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Nina Schuman

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A Physician's Ethical Dilemma When Patients Use Preimplantation Genetic
Diagnosis to Select for Genetically Defective Embryos

I. Introduction

“The desire to have health and happy children is the most basic parental instinct.”¹

Unfortunately, conceiving a healthy child is not always possible for some individuals because of infertility or the presence of genes that may result in children with fatal conditions. Assisted reproductive technology (ART) refers to technologies that enable biological reproduction of humans without engaging in sexual intercourse.² With the advent of ART, a procedure known as preimplantation genetic diagnosis (PGD) was developed to give patients the ability to screen for specific genetic disorders in embryos created via in vitro fertilization (IVF).³ The whole purpose of PGD was to offer a way for patients to completely avoid genetic diseases in their children.⁴ However, one reason parents may decide to have children is to have a genetic connection.⁵ A survey conducted by the Genetics and Public Policy Centre indicated that three percent of fertility clinics in the United States allow PGD for couples who want to screen an embryo for a specific disease or disability so the child would have the same characteristic as the parents.⁶ So,

¹ Mark Popovsky, *Jewish Perspectives on the Use of Preimplantation Genetic Diagnosis*, 35 J.L. MED. & ETHICS 699 (2007).

² JUDITH AREEN ET AL., FAMILY LAW 571 (6th ed. 2012).

³ Paul Brezina, *Preimplantation Genetic Testing in the 21st Century: Uncharted Territory*, 7 CLINICAL MED., available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3888077/>.

. INSIGHTS REPROD. HEALTH 17, 19 (2013).

⁴ *Bergero v. Univ. of S. California Keck Sch. of Med.*, No. B200595, 2009 WL 946874, at *2 (Cal. Ct. App. Apr. 9, 2009).

⁵ ROSAMUND SCOTT, CHOOSING BETWEEN POSSIBLE LIVES: LAW AND ETHICS OF PRENATAL AND PREIMPLANTATION GENETIC DIAGNOSIS 12 (2007).

⁶ ISABEL KARPIN AND KRISTIN SAVELL, PERFECTING PREGNANCY: LAW, DISABILITY, AND THE FUTURE OF REPRODUCTION 236 (2012).

is it that surprising that a couple with a genetic disorder, such as achondroplasia, would want to have children with the disease as well?

Achondroplasia, a form of dwarfism, is an autosomal dominant genetic disorder; there are roughly 1 in 8,000 to 10,000 births affected with this disorder.⁷ Some of the characteristics of individuals with achondroplasia are: short height, short limbs, and a prominent forehead.⁸ Although spinal deformities, sleep problems and obesity are medical concerns in people with achondroplasia, they tend to have normal intelligence and only minimal impairments in physical ability.⁹ However, individuals with achondroplasia do sometimes suffer from psychological and social issues because of their appearance.¹⁰ Other reasons why parents with achondroplasia would want to select embryos with achondroplasia include the ability to effectively discipline a child and to avoid further medical complications from pregnancy and delivery of an average sized baby.¹¹ Lastly, parents with dwarfism are also likely concerned with their child's feelings. A woman with dwarfism discussed the possibility of having a child of normal height and posed the question, "What is life going to be like for her, when her parents are different than she is?"¹²

Currently, there is no regulation of health care providers' use of PGD in the United States.¹³ They are essentially given "free reign to undertake PGD."¹⁴ This obviously presents issues when PGD reveals a genetic condition, such as achondroplasia, but the health care provider and patient have conflicting ideas about whether or not to pursue implantation because

⁷ HARRY J. MANKIN, 2 PATHOPHYSIOLOGY OF ORTHOPAEDIC DISEASES 125 (2009).

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ Rosamund Scott, *supra* note 5, at 314.

¹² Darshak Sanghavi, M.D., *Wanting Babies Like Themselves, Some Parents Choose Genetic Defects*, N.Y. TIMES, (Dec. 5, 2006), http://www.nytimes.com/2006/12/05/health/05essa.html?_r=0.

¹³ ISABEL KARPIN AND KRISTIN SAVELL, PERFECTING PREGNANCY: LAW, DISABILITY, AND THE FUTURE OF REPRODUCTION 233 (2012).

¹⁴ *Id.* at 236.

it questions not only the limits on patient autonomy but also the definition of “disability.”¹⁵

Because doctors undertake the Hippocratic Oath, an ethical dilemma can result when the patient decides to proceed with implantation involving a genetically defective embryo.¹⁶ Part II of this paper will provide an overview of ART, IVF, and PGD. Part III will next explore the historical development of reproductive freedom, inadequate ART case law in the United States, and current oversight framework for ART, in Part III. Part IV will delve into opinions and approaches taken by professional organizations, experts in the field, and fertility clinics. Part V looks into doctor’s ethical obligations under the Hippocratic Oath and the dilemma that can result when the patient decides to proceed with the implantation of a genetically defective embryo. Lastly, Part VI provides recommendations to address these concerns.

II. ART: IVF and PGD Overview

Infertility, or the inability to become pregnant after one year of attempting to become pregnant, affects roughly 15 percent of couples.¹⁷ According to the Centers for Disease Control and Prevention (CDC), six percent of married women, who are between the ages of 15-44, suffer from infertility.¹⁸ There are several causes of infertility in women including but not limited to ovulation disorders, abnormalities with the cervix or uterus, damage to the fallopian tubes, and

¹⁵ See 22 Ill. Prac., The L. of Med. Prac. in Ill. § 31:7 (3d ed. 2007).

¹⁶ See Howard Markel, “I Swear by Apollo” — On Taking the Hippocratic Oath, 350 NEW ENG. J. MED. 2026 (2004), available at <http://search.proquest.com/ezproxy.shu.edu/docview/223941903/fulltextPDF/8C9D7074FA7E4ACEPQ/1?accountid=146984>.

¹⁷ Infertility, MEDLINE PLUS, <http://www.nlm.nih.gov/medlineplus/infertility.html> (last updated Nov. 3, 2014).

¹⁸ Infertility, CTRS. FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/nchs/fastats/infertility.htm> (last updated Feb. 13, 2014).

endometriosis.¹⁹ Some of the causes of male infertility are infection, ejaculation issues, hormonal problems, and defective sperm ducts.²⁰

A. IVF

IVF is a type of ART that has enabled couple suffering from infertility to become pregnant.²¹ IVF is the process by which female eggs, or ova, are retrieved and inseminated with semen in a lab.²² Prior to egg retrieval, hormonal medication is administered to hyperstimulate ovaries, which allows for the production of several eggs.²³ Once an embryo has been created, the IVF technicians carefully monitor the embryo and will proceed with implantation when the embryo has divided to approximately eight cells.²⁴ However, IVF is not only used for infertility; another reason women undergo IVF treatment is because of genetic disorders.²⁵ By undergoing IVF treatments, couples have the ability to use PGD in order to screen embryos for genetic conditions.²⁶ IVF and PGD are complex processes that require the collaboration of an interdisciplinary team of professionals, are costly, and pose health risks.²⁷ IVF can range from \$15,000 to \$17,000.²⁸ Additionally, for those patients who undergo PGD, there is an additional average cost of \$4,500.²⁹

B. PGD

¹⁹ *Infertility: Basics*, MAYO CLINIC, <http://www.mayoclinic.org/diseases-conditions/infertility/basics/causes/con-20034770> (last updated July 2, 2014).

²⁰ *Male Infertility: Causes*, MAYO CLINIC, <http://www.mayoclinic.org/diseases-conditions/male-infertility/basics/causes/con-20033113> (last updated June 13, 2014).

²¹ *What is Assisted Reproductive Technology*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/art/> (last updated Aug. 28, 2014).

²² ANTHONY DYSON, *THE ETHICS OF IVF* 32 (1995).

²³ Laura S. Langley, J.D. & Joseph W. Blackston, M.D., J.D., *Sperm, Egg, and A Petri Dish Unveiling the Underlying Property Issues Surrounding Cryopreserved Embryos*, 27 J. LEGAL MED. 167, 173 (2006).

²⁴ *Id.*

²⁵ Paul Brezina, *supra* note 3.

²⁶ *Id.*

²⁷ *See infra*, Part II.B; II.C.

²⁸ Jennifer Uffalussy, *The Cost of IVF: 4 Things I Learned While Battling Infertility*, FORBES (Feb. 6, 2014), <http://www.forbes.com/sites/learnvest/2014/02/06/the-cost-of-ivf-4-things-i-learned-while-battling-infertility/>.

²⁹ *Id.*

There are three techniques that scientists can use to perform PGD after a patient undergoes IVF including polar body biopsy, blastocyst biopsy, and cleavage-stage embryo biopsy, but most clinics use the latter approach.³⁰ Cleavage-stage biopsy refers to the process whereby scientists biopsy a single cell from an embryo on the third day after an egg was retrieved.³¹ At this point, the embryo consists of six to ten cells.³² This process is challenging in that the scientists must extract a single cell with such precision to avoid harming the embryo with micromanipulators.³³ The main restriction of this approach is that the cell being evaluated may not be indicative of the embryo's overall genetic condition.³⁴ Polar body biopsy refers to testing on polar body cells that separate from the maturing egg.³⁵ Therefore, this technique only works for the detection of female chromosomal disorders and does not recognize any abnormalities after fertilization occurs.³⁶ Blastocyst biopsy is similar to cleavage-stage embryo biopsy except that the biopsy occurs on the fifth day after an egg was retrieved.³⁷ At this point, the egg is comprised of more than one hundred cells.³⁸ This gives patients either the ability to select only those embryos for implantation without genetic disorders or, alternatively, to screen for a certain genetic condition with a known genetic profile.³⁹

³⁰ Molina Dayal, *Preimplantation Genetic Diagnosis: Process*, MEDSCAPE, <http://emedicine.medscape.com/article/273415-overview#aw2aab6b4> (last updated Nov. 4, 2013).

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ Susannah Baruch et al., GENETICS & PUB. POL'Y CTR., PREIMPLANTATION GENETIC DIAGNOSIS: A DISCUSSION OF CHALLENGES, CONCERNS, AND PRELIMINARY POLICY OPTIONS RELATED TO THE GENETIC TESTING OF HUMAN EMBRYOS 1, 3 (2004), available at <http://www.dnapolicy.org/images/reportpdfs/PGDDiscussionChallengesConcerns.pdf>.

There are many professionals involved in PGD including physicians, scientists, nurses, genetic counselors, psychologists, and bioethicists.⁴⁰ The first type of physician employed by or affiliated with a fertility center is a reproductive endocrinologist; these are physicians who treat reproductive disorders and infertility.⁴¹ In order to become a reproductive endocrinologist, one must attend medical or osteopathic school, complete a four-year Accreditation Council for Graduate Medical Education (ACGME)-accredited residency in obstetrics and gynecology, and conclude with a three-year fellowship in reproductive endocrinology and infertility.⁴²

Another type of physician commonly found at a fertility center is a medical geneticist and these are physicians who recognize and treat patients with genetic conditions and birth defects.⁴³ These physicians must also undergo rigorous training; upon completion of medical school or osteopathic school, one must complete at least 24 months of training in an ACGME-accredited residency program in internal medicine, pediatrics, or obstetrics and gynecology.⁴⁴

Scientists for a fertility center have varying educational backgrounds including but not limited to a master's in reproductive genetics, a Ph.D. with an emphasis in male reproductive physiology, a Ph.D. in cytogenetics and embryology, or a Ph.D. in genetics.⁴⁵ PGD can be

⁴⁰ See *About Us*, GENETICS & IVF INST., <http://www.givf.com/aboutgivf/scientificteam.shtml> (last visited Nov. 27, 2014); *Team*, NYU LANGONE FERTILITY CTR., http://www.nyufertilitycenter.org/nyufc_team (last visited Nov. 27, 2014).

⁴¹ *About SREI*, SOC'Y. FOR REPROD. ENDOCRINOLOGY AND INFERTILITY, <http://www.socrei.org/detail.aspx?id=3142> (last visited Nov. 27, 2014).

⁴² *Many Doctors Provide Infertility Care. How can you tell if your doctor is best qualified to take care of you?*, SOC'Y. FOR REPROD. ENDOCRINOLOGY AND INFERTILITY, http://www.socrei.org/uploadedFiles/Affiliates/SOCREI/Publications/SREI_brochure.pdf (last visited Nov. 27, 2014); *Reproductive Endocrinology and Infertility: Fellowship Overview*, MASS. GENERAL HOSP., <http://www.massgeneral.org/education/fellowship.aspx?id=200> (last visited Nov. 27, 2014).

⁴³ *Medical Genetics: Overview*, ASS'N OF AM. MED. COLL., https://www.aamc.org/cim/specialty/list/us/339986/medical_genetics.html (last visited Nov. 27, 2014).

⁴⁴ *Training Options*, AMERICAN BOARD OF MEDICAL GENETICS AND GENOMICS, http://www.abmegg.org/pages/training_options.shtml (last visited Nov. 27, 2014) (Combined programs such as Internal Medicine/Medical Genetics are also an option).

⁴⁵ See *About Us*, GENETICS & IVF INSTITUTE, <http://www.givf.com/aboutgivf/scientificteam.shtml> (last visited Nov. 27, 2014).

performed at the fertility center itself or conducted at an outside laboratory.⁴⁶ Scientists who work in or with fertility clinics generally are responsible for lab services such as: sperm analysis, storage of sperm, preserving fertility in cancer patients, IVF, PGD, and storage/cryopreservation of eggs and embryos.⁴⁷

While fertility clinics vary in their team members, most fertility clinic teams also consist of genetic counselors, nurses, and some include psychologists.⁴⁸ Genetic counselors assist patients in understanding genetic conditions, and they also provide counseling for patients and their family members with genetic conditions.⁴⁹ Genetic counselors must earn a Master's degree in genetic counseling and pass a certification exam.⁵⁰ In order to become a nurse, one must either obtain a bachelor's or an associate's degree in nursing or earn a diploma from a nursing program.⁵¹ Additionally, registered nurses are required to be licensed.⁵² Some fertility clinics include psychologists on the team.⁵³ Psychologists usually earn a doctoral degree in psychology but a master's degree in psychology also suffices for certain positions.⁵⁴ Furthermore,

⁴⁶ Tochi Amagwula et al., *Preimplantation Genetic Diagnosis: A Systematic Review of Litigation in the Face of New Technology*, 98 FERTILITY AND STERILITY 1277,1281 (2012), available at [http://www.fertstert.org/article/S0015-0282\(12\)01836-5/pdf](http://www.fertstert.org/article/S0015-0282(12)01836-5/pdf).

⁴⁷ *Lab Services*, OREGON HEALTH & SCIENCE U. CTR. FOR WOMEN'S HEALTH, <http://www.ohsu.edu/xd/health/services/women/services/fertility/fertility-services/lab-services/index.cfm> (last visited Nov. 27, 2014).

⁴⁸ See *About Us*, GENETICS & IVF INST., <http://www.givf.com/aboutgivf/scientificteam.shtml> (last visited Nov. 27, 2014); *Team*, NYU LANGONE FERTILITY CTR., http://www.nyufertilitycenter.org/nyufc_team (last visited Nov. 27, 2014); *Clinicians and Staff*, YALE FERTILITY CTR., <http://www.yaleobgyn.org/yfc/people/index.aspx> (last visited Nov. 27, 2014).

⁴⁹ *About Genetic Counselors*, NAT'L. SOC'Y. OF GENETIC COUNSELORS, <http://nsgc.org/p/cm/ld/fid=175> (last visited Nov. 27, 2014).

⁵⁰ *How Do I Train to Become a Certified Genetic Counselor?*, AM. BD. OF GENETIC COUNSELING INC., http://www.abgc.net/Certification/become_a_genetic_counselor.asp (last visited Nov. 27, 2014).

⁵¹ *Occupational Outlook Handbook: Registered Nurses*, BUREAU OF LABOR STATISTICS, <http://www.bls.gov/ooh/healthcare/registered-nurses.htm> (last updated Jan. 8, 2014).

⁵² *Id.*

⁵³ *Our Psychologists*, NYU LANGONE FERTILITY CTR., <http://www.nyufertilitycenter.org/about-us/the-nyufc-team/shelley-s-lee-phd> (last visited Nov. 27, 2014).

⁵⁴ *Occupational Outlook Handbook: Psychologists*, BUREAU OF LABOR STATISTICS, <http://www.bls.gov/ooh/life-physical-and-social-science/psychologists.htm> (last updated Jan. 8, 2014).

psychologists who are actively practicing must be certified or licensed.⁵⁵ The psychologists at a fertility center provide emotional counseling and support for patients who are suffering from infertility and undergoing fertility treatment.⁵⁶

Bioethicists, while not typically employed by IVF clinics, are frequently consulted and often serve on advisory committees.⁵⁷ Bioethics aims to solve moral, social, and political issues that stem from biomedical research and the provision of health care.⁵⁸ Bioethicists strive to solve these issues.⁵⁹ Bioethicists have a diverse range of professional backgrounds and disciplines.⁶⁰

Although the collective effort of each of these professionals is ideal, fertility clinics have no standardized employee requirements. This is problematic, however, since a standardized team approach would provide physicians with input from a diverse range of employees. This input would be beneficial to the physician's decision-making process for PGD-related issues. Figure 1 presents those professionals involved with PGD.⁶¹ While this model is not representative of all fertility center teams, it is based on a compilation of various fertility center teams throughout the country and distinguishes between those professionals who are typically employed by or affiliated with a fertility clinic with those professionals who are not typically found at a fertility clinic.⁶² The educational backgrounds listed are the minimum requirements.⁶³

⁵⁵ *Id.*

⁵⁶ See *Our Psychologists*, *supra* note 53.

⁵⁷ See Arthur Caplan, Ph.D, NYU LANGONE DEP'T. OF POPULATION HEALTH, <http://pophealth.med.nyu.edu/faculty/caplaa01> (last visited Nov. 27, 2014); Loretta M. Kopelman, *Bioethics as a Second-Order Discipline: Who Is Not a Bioethicist?*, 31 J. OF MED. AND PHIL. 601 (2006).

⁵⁸ HET HÄYRY, *INDIVIDUAL LIBERTY AND MEDICAL CONTROL* 1 (1998).

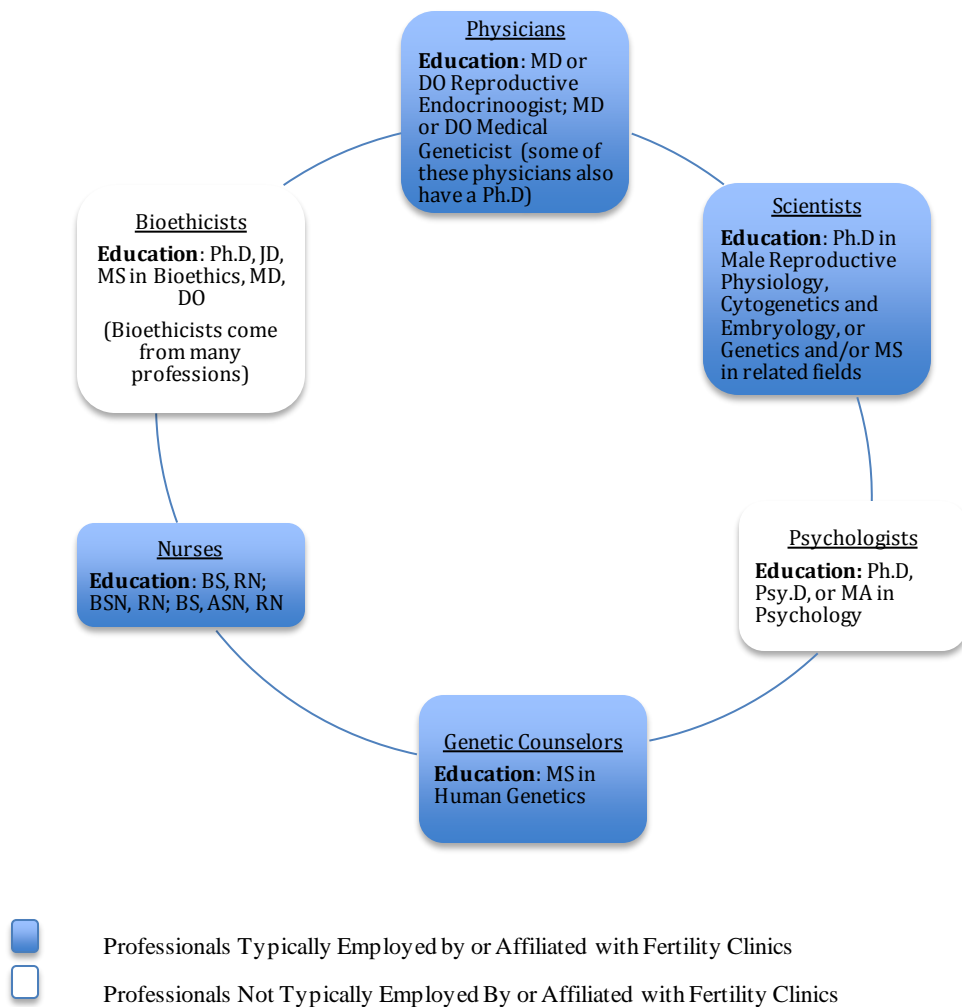
⁵⁹ *Id.*

⁶⁰ Loretta M. Kopelman, *Bioethics as a Second-Order Discipline: Who Is Not a Bioethicist?*, 31 J. OF MED. AND PHIL. 601, 602 (2006), available at <http://www.tandfonline.com/doi/pdf/10.1080/03605310601009414>.

⁶¹ See *infra* Figure 1.

⁶² See *About Us*, GENETICS & IVF INST., <http://www.givf.com/aboutgivf/scientificteam.shtml> (last visited Nov. 27, 2014) (The Genetics & IVF Institute employs doctors, scientists, nurses, and genetic counselors); *Team*, NYU LANGONE FERTILITY CTR., http://www.nyufertilitycenter.org/nyufc_team (last visited Nov. 27, 2014) (The NYU Fertility Center employs doctors, scientists, nurses, and psychologists); *Clinicians and Staff*, YALE FERTILITY CTR., <http://www.yaleobgyn.org/yfc/people/index.aspx> (last visited Nov. 27, 2014) (The Yale Fertility Center team includes physicians, nurses, scientists, and a social worker for emotional counseling); Arthur Caplan, Ph.D, NYU

Figure 1 Professionals Involved with PGD⁶⁴



LANGONE DEPARTMENT OF POPULATION HEALTH, <http://pophealth.med.nyu.edu/faculty/caplaa01> (last visited Nov. 27, 2014); Loretta M. Kopelman, *Bioethics as a Second-Order Discipline: Who Is Not a Bioethicist?*, 31 J. OF MED. AND PHIL. 601 (2006).

⁶³ See *Many Doctors Provide Infertility Care*, *supra* note 42; *Training Options*, *supra* note 44; *About Us*, *supra* note 45; *How Do I Train to Become a Certified Genetic Counselor*, *supra* note 50; *Occupational Outlook Handbook: Registered Nurses*, *supra* note 51; *Occupational Outlook Handbook: Psychologists*, *supra* note 54; Loretta M. Kopelman, *supra* note 60.

⁶⁴ See *Id.*

C. Health Risks of IVF/PGD

The long-term health concerns of IVF and PGD are not completely known.⁶⁵ Because IVF requires ovulation stimulation, there are risks associated with taking hormones such as ovarian cysts and ovarian hyperstimulation syndrome (OHSS).⁶⁶ OHSS is a condition where the ovaries swell and this can lead to mild symptoms such as abdominal bloating or severe, but rare, symptoms such as blood clots, damage to the kidneys, or fluid accumulation in the abdomen.⁶⁷ Furthermore, there are usually multiple embryos that are transferred during IVF meaning that a mother will likely carry more than one fetus.⁶⁸ Pregnancies with multiples are risky to the baby and the mother.⁶⁹ These babies are at an increased risk of being born prematurely, which often results in a lower birth weight and a higher chance of being born with disabilities.⁷⁰ PGD is a difficult process that is also quite time consuming.⁷¹ Some of the main concerns about PGD are: false positives and false negatives, misdiagnosis resulting from contamination, and the possibility that the removed cell is not representative of the overall genetic characteristics of the embryo.⁷² Lastly, there is not much data regarding PGD and injury to the embryo from the cell biopsy or the consequences to the development of the child.⁷³

⁶⁵ Susannah Baruch et al., *supra* note 39, at 3, 6.

⁶⁶ *Id.*; *Ovulation Induction*, EMORY HEALTHCARE, <http://www.emoryhealthcare.org/reproductive-center/fertility-treatments/ovulation-induction.html> (last visited Nov. 27, 2014).

⁶⁷ *Ovulation Induction*, EMORY HEALTHCARE, <http://www.emoryhealthcare.org/reproductive-center/fertility-treatments/ovulation-induction.html> (last visited Nov. 27, 2014).

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Twins, Triplets, Multiple Births*, MEDLINE PLUS, <http://www.nlm.nih.gov/medlineplus/twinstripletsmultiplebirths.html> (last visited Nov. 27, 2014).

⁷¹ EMILY JACKSON, *REGULATING REPRODUCTION* 243 (2001).

⁷² *Id.*

⁷³ *Id.*

III. Lack of Guidance From Current Oversight Framework and Case Law

Currently, ART in the U.S. is not fully regulated.⁷⁴ Because the federal government is not responsible for regulating the practice of medicine, oversight rests with the states, but there are no state laws that focus directly on PGD.⁷⁵ Governmental agencies do, however, have the ability to influence the safety of health services and products.⁷⁶ Advances in technology during the twenty-first century have created difficulties in developing a regulatory structure that can accommodate all of the new ethical dilemmas.⁷⁷ Furthermore, intense moral disagreement exists with respect to the appropriateness of human intrusion during the reproductive process.⁷⁸ Courts have been hesitant to intervene with such intimate matters and individual's decision-making.⁷⁹ Furthermore, case law surrounding PGD is scant and the current oversight framework is not robust.⁸⁰ Because of the aforementioned reasons, which will be discussed further below, doctors have little guidance when their patients want to use PGD to select genetically defective embryos. Consequently, they are often likely forced to tackle these difficult ethical dilemmas as they are faced with them.

A. Current Oversight Framework

Because ART is not fully regulated, current requirements offer little guidance for PGD ethical dilemmas⁸¹. There is no entity in the United States that gathers data on PGD practices,

⁷⁴ JUDITH AREEN, *supra* note 2.

⁷⁵ Susannah Baruch et al., *supra* note 39, at 7, 9.

⁷⁶ *Id.* at 7.

⁷⁷ EMILY JACKSON, *supra* note 71, at 1.

⁷⁸ *Id.*

⁷⁹ See *Skinner v. State of Okl. ex rel. Williamson*, 316 U.S. 535, 536 (1942); *Griswold v. Connecticut*, 381 U.S. 479, 486 (1965); *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); *Roe v. Wade*, 410 U.S. 113, 114 (1973).

⁸⁰ See *infra*, Part III.A and Part III.C.

⁸¹ See JUDITH AREEN, *supra* note 2.

which makes it difficult to assess the frequency of PGD testing and for which indications it is performed.⁸²

In 1992, Congress passed the Fertility Clinic Success Rate and Certification Act (FCSRCA).⁸³ This requires all ART clinics to submit data annually to the Centers for Disease Control and Prevention (CDC).⁸⁴ The CDC then publishes the success rates of each clinic based on the data.⁸⁵ Some of the data points reported are: the procedure performed, the medical diagnosis of the IVF patient, the number of transferred embryos, and the number of births.⁸⁶ This information is publicly available on the CDC's website which is not only beneficial for patients who are selecting which clinic to visit but also professionals so they can monitor clinic operation.⁸⁷ There is no requirement, however, for clinics to provide information about the babies' health status or whether a clinic used PGD or other diagnostic tests.⁸⁸ While the FCSRCA requires the CDC to publicly report clinic names that fail to provide data or that do not validate the data's accuracy, the clinics are not disciplined beyond the public reporting.⁸⁹ The lack of penalties likely provides little incentive for those noncompliant clinics to change their behavior.

⁸² Susannah Baruch, J.D., *Preimplantation Genetic Diagnosis and Parental Preferences: Beyond Deadly Disease*, 8 Hous. J. Health L. & Pol'y 245, 252 (2008).

⁸³ *The Fertility Clinic Success Rate and Certification Act*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/art/Policy.htm> (last updated Oct. 31, 2013) (The CDC is a federal agency overseen by the Department of Health and Human Services and its mission is to protect the U.S. through control and prevention of diseases).

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ Susannah Baruch et al., *supra* note 39, at 7.

⁸⁷ *Oversight of Assisted Reprod. Tech.*, AM. SOC'Y. FOR REPROD. MED. 6 (2010), available at [http://www.asrm.org/uploadedFiles/Content/About_Us/Media_and_Public_Affairs/OversiteOfART%20\(2\).pdf](http://www.asrm.org/uploadedFiles/Content/About_Us/Media_and_Public_Affairs/OversiteOfART%20(2).pdf).

⁸⁸ Susannah Baruch et al., *supra* note 39, at 7.

⁸⁹ *Id.* at 8.

There are three states (Florida, Massachusetts, and Michigan) that have collaborated with the CDC to implement additional tracking methods of ART outcomes.⁹⁰ This program is known as States Monitoring Assisted Reproductive Technology (SMART) and the aggregated data has enabled these states to compare outcomes of births resulting from ART against those conceived naturally.⁹¹ Because there is no penalty for clinics who fail to submit data and because states are not required to participate in programs such as SMART, the current requirements are almost voluntary in nature.⁹² This current scheme results in an inadequate overall picture and an inability to effectively regulate ART practices.

The Food and Drug Administration (FDA) has the authority to regulate ART/ PGD processes and several products to ensure the safety and effectiveness for human use.⁹³ The FDA requires screening of reproductive tissue for communicable diseases.⁹⁴ There is mandatory testing of the reproductive tissue for human immunodeficiency virus (HIV), hepatitis B and C, syphilis, chlamydia, and gonorrhea.⁹⁵ Inspectors who become aware of reproductive tissue that is infected with a communicable disease can order the tissue to be destroyed or recalled.⁹⁶ The FDA also reviews genetic tests, which are a type of in vitro diagnostic device (IVD), to ensure

⁹⁰ *States Monitoring Assisted Reproductive Technology Collaborative*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/art/SMART.htm> (last updated July 24, 2012).

⁹¹ *Id.*

⁹² Susannah Baruch et al., *supra* note 39, at 8.

⁹³ *What Does FDA Do?*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm> (last updated Nov. 18, 2014) (The FDA regulates foods, drugs, medical devices, radiation-emitting products, vaccines, blood & biologics, cosmetics, tobacco products, and animal & veterinary products).

⁹⁴ *What You Should Know – Reproductive Tissue Donation*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm232876.htm> (last updated Mar. 1, 2011) (Eggs and Sperm are considered reproductive tissue).

⁹⁵ *Id.*

⁹⁶ *Oversight of Assisted Reprod. Tech.*, *supra* note 87.

safety, efficacy, and design and manufacture quality of the device.⁹⁷ This oversight responsibility is in conjunction with supervision by the Centers for Medicare and Medicaid Services (CMS) over laboratories that perform these tests pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA).⁹⁸ CMS is responsible for ensuring the quality of clinical testing processes through mechanisms such as laboratory employee credentialing and daily assurances that devices are functioning properly.⁹⁹ The complexity of IVD regulation results from the two pathways in which they can be developed.¹⁰⁰ Device manufacturers can create commercial tests that are distributed to several laboratories or a laboratory itself can create its own test for solely its use.¹⁰¹ While the FDA has authority to regulate these laboratory created tests, it is often discretionary since the tests are low risk, easy to use, and reliant on expert analysis.¹⁰² Another challenge rests with FDA's lack of authority over the practice of medicine.¹⁰³ Specifically, the FDA is not permitted to control which physicians can use a device or how those physicians use the device.¹⁰⁴ While the FDA does not regulate the practice of medicine, it does have the authority to ensure that physicians are using devices that are not misbranded or adulterated.¹⁰⁵

Furthermore, there are three accreditation programs that can certify embryo laboratories including the Joint Commission on Accreditation of Healthcare Organizations (JACHO), the College of American Pathologists/American Society for Reproductive Medicine (CAP/ASRM),

⁹⁷ *Direct-to-Consumer Genetic Testing and the Consequences to the Public*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/NewsEvents/Testimony/ucm219925.htm> (last updated July 22, 2010) (IVDs are diagnostic devices used to detect certain diseases).

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ Susannah Baruch et al., *supra* note 39, at 8.

¹⁰⁴ *Overview of Medical Devices and Their Regulatory Pathways*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm203018.htm> (last updated Mar. 6, 2014).

¹⁰⁵ ADAMS, COOPER, HAHN & KAHAN, EDS., *FOOD AND DRUG LAW AND REGULATION* 707 (FDLI, 2ND ED. 2011).

and the New York State Tissue Bank certification for ART laboratories (NYSTB).¹⁰⁶ The CDC posts the accreditation information on the annual Success Rates reports.¹⁰⁷ These accreditation agencies conduct unannounced, sporadic inspections to ensure compliance with: (1) standards that ensure consistency when carrying out procedures, (2) implementation of quality assurance programs that ensure reliable laboratory procedures, and (3) preservation of laboratory test and procedure records.¹⁰⁸ Laboratories that fail to comply with those standards face possible revocation of certification.¹⁰⁹

B. Historical Development and Reproductive Freedom

Because of the minimal ART regulation, another source of guidance for PGD ethical dilemmas is the historical development of reproductive freedom. The constitutional right to procreate involves not only an individual's right to have genetically-related children by engaging in sexual intercourse but also by using ART according to many scholars.¹¹⁰ This constitutional right to procreate is well established in case law.¹¹¹ Case law involving reproductive choices has demonstrated a hands-off approach in the United States.¹¹² For example, in *Skinner v. Oklahoma*, a statute known as the Habitual Criminal Sterilization Act required sterilization for those individuals who were convicted at least twice "for crimes amounting to felonies involving moral turpitude."¹¹³ Because Skinner was convicted of robbery on numerous occasions, the Attorney General proceeded against Skinner so he would have to undergo a vasectomy.¹¹⁴ The Supreme

¹⁰⁶ *The Fertility Clinic Success Rate and Certification Act*, *supra* note 83.

¹⁰⁷ *Id.*

¹⁰⁸ 42 U.S.C.A. § 263a-2(d), (g) (West 1992).

¹⁰⁹ *Id.* at (i).

¹¹⁰ JUDITH AREEN, *supra* note 2, at 594.

¹¹¹ See *Skinner v. State of Okl. ex rel. Williamson*, 316 U.S. 535, 536 (1942); *Griswold v. Connecticut*, 381 U.S. 479, 486 (1965); *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); *Roe v. Wade*, 410 U.S. 113, 114 (1973).

¹¹² *Id.*

¹¹³ *Skinner v. State of Okl. ex rel. Williamson*, 316 U.S. 535, 536 (1942).

¹¹⁴ *Id.* at 537.

Court ultimately found the statute to be unenforceable and explained that the right to procreate is “one of the basic civil rights of man.”¹¹⁵ *Griswold v. Connecticut* was another case involving reproductive freedom.¹¹⁶ This case involved a statute that banned married couples from utilizing contraception.¹¹⁷ The court ultimately held that the statute interfered with a married couple’s right of privacy.¹¹⁸ Similarly, in *Eisenstadt v. Baird*, the court struck down a Massachusetts statute that prohibited contraceptives for unmarried individuals.¹¹⁹ The court recognized that individuals should not have to deal with government interference when making procreative decisions under the right of privacy.¹²⁰ Finally, in *Roe v. Wade*, the court invalidated a Texas statute that criminalized abortion at all stages unless the mother’s life was at stake.¹²¹ Although the court concluded that women have a right to choose, abortions were only permitted during the first trimester of pregnancy and with the approval of the attending physician.¹²²

Although history has demonstrated a hands-off approach for reproductive decisions, this provides little guidance to physicians for the PGD dilemma. These cases are largely based on the right to have a child, the right to prevent pregnancy, and the right to terminate pregnancy, but none of the case law involves the specific right to use a screening test to bring a genetically defective child into the world.¹²³ Therefore, it is essential to look specifically at ART case law to determine whether further guidance exists for the PGD dilemma.

C. Inadequate ART Case Law

¹¹⁵ *Id.* at 541.

¹¹⁶ *Griswold v. Connecticut*, 381 U.S. 479, 486 (1965).

¹¹⁷ *Id.* at 480.

¹¹⁸ *Id.* at 499.

¹¹⁹ *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972).

¹²⁰ *Id.*

¹²¹ *Roe v. Wade*, 410 U.S. 113, 114 (1973).

¹²² *Id.* at 164-165.

¹²³ See *Skinner v. State of Okl. ex rel. Williamson*, 316 U.S. 535, 536 (1942); *Griswold v. Connecticut*, 381 U.S. 479, 486 (1965); *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); *Roe v. Wade*, 410 U.S. 113, 114 (1973).

Unfortunately, there is not precedent from case law about the issue of using PGD to select for genetically defective embryos. Much of the ART case law deals with issues about parental status and issues with surrogacy agreements.¹²⁴ For example, in *In re Marriage of Witbeck-Wildhagen*, there was an issue about whether a man, who did not consent to his wife's attempt to become pregnant through artificial insemination from donor sperm, would be recognized as the legal father for support obligation purposes after the dissolution of their marriage.¹²⁵ The court ultimately determined that because the man had not provided consent, there was no father-child relationship.¹²⁶

With respect to surrogacy agreement disputes, *Matter of Baby M* involved a couple, Mr. and Mrs. Stern, who found a surrogate to carry their baby, using the surrogate's eggs and Mr. Stern's sperm since Mrs. Stern had an underlying health condition that could result in a risky pregnancy.¹²⁷ Mr. Stern entered into a surrogacy agreement whereby the surrogate would get paid after the child's birth and delivery of the baby to the Sterns, and the surrogate would be required to terminate all maternal rights.¹²⁸ Mrs. Stern was not a party to the contract since this would implicate the application of a statute that prohibited the use of money for adoptions.¹²⁹ After giving birth, the surrogate had a difficult time parting with the child.¹³⁰ The court ultimately found the contract to be void since it conflicted with state laws and policies against "baby-selling" but granted custody to the Sterns since it was in the child's best interest.¹³¹ As it can be seen, the aforementioned ART cases are not helpful to the PGD dilemma since they deal

¹²⁴ See JUDITH AREEN, *supra* note 2, at 678.

¹²⁵ *In re Marriage of Witbeck-Wildhagen*, 281 Ill. App. 3d 502, 503, 667 N.E.2d 122, 123 (1996).

¹²⁶ *Id.* at 125.

¹²⁷ *Matter of Baby M*, 109 N.J. 396, 414, 537 A.2d 1227, 1236 (1988)

¹²⁸ *Id.* at 1235.

¹²⁹ *Id.*

¹³⁰ *Id.* at 1236.

¹³¹ *Id.* at 1227.

with completely different issues. Therefore, reference to PGD-specific case law may be another source of guidance.

Lawsuits dealing specifically with PGD have largely been based on failure to provide adequate informed consent and negligence in performing PGD.¹³² Of the lawsuits involving failure to provide adequate informed consent, individuals alleged that the fertility clinic failed to sufficiently inform them of: errors that are inherent in PGD, the clinic's little experience in performing PGD, and the actual option to proceed with PGD.¹³³ Plaintiffs can also allege wrongful life claims in their lawsuits if the jurisdiction recognizes the cause of action.¹³⁴ Wrongful life actions are those cases where a parent of a child, who is born with a genetic condition, sues a health care provider for failure to properly guide the parents about a possible genetic disorder, thereby denying them the option to decide not to have the child.¹³⁵

For example, in *Paretta v. Medical Offices for Human Reproduction*, parents of a child afflicted with cystic fibrosis, a "chronic, debilitating progressive genetic disease," brought an action against doctors for failure to properly screen (using PGD) for the disease.¹³⁶ Their claims rested upon negligence and failure to provide proper informed consent.¹³⁷ Ultimately, the court concluded that a baby "does not have a protected right to be born free of genetic defects."¹³⁸

¹³² Tochi Amagwula et al., *supra* note 46.

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Turpin v. Sortini*, 31 Cal. 3d 220, 223, 643 P.2d 954, 955 (1982).

¹³⁶ *Paretta v. Med. Offices for Human Reprod.*, 195 Misc. 2d 568, 571, 760 N.Y.S.2d 639, 642 (Sup. Ct. 2003).

¹³⁷ *Id.* at 643.

¹³⁸ *Id.* at 646.

Based on this result, it can be implied that selecting for a genetic condition, such as dwarfism, would not be in violation of a child's protected right.¹³⁹

Coggeshall v. Reproductive Endocrine Associates of Charlotte was a case that involved alleged failure to provide adequate informed consent.¹⁴⁰ In this case, the wife underwent IVF treatment at the clinic and subsequently had a child born with Down Syndrome.¹⁴¹ The condition was discovered through amniocentesis at fourteen weeks, and the parents claimed they were never informed of the option to undergo PGD.¹⁴² Because the parents filed suit in South Carolina, the case was ultimately dismissed since the clinic was located in North Carolina and the court lacked jurisdiction to hear the case.¹⁴³

In *Doolan v. IVF America, (MA) Inc.*, a couple underwent IVF in order to avoid having a second child with cystic fibrosis since their first child had cystic fibrosis and later genetic testing revealed that they were both carriers of the disease.¹⁴⁴ After learning which embryo was free of the genetic condition, the couple decided to proceed with implantation.¹⁴⁵ Shortly after giving birth, Mrs. Doolan was informed that her son did have cystic fibrosis even though the laboratory assured her that this embryo did not carry the gene for the disease.¹⁴⁶ The parents brought a

¹³⁹ Sarah Aviles, *Do You Hear What I Hear?: The Right of Prospective Parents to Use Pgd to Intentionally Implant an Embryo Containing the Gene for Deafness*, 19 Wm. & Mary J. Women & L. 137, 147 (2012) ("If a child has no fundamental right to be born without a disability, parents and their doctor are not violating any inherent right of a child by using PGD to choose deafness prior to birth.")

¹⁴⁰ *Coggeshall v. Reprod. Endocrine Associates of Charlotte*, 376 S.C. 12, 655 S.E.2d 476 (2007).

¹⁴¹ *Id.* at 15.

¹⁴² *Id.*

¹⁴³ *Id.* at 19.

¹⁴⁴ *Doolan v. IVF Am. (MA), Inc.*, No. 993476, 2000 WL 33170944, at *1 (Mass. Super. Nov. 20, 2000)

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

wrongful life suit against the doctor on behalf of their son, but the court said that Massachusetts does not recognize wrongful life claims.¹⁴⁷

There are simply not enough cases involving PGD and the legal theories vary. The cases that do exist provide no direction for physicians if a patient uses PGD to select for genetic disorders. Therefore, case law is also inadequate as a source of guidance.

IV. Positions on PGD

Another source of guidance for PGD practices rests with opinions of professional organizations, experts in the field, and fertility clinics. However, there is a lack of explicit guidance, differing opinions, and minimal transparency from these sources.

A. Professional Organizations

Because the practice of medicine equips physicians with a specialized skillset and knowledge, physicians have some autonomy through self-regulation by professional organizations.¹⁴⁸ Despite the lack of regulation of PGD, professional organizations have issued best practice guidelines for PGD.¹⁴⁹ Affiliation with these professional organizations is voluntary, so individuals who choose not to join a professional organization are not obligated to follow the organization's standards.¹⁵⁰ Even though professional organizations cannot pursue legal actions against members who fail to abide by standards, the organizations can terminate membership of those members and the standards can be considered "evidence of standards of

¹⁴⁷ *Id.* at 3.

¹⁴⁸ *Oversight of Assisted Reprod. Tech.*, *supra* note 87, at 7.

¹⁴⁹ ISABEL KARPIN AND KRISTIN SAVELL, *supra* note 13, at 235.

¹⁵⁰ Susannah Baruch et al., *supra* note 39, at 9.

practice in legal settings.”¹⁵¹ Unfortunately, the professional organizations involved with ART do not provide much guidance on PGD practices.

The American Society for Reproductive Medicine (ASRM) is a non-profit organization comprised of medical, legal, and administrative professionals and special interest groups who have an interest in infertility and reproductive medicine.¹⁵² ASRM notes that the indication for PGD is for “couples at risk for transmitting a specific genetic disease or abnormality to their offspring.”¹⁵³ Additionally, they recommend genetic counseling for patients prior to PGD so they are fully informed of the ramifications of embryos with genetic conditions.¹⁵⁴ However, there is no guidance in this opinion for physicians when patients want to use PGD to select for a genetically defective embryo.

The American Congress of Obstetricians and Gynecologists (ACOG) is a non-profit organization that consists of professionals who provide women’s health care and who are committed to advocating for quality care.¹⁵⁵ ACOG issued a committee opinion that notes its outright ban on PGD for the selection of sex unless it is associated with the diagnosis of sex-linked genetic disorders.¹⁵⁶ ACOG, like ASRM, notes the importance of genetic counselors’ involvement in the process.¹⁵⁷ ACOG does mention the possibility of patients selecting for a specific genetic condition, specifically dwarfism, and notes that a choice like this “seem[s] to be

¹⁵¹ *Id.* at 9-10.

¹⁵² *About ASRM*, AM. SOC’Y. FOR REPROD. MED., <http://www.reproductivefacts.org/about/> (last visited Nov. 27, 2014).

¹⁵³ *Preimplantation Genetic Testing: A Practice Committee Opinion*, 90 FERTILITY AND STERILITY 136 (2008), available at [https://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/Preimplantation_genetic_testing\(1\).pdf](https://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/Preimplantation_genetic_testing(1).pdf).

¹⁵⁴ *Id.* at 142.

¹⁵⁵ *Leadership and Governance*, AM. CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS, <http://www.acog.org/About-ACOG/Leadership-and-Governance> (last visited Nov. 27, 2014).

¹⁵⁶ *ACOG Committee Opinion No. 410: Ethical Issues in Genetic Testing*, AM. CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS 1,6 (June 2008), <http://www.acog.org/-/media/Committee-Opinions/Committee-on-Ethics/co410.pdf?dmc=1&ts=20141206T2002040679>.

¹⁵⁷ *Id.* at 6.

antithetical to the best interests of the future child.”¹⁵⁸ Like ASRM, ACOG’s Committee opinion does not offer specific guidance to that matter.¹⁵⁹ Even though these professional organizations have issued best practice guidelines for PGD, they are not helpful in guiding physicians when patients want to use PGD to select for genetically defective embryos.

B. Experts in the Field

Because the professional guidelines do not offer much guidance, opinions made by experts in the field are another resource for the PGD dilemma. This subsection includes personal positions by experts in the field, independent from professional organization statements.

i. Physicians

Dr. Jami Grifo, M.D., Ph.D,¹⁶⁰ is a reproductive endocrinologist affiliated with the NYU Fertility Center and has explained that he is not against screening for a particular disorder, such as dwarfism, and posed the following thoughts:

Two dwarfs who are happy with their lives don’t see dwarfism as a disease like some people do. The more you think about the request, it’s not so unreasonable. Who should make this decision?...Don’t you think a dwarf couple knows what it’s like to be a dwarf? Why shouldn’t they be the ones to choose that, if that’s what they want? Why should I, as a doctor, be given that authority? I don’t have the training to be able to do that. ¹⁶¹

On the other hand, Dr. Robert J. Stillman, a reproductive endocrinologist of the Shady Grove Fertility Center in Rockville, Maryland, refuses to screen for disorders such as deafness or dwarfism and explained that, “...one of the prime dictates of parenting is to

¹⁵⁸ *Id.*

¹⁶⁰ Jami Grifo, M.D., Ph.D, NYU LANGONE FERTILITY CTR Dr. Jami Grifo, http://www.nyufertilitycenter.org/jamie_grifo (last visited Nov. 27, 2014) (Dr. Grifo is the Program Director of the NYU Fertility Center and Director of the Division of Reproductive Endocrinology at NYU School of Medicine).

¹⁶¹ Kevin O’Reilly, *Testing Embryos & Ethics: Where do We Draw the Line?*, AM. MED. NEWS (Feb. 26, 2007) <http://www.amednews.com/article/20070226/profession/302269966/4/> .

make a better world for our children...dwarfism and deafness are not the norm.”¹⁶² Based on the previous opinions, it can be seen that two physicians with the same training have such opposite viewpoints on this controversial matter. The varying viewpoints amongst physicians likely results in their handling of issues on an off-the-cuff basis. Several case studies have shown that “...ward ethics issues are handled, when they are handled at all, on an ad hoc basis. The message is that these issues are not that important.”¹⁶³ While there are various differences between the ethical issues encountered in a fertility clinic versus those encountered in a hospital ward, it is concerning that fertility clinic physicians are likely handling these ethical dilemmas on such basis. When fertility clinics lack the necessary policies and procedures to guide physicians in making ethical decisions, the physicians may inevitably handle situations based on their personal beliefs. Those physicians will likely not consult with other team members for advice if they feel so strongly about a certain issue. Unfortunately, those instances will likely result in patients succumbing to their physician’s beliefs, and a doctor may proceed with a plan that lacks proper attention to the patient’s situation and needs.

ii. Scientists

The availability of scientists’ opinions about PGD selection for genetically defective embryos is scarce. Yury Verlinksy, who earned his Ph.D. in cytogenetics and embryology, was the founder of the Reproductive Genetics Institute.¹⁶⁴ He was against patients using PGD to select for specific genetic conditions and stated,

¹⁶² Darshak Sanghavi, *supra* note 12.

¹⁶³ WARD ETHICS: DILEMMAS FOR MEDICAL STUDENTS AND DOCTORS IN TRAINING 27-28 (Thomasine K. Kushner & David C. Thomasma eds., 2001).

¹⁶⁴ *Remembering Yury Verlinksy*, REPROD. GENETICS INST., <http://www.reproductivegenetics.com/about-the-founder/> (last visited Nov. 27, 2014).

We are not participating in this kind of request, because our goal is to prevent disease, not to create disease. I can't judge someone who wants to have, for example, a Down syndrome child, but it does not have to be us to participate in it. That is not our goal as scientists and medical professionals.¹⁶⁵

In an anonymously reported interview, a scientist in the UK did not directly address the issue of using PGD for the selection of genetically defective embryos but offered insight into the overall process of guiding patients in their selection of embryos.¹⁶⁶ The scientist stated:

...You give them advice and you don't tell them what to do ...I mean you say the things in a way that, you know, makes it sound like, 'this is the best one.' Obviously in terms of morphology, you say, 'this has got the best chance of implanting,' but they have to have the other information as well to make their decision. And at the end of the day it's their embryos ...So if they decide not to have the normals put back and have the carriers, they have to live with the decision that when that child is growing up, that child might have some problems, but it was the one that had the nicest looking embryo ...They have to live with that decision they make. So you can't just be, 'We think it's this one, you should have this one.'¹⁶⁷

Essentially, this scientist explained that with such a technical process, it is important to fully inform patients and provide them with advice, but it is ultimately up to them to make their final decision.¹⁶⁸ As it can be seen, viewpoints from scientists also vary and this can be problematic for physicians who are looking for guidance during PGD dilemmas.

iii. Bioethicist

Arthur Caplan, PhD is the Director of the Division of Medical Ethics at NYU Langone

¹⁶⁵ Kevin O'Reilly, *Testing Embryos & Ethics: Where do We Draw the Line?*, AM. MED. NEWS (Feb. 26, 2007) <http://www.amednews.com/article/20070226/profession/302269966/4/>.

¹⁶⁶ Kathryn Ehrich et al., *Choosing Embryos: Ethical Complexity and Relational Autonomy in Staff Accounts of PGD*, 29 SOCIOLOGICAL HEALTH ILLNESS 1091, 1097-1098 (2007), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2440558/>.

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

Medical Center and is opposed to using PGD to screen for hereditary conditions.¹⁶⁹ He has served on numerous committees and formed the Center for Bioethics and the Department of Medical Ethics at the University of Pennsylvania.¹⁷⁰ Caplan's view is as follows:

My point of view on this is medicine shouldn't contribute to the creation of children knowing that they're going to lack function or lack impairment that might be viewed as normal. So I would oppose the use of PGD. I understand parents might want that; I understand they might have wishes to form a continuity or a bond between themselves and their children, but I don't think medical skills should be used to make anyone worse off. I think that's a misuse of the testing. It's not a path I would see those who can do PGD pursuing.¹⁷¹

Rosamund Scott, a professor of medical law and ethics who has also served on several committees, including the Ethics Committee of the Royal College of Obstetricians and Gynaecologists, notes that, "to grant these parents public resources to select a child with achondroplasia would be to ensure that more instances of a given type of difference existed but we have no obligation to replicate difference."¹⁷² While these views are not representative of all bioethicists, it demonstrates some bioethicists' opposition to selecting embryos with a particular genetic condition. As it can be seen from the aforementioned experts, there is much variation in opinions about PGD to select for genetically defective embryos. Therefore, guidance from experts in the field is also not definitive.

C. Fertility Clinics

¹⁶⁹ A.M. Gronowski, et al., *The Ethical Implications of Preimplantation Genetic Diagnosis*, 60 CLINICAL CHEMISTRY 28 (2014); Arthur Caplan, Ph.D, NYU LANGONE DEP'T. OF POPULATION HEALTH, <http://pophealth.med.nyu.edu/faculty/caplaa01> (last visited Nov. 27, 2014).

¹⁷⁰ Arthur Caplan, Ph.D, NYU LANGONE DEP'T. OF POPULATION HEALTH, <http://pophealth.med.nyu.edu/faculty/caplaa01> (last visited Nov. 27, 2014).

¹⁷¹ A.M. Gronowski, *supra* note 169.

¹⁷² Professor Rosamund Scott, KING'S COLL. OF LONDON, <http://www.kcl.ac.uk/law/people/academic/rscott.aspx> (last visited Nov. 27, 2014); ROSAMUND SCOTT, CHOOSING BETWEEN POSSIBLE LIVES: LAW AND ETHICS OF PRENATAL AND PREIMPLANTATION GENETIC DIAGNOSIS 314 (2007).

Fertility centers do not provide much guidance on their websites with respect to their approaches for PGD. The University of Pennsylvania's Penn Fertility Care indicates on its website that "embryos unaffected by the genetic or chromosomal disorder can be selected for transfer to the uterus."¹⁷³ While the website offers no further information, it seems from this statement that Penn Fertility Care would not allow a patient to transfer genetically defective embryos. The San Diego Fertility Center notes on its website:

PGD makes it possible for couples with serious inherited disorders to decrease the risk of having an affected child. PGD also can be considered for couples experiencing repeat pregnancy loss due to genetic disorders, and for couples that already have one child with a genetic disorder and are at high risk of having another.¹⁷⁴

This overview of PGD implies that the San Diego clinic only uses PGD to avoid selection of genetically defective embryos. The University of California, Los Angeles Fertility and Reproductive Health Center offers an even more vague explanation and approach for PGD on its website.¹⁷⁵ The clinic provides a brief question and answer about PGD:

Q: What is PGD and is it recommended?

A: PGD is an abbreviation for pre-implantation genetic diagnosis. It involves removing a single cell from an embryo, usually on the third day after fertilization, to determine if the cell or embryo is genetically normal or if the chromosomes are balanced. It can also be used to test for specific genetic mutations if planned in advance. There are numerous pros and cons to this procedure and an in-depth discussion with your doctor is warranted to see if PGD is appropriate for you.¹⁷⁶

This vague explanation does not allow for an implication that the clinic would or would not allow PGD use to select for genetically defective embryos. This clinic seems to prefer in person

¹⁷³ *What is Preimplantation Genetic Diagnosis?*, PENN FERTILITY CARE, <http://www.pennmedicine.org/fertility/patient/clinical-services/pgd-preimplantation-genetic-diagnosis/> (last visited Nov. 27, 2014).

¹⁷⁴ *What is PGD?*, SAN DIEGO FERTILITY CTR., <http://www.sdfertility.com/pgd.htm> (last visited Nov. 27, 2014).

¹⁷⁵ *Fertility FAQs*, UCLA HEALTH, <http://obgyn.ucla.edu/body.cfm?id=349#33> (last visited Nov. 27, 2014).

¹⁷⁶ *Id.*

discussions of PGD uses between the patient and doctor as opposed to providing information on its website.

While some fertility clinics do make their consent forms available online, the majority of clinics do not provide public access to their policies. The lack of transparency is concerning for two reasons. First, if patients are unable to view a fertility clinic's consents or policies prior to visiting a clinic, the patient will not know the fertility clinic's approach to PGD until her actual visit. If the patient goes for an initial consultation and feels comfortable with the fertility center team but then later discovers that the team's stance on PGD conflicts with her personal viewpoint, she may decide to find another clinic. Finding another clinic may be time consuming and frustrating for those patients. The second reason the lack of transparency is problematic is because it makes it more difficult for other clinics to determine what constitutes best practices. Therefore, fertility clinics are also not a helpful source of guidance for ethical issues surrounding PGD.

Although professional organizations offer best practice guidelines, the recommendations are quite broad and not narrowly tailored to address the PGD ethical dilemma. While experts in the field have offered their personal opinions, they are inconsistent. Furthermore, expert opinions of other professionals involved with PGD are not readily available. As highlighted in Figure 1, there are several professionals involved in PGD, yet opinions of only half of the team members are emphasized in literature.¹⁷⁷ This is problematic since nurses, psychologists, and genetic counselors are likely the professionals most closely involved with patients' emotional concerns throughout the PGD process, yet opinions based on that perspective are lacking. This emphasizes the notion that only some of the professionals, mainly physicians, are likely to be ultimately

¹⁷⁷ See *Supra*, Part II Figure 1.

responsible PGD decisions. Lastly, the lack of transparency across fertility clinics perpetuates a culture of isolation for each clinic when collaboration across clinics could be extremely useful.

V. The Hippocratic Oath

Because professional organization statements, expert opinions, and fertility clinics offer little guidance for PGD dilemmas, another source of ethical guidance for physicians is the Hippocratic Oath. As Section II demonstrated, there are several professionals involved with PGD, however, physicians seem to be the only professionals governed by an oath, which seems logical since they have so much authority over medical decision-making.¹⁷⁸ Even though scientists are dealing directly with the embryos, there is no equivalent to a Hippocratic Oath for these professionals.¹⁷⁹ Because of this huge responsibility, physicians must take full advantage of every resource they have when dealing with PGD ethical issues. “Given the myriad challenges facing almost every aspect of medicine in the 21st century, the need for physicians to make a formal warrant of diligent, moral, and ethical conduct in the service of their patients may be stronger than ever.”¹⁸⁰ The Hippocratic Oath, titled “*Oath*,” was intended for the induction of a medical apprentice.¹⁸¹ Today, most medical schools integrate the recitation of a version of this ancient Greek document at a ceremony.¹⁸² Not only is there disagreement about when the Hippocratic Oath was written, but there is also very little context for the Oath.¹⁸³ There are also

¹⁷⁸ See *supra*, Section II.

¹⁷⁹ Thomas Clanton, *Oaths for Scientists and Other Scholars: The Case for Developing a Common Scholar Oath*, 1 THE INT’L J. OF SCI. IN SOC’Y 151 (2009), available at http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCAQFjAA&url=http%3A%2F%2Fwww.researchgate.net%2Fprofile%2FThomas_Clanton%2Fpublication%2F236230956_Oaths_for_Scientists_and_Other_Scholars_The_Case_for_Developing_a_Common_Scholar_Oath%2527s_Oath%2527%2Flinks%2F00b7d5172bca623cdd000000&ei=X4GEVJWyH4bZsATzh4DwCg&usg=AFQjCNFd4j2m6471JphnWzsWPXKMIVzd2A&sig2=cfVB_Ddo6G-kcR6aRyMfw&bvm=bv.80642063,d.cWc.

¹⁸⁰ Howard Markel, *supra* note 16.

¹⁸¹ STEVEN H. MILES, 3 THE HIPPOCRATIC OATH AND THE ETHICS OF MEDICINE (2004).

¹⁸² *Id.*

¹⁸³ *Id.* (400 BCE is a reasonable approximation of the year in which it was written, but there is no evidence that Hippocrates wrote it.)

several versions of the Oath but this paper will focus on the 1966 version translated by von Staden since it is the most recent.¹⁸⁴ In sum, by reciting the oath, medical apprentices promised to be good physicians.¹⁸⁵ Furthermore, they vowed to avoid harm to their patients.¹⁸⁶ This section will analyze the conflict between the physician and patient when deciding to proceed with implantation of a genetically defective embryo while taking into consideration a doctor's duty to avoid harm under the Hippocratic Oath and to respect patient's autonomy.

A. 'First, Do No Harm'¹⁸⁷

The relevant section of the oath addressing a doctor's duty to avoid harm is as follows: "And I will use regimens for the benefit of the ill in accordance with my ability and my judgment, but from [what is] to their harm or injustice I will keep [them]."¹⁸⁸ Some have argued that this section refers to the duty of doctors to focus attention not just on their own patients but also on public health overall.¹⁸⁹ However, the literal meaning of this passage is that a doctor will use his or her knowledge and skillset to ensure that no harm or injustice is inflicted upon his or her patient.¹⁹⁰ Depending on how the physician proceeds, the harmed patient may be the resulting offspring or the parent, who is the paying customer.

By allowing a patient to proceed with PGD to select for genetically defective embryos, a doctor may ultimately inflict harm on the child that is born as a result of IVF. Although parents who have dwarfism may find it to be in their best interests to have a child with dwarfism, the

¹⁸⁴ *Id.* at xiii-xiv, 193.

¹⁸⁵ *Id.*

¹⁸⁶ Sheila McLean, 31 *First Do No Harm* (2006).

¹⁸⁷ *Finucan v. Maryland State Bd. of Physician Quality Assur.*, 151 Md. App. 399, 417, 827 A.2d 176, 187 (2003) (While this phrase is not explicitly contained in the Hippocratic Oath, it is a saying familiar to all doctors).

¹⁸⁸ Steven H. Miles, *supra* note 181, at xiii.

¹⁸⁹ *Id.* at 62.

¹⁹⁰ *See id.*

child could end up being harmed. While people with dwarfism can have fully functional lives and occasionally only suffer from psychological and social issues as noted earlier, the child who is brought to this world may resent the fact that the parents and the doctor were aware of the disability yet brought him or her to the world anyway.¹⁹¹ This may also open the floodgates of wrongful life actions by the child against the patients and/or the doctors if the child is in a jurisdiction that recognizes those actions.¹⁹² However, if the doctor does now allow a patient to proceed with PGD to select for genetically defective embryos, the doctor may ultimately harm the patient. As mentioned earlier, because there has been such an emphasis on reproductive freedom throughout history, this action by a doctor may be seen as interference with the fundamental right to privacy.¹⁹³ In the end, the doctor struggles in determining whose best interests are at stake –the parent who wants a “genetic connection” with a child sharing the same disability as the parent or the resulting child who will be afflicted with a genetic condition that could have been avoided.¹⁹⁴ Because the doctor could be inflicting harm in either instance, this section of the Oath does not offer much guidance and results in an ethical dilemma for a doctor.

B. Patient Autonomy

In ancient Greece, the physician-patient relationship was paternalistic according to most modern medical ethicists; the physician made decisions without consulting with the patient since patients were unable to handle bad news.¹⁹⁵ However, in today’s society, it is essential for the physician-patient relationship to include the patient in the medical decision-making process

¹⁹¹ See HARRY J. MANKIN, *supra* note 7.

¹⁹² See Tochi Amagwula et al., *supra* note 46.

¹⁹³ See *Skinner v. State of Okl. ex rel. Williamson*, 316 U.S. 535, 536 (1942); *Griswold v. Connecticut*, 381 U.S. 479, 486 (1965); *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); *Roe v. Wade*, 410 U.S. 113, 114 (1973).

¹⁹⁴ See Rosamund Scott, *supra* note 5.

¹⁹⁵ Steven H. Miles, *supra* note 181, at 125-126 (There is some disagreement between scholars; some scholars assert that ancient Greece did not promote medical paternalism).

through patient education, informed consent, and candid discussions about diagnosis and treatment.¹⁹⁶ There is now respect for patient's autonomy in medical decision-making.¹⁹⁷ Because of this need to respect patient autonomy, a physician must now balance this with his or her duty to provide the best possible care to patients while avoiding harm.¹⁹⁸ While it may be comfortable for some physicians working at fertility centers to take an ancient Greek, paternalistic approach with their patients who want to proceed with implantation of genetically defective embryos, they must be mindful that patient autonomy is important, especially with such a personal decision.¹⁹⁹

Personal decision-making, however, should not cause a physician to stray away from his duties under the oath. A reproductive endocrinologist indicated in an off-the-record interview that one of his patients, who had achondroplasia, told him that if he did not allow her to select embryos affected with achondroplasia for implantation, she would go to another clinic for IVF treatment but refuse PGD.²⁰⁰ She also said that she would undergo amniocentesis and threatened to abort any fetuses unaffected by achondroplasia.²⁰¹ Because the physician did not want to be responsible for a possible abortion, he proceeded with PGD.²⁰² As noted earlier, the main purpose of the oath is based on the promise to be a good physician and avoid harm.²⁰³ Making medical decisions because of duress seems to undermine the whole purpose of the oath.

¹⁹⁶ *Id.* at 126

¹⁹⁷ *Id.*

¹⁹⁸ *See id.*

¹⁹⁹ *See id.*

²⁰⁰ Kirsten Rabe Smolensky, *Creating Children with Disabilities: Parental Tort Liability for Preimplantation Genetic Interventions*, 60 HASTINGS L.J. 299, 305 (2008).

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ STEVEN H. MILES, *supra* note 181.

Although the Oath is still widely taken as noted earlier, its literal meaning deviates from the current state of medicine with respect to patients' autonomy.²⁰⁴ This can cause another obstacle for physicians when confronting complex ethical issues. For example, one section of the oath states, "*And likewise I will not give a woman a destructive pessary.*"²⁰⁵ In ancient Greece, vaginal pessaries, devices that are used to support the uterus or bladder and rectum, were commonly utilized.²⁰⁶ The type of pessary referred to in the Oath is one that caused an abortion.²⁰⁷ Although abortion was legal in ancient Greece, some argue that this passage is evidence of condemnation of abortion.²⁰⁸ During this time in Greece, women did not have the authority to make their own medical decisions; instead, their husbands or fathers made their medical decisions.²⁰⁹ "This dependence of women [on men] had profound implications for the physician-patient-guardian relationship in gynecology and can even be seen in the gynecological theories themselves."²¹⁰

Even though refusal to proceed with the implantation of genetically defective embryos is not the same as abortion, this passage from the Oath is relevant because of the progress in women's independence for gynecological matters. The decision to conduct PGD and ultimately whether or not to proceed with implantation of a genetically defective embryo is no longer the sole decision of a male as was the case in ancient Greece.²¹¹ By not allowing a patient to proceed with implantation of a genetically defective embryo, this could be viewed as reverting back to the paternalistic relationship between physicians and patients. Physicians involved in PGD

²⁰⁴ See *supra*, Section V.

²⁰⁵ *Id.* at 81.

²⁰⁶ *Id.* at 82; *Pessaries*, UCSF MED. CTR., <http://www.ucsfhealth.org/education/pessaries/> (last visited Nov. 27, 2014).

²⁰⁷ *Id.*

²⁰⁸ *Id.* at 81-82.

²⁰⁹ *Id.* at 85.

²¹⁰ *Id.* at 86.

²¹¹ See *id.* at 85.

should be conscious of this because imposing their personal decisions on a patient will deprive her of her autonomy. PGD should be a shared decision-making process between the patient, her partner or spouse (if applicable), and the doctor. The physician should, of course, intervene and not allow the patient's proposed suggestions if the harms in proceeding with the PGD significantly outweigh the benefits. Although the Oath is an ethical source of reliance for physicians, the aforementioned reasons highlight the struggle that physicians have when they try to fulfill their duties under the oath while still maintaining respect for patient's autonomy. Therefore, the Hippocratic Oath also offers inadequate guidance to physicians when facing PGD ethical dilemmas.

VI. Recommendations

Because professional organizations, experts in the field, and fertility clinics have not been specific with their approaches and opinions, definitive guidance is needed for PGD and the selection of genetically defective embryos. Accordingly, the recommendations to address the dilemma that can arise when a patient wants to pursue implantation of a genetically defective embryo are: the implementation of a robust ethics curriculum in medical school and residency, the implementation of comprehensive fertility clinic protocols, PGD reporting requirements, and fertility clinic team standardization.

A. PGD Reporting Requirements

Because no entity gathers data on PGD practices, the CDC should use this as an opportunity to take leadership and encourage clinics to provide PGD data.²¹² Although many clinics would find the extra data submission to be burdensome, the CDC could educate clinics

²¹² Susannah Baruch, *supra* note 82.

about the importance of transparency. The transparency on CDC's website about PGD indications would provide physicians with further guidance. The CDC could work with the accreditation agencies to ensure that the PGD data submission requirement is addressed during clinic inspections. Engaging multiple entities in the encouragement of PGD data submission will likely emphasize the importance of this practice.

B. Implementation of Robust Ethics Curriculum in Medical Schools and Residency

Since physicians have such differing approaches to PGD for the selection of genetically defective embryos, they are likely handling matters on an ad hoc basis as mentioned earlier.²¹³ In order to avoid this approach, it is essential that these ethical issues are addressed early in a physician's career and that fertility clinics are fully equipped to handle these matters. Tackling this issue of proper ethical decision-making during the initial training stages of a doctor's career is one way to address the PGD dilemma.

According to one survey, there lacks a uniform standard amongst medical schools for ethics-based courses.²¹⁴ In this study, surveys were sent to 125 U.S. medical schools and 16 Canadian medical schools to assess their overall ethics education.²¹⁵ Of the schools that participated in the survey, only 55% reported that an introductory course devoted to ethics existed in the curriculum.²¹⁶ Reasons for the deficiency in of ethics-based courses in medical school were attributable to: little time in the curriculum, not enough teachers available, and

²¹³ See *supra*, Section IV.B.i.

²¹⁴ Lisa Soleymani Lehmann et al. *A Survey of Medical Ethics Education at U.S. and Canadian Medical Schools*. 79 ACAD. MED. 682, 688 (2004), available at http://www.researchgate.net/publication/8473836_A_survey_of_medical_ethics_education_at_U.S._and_Canadian_medical_schools.

²¹⁵ *Id.*

²¹⁶ *Id.* at 683.

insufficient time in faculty members' schedules.²¹⁷ As previously mentioned, medical students undertake the Hippocratic Oath and promise to be good physicians.²¹⁸ Because medical school is the foundation for physicians' training, it is essential that doctors not only receive proper education in the sciences but also in ethics. If a medical school is not providing enough ethics-based courses or ethics training in its curriculum and during rotations, how will a medical student be fully equipped to be a "good physician?" Being a good physician does not necessarily mean only succeeding in medical school and advancing to clinical practice where one is able to correctly diagnose and treat patients. Being a good physician also requires one to understand ethical issues surrounding patient care and apply what he or she learned in ethics-based curriculum to a particular situation.

Implementing a robust ethics-based training program in medical school is not the only solution. During residency, ethics-based training should also be a priority. If medical schools are not providing this foundation, then medical residents will struggle as they have more frequent interactions and responsibilities with patients. Residency programs, especially in those fields where ethical issues tend to arise, should strive to incorporate ethics into the training. Johns Hopkins is one medical center that integrates a strong ethics curriculum in its surgery, pediatrics, and medicine residency programs.²¹⁹ Margaret Moon is an Assistant Professor of General Pediatrics and Adolescent Medicine and has been instrumental in creating the ethics program.²²⁰ She explained that attending surgeons provided positive feedback during the implementation phase of the ethics program and many of them agreed that ethical skills are just as important as

²¹⁷ *Id.* at 686.

²¹⁸ STEVEN H. MILES, *supra* note 181, at 3.

²¹⁹ *Current Empirical Work*, JOHNS HOPKINS BERMAN INST. OF BIOETHICS, <http://www.bioethicsinstitute.org/research/clinical-research/current-empirical-work> (last visited Dec. 3, 2014).

²²⁰ *Margaret Moon, MD, MPH*, JOHNS HOPKINS BERMAN INST. OF BIOETHICS, <HTTP://WWW.BIOETHICSINSTITUTE.ORG/PEOPLE/MARGARET-MOON-4> (last visited Dec. 3, 2014).

learning surgical skills.²²¹ Examples of the curriculum include ethics case-based discussions during noon conference, morning ethics conferences held seven to eight times each year, and weekly support groups facilitated by an attending physician where residents address ethical issues.²²² This program has been in place for five years and those participating residents have expressed an increase in their levels of confidence when dealing with patients and ethical issues.²²³ The more practice that residents have with ethics-related issues, the better equipped they will be when they are handling these matters alone after completion of their training and without the supervision of an attending physician.

C. Establishment of Comprehensive Fertility Clinic Protocols

The second recommendation involves ensuring that fertility clinics have implemented necessary protocols for PGD. The importance of policies and procedures are noted in a case study that concerned a resident intern at a French hospital who was involved in the care of an HIV positive man whose health had completely deteriorated.²²⁴ The patient was in septic shock and there was uncertainty as to whether or not his life support should be withdrawn.²²⁵ The attending physician took it upon himself to withdraw life support without consulting with the medical team or family and “project[ed] his own interests and values on the patient.”²²⁶ The commentary on this case study noted, “One cannot order a person to change his personality or to automatically stop believing in the paternalistic responsibilities of the physician. But one can

²²¹ *Maggie Moon: Teaching and Evaluating Ethics in Residency Training*, JOHNS HOPKINS BERMAN INST. OF BIOETHICS, <http://www.bioethicsinstitute.org/media/maggie-moon-teaching-and-evaluating-ethics-in-residency-training> (last visited Dec. 3, 2014).

²²² Department of Medicine: Educational Projects, JOHNS HOPKINS BERMAN INST. OF BIOETHICS, <http://www.bioethicsinstitute.org/research/clinical-research/ongoing-educational-programs/departement-of-medicine-educational-projects> (last visited Dec. 3, 2014).

²²³ *Maggie Moon*, *supra* note 221.

²²⁴ WARD ETHICS, *supra* note 163.

²²⁵ *Id.*

²²⁶ *Id.*

adopt policies or procedures...”²²⁷

While this case involves an HIV positive man and extreme circumstances that would hopefully never happen in the United States, it emphasizes the point that physicians should not impose their beliefs and values on their patients. Implementation of necessary policies and procedures would ensure that physicians would have to abide by standards rather than only making personal decisions for the patient. Of course, there will likely be unique situations that may not conform to the requirements of a protocol. In those instances, a physician should use the proper medical judgment and collaborate with other staff members. Furthermore, when creating these protocols, fertility clinics should rely on the input of all team members. For example, even though physicians are in the frontlines of care, they may not consider certain factors dealing with PGD that a fertility center scientist would consider. Because the team members have a diverse range of educational backgrounds and work experience, their collective input will allow for a protocol that will address a multitude of issues and scenarios dealing with PGD.²²⁸

Collaboration with internal team members is not the only way to establish comprehensive protocols. Although fertility clinics across the country technically are competitors, they should strive to work with one another by enhancing transparency across clinics. Clinics could achieve this by simply posting their procedures and protocols on their website. If clinics made their policies and consent forms more readily available, this would allow for greater collaboration between clinics in tackling the PGD ethical dilemmas. Clinics could also collaborate at conventions and present case studies to share their own experiences and how they handled PGD ethical dilemmas. Furthermore, the clinics could work with organizations like ACOG and ASRM

²²⁷ *Id.*

²²⁸ *See supra*, Section II.B.

to improve best practice guidelines so additional guidance on PGD for selection of genetically defective embryos is established.²²⁹

In the event that a particular case falls outside the scope of a policy or procedure, it could be referred to an ethics committee. At Albert Einstein College of Medicine's Montefiore Medical Center, any patients who request PGD for "family balancing" or sex selection that is not based on any medical indication, must have their case presented to the medical school's ethics committee.²³⁰ The committee balances the risks of PGD against the couple's justification for the procedure.²³¹ Until the committee makes a decision, there will be no treatment provided.²³² For fertility centers that are affiliated with an academic medical institution, this additional safeguard will provide them with further support in their decision-making process. This is similar to an Institutional Review Board, which is primarily responsible for ensuring that research involving human subjects is conducted appropriately and ensuring that subjects' rights are not compromised.²³³ If a patient wanted to proceed with PGD to select for genetically defective embryos, the ethics committee would assemble and review the patient's circumstances while taking the doctor's medical judgment into consideration.²³⁴ After the committee has carefully reviewed the case and completed a risk benefit analysis, it would provide its overall recommendation to the physician about how to proceed.²³⁵ Because revisions in policies often do not happen until circumstances arise that warrant the revisions, a particular case and the committee's suggestion could be helpful in making any necessary modifications to clinic

²²⁹ See *supra*, Section IV.A.

²³⁰ Harry Lieman and Andrzej Breborowicz, *Sex Selection for Family Balancing*, 16 AM. MED. ASS'N J. OF ETHICS VIRTUAL MENTOR 797, 800 (2014).

²³¹ *Id.*

²³² *Id.*

²³³ *Institutional Review Boards*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Guidances/ucml26420.htm> (last updated June 25, 2014).

²³⁴ See Harry Lieman and Andrzej Breborowicz, *supra* note 230.

²³⁵ *Id.*

protocols and policies.

In conclusion, ensuring the proper foundation in medical school and residency is not enough. Fertility clinics must also continue the necessary oversight through protocols to ensure that PGD is being performed in an ethically sound manner. Furthermore, clinics affiliated with academic medical centers should take advantage of the resources they already have to ensure that PGD issues are handled appropriately.

D. Fertility Clinic Team Standardization

Because there is a lack of uniformity in the composition of fertility team members across clinics, standardization requirements by accreditation agencies or states would foster a more collaborative approach to ethical issues encountered at fertility clinics. A standardized fertility team composition would ease the heavy decision-making burden on physicians for ethical dilemmas. Ensuring that professionals such as psychologists and bioethicists, who are not typically employed by or affiliated with fertility clinics, become a required component of fertility clinics would provide further guidance for physicians.²³⁶ This standardization requirement would likely bolster the credibility of expert opinions by other professionals involved in PGD whose expert opinions are not readily available in literature. If expert opinions by professionals not typically employed by or affiliated with fertility clinics were more readily available, physicians would have comprehensive guidance when dealing with PGD dilemmas. When accreditation agencies such as JACHO perform their surveys of fertility clinics, fertility team composition could be another required area to assess.²³⁷ If states also mandated standardized fertility clinic team members, the dual intervention would ensure adherence with requirements. While some

²³⁶ See *supra*, Section II.B.

²³⁷ See *The Fertility Clinic Success Rate and Certification Act*, *supra* note 83.

may disagree with the necessity of requiring professionals such as bioethicists at fertility clinics, the interdisciplinary approach would likely prove to be extremely beneficial for the fertility clinic providers on the frontlines of care.

VII. Conclusion

ART has enabled many people, incapable of conceiving, to become parents.²³⁸ Unfortunately, these new technologies raise many ethical concerns, and it is difficult to address all of these concerns through regulation.²³⁹ It is not surprising that some couples may use PGD to select genetically defective embryos in order to have a “genetic connection” to their children.²⁴⁰ Because PGD is a costly procedure that poses health risks to patients, physicians should strive to ensure safety for their patients, while still maintaining respect for their autonomy.²⁴¹

Unfortunately, many doctors are not prepared to handle complex ethical cases when a patient wants to use PGD to select genetically defective embryos. The current oversight framework of PGD and positions from professional organizations, experts in the field, and fertility centers provide little guidance.²⁴² Additionally, although there is vast range of health care professionals involved with PGD, many clinics across the country only employ physicians, scientists, nurses, and genetic counselors.²⁴³ Despite the fact that several professionals are involved with PGD, the heavy ethical decision-making burden seems to fall on physicians. Physicians owe a duty to their patients to be good physicians and this can be accomplished by being well rounded.²⁴⁴ By building a foundation in ethics during medical school and residency,

²³⁸ See *What is Assisted Reproductive Technology*, *supra* note 21.

²³⁹ Emily Jackson, *supra* note 71.

²⁴⁰ See Rosamund Scott, *supra* note 5.

²⁴¹ See Jennifer Uffalussy, *supra* note 28; *Ovulation Induction*, *supra* note 67.

²⁴² See *supra*, Section III.

²⁴³ See *About Us*, *supra*, note 62.

²⁴⁴ See STEVEN H. MILES, *supra* note 181, at 3.

physicians will be more prepared to handle these complex ethical issues.

Improving the ethics training during medical school and residency is not the only solution, however. Standardization of fertility center teams would also provide physicians with input from a diverse group of professionals, thereby eliminating independent decision-making for such complex ethical issues. Physicians could easily collaborate with all team members on such complex matters if they were all housed in the clinic. Additionally, fertility clinics affiliated with academic medical centers would greatly benefit if they consulted with the ethics committees.²⁴⁵ This collaboration would also allow for the proper implementation of comprehensive protocols and practices. Physicians would also benefit immensely from transparency between fertility clinics. Collaboration across clinics and with professional organizations would also further develop best practice guidelines. Lastly, the CDC should add data points about PGD on their website so physicians could easily refer to other clinic approaches for PGD indications. In conclusion, deploying each of the aforementioned recommendations would likely help physicians during PGD ethical dilemmas.

²⁴⁵ See Harry Lieman and Andrzej Breborowicz, *supra* note 230.