IQ of 160 and "nearly perfect" medical and mental health history. Yet an administrative mistake at the sperm bank revealed the truth. Instead of a clean bill of health, Donor #9623 had a significant

mental health history, including heritable disorders. He was not a PhD candidate but rather a convicted felon [42]. The Zelts argued that Xytex mislead them. The district court, however, granted a motion to dismiss. The court noted the state of Georgia does not recognize wrongful birth claims, as they are not "legally cognizable injur[ies]" due to public policy reasons [34]. While wrongful birth was not among the 13 state law claims made by the plaintiffs, both the district court and ultimately the 11th Circuit found that the Zelt's argument amounted to one. In this sense, the courts confer on clinics "a misguided immunity under the guise of barring suits for wrongful life" [40].

Professor Dov Fox suggests that for ART-related claims to succeed, courts must establish a new private cause of action [8]. Professor Fox notes that courts have long taken advantage of "tort law's ability to accommodate new technologies by filling the regulatory gap and warning of neglected risks when technological innovation transfers the nature of injuries" [8]. Intentional infliction of emotional distress emerged as a result of mass transportation [8]. Strict product liability came about to deal with defects from innovative goods that harmed their consumers [8]. Privacy torts developed in response to increased technological capacities to surveil [8]. Professor Fox's new private cause of action would address the most common forms of ART harms: the imposition of unwanted pregnancy, the deprivation of wanted pregnancy, or the confounding of efforts to avoid a child born with particular conditions. Perhaps with this tool in their arsenal, plaintiff's suing for reproductive negligence would see greater success in the courtroom.

Regulation of Cryopreservation

Once patients consent to care and undergo the necessary procedure(s), the "preservation" component of fertility preservation brings with it its own unique set of legal issues. When patient tissue reaches cryopreservation, a new regulatory paradigm theoretically steps in to protect patient interests: regulation of cryopreservation. However, the General Assembly of New Jersey said it best: "while technological advances in, and success rates of, IVF have increased since its inception 40 years ago, there is currently little state or federal regulation concerning the storage of embryos in embryo storage facilities" [43]. Limited state and federal oversight allows manufacturers to escape regulation and facilities to function without proper safeguards in place to prevent damage to stored reproductive material.

Storage of Reproductive Material

Federal Regulation

As discussed, the FDA does not regulate fertility preservation *procedures*—instead, the agency regulates the *biologics*, *drugs*, and *devices* used in assisted reproduction. Cryostorage tanks and other equipment used in cryopreservation would seem to fall squarely within the FDA's purview. In fact, Title 21 specifically includes "cryopreservation instrumentation and devices, used to contain, freeze, and maintain gametes and/or embryos at an appropriate freezing temperature" as "assisted reproduction accessories" within the scope of FDA regulation. Yet, a significant loophole exists—one manufactures predictably exploit. The FDA only regulates "when these devices are specifically labeled for use in ART procedures" [44]. If a manufacturer avoids labeling their product as a medical device, the FDA's enabling statutes prevent the agency from asserting jurisdiction. As a result, manufacturers of equipment used in cryopreservation (e.g., cryostorage tanks, dewars, thermostats, etc.) bypass FDA oversight by not labeling their products for ART use.

Equipment malfunctions over the last few years highlight the costs of these regulatory loopholes. One weekend in March 2018 brought with it two unrelated freezer malfunctions [44]. Pacific Fertility Center in San Francisco and University Hospitals Fertility Center near Cleveland both experienced problems with their cryopreservation systems. These problems resulted in the loss of thousands of embryos and eggs [44]. Several

clinic patients filed lawsuits, and at least 150 settled out of court [45]. While the aim of making patients "whole again" underpins settlements and damage awards, in many cases, money cannot make up for the harm caused. For several patients with embryos lost in the California and Ohio incidents, those embryos represented their only chance at biological children—a chance money cannot bring back [45]. This reality underscores the need for more robust regulation to prevent similar incidents from happening again.

State Regulation

The 2018 freezer malfunctions prompted several states to consider legislation regulating embryo storage facilities. Following the incidents, Ohio State Senator Joe Schiavoni consulted with ASRM and the College of American Pathologists ("CAP") to produce detailed operational rules for fertility clinics [46]. These rules included 24-h monitoring requirements, separating a patient's materials into multiple storage tanks to prevent complete loss, and increased liquid nitrogen training for staff [47]. However, the bill failed to get a vote before the end of the legislative session, and Ohio has taken no steps toward regulation since [48].

New Jersey, on the other hand, successfully enacted legislation regulating embryo storage facilities and instituting licensure requirements. The state assembly noted that "it [was] in the best interest of the State to require that the Department of Health promulgate regulations governing the storage of human eggs, pre-embryos, and embryos in embryo storage facilities to guard against catastrophic storage system failures, such as those that occurred in California and Ohio" [43]. The act, which came into effect December 4, 2019, imposes operating standards on the 19 facilities within the state that store reproductive material. These standards include the use of monitoring devices and alarm systems, as well as yearly facility inspections. The act also requires the state's Department of Health to implement a facility licensing system [43].

While New Jersey's act represents a notable step forward in the oversight of embryo storage facilities, the sector remains largely underregulated across the board. Most states fail to give regulation of storage facilities any attention. This nonexistent state regulation, coupled with lax federal oversight, leaves patients vulnerable despite the preventable nature of cryopreservation malfunctions.

Disposition of Reproductive Material

Thus far, this chapter addressed how the legal world makes sense of fertility preservation before a patient seeks services, as they begin the doctor-patient relationship, and during cryopreservation. This, of course, leaves the behemoth of legal issues imbedded in the question of "what happens once a patient finishes treatment?" Patients typically choose one of three disposition options for unused reproductive material: donate unused embryos for procreation (also known as "adoption"), donate for research, or discard the unused material [3]. Once seen as a fourth option, patients may also elect to store their material indefinitely; however, clinics now encourage patients to formalize their disposition decisions rather than delay the inevitable. Legal issues arise when unforeseen circumstances intervene in a patient's disposition decision (i.e., death or divorce) or interested parties disagree down the line. Death, divorce, or disagreement brings questions of what to do with unused reproductive material into the courtroom. Questions about the enforceability of disposition agreements and how to categorize embryos present challenges for successful litigation—challenges courts address through highly variable approaches.

Options for Disposition of Reproductive Materials

Electing to proceed with fertility preservation requires parties make long-term decisions about the fate of unused reproductive material. Most providers offer several disposition options in event of death, separation or divorce, successful completion of IVF treatment, a decision to discontinue IVF

treatment, or failure to pay cryopreservation storage fees [49]. Many clinics use model forms supplied by ASRM and the Society for Assisted Reproductive Technology ("SART"). One such clinic, West Coast Women's Reproductive Center ("WCWRC"), offers the following options to patients:

1. Discarding the cryopreserved embryo(s)
2. Donating the cryopreserved embryo(s) for approved research studies
3. Donating the cryopreserved embryo(s) to another couple in order to attempt pregnancy
4. Use by one partner with the contemporaneous permission of the other for that use [49]

Consistent with California legislation and SART guidance, WCWRC caps storage of cryopreserved embryos at 20 years [49]. While indefinite storage might appeal to patients unsure about family planning, model disposition agreements no longer include indefinite storage as an option. Indefinite storage not only carries a notable cost burden, it "simply put[s] off clear disposition decisions for another day; as people's memories fade, intentions are no longer clearly recalled and more difficult to prove and establish, or former patients cannot be located, so that those decisions often become more challenging as time goes on" [3]. Most states do not institute term limits for cryopreservation storage; though some international regulatory bodies like the United Kingdom's Human Fertilisation and Embryology Authority ("HFEA") follow term limits, after which, clinics must discard unused material [50].

Disposition decisions are not necessarily final; patients may change their disposition decisions with mutual consent. Issues arise when couples disagree on proposed changes or where written disposition agreements do not exist. Mix these disputes with a constantly shifting legal landscape, and the complexities of the legal aspects of reproductive material disposition come as no surprise.

What Happens When Death, Divorce, or Disagreement Intervenes?

When disagreement or unexpected events disrupt disposition decisions, parties often turn to the legal system. With this reality in mind, WCWRC's disposition declarations—and similar agreements at other clinics—include the following warning:

> The law regarding embryo cryopreservation, subsequent thaw and use, and parent-child status of any resulting child(ren) is, or may be, unsettled in the state in which either the patient, spouse, partner, or any donor currently or in the future lives, or the state in which the ART Program is located. [49]

This caution highlights the complexity of litigation in this sector: various legal entities address disposition disputes differently. Limited federal precedent exists in this arena, as the Supreme Court typically leaves issues of family law that do not concern constitutional rights to the states. While courts take varying approaches to adjudicating disposition agreements, Debele and Crockin suggest three models of dispute resolution dominate common law approaches: contractual approaches, contemporaneous mutual consent models, and balancing tests [3]. These approaches are not mutually exclusive; in fact, courts often mix and match. But exploring these models demonstrates the diversity found in courtrooms across the country, even when court's address the same question.

Contractual Model

Perhaps the most straightforward, the contractual approach uses traditional principles of contract law to evaluate disposition disputes. Under this view, courts consider disposition agreements created prior to fertility preservation valid contracts and generally enforce their terms. More specifically, courts often ask the following questions: "(i) did the parties enter into a disposition contract? (ii) is the contract adequate? (iii) should the contract be enforced as a matter of public policy?" [3]. The contractual approach appears relatively common among courts. A survey of notable cases across the country involving embryo disposition between 1992 and 2016 found that in 6 of the 11 cases analyzed, courts utilized a contractual approach [51].

However, despite the relatively straightforward nature of the inquiry, questions often remain. Are boilerplate disposition agreements provided by fertility clinics or storage facilities

enforceable or are more formal agreements akin to prenups required? What constitutes a violation of "public policy" and what societal values should these agreements reflect? The answer to these questions, like many things in the law, depends on the jurisdiction in question—a reality which creates challenges in terms of continuity and guiding practitioners.

Contemporaneous Mutual Consent Model

Similar to the contractual approach, the contemporaneous mutual consent model functions on the premise that the parties who produced the reproductive material retain ultimate decision-making authority over disposition. While each party has an equal say in disposition, the parties must contemporaneously agree to any action—i.e., whether to use, donate, or destroy their reproductive material [3]. By requiring contemporaneous consent, this approach protects parties from unwanted procreation. When disputes arise down the line, courts must determine whether parties achieved contemporaneous mutual consent when they made their disposition agreement [3]. To do this, courts consider whether the disposition agreement included sufficient safeguards to guarantee contemporaneous mutual consent. Yet, even then, enforcement decisions under this model often hinge on whether the agreements included language reserving each party's right to change their mind about disposition.

The contemporaneous mutual consent model is less common among courts than the contractual approach and is not without critics. Professors Glenn Cohen and Eli Adashi argue that, despite claiming to honor the views of both parties, the model "puts in place a veto rule that cannot be overridden: no use of embryos by either party, despite what was agreed to previously, if one party vetoes it now" [51]. Critics argue such a rule violates established principles of contract law, defeats the purpose of disposition agreements made prior to treatment, and essentially pushes final disposition decisions down the line—in opposition to ASRM and SART guidance.

Balancing Tests

The final approach commonly taken by courts rejects the contractual and contemporaneous mutual consent models in favor of weighing the interests of the parties involved. Courts occasionally develop balancing tests in response to cases without prior written disposition agreements or where the circumstances of the parties changed significantly. Certain jurisdictions consider these tests a last resort when no other evidence of an agreement between the parties exists [52]. Prominent cases in this line of thought include *Davis v. Davis* (a 1992 Tennessee Supreme Court decision) and *Szafranski v. Dunston* (before the First District Appellate Court of Illinois in 2015)—both concerning individuals facing iatrogenic infertility after cancer treatment. Both cases lacked formal disposition agreements. In the absence of formal agreements, both courts proceeded to weigh each party's interests in the use, preservation, donation, or destruction of the reproductive material. The court's balancing test in *Davis*, for example, found that the husband's right not to procreate outweighed his wife's interests, as she could start a family through additional IVF or adoption. Importantly, the court advised that in most cases, the party wishing to avoid procreation will prevail. The *Szafranski* court went the other way, awarding the female partner the embryos at issue. An oral agreement tipped the scales in her favor, as the agreement allegedly demonstrated the parties' intent to allow her to use the embryos even absent of her partner's consent [53].

While courts often either explicitly or implicitly invoke balancing tests, these tests arguably provide even less guidance to clinicians and patients than the former two approaches. Balancing tests center on fact-dependent inquiries catered to the parties in dispute. This individuality makes it difficult to extrapolate across cases, even within the same jurisdiction. Such haziness adds additional ambiguity for patients and providers seeking to understand the status of their disposition agreements.

To harmonize the various approaches taken by courts, Professors Cohen and Adashi argue

for a set of uniform codes for embryo disposition [51]. Notably, the code would separate the disposition agreement from the informed consent process. Some clinics combine informed consent for IVF or cryopreservation with the creation of a disposition agreement. Yet Cohen and Adashi point out such conflation undermines the purposes of both forms. Informed consent communicates medical information, while disposition agreements communicate legal information. In this vein, the authors suggest a separate legal form that makes clear to the parties the binding nature of their decision. Additionally, an ideal code would create a presumption that disposition agreements are binding, include a recognition that legal parenthood cannot be imposed on an objecting party, and contain a carve-out for unforeseeable loss of fertility. While by no means perfect, such a code might harmonize the legal landscape and offer some guidance to patients and providers.

State Legislation Addressing Disposition Disputes

To help guide patients and providers in this area, some states enacted legislation designed to clarify questions of disposition in the event of disputes. Both California and Florida require written embryo disposition directives, with the former also requiring the parties to set forth time limits for storage. In cases where no prior agreement exists, Florida vests decision-making authority jointly with the parties that created the material. Louisiana and Arizona stand at the other end of the spectrum. In Louisiana, if a patient surrenders their right to use their reproductive material, the embryos "shall be available for 'adoptive implantation' in accordance with the written procedures of the facility where it is housed or stored" [54]. Concerns about the rights of the "embryo" itself underpin such legislation [3]. Arizona similarly prioritizes concerns about the status of embryos. In July 2018, the state legislature instituted a law that grants "custody" of reproductive material to the party that intends to "develop [the embryos] to birth" if a dispute arises. Like the variability in how courts approach dispute resolution in this area, legislative divergences stem from differences in the legal status granted to reproductive material and the rights (if any) afforded to embryos.

Are Embryos "Property" or "People" Under the Law?

Differences in the legal status granted to embryos explain the high variability in approaches taken by courts and state legislatures. Whether decision-makers see embryos as property, persons, or something in between shifts their calculus. While courts often err on the property side, the so-called personhood movement continues to gain traction in state legislatures. At least 11 states introduced "personhood bills" over the past few years to grant embryo's personhood status in the eyes of the law [55]. Regardless of the approach, the legal status of embryos affects the rights afforded to them and their progenitors and impacts the practices of fertility preservation as a result.

The (Quasi-)Property Approach

Over the past 20 years, as courts developed jurisprudence in response to fertility preservation, a fairly common conceptualization of embryos emerged: one viewing embryos akin to property. As disputes often made their way into the courtroom via divorce or disposition disagreements, viewing embryos in the light of property allowed courts to use familiar methods of dispute resolution [3]. Some states go so far as to codify the property approach. Michigan's legislature specifically classifies embryos as "property" to allow researchers to derive new lines of embryonic stem cells from embryos donated for medical research [3]. Florida takes a similar approach; through statute, the state grants progenitors a "property interest" in their embryos [3].

While some courts make little distinction between embryos and traditional property, others consider embryos sui generis—or a special kind of property deserving particular attention. In a 2017 case, for example, the Missouri Court of Appeals held that the cryopreserved embryos in dispute constituted a unique form of joint or marital property that could not be split down the mid-

dle. The lower court granted each party equal "shares" in the embryos at issue, and the court of appeals affirmed [51, 56]. In its decision, the court expressly rejected arguments that embryos were "children" under a Missouri statute that defines life as beginning at conception [56]. Though the Missouri court rejected this argument, some state legislatures disagree.

The Personhood Approach

Louisiana and Arizona both categorize embryos as persons, and at least 11 states have pending legislation to that effect. In an effort to grant greater protections to cryopreserved embryos, Louisiana expressly rejects a property-based conceptualization and defines a human embryo as a "biological human being which is not the property of the physician who acts as an agent of fertilization or the facility which employs him or the donors of the sperm or ovum" [54]. In terms of disposition disagreements, the best interests of the embryo and its right to life govern [3]. As discussed above, if genetic parents choose not to implant their embryos, then the embryos become available for "adoptive implantation." Arizona follows a similar approach; 2018 legislation grants custody to the party most likely to "develop [the embryos] to birth" in instances of disposition disputes [57].

At least eight states will consider similar "personhood bills" in the 2021 legislative session. On March 18, 2021, the Montana House advanced a measure to change the state's definition of "persons" to the following: "all members of mankind at any stage of development, beginning at the stage of fertilization or conception, regardless of age, health, level of functioning or condition of dependency" [58]. At the hearing, opponents noted that such a definition impacts not only abortion access but the availability of fertility preservation and ARTs. Such arguments fell on deaf ears, as Rep. Sharon Greef responded: "in America, we have a holocaust happening in every state because we are denying that personhood begins at conception" [59]. That said, similar bills advance in the Montana House almost every year, and all have failed to reach the state's voters.

The effects of "personhood legislation" produce real challenges for fertility preservation. As advocacy group, RESOLVE, argues, "at a minimum, [such legislation] would force changes in the practice of reproductive medicine (e.g., limitations on the number of eggs that may be fertilized) that are not in patients' best interests and constitute inferior medical practice" [60]. "Personhood bills" threaten patient care in a variety of ways. In addition to limiting the number of embryos a patient can create, such bills may limit practices such as preimplantation genetic testing or prevent medical research using embryos.

To prevent these harms, advocacy groups and professional organizations argue in support of quasi-property understanding of the legal status of embryos. ASRM notes that "embryos should be afforded 'profound respect' but not the same moral and legal rights that are afforded human beings" [3]. Interim or sui generis status accomplishes this goal by recognizing the moral status of embryos, while preventing the "rights" of the embryo from trumping the rights of the other parties involved. While such sui generis status might circumvent the blatant attack on fertility preservation imbedded in personhood approaches, the feasibility of such an approach remains far from clear. Until a uniform code harmonizes various state approaches or the Supreme Court weighs in on the issue, disjointed jurisprudence regarding the legal status of embryos is inevitable—a reality practitioners and patients alike should be aware of when considering questions of disposition.

Conclusion

Unlike most developed countries—and unlike the robust training, certification, and licensing requirements of other specialties domestically—regulators in the United States have yet to adequately address fertility preservation [61]. Most experts advocate for increased regulation, with some referring to the "United States [as] the Wild West of the fertility industry" [62]. ASRM stands largely alone in asserting that "ART is already one of [the] most highly regulated of all medical

practices in the United States"—a claim not born out when one considers the significant gaps in regulatory oversight [62]. Insurance entities, professional organizations, and state medical boards attempt to fill these gaps. But the lack of cohesive regulation nevertheless creates a host of problems, including those related to insurance coverage, informed consent, cryopreservation, and disposition of reproductive material. This chapter surveyed the legal aspects of fertility preservation in relation to each of these stages but in no way claims to be dispositive. Rather, this chapter highlights some of the most glaring legal and regulatory issues pertinent to the practice of fertility preservation—offering clinicians a lay of the land and demonstrating that patients cannot just "bank" on legal infrastructure to protect their interests in the world of ARTs.

References

1. Pew Research Center. 33% of US adults used fertility treatments or know someone who has. Washington, DC: Pew Research Center; 2018. https://www.pewresearch.org/fact-tank/2018/07/17/a-third-of-u-s-adults-say-they-have-used-fertility-treatments-or-know-someone-who-has/.
2. Bloomberg Law. INSIGHT: Employer-subsidized egg freezing benefits—who really pays? https://news.bloomberglaw.com/health-law-and-business/insight-employer-subsidized-egg-freezing-benefitswho-really-pays.
3. Debele GA, Crockin SL. Legal issues surrounding embryos and gametes: what family law practitioners need to know. J Am Acad Matrimon Law. 2018;31:63. https://cdn.ymaws.com/aaml.org/resource/collection/B03D017A-76BC-459A-A464-EA00FFF95EC1/MAT107_13.pdf.
4. Federal government of the United States. Fertility clinic success rate and certification act of 1992. Washington, DC: U.S. Government Publishing Office; 1992. p. 3146–52. https://www.govinfo.gov/content/pkg/STATUTE-106/pdf/STATUTE-106-Pg3146.pdf.
5. CDC. What is assisted reproductive technology? Atlanta, GA: CDC; 2020. https://www.cdc.gov/art/whatis.html.
6. Federal government of the United States. Federal register, vol. 64, No. 139. Washington, DC: U.S. Government Publishing Office; 1999. p. 39376. https://www.govinfo.gov/app/details/FR-1999-07-21/context.
7. Kraschel K. Regulating devices that create life. In: Innovation and protection: the future of medical device regulation. Oxford: Oxford University Press; 2021. (forthcoming).
8. Fox D. Birth rights and wrongs. How medicine and technology are remaking reproduction. Oxford Scholarship Online. Oxford: Oxford University Press; 2019. p. 25. https://oxford.universitypressscholarship.com/view/10.1093/oso/9780190675721.001.0001/oso-9780190675721.
9. Rokosz GJ. Human cloning: is the reach of FDA authority too far a stretch? Seton Hall Law Rev. 2000;30(2):464–515.
10. FDA. Imported human cells, tissues, and cellular and tissue-based products (HCT/Ps). Silver Spring, MD: U.S. Food and Drug Administration; 2017. (Compliance Program Guidance Manual). https://www.fda.gov/media/73960/download.
11. Lewis MS. How subterranean regulation hinders innovation in assisted reproductive technology. Cardozo Law Rev. 2018;39(4):1. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3170376.
12. Storrow RF. Surrogacy American style. In: O'Byrne K, Gerber P, editors. Surrogacy, law, and human rights. New York, NY: Routledge Member of the Taylor and Francis Group; 2015. p. 191.
13. Louisiana State Legislature. Human embryo; definition. LA-RS 9. Baton, LA: Louisiana State Legislature; 2009. http://legis.la.gov/legis/Law.aspx?d=108438.
14. Carlson D, Thompson JN. Virtual mentor. AMA J Ethics. 2005;7(4):311–4. https://journalofethics.ama-assn.org/article/role-state-medical-boards/2005-04.
15. Federation of State Medical Boards. U.S. medical regulatory trends and actions 2018. Washington, DC: Federation of State Medical Boards; 2018. https://www.fsmb.org/siteassets/advocacy/publications/us-medical-regulatory-trends-actions.pdf.
16. The Patient Safety League. Rodriguez v. Salem, No. BC626618 (Cal. Super. Ct. Jan. 12, 2017); 2017. https://4patientsafety.org/documents/Salem,%20Rifaat%202017-01-12%20%20Rodriguez-v-Salem.pdf.
17. College of American Pathologists. Reproductive accreditation program. Northfield, IL: College of American Pathologists. https://www.cap.org/laboratory-improvement/accreditation/reproductive-accreditation-program.
18. Weigel G, Ranji U, Long M, Salganicoff A. Coverage and use of fertility services in the U.S. Kff.org. San Fransico, CA: Kaiser Family Foundation; 2020. https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/.
19. Centers for Disease Control and Prevention. ART and insurance. Atlanta, GA: CDC; 2019. https://www.cdc.gov/art/key-findings/insurance.html.
20. National Conference of State Legislatures. Legislative news, studies and analysis. Washington, DC: National Conference of State Legislatures. https://www.ncsl.org/.
21. Government of Colorado. Colorado revised statutes title 10. Insurance. Mandatory coverage provisions

2020 (Colorado) § 10-16-104(23)(g)(IV)(a)–(c). Denver, CO: Government of Colorado; 2020.
22. Government of Colorado. Revised fiscal note, Leg. Council Staff. Denver, CO: Government of Colorado; 2020. https://leg.colorado.gov/sites/default/files/documents/2020A/bills/fn/2020a_hb1158_r1.pdf.
23. Government of Delaware. Delaware code title 18. Insurance 2018 (Delaware) §3556. Dover, DE: Government of Colorado; 2018. https://delcode.delaware.gov/title18/c035/sc03/index.html.
24. Kondapalli LA, Crisci A. Incorporating insurance education into the fertility preservation process. In: Woodruff TK, Clayman ML, Waimey KE, editors. Oncofertility communication. New York, NY: Springer; 2014. p. 167–80.
25. Federal Government of the United States. Employment retirement income and security act of 1974. Washington, DC: U.S. Government Publishing Office; 1974. https://www.govinfo.gov/content/pkg/STATUTE-88/pdf/STATUTE-88-Pg829.pdf
26. Kaiser Family Foundation. 2019 Employer health benefits survey, Section 10: Plan funding. San Fransico, CA: Kaiser Family Foundation; 2019. https://www.kff.org/report-section/ehbs-2019-section-10-plan-funding/.
27. Reinecke J. States add coverage mandates to cover infertility treatment following cancer treatments. Washington, DC: NASHP. https://www.nashp.org/states-add-coverage-mandates-to-cover-infertility-treatment-following-cancer-treatments/.
28. Bergthold LA. Medical necessity: do we need it? Health Aff. 1995;14(4):180–90.
29. Sircar N. Your claim has been denied: mental health and medical necessity. Health Law Pol Brief. 2017;11:1.
30. Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. Fertil Steril. 2013;99(1):37–43.
31. Crockin SL, Altman AB, Edmonds MA. The history and future trends of ART medicine and law. Fam Court Rev. 2021;59(1):22–45.
32. ASRM Practice Committee. Fertility preservation in patients undergoing gonadotoxic therapy or gonadectomy: a committee opinion. Fertil Steril. 2019;112(6):1022–33.
33. Canterbury v. Spence. Vol. 464, F.2d; 1972. p. 772. https://scholar.google.com/scholar_case?case=16106013819601769055&hl=en&as_sdt=6&as_vis=1&oi=scholarr.
34. Wang Y. This couple says everything they were told about their sperm donor was a lie. Wash Post. 2015. https://www.washingtonpost.com/news/morning-mix/wp/2016/04/15/this-couple-says-everything-they-were-told-about-their-sperm-donor-was-a-lie.
35. Beauchamp TL, Childress JF. Principles of biomedical ethics. 7th ed. New York, NY: Oxford University Press; 2012. p. 126.
36. Gorman A. At egg freezing parties, women sip wine, chat about postponing motherhood. Chicago Tribune. 2017. https://www.chicagotribune.com/lifestyles/health/ct-egg-freezing-parties-20171116-story.html.
37. HHS. Federal policy for the protection of human subjects. Washington, DC: HHS; 2009. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html.
38. Posada TE. Whose sperm is it anyways in the wild, wild west of the fertility industry? Georgia State Univ Law Rev. 2018;34(3):847–92. https://readingroom.law.gsu.edu/cgi/viewcontent.cgi?article=2935&context=gsulr.
39. Crockin SL, Gottschalk KC. Legal issues in gamete and embryo cryopreservation: an overview. Semin Reprod Med. 2018;36(5):299–310.
40. Billauer BP. The sperminator as a public nuisance: redressing wrongful life and birth claims in new ways (AKA new tricks for old torts). SSRN Electron J. 2019; https://doi.org/10.2139/ssrn.3333787.
41. Sabatello M. Disclosure of gamete donation in the United States. Indiana Health Law Rev. 2013;11(1):29–81.
42. Zelt v. Xytex Corp. vol. 766, Fed. Appx; 2019. p. 735. https://images.law.com/contrib/content/uploads/documents/404/25731/11th-Circuit-Zelt-v.-Xytex.pdf.
43. New Jersey Legislature. An Act concerning the regulation and licensure of embryo storage facilities and supplementing Title 26 of the Revised Statutes (New Jersey) Title 26. Trenton, NJ: New Jersey Legislature. https://www.njleg.state.nj.us/2018/Bills/PL19/268_.PDF.
44. Gardella R, Edwards E, Robins M. Heartbreak, anxiety, lawsuits: the egg-freezing disaster a year later. NBC News. 2019. https://www.nbcnews.com/news/all/heartbreak-anxiety-lawsuits-egg-freezing-disaster-year-later-n978891.
45. SART. Frozen embryos continue to make litigation headlines. Birmingham, AL: SART. https://www.sart.org/news-and-publications/news-and-research/legally-speaking/frozen-embryos-continue-to-make-litigation-headlines2/.
46. Peiffer Wolf Carr Kane & Conway, LLP. Embryo oversight needed in Ohio. The Toledo Blade. 2019. https://www.peifferwolf.com/embryo-oversight-needed-in-ohio/.
47. Cha AE. Embryo storage bill seeks oversight of fertility centers and penalties for those that violate safeguards. Wash Post. 1974. https://www.washingtonpost.com/news/to-your-health/wp/2018/07/05/embryo-storage-bill-seeks-oversight-of-fertility-centers-and-penalties-for-those-that-violate-safeguards/.
48. Joe Schiavoni. Outgoing State Sen. Joe Schiavoni hopes statehouse will take up his embryo bill. Wosu.org. 2019. https://radio.wosu.org/post/outgoing-state-sen-joe-schiavoni-hopes-statehouse-will-take-his-embryo-bill#stream/0.
49. West Coast Women's Reproductive Center. Disposition of embryos. Los Angeles, CA: West

Coast Women's Reproductive Center. https://womensreproduction.com/wp-content/uploads/2018/11/WCWRC-Disposition-Of-Embryos-Declaration.pdf.
50. HFEA. Welcome to the HFEA. London: Human Fertilisation and Embryology Authority. https://www.hfea.gov.uk/.
51. Cohen IG, Adashi EY. Embryo disposition disputes: controversies and case law. Hast Cent Rep. 2016;46(4):13–9.
52. Davis v. Davis. vol. 842, S.W.2d; 1992. p. 588. https://law.justia.com/cases/tennessee/supreme-court/1992/842-s-w-2d-588-2.html.
53. Szafranski v. Dunston. vol. 34, N.E.3d; 2015. p. 1132. https://1.next.westlaw.com/Document/I8fc1fb0811cd11e5a795ac035416da91/View/FullText.html?transitionType=UniqueDocItem&contextData=(sc.Search)&userEnteredCitation=34+N.E.3d+1132+(Ill.+App.+Ct.+2015).
54. Louisiana State University. Human embryos. LA-RS 9 §130 Duties of donors. Baton Rouge, LA: Louisiana State University; 2020. https://biotech.law.lsu.edu/cases/la/health/embryo_rs.htm.
55. Cohen IG, Adashi EY. Personhood and the three branches of government. N Engl J Med. 2018;378(26):2453–5. https://www.nejm.org/doi/pdf/10.1056/NEJMp1801940?articleTools=true
56. Peeler E. Frozen pre-embryos classified as marital property of a special character and awarded jointly to divorced couple. Child Law Pract Today. 2017. https://www.americanbar.org/groups/public_interest/child_law/resources/child_law_practiceonline/child_law_practice/vol-36/mar-apr-2017/frozen-pre-embryos-classified-as-marital-property-of-a%2D%2Dspecial-/.
57. Arizona Legislature. https://www.azleg.gov/legtext/53leg/2R/bills/sb1393s.pdf.
58. Montana State Legislature. https://leg.mt.gov/bills/2021/HB0399/HB0337_1.pdf.
59. Montana SI. House advances "personhood" bill to limit abortions. New York, NY: Associated Press; 2021. https://apnews.com/article/bills-montana-810bee54e0b6b6fd5795414a00e10c9e.
60. RESOLVE: The National Infertility Association. Learn RESOLVE's Policy on "Personhood" Legislation. RESOLVE. 2020. https://resolve.org/resolves-policy-personhood-legislation/.
61. The Pew Charitable Trusts. States not eager to regulate fertility industry. Philadelphia, PA: The Pew Charitable Trusts. https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/3/18/states-not-eager-to-regulate-fertility-industry.
62. American Society for Reproductive Medicine. Oversight of assisted reproductive technology. Washington, DC: American Society for Reproductive Medicine; 2021. https://www.asrm.org/globalassets/asrm/asrm-content/about-us/pdfs/oversiteofart.pdf.