

INVOLUNTARY CLONING: A BATTERY

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Mr. and Mrs. Jon Jones desperately want a baby. They look forward to the joys of parenthood, but are fearful of having a child afflicted with cystic fibrosis—a disease that runs in both of their families. Would they have to adopt or face an abortion decision? Was there some magical procedure that could test their gametes or embryos formed *in vitro*?

INTRODUCTION

Couples like the Joneses and those plagued by infertility¹ have been turning to the latest reproductive technique, preimplantation genetic diagnosis (“PGD”), for answers.² The information supplied by PGD is utilized by couples and their *in vitro* fertilization (“IVF”) clinician to determine which embryos are to be implanted. By submitting to a series of processes that identify the existence of genes for targeted conditions, unaffected

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¹ A significant proportion of American society has problems of infertility. See Alexander N. Hecht, *The Wild Wild West: Inadequate Regulation of Assisted Reproductive Technology*, 1 HOUS. J. HEALTH L. & POL’Y 227, 230 (arguing that between ten and seventeen percent of American couples cannot procreate in the usual manner) (citing Kathryn Venturatos Lorio, *Alternative Means of Reproduction: Virgin Territory for Legislation*, 44 LA. L. REV. 1641 (1984)); Jason Christopher Roberts, *Customizing Conception: A Survey of Preimplantation Genetic Diagnosis and the Resulting Social, Ethical, and Legal Dilemmas*, 2002 DUKE L. & TECH. REV. 12, 12 (2002) (stating that more than sixteen percent of couples have difficulty conceiving a child); see also Am. Soc’y of Reprod. Med., *Quick Facts about Infertility*, at <http://www.asrm.com/Patients/faqs.html> (last visited Jan. 13, 2005) (infertility affects ten percent of population).

² See Jeffrey R. Botkin, *Ethical Issues and Practical Problems in Preimplantation Genetic Diagnosis*, 26 J. L. MED. & ETHICS 17, 17 (1998). Many women who have delayed having families find PGD particularly useful in screening for chromosomal abnormalities. *Id.* at 18; see also Richard J. Tasca & Michael E. McClure, *The Emerging Technology and Application of Preimplantation Genetic Diagnosis*, 26 J.L. MED. & ETHICS 7, 8 (1998).

embryos can be separated out and tagged for implantation in the intended mother.³

Formerly, chromosomal abnormalities or diseases, such as cystic fibrosis, were detected only by post-implantation methods, such as amniocentesis or chorionic villus sampling.⁴ Positive results from prenatal diagnostic testing required women to choose between birthing an infant not considered "healthy," or aborting the fetus. Both options present conundrums for many women. Thus, technology that allows for preimplantation diagnosis may be welcomed by some as a way of avoiding either circumstance. However, if PGD offers such great benefit, why is it recommended only where there is a risk of serious abnormality?⁵

One reason could be that this "state of the art" procedure is technically demanding, thereby requiring special expertise to be performed safely and accurately.⁶ Further, PGD and other

³ See M. Cathleen Kaveny, *Cloning and Positive Liberty*, 13 NOTRE DAME J.L. ETHICS & PUB. POL'Y 15, 22 (1999) (noting that a woman who is the intended mother need not be the progenitor of the human egg).

⁴ See Sherman Elias, *Preimplantation Genetic Diagnosis by Comparative Genomic Hybridization*, 345 NEW ENG. J. MED. 1569, 1569 (2001). Both these methods are generally considered "safe" despite the 0.5–1.0 percent of cases resulting in loss of the fetus. *Id.* at 1570; see also Tasca & McClure, *supra* note 2, at 7. Today, there is an additional method that samples fetal cells that are sloughed naturally from the developing fetus and circulate through the mother's bloodstream. Karen Sermon & Inge Liebaers, *Preimplantation Genetic Diagnosis and Screening, in REPRODUCTIVE MEDICINE: MOLECULAR, CELLULAR AND GENETIC FUNDAMENTALS* 515, 517 (Bart C.J.M. Fauser et al. eds., 2003) (discussing uterine lavage). This new procedure is non-invasive. Therefore, unlike amniocentesis, it does not put developing fetuses at risk of being aborted.

⁵ Roberts, *supra* note 1, at 28. Currently, most clinicians agree that the process should only be used to diagnose the most seriously impaired embryos. *Id.*

It is unlikely that future use of PGD will be confined to the identification of serious abnormality in the targeted embryo. As use of genetic technologies increases, it will become more difficult to restrain its use. Notions of what is normal and what is enhancement will evolve and standards will become less clear, governed by a goal of painless and immortal existence. See Leon R. Kass, *Triumph or Tragedy? The Moral Meaning of Genetic Technology*, 45 AM. J. JURIS. 1, 11 (2000). Ironically, Kass notes that the "utopian project will not eliminate suffering but merely shift it around." *Id.* at 12. He points out that despite medical advancements that have attained the goal of prolonging life and alleviating suffering, satisfaction has not improved. *Id.*

⁶ E. Kanavakis & J. Traeger-Synodinos, *Preimplantation Genetic Diagnosis in Clinical Practice*, 39 J. MED. GENETICS 6, 6 (2002), available at <http://jmg.bmjournals.com/cgi/content/full/39/1/6?maxtoshow=&HITS=10&hits=1&RESUL>. (last visited Jan. 13, 2005). It is unclear whether PGD has advanced from the experimental stage toward standard practice. See Erik Parens & Lori P. Knowles, *Reprogenetics*

assisted reproductive technologies (“ART”) have become “big business”⁷ despite having bypassed the normal research and testing phase.⁸ Despite the mixed evaluations of its safety, PGD has been gaining popularity⁹ and may soon be considered safe enough for more widespread use.

Even if considered safe and accurate,¹⁰ PGD poses additional ethical constraints that may limit its application.¹¹ In the

& *Public Policy: Reflections and Recommendations*, 33 HASTINGS CENTER REPORT S1, S6–S7 (2003) (urging limits similar to those in other countries); Moshe Zilberstein & Mabelle M. Seibel, *Preimplantation Genetics and Preimplantation Diagnosis*, in INFERTILITY: A COMPREHENSIVE TEXT 761, 764–65 (Mabelle M. Seibel ed., 2d ed. 1997) (“In reproductive medicine, more than most other areas of medical practice, the line between clinical innovation and human experimentation is fuzzy; Consequently, reprogenetics raises concerns about the safety.”).

⁷ ART is a four billion dollar industry. Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past-Present, and Future?*, 36 CONN. L. REV. 125, 191 (2003); Roberts, *supra* note 1, at 1. Because ART involves experimentation with human embryos, it is ineligible for federal funding. Therefore, the government has no oversight over the manner in which the experimental procedures are performed. There is no need for approval from an institutional review board, which would review the research protocol and the documents providing informed consent. *Id.*; see also Tasca & McClure, *supra* note 2, at 8.

⁸ Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 617–18 (2003). Because there is no research and testing phase, ART clinics began using techniques without studying the health consequences on the resulting children. Robin Fretwell Wilson, *Uncovering the Rationale for Requiring Infertility in Surrogacy Arrangements*, 29 AM. J.L. & MED. 337, 343 (2003). Studies revealed a significant increase in major birth defects following ART. *Id.* at 343–46.

⁹ PGD became feasible in the 1980s. See Kanavakis & Traeger-Synodinos, *supra* note 6, at 6. This is amazing considering the first successful *in vitro* fertilization baby was not born until 1978. See William W. Bassett, *Private Religious Hospitals: Limitations Upon Autonomous Moral Choices in Reproductive Medicine*, 17 J. CONTEMP. HEALTH L. & POL’Y 455, 513 (2001).

By 1996, PGD was utilized in very few American centers, and only to detect severe genetic conditions such as Tay Sachs disease and cystic fibrosis. Only 40 children whose embryos had been subjected to embryo biopsy were born worldwide. John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 452 (1996). By 1997, there were thirty centers world-wide that offered the procedure, which resulted in over one hundred births. Kangpu Xu, *Preimplantation Genetic Diagnosis (PGD)*, in AN ATLAS OF HUMAN GAMETES AND CONCEPTUSES: AN ILLUSTRATED REFERENCE FOR ASSISTED REPRODUCTIVE TECHNOLOGY 97 (Lucinda L. Veeck ed., 1999). This number has increased to almost 400 births by 2001. David Cram & David de Kretser, *Genetic Diagnosis: the Future*, in ASSISTED REPRODUCTIVE TECHNOLOGY: ACCOMPLISHMENTS AND NEW HORIZONS 186, 195 (Christopher J. De Jonge & Christopher L.R. Barratt eds., 2002).

¹⁰ It may be hard to get a true picture of its accuracy since false positives are likely to be unacknowledged. Andrea Bonnicksen, *Genetic Diagnosis of Human Embryos*, in LIFE CHOICES: A HASTINGS CENTER INTRODUCTION TO BIOETHICS 407, 410 (Joseph H. Howell & William F. Sale eds., 2d ed. 2000).

forefront are concerns about eugenics¹² and genetic discrimination.¹³ If PGD permits only "healthy" embryos to be

¹¹ John Robertson has suggested that the main objections to PGD are the burdens on women, the impact on embryos, and the potential for abuse by extension to less serious conditions. Robertson, *supra* note 9, at 449; *see also* Joseph D. Schulman et al., *Preimplantation Genetic Testing for Huntington Disease and Certain Other Dominantly Inherited Disorders*, in *CLINICAL GENETICS* (1996), reprinted by Genetics & IVF Inst., <http://www.givf.com/pgthuntingtonv.cfm> (last visited Jan. 13, 2005) (noting that PGD is recommended for at-risk couples to screen out embryos free of the gene for Huntington's disease, affecting only adults); MAXWELL J. MEHLMAN, *WONDERGENES: GENETIC ENHANCEMENT AND THE FUTURE OF SOCIETY* 30, 56 (2003) (PGD is already being used to eliminate embryos with genes for late-onset diseases and will become important to select for genetic enhancement). A problem with the application of PGD for genetic enhancement is the inability to assess the benefit in light of offsetting harms. *Id.* at 81.

Other concerns relate to a variety of important moral and ethical issues. For example, there is great concern over inefficient resource allocation. *See* Vicki G. Norton, *Unnatural Selection: Nontherapeutic Preimplantation Genetic Screening and Proposed Regulation*, 41 *UCLA L. REV.* 1581, 1610 (1994); Roberts, *supra* note 1, at 23–24 (2002). Another relates to sanctity of life issues such as whether one is obliged to transfer all IVF-produced embryos. Guido de Wert, *Ethics of Assisted Reproduction*, in *REPRODUCTIVE MEDICINE: MOLECULAR, CELLULAR AND GENETIC FUNDAMENTALS* 645, 650 (Bart C.J.M. Fauser et al. eds., 2003). There is grave concern that more embryos are created when PGD will be employed. Jeffrey Botkin, for example, raised the issue of informed consent concerns as an ethical issue with respect to the use of PGD. Botkin, *supra* note 2, at 21. "Genetic diversity may be affected." Bonnicksen, *supra* note 10, at 410. Other concerns include the impact on the gene pool. *See* Peter H. Huang, *Herd Behavior in Designer Genes*, 34 *WAKE FOREST L. REV.* 639, 658 (1999) (applying game theory to demonstrate how to positively influence parental reprobogenic choice).

¹² *See* Botkin, *supra* note 2, at 20, 25–26; Rebecca Knox, *Preimplantation Genetic Diagnosis: Disease Control or Child Objectification?* 22 *ST. LOUIS U. PUB. L. REV.* 435 (2003) (discussing discrimination and objectification of children); Cram & de Kretser, *supra* note 9, at 195 (noting that PGD is likely to be used in detecting desirable physical and social traits). PGD impacts germ-line therapy and genetic enhancement. *Id.*; *see also* Robertson, *supra* note 9, at 450–52. Germ-line manipulation, issues of genetic discrimination, decreasing genetic diversity, and the reduction of human dignity are all issues that relate to increased manipulation of the human genome on the international scale. Jennifer Elle Tauer, *International Protection of Genetic Information: The Progression of the Human Genome Project and the Current Framework of Human Rights Doctrines*, 29 *DENVER J. INT'L L. & POL'Y* 209, 224–28 (2001). Genetic determinism, which places such great weight on the effect of a particular genome, links PGD to eugenics. Barbara Katz Rothman, *Not All That Glitters Is Gold*, in *LIFE CHOICES: A HASTINGS CENTER INTRODUCTION TO BIOETHICS* 423, 430 (Joseph H. Howell & William F. Sale eds., 2d ed. 2000).

¹³ Roberts, *supra* note 1, at 13–16. Jeffrey Botkin, for example, raised the issue of informed consent concerns as an ethical issue with respect to the use of PGD. Botkin, *supra* note 2, at 22 (addressing the rejection of those with disabilities). *But see* Robertson, *supra* note 9, at 452. Professor Robertson does not believe that PGD is likely to be used with sufficient frequency to "affect gender role ratios, cause discrimination against women or persons with disabilities, or lead to other

implanted, then those who are born with conditions that would ordinarily be selected for discard could be viewed as inferior. This could give rise to a genetic class structure that would be exacerbated by the inability of lower-income individuals to have access to the very technology that could improve their status.¹⁴ The fact that IVF yields as many as fifteen embryos¹⁵ allows parents who can afford the technology to significantly improve their chances to have an offspring with desirable traits—especially as PGD becomes available to a wider scope of conditions. This raises several additional concerns. One of these is the widening gap between those who can afford the technology and those who cannot.¹⁶ Another relates to an extension of the view that the existence of reproductive technology causes women to be exploited,¹⁷ children commodified,¹⁸ and reproduction dehumanized.¹⁹ Yet another is the pressure on parents who can

untoward consequences.” *Id.* Prof. Robertson has been involved in the PGD debate from the very beginning and has been a member of the American Society for Reproductive Medicine (“ASRM”) (or its precursor, the American Fertility Society (“AFS”)) since embryo biopsy was announced in 1990.

¹⁴ Norton, *supra* note 11, at 1611–13.

¹⁵ See LORI B. ANDREWS, ET AL., GENETICS: ETHICS, LAW AND POLICY 291 (2002). Problematic is the neglect of the potential health problems to women resulting from the massive stimulation of the ovaries that is done to produce an overabundance of embryos from which to select the most perfect. Regine Kollek, *Technicalisation of Human Procreation and Social Living Conditions*, in THE ETHICS OF GENETICS IN HUMAN PROCREATION 139, 145 (Hille Haker & Deryck Beyleveld, eds. 2000).

¹⁶ Maura Ryan, *Creating Embryos for Research: On Weighing Symbolic Costs*, in CLONING AND THE FUTURE OF HUMAN EMBRYO RESEARCH 50, 58 (Paul Lauritzen ed. 2001); Botkin, *supra* note 2, at 18 (stating that PGD may become a “boutique service” in the commercial market); Maxwell Mehlman, *The Law of Above Averages: Leveling the New Genetic Enhancement Playing Field*, 85 IOWA L. REV. 517, 534, 591 (2000); Roberts, *supra* note 1, at 5.

¹⁷ See, e.g., Michael Prowse, *Ethical Decisions Must be Made Before Science Forces Them on Us*, FINANCIAL TIMES (LONDON), July 5, 2003, at 13 (stating that humans are becoming instrumentalized with the help of practitioners).

¹⁸ ROBERT BLANK & JANNA C. MERRICK, HUMAN REPRODUCTION, EMERGING TECHNOLOGIES, AND CONFLICTING RIGHTS 15–17 (1995); Barry Nelson, *Happy Families by Design*, NORTHERN ECHO, June 20, 2003, at 10 (on reserve with author); Vicki Norton, *Allowing Parents to Genetically Screen Embryos is Unethical*, in REPRODUCTIVE TECHNOLOGIES 115, 118–19 (Carol Wekesser et al. eds., 1996) (non-therapeutic exploitation compared to slavery); Norton, *supra* note 11, at 1604, 1610 (implying that children are used as commodities based on selecting specific traits or because of tissue-match potential); Roberts, *supra* note 1, 23–24.

¹⁹ Kass, *supra* note 5, at 10. Kass notes that under the guise of “benevolent humanitarianism,” reproduction is moving from procreation to manufacture. Reducing the embryo to a “product” enables control over it to be transferred among interests, including economic ones. Procreation is thereby dehumanized and nascent

afford the technology to use it to the fullest extent possible to avoid being seen as “neglectful” toward their children.²⁰ Will there be additional pressure from insurance lobbies or government for couples at risk to refrain from producing offspring with serious disabilities?²¹

Although the current ethos is to offer PGD only where there is a risk of serious abnormality, its use has already been expanded. PGD has been utilized to select embryos for their matching-tissue stem cells.²² It has also been used for gender selection.²³ It is conceivable that reproduction rights advocates will press for PGD application in a variety of contexts: less

human life has been commodified. *Id.* See also Owen D. Jones, *Allowing Parents to Genetically Screen Embryos Can Be Ethical*, in REPRODUCTIVE TECHNOLOGIES 138, 139 (Carol Wekesser et al. eds., 1996). ART's focus on “product” rather than “process” makes the distinction between reproduction and production disappear. *Id.*

²⁰ See George Annas, *Turning Point for the Human Species*, TRIAL 24, 27–29 (July 2001) (discussing parental incentive to utilize some “cloning technique” (presumably PGD) to make their children “better”). See also Sonia Mateu Suter, *The Routinization of Prenatal Testing*, 28 AM. J.L. & MED. 233, 255 (2002) (where the routinization of prenatal testing results in an “illusion of choice” as what should be an option becomes more like an imposition). *But see* Robertson, *supra* note 9, at 452 (doubting that many will take advantage of PGD for trait selection).

²¹ Anita Cecchin, *Genetic Screening of Embryos: An Overview*, in REPRODUCTIVE TECHNOLOGIES 111, 113 (Carol Wekesser et al. eds., 1996).

²² ANDREWS, *supra* note 15, at 291. Several children have been conceived with the specific purpose of producing a child whose tissue would have a great potential for matching that of a diseased sibling. LYNDIA BECK FENWICK, PRIVATE CHOICES, PUBLIC CONSEQUENCES: REPRODUCTIVE TECHNOLOGY AND THE NEW ETHICS OF CONCEPTION, PREGNANCY, AND FAMILY 166–69 (1998) (chronicling the genetically engineered matches for Anissa Ayala and Natalie Curry). In 2000, parents Lisa and Jack Nash utilized PGD in conjunction with IVF to assure a proper tissue match for their daughter, who suffered from Fanconi anemia. ANDREWS, *supra* note 15, at 291–92. See also Susan M. Wolf, Jeffrey P. Kahn, & John E. Wagner, *Using Preimplantation Genetic Diagnosis to Create a Stem Cell Donor: Issues, Guidelines & Limits*, 31 J.L. MED. & ETHICS 327 (2003) (discussing the implications of utilizing pre-implantation HLA-matching).

²³ Gina Kolata, *Ethics Specialist Supports Some Sex Selection*, MIAMI HERALD, Sept. 28, 2001, at 13A. The Genetics & IVF Institute, which offers PGD services, advertises gender selection for gender balancing. See Genetics & IVF Inst., *Preimplantation Genetic Diagnosis for Family Balancing*, at http://www.givf.com/gender_selection.cfm (last visited Jan. 13, 2005). ASRM ethics committee chair John Robertson clarified that the Society's position on gender selection had changed from “discouraged” in 1999 to “acceptable,” at least insofar as it allowed the couple to select an embryo that was the opposite sex than its “sibling.” Kolata, *supra*, at 13A. Currently, PGD solely for selecting an offspring's gender is being offered by clinics. Helen M. Alvare, *The Case for Regulating Collaborative Reproduction: A Children's Rights Perspective*, 40 HARV. J. ON LEGIS. 1, 23–24 (2003); June Mary Zekan Makdisi, *Genetically Correct: The Political Use of Reproductive Terminology*, 32 PEPPERDINE L. REV. 1, 31–32 (2004).

serious illnesses, late-onset diseases, and, as genes are identified for merely desirable traits, for those as well.²⁴

Hidden among all these weighty concerns and overshadowed by them is yet another troubling issue: the process that permits preimplantation genetic diagnosis requires the separation and destruction of a totipotent cell²⁵ that itself has the potential to develop into a separate human being.²⁶ This creation of what some have classified as a “clone” or “twin” is controversial—that it occurs with knowledge of impending destruction likewise raises troubling moral and ethical concerns.²⁷ This Article addresses this issue and analyzes it in the legal context of consent.

Part I provides an overview of the medical procedures relating to embryo biopsy, preimplantation diagnosis, and the consequent creation of a blastomere clone. Part II describes a framework for the application of consent to PGD.²⁸ Finally, based on the criteria needed for consent, the article analyzes whether clinicians who fail to provide information that a clone is

²⁴ See MAXWELL J. MEHLMAN, WONDERRGENES: GENETIC ENHANCEMENT AND THE FUTURE OF SOCIETY 56 (2003). PGD is already being used to avoid implanting embryos with late-onset Huntington disease as well as genetically caused Alzheimer's. *Id.* at 56, 174. Although trait-enhancement is not now available through PGD, evidence of its use for that purpose should such genetic tests be developed is likely given the interest in obtaining gametes from humans with desirable traits. *See id.* at 56.

²⁵ See MOSBY'S NURSING & ALLIED HEALTH DICTIONARY 1728 (6th ed. 2002) [hereinafter MOSBY'S] (describing totipotency as “the ability of a cell, particularly a zygote, to differentiate into any of a number of specialized cells and thus form a new organism or regenerate a body part”).

²⁶ See *infra*, notes 63–67 and accompanying text.

²⁷ See William FitzPatrick, *Surplus Embryos, Nonreproductive Cloning, and the Intend/Foresee Distinction*, HASTINGS CENTER REP. 29, 29–30 (May-June 2003). The article indicates that some believe that creating clones for research purposes is indistinguishable from the creation of embryos in the IVF setting. The author disagrees. In IVF, the purpose is to create embryos for reproductive purposes. That some will be destroyed is merely foreseeable, but not intended. Thus, by operation of the principal of double effect, it may be ethically sound. See A.B. Shaw, *Two Challenges to the Double Effect Doctrine: Euthanasia and Abortion*, 28 J. MED. ETHICS 102, 102 (2002) (explaining that the principle of double effect morally allows actions with both good and bad effects). By contrast, no double effect applies to embryos created for research purposes. It is not merely foreseeable that some will be destroyed. All will be destroyed; the intent cannot be to reproduce. See FitzPatrick, *supra*, at 30–31. This has direct application to PGD. Once the totipotent cell is separated from its “parent” embryo, it is certain to be destroyed because it cannot survive the testing process.

²⁸ See Botkin, *supra* note 2, at 25.

formed during the PGD process expose themselves to liability in negligence, under a theory of lack of informed consent, or in battery, based on the absence of consent.

I. WHAT IS PGD AND HOW IS IT ACCOMPLISHED?

Preimplantation genetic diagnosis, originally developed as an extension of prenatal diagnosis,²⁹ is possible because of IVF technology.³⁰ While the aims of IVF are to join eggs and sperm outside the human body, the aim of PGD is to evaluate those embryos and, on that basis, to select the most desirable embryos for transfer.³¹ Initially, the purpose of PGD was to diagnose—and thereby eliminate—embryos with serious genetic diseases.³² The only diseases that have the chance of being detected are those for which tests have been developed and applied during the PGD process.³³ To accomplish the diagnosis, two steps must be performed: the removal of a portion of the IVF-produced embryo, and the application of a diagnostic test.³⁴

A. Embryo Biopsy

The removal process is typically described as performing a “biopsy”³⁵ on the embryo—either a “blastomere biopsy,” or

²⁹ Elias, *supra* note 4, at 1570.

³⁰ Xu, *supra* note 9, at 97.

³¹ de Wert, *supra* note 11, at 650.

³² Jeffrey R. Botkin, *Prenatal Diagnosis and the Selection of Children*, 30 FLA. ST. U. L. REV. 265, 280–81 (2003). The technology allowed couples to potentially avoid facing an abortion decision if PGD accurately diagnosed genetic disease prior to implantation. *Id.*

³³ Botkin, *supra* note 2, at 19. The accuracy rate varies. It has been estimated that between 10–20% of the tests are unsuccessful either because of unsuccessful PCR amplification (10%), allelic drop out when the DNA of single blastomeres are amplified (20%), or because of the technical difficulties of the FISH technique that is used for detecting chromosomal abnormalities (15%). Kanavakis & Traeger-Synodinos, *supra* note 6, at 8.

³⁴ See Kanavakis & Traeger-Synodinos, *supra* note 6, at 6–7.

³⁵ Magdalena Bielanska et al., *Chromosomal Information Derived from Single Blastomeres Isolated from Cleavage-Stage Embryos and Cultured In Vitro*, 79 FERTILITY & STERILITY 1304, 1304–05 (2003).

It is also possible to apply testing to blastocysts that were fertilized *in utero*. Before the blastocysts have implanted into the womb, they are washed from the uterus and “tested.” Sermon & Liebaers, *supra* note 4, at 517 (arguing that uterine lavage is disappointing because of the paucity of cells collected). Embryos without the undesirable characteristics are reinserted into the womb for normal growth and development. Because only naturally sloughed cells are subject to testing, no totipotent cells are removed. Thus, the moral issues relating to blastomere

“cleavage-stage biopsy.”³⁶ This occurs on the second or third day post *in vitro* fertilization, when the embryo has developed into a mass of between six and ten cells.³⁷ An opening is made in the zona pellucida that surrounds the developing embryo, and one or two of the cells—known as blastomeres—are removed.³⁸ While several removal techniques currently exist, the method first employed—aspiration through a micropipette³⁹—is still the most popular.⁴⁰

separation do not attach.

³⁶ LUCINDA L. VEECK, AN ATLAS OF HUMAN GAMETES AND CONCEPTUSES: AN ILLUSTRATED REFERENCE FOR ASSISTED REPRODUCTIVE TECHNOLOGY 193 (1999) (blastomere biopsy); Sermon & Liebaers, *supra* note 4, at 516 (cleavage-stage biopsy). On day one of *in vitro* fertilization, the sperm is combined with the egg. The penetrating sperm and oocyte (or egg) chromosomes come together as pronuclei surrounded by a nuclear membrane. The pronuclei then fuse, forming a single nucleus contained in the single-celled embryo, called a zygote. The zygote is unlike either the haploid egg, with its 23-chromosomal component, or the haploid sperm, with its haploid chromosomal component. The zygote has again become diploid, like each of its parents, with the full complement of 46 chromosomes. But the zygote's chromosomal component, that was derived from each biological parent, is unique. The zygote then grows by mitosis, which is the same process of dividing that occurs in all other somatic cells. Two diploid daughter cells are formed, each of which is called a blastomere. Each of these mitotic divisions that are part of the developmental process of the embryo is called a cleavage division. See Zilberstein & Seibel, *supra* note 6, at 763.

³⁷ See VEECK, *supra* note 36, at 193; Sermon & Liebaers, *supra* note 4, at 516–17 (arguing that there are seven or more cells); see also MARJORIE A. ENGLAND, LIFE BEFORE BIRTH 4 (2nd ed. 1996) (describing the stages of embryonic development).

³⁸ See VEECK, *supra* note 36, at 193; Sermon & Liebaers, *supra* note 4, at 516–17. Twenty-five percent of the embryo's cell mass can be safely removed. This can amount to one blastomere from a 4-cell stage, or up to 2 from an embryo at the 8-cell stage. Zilberstein & Seibel, *supra* note 6, at 767; see also Alan R. Thornhill & Karen Snow, *Molecular Diagnostics in Preimplantation Genetic Diagnosis*, 4 J. MOLECULAR DIAGNOSTICS 11, 13 (2002), available at <http://jmd.amjpathol.org/cgi/content/full/4/1/11> (last visited Jan. 13, 2005). Blastomeres are generally aspirated out through a glass micropipette attached to a suction system. *Id.* (providing an exhaustive description of the various techniques of PCR, FISH, and whole genome hybridization techniques).

³⁹ Elias, *supra* note 4, at 1570. Alan H. Handyside, a pioneer in the field, reported the technique in 1989. *Id.* at 1570–71, 1571 n.3. He and his colleagues described the sexing of preimplantation embryos at risk for a sex-linked disease followed by the births of several female, healthy babies. *Id.*

Professor Scott describes an inherent flaw in using law to resolve ethical dilemmas. A result is that legal rules establish minimum conduct while ethical ideals are likely to be lost. The focus turns away from an ethical resolution and toward avoiding the legal “punch” received when conduct falls below the legally minimal standard. Charity Scott, *Why Law Pervades Medicine: An Essay on Ethics in Health Care*, 14 NOTRE DAME J.L. ETHICS & PUB. POL'Y 245, 245, 273–74, 295–96 (2000). When applied to manipulations of the early embryo, the ethical standard of

B. Diagnostic Testing

Once the blastomere is removed, it is prepared for diagnostic testing⁴¹ for one of three major categories⁴² of genetic disease: sex-linked diseases (such as Duchenne's muscular dystrophy), chromosomal disorders (such as Down's syndrome), or single gene mutations (such as cystic fibrosis and sickle cell anemia).⁴³

"respect" becomes meaningless. In its place arises the legal rule which does not punish manipulation of embryos unless the embryo has attained the developmental age of 14 days, which also corresponds to the time of implantation.

⁴⁰ Sermon & Liebaers, *supra* note 4, at 516.

⁴¹ Currently, there are at least 48 PGD-testable conditions including achondroplasia (dwarfism), Franconi's anemia, spinal/bulba muscular atrophy, Becker's muscular dystrophy, hemophilia A and B, phenylketonuria, early-onset Alzheimer's, Gaucher's disease, Marfan's syndrome, Fragile X syndrome and Thalassemia. Luca Gianaroli et al., *Preimplantation Genetics in Human Embryology*, in BIOTECHNOLOGY OF HUMAN REPRODUCTION, 301, 304 (Alberto Revelli et al. eds., 2003).

Genetic diagnosis of a polar body, which is a small cell that is naturally shed by the much larger oocyte during meiotic division, may be performed instead. Thornhill & Snow, *supra* note 38. Information provided by genetic testing of the biopsied polar body does not include an assessment of the male's genetic contribution to an embryo produced with the egg that shed the polar body. Because polar body biopsy does not involve totipotent cells, *see id.*, none of the issues discussed in this paper are impacted by polar body biopsy.

⁴² Frances A. Flinter, *Preimplantation Genetic Diagnosis: Needs to be Tightly Regulated*, 322 BMJ 1008-09 (2001), available at <http://bmj.com/cgi/content/full/322/7293/> (last visited Jan. 13, 2005). See Norton, *supra* note 11, at 1588-92 (providing an excellent and understandable biological description of the origins of genetic diseases).

⁴³ Flinter, *supra* note 42, at 1009; Xu, *supra* note 9, at 98-99. Other sex-linked diseases that can be detected by FISH include Lesch Nyhan syndrome. Other conditions related to improper chromosomal number include Turner syndrome, which can appear when only one "X" chromosome is present. Other autosomal recessive disorders, or those related to single gene mutations, include Tay Sachs disease, Rh D blood typing, thalassemia, and sickle cell anemia. Joy D. A. Delhanty et al., *Genetic Diagnosis Before Implantation: Applications of the Technique are Growing*, 315 BMJ 828 (1997), available at <http://bmj.com/cgi/content/full/315/7112/828> (last visited Jan. 13, 2005). Not long ago an embryo was tested for the Alzheimer's gene. Several ethical issues surrounded the case. First, PGD was supposed to be performed only on embryos at risk for serious disease. Here, if permitted to survive, the condition would appear only after several decades. Second, some questioned whether any parent who themselves would succumb to the genetically caused early-onset Alzheimer's disease should utilize ART to create a child that they would be unable to care for. Jerome Groopman, *Designing Babies*, WALL ST. J., Mar. 4, 2002, at A14. See generally Tasca & McClure, *supra* note 2, at 9-10 (describing cystic fibrosis, Tay-sachs disease, Duchenne's, fragile X syndrome, and Down syndrome).

There is some disagreement as to whether PGD is considered experimental or standard of care. Fertility specialists seem to consider PGD standard practice. See Thornhill & Snow, *supra* note 38, at 11, 11 n.147. Current medical textbook authors

Sex-linked conditions may be eliminated by implanting only female embryos.⁴⁴ Thus, embryos containing the male “XY” chromosomal pairing are eliminated, while embryos containing the female “XX” pairing are selected for possible implantation.

In order to examine the genetic or chromosomal components of the blastomere, its DNA must be removed, thereby destroying the cell.⁴⁵ To check for chromosomal abnormality, fluorescent “probes” are added to the DNA and coaxed to bind with specific chromosomes in a technique called “fluorescence *in situ* hybridization” (“FISH”).⁴⁶ The fluorescent markers make the targeted chromosomes readily visible, thereby enabling researchers to determine the sex as well as whether the chromosomes targeted for inspection have been properly paired.⁴⁷ Inappropriate pairings (such as “X” or “XXY” instead of “XX” or “XY”), called “aneuploidy,”⁴⁸ are responsible for causing conditions such as Down’s syndrome.⁴⁹ Noting an absence of chromosomal abnormality in a blastomere suggests that its

and some others seem to feel it is still experimental. *See, e.g.*, de Wert, *supra* note 11, at 656; Botkin, *supra* note 2, at 18. There is no consensus on which of the various mutation detection strategies should be used to evaluate the presence of any particular disease, even among those who consider PGD a standard of care. *See* Thornhill & Snow, *supra* note 38, at 24–25.

⁴⁴ *See* R.G. Edwards & Ruth E. Fowler, *Human Embryos in the Laboratory*, 223 *SCI. AM.* 4454 (1970); Sermon & Liebaers, *supra* note 4, at 516 (first clinical use of PGD was on sex embryos who were at risk of having sex-linked diseases).

⁴⁵ de Wert, *supra* note 11, at 650; Rebecca Kolberg, *Human Embryo Cloning Reported*, 262 *SCIENCE* 652, 653 (1993); Fr. Germain Kopaczynski, *Preimplantation Genetic Diagnosis*, 27 *ETHICS & MEDICS* 1, 1 (2002).

⁴⁶ *See* NHGRI Fact Sheet, *Fluorescence In Situ Hybridization (FISH) available at* http://www.accessexcellence.org/RC/VL/GG/nhgri_PDFs/fish_TXT.pdf (last visited Jan. 13, 2005).

⁴⁷ Gianaroli et al., *supra* note 41, at 303. Utilizing the FISH technique enables the examination of about nine chromosomes, including the sex chromosomes X and Y, as well as 13, 15, 16, 18, 21, and 22. *Id.* FISH also enables the detection of other chromosomal abnormalities such as translocations and inversions. Flinter, *supra* note 42, at 1009. New approaches seek to analyze the entire chromosomal complement via comparative genomic hybridization (“CGH”). Inge Liebaers & Joe Leigh Simpson, *Genetic Counseling in Reproductive Disorders*, in *REPRODUCTIVE MEDICINE: MOLECULAR, CELLULAR AND GENETIC FUNDAMENTALS* 497, 510 (Bart C.J.M. Fauser et al. eds., 2003). In CGH, the entire genome is amplified and compared with a control cell’s DNA. Each is labeled with a different fluorescent marker before amplification. If the colors of any of the chromosomes are not in a 1:1 proportion following amplification, it indicates that the chromosome is aneuploid and, therefore, abnormal. *Id.*

⁴⁸ *See* MOSBY’S, *supra* note 25, at 95 (stating that aneuploidy is “any variation in chromosome number that involves individual chromosomes”).

⁴⁹ Xu, *supra* note 9, at 97 (discussing a trisomy of chromosome 21).

embryonic twin would also be free of the abnormality.⁵⁰ Therefore, the embryos from which those blastomeres were derived are the ones selected for implantation. Presently, the largest category of chromosomal abnormality generating the use of FISH techniques constitutes women whose age causes them to be at a greater risk of producing eggs with chromosomal abnormalities.⁵¹

Inspecting for single-point mutations parallels the methodology used in crime labs. Once the DNA is extracted from a blastomere, sections of the DNA molecule, in which the mutation under investigation would appear, are amplified over a billion times by the polymerase chain reaction ("PCR") process.⁵² Again, if the blastomere is diagnosed with the condition, then its embryonic twin is also expected to be affected. Only embryos corresponding to unaffected blastomeres are likely to be selected for implantation.

C. Physical Intervention Related to PGD and the Nature of the Consent Given

As described above, significant physical intervention occurs in connection with PGD. Women must endure dangerous

⁵⁰ Occasionally, mosaicism exists whereby the embryonic chromosomal component is paired differently than its removed blastomere. Sermon & Liebaers, *supra* note 4, at 516. Thus, to assure the non-existence of a particular set of conditions, pre-natal, *in utero* testing might still need to be performed.

⁵¹ Kanavakis & Traeger-Synodinos, *supra* note 6, at 6-7 (placing the amount at about half). Women are born with a complete set of eggs. Unlike sperm, which are produced cyclically, a woman's eggs are as old as the woman. As the mechanism that directs meiotic division during egg ripening also ages, mistakes are more likely. Thus, during meiotic division, chromosomes do not always separate properly. Chromosomal abnormalities may also be tested before an embryo is created. During the meiotic division whereby an egg is created, smaller polar bodies are naturally discarded. These also contain the equivalent genetic material and may be tested instead of the severed blastomere. See Inst. for Reprod. Med. & Sci. of Saint Barnabas, *Preimplantation Genetic Diagnosis (PGD) for Aneuploidy*, at http://www.s bivf.com/pgd_aneuploidy.htm (last visited Jan. 13, 2005).

⁵² Gianaroli et al., *supra* note 41, at 303; Xu, *supra* note 9, at 98 (detailing how PCR is used to detect single-gene mutations). The blastomere is placed in a microcentrifuge tube, which contains a chemical solution that aids in extracting the DNA. Gianaroli et al., *supra* note 41, at 303. The PCR process is also used to amplify DNA samples found at crime scenes (usually from blood) in order to match genes to the victim or alleged perpetrator. See Edward J. Imwinkelried & D.H. Kaye, *DNA Typing: Emerging or Neglected Issues*, 76 WASH. L. REV. 413, 471 (2001); Peter Neufeld, *Preventing the Execution of the Innocent: Testimony Before the House Judiciary Committee*, 29 HOFSTRA L. REV. 1155, 1161 n.47 (2001).

hormonal treatments to ripen multiple eggs simultaneously.⁵³ Further, they must undergo surgery—generally laparoscopic—to harvest the ripened ova.⁵⁴ Men must provide the sperm that mixes with the eggs. Following fertilization, the embryos must be subjected to microsurgery to remove the blastomeres, which themselves are subjected to caustic chemicals.⁵⁵ To avoid liability for the complex series of manipulative “touching,” consent must be obtained.⁵⁶

What constitutes consent to PGD? If a clinician discloses the risks of harm the parents or embryos may encounter at each step along the way, then negligence liability may be avoided because consent will have been “informed.”⁵⁷ But is disclosure of those risks *all* that is required? What if information about a major feature of the touching were incomplete? Would that render consent invalid? Application to a common experience suggests that it would. Suppose, for example, that a washroom attendant handed a towel to a patron. The patron agrees to accept the towel’s touch for the purpose of drying her hands. But what if the attendant had just sneezed into the towel? Although the purpose of drying hands is accomplished, the germ-laden

⁵³ LORI B. ANDREWS, *THE CLONE AGE: ADVENTURES IN THE NEW WORLD OF REPRODUCTIVE TECHNOLOGY* 50–54 (1999). Superovulation is achieved by administering LH (leutinizing hormone) through nasal spray or through subcutaneous injection along with r-FSH. This occurs daily until several follicles have attained 18 mm in diameter. Then hCG is self-injected. Michael C. Macnamee & Peter R. Brinsden, *Superovulation Strategies in Assisted Conception*, in *A TEXTBOOK OF IN VITRO FERTILIZATION AND ASSISTED REPRODUCTION: THE BOURN HALL GUIDE TO CLINICAL AND LABORATORY PRACTICE* 91, 94 (Peter R. Brinsden ed., 2d ed. 1999).

⁵⁴ See Patricia M. McShane, *In Vitro Fertilization, GIFT and Related Technologies—Hope in a Test Tube*, in *EMBRYOS, ETHICS AND WOMEN’S RIGHTS* 31, 43 (E. Baruch et al. eds., 1987).

⁵⁵ See Inst. for Reprod. Med. & Sci. of Saint Barnabas, *supra* note 51.

⁵⁶ See David M. Vukadinovich, *Assisted Reproductive Technology Law: Obtaining Informed Consent for the Commercial Cryopreservation of Embryos*, 21 *J. LEGAL MED.* 67, 68–77 (2000) (discussing the potential liability that medical facilities are exposed to and possible ways to avoid future litigation); DAN B. DOBBS, *THE LAW OF TORTS* 53–55 (2001) (discussing battery liability for medical interventions).

⁵⁷ See Aaron D. Twerski & Neil B. Cohen, *Informed Decision Making and the Law of Torts: The Myth of Justiciable Causation*, 1988 *U. ILL. L. REV.* 607, 618 (1988) (explaining that informed consent is usually relevant only when undisclosed risks caused harm); Vukadinovich, *supra* note 56, at 69 (advising that a doctor “must explain to the patient the nature of the procedure or treatment, the risks and possible complications, the expected benefits, and the alternative treatments or procedures and their risks and benefits”).

nature of the towel changes the nature of the touch because the instrument of wiping has unexpectedly become a vehicle of infection. Since knowledge of the towel's contamination would render the otherwise consented-to touch offensive, the undisclosed fact of contamination would be material to a decision to be touched by the towel offered. Similarly, the nature of a sexual touching is altered if a party who is knowingly fertile asserts that he is sterile.⁵⁸ In the medical context, if a physician were to recommend transurethral prostate resectioning to resolve a urinary problem, must not the known certain consequence of sterility also be disclosed? If the sterility component that is a characteristic nature of the touch is not disclosed, and if it is material to the decision to undergo the procedure, then non-disclosure invalidates consent and subjects the physician to liability in battery.⁵⁹ That is the test: facts that characterize the nature of the touching, and which are material to the decision to accept the touch, must be disclosed. Nondisclosure negates consent, and subjects the actor to liability in battery.⁶⁰

Is there some material fact about the nature of PGD that must be disclosed to avoid subjecting clinicians to battery actions? PGD is presented as a method providing insight into the genetic and chromosomal components of embryos that are produced by means of IVF.⁶¹ Descriptions artfully explain that blastomeres will be removed from six- to eight-celled embryos and, focusing on the embryo originator, represent that risks to

⁵⁸ See *Barbara A. v. John G.*, 193 Cal. Rptr. 422, 425 (Cal. Ct. App. 1983) (finding that the ability to produce the resultant consequence—pregnancy—changed the nature of the touching).

⁵⁹ See *Bang v. Charles T. Miller Hosp.*, 88 N.W.2d 186, 190 (Minn. 1958) (stating that known consequence of sterilization was material to the nature of the procedure).

⁶⁰ See *DOBBS*, *supra* note 56, at 232 (2001) (referencing *Bartell v. State*, 82 N.W. 142, 143 (Wis. 1900) (where a nude massage was given or where physical violence was passed off as “therapeutic”); see also *Rains v. Superior Court*, 198 Cal. Rptr. 249, 253–54 (Cal. Ct. App. 1984) (finding liability for nondisclosure where physical violence was allegedly “therapeutic”).

⁶¹ See, e.g., Ctr. for Genetics and Soc’y, *Other Human Genetic and Reproductive Technologies: Preimplantation Genetic Diagnosis (PGD) and Screening*, available at <http://www.genetics-and-society.org/technologies/other/pgd.html> (last visited Jan. 13, 2005); Genetics & IVF Inst., *supra* note 23; Inst. for Reprod. Med. & Sci. of Saint Barnabas, *supra* note 26; Reprogenetics, *About Reprogenetics: Everything Associated with PGD*, available at <http://www.reprogenetics.com/> (last visited Jan. 13, 2005).

the embryo are minimal.⁶² Consent, one can argue, has been informed. But the descriptions may not sufficiently address other aspects of the procedure that are both characteristic to its nature and material to the decision to authorize PGD.

Focusing on the embryo may inadvertently or purposefully divert attention from a certain consequence of the embryo biopsy touching. The same peculiarity of the early stage embryo that enables it to retain a full panoply of information, despite the removal of up to one quarter of its contents, applies equally to the removed cell. It also is totipotent.⁶³ The significance of this totipotency is that, unlike the stem cells removed from a developing blastocyst,⁶⁴ each of the blastomeres removed from these earlier stage embryos has the potential to differentiate and form not only the organism, but the “extra-embryonic membranes and other tissues” that are necessary to support

⁶² See, e.g., Inst. for Reprod. Med. & Sci. of Saint Barnabas, *supra* note 51. The Institute for Reproductive Medicine and Science of Saint Barnabas, which performs PGD, does discuss totipotency of blastomeres and its non-deleterious effect on the embryo, but does not meaningfully address its significance to the severed blastomere:

No part of the future fetus will be lacking because one or two cells are removed from the embryo approximately two days after fertilization. All the cells of the embryo remain totipotent until about the fourth day. . . . [E]ach cell by itself can grow into a whole and perfect fetus. The procedure merely delays continued cell division for a few hours, after which the embryo reaches the same number of cells as before and continues its normal development.

Id. See also IntegraMed Am., *PGD (Preimplantation Genetic Diagnosis) Can Help Avoid Genetic Birth Defects Such as Cystic Fibrosis*, at <http://www.integramed.com/consumer/preimplan.htm> (last visited Jan. 13, 2005); Or. Health & Sci. Univ., *Preimplantation Genetic Diagnosis (PGD)*, at http://www.fertilityoregon.com/lab/pre_implantation.htm (last visited Jan. 13, 2005) (stating that the embryo is not harmed). An article by Linda Hammer Burns on counseling describes PGD as follows: “one or two cells of an embryo created via IVF are biopsied and tested.” It then notes the beneficial avoidance of abortion as well as its comparative success and accuracy rates. Linda Hammer Burns, *Genetics and Infertility: Psychosocial Issues in Reproductive Counseling*, 17 *FAM., SYS. & HEALTH* 87, 102 (1999).

⁶³ Howard W. Jones et al., *On Attempts at Cloning in the Human*, 61 *FERTILITY & STERILITY* 423, 423 (1994); Kopaczynski, *supra* note 45, at 1.

⁶⁴ See Peter R. Brinsden, *Oocyte Recovery and Embryo Transfer Techniques for In Vitro Fertilization*, in *A TEXTBOOK OF IN VITRO FERTILIZATION AND ASSISTED REPRODUCTION: THE BOURN HALL GUIDE TO CLINICAL AND LABORATORY PRACTICE* 171, 181 (Peter R. Brinsden ed., 2d ed. 1999). During the blastocyst stage, the outer layer, or trophoctoderm, forms the extraembryonic structure that surrounds the embryo and attaches to the uterine wall. The inner cell mass of the blastocyst forms the embryo. *Id.* Blastomeres removed from blastocysts for stem cell purposes have already lost some of the ability of flexible development. This change in ability for a blastomere of a later age is certain to be lost on lay persons.

fetal development.⁶⁵ This cellular totipotency is what allows zygotes to split early in development and thereby form identical twins. In fact, a newly formed zygote is itself the functional equivalent of a totipotent cell—one that can develop into an embryo and supporting tissue.⁶⁶ In short, the process of blastomere separation, or embryo biopsy, in biological reality, constitutes the creation of a blastomeric “clone” or “twin.”⁶⁷

When successful blastomere separation was first announced, the creation of a clone was openly acknowledged.⁶⁸ The announcement created controversy.⁶⁹

⁶⁵ See Miranda Biven, *Administrative Developments: NIH Backs Federal Funding for Stem Cell Research*, 27 J.L. MED. & ETHICS 95, 95 (1999) (explaining the significance of totipotency). Similarly, Mosby's medical dictionary defines the term as: “an entity capable of carrying on life functions.” MOSBY'S, *supra* note 25, at 1233.

⁶⁶ President's Council on Bioethics, *Human Cloning and Human Dignity: An Ethical Inquiry*, ch.3, 9 (July, 2002), available at <http://www.bioethics.gov/reports/cloningreport/terminology.html> (last visited Jan. 13, 2005). It is the “functional” equivalent because “zygote” refers to a stage immediately following the union of egg and sperm, which is essential for biological growth of a new being. *Id.* While there is no egg/sperm union, the stage created by SCNT is identical insofar as growth of an embryo begins. *See id.* at 8–9; *see also* June Mary Zekan Makdisi, *The Slide From Human Embryonic Stem Cell Research to Reproductive Cloning: Ethical Decision-Making and the Ban on Federal Funding*, 34 RUTGERS L.J. 463, 485–86 (2003).

⁶⁷ Kopaczynski, *supra* note 45, at 1. The explanation for this phenomenon is that blastomeres that are “biopsied,” unlike those relating to SCNT cloning, result from indeterminate cleavage. *Id.* Mosby's Medical Dictionary defines “indeterminate cleavage” as “mitotic division of the fertilized ovum into blastomeres that have similar developmental potential and, if isolated, can give rise to a complete individual embryo.” MOSBY'S, *supra* note 25, at 885. Blastomeres derived from cells produced during the early embryonic cellular divisions each may develop into an individual embryo. *Id.* By contrast, SCNT clones derive their blastomeres from blastocysts. At that stage, the blastomeres have already begun to differentiate. Thus, each blastomere is only pluripotent. Removal of blastomeres at that stage, unlike with respect to PGD, destroys the embryo from which it is withdrawn. *See also* Makdisi, *supra* note 66, at 485–86.

⁶⁸ See RICHARD J. DEVINE, GOOD CARE, PAINFUL CHOICES: MEDICAL ETHICS FOR ORDINARY PEOPLE 134–35 (2d ed. 2000); LOIS WINGERSON, UNNATURAL SELECTION: THE PROMISE AND THE POWER OF HUMAN GENE RESEARCH 80 (1998); Jones, *supra* note 63, at 423, 424 (acknowledging cloning, but preferring to reserve the word “clone” for nuclear transplantation). The first public cloning report occurred at the annual meeting of the American Fertility Society in Montreal in 1993. There, Jerry Hall, director of the In Vitro Fertilization and Andrology Laboratory at George Washington University School of Medicine in Washington, D.C. delivered his paper describing the creation of 48 embryos derived from 17 two-to-eight-celled IVF embryos. Although few had survived to the implantation stage of development, it proved that it could be done. Rebecca Kolberg, *supra* note 45, at 652.

Those who have acknowledged that the process produced clones included Hall,

Scientists have not reversed their original position that clones are produced during the process. As stated in one medical textbook: “The individual blastomeres of the embryo are totipotent: they have exactly the same developmental potential as an embryo. Therefore, isolating a blastomere involves the creation of a second, duplicate embryo, which will be destroyed during the diagnostic procedures.”⁷⁰ The reality of creating a duplicate embryo, or clone, raises significant consent issues. Must this fact be disclosed as part of the consent process? If so, what is the appropriate cause of action for failure to disclose?

who indicated that he would not implant any embryos until the American Fertility Society developed guidelines. Hall saw this as a means to increase the number of embryos available for implantation and recommended PGD application at that time. *Id.* at 652–53. Some hailed the possibility of a “twin-in-reserve . . . for replacement or spare parts.” Jones et al., *supra* note 63, at 426. Others who have acknowledged that cloning had been performed include: Lucinda Veeck, the director of embryology at the Jones Institute for Reproductive Medicine in Norfolk, Va.; John Robertson, a member of the American Fertility Society (“AFS”) ethics committee; Margaret Somerville, the director of the McGill Center for Medicine, Ethics, and Law in Montreal; and Arthur Caplan, the president of the American Association of Bioethics. See Kolberg, *supra* note 45, at 652–53 (labeling the separated blastomeres as “test-tube twins”). The AFS became the American Society of Reproductive Medicine (“ASRM”). See Luigi Mastroianni Jr., *Risk Evaluation and Informed Consent for Ovum Donation: A Clinical Perspective*, 1 AM. J. BIOETHICS 28, 28 (Fall 2001). The AFS guidelines, which utilized the terminology “pre-embryo research” instead of the term “cloning,” condoned the research. See Kolberg, *supra* note 45, at 653.

⁶⁹ See Jones et al., *supra* note 63, at 426 (regarding the practice of separation at the four-cell stage: “It was this type of cloning usually referred to as blastomere separation, which caused the ethical hullabaloo by the prize paper [Hall’s] at the 1993 Conjoint Annual Meeting of the American Fertility Society and the Canadian Fertility and Andrology Society in Montreal.”); see also Kolberg, *supra* 45, at 652–53. Interestingly, while the NIH Human Embryo Research Panel recognized that cloning resulted from blastomere separation, it attempted to separate it from the PGD process. The Panel concluded that federal funding could not be provided for the “[c]loning of human preimplantation embryos by separating blastomeres” nor for “preimplantation genetic diagnosis for sex selection, except for sex-linked genetic diseases.” *Human Embryo Research Panel Report*, in CLONING AND THE FUTURE OF HUMAN EMBRYO RESEARCH 251, 263 (Paul Lauritzen ed., 2001). By inference, the Panel recognized the cloning, but wished to reserve the word “cloning” to represent only reproductive cloning.

⁷⁰ de Wert, *supra* note 11, at 650.

II. CONSENT

A. Liability for the Breach of a Duty to Inform

Except for a few states, failure to disclose information relating to a medical treatment decision generally falls within the scope of a negligence action.⁷¹ Under a negligence theory, a client would have to prove that a biopsy practitioner breached a duty to inform, premised upon what a reasonable practitioner would disclose—or what a reasonable client would want to know—depending on the jurisdictional standard.⁷² Even if a breach were proven, a clinician would have a potential defense based on a therapeutic exception. A privilege to withhold information exists where “full disclosure would be detrimental to a patient’s total care and best interests.”⁷³ If a negligence theory were applied, the therapeutic exception could theoretically release all clinicians from liability, premised on a concession that knowledge about blastomere clone production—and subsequent destruction—would be emotionally detrimental. Thus, the principle elements of a negligence action would be difficult to establish. Further, even if this hurdle could be surmounted, a negligence plaintiff may have difficulty proving what damage had been caused by the non-disclosure.

Perhaps a more successful avenue under a negligence theory would be to allege that disclosure was necessary to avoid a clinician’s clouded judgment because of a self-interest⁷⁴ in promoting PGD. The self-interest relates, in part, to the manner in which PGD and other IVF technologies are regulated. Unlike other medical technologies, which are generally subjected to rigorous safety and effectiveness testing,⁷⁵ the assisted reproductive technologies (“ART”) have quickly and quietly

⁷¹ See RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 28–38 (1986); JOHN H. ROBINSON ET AL., A HEALTH LAW READER: AN INTERDISCIPLINARY APPROACH 241 (1999).

⁷² See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 786 (D.C. Cir 1972) (distinguishing professional rule from patient rule); *Cobbs v. Grant*, 502 P.2d 1, 7–8 (Cal. 1972); *Scott v. Bradford*, 606 P.2d 554, 556–58 (Okla. 1979).

⁷³ *Scott*, 606 P.2d at 558. Other exceptions include cases of emergency and cases where the patient knew or should have known the undisclosed fact. *Id.*

⁷⁴ See *Moore v. Regents of the Univ. of California*, 793 P.2d 479, 483–84 (Cal. 1990) (demonstrating that the defendant’s professional judgment was clouded by undisclosed research interests).

⁷⁵ Noah, *supra* note 8, at 617–18.

marked their presence⁷⁶ absent those rigors.⁷⁷ Instead, the IVF industry presents more of a commercial face than a medical one,⁷⁸ and is relatively self-regulatory.⁷⁹ The sole federal regulation is the Fertility Clinic Success Rate and Certification Act of 1992.⁸⁰ The Act imposes few requirements on ART clinics, but does require the submission of an annual report on its pregnancy success rate.⁸¹ PGD may increase the IVF pregnancy success rate for chromosomally at-risk couples, since many

⁷⁶ Bonnicksen, *supra* note 10, at 418; M. Alexander Otto, *Medical Research: Bioethics Panel Urges Federal Regulation of In Vitro, Other Reproduction Technologies*, 12 HEALTH L. REP. 1192, 1193 (2003) (“With no regulation, ‘novel technology moves from the experimental context to clinical practice with very little oversight or deliberation. . . . Use becomes widespread rapidly.’” (quoting a working paper released by the President’s Council on Bioethics)); Roberts, *supra* note 1, at 1 (stating that IVF was introduced without a research phase).

⁷⁷ Tasca & McClure, *supra* note 2, at 8.

⁷⁸ See George J. Annas, *The Shadowlands – Secrets, Lies, and Assisted Reproduction*, 339 NEW ENG. J. MED. 935, 938 (1998). Unlike other medical procedures, which offer treatment for illness, PGD is marketed as a service to potential clients. See Bonnicksen, *supra* note 10, at 411–12. Additionally, it differs from other medical interventions (including prenatal testing) because clinics performing PGD enjoy the full financial benefits of its use. The PGD clinic retains control, performs the tests, and receives the profit. *Id.* at 409, 419.

⁷⁹ Noah, *supra* note 8, at 618; Norton, *supra* note 11, at 1614. According to some, the scope of what may be done is limited only by money. Lori B. Andrews & Nanette Elster, *Regulating Reproductive Technologies*, 21 J. LEGAL MED. 35, 45 (2000).

⁸⁰ Pub. L. No. 102-493, 106 Stat. 3146 (codified as amended at 42 U.S.C. §§ 263a-1–a-7). Government has mostly avoided ART issues, taking a minimalist approach. ANDREA L. BONNICKSEN, CRAFTING A CLONING POLICY: FROM DOLLY TO STEM CELLS 182 (2002).

⁸¹ 42 U.S.C. § 263a-1 (2004). Each ART program must also identify the specific embryology labs used along with IVF certification status. *Id.* Section 263a-2(g) authorizes inspection of IVF laboratories. *Id.* § 263a-2(g). Lastly, section 263a-2(a) provides for, but does not require, certification. *Id.* § 263a-2(a). The Centers for Disease Control and Prevention, which is the reporting agency, has additional requirements, including the reporting of complications related to ART treatment. Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs, 65 Fed. Reg. 53,310 (Sept. 1, 2000).

All laboratories must also be certified under the Clinical Laboratories Improvement Amendments of 1988 (“CLIA”) in order to examine biological materials (including human embryos) for diagnostic or other purposes. 42 U.S.C. § 263a (a)–(b) (2004). Interestingly, while PGD offers diagnosis (including sex-typing) based on the examination of a single cell, federal regulations authorized by CLIA would seem to require more. The standard for cytogenetic clinics to make sex determinations based upon X and Y chromatin counts is to examine an “adequate number of cells.” 42 C.F.R. § 493.1267 (a) (2002). Although the number is indeterminate, the use of a plural suggests that the examination of more than one cell is expected for accuracy.

chromosomally damaged embryos do not implant.⁸² Thus, a clinician may be tempted to encourage PGD to further the pregnancy success rate, and to not disclose the production of embryo clones, where the clinician feared rejection of the procedure on that basis. A practitioner may not even be consciously aware of the underlying self-interested motivations. But, of course, that is the premise for an expanded use of the informed consent doctrine—clouded judgment.⁸³

The hazard becomes more apparent when analyzed in conjunction with a principle that has dominated the medical field from the beginning—beneficence.⁸⁴ Beneficence is the

⁸² See Noah, *supra* note 8, at 627 (explaining that improved PGD techniques screen out embryos unlikely to implant); see also Ladislava Jelinkova et al., *Improved Implantation Rate After Chemical Removal of the Zona Pellucida*, 79 FERTILITY & STERILITY 1299, 1299 (2003) (noting that “[t]he ability of an embryo to develop and implant primarily relates to the quality of originating gametes and intrinsic characteristics of the embryo.”). Pre-selecting chromosomally normal embryos increases the “take home” baby rate. Bonnicksen, *supra* note 10, at 412–13. On the whole, however, statistics may suggest that PGD take-home baby rates fare lower than IVF generally. See Burns, *supra* note 62, 102 (tying statistics to embryos produced in comparison to babies born rather than implanted embryos in comparison to babies).

⁸³ See *Moore v. Regents of the Univ. of California*, 793 P.2d 479, 485–86 (Cal. 1990) (demonstrating that professional judgment was clouded by undisclosed research interests). The tendency to overreach is part of our human nature; that is precisely the reason consent is needed. See James F. Childress, *Protestant Perspectives on Informed Consent (Particularly in Research Involving Human Participants)*, 30 FORDHAM URB. L.J. 187, 201 (2002). Some clinicians subject women to experiments and to increased dangers surreptitiously to improve clinical success statistics. ANDREWS, *supra* note 53, at 48–49, 53–54.

⁸⁴ Jay Katz, *Informed Consent—Must It Remain a Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL'Y 69, 73 (1993). Beneficence is the underlying principle that would allow a physician to make a decision on behalf of and for the benefit of his or her patient. *Id.* However, as values differ between a physician and patient, the patient is the one who should really be making the choice. *Id.* at 76–86.

PGD has the potential to not only benefit the deciding couple but also to result in a broader accrued benefit in the form of reducing the occurrence of genetic disease. Roberts, *supra* note 1, at 9. Therefore, practitioners are motivated to suggest PGD because of their desire to prevent the birth of children with genetic disorders. Bonnicksen, *supra* note 10, at 408.

Practitioners' orientation toward eliminating disease may influence their presentation. “What is offered as objective clinical reality is often the subjectivity of a devout disciple of the philosophy that death is an implacable enemy.” Katz, *supra* note 84, at 87 (citing SHERWIN B. NULAND, HOW WE DIE 258 (Knopf 1994)) (“He dispenses only as much information as he deems fit, thereby influencing a patient's decision-making in ways he does not recognize as self-serving.”). Thus, because the clinician's values may differ remarkably from the client, it is imperative that all the issues are disclosed so that the individual (or couple) can evaluate all the facts in accord with their personal views. If pieces of factual information are missing, the

residual view that a physician knows what is best for his or her patient.⁸⁵ Because of this genuine interest in improving the physical well-being of a client, a practitioner may be motivated to apply the most advanced technology. PGD technology, which becomes more routine with each application, may improve the chances of successful IVF pregnancy for an at-risk couple.⁸⁶ Therefore, in the absence of federal regulation,⁸⁷ there may be an incentive to encourage PGD based on a perceived benefit to the couple. Its use could also benefit the clinician, as statistics could potentially translate into better reporting data, if the at-risk couple utilizes PGD in addition to IVF to achieve pregnancy, and thereby provide fodder for clinical advertising. Further, recommending use of the most advanced technology protects practitioners against liability.⁸⁸

This suggests that a clinician who is protected from liability based on the therapeutic privilege has a potential to manipulate a decision regarding the use of PGD, and thereby seriously interfere with a client's autonomous choice concerning the procedure.⁸⁹ Even if a claimant could prove clouded judgment

decision will be imbalanced and more likely to correspond with the clinician's views on the moral status of the blastomere clone and the appropriate lines to be drawn regarding its laboratory production and use.

⁸⁵ See Joel N. Ephross, *In Vitro Fertilization: Perspectives on Current Issues*, 32 JURIMETRICS J. 447, 453–54 (1992).

⁸⁶ See Tomas Escudero et al., *Predictive Value of Sperm Fluorescence In Situ Hybridization Analysis on the Outcome of Preimplantation Genetic Diagnosis for Translocations*, 79 FERTILITY & STERILITY 1528, 1532 (2003) (stating that the success rate was relatively high—sixty percent—when the transferred embryos were morphologically and developmentally normal). Nevertheless, overall, the success rate for PGD is still low. See Helen M. Alvare, *Catholic Teaching and the Law Concerning the New Reproductive Technologies*, 30 FORDHAM URB. L.J. 107, 115 (2002); Kanavakis & Traeger-Synodinos, *supra* note 6, at 6.

⁸⁷ The absence of laws prohibiting or regulating PGD may symbolically represent acceptance. See Kaveny, *supra* note 3, at 33–34. Thus, a perception of beneficence is not restricted either legally or by a forced recognition of conflicting moral views.

⁸⁸ See Michael J. Malinowski, *Coming Into Being: Law, Ethics, and the Practice of Prenatal Genetic Screening*, 45 HASTINGS L.J. 1435, 1506–07 (1994); Julia Walsh, *Reproductive Rights and the Human Genome Project*, 4 S. CAL. REV. L. & WOMEN'S STUD. 145, 173 (1994); see also Botkin, *supra* note 32, at 283 (discussing malpractice in the prenatal context). If older women must be counseled about their increased risk of conceiving a genetically abnormal child, then it will be only a matter of time before PGD must also be suggested or recommended.

⁸⁹ See FADEN & BEAUCHAMP, *supra* note 71, at 364. There has been concern about physician abuse of the “therapeutic” exception where information is withheld not only “to avert significant harm to patients but as a convenient means of

and self-interest, a clinician may counter that the undisclosed facts relate solely to the motives to encourage the use of the most advanced technology. Thus, the fact of blastomere clone production could potentially remain undisclosed. And, of course, a plaintiff would still have to overcome the obstacle of proving damages. Thus, a negligence argument is likely to be unsuccessful.

B. The Development of the Informed Consent Theory

1. The Birth in Battery

Negligence is not the only recourse for complaints about inadequate disclosures. The four cases generally credited with acknowledging the importance of informational disclosures in the context of medical intervention and providing the backdrop to informed consent are all grounded in battery:⁹⁰ *Schloendorff v. Society of The New York Hospital*,⁹¹ *Mohr v. Williams*,⁹² *Pratt v. Davis*,⁹³ and *Rolater v. Strain*⁹⁴ all deal with information passed between physician and patient and the physicians' inadequate disclosures.⁹⁵ In *Schloendorff*, the patient consented to an abdominal examination under anesthesia, but not to an operation. The physician's removal of a fibroid tumor was found to have exceeded the scope of consent.⁹⁶ In *Mohr*, the plaintiff consented to surgery on the right ear. Once the patient was anesthetized, however, the physician performed a full

manipulating patients into consenting to their recommendations." *Id.* (citing Charles W. Lidz & Alan Meisel, *Informed Consent and the Structure of Medical Care*, in 2 PRESIDENT'S COMMISSION, MAKING HEALTH CARE DECISIONS (1983)); see also Alan Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decisionmaking*, 1979 WIS. L. REV. 413, 461 (1979).

⁹⁰ See FADEN & BEAUCHAMP, *supra* note 71, at 120–23.

⁹¹ 211 N.Y. 125, 105 N.E. 92 (1914) (opinion by Cardozo, J.).

⁹² 104 N.W. 12 (Minn. 1905).

⁹³ 79 N.E. 562, 563–64 (Ill. 1906). In this case, the physician performed a hysterectomy on an epileptic without consent. *Id.* The court rejected the argument that the epileptic condition rendered the patient incompetent to decide. *Id.* at 564.

⁹⁴ 137 P. 96 (Okla. 1913).

⁹⁵ See *Pratt*, 79 N.E. at 564; *Mohr*, 104 N.W. at 13; *Schloendorff*, 211 N.Y. at 128, 105 N.E. at 93; *Rolater*, 137 P. at 97.

⁹⁶ *Schloendorff*, 211 N.Y. at 131–32, 105 N.E. at 94. The plaintiff lost the case because his case focused on the hospital's liability rather than the physician's, and the hospital had not violated the patient's informed consent. *Id.* at 131, 135, 105 N.E. at 94–95.

examination of her left ear.⁹⁷ Determining that the left ear was more damaged, he performed a surgical procedure on the left ear instead of the right one that had been the subject of the consent.⁹⁸ Liability was premised on lack of consent because the wrong body part had been touched.⁹⁹ In *Pratt*, the physician believed his patient was incompetent to make proper decisions.¹⁰⁰ Therefore, he knowingly provided deceptive information, inducing the patient's consent to a treatment that ultimately resulted in a hysterectomy.¹⁰¹ In *Rolater*, the patient consented to having her foot drained, but not to the removal of any bones.¹⁰² The court held the physician liable for removing her bone because he performed the operation in a manner substantially different from the agreed-upon intervention.¹⁰³

In each of the above cases, the actions for injuries based on a lack of informed consent originated in battery because of the dignitary interest at stake. This interest is deeply rooted in the principle of autonomy,¹⁰⁴ the right to self-determination, and bodily integrity.¹⁰⁵ The right to make autonomous decisions regarding one's body is considered so important that unauthorized touching will result in liability, even if an

⁹⁷ *Mohr*, 104 N.W. at 13.

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Pratt*, 79 N.E. at 563–64.

¹⁰¹ *Id.* at 563.

¹⁰² *Rolater v. Strain*, 137 P. 96, 97 (Okla. 1913).

¹⁰³ *Id.*

¹⁰⁴ JOHN H. ROBINSON ET AL., *A HEALTH LAW READER: AN INTERDISCIPLINARY APPROACH* 239 (1999). Informed consent and autonomy both preserve human dignity, seek to equalize the inequalities between professional and client, and diminish “medical dehumanization.” *Id.* See also FADEN & BEAUCHAMP, *supra* note 71, at 25. Prof. Sulmasy further distinguishes autonomous choices, which are reflected in the secular model of informed consent, and autonomous persons, defined by the natural law model to be not free to make wrong moral choices. Daniel P. Sulmasy, *Informed Consent Without Autonomy*, 30 *FORDHAM URB. L.J.* 207, 207–12 (2002). This point provides support to a growing concern that individuals not make reproductive choices independent of social consideration.

¹⁰⁵ See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 780, 786 (D.C. Cir. 1972). The court concluded that the inadequate disclosure issue was appropriate for a battery cause of action: “uninformed consent to an operation does not confer the necessary authority.” *Id.* at 793; see also *Schloendorff v. Soc’y of New York Hosp.*, 211 N.Y. 125, 129, 105 N.E. 92, 93 (1914) (“Every human being of adult years and sound mind has a right to determine what shall be done with his own body.”). See also Ken Marcus Gatter, *Protecting Patient-Doctor Discourse: Informed Consent and Deliberative Autonomy*, 78 *OR. L. REV.* 941, 946–53 (1999) (discussing negligence and battery in the context of informed consent).

intervention is beneficial.¹⁰⁶ So why, in protecting this right, has there been a shift from battery to negligence?

2. The Drift Towards Negligence

*Salgo v. Leland Stanford Junior University Board of Trustees*¹⁰⁷ was one of the early disclosure cases and has been attributed with linking the two concepts of “informed” and “consent.”¹⁰⁸ The court’s conclusion that a plaintiff could recover based on a physician’s duty to disclose “any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment”¹⁰⁹ coincided with the publication of an influential article by the noted legal scholar Allan McCoid.¹¹⁰ McCoid proposed that all physician misconduct should find remedy in negligence¹¹¹ for “reasons of consistency” and historical good faith beneficence on the part of physicians.¹¹² The article had significant impact on courts, influencing them to reject battery and instead adopt a negligence framework in the context of consent to medical interventions.¹¹³

¹⁰⁶ FADEN & BEAUCHAMP, *supra* note 71, at 28, 123; *see, e.g.*, Clayton v. New Dreamland Roller Skating Rink, Inc., 82 A.2d 458, 459 (N.J. Super. Ct. App. Div. 1951), *cert. denied*, 100 A.2d 567 (1953) (where a skating rink attendant attempted to set patron’s broken arm for her physical well-being amidst her protests).

¹⁰⁷ 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957) (addressing a physician who failed to inform the patient of the risks of a new procedure that left him paralyzed).

¹⁰⁸ FADEN & BEAUCHAMP, *supra* note 71, at 125–26. The doctrine itself “reflects an ethical shift away from professional paternalism [beneficence] . . . and toward individual autonomy.” Scott, *supra* note 39, at 266. The shift reflects a social consensus that the principle of respect for autonomy trumps beneficence. *Id.*

¹⁰⁹ *Salgo*, 317 P.2d at 181.

¹¹⁰ FADEN & BEAUCHAMP, *supra* note 71, at 127–28.

¹¹¹ *See generally* Allan H. McCoid, *A Reappraisal of Liability for Unauthorized Medical Treatment*, 41 MINN. L. REV. 381, 434 (1957).

¹¹² FADEN & BEAUCHAMP, *supra* note 71, at 127 (referencing McCoid, *supra* note 111). A vestige of this attitude continues as the government continues to defer to the judgment of medical professionals, even to the extent of not regulating anything perceived to interfere with a doctor’s autonomy. *See* BONNICKSEN, *supra* note 80, at 111 (an intervention defined as a “practice of medicine,” is without FDA oversight). Now the FDA has limited jurisdiction over a few fertility-related procedures, such as ooplasm transplantation between eggs, based on grounds that biologic “products” are created. But FDA oversight does not review ethical issues; its jurisdiction extends only to safety and efficacy. Parens & Knowles, *supra* note 6, at S6.

¹¹³ FADEN & BEAUCHAMP, *supra* note 71, at 128. A few jurisdictions—Pennsylvania, for example—retained the medical battery actions. *See* JESSICA W. BERG ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 54 (2d ed. 2001).

Two additional circumstances influenced the new judicial attitudes. Technological advances resulted in increased availability of treatment alternatives.¹¹⁴ Additionally, publicity about Nazi atrocities and American abuses in human subject research undermined trust in the profession.¹¹⁵ As a result, a cultural acceptance of physician beneficence shifted to an emphasis on patient autonomy, not just from unwanted touching, but with respect to medical decision-making as a whole.¹¹⁶ To make the important decisions intelligently, physicians were charged with a duty to provide information material to the decision, thereby affording patients a reasonable means of self-protection.¹¹⁷

To a large extent, the shift to a negligence analysis made sense. Pragmatically, battery actions often too narrowly constrained plaintiffs. Negligence, on the other hand, appeared more flexible and also provided plaintiffs a longer statute of limitations.¹¹⁸ Application of a negligence theory was also an advantage to practitioners, allowing them to avoid the undue demands of second guessing patients' individual perspectives regarding informational needs.¹¹⁹ Liability in negligence for inadequate disclosure¹²⁰ also seemed a fairer approach when,

¹¹⁴ See Bassett, *supra* note 9, at 500; Sandra Anderson Garcia, *Sociocultural and Legal Implications of Creating and Sustaining Life Through Biomedical Technology*, 17 J. LEGAL MED. 469, 469 (1996).

¹¹⁵ See David Dickson, *Europe Split on Embryo Research*, 242 SCIENCE 1117, 1117 (1988) (addressing the outrage over Nazi experiments which lead to laws forbidding harmful experiments on human embryos); Larry I. Palmer, *Disease Management and Liability in the Human Genome Era*, 47 VILL. L. REV. 1, 28–31 (2002) (discussing abuses within the United States).

¹¹⁶ BERG ET AL., *supra* note 113, at 20.

¹¹⁷ *Id.*

¹¹⁸ See Jennifer Wriggins, *Domestic Violence Torts*, 75 S. CAL. L. REV. 121, 139 (2001).

¹¹⁹ See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972) (concluding that a “reasonable patient” perspective resolves the materiality issue in favor of individuals while not subjecting physicians to unreasonable whims of which they could not have been aware). The court concluded that the inadequate disclosure issue was appropriate for a battery cause of action: “uninformed consent to an operation does not confer the necessary authority.” *Id.* at 793. Nevertheless, the court held the defendant liable in negligence because the one-year statute of limitations would have defeated the battery action. *Id.*

¹²⁰ VICTOR E. SCHWARTZ ET AL., PROSSER, WADE AND SCHWARTZ'S TORTS 98–99 (10th ed. 2000) (discussing how the doctrine of informed consent generally concerns the disclosure of risks related to a proposed medical intervention); see also BERG ET AL., *supra* note 113, at 55–60. The risks can be further broken down to including disclosures relating to: “(1) the nature of the risk, (2) the magnitude of the risk, (3)

although the physician had performed the treatment properly, he had failed to address the collateral issues of associated risks.¹²¹ The negligence route also provided additional benefits, including the availability of added defenses,¹²² the requirement of harm caused by the lack of disclosure,¹²³ and a decreased exposure to punitive damages.¹²⁴

The application of negligence law to evaluate physician conduct regarding disclosure of treatment risks melds well with the basic principles of negligence, which are all about balancing risks and burdens.¹²⁵ However, by exclusively focusing on negligence and its corresponding concentration on liability reduction, we risk losing sight of the underlying principle of autonomy and its corresponding collaborative decision-making process.¹²⁶ In short, a lingering tension between the legal rationale and its underlying basis persists.¹²⁷ Thus, despite a

the probability that the risk might materialize, and (4) the imminence of risk materialization" *Id.* at 56; DOBBS, *supra* note 56, at 654. The elements of a claim for lack of informed consent are:

- (1) nondisclosure of required information; (2) actual damage such as loss of a leg; (3) resulting from the *risks of which the patient was not informed*; (4) cause in fact, which is to say that the plaintiff would have rejected the medical treatment *if she had known the risk*; and (5) that reasonable persons, if properly informed, would have rejected the proposed treatment.

DOBBS, *supra* note 56, at 654. (emphasis added).

¹²¹ See, e.g., *Natanson v. Kline*, 350 P.2d 1093, 1106 (Kan. 1960) (finding that the doctor's failure to inform patient of side-effects associated with a mastectomy was negligent because these risks were foreseeable); see also *Nelson v. Patrick*, 293 S.E.2d 829, 831 (N.C. Ct. App. 1982) (holding that a lack of information logically leads to an action in negligence, not battery, because battery actions are limited by a one year statute of limitations); *Wilkinson v. Vesey*, 295 A.2d 676, 686 (R.I. 1972) (finding that a lack of disclosure related to treatment-associated risks of radiation treatment sounded in negligence).

¹²² *Katz, supra* note 84, at 78.

¹²³ See DOBBS, *supra* note 56, at 654.

¹²⁴ Alexander Morgan Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 418 (1974).

¹²⁵ See, e.g., *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947); W. PAGE KEETON ET AL., *PROSSER AND KEETON ON THE LAW OF TORTS*, 169-73 (5th ed. 1984).

¹²⁶ John Lantos, *Informed Consent: The Whole Truth for Patients?*, 72 *CANCER* 2811 (1993), in *A HEALTH LAW READER: AN INTERDISCIPLINARY APPROACH* 250, 252-53 (John H. Robinson et al. eds., 1999). Ethicist Alexander Capron considered battery as closer to the spirit of the doctrine. Capron, *supra* note 124, at 418-20. A focus on collaboration in the decision-making process reflects that autonomy may not be "perfect." Instead, it is "deliberative." See Gatter, *supra* note 105, at 961. To be deliberative while respecting a decision-maker's autonomy suggests that material information must be brought to the table for discussion.

¹²⁷ See *Katz, supra* note 84, 77-81; see also *Canterbury v. Spence*, 464 F.2d. 772

trend toward negligence, actions in battery are still viable.¹²⁸ In an industry lacking regulations and the consequent imposition of a standard of care, a battery action may be a more appropriate cause of action.¹²⁹

3. The Availability of Both Battery and Negligence

The plaintiff in a battery action—at least since the drift toward a negligence analysis—would be charged with the difficult task of persuading a court that the decision-maker was deprived of more than collateral information relating to treatment-related risks. To succeed, the non-disclosure must have been tantamount to a plaintiff's substantial mistake about the nature or character of the medical intervention.¹³⁰ The slippery distinction between the plaintiff's ignorance of risk, suggesting negligence, and her mistake about the nature of the operation,¹³¹ suggesting battery, requires proving more than a lack of informed consent; consent itself must be negated.¹³²

C. Negated Consent and Battery

One way of determining whether consent is negated is by examining the context of the touch. When circumstances related to the touch transform an otherwise authorized touch to one that is offensive, consent is negated by the existence of those known, but undisclosed, facts.¹³³ For example, consent to sex may be vitiated by a material mistake about the person who delivers the

(D.C. Cir. 1972) (employing a schizophrenic approach, which recognizes autonomy, but ultimately favors objectification of the decision-making process); *Scott v. Bradford* 606 P.2d 554 (Okla. 1979).

¹²⁸ DOBBS, *supra* note 56, at 232. The classic case is where there had been no authorization at all. *See, e.g., Vitale v. Henchey*, 24 S.W.3d 651 (Ky. 2000) (holding that lack of authorization to perform a surgery resulted in battery liability). Courts specifically affirm that negligence based on lack of informed consent has not “supplanted” battery actions even where there has been some manifestation of consent. *Id.* at 657; *Kus v. Sherman Hosp.*, 644 N.E.2d 1214, 1220 (Ill. App. Ct. 1995) (stating that a claim for medical battery exists where treatment given was “substantially at variance” from consented-to treatment).

¹²⁹ *See Palmer*, *supra* note 115, at 31–32.

¹³⁰ RESTATEMENT (SECOND) OF TORTS § 892B (1979); DOBBS, *supra* note 56, at 232; KEETON ET AL., *supra* note 125, at 114.

¹³¹ DOBBS, *supra* note 56, at 243.

¹³² RESTATEMENT (SECOND) OF TORTS § 892B (1979); DOBBS, *supra* note 56, at 232 (2000); KEE

TON ET AL., *supra* note 125, at 118–19.

¹³³ KEETON ET AL., *supra* 125, at 119–20.

touch. If the plaintiff were a victim of a mock marriage, for instance, a defense of consent to the sexual touching is ineffective.¹³⁴ Consent is also negated when induced by deceit¹³⁵ or by a mistake as to the necessity of the touch.¹³⁶ Additionally, a battery action for lack of consent is viable for medical interventions applied to the wrong body part¹³⁷ or for wrong interventions applied to a correct body part.¹³⁸ In each instance, the context of the touch is considered sufficiently serious so as to be material in defining its character. In such instances, a

¹³⁴ *Blossom v. Barrett*, 37 N.Y. 434 (1868). In a medical context, consent to surgery may be negated in some jurisdictions if performance may be impaired by a surgeon's undisclosed condition. *See, e.g., Hawk v. Chattanooga Orthopaedic Group*, 45 S.W.3d 24 (Tenn. Ct. App. 2000) (finding that failure to disclose physician's disabling hand condition was material to the decision to undergo hip replacement surgery).

¹³⁵ *See, e.g., Barbara A. v. John G.*, 193 Cal. Rptr. 422, 426–27 (Cal. Ct. App. 1983) (stating that consent to intercourse may be vitiated by lack of consent to resultant pregnancy). The defendant had told plaintiff that he was unable to impregnate her and thereby induced her consent to intercourse. *Id.* Thus, the plaintiff did not consent to the nature of the touching because she did not have knowledge of its true nature and possible consequences. *See id.; see also Hobbs v. Kizer*, 236 F. 681 (8th Cir. 1916). In *Hobbs*, the defendant physician impregnated his patient. *Id.* Then, when she complained of a pregnancy, the physician said the symptoms were instead caused by an abscess. *Id.* Plaintiff consented to surgery whereby an abortion that was represented to be another operation was performed to the detriment of the patient. *Id.* at 682.

¹³⁶ *See, e.g., Rains v. Superior Court*, 198 Cal. Rptr. 249, 251–53 (Cal. Ct. App. 1984) (holding that consent to physical therapy was vitiated due to lack of necessity); *Clair v. Reprod. Health Servs.*, 720 S.W.2d 793, 794–95 (Mo. Ct. App. 1986) (involving a plaintiff who consented to an unneeded abortion because negligently performed tests indicated that she was pregnant); *Bartell v. State*, 82 N.W. 142, 143 (Wis. 1900) (holding that consent to a physician's liberal touching is negated if the patient is unaware that the touching was medically unnecessary). For instance, in *Cacdac v. West*, the plaintiff was advised that she faced a risk of paralysis possibly just by stepping off a curb if she did not undergo back surgery. 705 N.E.2d 506, 509, 512 (Ind. Ct. App. 1999). This potentially constituted fraudulent inducement, which also vitiates consent.

¹³⁷ *Barrette v. Lopez*, 725 N.E.2d 314, 316 (Ohio Ct. App. 1999) (permitting the plaintiff to pursue her claim in battery for unauthorized removal of part of stomach during corrective surgery on small intestine). This line of cases resembles the classic case of *Mohr v. Williams*, 104 N.W. 12 (Minn. 1905).

¹³⁸ *See, e.g., Bey v. Sacks*, 789 A.2d 232, 235, 240 (Pa. Super. Ct. 2001) (holding that consent was given only for surgical extraction rather than the simple extraction that was actually performed); *see also Hobbs*, 236 F. at 682 (finding consent to remove abscess but not to perform an abortion); *Blanchard v. Kellum*, 975 S.W.2d 522, 524–25 (Tenn. 1998) (discussing a case where plaintiff consented to the removal of all thirty-two of her teeth, but not a procedure that removed them all during a single visit).

plaintiff's lack of contextual awareness renders any consent ineffective.

In each of the preceding examples, withholding material facts thwarted intelligent decision-making. The undisclosed facts concerned more than mere collateral matters; they related to "a major feature of the transaction."¹³⁹ Notwithstanding the general rule that undisclosed risks are generally treated as collateral matters to be resolved under negligence rules, there are three categories of circumstances where undisclosed risks could be considered a major feature of the transaction and thereby change the nature of the touching.

The first category concerns medical interventions whose experimental nature has not been disclosed.¹⁴⁰ When a person consents to medical treatment, it is with the knowledge that certain known and reasonable risks may be encountered during treatment. With experimental procedures, however, the risks are unknown. Therefore, if a patient has consented to a particular medical intervention and has not been made aware of its experimental nature, the intervention may be considered a substantial variance from the treatment for which consent had been given.¹⁴¹ This renders the recipient of the treatment ignorant as to the nature of the procedure.¹⁴² The resultant battery action can co-exist with a separate action in negligence.¹⁴³ While the negligence action deals with foreseeable risks of an agreed upon procedure, the battery action's viability rests instead upon a consideration that the facts "did not mean

¹³⁹ DOBBS, *supra* note 56, at 232; *see also* RESTATEMENT (SECOND) OF TORTS § 892B (1979); KEETON ET AL., *supra* note 125, at 119.

¹⁴⁰ *See, e.g.*, *Gaston v. Hunter*, 588 P.2d 326, 331, 352 (Ariz. Ct. App. 1978) (permitting case to go to the jury on the issue of some committed errors by defendant doctors); *Kus v. Sherman Hosp.*, 644 N.E.2d 1214, 1217, 1220 (Ill. App. Ct. 1995) (finding that a hospital and physician may be held liable for the undisclosed experimental nature of the intraocular lenses used in the procedure); *Shadrick v. Coker*, 963 S.W.2d 726, 729–30 (Tenn. 1998) (discussing the experimental nature of pedicle screws inserted during back surgery). A battery-based theory is useful in the experimental or research context because information is not just about informing a patient of foreseeable risks, it also allows the subject to determine whether to participate at all. *Palmer, supra* note 115, at 27.

¹⁴¹ *See Kus*, 644 N.E.2d at 1220–21.

¹⁴² *Gaston*, 588 P.2d at 350–51.

¹⁴³ *Shadrick*, 963 S.W.2d at 731–32 (discussing a health care provider's failure to disclose known risks associated with the particular treatment and the subsequent tort liability).

anything” to the patient until he learned of their experimental nature.¹⁴⁴

The second risk category is based on a calculation that the withheld facts expose the unknowing recipient to a known high risk of serious harm. A familiar example renders consent to sexual intercourse ineffective if a party, with knowledge of their condition, did not disclose that he or she had a sexually transmittable condition.¹⁴⁵ While the pleasurable purpose of the touching was satisfied, the additional known consequence—exposure to a sexually transmitted disease—was improperly withheld. The same probabilistic standard may be applied in the medical context. In one exemplary case, a physician failed to warn a patient that a proposed bi-lateral thyroidectomy would expose her to a serious threat of vocal chord paralysis.¹⁴⁶ The undisclosed risk was considered an essential feature of the procedure, rather than a mere collateral matter, because of the elevated probabilities in conjunction with the seriousness of the consequences. Denying the patient information about such facts that are material to the decision denied her the right to autonomous decision-making and bodily integrity.¹⁴⁷ Thus, despite the general rule that a lack of informed consent may generally be regarded as negligence, when undisclosed potential risks rise to the level of a high likelihood of serious harm, mere negligence rules do not apply. Instead, consent is considered ineffective, and not merely uninformed.

Finally, consent is not effective if a known material consequence that is certain to occur has not been disclosed.¹⁴⁸ Two examples provide illustration. In *Bang v. Charles T. Miller Hospital*, the physician determined that the patient’s bladder complaint related to a prostate gland problem.¹⁴⁹ Following the

¹⁴⁴ *Id.* at 734 (experimental pedicle screw installation during back surgery).

¹⁴⁵ See, e.g., *Leleux v. United States*, 178 F.3d 750, 754– 55 (5th Cir. 1999) (accepting the standard that fraudulent concealment of venereal disease during consensual sex constitutes a battery); *Doe v. Johnson*, 817 F. Supp. 1382, 1389, 1391 (W.D. Mich. 1993) (finding a battery where defendant was infected with the HIV virus, had AIDS’s associated symptoms, or knew a prior sex partner had been diagnosed); *Hogan v. Tavzel*, 660 So. 2d 350, 353 (Fla. Dist. Ct. App. 1995) (finding the consent given without any knowledge of possible exposure to STD was equivalent to giving no consent at all).

¹⁴⁶ See *Congrove v. Holmes*, 308 N.E.2d 765, 767 (Ohio Ct. Com. Pl. 1973).

¹⁴⁷ *Id.* at 770.

¹⁴⁸ KEETON ET AL., *supra* note 125, at 120.

¹⁴⁹ 88 N.W.2d 186, 187 (Minn. 1958).

patient's consent to a transurethral prostate resection to cure the bladder trouble, the physician successfully performed the surgery.¹⁵⁰ A routine part of the procedure included severing the spermatic cords, thereby rendering the patient sterile.¹⁵¹ Because of its seriousness, the consequence of sterility should have been disclosed, to give the patient the opportunity to make an intelligent decision about whether to undergo the treatment.¹⁵² In *Montgomery v. Bazaz-Sehgal*, the material consequence was the routine insertion of a penile implant during a revascularization procedure.¹⁵³ The procedure's certain association with penile implantation required disclosure of that fact in order for the patient to have a true understanding of the nature of the operation.¹⁵⁴ The undisclosed facts did not affect the cures sought, which were achieved in both cases.¹⁵⁵ Nevertheless, the undisclosed facts were an essential feature of the procedure because they were a consistent consequence of the touching. It can also be inferred that the certain consequence was of sufficient import to be material to the choice regarding whether to undergo the treatment.¹⁵⁶

III. BATTERY APPLIED TO PGD

A. Cloning As Essential to Its Nature

The application of battery to PGD based on ineffective consent most resembles the last category addressed above.¹⁵⁷ In PGD, the diagnostic purpose associated with severing the blastomere is met, but an additional certain consequence has not been revealed. This situation contrasts sharply with negligence actions premised on a lack of informed consent. Unlike the circumstance in negligence actions, which protect physicians from unfair liability for medical judgments regarding the probable risks that one *might* encounter, the certain consequence

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.* at 190.

¹⁵³ 798 A.2d 742, 747 (Pa. 2002).

¹⁵⁴ *Id.* at 748.

¹⁵⁵ See *Bang*, 88 N.W.2d at 188 (noting that surgery was done to correct bladder problems); *Montgomery*, 798 A.2d at 744–46 (commenting on the procedure performed corrected plaintiff's impotence).

¹⁵⁶ See *Montgomery*, 798 A.2d at 748.

¹⁵⁷ See *supra* notes 133–57 and accompanying text.

of blastomere clone production involves no medical evaluation of risks. Since the practitioner-known¹⁵⁸ consequence of cloning is routine to the procedure of embryo biopsy, it constitutes part of its essential nature.¹⁵⁹ Because the undisclosed fact details an essential feature rather than a mere collateral risk associated with the touching, consent is nullified rather than uninformed, provided that the undisclosed information is material to the decision.¹⁶⁰ Therefore, a client's right to bodily integrity is more appropriately addressed in battery.

Having concluded that issues of consent to embryo biopsy should be analyzed in battery, we must next determine whether the failure to reveal this essential clone-producing nature of the process would be material to a decision to authorize PGD.¹⁶¹

B. Cloning as Material to the Decision

Information is material if its sufficient importance could cause one to decide differently.¹⁶² Two arguments could be advanced in concluding that the consequential creation (and destruction) of a blastomere clone during embryo biopsy is not material to the decision. The first concentrates on the clinician. A biopsy practitioner's reluctance to divulge the significance of the severed totipotent blastomere may result from the current

¹⁵⁸ It would also have to be known by the clinician. See KEETON ET AL., *supra* note 125, at 232. This is easily satisfied by the direct statements found in a medical textbook. See, e.g., de Wert, *supra* note 11, at 650.

¹⁵⁹ See *supra* notes 67–68 and accompanying text (describing how blastomere clone creation is a natural result of embryo biopsy).

¹⁶⁰ DOBBS, *supra* note 56, § 100 (stating that, unlike collateral risks, material risks are sufficient to vitiate consent).

¹⁶¹ *Id.*

¹⁶² Mary Z. Pelias & Nathan J. Markward, *The Human Genome Project and Public Perception: Truth and Consequences*, 49 EMORY L.J. 837, 842 (2000) (citing *Canterbury v. Spence*, 464 F.2d 772, 786–87 (D.C. Cir. 1972)). Materiality is based on a subjective view of what is important to consider or know about the procedure. Causation itself is separate. FADEN & BEAUCHAMP, *supra* note 71, at 303–04; see also *Scott v. Bradford*, 606 P.2d 554, 557–58 (Okla. 1980) (dealing with informed consent).

Adrienne Asch contends that couples who are provided prenatal diagnostic information should also be provided with educational information about the diseases for which the results were positive, thereby mitigating the negativity. By offering the information, the choice will be more informed. See Botkin, *supra* note 32, at 285; Benjamin Wilfond, *Newborn Screening and Carrier Detection for Cystic Fibrosis: Complementary or Contradictory?*, 29 J. L. MED. & ETHICS 30 (Supp. 2001). By analogy, a couple thinking about utilizing PGD should be informed about the creation of the blastomere clone in addition.

widespread disapproval of reproductive cloning.¹⁶³ PGD clinicians who have no interest in reproductive cloning may not be focused on the potentiality for life in the separated blastomere. To them, the creation of a blastomere clone as a result of its totipotency could be considered not material because its reproductive potential is not critical to its purpose. The effect of the diagnostic objective is not growth, but cessation of development.

The second argument, which assumes that a reasonable PGD client would decide in favor of embryo biopsy even if the generation of blastomere clones were known, flows naturally from the first. In support of the assumption, it could be noted that the ultimate purpose of improving the chances of producing genetically related children that do not suffer from defined abnormalities has been met. Additionally, the couple has already agreed to produce several embryos knowing that there is little likelihood that all will survive. Therefore, any subsequent production (and destruction) of blastomere clones to aid in the selection process would presumably be of little import to the decision to authorize the procedure. One could argue that consent may be inferred based on the following: a reasonable person in the position of one who is deciding to utilize PGD in conjunction with IVF would consent to embryo biopsy even if the fact of blastomere clone creation had been disclosed.

The arguments are logically appealing. It is true that neither party has the intent of reproductive life in the context of preimplantation diagnosis. It is also true that the client has consented to the production of potential life with knowledge of the risks that some of the embryos will not be permitted to survive.¹⁶⁴ When taken together, the arguments suggest that

¹⁶³ See, e.g., Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong. § 301(a) (2003); Human Cloning Ban and Stem Cell Research Protection Act of 2003, S. 303, 108th Cong. § 301(a)(1) (2003); Human Cloning Prohibition Act of 2002, 107th Congress, S. 2439, § 301(a)(1) (2002); Human Cloning Prohibition Act of 2001, S. 1899, 107th Cong. § 301(1) (2002) (passed by the House on July 31, 2001); Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong. § 301(1) (2001) (engrossed); CAL. HEALTH & SAFETY CODE §§ 24185–24186 (Deering 2001). Each of these acts prohibited reproductive cloning. See also Lori B. Andrews & Nanette Elster, *Regulating Reproductive Technologies*, 21 J. LEGAL MED. 35, 43 (2000) (observing an “overwhelming negative public response” to human cloning).

¹⁶⁴ See *infra* notes 172–77 and accompanying text.

the clients have already weighed and balanced both the production of potential new life and its destruction.

Despite this logical appeal, both arguments have serious flaws. At least one pretends that creation is not important because destruction is certain. Both ignore any ethical concerns over production separate from an intent to implant.

1. Intend/Foresee Distinction¹⁶⁵

Verbalizing consent to the production of IVF embryos despite knowledge that those not needed for the couple's reproductive purposes may be destroyed does not mean that the commissioning couple has weighed and balanced all the facts relevant to PGD. The couple has only balanced facts related to the issue presented—the effect on the host embryo.¹⁶⁶ If the explanation concerning the destruction of blastomeres during the testing process does not include the clonal nature of those cells, then the couple has not been presented with all the facts necessary to perform the decisional balancing.

¹⁶⁵ See generally FitzPatrick, *supra* note 27, at 29–30 (describing and labeling the analysis the “intend/foresee distinction”).

¹⁶⁶ See, e.g., Inst. for Reprod. Med. and Sci. of Saint Barnabas, *supra* note 51. The Institute for Reproductive Medicine and Science of Saint Barnabas, which performs PGD, does discuss totipotency of blastomeres and its non-deleterious effect on the embryo, but does not meaningfully address its significance to the severed blastomere:

No part of the future fetus will be lacking because one or two cells are removed from the embryo approximately two days after fertilization. All the cells of the embryo remain totipotent until about the fourth day. . . . [E]ach cell by itself can grow into a whole and perfect fetus. The procedure merely delays continued cell division for a few hours, after which the embryo reaches the same number of cells as before and continues its normal development.

Id. Without more information, intelligent people may not understand that the severed blastomere also has the potential for development. I tested the effect of the statement in my Torts class on Sept. 17, 2003. Sixty-three percent of my class did not understand the significance of totipotency to the severed blastomere. See also Burns, *supra* note 62, at 87; IntegraMed Am., *supra* note 62 (explaining process, risks to embryo, formation of complete embryo despite cell removal, utilitarian value of removed blastomeres). An article on counseling describes PGD as follows: “one or two cells of an embryo created via IVF are biopsied and tested.” Burns, *supra* note 62, at 87. It then notes the beneficial avoidance of abortion as well as its comparative success and accuracy rates. *Id.* But the only moral objections explained to reproductive counselors related to the destructive nature on affected biopsied embryos and the potential for abusive use based on parental preference. *Id.* The counseling journal ignores any moral objection to the production of blastomere clones or their subsequent destruction, thereby suggesting a gap in client-proffered information.

Evidence materializing from the stem cell debate demonstrates why consenting to one does not authorize the other. Some consider there to be a moral distinction between permitting left-over IVF embryos to be used for stem cell purposes, and producing the embryos for that purpose.¹⁶⁷ Similar to the application of PGD testing, extraction of stem cells is biologically fatal.¹⁶⁸ Assuming *arguendo* that consent to the production of blastomere clones may be inferred, one may not further infer consent to their subsequent destruction during diagnostic testing. This illustrates the difference between results that are intended and those that are merely foreseeable.

When embryos are produced in order to harvest their stem cells, all the plans and courses of action are focused on the goal of procuring stem cells. It is known at the time of the decision to produce those embryos that harvesting may be accomplished only by resulting catastrophe to the host.¹⁶⁹ The decision thereby corresponds to a legal definition of intent: when a person who sets a force in motion knows with substantial certainty that a particular consequence will come about, the result is intended.¹⁷⁰ In this case, the intended consequence is destruction of the research embryo. Because blastomeres are produced knowing

¹⁶⁷ Ryan, *supra* note 16, at 51; *see also* FitzPatrick, *supra* note 27, at 29; Gene Outka, *The Ethics of Stem Cell Research*, Paper Presented to The President's Council on Bioethics (April 2002), available at <http://www.bioethics.gov/background/outkapaper.html> (last visited Jan. 13, 2005) (application of the "nothing is lost principle" notes that embryos already in existence would be destroyed anyway). Notable public figures make the distinction between using embryos for research that will not be implanted and creating them solely for research purposes. FitzPatrick, *supra* note 27, at 29. Among these are Georgetown University professor of medical ethics, Edmund Pellegrino, and past member of the Human Embryo Research Panel, Patricia King, who considered fertilizing human ova just for research "unnerving." WINGERSON, *supra* note 68, at 82–84. "The notion of creating embryos solely for research, which will necessarily entail their destruction, is much more controversial" than using IVF embryos that have already been created and will die any way. Alexander Morgan Capron, *Placing a Moratorium on Research Cloning to Ensure Effective Control Over Reproductive Cloning*, 53 HASTINGS L. J. 1057, 1058 (2002). Creating potential life knowing that it will be destroyed is "ethically problematic" even if using pre-existing embryos may not be. James J. McCartney, *Embryonic Stem Cell Research and Respect for Human Life: Philosophical and Legal Reflections*, 65 ALB. L. REV. 597, 615–16 (2002).

¹⁶⁸ *See* Makdisi, *supra* note 66, at 481.

¹⁶⁹ *See* FitzPatrick, *supra* note 27, at 30 (stating that "an embryo is being created with a view to its destruction").

¹⁷⁰ *See, e.g.*, Joseph H. King, Jr., *Defining the Internal Context for Communications Containing Allegedly Defamatory Headline Language*, 71 U. CIN. L. REV. 863, 903 (2003).

that they will be subject to diagnostic testing that results in certain destruction, their destruction is likewise intended.¹⁷¹

By contrast, destruction of unused embryos is not intended, because the link between creation and destruction is far less certain. During the IVF process that precedes embryo biopsy, a couple typically commissions the production of several embryos for reproductive purposes. Although only two or three are generally expected to be simultaneously implanted,¹⁷² many more are usually produced.¹⁷³ Since the success rate for IVF is so low,¹⁷⁴ some prefer ripening, harvesting, and fertilizing many eggs at a time over having a woman repeat the risky, painful, and expensive¹⁷⁵ hormone stimulation program and surgical intervention.¹⁷⁶ How many of the embryos are left over depends upon how soon successful pregnancy is achieved. Although destruction of some may be reasonably anticipated, there is no expectation that all will be destroyed. A reasonably anticipated consequence is not considered intended, but foreseeable.¹⁷⁷

Based on this legitimate distinction between what is intended and what is foreseeable, no justifiable conclusion may be drawn that consent to the production of IVF embryos impliedly authorizes the creation of blastomere clones.

2. Materiality Based on Other Factors

One could assert that blastomere clone production is not material since current scientific technology is incapable of

¹⁷¹ See FitzPatrick, *supra* note 27, at 30 (describing and labeling the analysis the "intend/foresee distinction").

¹⁷² See Ephross, *supra* note 85, at 457–58 (stating that any more than three poses a high risk to the woman).

¹⁷³ Cynthia B. Cohen, *Protestant Perspectives on the Uses of the New Reproductive Technologies*, 30 FORDHAM URB. L.J. 135, 144–45 (2002) (stating that Protestants agree that respect is owed early embryos, but do not agree on when they become discrete individuals or the extent to which ART may be utilized).

¹⁷⁴ Norton, *supra* note 11, at 1596; see also Hossam E. Fadel, *The Islamic Viewpoint on New Assisted Reproductive Technologies*, 30 FORDHAM URB. L.J. 147, 152 (2002) (comparing fertilization to live birth).

¹⁷⁵ Robertson, *supra* note 9, at 452 n.123. In 1992, PGD cost \$2000–3000 per cycle in addition to the \$7000–8000 for IVF. *Id.* Egg retrieval ranged from \$67,000 for the first cycle to \$114,000 for the sixth cycle (1994 statistics). Botkin, *supra* note 2, at 18. Eighty-five percent of IVF costs are not covered by insurance. *Id.*

¹⁷⁶ Parens & Knowles, *supra* note 6, at S6 (stating the greatest risk is from the ovarian hyperstimulation drugs).

¹⁷⁷ FitzPatrick, *supra* note 27, at 30.

maintaining it to its full life capacity.¹⁷⁸ Therefore, any potential for full life may be disregarded. This argument, however, fails to consider the inevitability of survival.¹⁷⁹ As with embryos produced *in vitro*,¹⁸⁰ over time, the right life-sustaining technology is likely to be discovered. A focus on survival circumvents rather than addresses the real issues. If survival were dispositive of legal consideration, then we could, at our discretion, euthanize the terminally ill and infants born without chance of survival—most notably, anencephalic babies. In the end, the real issue is not viability at all. The real issue is how one views human biological life at its very earliest stages. It is precisely because views on this subject differ, and may influence the PGD decision, that it should be left to the decision-makers to evaluate, following specific disclosure. This is especially true

¹⁷⁸ See Bielanska et al., *supra* note 35, at 1304–05.

¹⁷⁹ Researchers have been experimenting on fertilization techniques for a half a century. Harold Varmus suggests that 1944 is the date of origin, when Miriam Menkin and John Rock first observed human *in vitro* fertilization. Harold E. Varmus, *The Challenge of Making Laws on the Shifting Terrain of Science*, 28 J. L. MED. & ETHICS 46, 49–50 (2000) (keynote speech). Another author reports that the first external fertilization of a mammalian egg was performed in 1959 while the first human egg fertilization occurred in 1971. Th. Shannon, *In Vitro Fertilization: Ethical Issues*, in EMBRYOS, ETHICS AND WOMEN'S RIGHTS 155, 157 (E. Baruch et al. eds., 1987). Baby Louise Brown, the first successful IVF-conceived baby, was born seven years later. Varmus, *supra*, at 50. The development of survivable blastomeres is likely to take the same discovery route—provided that there is an interest in the end. Research has been underway for developing an artificial zona pellucida to contain the developing embryo for a decade. See Jones et al., *supra* note 63, at 426; Richard Bronson, *A Case of Identical Twins*, Contexts (Institute for Medicine in Contemporary Society, Stony Brook University), Mar. 1998, available at <http://www.uhmc.sunysb.edu/prevmed/mns/imcs/contexts/clone/twins.html> (where Hall and Stillman used alginate in the early 1990s to create an artificial zona in which to grow blastomeres severed from embryos whose fertilization by two sperm prevented survival beyond a few divisions). Scientists are currently working on improving the proliferation of severed blastomeres. Bielanska et al., *supra* note 35, at 1305 (noting that the purpose was to have more cells available for testing). The study also included the insertion of (mouse) blastomeres into a zona and implanted into recipients. *Id.* at 1310. This suggests the further study of blastomeres as potential reproductive entities.

¹⁸⁰ Before baby Louise Brown was a twinkle in the eye, scientists were faced with some of the same issues presented here. In the early seventies, IVF technology and methodologies were still under construction, so all the attempted and actualized embryos perished. Scientists were “well aware that this work present[ed] challenges to a number of established social and ethical concepts.” R.G. Edwards & Ruth E. Fowler, *Human Embryos in the Laboratory*, 223 SCI. AM. 4454 (1970). Nevertheless, they opined that “the emphasis should be on the rewards that the work promises in fundamental knowledge and in medicine.” *Id.* Nowhere did the scientists fail to recognize that embryonic life had been created.

since the intervention is more deeply linked with personal beliefs than is typical for medical treatment.

An additional reason that consent to cloning cannot be considered implied relates to industry standards. IVF clinicians have been cautioned to notify clients who wish to donate supernumerary embryos to science that cloning could occur.¹⁸¹ If the ASRM considers the fact material to the donation decision, then there is no reason to treat PGD authorizations differently.

Governmental policies provide further insight into the materiality of the severed blastomere's clonal nature. If governments were homogeneous in their endorsement of PGD, then perhaps a practitioner should be entitled to an inference of consent based on the clinician's reasonable expectations. Disparate views, on the other hand, would suggest that practitioners should not benefit from the evidentiary rule that permits actors to infer consent absent express verbalization to the contrary.¹⁸²

States differ in their acceptance of PGD, as do foreign countries. Ten states ban all research on embryos. Of these, a little more than half make an exception for PGD.¹⁸³ Based on such statistics, a uniformly favorable policy toward PGD can hardly be inferred.¹⁸⁴ The same is true for foreign countries.

¹⁸¹ See *Embryo Splitting for Infertility Treatment*, 67 FERTILITY & STERILITY 5, 4S-5S (1997) ("Persons asked to donate gametes or embryos for such research should be fully informed that research in embryo splitting is intended or planned as a result of their donation.") (statement developed by the American Society for Reproductive Medicine ("ASRM")).

¹⁸² See DOBBS, *supra* note 56, at 56-57 (explaining the applicability of the evidentiary rule).

¹⁸³ See Timothy Stoltzfus Jost, *Rights of Embryo and Foetus in Private Law*, 50 AM. J. COMP. L. 633, 640 (2002) (noting that six states exempt preimplantation screening); see also Richard M. Doerflinger, *Ditching Religion and Reality*, 2 AM. J. BIOETHICS 31, 31 (2002). ("[Twenty-nine] states have legal declarations that human life begins at conception or fertilization, and nine states prohibit harmful experimentation on human embryos. Louisiana even defines the embryo fertilized in vitro as a juridical person.") (internal citations omitted).

¹⁸⁴ Even in those states that grant an exception, it is not clear that the legislatures considered the cloning issue. It would not be the first time legislation was premised upon an incomplete or incorrect understanding of the relevant scientific issues. See generally Henry T. Greely, *Banning "Human Cloning": A Study in the Difficulties of Defining Science*, 8 S. CAL. INTERDISC. L.J. 131, 132, 142 (1998) (explaining that some legislative products are a result of lack of understanding or bad drafting, while others, such as the Feinsein Bill, deliberately—and nearly invisibly—craft a loophole). According to a Westlaw search, conducted on October 19th, 2004, there are no federal or state cases about PGD.

One study revealed that policies toward PGD ranged from outright ban to absence of regulation.¹⁸⁵ The United Kingdom, for example, has taken a somewhat liberal position. The Human Fertilization and Embryological Authority (“HFEA”) has adopted a standard that embryos before the age of fourteen days may be subjected to experimentation. The authorizing agency thus permits PGD—but only under certain circumstances.¹⁸⁶ By way of contrast, Germany¹⁸⁷ is at the other end of the spectrum. Because a clone is created during the process, the German Embryo Protection Act prohibits PGD.¹⁸⁸ This lack of governmental consensus further suggests that a severed blastomere’s clonal nature could be material to a PGD decision.

Even if the state in which the procedure were performed did not prohibit PGD, one must examine other social standards to determine whether a clinician may invoke the benefit of implied consent to counter assertions of materiality. Religious perspectives provide one reliable measure, since religion plays a central role in personal attitudes toward the various reproductive technologies.¹⁸⁹ Disagreement between religions

¹⁸⁵ See Thornhill & Snow, *supra* note 38, at 25 n.142. In the absence of a clear policy about PGD, one can also examine policies regarding cloning. Members of the United Nations have been considering a world-wide ban on cloning for at least two years. *Id.* Currently at least forty nations want all forms of cloning banned, scientific as well as reproductive. See *Cloning: U.S. Again Seeks Worldwide U.N. Cloning Ban*, BioTech Watch (BNA) (Sept. 29, 2003).

¹⁸⁶ Roberts, *supra* note 1, at 11. The HFEA will authorize PGD when there is a genetic test available to avoid implantation of diseased babies, but will not authorize PGD just to match tissues with a diseased “sibling.” See Nelson, *supra* note 18, at 10. Therefore, the HFEA refused to authorize PGD for purposes of conceiving a tissue donor sibling for Charlie Whitaker, who suffered from Diamond Blackfan Anaemia, for which there is no genetic test. See *id.* The HFEA did authorize PGD for the Hashmi family. See *id.* Although they were permitted to match the tissues, it was because the process enabled them to eliminate diseased embryos. See *id.* This suggests that the HFEA recognizes that there is a moral line to be drawn; thus there is room for others to draw the line differently.

¹⁸⁷ See Regina Kenen, *Genetic Screening of Embryos Could Harm Society*, in REPRODUCTIVE TECHNOLOGIES 121, 132 (Carol Wekesser et al. eds., 1996). Norway, Austria, and Australia also ban or oppose PGD. See *id.*

¹⁸⁸ See de Wert, *supra* note 11, at 650. German concern over the moral status of early human life has materialized into a policy that permits only three embryos to be produced, all of which must be implanted under the Act. See Helga Kuhlmann, *Crisis Pregnancies in the Age of Human Genetic Diagnosis: Women’s Right to Self-determined Pregnancies and the Right of the “Other,”* in DESIGNING LIFE? GENETICS, PROCREATION AND ETHICS 93, 96 (Maureen Junker-Kenny ed., 1999).

¹⁸⁹ See Genetics & Pub. Policy Ctr., Phoebe R. Berman Bioethics Inst. at Johns Hopkins Univ., *Research Highlights: Adding the Religious Public’s Voice to the*

can be explained by different beliefs about the moral status of pre-implantation human biological life.¹⁹⁰

Since PGD involves the production of clones, one may consider religious perspectives on PGD to approximate those of cloning. As is true for governments, there is no uniform belief. Conservative religions, which comprise the largest population group, would prohibit the interventions.¹⁹¹ This is because non-therapeutic interventions would impermissibly compromise the dignity and full respect that must be accorded to nascent human life.¹⁹² According to this view, since science has shown that biological life begins at fertilization, any doubts about moral status should be resolved in favor of granting full human dignity.¹⁹³

Most of the more liberal religions would neither ban nor promote, but would accommodate the pace of science and social

Debate, (Sept. 2003). A recent Gallup poll substantiates this with its recent survey indicating that between 84% and 94% of the U.S. population considers religion to be an important part of their lives. See *How Important is Religion to Americans?*, MIAMI HERALD, Oct. 4, 2003, at 2E (reprinting statistics from Gallup poll). Thirty-six to 56% of Americans polled considered religion as "very important"; 35–47% considered religion "fairly important"; and only between 6 and 16% considered it "not very important." *Id.* See also Celia F. Fisher, *A Goodness-of-Fit Ethic for Informed Consent*, 30 FORDHAM URBAN L.J.159, 161 (2002) (accommodating moral values as important in consent).

¹⁹⁰ See Michael R. Panicola, *Three Views on the Preimplantation Embryo*, 2 NAT'L CATH. BIOETHICS Q. 69, 69–71 (2002) (providing insight on the three predominant views on the moral status of the human embryo: the "personal" position, the "pre-personal" position, and the "nonpersonal" position). The "personal" position on the moral status of early biological human life is that fertilization marks the time that full respect and dignity must be accorded because that is the time when personal life begins. *Id.* at 71; see also Roberts, *supra* note 1, at 1.

¹⁹¹ See Courtney S. Campbell, *Cloning Human Beings: Religious Perspectives on Human Cloning*, at D-22, 32–35, 37–39 (paper commissioned by the NBAC), available at www.georgetown.edu/research/nrcbl/nbac/pubs/cloning2/cc4.pdf (last visited Jan. 13, 2005) (analyzing why African-American churches (with respect to reproductive cloning), Orthodox Christians, Conservative Evangelical Christians, and Roman Catholics would likely prohibit human cloning). Together, this group comprises almost seventy percent of the religious U.S. population. See *id.* at D-21, D-32, D-33, D-37. Muslims have been included in this group as well. See generally Fadel, *supra* note 174, at 155–57 (explaining why Islam has declared cloning unlawful).

¹⁹² See Panicola, *supra* note 190, at 72–74 (according to the "personal" position regarding the moral status of early biological human life).

¹⁹³ See *id.* The gravity of making an improper choice to disregard the moral status of pre-implantation life (if one could know it to be improper in an absolute objective sense) can be seen by clinical example. In one publicized study of eleven patients, ninety-nine embryos were produced and biopsied, which resulted in sixteen transfers and four pregnancies. See Escudero et al., *supra* note 86, at 1531.

deliberation.¹⁹⁴ This middle ground position suggests that there may be some doubt about the moral status of early biological life, but these doubts need not be resolved by taking “the morally safest course.”¹⁹⁵ According to this view, respect, but not full human dignity, must be granted because the human organism has no individual personhood until the blastomeres have lost the ability to differentiate fourteen days after fertilization.¹⁹⁶ This position finds it significant that blastomeres may, after primitive streak development at day fourteen, separate and form twins. Therefore, it is only then that an entity is unique and entitled to respect as a human individual.¹⁹⁷

Only a few religions would permit outright some form of cloning.¹⁹⁸ Such a position is consistent with a “nonperson” view of the pre-implantation embryo. As such, no respect or protection is owed.¹⁹⁹ The basis for this belief rests in a consideration that early human life forms are incapable of self-consciousness, and sentience does not begin until at least six-weeks post-fertilization.²⁰⁰

Based on the brief explanation of a variety of religious viewpoints, one can reasonably infer that clients’ perspectives regarding the production of a blastomere clone are unlikely to be uniform. Because perspectives differ, a biopsy practitioner cannot take for granted that clients would consider the fact of blastomere clone production during PGD immaterial to the decision. Thus, consent cannot be regarded as implied.

¹⁹⁴ Campbell, *supra* note 191, at D-21–32, D-35–37 (listing African-American Churches (research cloning), Buddhism, Hinduism, Islam, Judaism, Native American, and some Mainline Protestant Christians); *see also* Jane Maienschein, *What’s in a Name: Embryos, Clones, and Stem Cells, in Stem Cell Research: A Target Article Collection*, 2 AM. J. BIOETHICS 3, 15 (2002) (noting that some Jewish and Muslim scholars, for example, would not object because they do not believe that life begins until day forty).

¹⁹⁵ Panicola, *supra* note 190, at 79.

¹⁹⁶ *See id.* at 77–79.

¹⁹⁷ *See id.* at 78. Under this view, however, it would be logical to conclude that clones such as Dolly (were she human) would not be considered a separate individual person because of its derivation from another life of the same genetic component. *See id.* at 81.

¹⁹⁸ Campbell, *supra* note 191, at D-35–37. Some of the Mainline Protestant Christians (who constitute seventeen percent of the religious population) would permit research cloning. *Id.* This group is comprised of American Baptists, Disciples of Christ, Episcopalians, Evangelical Lutherans, United Methodists, Presbyterians, and members of the United Church of Christ. *Id.* at D-35–36.

¹⁹⁹ Panicola, *supra* note 190, at 75.

²⁰⁰ *Id.* at 83–84.

Characterization of the PGD decision as not primarily medical²⁰¹ further enhances the strength of personal autonomy and “individualized values” as the guideposts.²⁰² Unlike medical decisions that rely on a physician’s expertise,²⁰³ a decision to undergo PGD reflects a moral choice²⁰⁴ that even physicians acknowledge as important.²⁰⁵ Valuing personal ethics when making decisions about whether to condone the production and subsequent destruction of blastomere clones to assist in selecting the “right” embryos for implantation would be consistent with general attitudes about genetic²⁰⁶ and reproductive decisions—including those related to IVF²⁰⁷ and prenatal testing.²⁰⁸ Since

²⁰¹ Bonnicksen, *supra* note 10, at 411 (embryo manipulations are not medically necessary). Unlike the medical norm, PGD along with other assisted reproductive technologies serve to circumvent rather than treat any underlying condition. See Noah, *supra* note 8, at 652. Moreover, ART as a whole differs significantly from medical procedures because it provides special services as well as a product: babies. See BLANK & MERRICK, *supra* note 18, at 15–17; Judith F. Daar, *Regulating Reproductive Technologies: Panacea or Paper Tiger?*, 34 HOUS. L. REV. 609, 616, 656 n.259 (1997). Men and women are seen as “consumers of reproductive services and products.” BLANK & MERRICK, *supra* at 17.

²⁰² See Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 900–01 (1994) (stating that the greater the privacy interests, the greater the respect for autonomy and “individualistic values”). Respect for dignity and its concurrent consent requirements means that a practitioner “must prefer the patient’s interests to her own.” *Id.* at 921 (emphasis in original). “The more private the choice—that is, the more it concerns the integrity of the individual’s own projects and self-conception and the less it directly affects others—the more robust this [individual autonomy] should be.” *Id.* at 924. Thus, individual choice as to whether PGD is an offensive touching is distinguished from whether this person should be eligible for access to PGD.

²⁰³ See Katz, *supra* note 84, at 69 (discussing a rationale for maintaining physician authority over decision-making as based on the physician’s superior knowledge, the patient’s incapability in making medical decisions, and physician altruism safeguarding abuse of their professional authority). Conflict-of-interest in the multi-billion dollar reproductive technology industry seriously erodes the altruism rationale.

²⁰⁴ See Roberts, *supra* note 1, at 9 (“Provided the parents are not hindered by their view of the moral status of the embryo, PGD can obviate the twenty-five percent to fifty percent risk of passing on specific genetic abnormalities.”). Reproductive decisions as a whole involve a moral perspective not present in other kinds of medical decisions. Therefore, greater deference to personal values should occur. See Botkin, *supra* note 32, at 291. Jeffrey Botkin, for example, raised the issue of informed consent concerns as an ethical issue with respect to the use of PGD. Botkin, *supra* note 2, at 25 (concerned about the lack of oversight over PGD, and the “value-laden context of PGD”).

²⁰⁵ Elias, *supra* note 4, at 1570.

²⁰⁶ See Pelias & Markward, *supra* note 162, at 839–40.

²⁰⁷ See Bonnicksen, *supra* note 10, at 419. Not everyone agrees on the “allocation of authority between individuals and society in the area of reproductive

deeply felt personal moral judgments form the basis of the decision about whether to authorize PGD, facts upon which the decision must rely are material and must be disclosed for consent to be effective.²⁰⁹ Thus, failure to explain the clonal nature of the embryo biopsy that precedes the preimplantation diagnosis renders the intervention a battery.

decision-making.” Carl H. Coleman, *Assisted Reproductive Technologies and the Constitution*, 30 *FORDHAM URB. L.J.* 57, 59 (2002). When consumers would choose to implant more embryos than can reasonably flourish, limiting their choice to do so may seem particularly appropriate. See Noah, *supra* note 8, at 629, 636–37. Some would qualify a couple’s autonomy under some circumstances. For example, some practitioners would deny access to intracytoplasmic sperm injection (“ICSI”) unless the man either submits to genetic testing or agrees to PGD. The reason is that there is a high frequency of genetic or chromosomal anomalies in subfertile males who require the ICSI treatment to conceive. de Wert, *supra* note 11, at 654. To overcome subfertility in men, ICSI is sometimes used in conjunction with IVF. As its name implies, fertilization is accomplished by inserting a single sperm cell directly into the egg’s cytoplasm. Tasca & McClure, *supra* note 2, at 8.

The limitations on autonomy seem to relate to rights-based arguments. See, e.g., Norton, *supra* note 11, at 1623–28; Alvare, *supra* note 23, at 38, 56 (constitutional analysis revealing no protected right to collaborative reproduction through ART, and noting the connection between rights-based arguments, ART, and cloning). That is not the sense of autonomy under discussion in this article. The focus here is on a couple’s right to be informed of material information that would enable them to discern whether touching related to PGD would be offensive to them. The question of whether autonomy should be limited when the touching would be unoffensive is a different, and perhaps subsequent, issue that also must be addressed. One way would be to re-examine the definition of autonomy in the rights-based context. While de Wert believes that practitioners who limit access to ART under defined circumstances rightly limit autonomous choice, another interpretation is that those practitioners have simply incorporated a natural law view of autonomy.

²⁰⁸ See Judith F. Daar, *Regulating the Fiction of Informed Consent in ART Medicine*, 1 *THE AM. J. BIOETHICS* 19, 19 (2001) (noting that decisions about medical treatment are frequently made because of “fear, emotion and religious beliefs,” which have nothing to do with scientific or medical accuracy). See also Suter, *supra* note 20, at 263 (where the point of disclosure [of the implications as well as the risks of prenatal testing] is to enable patients to incorporate their own personal values in the decision about whether to undergo the testing).

²⁰⁹ See Botkin, *supra* note 32, at 285. This gives effect to societal views about the importance of autonomous decision-making that gave rise to the doctrine of informed consent. See Scott, *supra* note 39, at 266 (where, in cases of conflict, autonomy trumps beneficence). The spirit of the doctrine was meant to foster, not inhibit, conversations that would result in decisions that incorporated ethical reflection. *Id.* at 295–96. See also Gatter, *supra* note 105, at 961 (where patient autonomy is protected not by the consent document, but by meaningful participation through doctor-patient discourse).

CONCLUSION

PGD clients are likely to disagree about the morality of producing blastomere clones. While some may view the production as morally licit, others would consider it morally unacceptable. A third group may be uncertain about the virtue of cloning for diagnostic purposes. This group can be further subdivided. Some might consider PGD preferable to other selection alternatives once the decision has been made to undergo IVF to achieve pregnancy and to birth only "healthy" babies. PGD could be depicted as less invasive than pre-natal diagnosis,²¹⁰ as posing fewer risks to a surviving embryo than amniocentesis,²¹¹ and as avoiding the moral quandary of abortion.²¹² Others in this middle group may conclude differently, reasoning uncertainty about the morality of cloning outweighs the advancement that of personal reproductive interests.²¹³ Clients may decide differently based on the fact of blastomere clone production. Therefore, this fact is material to the decision.

When the information is withheld, clients are prevented from making a reasoned decision that is guided by their own deeply felt moral beliefs. They are also subject to potential manipulation by practitioners who may have different value preferences than their clients.²¹⁴ Unlike clients, practitioners

²¹⁰ See Ephross, *supra* note 85, at 466. Given the manipulation to the woman's body during IVF treatment, the idea that PGD is less invasive seems strange. Perhaps the author considered invasiveness only in the IVF context.

²¹¹ See *id.*

²¹² Elias, *supra* note 4, at 1570; Kuhlmann, *supra* note 188, at 97; see also C. Cameron & R. Williamson, *Is There an Ethical Difference Between Preimplantation Genetic Diagnosis and Abortion?*, 29 J. MED. ETHICS 90 (April 2003) (arguing that a pre-implantation embryo need be accorded less respect than an implanted embryo to whom the mother has developed an emotional attachment).

A gnawing concern is that PGD technology allows couples to eliminate embryos that they would not choose to abort. Thus, while avoiding the specific abortion quandary, couples are faced with a different ethical query involving eugenic choices. See Cecchin, *supra* note 21, at 112; Robertson, *supra* note 9, at 450–51. On the other hand, Lori Andrews suggests that, unlike abortion, once couples have made the choice to utilize IVF, implantation decisions are made for rather than against. ANDREWS, *supra* note 53, at 164–65.

²¹³ See Robertson, *supra* note 9, at 452 (stating that some may find PGD "symbolically distasteful").

²¹⁴ See Gianaroli et al., *supra* note 41, at 310 ("[T]he major goal is to provide the best of our own scientific knowledge and technical possibilities for the birth of healthy children."); Katz, *supra* note 84, at 75 (revealing the need for dialogue between the clinician and patient).

are likely to have value preferences based in science, which often conflicts with moral values.²¹⁵

Because there is no consensus on the morality of producing a blastomere clone, disclosure must go beyond detailing the technical procedures and risks to embryos whose blastomere is removed and tested. In place of the distracting information that causes confusion about the fact of cloning,²¹⁶ decision-makers will need direct statements that these blastomeres, unlike those removed for stem cell research, have the potential to fully develop. Although the procedure's focus does not envision survival, the fact of clone production has significance. Unlike biopsies of somatic cells for diagnostic information, the consequence of performing an embryo biopsy is the production of a new body with independent biological significance. This fact

Manipulation is relatively easy. Counselor-controlled presentation of the questions, information, and options leads to client-receptivity to the choice favored by the presenter. Kass, *supra* note 5, at 8. A serious problem is that, contrary to popular misconception, the scientific view of human life is not morally neutral. *Id.* It is grounded not on the reverence for human dignity that distinguishes Man from animal, which some scientists wish to dismiss as anachronistic "tribal" theology, but on a humanist position that elevates curing disease and prolonging life as the principles worthy of moral power. *Id.* at 11–12, 14–15.

²¹⁵ FADEN & BEAUCHAMP, *supra* note 71, at 117 (quoting from Martin S. Pernick, *The Patient's Role in Medical Decisionmaking: A Social History of Informed Consent in Medical Therapy*, in 3 PRESIDENT'S COMMISSION, MAKING HEALTH CARE DECISIONS 3 (1983)); see also Edmund Pellegrino, *The Physician's Conscience, Conscience Clauses, and Religious Belief: A Catholic Perspective*, 30 FORDHAM URB. L.J. 221, 234–36, 241 (expressing concern that medical school applicants are asked to state their views on reproductive technologies and other religiously sensitive issues, and the reduction of moral values in medicine).

²¹⁶ See, e.g., Fred Guterl, *To Build a Baby*, NEWSWEEK, June 9, 2003, at 70 (discussing tissue matching for Molly Nash through PGD, the potential for commodifying children and the specter of eugenics, the article leads one to infer the absence of cloning: "While the world panics over false claims of human cloning, PGD is quietly transforming reproductive medicine."). The use of the term "biopsy" is itself distracting. While it certainly conveys the message of testing, it infers the non-importance of the cell being tested. Some popular media altogether skip the "biopsy," just mentioning that the IVF embryos were "tested." While mentioning the potential for abuse, the focus was on the benefits of eliminating disease and debunking the fear. See Jerome Groopman, *Designing Babies*, WALL ST. J., March 4, 2002, at A14. Some of the PGD pioneers prefer the acronym "BABI" (blastomere analysis before injection). See WINGERSON, *supra* note 68, at 50. In general, there is a lack of public understanding about genetics and genetic technology, and institutions "prey on this dearth of general knowledge." Pelias & Markward, *supra* note 162, at 854 (stating that lack of public understanding leads to bans on experiments rather than making beneficial use of the outcomes of the HGP). Another factor is the distraction of noting that the host embryo is not affected, diverting attention away from the totipotency of the cell removed.

alters the nature of the biopsy procedure and must be disclosed in light of the varied views among decision-makers, who are in a better position than clinicians to evaluate the moral significance of the procedure.²¹⁷

The absence of consensus and the lack of medical necessity for the procedure mandate that practitioners cannot rely on a "reasonable person" perspective to bolster implied consent or to defend against charges that no consent has been proffered based on the inadequate provision of material information regarding the nature of the procedure. Devoid of specific disclosures, a clone will involuntarily be produced because effective consent to PGD does not exist. Those who perform the intervention thereby inflict a battery.

²¹⁷ See Maureen L. Condic & Samuel B. Condic, *The Appropriate Limits of Science in the Formation of Public Policy*, 17 NOTRE DAME J.L. ETHICS & PUB. POLY 157, 161 (2003) (noting that science is about possibilities rather than morality). Thus, clinicians are likely to come from a different perspective than their clients.