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Treating Infertility: The New Frontier of Reproductive Medicine

Edited by Emma Waters and Natalie Dodson





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Treating Infertility: The New Frontier of Reproductive Medicine

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Introduction to Restorative Reproductive Medicine

Natalie Dodson

For a married couple, the desire for biological children is natural. Yet, with birth rates declining and infertility rates rising in the United States, more couples are experiencing the devastation of infertility. In conventional reproductive healthcare, the solution to this crisis is fertility clinics and assisted reproductive technology (ART). Nevertheless, ART should not be the first solution offered to couples who suffer from infertility; restorative reproductive medicine (RRM) should be.

One of the major differences between ART and RRM is that the former seeks to circumvent the infertility, and the latter seeks to treat the underlying causes of infertility.

Conventional Reproductive Healthcare's Response to Infertility

Infertility is not a disease or condition. Instead, it is a symptom of underlying reproductive dysfunction and can often present with other symptoms. In Abigail Anthony's case (see "How Doctors Ignored My Stage Four Endometriosis"), for example, while not experiencing infertility—she was not trying to conceive—her other symptoms, such as intense pain, revealed her reproductive health condition: endometriosis. Her pain was not the disease; endometriosis was. In the same way, infertility is not a disease, but conventional reproductive healthcare treats it like one.

For many symptoms of reproductive health conditions or diseases, the medical professions' instinctive response is pharmaceutical Band-Aids to mask and ignore the symptoms for as long as possible. Likewise, for infertility, the common response is in vitro fertilization (IVF), which circumvents the infertility by producing the child outside of the body without attempting to treat the underlying cause of the infertility. Both approaches fail to restore health and may instead contribute to worsening health for all patients involved. As some of this section's authors describe, circumventive technology often sells couples a pervasive yet ineffective promise. While ART can produce an embryo outside of the uterus, it cannot guarantee successful implantation or live birth of that child. The reproductive dysfunction persists with ART, often leading to unsuccessful IVF cycles and repeated heartbreak for couples.

Restorative Reproductive Medicine

RRM is a comprehensive approach to addressing the symptoms and causes of reproductive dysfunction. Rather than treating reproductive or bodily dysfunction in a piecemeal manner, RRM examines the whole body and the multitude of conditions or comorbidities that may contribute to the symptoms patients experience. Once the underlying causes of the symptoms are identified, often through fertility awareness-based methods (FABMs), RRM protocols treat them through hormone-balancing, dietary and nutritional adjustments, environmental changes, and, in some cases, surgery.

Rather than suppressing or circumventing distressing symptoms of reproductive health conditions with pharmaceutical Band-Aids or ART, RRM treats the conditions and seeks to return the individual to peak health. While conventional reproductive medicine offers inadequate options to women suffering from symptoms of reproductive health conditions or couples struggling with infertility, RRM does not sell women or couples quick fixes. Instead, RRM requires the difficult yet necessary work of treating the underlying diseases, conditions, and dysfunction.

Unfortunately, funding for reproductive health condition research is sorely lacking.² In response to this gap, independent health organizations and RRM specialists have created their own databases and research projects.³ These medical professionals, like Dr. Marguerite Duane ("An Overview of Restorative Reproductive Medicine") and Dr. Patrick Yeung ("Restorative Reproductive Medicine: A Surgical Approach to Treating Endometriosis"), have also undertaken the burden of training the next generation of medical professionals in RRM.⁴ Up to this point, policy has failed to address reproductive dysfunction comprehensively and instead has narrowly promoted

pharmaceutical Band-Aids. With ongoing discussions about the infertility crisis in the United States, legislators and the Administration have an opportunity to support treatment for the root causes of infertility and restorative reproductive medicine.

The articles in this section will provide an introduction to RRM. The authors describe the present flaws in conventional reproductive medicine and how RRM produces much-needed solutions to these failings. As medical professionals, bioethicists, and patients, these authors draw from personal experience and evidence-based data to support RRM and its medical protocols.

The authors discuss why restorative reproductive medicine should be an alternative to, or at least a prerequisite to, assisted reproductive technology. One article ("Putting All Our Eggs In One Basket") will examine the cost and success rates of assisted reproductive technology and restorative reproductive medicine, finding that "success rates for [restorative reproductive medicine] are similar to or better than IVF for many couples." Our hope is that this section provides an introduction to restorative reproductive medicine, a new and burgeoning area of medicine.

Natalie Dodson is a Policy Analyst at the Ethics and Public Policy Center.

Conventional "Reproductive Health Care" Compared to Restorative Reproductive Medicine

Grace Emily Stark

Setting aside at once the phrases "reproductive health" and "women's health" as they are popularly used in the media (that is, often as a euphemism for abortion), let us turn to them as they are next most frequently employed: to collectively reference the hormones, pharmaceuticals, and devices used to manage women's menstrual cycles, whether for contraceptive purposes or to alleviate the symptoms of common gynecological disorders such as endometriosis, polycystic ovary syndrome (PCOS), and uterine fibroids, which often present as painful, heavy, and/or irregular periods (among other symptoms) in adolescence and if left untreated will likely lead to struggles with infertility as an adult.

Modern reproductive healthcare is a narrowly conceived vision of women's health. Restorative reproductive medicine (RRM), on the other hand, is an authentic, more comprehensive approach to women's health.

A Brief History of the Reproductive Health Industry's Reliance on Pharmaceuticals

That contraception has become synonymous with "women's health" is a phenomenon nearly eighty years in the making. Enovid, the first contraceptive pill to hit the U.S. market, was first approved in 1957 for the treatment of "gynecological and menstrual disorders," with the caveat that it could inhibit ovulation as a side effect.⁵

What was referred to as the "contraceptive activity" of the Pill almost immediately became so well known among women and their doctors alike that "a suspiciously large number of women [were] treated with the pill [beginning in] 1957 for 'severe menstrual disorders," as Nicholas Bakalar put it in a 2010 edition of *The New York Times*'s "First Mention" feature on contraceptive pills.⁶

But whether American women of the late 1950s were using Enovid as contraception or to control the symptoms of endometriosis, fibroids, or any of the other poorly understood gynecological disorders that have plagued women for centuries, birth control's popularity upon its initial approval was staggering: As Lara Marks notes in *Sexual Chemistry: A History of the Contraceptive Pill*, by 1961 (one year after Enovid's approval as a contraceptive in 1960), half a million American women were regularly taking hormonal contraception. 8

While Enovid's entry into the market could be considered a "soft opening" of sorts—intended to gauge women's interest in taking a daily medication with no therapeutic purpose—hormonal contraceptives *did* prove effective at managing the symptoms of certain gynecological disorders, chief among them endometriosis and fibroids, and, more commonly today, PCOS. Today, hormonal contraception is still used (often off-label) as a frontline treatment for these issues and, more generally, to "regulate" a woman's cycle when she presents with irregular and/or heavy, painful periods. By flatlining the ebb and flow of a woman's natural cycle with the synthetic versions of the female reproductive hormones estrogen and progesterone (progestin), modern hormonal contraceptives (whether in the form of a pill, patch, injection, ring, or intrauterine device [IUD]) still mask many of the symptoms of common gynecological disorders, just as Enovid once did.

How Hormonal Contraceptives Work

It's important to note that hormonal contraception does not treat the root causes of PCOS, endometriosis, or any of the gynecological disorders for which doctors commonly prescribe it. Hormonal contraceptives also come with their own side effects and risks, some as benign as nausea and bloating and others as serious as cancer, blood clots, and depression. Many women and their doctors alike are ill informed about the extent of these risks.

It is a little-known fact—or a little-discussed one—that hormonal contraception functions by keeping women from having menstrual cycles. The synthetic hormones in hormonal contraceptives function primarily to prevent pregnancy by keeping women from ovulating and likewise from menstruating. ¹⁰ For many women afflicted with a variety of gynecological disorders, the overriding of their natural, cyclic hormonal fluctuations by hormonal contraception manages symptoms such as painful and/or heavy periods. The logic is simple: No menstrual cycle means no symptoms of a menstrual disorder.

It is undeniably quicker, cheaper, and easier for a physician to prescribe hormonal contraception to a female patient than it is for him to take the time to diagnose or investigate the underlying causes of her irregular and/or painful cycles (which may include, among other things, a detailed review of the patient's menstrual cycle history, hormone analysis, imaging studies, physical or surgical exams, etc.). For the busy physician, prescribing hormonal contraception is a quick solution that may also make his patient's life more manageable—at least until she discontinues it, for example if she wants to get pregnant or if side effects become intolerable. In fact, the very existence of hormonal contraceptives may be part of the reason

why these disorders remain chronically underdiagnosed, undertreated, and under-researched despite impacting a significant percentage of the female population.

Perhaps this is why it takes, on average, between eight to twelve years for a woman to receive a diagnosis of endometriosis¹¹—a condition that affects more than six million American women—making it a condition as common as diabetes¹² (PCOS has a similar prevalence, and uterine fibroids may actually affect as many as 80 percent of women). These conditions also represent the leading causes of infertility in the United States. Strikingly, an estimated 70 percent of teenage girls who present with dysmenorrhea (painful menstrual cramps) are eventually diagnosed with endometriosis.¹³ But that diagnosis often comes after years of needless suffering, with pharmaceutical "Band-Aids" placed over symptoms and the heartbreak of miscarriage and/or infertility.

Why Women Need Healthy Cycles

The problem with the immediate recourse many physicians take towards prescribing hormonal contraceptives for painful and/or irregular cycles is twofold. It not only fails to address the root causes of these issues but also blithely ignores the fact that *women need their cycles* for the good health and proper development of nearly every major organ system of the body. This is precisely why, since 2015, the American College of Obstetricians and Gynecologists has said that the menstrual cycle should be treated as a "vital sign" (alongside the other four measurements of the body's essential functions: body temperature, pulse rate, respiratory rate, and blood pressure). Is

To illustrate this point by means of an analogy: Consider that we do not shut down a patient's heart when her heartbeat is irregular. We understand, correctly, that the irregular heartbeat calls for investigation, indicating that it says something important about the patient's cardiac health. We likewise understand that issues with cardiac health do not stay within the heart; instead, they have far-reaching implications for a patient's overall well-being.

Why, then, have we decided to shut down women's menstrual cycles when their periods are irregular?

What Authentic Women's Health Should Look Like

For far too long, doctors and patients alike have accepted the false belief that hormonal contraception is the best—indeed, the only—remedy for gynecological disorders. (For too long, women have also accepted that those

same risks and side effects are a necessary trade-off for effective pregnancy prevention.) This mentality has arguably set back medicine's understanding of women's health in an untold number and manner of ways. But health-care professionals who have embraced the field of restorative reproductive medicine, which uses the detailed knowledge of a female patient's menstrual cycles to gain information about a woman's fertility and overall health, have rejected the quick fix of contraception and are committed to investigating and treating the root causes of cycle issues—improving the patient's fertility and overall health in the process.

In other words, RRM-trained healthcare professionals are not content to simply override a woman's cycle by flooding her body with various pharmaceuticals and/or synthetic hormones via pills, injections, or devices. Instead, they are armed with training in natural procreative technology (NaProTechnology), fertility education and medical management (FEMM), NeoFertility, and other practices that are committed to the understanding that a woman's cycle (and likewise, her fertility) is not a disease to be cured but rather a fifth "vital sign"—that is, a biomarker that can indicate something about the overall health of a woman to the knowledgeable healthcare professional. In the hands of such a professional, a detailed accounting of a woman's menstrual cycles (commonly captured via digital or analog charts of fertility biomarkers such as menstrual bleeding, basal body temperature, cervical mucus, and/or hormonal tests) is as powerful and essential to good knowledge of a patient's health as an EKG tracing is in the hands of a cardiologist.

It is time to revolutionize women's health—to see it as more than a euphemism for abortion or pregnancy prevention but instead as a field of medicine that understands the truth that a woman's cycle impacts (and is, in turn, impacted by) her overall health. One's cycle is not an independent function of the body that can (or should) be shut down with little regard for the workings of the whole. Indeed, this has been the fundamental mistake of the majority of women's health solutions since 1957. But thanks to restorative reproductive medicine, the field of women's health is finally changing for the better. In the next essay, Dr. Marguerite Duane of FACTS About Fertility will explain how.

Grace Emily Stark is a writer, editor, and speaker whose expertise includes fertility awareness, women's health, and bioethics.

An Overview of Restorative Reproductive Medicine

Marguerite Duane, MD

Restorative reproductive medicine (RRM) is an approach to health care designed to identify and treat root causes of reproductive or hormonal dysfunction to restore the reproductive system to the way it is designed to function. Although infertility is commonly labeled as a causal diagnosis of reproductive concerns, it is not the root cause but rather a symptom; RRM thus seeks to identify and treat the true underlying causes of infertility to restore health and fertility.

The reproductive system is the only system in the human body that requires cooperation with another human being to function to its full capacity. The goal of the reproductive system is to enable a person to reproduce, but human beings do not reproduce on their own. For a man and a woman to reproduce, the male sperm must fertilize the female ovum (egg) to create a genetically unique human being. In some cases, it is difficult to assess whether the reproductive system is fully functional until a couple attempts to have children.

More couples are now unable to conceive, a condition known as infertility. The standard medical definition of infertility is an inability to conceive after one year of random acts of intercourse. In couples who engage in fertility-focused intercourse, infertility is defined as the inability to conceive after six months. The couple learns to identify the days when a woman is likely fertile—the fertile window—and has sexual relations during that window.

In women who are over thirty-five years old, if the couple is unable to conceive after six months of random acts of intercourse, they are deemed infertile. Given the precipitous decline in fertility as women and men age, this designation should expedite the clinical evaluation to identify and treat potential root causes of infertility.

Infertility and Fertility Awareness-Methods

Although healthy men are almost always fertile, healthy women of reproductive age are almost always infertile. In women, the fertile window typically lasts only three to six days per cycle. Identifying a woman's window of fertility is key to successful reproduction, which is a distinct advantage of using fertility awareness—based methods (FABMs). With FABMs, women can track observable signs (external physical biomarkers) that reflect internal hormonal changes, empowering a woman to identify the time when she

may be able to conceive during each cycle. Research demonstrates that in a healthy ovulating woman, the probability of pregnancy in any one cycle is only 20-25 percent.¹⁶

Many medical professionals mistakenly view infertility as a disease when it is, in fact, a symptom of underlying conditions that contribute to a couple's inability to procreate. In most cases, infertility does not result from a single factor but multiple underlying health issues present in males and females. Infertility is due to a female factor 30 percent of the time, a male factor 30 percent of the time, and combined female and male factors 40 percent of the time. Medical care is incomplete, and we do a disservice to our patients if we do not consider potential underlying causes of infertility and treat them in both the man and the woman.

When a woman charts her cycle with a FABM, this provides a daily diary of her hormonal health and allows medical professionals trained in RRM to identify underlying abnormalities. Multiple evidence-based natural methods are available that use various observable signs or biomarkers; these include a woman's cervical fluid secretions (cervical mucus), the menstrual bleed (period), basal body temperature, and urinary hormones. FABMs that enable a woman to track her cycle using these biomarkers include the Billings Ovulation Method, the Creighton Model, the Sympto-Thermal Method, Fertility Education and Medical Management, the Marquette Model, and NeoFertility.

The American College of Obstetricians and Gynecologists and the American Academy of Pediatrics recognize the female menstrual cycle as the "fifth vital sign." For a woman, her cycle is a vital sign as valuable as her temperature or blood pressure. In most cases of infertility, a likely diagnosis can be discovered through the medical history and the chart of a woman's cycle, which reflects the details of her daily hormonal changes.

Restorative Reproductive Medicine Protocols

Once the underlying causes of infertility have been identified, clinicians trained in RRM seek to treat these causes. Using medical protocols developed in conjunction with FABMs, our goal is to restore the reproductive health of the female and male body to enable a couple to procreate naturally.

Several comprehensive medical protocols have been developed, including Natural Procreative Technology (NaProTechnology), which is based on the Creighton Model. NaProTechnology aims to identify and treat underlying conditions through medical and surgical management to facilitate natural procreation. Dr. Phil Boyle, who was trained in NaProTechnology,

has since developed NeoFertility, which can be used with the ChartNeo app or other FABMs to expand treatment options for infertility. NeoFertility is the newest RRM approach and seeks to address many more of the underlying issues that can contribute to infertility, including hormonal imbalances as well as autoimmune and inflammatory conditions. Fertility Education and Medical Management (FEMM) collaborates closely with the Reproductive Health Research Institute to address a wide range of women's hormonal health issues using evidence-based medical protocols.

A Patient Story

As a family physician, when I see a couple with infertility, I evaluate and treat the couple, not just the woman. Using an RRM approach, I consider potential reproductive health conditions in women, such as endometriosis, polycystic ovary syndrome (PCOS), and uterine fibroids, and conditions in men, including insulin resistance, high blood pressure, and poor sperm quality. After a thorough evaluation, I may refer patients to other specialists trained in RRM, such as surgeons and nutritionists, to assist with the management of the underlying conditions causing infertility. In restorative medicine, collaboration is key, and each medical professional plays a unique role.

For example, a thirty-year-old woman presented to my practice with secondary infertility and recurrent miscarriage. She had been previously diagnosed with infertility and PCOS, and after a minor diagnostic surgery, she conceived and had a child. However, two years later, when the couple started trying to expand their family, they experienced a miscarriage. Then another, and another. After her third miscarriage, a reproductive endocrinology and infertility (REI) physician recommended in vitro fertilization (IVF). She questioned the advice as her difficulty was not in *getting* pregnant but *staying* pregnant; at that point, she found my practice.

Almost immediately, we identified multiple factors contributing to her recurrent miscarriages and now secondary infertility. To address her PCOS, I helped her change her diet. I also diagnosed Hashimoto's thyroiditis and began treatment. Several hormonal issues were identified, and it became clear she not only had PCOS but potentially endometriosis as well. As this condition is beyond the scope of my family medicine practice, I explained that I needed to engage the services of a restorative reproductive medicine colleague.

I referred her to a NaProTechnology trained surgeon who performed surgery for PCOS, and the patient conceived two months later. Given her history of recurrent miscarriage, we used progesterone supplementation to support her natural hormones, and, ultimately, she carried the child to term. Five years after the birth of her first child, she welcomed her second. By restoring this woman's reproductive system to the way it was designed to function, this couple conceived their third child less than two years later without any additional interventions.

A Comprehensive Approach to Women's Health

So what sets restorative reproductive medicine apart from conventional reproductive endocrinology and infertility (REI)?

The difference between REI, the mainstream approach to treating infertility, and restorative reproductive medicine is that REI treats infertility itself as the disease rather than as a symptom of underlying causes. REI seeks to treat infertility by producing embryos in test tubes rather than treating its cause. The embryo must then be transferred back into the woman's body to carry the child to term. By not identifying root causes of infertility, REI may lead to pregnancy loss because the woman is not healthy enough to carry the child to a full-term delivery. If the answer was simply creating the embryo in the test tube, then assisted reproductive technology would have a 100 percent success rate, but it does not.

In contrast to assisted reproductive technologies (ART), RRM offers a comprehensive approach focused on identifying and treating root causes of infertility to make women and men healthy and fertile again. RRM restores natural fertility and effectively treats common causes of infertility, such as endometriosis and PCOS, while also leading to healthier individuals and couples. Treating underlying conditions that cause infertility should be the goal of every medical professional who cares for these patients, and restorative reproductive medicine is an effective, patient-centered approach to achieve this goal.

Marguerite Duane, MD, is a Board Certified Family Physician, and Co-Founder and Executive Director of Fertility Appreciation Collaborative to Teach the Science (FACTS).

Restorative Reproductive Medicine: A Surgical Approach to Treating Endometriosis

Patrick Yeung Jr., MD

Reproductive health conditions such as endometriosis are underdiagnosed and undertreated. These conditions are very common but rarely mentioned by mainstream medicine.

What is Endometriosis?

Endometriosis develops when the cells that line the uterus are found outside of the uterus. This condition often leads to pain and infertility, but treatments can help with these symptoms and restore fertility. As endometriosis progresses, it can go beyond the surface of the uterus and can develop in and on other organs, such as the ovaries and bowels. There are many theories for how and why endometriosis develops, but none have been proven, and some of these theories have led to pervasive myths and falsehoods about the disease. For example, one myth is that removing the uterus (a hysterectomy) or shutting off periods through medically induced menopause cures endometriosis. This is not true. Neither option treats the already existing endometriosis or slows the growth of the disease. And hormonal suppression is a risk factor for more advanced disease later in life.

At least one in ten women has endometriosis in an asymptomatic population of women, but within the population of women suffering from infertility, the number is closer to 50 percent of women without pain and 80 percent of patients who have pain even with hormonal suppression. ¹⁷ According to the University of St. Louis's ten-year database, over 90 percent of women with pain and infertility have endometriosis. Unfortunately, most of these women have likely been told they have unexplained infertility. ¹⁸

As a medical professional intimately affected by endometriosis through my wife's experience with the disease, I know that it is bad enough that women suffer from infertility, but the added burden of not knowing the cause of one's infertility adds insult to injury. My wife is the first to say, "If a woman is not getting pregnant, there should be a reason why." Indeed, a woman's body is designed to have the capacity to get pregnant.

The usual treatments that are offered—pharmaceutical Band-Aids, bypass therapy for infertility, or repeated surgeries for the rest of one's life—are not satisfactory. At my practice, the RESTORE Center for Endometriosis, we offer root-cause treatment to remove the disease and thus avoid

long-term pharmaceutical Band-Aids and even the need for post-operative hormonal suppression. Root-cause treatment can also lead to naturally recurring fertility.

Surgical Treatment of Endometriosis

Early in my medical career, I realized that to be skilled in this area of medicine, I could not simply perform these surgeries part time, and surgical excision of endometriosis became my exclusive focus. I have performed around four thousand of these surgeries in the past fifteen years, in addition to completing two residencies and two fellowships, one in minimally invasive gynecologic surgery and another in laser removal of endometriosis, which is my tool of choice for these surgeries. ¹⁹ My education and experience enable me to excise endometriosis where other medical professionals may not be able to do so, such as near the bowel and fallopian tubes.

Root-cause treatment leading to natural fertility or one-and-done surgery makes sense to patients. It resonates with those who suffer from chronic pain and infertility. But many medical professionals are not supportive of this approach. They do not want to be done with the patient after one surgery. The money isn't in these surgeries. It is in Big Pharma and in vitro fertilization (IVF), not in restoring natural fertility. Offering one-and-done surgery takes away from these medical professionals' businesses. These surgeries also take a lot of effort, training, and risk because they aim to remove the disease entirely, which is the definition of optimal excision of endometriosis. It's a lot easier to remove a few spots and then put a patient on long-term pharmaceutical suppression or send her off for IVF. My approach requires a very different mindset.

Most of my patients have had previous surgeries for their endometriosis, including ablation, burning the disease at the surface, or inadequate excision. The rate of repeat surgeries after ablation, which is the most common surgical method for endometriosis, is between 40–60 percent in one to two years. ²⁰ The disease is not constantly coming back after each surgery; it is really the same disease seen over and over again since it has not been treated or has only been partially treated. With ablation of the disease, energy is used to try to destroy the implants of the disease, but nothing is removed from the body.

Comparably, complete excision seeks to treat all of the disease and prevent adhesions, which are bands of scar tissue that consist of endometrial tissue, by producing and removing the specimen of the disease from the body. Rather than burning the surface of the disease, excision cuts to the

root of the disease and removes it, leaving behind only the healthy tissue. In producing the specimen, I am able to send it to the lab for pathology, which allows me to give a certain diagnosis of disease and the amount of it. My rate of repeat surgery from the ten-year database is 2.5 percent in ten years. ²¹ And the majority of my patients took no long-term pharmaceutical suppression post-operation, which is a common approach for patients who have frequent repeat surgeries.

One-and-done surgery is possible, and it should be the main option that medical professionals offer to patients.

But one-and-done surgery takes time. Excising endometriosis completely can take hours, and there's only one billing code if you are in network. No medical professional can survive in network by excising endometriosis. We, like all centers of endometriosis, provide these services out of network or on a cash-pay basis in order to be able to do a good job. It takes time, expertise, and risk to go after all of the disease. And in some cases, there is a lot of it. For example, I have found endometriosis in the bowel, ovaries, fallopian tubes, and diaphragm, but it has also been found in the lungs, brain, and the back of the eye.

Unfortunately, there is a bottleneck issue. There is high demand for these surgeries, but there are too few surgeons. If medical professionals commit to comprehensive root-cause treatment, as I have, that requires a lot of surgery, but it takes time to train enough surgeons to do this type of operation. The first part of my career has been focused on collecting and publishing the data on this surgical approach. The second part of my career will hopefully be focused on training others to provide this treatment.

It is incredibly validating for patients suffering from symptoms of endometriosis, including infertility, to get answers through pictures and pathology. There is so much value in being able to say to patients, "Congratulations, you're not crazy; you were sick." Most women want answers and to know that something is really wrong, and I am able to give them the answers they've been searching for, often for many years. On top of that, I am able to help patients feel better. As medical professionals, that should be the goal, and we need to begin offering our patients more than Band-Aids and circumventive technology. We need to offer them real answers and root-cause treatment.

Patrick Yueng Jr., MD, is the Founder and Owner of RESTORE Center for Endometriosis.

Putting All Our Eggs in One Basket: Is In Vitro Fertilization the Only Way Couples with Infertility Can Conceive?

Craig Turczynski, PhD, and Phil Boyle, MD

The American Association for Reproductive Medicine (ASRM), the primary medical society in the United States supporting the practice of in vitro fertilization (IVF), has become increasingly active politically through its Center for Policy and Leadership (CPL).²² It presents itself as the factual authority on assisted reproductive technology even though it is also the primary financial beneficiary of the pro-IVF position. Restrictive policy makes the practice of IVF more difficult and potentially less lucrative for those who work in this field. Therefore, when lawmakers see very carefully crafted messages from the CPL, it would be prudent for them to consider potential bias cleverly disguised as patient advocacy.

Infertility is a chronic condition caused by multiple underlying anatomic and/or health-related issues.²³ The infertile couple experiences significant psychological pain and suffering due to the loss of what many take for granted: the ability to conceive and give birth to a child. Diagnostic procedures, needle sticks, and technical treatments for infertility add more stress and can harm the couple's relationship. Assisted reproductive technology (ART), a group of related, powerful procedures for conceiving that includes IVF and that handles either eggs or embryos outside of the woman's body,²⁴ treats infertility as an acute condition. Each procedure results in one attempt for pregnancy, with the success highly dependent upon the age of the woman. It is not therapeutic for the parents or the subsequent children, especially during the embryonic stage, and it does not cure the underlying issues that lead to infertility. While IVF is a significant technical development that has resulted in successful births for millions, it has suppressed investigation into ways to correct underlying diseases. A definitive diagnosis is not even necessary for IVF because the treatment remains similar regardless of the cause. This ambiguity about diagnosis often forces the patient to move quickly to IVF rather than doing the tedious work that getting a precise diagnosis would require. And since IVF doctors are paid handsomely to use their high-tech laboratories and highly trained embryologists, they may be hesitant to convince the patient otherwise. Today, many ART procedures are conducted for reasons that have nothing to do with infertility, such as egg and embryo banking, screening for genetic traits, and nontraditional family procreation.²⁵

There is another form of treatment for infertility, however, that is not well known or widely taught or researched in mainstream academic medical schools. It is called restorative reproductive medicine (RRM). Clinicians trained in this science focus investigations and treatments on correcting abnormalities rather than suppressing, destroying, or bypassing normal reproductive function. ²⁶ RRM started with physicians and women's health specialists who, in response to their patients' ethical or religious objections, found alternatives to the conventional approach to reproductive medicine. First, they scientifically defined how to use biomarkers of the woman's menstrual cycle such as bleeding, cervical mucus, basal body temperature, and urinary hormones to assist the woman in identifying her fertile window. ²⁷ The couple could then use this information to target intercourse and either avoid or achieve pregnancy. Subsequently, physicians recognized the utility of this fertility awareness–based method (FABM) for the diagnosis of menstrual cycle abnormalities.

Today, blood collection for diagnostic hormone analysis and therapeutic treatments are applied to the precise day of the menstrual cycle and represent an important component of RRM. ²⁸ For example, day 21 of the cycle has conventionally been identified as important for diagnosing post-ovulatory hormone levels since it is twenty-one days after the start of a new menstrual bleed. Because of the variability of a woman's cycle, however, day 21 is also highly variable, leading to inconsistent results.²⁹ When a woman is using a scientifically validated fertility awareness method, this day corresponds to seven days after she experiences her peak fertility sign, and it is a very accurate marker for healthy ovulation by measuring the hormones estradiol and progesterone. If ovulation is dysfunctional, medications such as Letrozole and HCG are prescribed to correct this abnormality and optimize fertility. Diagnostic evaluation of systems such as thyroid, uterine, and metabolic functions is performed, sometimes leading to surgical repair and medications such as levothyroxine, naltrexone, metformin, and others used to treat these underlying health issues.³⁰ Cycle health is continuously monitored so that the treatments can be assessed. While this is going on, investigation and treatment of the man is also conducted.

This is just one example of how physicians, guided by cycle-tracking methods and apps used by their patients, can apply multiple and sustained interventions over time. Like conventional reproductive endocrinologists, RRM physicians use ultrasound, surgery, blood hormone analysis, and ovarian stimulation drugs, but their use is less about taking over reproductive function and more about assisting it so the function can proceed normally while both partners are healthy, leading to the best chance of a healthy pregnancy and baby.

TABLE 1

Summary of Data Sources

				Avg. % Live		
Data source	Year(s)	# Patients	Avg. Age	Birth	% Twins	% Multi
RRM-Stanford et al., 2008	1998-2002	1,072	35.8	26%	4.6%	0.0%
IVF-SART 2003	2003	82,930	35.7*	29%	30.0%	6.0%
RRM-Tham et al., 2012	2000-2006	108	35.4	38%	0.0%	0.0%
IVF-SART 2006	2006	90,233	36.0*	29%	29.0%	1.8%
RRM-NeoFertility 2019	2019	193	36.4	40%	2.5%	0.0%
IVF-SART 2019 single-ET	2019	126,935	36.5*	29%	6.0%	0.1%
IVF-SART 2019 multi-ET	2019	127,175	36.5*	37%	6.7%	0.1%

^{*} Estimated from data reported in age ranges.

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Success rates for RRM are similar to or better than IVF for many couples, and they are free of IVF's host of unresolvable ethics and regulatory problems. And when RRM-treated couples don't give birth to a child, they often still benefit from the treatments, which have been designed to improve their health and well-being. So they don't leave empty-handed. ART, on the other hand, is associated with increased adverse outcomes for the woman and her baby, and those who are not successful often leave sick, broke, and brokenhearted.

By compiling data published by the Society for Assisted Reproductive Technology (SART)³³ for IVF success and comparing it to similar-year data published for RRM in 2008³⁴ and 2012,³⁵ we can make some comparisons between the two approaches. We also added unpublished data obtained from an established RRM clinic in Dublin, Ireland, called NeoFertility.³⁶ The IVF rates are based on one IVF retrieval and embryo transfer attempt, and the rates for RRM are based on a cumulative period of up to 18 months

(NeoFertility) or 24 months (NaPro) of trying natural conception. The last column in the table below includes data from multiple embryo transfers, which adds all the subsequent transfers of frozen embryos that resulted from that one retrieval. Since each natural conception cycle ovulates one egg, resulting in about twelve eggs per year, and each IVF cycle results in an average of nine eggs, ³⁷ this comparison may be the most valid. In addition, one can see the excessively high rate of twins, triplets, or higher number multiples that are born from IVF. Although these rates were significantly reduced between 2003 and 2019, they are still higher than RRM rates.

A review of SART 2019 data shows that IVF babies had more multiple pregnancies and even the singleton pregnancies had 3 times more premature deliveries compared to RRM, (14.4% vs 3.9%). The additional financial and health burden associated with multiples and premature delivery need to be considered in the analysis of cost involved with IVF treatment. Unfortunately, not all causes of infertility can be solved with a restorative approach. Severe forms of male infertility are beyond its scope; for example, if a man has a total absence of sperm in his ejaculate, he will not be able to conceive a child. Assisted reproductive procedures can retrieve the sperm surgically, and then injection of the sperm directly into an egg that has been retrieved through IVF will result in fertilization. Conception would otherwise be impossible, which is why some people choose this approach, but it must also be considered that it puts the burden of medical treatment on the woman. If instead research was applied to learn how to surgically reconstruct abnormal anatomy or regenerate sperm production, this treatment could restore fertility and lead to repeat conceptions.³⁸ This same IVF approach is offered to men with other forms of male infertility. Another example not currently solvable by RRM is that of a woman who has lost her fallopian tubes due to previous ectopic pregnancies or severe tubal blockage. Until the 1970s, a procedure was used to transplant the ovary into the uterus so the egg would ovulate in a location where a sperm could fertilize it. The procedure had a low success rate of about 10 percent but was abandoned even though IVF was less successful than that at the time.³⁹ These potential treatments deserve to be pursued.

As one might expect, decisions can be influenced by finances. A significant amount of revenue is needed to support an ART clinical program. The cost to set up the laboratory ranges from \$500,000–\$1,000,000.⁴⁰ Reproductive endocrinologist salaries range from \$225,002–\$733,793,⁴¹ and the average embryologist earns \$108,046.⁴² This does not include administrative support and nursing staff. There is still a need for laboratory services with RRM for things like blood hormone monitoring and semen analysis, but

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these services are typically not performed in-house and don't contribute significantly to overhead. A single IVF can cost between \$12,400–\$25,000 per cycle depending on the extent of other procedures used, such as genetic testing, freezing, sperm injection, etc., and the cost per live birth can exceed \$60,000.⁴³ The base IVF fee, which does not include diagnostics, surgery, or medications, ranges from \$9,000–\$14,000 per attempt.⁴⁴ This cost can be compared to the alternative RRM care provided by the NeoFertility clinic in Dublin, Ireland, which similarly does not include diagnostic testing, surgery, or medications.

Converted to U.S. dollars, the NeoFertility medical management plan, which would provide up to eighteen months of care, costs \$2,647. A similar RRM clinic in the United States includes the cost of the initial baseline and monthly lab tests, eight hours with a dietitian or health coach, and monitoring during early pregnancy for a total charge of \$9,000.⁴⁵ RRM clinicians are typically trained in family medicine or gynecology and are less highly compensated than reproductive endocrinologists, ⁴⁶, ⁴⁷, and there is no need for a high-tech ART lab or laboratory personnel. These factors make the cost to the patient a fraction of IVF.

In conclusion, ART is a powerful and highly refined technology that has helped millions to conceive a child. But it has blossomed into an enormous industry that has supplanted the scientific pursuit of alternative therapeutic methods and is associated with a host of ethical and health-related issues. RRM represents an emerging "medical treatment process" that is already demonstrating impressive results and is as effective as one IVF retrieval with multiple embryo transfers. Although the process is longer, it can be done at a fraction of the cost of ART. With additional awareness and research funding, tremendous progress could be made, reducing the need for many to use ART.

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The Impact of Nutrition on Fertility and the Central Role It Ought to Play in Fertility Care

Victoria Peck-Gray, RD

Proper nutrition is a critical factor for both men and women in optimizing fertility, but it is often underappreciated, or sometimes wholly overlooked, within the conventional fertility care model. In this model, the underappreciation for nutrition can go so far as being reduced to a simple question in an appointment: "Are you taking a prenatal multivitamin?" Couples struggling to conceive frequently receive this advice from their doctor: "Try for twelve months, and if you're not pregnant, we will discuss your options"—"options" typically being to jump straight to assisted reproductive technologies (ART) such as in vitro fertilization (IVF). Not much guidance, however, is generally given for what the couple could do to increase their chances of natural conception, particularly how they could harness the power of food and nutrition.

Most couples want guidance on how to support their fertility with natural solutions such as nutrition and lifestyle changes. Since these solutions do not play a prominent role in the conventional fertility care model, many couples are seeking out providers like me who practice restorative reproductive medicine (RRM), a model of fertility care that aims to identify and correct root causes impacting fertility, often using targeted nutrition support as part of the care. I propose that nutrition optimization ought to be part of any fertility care plan prior to escalating to options like ART. In fact, the impact of nutrition and lifestyle changes could potentially prevent the need for ART, saving couples money, time, and effort as well as dramatically reducing their health-care costs.

Below I describe the three major ways nutrition impacts fertility and explain how the RRM model of care embraces nutrition and why the standard model of fertility care ought to do the same.

The Link Between Nutrition and Fertility

The food we eat literally becomes our body, powering every single process and chemical reaction that occurs each moment we are alive. When it comes to fertility, food and nutrients influence the health of eggs and sperm, support the hormonal cycles that drive conception, and even lay the foundation for a healthy pregnancy. Nutrition literally powers the creation of life and its sustenance.

Nutritional support can play many roles in optimizing and restoring fertility, including the following:

- 1. Correcting metabolic dysfunction, which is especially important in the condition polycystic ovarian syndrome (PCOS)⁴⁹
- 2. Restoring nutrient deficiencies, which can impact numerous facets of fertility
- 3. Reducing inflammation, which has a role in endometriosis

Metabolic Health and Fertility

In the United States and most Westernized countries, metabolic dysfunction is widespread. An estimated 93 percent of American adults have at least one biomarker indicating metabolic dysfunction, which is an impairment in the body's ability to efficiently convert food into energy. Two of the most common conditions of metabolic dysfunction include insulin resistance and excess weight. These conditions are also known risk factors for infertility.

For example, at least 75 percent of women with PCOS, a metabolic condition affecting about one in twenty women that often creates challenges with conceiving, have insulin resistance (a form of blood sugar dysregulation).⁵¹ High levels of insulin in women can disrupt the delicate balance of hormones needed for strong ovulation and successful conception.

Insulin resistance does not affect just women. Male factor infertility accounts for up to a shocking 50 percent of infertility cases, and insulin resistance is more prevalent in men with poor sperm quality and reduced sperm count. 52

Blood sugar dysregulation can show up in a multitude of symptoms day to day, including fluctuating energy levels, sleep disturbances, weight gain, and excessive cravings. These kinds of symptoms are so common among Americans that it almost seems a part of the modern cultural experience to be "tired and hangry." But these symptoms often are red flags of burgeoning metabolic dysfunction.

If left unresolved, the underlying metabolic dysfunction of insulin resistance can advance from just an annoying extra few pounds of weight to reproductive dysfunction and inability to conceive. In my women's health and fertility nutrition practice, I coach my clients in supporting blood sugar balance and reducing insulin resistance through nutrition and lifestyle

adjustments. The process of restoring blood sugar regulation can be fairly simple and has proven successful as a means of improving energy, overcoming resistant weight loss, and even getting pregnant.

Given the prevalence of metabolic dysfunction like insulin resistance and its known impact on fertility, and given how relatively simple and affordable it is to correct this dysfunction through nutrition and lifestyle changes, it only makes sense to feature nutrition support as part of the fertility care model.

The Impact of Nutritional Deficiencies on Fertility

In addition to blood sugar and overall metabolic health, nutrient status plays an influential role in fertility. Essential nutrients include amino acids (from proteins) and essential fatty acids (omega-3 and omega-6), along with a multitude of vitamins and minerals. Deficiencies in any of these nutrients can impact reproductive health by impairing the development and quality of eggs and sperm as well as disrupting hormone signaling that conducts the whole reproductive process.

Here are just a few examples:

- Magnesium is a mineral used in over three hundred processes in the body, including energy production inside eggs and sperm, hormone signaling, and blood sugar regulation, to name a few that directly impact fertility. But research shows that close to 50 percent of the U.S. population is not meeting the minimum daily requirements for magnesium.⁵³
- Zinc is a mineral that supports the maturation of eggs, assists in hormone production, and enhances sperm quality. Low zinc levels have been associated with reduced fertility in both men and women.
- Omega-3 fats play a key role in reducing inflammation and promoting healthy blood flow to the reproductive organs, improving the chances of implantation. But according to NHANES data, around 89 percent of adults have low blood concentrations of these essential fats, which puts them at risk for cardiovascular issues and fertility challenges.⁵⁴

Nutrient deficiencies can occur due to factors such as poor dietary intake and depletion from chronic stress, which can often leave people with low levels of essential nutrients well beyond the duration of the stressor if nutrients are not intentionally replenished. Therefore, identifying personal nutrient deficiencies and providing nutrition support to replenish nutrient levels can have a profound impact on fertility care.

Nutrition's Role in Endometriosis Care

Alongside PCOS, another common condition that can negatively impact fertility is endometriosis, which is a factor in about 50 percent of infertility cases. Most medications prescribed for endometriosis do not address the root cause of the disease. The RRM model of care, which includes fertility awareness—based methods and laparoscopic excision of endometriosis, on the other hand, can identify and treat endometriosis earlier.

The RRM approach to endometriosis often embraces nutrition support as a complement to this care process. Nutrition guidance, often including an anti-inflammatory diet and targeted supplementation, can help to further alleviate pain and inflammation, along with balancing hormones in order to enhance recovery and prevent progressionw of the condition.

A Call to Action: Elevating the Role of Nutrition in Fertility Care

Optimizing nutrition can play a profound role in fertility care, including reversing metabolic dysfunction to promote a fertile environment in the body, supplying the nutrients needed for the development of healthy eggs and sperm, and helping patients to recover from conditions such as PCOS and endometriosis that pose challenges to fertility. Targeted nutrition and lifestyle changes can provide natural solutions in fertility care that address root causes, promote overall thriving health, and come at a fraction of often cost-prohibitive ART.

Despite these facts, the standard model of fertility treatment regularly bypasses these foundational, natural options for restoring reproductive health and instead typically leans on costly ART that do not address root causes. The RRM model recognizes and embraces nutrition support as a foundational component of fertility care along with other natural options that can be used before sending couples to ART.

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A Couple's Journey to Healing Infertility

Marie Meaney, PhD, and Joseph Meaney, PhD

Couples do not embark on the in vitro fertilization (IVF) journey with a light heart. Most would prefer treatments that heal their infertility so they can have children without resorting to fertility technology. Having one's babies conceived in a lab, sorted and selected by technicians, thrown away if not deemed healthy enough, or frozen for possible future use are not nice thoughts—even if one doesn't fully appreciate the grave ethical violations. IVF was never an option we considered because of our religious and moral objections to the procedure. We wish we had been offered other possibilities without needing to search far and wide, spending significant amounts of money, and having to travel long distances to avail ourselves of the most promising treatments offered by restorative reproductive medicine. This, it seems to us, is the kind of compassionate care that couples suffering from infertility deserve. Almost everywhere we turned, IVF was the default proposition for infertility, and this surprised us given the high cost and failure rates of IVF when compared to other ways of addressing the causes of childlessness.

Early in our marriage, we realized that babies weren't arriving as we had hoped, and we were devastated. The thought of a life without children stretching out in front of us seemed like one unending heartbreak. We considered the beautiful option of adopting a child, but the difficulties of this path were daunting, and ultimately, we didn't feel it was our calling. Those nine years it took us to finally hold our little daughter Thérèse in our arms seemed endless. Many people going through this experience speak of a feeling of powerlessness. After undergoing various tests, we had a sense of what our medical issues were (many don't, since there is still a substantial amount of unexplained infertility even today). The question was how best to address them.

One of the most promising infertility care centers for the last few decades has been the Saint Paul VI Institute for the Study of Human Reproduction in Omaha, Nebraska, founded by Dr. Thomas Hilgers, who developed the Creighton Model FertilityCare System (CrMS) and the women's health science of NaProTechnology (short for Natural Procreative Technology). Dr. Hilger's various treatments have proved far more successful than IVF (ranging from 81.9 percent in case of anovulation, 56.7 percent in case of endometriosis, to 38.4 percent in case of tubal occlusion), yet the average gynecologist remains completely ignorant of this option for couples suffering from infertility. ⁵⁵

First, one learns the Creighton Model, a fertility awareness-based method that looks in detail at the woman's menstrual cycle (her cervical mucus, the consistency, stretchiness, and color of which yield important information about her fertility and must be recorded accurately).⁵⁶ At the time, Marie had to drive more than an hour to meet up with a teacher to help her learn the method (now, happily, one can go through the process online). The tracked cycles are then sent to a practitioner. We were in direct contact with the Saint Paul VI Institute. The information helps the specialists to determine whether there is a high likelihood of endometriosis or other issues (vitamin or hormonal deficiencies can be treated more easily than these conditions). If the first seems to be the case, then NaProTechnology has several promising potential interventions, and a laparoscopy may become necessary. If the endometriosis isn't too severe, it is removed immediately (leaving hardly any scar tissue behind); otherwise, another, longer surgery is scheduled. We traveled to Omaha from Virginia for the first intervention, but even today, doctors trained in NaProTechnology are scarce and far apart. It takes quite a bit of commitment to access treatment.

In our case, Marie only had the first laparoscopy done. Before getting to the second phase of the treatment—the longer surgery—Joseph underwent a surgical intervention to remove a varicocele. Then, Marie tried a massage treatment with Clear Passage, acting on the scar tissue attachments produced by endometriosis. This can help resolve infertility issues (the treatment was innovative at the time, but fortunately today one can more easily find physiotherapists using different techniques aimed at the same results). Though the deep-tissue massage helped reduce the recurring pain caused by endometriosis, it was another two years before our long-desired child was born.

We threw everything we could at the factors leading to our infertility. We also tried alternative medical treatments, psychological help, and spiritual healing. The question of which treatment options to select was difficult; the temptation to second-guess ourselves remained a constant preoccupation. Many doctors helped us, and many prayers went up to Heaven. Finally, Marie conceived naturally, and after a full-term pregnancy and long labor, we had the joy of welcoming our precious daughter into the world.

To our distress, we experienced secondary infertility after her birth. This subsequent infertility was also very painful. Our hope for more children lasted as long as our biological clocks allowed and through a heartbreaking miscarriage along the way. At that point, we were living in Italy and found some Catholic fertility doctors in Rome. We were blessed all along our journey, but others are less so. Some may not have the means to travel or

pay for different kinds of treatments, or they may have to fight with their health insurance providers for coverage. It takes a lot of stamina to research options and follow through with them. Given the heavy psychological burden couples already carry when infertility weighs on them, making medical care for infertility more easily accessible would be incredibly helpful.

Allocating money for research into the causes and treatments for infertility rather than mainly relying on IVF would give hope and eventually more good options to couples. Informing them of their chances of carrying a child to term if they turn to the Creighton Model and NaProTechnology and other methods of restorative reproductive medicine rather than IVF would be the honest and compassionate thing to do. The current status quo of near-total ignorance of alternatives to IVF among medical professionals is simply unacceptable.

Our successful journey to overcome infertility through the use of restorative reproductive medicine is an example of what is possible. True informed consent would involve offering real alternatives to couples facing infertility rather than simply directing them to IVF centers.

Marie Meaney, PhD, is a Mother and the Author of *Embracing the Cross of Infertility*. **Joseph Meaney, PhD,** is a Senior Fellow at the National Catholic Bioethics Center.

How Doctors Ignored My Stage-Four Endometriosis

Abigail Anthony

Pharmaceutical suppression in the form of birth control was pushed on me as soon as I began menstruating. When I had the typical adolescent experience with unsightly acne, the drug was presented as a cure that would regulate my hormones and clear up my skin. Since I was a competitive dancer, doctors and coaches insisted that my period prevented optimal athleticism; supposedly, birth control would alleviate any monthly symptoms and improve my performance. Although I was not sexually active, doctors suggested that I strategically begin birth control so that I could eventually engage in casual sex without concerns about pregnancy. I repeatedly refused to take the drug.

My health began deteriorating in high school. I was moody and irritable, which everyone—including my parents—dismissed as standard teenage misery. Physical symptoms started hindering me and only worsened: I regularly felt as though my stomach was filled with barbed wire, I had very little appetite, and no amount of sleep or caffeine could energize me. In college, I had difficulty sitting for more than an hour because a pinching sensation would develop in my stomach. My weight fluctuated even though I maintained a consistent diet. But perhaps the most noticeable physical changes were apparent in my unpredictable menstrual cycle: I had my period for six months straight, or every two weeks, or not at all.

Yet, during every annual checkup, doctors concluded I was healthy. Indeed, my bloodwork always showed perfectly normal results. My academic success was cited as circumstantial evidence that whatever I claimed to experience really wasn't that bad. Since no particular medical issue had been identified, everyone believed I was imagining the physical symptoms. As for my erratic menstrual cycle, doctors simply assumed that I had a hormonal imbalance that resulted from years of intense athletic training, and they suggested birth control as a treatment. The communal diagnosis was that I was debilitated by maintaining a perfectionist mindset at a demanding Ivy League university, so I was prescribed an antidepressant and Adderall. Yet even with those stimulants, I felt lethargic, unmotivated, and ultimately, severely depressed.

One morning, during my senior year at university, I woke up with a stabbing sensation near my right hip, so I swallowed some Advil and assumed I'd be back to normal in an hour. But the pain only intensified. I finally admitted myself to the university's healthcare center and was rushed to the nearby

emergency room for appendicitis. After some tests, it was clear that I didn't have appendicitis. I insisted to the physicians that something must be wrong because I felt intense pain—even after I had been given morphine. But a doctor dismissed me and sent me back to campus. His explanation for the whole ordeal was that I was "maybe just having a bad menstrual cycle."

I was willing to accept his explanation that I was experiencing particularly bad menstrual symptoms, but I knew that such debilitating symptoms—especially those that persisted after taking an opioid—were suggestive of something seriously wrong with my reproductive system.

I scheduled an appointment with a respected OBGYN in New York City, and he performed my first vaginal ultrasound. Nothing alarming appeared on the screen—no cysts, no tumors, no fibroids, no polyps. But I felt excruciating pain as if the probing device were a sharp sword. The doctor noticed my discomfort as I dug my nails into the exam table, and that was enough for him to diagnose me with endometriosis.

I had never heard of the condition. The doctor explained that endometriosis (sometimes called "endo") is a disease where uterine tissue grows outside the uterus; it is commonly found in the ovaries, fallopian tubes, bladder, and bowel, although it can spread pretty much anywhere, including the breasts, nose, eyes, and even the brain. The disease is relatively common and affects roughly 10 percent of women, but it is particularly difficult to diagnose because there is no known cause, and the tissue rarely appears through imaging. Medications—including birth control—might alleviate the crippling symptoms of endometriosis, but the only effective treatment is to undergo excision surgery, during which the tissue is severed and removed. And so, I scheduled surgery for just a day after I submitted my last undergraduate exam.

Since endometriosis rarely appears on scans like ultrasounds or MRIs, I wasn't even certain that I had the disease. As I waited for the anesthesia to knock me out on the day of my surgery, I was preoccupied with concerns: What if the surgeons don't find any of the tissue, or what if there's only a tiny bit? I worried that I wouldn't feel much better after the procedure.

I woke up in a new room over five hours later, where my parents waited. Although I had blurry vision and a foggy mind, I remember very clearly what my parents said: The doctors found endometriosis—a lot of it. The tissue had been on eight organs. (It had entirely covered my appendix, which probably explains the sudden pain that sent me to the emergency room earlier that year.) When I was visited by the surgeons, I was informed that my condition had been classified as stage four. One doctor said I had one of the worst cases that he had ever seen, and another was shocked that I had

been able to manage daily activities. The lead surgeon—the man who had diagnosed me—looked at me with a smile and said, "You're going to feel like a new person." Now, I can say that he was right.

Sometimes, I wonder how dramatically different the past decade would have been if a doctor—just one doctor—had properly identified my condition. After all, it should have been an easy diagnosis: The disease is about as common as diabetes, and I had exhibited nearly every symptom. Instead of recommending the appropriate treatment, the medical industry presented birth control as a panacea for every reproduction-related issue. Perhaps I might have undergone surgery much earlier if I had just stumbled upon a single infographic on social media about endometriosis, or if I had met one other woman who endured the disease, or if my sex education classes in school had offered even a brief mention of common reproductive diseases. I'm deeply indebted to the doctors who finally listened to me and, more importantly, believed my accounts of seriously debilitating symptoms. I just wish it hadn't taken eight years to find them.

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Introduction to the Fertility Industry: Assisted Reproductive Technology

Emma Waters

The desire to have children is one of the most fundamental human experiences. Infertility, by extension, is one of the most painful. It is in this vulnerable state of desire and physical limitation that doctors refer parents to fertility clinics for treatment. Yet in recent years, these same parents have begun to sound the alarm on the abuses and bad incentive structures within the fertility industry.

It is precisely because we, like these parents, value children and the gift of life that we must critically examine the fertility industry—an under-regulated, multi-billion-dollar global enterprise that profits from the creation and selection of human life. This industry includes reproductive technologies such as in vitro fertilization (IVF) and third-party reproductive arrangements, including surrogacy and egg, sperm, and (in some cases) embryo "donation."⁵⁸

Medical Care vs. the Fertility Industry

At its core, medicine seeks to diagnose, treat, and heal the human body. The fertility industry, however, tends to prioritize costly procedures that circumvent the human body altogether. While many medical professionals working in fertility clinics are well-intentioned, the industry itself is shaped by financial structures that often prioritize profit ability over patient care. Unlike traditional medical practices, which are typically owned and managed by physicians, the fertility sector is increasingly dominated by private equity firms and venture capital investors seeking rapid returns.⁵⁹

The ownership structure of fertility clinics reflects this change. Between 2010 and 2017, private equity acquisitions in the healthcare sector increased by 187%, ⁶⁰ with fertility clinics becoming a prime target. By 2023, an estimated one-third of all IVF cycles ⁶¹ in the United States were performed at clinics affiliated with private equity firms. These investor-driven clinics are significantly more likely to promote high-margin procedures, such as preimplantation genetic testing (PGT) or egg freezing for otherwise fertile women. ⁶²

As a result, what began as a specialized field of medicine rooted in research and patient care has evolved into a highly lucrative, investor-driven enterprise in which financial interests often take precedence over ethical and medical care.

Self-Regulated Industry with Few Legal Protections for Parents and Embryos

Unlike other sectors of medicine, the fertility industry operates with minimal regulatory oversight.

In 1992, Congress passed the Fertility Clinic and Success Rate Certification Act which requires clinics to report basic success rates and at-birth demographics. Over 30 years old, the Act lacks a strong enforcement mechanism and few standards governing how fertility clinics operate. In addition to this, there is some measure of federally mandated quality control with the Food and Drug Administration and the Centers for Medicare and Medicaid Services who are responsible for overseeing the medical and clinical standards for IVF, respectively. Nonetheless, most standards in the fertility industry related to procedure and ethics is "self-regulated through membership with and recommendations from organizations such as the American Society for Reproductive Medicine." These guidelines, however, are neither legally binding nor subject to enforcement by an external authority. The result is an industry in which clinics can—and frequently do—operate without meaningful accountability, 4 leaving both parents and embryos vulnerable to irreversible harm.

The articles in this section will provide an overview of the fertility industry in the United States. Drawing from the perspective of bioethicists, medical professionals, and industry experts, these essays will explore the need for a renewed national discussion on bioethics and the treatment of embryos, the lack of legal and ethical protections in third-party reproduction, developments in embryo adoption, and future reproductive technologies that redefine our understanding of procreation.

Without meaningful oversight, the fertility industry risks prioritizing financial gain over the well-being of the very lives it helps create. As we navigate the complexities of modern reproductive technologies, it is essential to ask: Who is truly benefiting from these advancements, and who is paying the price? Our hope is that the essays in this section provide an overview of the specific practices within the fertility industry and help facilitate a muchneeded discussion about the ongoing ethical, medical, and legal challenges that exist in this industry.

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Responsible Self-Governance and Assisted Reproductive Technologies

Carter Snead, JD, and Yuval Levin, PhD

In February 2024, the Alabama Supreme Court ruled that the state's wrongful death statute offered an avenue of relief to a family alleging that an in vitro fertilization (IVF) clinic's negligence had led to the destruction of its embryonic offspring stored in that clinic's freezers. The court concluded, correctly, that since the statute had already been authoritatively construed to protect human beings at the embryonic stage of development in utero, it likewise applied to living human embryos ex utero who were killed as a result of a defendant's negligence. The court concluded that it was not its role to carve out judge-made exceptions to the scope of the statute, especially when the injured parents in cases such as this suffered the very same kind of injury as those who enjoyed the protection of the law, namely, the loss of their embryonic child due to the negligence of others. It was, the court argued, for the state legislature to draw such lines, not for the judicial branch. It was a modest, common-sense decision by the Alabama Supreme Court.

Unfortunately, powerful political interests on the left immediately mobilized to create a false narrative that the court had banned IVF in the name of a theological judgment concerning the value of human life at its earliest stages and that this was simply a predictable consequence of the overturning of *Roe v. Wade* by the Supreme Court of the United States and the extremism of the pro-life movement. Enabled by some high-profile medical care providers in Alabama, a sympathetic media, and prominent politicians, including then-President Joe Biden and Vice President Kamala Harris, this false narrative took hold and spread across the nation for several weeks.

These events led, in turn, to Republicans both in Alabama and in Washington, DC, declaring their passionate support for IVF and resolving to find a legislative mechanism to increase access to it. (The Alabama state legislature went so far as to offer blanket immunity to clinics for any claims relating to "damage or death" of embryonic human beings during the provision of IVF treatment.) Enthusiasm for such a law appears to persist both as a policy matter and as a political strategy whose aim is to counter the relentless attacks on Republicans on the issue of abortion.

Given this appetite for federal legislation promoting IVF, it is useful to pause a moment to consider the complexity of the issue before moving forward. Yes, IVF has made it possible for many families to have the beautiful

blessing of children. But the practice of IVF in America is also fraught with serious peril, especially in light of the following:

- 1. The current state of nonregulation of the IVF industry as such (often described as a legal "Wild West" by commentators across the political spectrum)
- 2. The absence of longitudinal studies on the health and safety of children and mothers in this domain
- 3. The speed with which experimental procedures in this field become routine practice
- 4. The widespread use of ethically questionable nonmedical interventions such as sex selection and the marketing of testing for trait selection, including intelligence and appearance
- 5. The commodification of the body and its parts, including the buying and selling of eggs, sperm, and embryos

The fact that IVF involves the creation, screening, transfer, storage, and sometimes destruction of a living human being at the earliest stages of development. Facing these risks are uniquely vulnerable and desperate patients who feel betrayed by their own bodies in the effort to become what they most want to be, namely, parents of their beloved children.

For all of these reasons, legislating on IVF is not a simple matter, and lawmakers would be well advised to proceed with caution. Below are a few points for consideration, enlarging briefly upon the concerns set forth above.

Twenty-one years ago, the President's Council on Bioethics report *Reproduction and Responsibility: The Regulation of New Technologies* declared that there is "no comprehensive, uniform, and enforceable mechanism for data collection, monitoring, or oversight, of how the new reproductive biotechnologies affect the well-being of the children conceived with their aid, the egg-donors, or the gestational mothers." Our own research (including in Snead's book *What It Means to Be Human: The Case for the Body in Public Bioethics*, especially Chapter 4) confirms that this is still the case.

Nor are assisted reproduction technologies (ART) subject to the kinds of rules and norms that govern clinical research or the development and sale of new drugs and medical devices. There is essentially no information about adverse effects involved in novel practices, nor are there requirements to produce or provide any.

A similar regulatory vacuum surrounds the kind of cryogenically stored embryos specifically at issue in the Alabama case. In the United States (unlike in much of Europe), there are no standard rules or practices around the numbers of embryos created, how they are preserved and handled, or what becomes of those that are not implanted and brought to term.

No information is required to be collected or made available to consumers about the effects extended cryogenic preservation might have on the children who are ultimately born. There is no legal or policy framework for dealing with the complicated circumstances that surround human beings in this earliest stage of development outside the womb. Indeed, no definitive information exists about the number of embryonic human beings currently in cryostorage in the United States, though it is often suggested that the number may exceed one million.⁶⁶

Make no mistake: Elected officials who have committed themselves to protecting the unborn should have serious concerns about this total lack of oversight or protection for human beings at the embryonic stages of development in the IVF process.

The only federal statute specifically dedicated to ART, the Fertility Clinic Success Rate and Certification Act of 1992, is a toothless consumer-protection law. It requires the Centers for Disease Control and Prevention (CDC) to propose a model program for the certification of embryo laboratories and leaves states free to voluntarily adopt the program. We see no evidence that this has had any perceptible effect on the industry's practices.

The law also requires the CDC to collect some very basic data on IVF success rates. But the CDC does not report information of crucial relevance to prospective patients: It provides no data on the types or rate of adverse health outcomes to mothers or children (beyond noting the percentage of term, normal-weight, and singleton births) or on the costs of procedures. It does not speak in any way to the fact that the boundaries between fertility treatment, biomedical research, and the commercial economy are permeable and unmonitored. And it has no mechanisms for reliable auditing or meaningful enforcement of reporting requirements. No state adequately addresses these concerns either.

There are no laws specifically designed to protect the health and flourishing of mothers undergoing IVF or their children. There are no limitations on practices (such as the creation and transfer of multiple embryos per cycle) that might increase the risks of preterm births, low birth weight, and related adverse health consequences. Even though the CDC has noted a correlation between IVF and an increased incidence of birth defects and other maladies, there have been no federally funded longitudinal studies

to explore such possibilities in depth. Clinics offer genetic screening and selection of embryos for nonmedical purposes, including sex selection (which, according to one recent academic study, is available in 73 percent of IVF clinics in the United States⁶⁷). Meanwhile, companies sell predictive tests for screening embryos and aggregating data to create "polygenic risk scores" for low intelligence (with the promise of testing for high intelligence in the near future). ⁶⁸ Other companies provide embryo screening for hair and eye color. People buy and sell sperm, eggs, and even "batches" of embryos at a discounted rate and organized according to preferred traits. ⁶⁹

But ultimately, consumer protection is only the crudest of the tools our society should employ to protect Americans in this sensitive domain. The would-be parents seeking fertility treatment and the children they bring into the world are not, first and foremost, consumers, let alone political combatants. They are families, held together by a bond of love and mutual obligation and dependent upon one another and on the support of the larger society. Both the practice and regulation of assisted reproduction should proceed from the understanding that the animating goal is to form a family, which requires consideration of both the parents and the children at all stages of the children's development and at every step of the parents' treatment process.

In any decent society, parents and children have a claim on all of us for support. Such support calls for the quality that has been most sorely lacking in the political response to the Alabama controversy: responsibility. It demands that we see fertility treatment in all its human dimensions, that we sympathize with the people involved, and that we also grasp the ways in which the most vulnerable among them sometimes need protection.

For our elected officials on Capitol Hill, we respectfully suggest that senators, Congress members, and their staffs carefully study all of the aforementioned risks and complexities carefully—including the irresponsible practices of the IVF industry itself—before moving forward with legislation in this fraught domain.

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For Further Reading

• Yuval Levin and O. Carter Snead, "The Real Lessons of the Alabama IVF Ruling," *The Atlantic*, March 15, 2024, https://www.theatlantic.com/ideas/archive/2024/03/alabama-ivf-ruling-regulation/677747/

(on which this piece is partially based).

- Snead, What It Means to Be Human: The Case for the Body in Public Bioethics (Harvard University Press, 2020) (especially Chapter 4).
- The President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies*, report, March 2004, https://bioethicsarchive.georgetown.edu/pcbe/reports/reproductionandresponsibility/fulldoc.html (especially Chapter 2).

Five Things You Need to Know About the Egg and Sperm "Donation" Industry

Jennifer Lahl, RN

The World Egg and Sperm Bank, located in Arizona, boasts that since 2004 it has been the leader in making "building a family simple." Egg donors are told they can "make an impact by helping grow a family," and sperm donors are told that they can "change the world, and the world will change you." These altruistic-sounding messages lure young men and women in need of money to respond by selling their genetic material and their future children, with little understanding of the medical, ethical, and legal issues at stake.

Much of my work has focused on these ethical questions surrounding in vitro fertilization (IVF) and what is called third-party reproduction, which includes surrogacy and the use of egg "donation" and/or sperm "donation." But who are these mostly anonymous men and women selling their genetic material? What are the rights of "donor-conceived" children to know and be known by their biological parents and extended family? What are the risks to the short- and long-term health of women who sell their eggs and children born of assisted reproductive technologies? These are important questions that policymakers need to address.

While egg and sperm "donation" may seem like a net positive for society, there are five things you need to know about this industry.

1. Egg and sperm "donation" is a misnomer.

I intentionally use quotations around the words "donor" and "donation" because most harvested eggs and sperm are bought and sold, not donated. The global egg market is currently worth almost \$4 billion and is projected to hit \$5.3 billion by 2030.70 The global sperm market is almost \$5 billion, with growth to \$6.5 billion predicted by 2032.71 Both eggs and sperm are small and can be frozen and shipped all over the world, making this an easy global market for buying and selling human gametes (egg and sperm). Since the procedure of egg retrieval and egg harvesting is onerous and risky, women who sell their eggs are paid thousands of dollars in many cases. Men may make up to \$1,500 a month for two "donations" a week since sperm "donation" requires no medical procedures or drugs and very little time.⁷²

2. Egg and sperm "donation" targets vulnerable men and women.

Advertising around the buying and selling of gametes is slick and enticing. Words like "be an angel" target women considering selling their eggs, and slogans like "inside every hero, there are a million more" refer to the man as the hero for his millions of sperm. Language like "help build a family" and "give the gift of life" is coupled with promises of money and sometimes offers of free vacations. But there is no real gift being given because the companies running this advertising are buying and selling gametes. These markets heavily target people in need of money, often university students who are strapped for cash.

3. Egg and sperm "donation" can harm "donors" physically and psychologically.

The practice of sperm donation itself carries very little medical risk to the man's health. But pornography plays a role in sperm collection, and its effects on men should not be ignored—especially when medical professionals are encouraging its use.

For the egg donor, however, there are serious short- and long-term health risks. The most serious short-term risk is ovarian hyperstimulation syndrome (OHSS), which is caused by the fertility drugs the woman takes to encourage her ovaries to produce as many as sixty eggs in one cycle. 73 This can cause swelling and fluid retention in the abdomen and can put the woman at risk for strokes due to blood clots, kidney failure, and shortness of breath due to abdominal swelling. Longer-term risks are damage to the woman's own fertility, along with cancer risks associated with the fertility drugs.74 But since egg donors aren't tracked and monitored, the data we have on these risks is paltry.75 I have interviewed many egg donors who have later suffered strokes, life-threatening hemorrhaging, loss of their own fertility, and cancer. These women were not informed of such risks because Big Fertility tells them there are no known risks." That claim can only be made, though, because the phenomenon of taking otherwise young women with healthy fertility and putting them on powerful hormones to harvest their eggs has not been adequately studied.

The psychological risks to both the egg and sperm donor may become apparent only later, to those who realize they may have dozens or even

heritage.org

hundreds of children born from their gamete. This can be especially distressing to women who lost their fertility while selling their eggs and know they will never be able to conceive.

4. Egg and sperm "donors" are selected based on their looks, health, or IQ.

The targeting of gamete sellers is specific to the ethnicity, age, intellect, religion, medical history, and general background of the individual. Ivy League donors are highly desirable and can often fetch six-figure compensation. One agency offers personal concierge service to people looking to buy eggs and sperm, boasting that its large database can have customers matched with the perfect donor in two to three weeks.

5. Donor-conceived children often suffer the most.

The narrative donor-conceived children are often told is about how they were so wanted by their parents. This is often true, but as the donor-conceived community grows and shares experiences as part of the search for biological parents, siblings, and extended family members, it becomes clear that there is much more to the story. The phenomenon of "genealogical bewilderment," often experienced by adoptees, has been expanded to include donor-conceived children.⁷⁸ Genealogical bewilderment is the struggle that comes when one's personal identity is a mystery. The widespread fascination with genealogy demonstrates, at a minimum, curiosity about one's origins. Whom do I look like? Why does no one else in my family share my interests? Do my biological parents ever think about me and wonder where I am? Do I have siblings in the world? The longing for answers to questions like these can lead to stress and anguish that cannot be satisfied by just saying that a child was so wanted. This is in large part why donor-conceived people are taking advantage of services like 23andMe and Ancestry.com to find their family. Matches are made everyday thanks to databases like the Donor Sibling Registry, founded in 2000 by Wendy Kramer and her son Ryan. Ryan was born from anonymous sperm donation, and as he got older he longed to find his biological father. Ryan eventually did find his father. Wendy realized that no such group existed to help people like her son. Now the registry has matched tens of thousands of people to the family. There have also

been numerous stories of fertility doctors impregnating their unsuspecting female patients⁷⁹ and young men literally siring hundreds of children.⁸⁰ This is a more complex web to untangle as husbands and their wives discover the children, they have raised children they thought were their biological children are indeed not. The impact on these children is severe as well as they learn of their story of origin and the knowledge that their biological parents and half-siblings are perhaps numerous and scattered around the world.

Slowly, international laws are changing to provide this information to donor-conceived people in search of family ties. In the United States, Colorado is the only state that has prohibited the practice of anonymous egg and sperm donation.⁸¹

Medicine is tasked first with doing no harm. Egg donors and sperm donors are not patients. They are people with healthy fertility. Healthy women are put on powerful medications for which they have no medical need in exchange for money. Sperm donors too are offered financial incentives to sell their biological children. While both may be offered anonymity, the advances in DNA cannot hide the truth of the genetic origins of the donor conceived person. The policies around these processes take little interest in the health of fertile young women and certainly seem to ignore the consideration of the rights of the child conceived in this manner who may long to know at least their medical history. There is much harm being done and medicine and our policies need to take into account this side of the story.

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Commercial Surrogacy

David Smolin, JD

Surrogacy is not merely a technology but rather the use of a woman's body and reproductive capacities to fulfill the procreative purposes of others (the intending/intended parents). Surrogacy employs assisted reproductive technology (ART), typically in the form of in vitro fertilization (IVF) and potentially genetic selection of embryos.

Commercial surrogacy typically involves four parties: intending/intended parent(s), surrogate mother, intermediaries, and child. Gamete donors may also be involved. The term "intermediary" includes surrogacy agencies but can be broader, as it includes any person, organization, or network facilitating the initiation, continuation, and/or finalization of surrogacy arrangements. The parties who play that role can include agencies, doctors, medical clinics, or attorneys, but those who merely provide medical or legal services are not included as intermediaries.⁸²

Typically, there are multiple contractual relationships: between the intending parents and the intermediary, between the intending parents and the surrogate mother, and sometimes between the intermediary and the surrogate mother. The child alone remains unrepresented even though he or she is the purpose of those contracts.⁸³

Surrogacy in the United States, both domestic and international, is governed almost exclusively by state laws, which vary considerably. Federal law generally does not directly address surrogacy, but some federal regulations may incidentally address components of surrogacy, such as citizenship rules for surrogate-born children.⁸⁴

What Are Intending Parents Paying For?

Intending parents are the paying customers of surrogacy, but there is controversy about how to characterize what they are paying for. Certainly, intending parents are paying for various kinds of services (gestational, intermediary, legal, medical, etc.). But intending parents are not merely paying for a child to be created, gestated, and birthed, for they certainly would not be satisfied unless they were also given exclusive physical and legal custody of the child. Commercial surrogacy contracts are often explicit in requiring the surrogate mother to participate in the legal and physical transfer of the child to the intending parents. These contractual provisions commonly appear even in states that employ the legal fiction that the child

was never in the physical or legal custody of the woman who gestated and birthed the child. Thus, it may be fair to interpret commercial surrogacy contracts as facilitating the sale of a child, or at least as providing payment for legal and physical transfer of a child.⁸⁵

The Rights of Surrogate Mothers

There is often an ongoing power struggle between the intending parents and surrogate mother, centered on the body, health care, and life of the surrogate mother. For example, contracts may state that the surrogate mother is expected to undergo an abortion if chosen by the intended parents, including a "reduction abortion" in a multiple pregnancy or abortion if the unborn child is diagnosed with a disability. Sometimes these conflicts lead to litigation.⁸⁶

For example, in *Cook v. Harding* (2018), the surrogacy agency matched a forty-seven-year-old surrogate mother, Melissa Cook, with a fifty-year-old single intending father. Three embryos were transferred, leading to a triplet pregnancy. Conflicts arose when the intending father demanded a reduction abortion and Cook refused. The intending parent's attorney informed Cook in writing that by refusing the abortion she was in breach of the contract and liable for monetary damages. Cook still refused the abortion and went on to unsuccessfully litigate for parental rights, claiming that the intending father was neglecting the children's needs.⁸⁷

Such intimidation tactics rest on shaky legal grounds, as the surrogate mother has common law and constitutional rights to refuse unwanted medical procedures, even after the overruling of the constitutional abortion right. Yet, intending parents commonly use contracts and communications to attempt to control the lifestyle of the surrogate mother, including not only obvious restrictions on smoking, drinking, and drug use but also specific dietary restrictions and restrictions on the surrogate mother's sexual activity. There may also be power struggles regarding the health care of the surrogate mother and the details of the medical aspects of the surrogacy. For example, intending parents may prefer the transfer of multiple embryos into the surrogate mother because it increases the odds of pregnancy ensuing in each cycle, with a backup plan of reduction abortion for multiples, while surrogate mothers may object to the risks of transferring multiple embryos. Yet as the surrogate mothers may object to the risks of transferring multiple embryos.

In the Global South, frequently the surrogate has virtually no control over her own life and health-care decisions. She may live in a dormitory with other surrogate mothers and have her daily schedule, diet, access to her own children and husband, and permission to leave the clinic controlled by intermediaries. The huge economic and social inequalities between intermediaries and surrogate mothers and between wealthy intending parents and surrogate mothers often leave surrogate mothers in the Global South with little practical scope of autonomy. This scope of autonomy is even more restricted when intermediaries take surrogate mothers across national boundaries, removing them from their own countries. 90

The Rights of Surrogate-Born Children

Surrogate-born children in the United States lack even basic protections in many jurisdictions. Intending parents are not subjected to criminal conviction or child abuse screenings; courts do not conduct suitability reviews and do not make best interests of the child determinations. This lack of protection is an intended consequence of recently enacted surrogacy laws, based on an ideology of a "right to procreate," rather than an accident or oversight. Under such state laws, the trial court must award exclusive and full parental rights to the intending parents so long as the contract was entered into prior to pregnancy, the surrogate mother had independent counsel, and the financial arrangements and escrow procedures were in place. The trial judge is not permitted to consider matters relevant to suitability or best interests, which are deemed irrelevant. A child, in short, is obtained with a credit card and a contract, and the court has no power to protect the child from inappropriate placements.

Surrogate-born children in many jurisdictions in the United States lack identity rights, meaning that information about their genetic and gestational origins is not recorded and stored for their access as adults. This is in contrast to developments in state adoption laws, which have increasingly acknowledged that adult adoptees very commonly wish to obtain, at a minimum, information about their origins information that is basic to their identity. Thus, particularly regarding new adoptions, truly closed adoptions are rare. The legal fiction that adoptees have no relationship to their genetic and gestational parents and relatives has increasingly shifted into a recognition of the necessarily complex identity of adopted persons, even in the most loving and successful adoptive homes. The failure of surrogacy systems of law and practice to implement the lessons learned from adoption is another indication of the way that children are viewed as paid-for products of surrogacy systems rather than as persons with rights and interests of their own. Indeed, this model of commercial surrogacy without suitability reviews, best interest determinations, or identity rights has been proffered

to the world as an American model suitable for global export, with unsurprising rejection and critique by many concerned with children's rights.⁹²

Surrogacy in the United States: Costs, Clients, International Options, and Legal Rights

The United States represents the high end of the global surrogacy market. Intending parents from around the world pay around \$150,000 per surrogacy arrangement. 93 They often come to the United States to evade restrictions on commercial surrogacy in their own countries, intending to bring the child after birth to their own country.94 The children of foreign intending parents born in the United States acquire American citizenship, which is one of the benefits justifying the high cost of American surrogacy. Surrogacy agencies in the United States intentionally advertise surrogacy to intending parents from countries that restrict surrogacy, offering facilitators who speak their languages and advertising the benefits of attaining American citizenship. 95 Foreign intending parents may constitute half or more of the customers of particular American surrogacy agencies; the majority of them come from China, Western Europe, and Australia. Foreign intending parents constitute about a third of surrogacies in the United States. 96 Protections for children with foreign intending parents are even more difficult to implement since there can be no pre-surrogacy cooperative mechanism with countries that prohibit commercial surrogacy, and, even if there were a desire to access information about intending parents, it would be very difficult to verify. In effect, foreign intending parents come to America to buy access to the bodies of surrogate mothers and to create a child who will be an American citizen and yet will likely leave America immediately to be raised in the nation of his or her intending parents.

Intermediaries profit the most from commercial surrogacy. Of the approximately \$150,000 cost of American surrogacies, \$40,000 to \$70,000 goes to the surrogate mother, and then there are various costs for medical and legal services. Intermediaries receive much less than surrogate mothers *per arrangement*, but of course intermediaries can arrange innumerable surrogacies while surrogate mothers are necessarily limited by time and biology. Hence, intermediaries benefit the most financially from an industry that, in the United States, likely receives more than \$750 million per year, including both domestic and international surrogacies. (Some make much higher estimates, but those seem speculative.)

In order to avoid the high costs of American surrogacy, some American intending parents go to other countries for surrogacy. Eastern European

nations such as Ukraine and Russia have comprised the middle of the market, while a variety of Global South nations have constituted the low-cost segments of the market. National policies on surrogacy change over time; for example, Russia and India have, in recent years, enacted rules purporting to end their roles in international surrogacy. The global international surrogacy market thus is not stable but is constantly subject to shutdowns and scandals. Most countries prohibit commercial surrogacy or lack laws on commercial surrogacy, and thus the number of nations that have officially sought roles as international surrogacy hubs is limited and constantly changing.⁹⁷

Surrogacy: Reproductive and Economic Freedom or Moral Harm?

Anti-surrogacy viewpoints predominated across left–right perspectives for some years, as evident in the 1988 *Baby M*. case, in which the New Jersey Supreme Court invalidated a commercial surrogacy contract. Commercial surrogacy was viewed as exploitative of women and as commodifying (or selling) children. These concerns with exploiting women and commodifying children have increased relevance in today's globalized commercial surrogacy industry, where women are moved across national boundaries to global surrogacy hubs, as in the recent case in which a Chinese fertility company moved Thai women to the nation of Georgia for purposes of harvesting and selling eggs and surrogacy, with the children in effect being sold to foreign intended parents. Three of the women claimed they were held in a house against their will, and a trafficking investigation was opened.

The transition from traditional surrogacy using artificial insemination, in which the surrogate mother was genetically related to the child, to gestational surrogacy using IVF, in which the surrogate mother is genetically unrelated, provided a claimed rationale for a reassessment toward a positive view of commercial surrogacy, as exemplified by the 1993 *Johnson v. Calvert* case from the California Supreme Court. Nonetheless, the real change has been ideological. Commercial surrogacy has been embraced by some on the right as a form of economic freedom. These supporters use reasoning similar to that of Elizabeth Landes and Richard Posner in "The Economics of the Baby Shortage," who infamously argued for laws allowing the sale of parental rights for adoption, a position defended for decades by Judge Posner and others in the law and economics movement. Many on the left have strongly supported commercial surrogacy as a matter of reproductive freedom and equality. These ideological emphases on economic and

reproductive freedom and the shift to gestational surrogacy do not provide convincing answers to the intrinsic and practical critiques of commercial surrogacy. Indeed, the emerging model of commercial surrogacy typified by California law¹⁰³ and by the Uniform Parentage Act of 2017 (enacted in various forms into some state laws)¹⁰⁴ exacerbates these problems by unleashing a large commercial surrogacy industry that has successfully insisted on a form of contractual, for-profit surrogacy with little regard for the interests and rights of children and the rights and humanity of surrogate mothers.

Recommendations

Federal law should address the abusive practices of the commercial surrogacy industry in targeting foreigners from countries that restrict commercial surrogacy. The United States has an interest in not allowing this industry to facilitate the evasion of the laws of other countries. The United States has an interest in not allowing American citizenship to be sold by American surrogacy agencies. The United States has an interest in not allowing surrogacies to be conducted within its borders under circumstances where it is virtually impossible to protect the children since the foreign intending parents are not screened and there are no criminal background checks. Indeed, these children are American citizens born to American-citizen surrogate mothers but then are immediately taken by unscreened foreign intending parents to other countries beyond the protections of the United States. The United States has an interest in not permitting these children to become the paid-for products of an almost billion-dollar industry.

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Preimplantation Genetic Testing and In Vitro Gametogenesis

Aaron Kheriaty, MD

This paper will briefly describe two novel techniques used in conjunction with assisted reproductive technologies like in vitro fertilization (IVF). The first, preimplantation genetic testing (PGT), has been commercially available for several years and is now widely deployed in IVF clinics to detect potential genetic diseases or other anomalies in embryos created in the lab. The second technique, in vitro gametogenesis (IVG), is not yet available for use in humans but likely will be in the next few years. As this paper will explore, both of these techniques have the potential for serious harm, including discriminatory eugenics practices in the first case and a radical restructuring of familial ties and human lineage in the second.

Preimplantation Genetic Testing

PGT is a technique used to test embryos created in a lab via IVF for genetic diseases and other genetic traits. During a typical IVF cycle, in order to increase the chances of producing a viable pregnancy, multiple human embryos—up to six or eight—are produced in the lab. Prior to implanting one or more of these embryos in the woman's uterus, the embryos can be genetically tested. Techniques for doing this, which do introduce some risks to the embryos, were originally developed to screen for genetic diseases. Once genetic anomalies are identified, only apparently genetically healthy embryos are selected for implantation and the opportunity to be brought to birth. Those deemed genetically "unfit" are typically destroyed.

While this method of PGT is sometimes described as a "treatment" for genetic diseases, it is important to note that the method does not actually *treat* an individual affected by a disease. It merely identifies that individual and discards him or her, denying that human being in its earliest stage of development the opportunity for continued existence. In short, PGT doesn't treat or heal maladies; it ultimately destroys the affected embryo altogether.

It is also worth noting that while this technique is often framed in terms of eliminating disease, there are other common uses for PGT. It is frequently employed, for example, for sex selection. This practice is banned in most of the world but not in the United States. Many intending parents, especially those from cultures that tend to disvalue female children, use PGT to ensure they do not become pregnant with a girl. Thus this technique perpetuates

discriminatory attitudes and social practices regarding sex. Meanwhile, many in the United States use PGT sex selection precisely because they prefer girls. ¹⁰⁵

As our knowledge of the complex relationships between genes and biological traits advances, PGT could be used not only to eliminate those with diseases or disabilities but to select for "desirable" traits—to produce bigger, faster, stronger, smarter, or more physically attractive children—or simply children with a particular hair or eye color. Orchid, for example, is a company that provides a "whole genome embryo report" and advertises its service with the tagline "Have healthy babies." Another U.S. company, Heliospect Genomics, offers services that go beyond screening for genetic diseases to predicting human behavior, including IQ screening of embryos at a cost of \$50,000—a practice that violates U.K. law but is legally permitted in the United States. ¹⁰⁶

Some misguided ethicists even argue that PGT is a more "responsible" way to produce children and predict that within a few decades most people in developed countries who can afford these services will stop having sex for the purpose of reproduction. While some celebrate this as a technological advance, we should worry about the possibility of creating a dystopian society in which children are "manufactured" using industrial quality-control measures and only those deemed most "fit" are permitted to survive.

PGT revives the dark specter of eugenics: the use of medical technology to eliminate those deemed genetically unfit because of disease, sex, or other "undesirable" traits. While our new "liberal eugenics" may not be top-down or government-mandated—as with forced sterilization in the United States and euthanasia of the "unfit" in Germany during the twentieth century—the same ugly attitudes are manifest in these new eugenic practices. Consumer-driven eugenics is not necessarily less discriminatory against women, men, or those with disabilities than a coercive, government-sponsored eugenics program.

In Vitro Gametogenesis

While it has not yet been perfected in humans, we now have the capability in other mammals to produce gametes—either eggs or sperm—from adult stem cells such as skin cells using techniques of genetic manipulation. The procedure, known as in vitro gametogenesis, involves programming stem cells to differentiate into gametes—sperm or eggs. In 2018, the first human egg cells (though not viable eggs usable for IVF) were created in a lab using this method. In 2024, researchers at Oregon Health Science University developed a more efficient technique in mice that avoids problematic

genetic alterations. ¹⁰⁸ Many researchers are working on applying these IVG techniques to humans.

This procedure would allow many people who are unable to have genetically related children to do so, including, for example, women of advanced maternal age or women unable to produce viable eggs due to cancer treatment or other medical issues. Such promises make IVG attractive to many prospective parents. More radically, however, because it may be possible to produce eggs from male cells or sperm from female cells, IVG would allow men (or women) in same-sex relationships to have children who are genetically related to both fathers (or both mothers), one of whom would supply an artificial egg and the other the sperm. This would deny children the right to have both a genetic father and mother and dramatically alter our culture's notions of human lineage, motherhood, and fatherhood.

As explained in the previous section on embryonic genetic testing, a typical IVF egg-harvesting cycle can produce at best only about half a dozen eggs, thus limiting the number of embryos that can be created and destroyed in a laboratory. But because the IVG technique uses skin or other easily obtainable cells rather than an invasive procedure, it would permit an *inexhaustible supply* of eggs, and thus would create the potential to easily produce hundreds of embryos in the lab. This technique would amplify the potential for commercial eugenics on a massive scale via "embryo farming," in which hundreds of embryos are tested and only the genetically "strong" or "select" few are allowed to survive.

IVG would likewise permit other frankly bizarre scenarios, such as the unauthorized use of someone's genetic material to produce offspring who are genetically related to a person who did not consent to have children. The hotel maid who wants to have Brad Pitt's children could merely scrape some skin cells from his pillow and pay a firm to turn these into sperm using IVG, then use that sperm in an IVF procedure.

The deployment of IVG portends a radical refashioning of family structures that could alter the relationships between generations in ways that we can scarcely imagine. Some IVG enthusiasts, for example, celebrate the potential for "multiplex parenting." Suppose four individuals wanted to have a child who was genetically related to all four of them. They could pair up and use IVF to create two embryos in the lab—one related to one pair and the other to another pair in the foursome. Next embryonic stem cells could be extracted from each of those embryos, and through IVG another set of sperm and eggs could be created from those embryos. Those two embryos could be discarded, and the gametes derived from them would be used to create a third embryo, which would then be brought to birth.

All four members of the group would be genetically related to the child; technically, they would be genetic grandparents, not parents. The genetic parents would actually be two embryos that were created and destroyed in the lab. In fact, this cycle of embryonic stem cells to gametes to embryos to embryonic stem cells and so forth could be theoretically repeated as many times as one wanted in a lab—ultimately producing a child with no living genetic relatives, a child whose parents, grandparents, great-grandparents, etc., were all embryos created and destroyed in a lab. The generations would be "compressed" in space and time, and the resultant living human being would be without a meaningful family history or genetic lineage of people who had actually lived full human lives.

Those who are ready to embrace this brave new world of human reproduction seem *incapable* of thinking deeply about the seriously harmful likely effects on children, on the relationship between generations, on family structure, and on an individual's genetic identity. If such a dystopian scenario becomes our reality, we will have turned procreation into a manufacturing process, instrumentalizing human life and discarding—on a massive scale—human lives deemed unfit to exist.

These "Wild West" domains of human reproduction are subject to virtually no regulation at the federal or state level and have been subjected to almost no public discussion or democratic debate. Thoughtful regulatory action is now necessary since these techniques are already available (in the case of PGT) or will soon be available (in the case of IVG) for use on human beings.

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Embryo Adoption: A Humane and Compassionate Response to Frozen Embryos

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One of the most serious ethical concerns with in vitro fertilization (IVF) is that for every child born with the help of IVF there are typically many other children—the "spare" embryos produced by the IVF process—who are kept in cryostorage and consigned to an uncertain fate. Most of these human beings will remain frozen indefinitely until their parents eventually stop paying the storage fees and they are allowed to die. Although the lack of reporting requirements makes it difficult to get accurate numbers, experts estimate that there are roughly five million frozen embryonic children (some put the number as high as ten million) in the United States alone. ¹¹⁰

Biologically, there is no doubt that these are genuine human beings, just like you and me at that early stage of life. All that they need to continue their lives and grow to maturity—allowing their unique human potential to unfold—is an adequate environment that provides them with oxygen, nutrition, and protection, and at this stage of life the only environment that can provide them with those basic needs is a woman's womb.

Why Embryo Adoption?

For all who recognize the profound, equal, and intrinsic dignity of every human being, the fate of these tiniest and most vulnerable of human lives is a tragedy that calls for a humane and compassionate response. That response is embryo adoption. In other words, when the parents of frozen embryos are unable or don't want to gestate and raise them, we should treat these embryonic orphans just like other orphaned children and facilitate their adoption into a loving family. (We should also enact sensible regulations that prevent IVF clinics from routinely creating "spare" embryos in the first place, as Germany and Italy have done. These countries have also passed regulations that make it illegal to create embryos for the purpose of selling them to prospective parents—a practice that unfortunately already occurs here in the United States. (13)

How Does Embryo Adoption Work?

There are several agencies that facilitate embryo adoption, but the only fully licensed adoption agency that does embryo adoption is Nightlight Christian Adoptions, which has an embryo adoption program called Snowflakes.¹¹⁴

Like other adoption agencies, Snowflakes requires that prospective adoptive parents complete a home study with a licensed adoption agency and facilitates "matching" between the embryos' current legal parents and the prospective adoptive parents. This is similar to the matching process that occurs between birth mothers and prospective adoptive parents in infant adoption.

In other words, parents who want to place their embryos for adoption would contact Snowflakes (or another agency) and submit a family profile, including relevant medical history and information about the embryos. Prospective adoptive parents likewise prepare a family profile and also indicate to Snowflakes what their preferences are regarding things like racial background and the number of embryos they would like to adopt (Snowflakes tries to keep siblings together, asking prospective adoptive parents to adopt all of the remaining embryos from a particular set of parents).

Once a match has been agreed upon by both parties, an adoption contract is signed, officially transferring ownership of the embryos to the adoptive parents. Unlike the adoption of already born children, the embryos are legally treated as property rather than as persons. For this reason, the embryo adoption contract is a property transfer contract. Finally, the embryos are shipped to a participating fertility clinic, where the embryos will be transferred one or two at a time into the uterus of the adoptive mother in the hopes of achieving a successful pregnancy.

Embryo Adoption Success Rate and Best Medical Practices

Sadly, although clinics do their best to ensure that the conditions in the adoptive mother's uterus are favorable (often by giving the woman estrogen to build up her uterine lining and then giving progesterone both before and after the embryo transfer to facilitate implantation), the embryos do not always implant for various reasons (sometimes simply because they are not healthy enough). But the implantation rates following the transfer of previously frozen adopted embryos are no worse, on average, than implantation rates in IVF more generally: Roughly one-third of embryo transfers result in implantation, and roughly one-fourth result in live birth. The process does, therefore, involve some risk both to the child and to the adoptive mother, especially if miscarriage occurs after implantation. But the embryo transfer protocol itself has minimal risks to the adoptive mother, and for the embryo the risks are clearly outweighed by the

prospective benefits, given that the alternative is indefinite cryostorage and eventually death.

Just like other forms of adoption, embryo adoption sometimes results in heartache and disappointed hopes, but it also involves many joys, including allowing the adoptive mother to gestate and breastfeed her adoptive child and thus begin the bonding process even earlier than in traditional postnatal adoption, as well as enabling the adoptive parents to ensure that the child is well cared for during pregnancy (something that is usually far from guaranteed in infant adoption) and saving the child from having to suffer the "primal wound" of separation from the birth mother. Ultimately, it is the only humane and compassionate way to deal with these millions of children whose lives are currently in limbo and whose only prospect for survival is to be adopted by loving parents willing to gestate and raise them.

What can legislators do to help? Apart from passing sensible IVF regulations to prevent additional human beings from being created only to be consigned to indefinite cryostorage, legislators can help the millions of embryonic human beings who already exist by promoting and facilitating the practice of embryo adoption. Here are two concrete suggestions: First, just as the government facilitates postnatal adoption through measures like tax credits for adoption-related expenses, the same should be done for embryo adoption. Currently, because embryo adoption is not legally treated as an adoption, couples who pursue embryo adoption do not qualify for adoption tax credits, making the costs of embryo adoption—which include both agency fees and the costs of the embryo transfers, neither of which is usually covered by insurance—prohibitive for some people. Changing the legal definition of adoption to include embryo adoption or changing the tax rules to allow embryo adoption to count for the adoption tax credit is one important step that legislators should take to promote the compassionate and life-saving practice of embryo adoption. Second, legislators should place legal limits on the number of years that parents can keep embryos in cryostorage without any attempt or other sign of genuine intent to try to gestate them. After that time limit has passed, the embryos should be declared abandoned and they should be made available for adoption.

Although such measures will not resolve the problem posed by these millions of frozen embryos, they are crucial steps toward building a society in which even the smallest and most vulnerable of our fellow human beings are treated with the dignity and respect that they deserve.

Endnotes

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- 108. Aleksei Mikhalchenko et al., "Induction of Somatic Cell Haploidy by Premature Cell Division," Science Advances Vol. 10, No. 10 (2024), pp. 1-11.
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- 110. Jessica Hamzelou, "Inside the Strange Limbo Facing Millions of IVF Embryos," *MIT Technology Review*, January 13, 2025, https://www.technologyreview.com/2025/01/13/1109922/inside-the-strange-limbo-facing-ivf-embryos/ (accessed March 18, 2025).
- 111. Nothing that I say here should be taken as a condemnation of the embryos' parents, who are typically just taking their doctors' advice and following the standard IVF protocols, without even being given the option to limit the number of embryos that they attempt to produce. Further, most couples struggling with infertility are also unaware of alternatives to IVF—such as NaProTechnology and other forms of restorative reproductive medicine—that, unlike IVF, actually identify and treat the underlying causes of infertility. These alternatives are not only more successful and less costly than IVF but also involve significantly fewer health risks to mother and child and are free from the many ethical concerns surrounding IVF.
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- 113. The California Conceptions Donor Embryo Program buys eggs and sperm from "donors" and then uses them to make embryos for prospective parents, who pay a handsome fee for this service. Although a sponsored link to this program is the first thing that appears in response to a Google search for "embryo adoption agencies," this program is the antithesis of embryo adoption. The purpose of embryo adoption is to welcome existing embryos into a loving family that will gestate and raise them, but programs like this one actually create new embryos for prospective parents.
- 114. "Building Families Together," Snowflakes Embryo Adoption Program, https://nightlight.org/snowflakes-embryo-adoption-donation/ (accessed March 2, 2025). Other agencies, such as the National Embryo Donation Center and Embryos Alive, try to mimic adoption best practices to some extent but are not licensed adoption agencies. There are also embryo donation programs run by some fertility clinics, which typically involve anonymous embryo donation and more generally do not follow the best practices of adoption.
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