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Perfecting Pregnancy via Preimplantation Genetic Screening: The Quest for an Elusive Standard of Care

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Perfecting Pregnancy via Preimplantation Genetic Screening: The Quest for an Elusive Standard of Care

Jolene S. Fernandes*

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INTRODUCTION

Imagine a thirty-eight-year-old female patient who has suffered three

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spontaneous miscarriages within the past two years and is now seeking treatment at a local fertility clinic. Preliminary tests show that the patient's most recent abortus (i.e., an aborted fetus less than twelve weeks old) contains several chromosomal abnormalities (also known as "aneuploidies"), and the physician determines that preimplantation genetic screening (PGS)¹ may be warranted to help counter the patient's history of recurrent pregnancy loss. The fertility clinic is familiar with traditional aneuploidy screening techniques, which involve biopsying one to two cells from cleavage-stage embryos and conducting fluorescent in situ hybridization (FISH) analysis—a procedure that was developed over ten years ago and is frequently practiced by a majority of fertility clinics that assist in the identification and transfer of viable embryos.² The physician, through her own independent research, learns of a fairly new PGS-aneuploidy screening technique that (a) is less likely to damage the patient's embryos (which are, without question, invaluable to individuals struggling with infertility) during the biopsy step, and (b) yields more complete, accurate, and reliable genetic information than FISH analysis. However, PGS-aneuploidy screening is still regarded as an experimental technique within the medical community.³ Additionally, the American Society for Reproductive Medicine's (ASRM)⁴ existing clinical practice guidelines (CPGs) recommend against the routine application of PGS-aneuploidy screening in patients diagnosed with repetitive pregnancy loss.⁵ Moreover, the ASRM's CPGs fail to recommend preferred PGS-aneuploidy screening protocols that would signal the standard of care that is expected of a physician performing these procedures.⁶

The physician is now confronted with a difficult choice—should she minimize her risk of liability by recommending the traditional aneuploidy screening technique that has been available for the past decade and appears to be a customary practice within the field? Or should she recommend the newer, optimized technique that is arguably more beneficial in terms of clinical outcome, but is not yet a generally accepted practice? Legal ambiguity as to what the proper standard of care is under these circumstances creates uncertainty about the risk of malpractice liability for adopting emerging technologies that are not yet generally

1. PGS is a technique that seeks to improve the outcomes of assisted reproductive treatments by ensuring that the embryos selected for transfer are chromosomally normal.

2. Elpida Fragouli & Dagan Wells, *Aneuploidy Screening for Embryo Selection*, 30 SEMINARS REPROD. MED. 289, 290 (2012).

3. Practice Comm. of the Soc'y for Assisted Reprod. Tech. & Practice Comm. of the Am. Soc'y for Reprod. Med., *Preimplantation Genetic Testing: A Practice Committee Opinion*, 90 FERTILITY & STERILITY S136, S141–42 (2008) [hereinafter SART & ASRM].

4. The ASRM is a professional medical society that oversees developments in the field of reproductive medicine. *About Us: Vision of ASRM*, ASRM, <http://www.asrm.org/about/> (last visited Dec. 20, 2014).

5. Practice Comm. of the Am. Soc'y for Reprod. Med., *Evaluation and Treatment of Recurrent Pregnancy Loss: A Committee Opinion*, 98 FERTILITY & STERILITY 1103, 1105 (2012) [hereinafter ASRM].

6. *See id.*; SART & ASRM, *supra* note 3.

accepted by the medical community. Such uncertainty may effectively deter physicians from adopting new medical techniques and devices, even if the technologies offer broad social benefits in the form of superior clinical outcomes. An unfortunate side effect of this reluctance is that patients with poor medical prognoses are more likely to receive suboptimal PGS-aneuploidy screening services because physicians either fail to recommend or to provide the improved technology.

One possible solution is to impose a legal duty on assisted reproductive technology (ART) specialists to offer and provide optimized PGS-aneuploidy screening services as part of the standard of care for patients that have an elevated risk of miscarriage or low implantation rates. However, despite the vast literature on the legal, social, and ethical ramifications of preimplantation genetic diagnostic (PGD) testing,⁷ there is barely any scholarship that directly addresses the standard of care that ART physicians owe to their patients in the context of adopting emerging technologies. This Note attempts to resolve this apparent gap by defining a standard of care that is dynamic, easy to administrate, and circumvents the problems of over- and underinclusiveness, thereby ensuring that similarly situated defendants will be treated equally under the law. Ease of application reduces the burden on courts, juries, and litigants by facilitating the resolution of malpractice claims. Dynamism, or flexibility, guarantees that the law adapts to “changes and improvement in medical science.”⁸ Circumventing the problems of over- and underinclusiveness involves tailoring the law as closely as possible, neither to hold too many nor too few defendants accountable for their conduct. Part I evaluates the clinical benefits of integrating optimized PGS-aneuploidy screening with routine in vitro fertilization (IVF) procedures, especially in patients with an elevated risk of implantation failure or recurrent pregnancy loss. Part II explores current legal doctrines that define a physician’s standard of care in the context of adopting novel medical technologies. Part III of this Note argues that courts should apply the “reasonable physician” standard rather than a custom-based, or CPG-based, standard of care with respect to emerging ART technologies if the end goal is to remain fair and realistic as the practice of reproductive medicine continues to evolve. Ultimately, this Note argues that imposing a duty on ART physicians to provide optimized PGS-aneuploidy screening services as part of the standard of care is both tenable and opportune in

7. See, e.g., COLIN GAVAGHAN, DEFENDING THE GENETIC SUPERMARKET: LAW AND ETHICS OF SELECTING THE NEXT GENERATION (Sheila A.M. McLean ed., 2007); REPROGENETICS: LAW, POLICY, AND ETHICAL ISSUES (Lori P. Knowles & Gregory E. Kaebnick eds., 2007); ROSAMUND SCOTT, CHOOSING BETWEEN POSSIBLE LIVES: LAW AND ETHICS OF PRENATAL AND PREIMPLANTATION GENETIC DIAGNOSIS (2007); THE SORTING SOCIETY (Loane Skene & Janna Thompson eds., 2008); Judith F. Daar, *ART and the Search for Perfectionism: On Selecting Gender, Genes, and Gametes*, 9 J. GENDER RACE & JUST. 241 (2005).

8. *Nowatske v. Osterloh*, 543 N.W.2d 265, 272 (Wis. 1996), *abrogated by* *Nommensen v. Am. Cont'l Ins. Co.*, 629 N.W.2d 301 (Wis. 2001).

light of recent advances in comprehensive molecular cytogenetics and embryo biopsy procedures.

I. ASSESSING THE CLINICAL BENEFITS OF OPTIMIZED PGS-ANEUPLOIDY SCREENING TECHNIQUES

One of the major challenges ART physicians currently face is how to reduce the risk of multiple pregnancy while improving overall pregnancy rates. As the ART field attempts to move toward single embryo transfer, developing reliable methods that accurately predict which embryos are likely to produce a healthy child becomes increasingly important. Chromosomal abnormality, or aneuploidy, negatively impacts embryo viability and is one of the major causes of recurrent miscarriages⁹ and failed IVF attempts.¹⁰ One proposal to improve implantation and pregnancy rates after IVF involves the identification and preferential transfer of chromosomally normal (euploid) embryos since the transfer of a chromosomally abnormal embryo is unlikely to result in a healthy live birth.¹¹ For the past decade, a growing number of fertility clinics have adopted chromosome screening techniques to assist in the identification and transfer of viable embryos.¹² The most common approach involves the biopsy of one or two cells from embryos at the cleavage stage (three days after fertilization), followed by chromosomal analysis via FISH and the preferential transfer of euploid embryos.¹³ This approach is commonly referred to as PGS, and has mostly been targeted at patients with poor medical prognoses, such as recurrent pregnancy loss, repeated implantation failure, or advanced maternal age.¹⁴ Although several pioneering groups have reported improvements in IVF outcomes after PGS,¹⁵ a number of

9. M.D. Stephenson et al., *Cytogenetic Analysis of Miscarriages from Couples with Recurrent Miscarriage: A Case-Control Study*, 17 HUM. REPROD. 446, 446–51 (2002).

10. Y. Verlinsky et al., *Pregnancies Following Pre-Conception Diagnosis of Common Aneuploidies by Fluorescent In-Situ Hybridization*, 10 HUM. REPROD. 1923, 1923–27 (1995).

11. Santiago Munné, *Preimplantation Genetic Diagnosis and Human Implantation—A Review*, 24 PLACENTA S70, S70–S76 (2003).

12. Fragouli & Wells, *supra* note 2, at 290.

13. *Id.* (“[T]he vast majority of PGS cases have continued to be conducted on day 3. The reasons for the continued application of chromosome screening at the cleavage stage may be due to most embryologists having little experience with embryo biopsy at other stages, limiting exploration of alternatives, and due to publications providing reassurance that . . . the proportion of embryos misdiagnosed is low.”).

14. Santiago Munné et al., *Diagnosis of Major Chromosome Aneuploidies in Human Preimplantation Embryos*, 8 HUM. REPROD. 2185, 2185–91 (1993).

15. See John G. Garrisi et al., *Effect of Infertility, Maternal Age and Number of Previous Miscarriages on the Outcome of Preimplantation Genetic Diagnosis for Idiopathic Recurrent Pregnancy Loss*, 92 FERTILITY & STERILITY 288, 288–95 (2009); Luca Gianaroli et al., *Preimplantation Genetic Diagnosis Increases the Implantation Rate in Human In Vitro Fertilization by Avoiding the Transfer of Chromosomally Abnormal Embryos*, 68 FERTILITY & STERILITY 1128, 1128–31 (1997); Santiago Munné et al., *Improved Implantation After Preimplantation Genetic Diagnosis of Aneuploidy*, 7 REPROD. BIOMEDICINE ONLINE 91, 91–97 (2003); Santiago Munné et al., *Positive Outcome After Preimplantation Diagnosis of Aneuploidy in Human Embryos*, 14 HUM. REPROD. 2191, 2191–99 (1999); Santiago Munné et al., *Preimplantation*

studies have failed to demonstrate improvements in IVF outcomes for patients of advanced maternal age, thus causing researchers to question the clinical efficacy of PGS screening.¹⁶ In fact, a seminal study revealed that the ongoing pregnancy rate and live birth rate were significantly lower in women who underwent PGS screening compared to their untreated counterparts.¹⁷

There are several biological and technical explanations for why PGS via FISH failed to improve implantation and pregnancy rates. First, PGS is based on the faulty assumptions that the single cell biopsied is representative of the rest of the embryo given, and that approximately twenty to forty percent of human cleavage-stage embryos are mosaic.¹⁸ Embryonic mosaicism thus poses significant accuracy problems for diagnostics based on the sampling of a single cell. Second, PGS specialists cannot improve testing accuracy by running duplicate experiments because the biopsied cell only provides enough genetic material to conduct one to two genetic tests, at most.¹⁹ Third, the removal of even a single cell from a cleavage-stage embryo may lead to reduced viability and implantation rates.²⁰ This reduction in implantation rate is likely to be much higher if experienced practitioners do not perform the biopsy procedure, which could potentially eliminate any benefit obtained by embryo screening.²¹ Fourth, the overall

Genetic Diagnosis Significantly Reduces Pregnancy Loss in Infertile Couples: A Multicenter Study, 85 FERTILITY & STERILITY 326, 326–32 (2006).

16. See T. Hardarson et al., *Preimplantation Genetic Screening in Women of Advanced Maternal Age Caused a Decrease in Clinical Pregnancy Rate: A Randomized Controlled Trial*, 23 HUM. REPROD. 2806, 2806–12 (2008); Sebastiaan Mastenbroek et al., *In Vitro Fertilization with Preimplantation Genetic Screening*, 357 NEW ENG. J. MED. 9, 9–17 (2007); Catherine Staessen et al., *Comparison of Blastocyst Transfer with or Without Preimplantation Genetic Diagnosis for Aneuploidy Screening in Couples with Advanced Maternal Age: A Prospective Randomized Controlled Trial*, 19 HUM. REPROD. 2849, 2849–58 (2004).

17. Mastenbroek et al., *supra* note 16, at 9; see also Hardarson et al., *supra* note 16, at 2806.

18. Evelyne Vanneste et al., *Chromosome Instability Is Common in Human Cleavage-Stage Embryos*, 15 NATURE MED. 577, 577–83 (2009); Lucille Voullaire et al., *Chromosome Analysis of Blastomeres from Human Embryos by Using Comparative Genomic Hybridization*, 106 HUM. GENETICS 210, 210–17 (2000). Mosaicism refers to a condition where not every cell in the embryo has the same chromosome structure.

19. Jaime King, *Predicting Probability: Regulating the Future of Preimplantation Genetic Screening*, 8 YALE J. HEALTH POL'Y L. & ETHICS 283, 297–98 (2008) (“Having only the biopsied cell’s DNA available for testing greatly limits testing options Currently, couples must choose between conducting an analysis on five to nine chromosomes and conducting one to two genetic tests, as these tests examine the DNA in different ways.”).

20. Jacques Cohen et al., *Removal of 2 Cells from Cleavage Stage Embryos Is Likely to Reduce the Efficacy of Chromosomal Tests That Are Used to Enhance Implantation Rates*, 87 FERTILITY & STERILITY 496, 496–503 (2007); A. De Vos et al., *Impact of Cleavage-Stage Embryo Biopsy in View of PGD on Human Blastocyst Implantation: A Prospective Cohort of Single Embryo Transfers*, 24 HUM. REPROD. 2988, 2988–96 (2009).

21. Fragouli & Wells, *supra* note 2, at 291; William B. Schoolcraft et al., *Clinical Application of Comprehensive Chromosomal Screening at the Blastocyst Stage*, 94 FERTILITY & STERILITY 1700, 1704 (2010). Excessive biopsy damage appears to have been a contributing factor in at least one PGS study that found no benefit of chromosome screening. Jacques Cohen & James A. Grifo, *Multicentre Trial of Preimplantation Genetic Screening Reported in the New England Journal of Medicine: An In-Depth Look at the Findings*, 15 REPROD. BIOMEDICINE ONLINE 365, 365–66 (2007); *Preimplantation Genetic Diagnosis Pioneers from the USA and Europe Refute New England Journal of Medicine Article*, MED. NEWS TODAY

effectiveness of single-cell FISH analysis is hampered by several technical limitations. Single-cell FISH involves technically challenging steps, like cell fixation on a microscope slide that is sensitive to changes in temperature and humidity, and if performed incorrectly, can yield inconclusive results.²² Furthermore, more than one-half of the chromosomes in each biopsied cell remain unexamined after FISH analysis,²³ enabling some chromosomally abnormal embryos to be classified as “normal,” and thus erroneously selected for transfer.²⁴

Fortunately, advances in PGS-aneuploidy screening have led to the creation of techniques that overcome most of the problems that limit FISH-based PGS methods. The first improvement involves performing the embryo-biopsy procedure at the blastocyst stage, two days later than traditional PGS methods.²⁵ Unlike individual cells in cleavage-stage embryos, trophectoderm cells sampled during blastocyst biopsy have much lower rates of mosaicism, and are thus highly representative of the remainder of the embryo.²⁶ Although it is typical to extract about five cells, the relative proportion of the embryo volume that is removed during the blastocyst stage is smaller than that associated with single-cell biopsy at the cleavage stage.²⁷ Moreover trophectoderm cells are destined to form the placenta rather than the actual fetus.²⁸ Thus, unlike cleavage-stage embryo biopsy, trophectoderm sampling is less likely to be detrimental to embryo viability, a notion that is supported by high survival and implantation rates.²⁹ Emerging data also reveals that comprehensive molecular cytogenetic methodologies, like comparative genomic hybridization (CGH), SNP microarrays, and qPCR-based comprehensive chromosome screening (CCS) technology, could offer clinical benefits to certain women at high risk for an aneuploid pregnancy.³⁰ Furthermore,

(July 10, 2007, 1:00 AM), <http://www.medicalnewstoday.com/articles/76269.php> [hereinafter *PGD Pioneers*].

22. Fragouli & Wells, *supra* note 2, at 291.

23. *Id.* at 290 (“This was due to the fact that only five distinct colors (fluorochromes) in the visible spectrum were available for probe labeling, and consequently the number of chromosomes that could be simultaneously assessed was limited . . .”).

24. King, *supra* note 19, at 293 n.37. Even the best FISH-based methods fail to detect about twenty percent of abnormal embryos, not to mention other FISH-based methods where more than one-half of the abnormal embryos may go undetected. Schoolcraft et al., *supra* note 21, at 1704.

25. *Single Euploid Blastocyst Transfer Recent Technology*, FERTILITY CTR. & APPLIED GENETICS FLA., <http://geneticsandfertility.com/blastocyst-transfer-recent-technology/> (last visited Oct. 22, 2014).

26. E. Fragouli et al., *Comprehensive Molecular Cytogenetic Analysis of the Human Blastocyst Stage*, 23 *HUM. REPROD.* 2596, 2596–608 (2008).

27. Fragouli & Wells, *supra* note 2, at 296.

28. *Id.*

29. Steven J. McArthur et al., *Pregnancies and Live Births After Trophectoderm Biopsy and Preimplantation Genetic Testing of Human Blastocysts*, 84 *FERTILITY & STERILITY* 1628, 1628–36 (2005); Schoolcraft et al., *supra* note 21, at 1704.

30. E.J. Forman et al., *Single Embryo Transfer with Comprehensive Chromosome Screening Results in Improved Ongoing Pregnancy Rates and Decreased Miscarriage Rates*, 27 *HUM. REPROD.* 1217, 1217–22 (2012) (evaluating the efficacy of single embryo transfer with qPCR-based CCS in an infertile population); Ali Hellani et al., *Successful Pregnancies After Application of Array-Comparative Genomic Hybridization in PGS-Aneuploidy Screening*, 17 *REPROD. BIOMEDICINE ONLINE* 841, 843 (2008) (showing successful clinical

several recent studies show that comprehensive molecular cytogenetic methodologies also improve the success rate of single-embryo transfers in good prognosis IVF patients, thereby reducing the risk of a multiple pregnancy.³¹ Taken together, these data strongly suggest that PGS screening can improve IVF outcomes in patients, regardless of age or medical prognosis.

PGS-aneuploidy screening techniques involving CGH, SNP, or CCS are diagnostically superior because, unlike FISH-based methods, they can gather information on the entire chromosome complement of individual cells, thereby minimizing the likelihood of selecting chromosomally abnormal embryos for transfer.³² These screening methods are less difficult compared to FISH because they do not require cell fixation on a microscope slide,³³ and the two to five cells removed during trophoctoderm biopsy provide more than enough starting genetic material to analyze all twenty-three pairs of chromosomes.³⁴ Perhaps the most important advantage that these comprehensive molecular cytogenetic approaches have over FISH is that they are far less susceptible to errors caused by mosaicism than FISH, and thus, they maximize the likelihood of identifying euploid embryos for preferential transfer.³⁵

application of CGH-based screening in advanced maternal age patients with recurrent IVF failures); Schoolcraft et al., *supra* note 21, at 1705; William B. Schoolcraft et al., *Comprehensive Chromosome Screening (CCS) with Vitrification Results in Improved Clinical Outcome in Women >35 Years: A Randomized Control Trial*, 98 FERTILITY & STERILITY S1, S1 (2012) (finding that interrogating embryos by array-CGH resulted in significantly higher pregnancy rates compared to non-PGS-treated controls); William B. Schoolcraft et al., *Live Birth Outcome with Trophoctoderm Biopsy, Blastocyst Vitrification, and Single-Nucleotide Polymorphism Microarray-Based Comprehensive Chromosome Screening in Infertile Patients*, 96 FERTILITY & STERILITY 638, 639 (2011) (finding that the combination of trophoctoderm biopsy, blastocyst vitrification, and SNP microarrays for CCS results in high implantation and live birth rates in infertile patients); R.T. Scott, Jr. et al., *A Prospective Randomized Controlled Trial Demonstrating Significantly Increased Clinical Pregnancy Rates Following 24 Chromosome Aneuploidy Screening: Biopsy and Analysis on Day 5 with Fresh Transfer*, 94 FERTILITY & STERILITY S2, S2 (2010) (evaluating the efficacy of single embryo transfer with qPCR-based CCS in IVF patients less than forty-three years of age with no history of failed cycles).

31. E.J. Forman et al., *Blastocyst Euploid Selective Transfer (BEST): An RCT of Comprehensive Chromosome Screening—Single Embryo Transfer (CCS-SET) vs Double Embryo Transfer (DET)—Equivalent Pregnancy Rates, Eliminates Twins*, 98 FERTILITY & STERILITY S49, S49 (2012) (evaluating the efficacy of single embryo transfer with qPCR-based CCS compared to the current standard of care, a double unscreened embryo transfer); Zhihong Yang et al., *Selection of Single Blastocysts for Fresh Transfer via Standard Morphology Assessment Alone and with Array CGH for Good Prognosis IVF Patients: Results from a Randomized Pilot Study*, 5 MOLECULAR CYTOGENETICS 24, 24 (2012) (evaluating the efficacy of single embryo transfer with CGH in good prognosis IVF patients).

32. See studies cited *supra* notes 29–31.

33. Schoolcraft et al., *supra* note 21, at 1705.

34. Paul R. Brezina et al., *Single-Gene Testing Combined with Single Nucleotide Polymorphism Microarray Preimplantation Genetic Diagnosis for Aneuploidy: A Novel Approach in Optimizing Pregnancy Outcome*, 95 FERTILITY & STERILITY 1786.e5, 1786.e6 (2011).

35. Fragouli & Wells, *supra* note 2, at 297.

Specifically, methods such as aCGH or SNP microarrays provide an average view of the biopsied TE sample, and aneuploidy is generally not detected unless it is present in more than a third of the cells sampled. It could be argued that the failure to detect low levels of

In sum, studies combining optimized biopsy procedures and comprehensive molecular cytogenetic screening methods have, thus far, yielded extremely promising IVF outcomes, and “may finally allow preimplantation genetic screening to achieve the benefits predicted by theory.”³⁶ Advances in PGS-aneuploidy screening represent a major milestone in the medical community’s movement toward single embryo transfer, and have the potential to transform routine medical procedures in fertility clinics throughout the globe.

II. CONTEMPORARY LEGAL DOCTRINES GOVERNING A PHYSICIAN’S STANDARD OF CARE FOR EMERGING MEDICAL TECHNOLOGIES

Early adoption of cutting-edge medical technologies by physicians is accompanied by some degree of malpractice liability risk. The standard of care for malpractice liability claims varies between jurisdictions but generally requires an evaluation of the physician’s conduct against professional custom, or the “reasonable physician” standard.³⁷ At the same time, medical malpractice and negligence doctrines make it clear that standards of care are evolutionary rather than static, and health-care providers have a “duty to stay abreast” of new techniques and advances.³⁸ But the simple recognition that medical knowledge evolves over time

provides scarce insight into the reality that those changes do not occur seamlessly, but by fits and starts, with the serial introduction of a multitude of new drugs, new devices, and new techniques, each of which starts out as experimental agent with imperfectly known risks, and each of which involves a departure from what most physicians are doing, *ex ante*, in providing care for their patients.³⁹

Far less clear is how the standard of care analysis applies to a situation where an injury results from the use of emerging technologies that have not yet been incorporated into the standard customary practices of most physicians.

Part II is thus concerned with identifying the existing legal frameworks that define a physician’s standard of care for adopting emerging medical technologies. Part II.A examines the courts’ movement away from a custom-based standard of

abnormal cells is a disadvantage of these methods applied to blastocyst biopsies. However, in most cases, low-level mosaicism is probably of little clinical significance.

Id.

36. Schoolcraft et al., *supra* note 21, at 1700.

37. Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 165–88 (2000); Donald E. Kacmar, Note, *The Impact of Computerized Medical Literature Databases on Medical Malpractice Litigation: Time for Another Helling v. Carey Wake-Up Call?*, 58 OHIO ST. L.J. 617, 647 (1997).

38. See generally Carter L. Williams, Note, *Evidence-Based Medicine in the Law Beyond Clinical Practice Guidelines: What Effect Will EBM Have on the Standard of Care?*, 61 WASH. & LEE L. REV. 479, 508–12 (2004).

39. Michael D. Greenberg, *Medical Malpractice and New Devices: Defining an Elusive Standard of Care*, 19 HEALTH MATRIX 423, 424–25 (2009).

care, toward a “reasonable physician” standard of care. Part II.B delves into the commonly recited yet nebulous duty to stay abreast and its impact on the appropriate standard of care for medical professionals. Part II.C explains why CPGs, despite their usefulness, should not be treated as the panacea for determining the standard of care. Finally, Part II.D analyzes the common law doctrine of the duty to inform patients of a newly developed, alternative therapy. Taken together, these concepts and legal frameworks help mitigate a physician’s reluctance in adopting new technologies due to the ill-defined malpractice liability risks associated with doing so. A liberal interpretation of the malpractice standard of care with respect to emerging technologies would promote both physician and patient autonomy, foster innovation and rapid optimization of new medical techniques and devices, and reduce costs on patients, thereby contributing to an elevated standard of professional care.

A. The Demise of Judicial Deference to Custom in Medical Malpractice

The goal of the malpractice standard of care is to ensure that physicians fulfill their professional obligations with appropriate skill and care. Much like a negligence claim, to prevail in a medical malpractice suit, the plaintiff must prove that (1) the defendant owed a duty to the plaintiff, (2) the defendant breached that duty, and (3) the plaintiff’s injuries were causally related to the defendant’s breach.⁴⁰ What separates a medical malpractice claim from an ordinary negligence claim is the duty owed by the defendant, or the “standard of care.” Physicians traditionally have only needed to conform to the customs of their peers.⁴¹ Consequently, the relevant inquiry under a custom-based standard of care is not whether the defendant behaved like a reasonable person (or even a reasonable physician for that matter), but instead whether the defendant’s actions were consistent with professional norms. Thus, evidence of the ineffectiveness of customary practices is often excluded under the custom-based standard of care.⁴²

A key concern with maintaining a custom-based standard of care is that the

40. W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 30, at 164–65 (5th ed. 1984); see also RESTATEMENT (SECOND) OF TORTS § 281 (1965).

41. See 61 AM. JUR. 2D PHYSICIANS, SURGEONS & OTHER HEALERS § 348 (1981). Historically, a jury’s determination of the applicable standard of care was limited by the “locality rule,” which holds the physician to the standard of care exercised by physicians in the defendant’s own community or locality. See Katherine Randall Bowden, Comment, *Standard of Care for Medical Practitioners—Abandonment of the Locality Rule*, 60 KY. L.J. 209, 209–15 (1971); Jon R. Waltz, *The Rise and Gradual Fall of the Locality Rule in Medical Malpractice Litigation*, 18 DEPAUL L. REV. 408 (1969). The locality rule developed as a method for evaluating the applicable standard of care by taking into account the variety of resource conditions that existed within different communities. E. Haavi Morreim, *Cost Containment and the Standard of Medical Care*, 75 CALIF. L. REV. 1719, 1729 (1987). However, the rationale for the locality rule has continued to erode over the past several decades as a result of advances in technology, standardized curricula in medical schools, required physician certification, and increased access to technology and resources. *Id.* at 1730.

42. See, e.g., *Schneider v. Revici*, 817 F.2d 987, 990 (2d Cir. 1987) (“[T]he issue in medical malpractice is not whether a particular treatment is effective but whether that treatment is a deviation from accepted medical practice in the community.”).

standard “may create perverse incentives that have little to do with preventing or compensating medical injuries, and far more to do with physicians’ perceptions about the potential risks to themselves associated with medical innovation.”⁴³ To understand the potential for perverse incentives, one must evaluate the costs and benefits associated with new technology, and how new technology adoption operates generally.⁴⁴ The cost of developing and obtaining new medical technology is often astronomical. Such costs are necessarily balanced or outweighed by a set of clinical benefits if the technology is to remain marketable. For instance, the new technology may confer therapeutic benefits that are otherwise unavailable, or function as a risk-superior alternative to existing treatments. Thus, a new technology that is more effective compared to the status quo might result in a range of long-term social welfare benefits, including reduced mortality risks, improved patient outcomes, and lower health-care utilization and costs.⁴⁵

But the danger posed by a custom-based standard of care is that it escalates the risks and costs associated with adopting new technology, apart from any underlying clinical risks associated with the technology itself.⁴⁶ Consequently, physicians’ perceptions about elevated malpractice risks would effectively deter them from considering new technologies that could otherwise be cost-effective and risk-reducing.⁴⁷ But creating disincentives to innovation certainly cannot be the intended purpose of the malpractice doctrine. Rather, the aim of establishing a standard of care is to ensure that providers use appropriate prudence and skill in delivering medical services, regardless of treatment modality.⁴⁸ Malpractice law is thus charged with maintaining an equitable balance between competing interests—on the one hand, the legal regime should encourage providers to carefully scrutinize new technology to protect patients against avoidable, incremental clinical risks, and to apply any new technology with prudence and skill.⁴⁹ On the other hand, the law should also promote the adoption of new technology when it confers broad social benefits that go beyond those that accrue directly to patients.⁵⁰ While it is important to have laws that force physicians to carefully assess the risks and benefits of new technology prior to adopting it, we do not want to create a regime that effectively prevents the standard of care from evolving. Consequently, a custom-based standard of care arguably creates potential disincentives to adopting new medical technology that are neither intended nor socially desirable.

Fortunately, judicial deference to physician customs has been gradually

43. Greenberg, *supra* note 39, at 440.

44. *Id.*

45. *Id.*

46. *See id.* at 441.

47. *Id.*

48. *Id.*

49. *Id.* at 442.

50. *Id.*

eroding over the past several decades.⁵¹ A quarter of the states have expressly rejected deference to medical customary norms.⁵² Nine additional states, although not directly addressing the role of custom, have rephrased the malpractice standard of care in terms of what a reasonable physician would do, rather than what is customarily done.⁵³ The “reasonable physician” standard of care is the same test employed by the states that have expressly rejected a custom-based standard of care. Instead of focusing on what is customarily done, the reasonable physician standard concentrates on what is “reasonable to expect of a professional given the state of medical knowledge at the time of the treatment in issue.”⁵⁴ The differences between the reasonable physician standard and the custom-based standard may be subtle at times because, in most instances, the customary practices of most physicians correspond closely to an objective standard of reasonableness based on the current state of the art in medicine.⁵⁵ But unlike a custom-based standard, adherence to customary practices does not categorically immunize a physician from malpractice liability. The reasonable physician standard also involves examining the expertise of the physician, the health of the patient, the state of medical knowledge, the risks and benefits of the recommended treatment, and other patient-specific factors that may have influenced the choice of treatment.⁵⁶ Thus, in principle, the objective “reasonable physician” standard gives courts more latitude in reviewing medical knowledge and customs, and in deciding what the malpractice standard of care should be in a given situation.

Moreover, jurisdictions that ostensibly endorse custom actually apply the custom-based standard of care in a way that operates very much like a reasonable physician standard.⁵⁷ Courts that theoretically continue to defer to custom have created several subsidiary doctrines that attempt to set limits on a custom-based standard of care.⁵⁸ These doctrines include (a) an iteration of an “acceptable alternatives” rule, including the “two schools of thought” or “respectable minority” rule, which establishes that the standard of care in medicine is not unitary, and that there are myriad situations where several forms of medical treatment may be consistent with reasonable care;⁵⁹ (b) the best judgment rule,

51. Peters, Jr., *supra* note 37, at 170–85.

52. *Id.* at 172–79.

53. *Id.* at 180–85.

54. Nowatske v. Osterloh, 543 N.W.2d 265, 272 (Wis. 1996), *abrogated by* Nommensen v. Am. Cont’l Ins. Co., 629 N.W.2d 301 (Wis. 2001). *See generally* Peters, Jr., *supra* note 37, at 180–85.

55. *See* Richard A. Epstein, *The Path to The T.J. Hooper: The Theory and History of Custom in the Law of Tort*, 21 J. LEGAL STUD. 1, 1–6 (1992). *See generally* Peters, Jr., *supra* note 37, at 188–90.

56. J. Brad Kallmyer, Note, *A Chimera in Every Sense: Standard of Care for Physicians Practicing Complementary and Alternative Medicine*, 2 IND. HEALTH L. REV. 225, 257 (2005).

57. Peters, Jr., *supra* note 37, at 185–88.

58. *Id.* at 170.

59. *See, e.g.*, Hirahara v. Tanaka, 959 P.2d 830, 834 (Haw. 1998) (“It is not negligent for a physician, based on the knowledge that he reasonably possesses at the time, to select a particular course of treatment among acceptable medical alternatives.”); Downer v. Veilleux, 322 A.2d 82, 87 (Me. 1974) (“[A] physician does not incur liability merely by electing to pursue one of several recognized courses of treatment.” (citation omitted)).

which requires physicians with unique information to use it regardless of customary norms;⁶⁰ and (c) the common knowledge rule, which permits plaintiffs' verdicts despite evidence that physicians complied with customary standards.⁶¹

Another observation worth noting is that courts within these custom-based jurisdictions frequently fail to enforce the standard of care by not requiring plaintiffs' experts to prove that a prevailing custom existed, and that the defendant deviated from the custom.⁶² This tendency toward loose application of the custom-based standard of care may be partially attributable to the significant obstacles to proving the existence of a prevailing customary norm. First, courts have retreated from reliance on local customs in favor of a standard based on similar localities or a national standard.⁶³ But medical customs vary widely from one geographic community to another,⁶⁴ and given these variations in physician practice patterns across the country, the notion of a national custom seems less than realistic. Second, variability in patient pools, illnesses, and possible therapeutic responses,⁶⁵ as well as the economic stratification of patients, act as barriers to the formation of stable customs.⁶⁶ Finally, even when a widely favored practice actually exists, ascertaining that custom at a reasonable cost may be impossible.⁶⁷ In the real world of malpractice litigation, expert witnesses base their opinions on their experience and the readily available medical literature, but

60. *E.g.*, *Toth v. Cmty. Hosp. at Glen Cove*, 239 N.E.2d 368, 373 (N.Y. 1968) (finding negligence notwithstanding a physician's adherence to customary practice where defendant's choice among the available alternatives was unreasonable in light of contrary data); *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875, 879–80 (App. Div. 1982) (same).

61. *See, e.g.*, *Ault v. Hall*, 164 N.E. 518, 522–23 (Ohio 1928) (permitting the sponge count issue to reach the jury despite evidence that the physician complied with custom); 1 BARRY R. FURROW ET AL., *HEALTH LAW* § 6-2, at 368 (1995) (describing common knowledge exception).

62. *E.g.*, *McGrady v. Wright*, 729 P.2d 338, 341 (Ariz. Ct. App. 1986) (permitting plaintiff to reach the jury with testimony that the defendant's conduct was not "reasonable"); *Sanders v. Ramo*, 416 S.E.2d 333, 335 (Ga. Ct. App. 1992) (accepting plaintiff's expert testimony that merely stated that the defendant "departed from reasonable standards of surgical care"); *Hiers v. Lemley*, 834 S.W.2d 729, 733 (Mo. 1992) (accepting testimony about defendant's "failure to exercise that degree of skill and learning that an ordinarily careful and prudent physician would have exercised").

63. *E.g.*, *Moeller v. Hauser*, 54 N.W.2d 639 (Minn. 1952); *Tallbull v. Whitney*, 564 P.2d 162 (Mont. 1977), *abrogated by* *Chapel v. Allison*, 785 P.2d 204 (Mont. 1990); *Cavallaro v. Sharp*, 121 A.2d 669 (R.I. 1956); *see, e.g.*, WILLIAM J. CURRAN ET AL., *HEALTH CARE LAW AND ETHICS* 343–44 (5th ed. 1998) (discussing loosening of locality rule); 1 FURROW ET AL., *supra* note 61, § 6-2, at 360 (stating national standard is majority rule).

64. *See* Jack E. Wennberg, *Improving the Medical Decision-Making Process*, 7 HEALTH AFF. 99, 99 (1988).

65. *See* MARK A. HALL, *MAKING MEDICAL SPENDING DECISIONS* 84–88 (1997) (commenting on the complex and patient-specific nature of individual treatment decisions); James A. Henderson, Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1390 (1994) (concluding that "highly differentiated nature of medical problems" hinders the formation of stable medical customs); Alan H. McCoid, *The Care Required of Medical Practitioners*, 12 VAND. L. REV. 549, 584 (1959) (explaining that "there is no standard patient").

66. *See* Henderson, Jr. & Siliciano, *supra* note 65, at 1393–94 ("[E]conomic stratification of the patient population precludes formation of a stable unitary custom.").

67. Peters, Jr., *supra* note 37, at 187.

typically do not know the actual percentage of physicians who would act as the defendant did under the specific circumstances. Thus, one plausible explanation for the lack of strict enforcement of the custom-based standard of care is that courts are aware of the obstacles to obtaining proof of deviation from an established custom.⁶⁸

Courts are always cognizant of their role in altering tort law to reflect societal change. Indeed, it is the judicial system's responsibility "to modernize traditional principles of tort law when such becomes necessary 'to ensure that the law remains both fair and realistic as society and technology change.'"⁶⁹ Public deference to the judgment of medical professionals has gradually declined in the past sixty years.⁷⁰ One possible explanation for this phenomenon is increased patient awareness of medical error, which is not unexpected given the pervasive nature of contemporary media.⁷¹ As the general level of education and public awareness of health issues continue to grow, patients tend to be more knowledgeable and to seek more autonomy with respect to medical decision making.⁷² Courts are also more reluctant to trust physicians to regulate themselves, and have transitioned away from the belief that physicians are sufficiently different from engineers, product manufacturers, and other businesses to justify the special privileges previously accorded to physicians.⁷³ Indeed, the creation of common law doctrines, including (a) the duty to stay abreast, which obligates physicians to be aware of evolving practices in medical care and make appropriate use of new scientific knowledge as it emerges;⁷⁴ (b) the duty to inform the patient of appropriate alternative treatments under the informed consent doctrine;⁷⁵ and (c) experimental protocol cases that permit patients to consent to noncustomary

68. *Id.*

69. *Conley v. Boyle Drug Co.*, 570 So. 2d 275, 284 (Fla. 1990) (quoting *Ins. Co. of N. Am. v. Pasakarnis*, 451 So. 2d 447, 451 (Fla. 1984), *abrogated by* *Ridley v. Safety Kleen Corp.*, 693 So. 2d 934 (1996)); *see also* *Schmitz v. Smentowski*, 785 P.2d 726, 736 (N.M. 1990) ("[Our State] has recognized that tort law is not static—it must expand to recognize changing circumstances that our evolving society brings to our attention.").

70. *Peters, Jr.*, *supra* note 37, at 196.

71. *See, e.g.*, Robert J. Blendon et al., *Patient Safety: Views of Practicing Physicians and the Public on Medical Errors*, 347 NEW ENG. J. MED. 1933 (2002) (noting the fact that surveys indicated that half of the American public followed media coverage of a recent report by the Institute of Medicine, entitled *To Err Is Human*, which concluded that more Americans die as a result of medical errors made in hospitals than as a result of injuries from automobile accidents); *Preventing Medication Errors*, INST. MED. (July 20, 2006), <http://www.iom.edu/~media/Files/Report%20Files/2006/Preventing-Medication-Errors-Quality-Chasm-Series/medicationerrorsnew.pdf>; *To Err is Human: Building a Safer Health System*, INST. MED. (Nov. 1, 1999), <http://www.iom.edu/~media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf>.

72. Hunter L. Prillaman, *A Physician's Duty to Inform of Newly Developed Therapy*, 6 J. CONTEMP. HEALTH L. & POL'Y 43, 46 (1990).

73. *Peters, Jr.*, *supra* note 37, at 192, 199–200.

74. *See* *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875, 879–80 (App. Div. 1982); *Nowatske v. Osterloh*, 543 N.W.2d 265, 272 (Wis. 1996), *abrogated by* *Nommensen v. Am. Cont'l Ins. Co.*, 629 N.W.2d 301 (Wis. 2001); *Williams*, *supra* note 38, at 508–12.

75. *Smith v. Karen S. Reisig, M.D., Inc.*, 686 P.2d 285, 288–89 (Okla. 1984); *Keogan v. Holy Family Hosp.*, 622 P.2d 1246, 1252–53 (Wash. 1980).

experimental treatments⁷⁶ appear to be a judicial response to the public's declining trust in health-care providers and represent a further shift towards replacing the traditional custom-based standard of care.

B. *The Physician's Duty to Stay Abreast*

One element of the standard of care for medical malpractice is that a physician has the duty to keep reasonably abreast of the latest advances in medical science.⁷⁷ However, the exact scope of this common law doctrine and its implications on medical malpractice liability remain unclear. This section describes the evolution of the duty to stay abreast, highlights the failure of courts to define the exact scope of this heavily recited doctrine, and concludes with this Note's stance on how this duty should be interpreted.

Courts began asserting the duty to stay abreast as early as the mid-nineteenth century.⁷⁸ Although courts do not require physicians "to possess extraordinary knowledge and ability that belongs to a few . . . [courts may require them] 'to keep abreast of the times and to practice in accordance with the approved methods and means of treatment in general use.'"⁷⁹ While the duty to stay abreast typically manifests itself as qualifying language within a custom-based standard of care,⁸⁰

76. *E.g.*, *Karp v. Cooley*, 493 F.2d 408, 423–24 (5th Cir. 1974) (reasoning that patient's informed consent precludes physician liability for an experimental procedure).

77. *Reed v. Church*, 8 S.E.2d 285, 288 (Va. 1940) (holding that physician was liable for causing plaintiff's injury because the physician had easy access to information that clearly warned against continued drug treatment if vision problems arose); R. CRAWFORD MORRIS & ALAN R. MORITZ, *DOCTOR AND PATIENT AND THE LAW* 331 (5th ed. 1971).

78. *E.g.*, *McCandless v. McWha*, 22 Pa. 261 (Pa. 1853).

[I]n a given case, regard is to be had to the advanced state of the profession at the time. Discoveries in the natural sciences for the last half-century have exerted a sensible influence on all the learned professions, but especially on that of medicine, whose circle of truths has been relatively much enlarged. And besides, there has been a positive progress in that profession resulting from the studies, the experiments, and the diversified practice of its professors. *The patient is entitled to the benefit of these increased lights. The physician or surgeon who assumes to exercise the healing art, is bound to be up to the improvements of the day.* The standard of ordinary skill is on the advance; and he who would not be found wanting, must apply himself with all diligence to the most accredited sources of knowledge.

Id. at 269 (emphasis added).

79. *Williams*, *supra* note 38, at 508–09 (quoting *Pike v. Honsinger*, 49 N.E. 760 (N.Y. 1898)); *see also* *Mitchell v. United States*, 141 F.3d 8, 13 (1st Cir. 1998) (citing *Poysner v. United States*, 602 F. Supp. 436, 438–39 (D. Mass. 1984)) (applying Massachusetts law and stating that "[a] physician is held to the standard of care and skill of the average practitioner of the medical specialty in question, taking into account the advances in the profession" (citation omitted)); *Ward v. United States*, 838 F.2d 182, 187 (6th Cir. 1988) (citing *Ogle v. Noe*, 6 Tenn. App. 485 (1927)) (applying Tennessee law and stating, "In determining the degree of learning and skill required of a medical practitioner in the treatment of a particular case, regard must be given to the state of medical science at the time.").

80. Examples of such language include "taking into account," "having regard to," or "in light of" advances in medical science. *See, e.g.*, *Schwartz v. Goldstein*, 508 N.E.2d 97, 99 (Mass. 1987) (emphasis added) (citations omitted) ("A doctor undertakes to use a reasonable degree of care such as ordinarily possessed by others providing medical care and treatment, having regard to the current state of care and treatment."); *Dietsch v. Mayberry*, 47 N.E.2d 404, 409 (Ohio Ct. App. 1942) (emphasis added) (citations omitted) (recognizing physician's duty "to exercise the average degree of

several courts have been more explicit in their pronouncement that physicians have a legal obligation to keep abreast of medical advances.⁸¹

Several court decisions have directly confronted the issue of whether a physician can escape liability by strictly adhering to medical custom without considering the adequacy of such custom *in light of current medical advances*.⁸² In *Nowatske v. Osterloh*, a plaintiff brought a malpractice suit against his physician for injuries that arose after the defendant performed a scleral buckling procedure to reattach the patient's retina.⁸³ On appeal, the plaintiff argued that the lower court's jury instruction was defective because it equated the legal standard of care with the medical customary practice without taking current medical advances into account.⁸⁴ The plaintiff argued that failure to consider the custom in light of current science would allow an unreasonable and outdated custom to shield clearly negligent conduct from malpractice liability.⁸⁵ In its analysis, the *Nowatske* court cited *Gates v. Fleischer* for the proposition that the current state of medical science is a relevant factor in the standard of care.⁸⁶ The *Nowatske* court reasoned that "should customary medical practice fail to keep pace with developments and advances in medical science, adherence to custom might constitute a failure to exercise reasonable care."⁸⁷ The court then concluded that the instruction was sufficient because the language "due regard for the state of medical science" accurately informed the jury that the competent physician is one who keeps abreast of current medical advances.⁸⁸

The case law makes clear that the duty to keep abreast only extends to medical information known or available at the time of treatment.⁸⁹ For instance, in

skill, care, and diligence exercised by members of the same profession . . . in the light of the present state of medical and surgical science").

81. *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875, 879–80 (App. Div. 1982); *Nowatske v. Osterloh*, 543 N.W.2d 265, 273 (Wis. 1996) ("[A] reasonably competent practitioner is one who keeps up with advances in medical knowledge."), *abrogated by* *Nommensen v. Am. Cont'l Ins. Co.*, 629 N.W.2d 301 (Wis. 2001).

82. *Toth v. Cmty. Hosp. at Glen Cove*, 239 N.E.2d 368 (N.Y. 1968) (finding that where a physician fails to employ his best judgment, he is not immunized from liability because he followed customary practice); *Burton*, 452 N.Y.S.2d at 879–80 (finding that although conventional medical wisdom was that increased oxygen was essential to the survival of premature infants, defendants were not relieved of liability when they were clearly aware of the dangers of following the customary practice); *Helling v. Carey*, 519 P.2d 981 (Wash. 1974) (holding that custom is never dispositive of reasonableness where custom itself is lagging behind an established, cost-effective, and scientifically reliable trend); *Nowatske*, 543 N.W.2d at 272 (finding that the standard of care owed by physicians cannot be established by the sum of the customs which those practitioners follow).

83. *Nowatske*, 543 N.W.2d at 266.

84. *Id.* at 269–70.

85. *Id.*

86. *Id.* at 271 (citing *Gates v. Fleischer*, 30 N.W. 674, 675 (Wis. 1886)).

87. *Id.*

88. *Id.* at 273.

89. *McBride v. Saylin*, 56 P.2d 941, 941 (Cal. 1936) (stating that a physician's malpractice liability depends on whether "the treatment given by the defendant [was] consistent with that reasonable degree of learning and skill usually possessed and rendered by others of his profession . . . *having regard to the state of scientific learning at the time*" (emphasis added)); *Tomer v. Am.*

Mallet v. Pirkey, a patient brought a malpractice suit against a physician for injuries suffered as a result of a prescribed drug's side effects.⁹⁰ The court held that the physician was not liable as a matter of law for the drug's side effects where "[t]he medical literature did not reveal *any* serious complication in its use."⁹¹ In contrast, the court in *Reed v. Church* found the defendant physician liable for injuries that were sustained as a result of a recommended drug treatment⁹² because the physician had in his possession pamphlets from the drug manufacturer that listed blindness as a possible side effect and described the symptoms of its onset.⁹³ Unlike *Mallet*, the physician in *Reed* had easy access to medical information that clearly warned against continued use of the drug if vision problems arose.⁹⁴ *Mallet* and *Reed* thus define a spectrum in which physicians are held accountable to know information to which they had reasonable access at the time of the treatment.

Although many cases recite the duty to stay abreast, courts have rarely addressed what exactly this duty entails.⁹⁵ Physicians are largely uninformed as to what it means to "stay abreast" because the current doctrine only defines the duty in vague terms. The scope of the doctrine is also unclear because courts originally articulated the duty to stay abreast when medical knowledge progressed at a much slower pace and staying abreast involved significantly less effort than it does today.⁹⁶ But this lack of clarity does not necessarily mean that "the duty to stay abreast should fall in the face of rapid advances in medical science," because "such a paradox would belie the policy that led to the rule in the first place."⁹⁷ Instead, the definition of what it means to stay abreast needs to be fleshed out so as to instruct physicians on how to avoid liability in light of the nontrivial task of staying abreast with the fast-paced advances in modern medicine.⁹⁸

Indeed, current legal scholarship reflects the significant confusion over the scope of the duty to stay abreast. Some scholars construe the duty to stay abreast as "a duty to keep abreast *of customary medical practice*,"⁹⁹ whereas others believe that the duty to stay abreast effectively demands "adherence to the state-of-the-art

Home Prods. Corp., 368 A.2d 35, 38 (Conn. 1976) ("[T]he standard of care which was applicable to the doctors in the use of Halothane was *dependent upon the state of their art at the time* that they were allegedly negligent." (emphasis added)); King v. Ditto, 19 P.2d 1100, 1102 (Or. 1933) ("As a general rule, the degree of care and skill depends somewhat upon . . . *the advanced state of medical and surgical science at the time services to patient were rendered*. . . . What might have been considered due care twenty years ago would be gross negligence to-day." (emphasis added)).

90. *Mallet v. Pirkey*, 466 P.2d 466, 468 (Colo. 1970).

91. *Id.* at 470.

92. *Reed v. Church*, 8 S.E.2d 285, 287 (Va. 1940).

93. *Id.* at 290.

94. *Id.*

95. For examples of formulations of the duty to stay abreast, see *supra* note 89.

96. Williams, *supra* note 38, at 513.

97. *Id.* at 514.

98. *Id.*

99. Kacmar, *supra* note 37, at 641.

rather than simply [abiding by] existing custom.”¹⁰⁰ This Note takes a more conservative stance than the latter viewpoint and contends that, at minimum, “the duty to stay abreast” entails more than keeping up with customary medical practice¹⁰¹ because adhering to a custom-based standard may actually serve to entrench poor or harmful customs into mainstream practice,¹⁰² which is contrary to the doctrine’s intended purpose (i.e., permitting the standard of care to evolve in response to medical advances). Moreover, the scope of the duty to stay abreast must align with the “best judgment” rule, a parallel common law doctrine that expressly permits departure from customary practices in the event that a physician becomes aware of new medical information that impacts treatment decisions. For example, in *Burton v. Brooklyn Doctors Hospital*, the court considered whether the defendants, a physician and a hospital, were liable for injuries the plaintiff incurred due to prolonged oxygen exposure following the plaintiff’s premature birth.¹⁰³ The defendants argued that they should be insulated from liability because they acted in accordance with conventional medical wisdom that considered increased oxygen essential to the survival of premature babies.¹⁰⁴ The *Burton* court imposed liability because the defendants were clearly aware of the dangers of administering excess oxygen to premature babies at the time of treatment based on several research studies, including their own.¹⁰⁵ The *Burton* court effectively held that the defendants were liable for failing to keep up with the latest medical advances and failing to exercise sound medical judgment when they were aware of the dangers of a generally accepted customary practice.¹⁰⁶ The duty to stay abreast is thus tightly intertwined with the “best judgment” rule, which requires a physician to employ his expertise, or best judgment, when he acquires new, relevant medical information, regardless of existing customary practices.

Awareness of medical information thus impacts both treatment decisions

100. Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 463 (2002).

101. A comparison to how other professionals view the duty to stay abreast might be useful in ascertaining what exactly this duty entails for medical practitioners. For instance, attorneys appear to be held to a more pronounced duty to stay abreast in that they face a higher risk of liability if they do not keep up with the latest changes in the law. See Brian Kibble-Smith & Arthur W. Hafner, *The Effect of the Information Age on Physicians’ Professional Liability*, 36 DEPAUL L. REV. 69, 92 (1986) (stating that failure to Shepardize is a way in which “an attorney’s failure to keep abreast in law can easily result in malpractice liability”); see also Fiorentino v. Rapoport, 693 A.2d 208, 213 (Pa. Super. Ct. 1997) (stating that the court does not expect the attorney “to be infallible,” but does expect him to conduct that degree of research sufficient to enable the client “to make an informed decision”). Courts have explained that attorneys have a duty to not only know “plain and elementary principles of law which are commonly known by well-informed attorneys,” but must also “discover those additional rules of law which, although not commonly known, may readily be found by standard research techniques.” *Smith v. Lewis*, 530 P.2d 589, 595 (Cal. 1975). Thus in the context of the law of legal malpractice, the duty to stay abreast goes beyond keeping up with customary norms within the profession.

102. See Kacmar, *supra* note 37, at 642–43.

103. *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875 (App. Div. 1982).

104. *Id.* at 879–80.

105. *Id.*

106. *Id.*; see also *Toth v. Cmty. Hosp. at Glen Cove*, 239 N.E.2d 368, 372–73 (N.Y. 1968).

and the applicable standard of care. Advances in information technology over the past two decades provide physicians with rapid access to cutting-edge medical research, allowing them to evaluate diagnostic and treatment decisions against broader background information. Consequently, the scope of the physician's duty to stay abreast will continue to evolve as breakthroughs in information dissemination and medical science occur.

*C. Clinical Practice Guidelines:
An Incomplete Solution to Defining the Standard of Care*

Applying rapid advances in fields such as cell biology, genomics, immunology, and pharmacology to medical practice poses a dual challenge. On one hand, new scientific information reported in the literature fails to efficiently translate into new practice styles.¹⁰⁷ Conversely, there are concerns that expensive, new technology may be adopted uncritically before its efficacy is adequately assessed.¹⁰⁸ Because of this apparent lack of coordination between technology assessment and clinical practice,¹⁰⁹ and the lack of consensus as to what the best methods and treatments are,¹¹⁰ various medical professional societies have promulgated CPGs to evaluate the efficacy of various medical practices.¹¹¹ CPGs are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”¹¹² In addition to coordinating technology assessment and clinical practice,¹¹³ and

107. Ann Lennarson Greer, *The State of the Art Versus the State of the Science: The Diffusion of New Medical Technologies into Practice*, 4 INT'L J. TECH. ASSESSMENT HEALTH CARE 5, 5 (1988) (describing physician skepticism of new procedures and reliance upon tradition); Edward J. Huth, *The Underused Medical Literature*, 110 ANNALS INTERNAL MED. 99, 99 (1989) (citing “time and effort” involved in obtaining information from the literature as the primary barrier to incorporation into practice).

108. OFFICE OF TECH. ASSESSMENT, ASSESSING THE EFFICACY AND SAFETY OF MEDICAL TECHNOLOGIES 93–94 (1978); Greer, *supra* note 107, at 5–6 (“Technologies believed to be efficacious are often very slow in achieving an impact, while technologies of questionable value diffuse rapidly . . .”).

109. OFFICE OF TECH. ASSESSMENT, *supra* note 108, at 89–90.

110. See BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 12 (6th ed. 2008) (“Although there are generally accepted treatments for many diseases, and doctors can agree that there has been bad care in some cases, for many others there are no generally agreed standards of what is ‘the best’ care.”).

111. See, e.g., J. Sanford Schwartz et al., *Safety, Efficacy, and Effectiveness of Clinical Practices: A New Initiative*, 96 ANNALS INTERNAL MED. 246 (1982); *Practice Committee Documents*, AM. SOC'Y FOR REPROD. MED. (Apr. 4, 2013), <http://www.asrm.org/Guidelines>; *Clinical Practice Guidelines*, NAT'L HEART, LUNG, & BLOOD INST. (Apr. 8, 2013), <http://www.nhlbi.nih.gov/health-pro/guidelines>. Scholars estimate the number of CPGs currently in existence to range from 1600 to 2000. See Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 685 (2001) (noting that more than 1600 guidelines exist); Noah, *supra* note 100, at 418 (“More than 2000 guidelines exist today.”).

112. INST. OF MED., GUIDELINES FOR CLINICAL PRACTICE: FROM DEVELOPMENT TO USE 27 (Marilyn J. Field & Kathleen N. Lohr eds., 1992).

113. See Richard E. Leahy, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines*, 77 CALIF. L. REV. 1483, 1488–89 (1989) (explaining development

expressing a consensus on the best practices,¹¹⁴ CPGs help counter the information explosion in medicine¹¹⁵ by providing a necessary abridgement of the scientific literature¹¹⁶ and reflecting the judgments of leaders in the medical community.¹¹⁷ CPGs have also been used as barometers for establishing conventional standards of care in some jurisdictions.¹¹⁸

However, the use of CPGs to define the appropriate standard of care is not without its criticisms. First, many physicians construe CPGs as an impediment to exercising independent clinical judgment,¹¹⁹ especially when there may be more than one effective treatment in a given instance.¹²⁰ Physicians may feel unduly compelled to adhere to CPGs, even if the guidelines conflict with a physician's best judgment, because of underlying liability concerns that could potentially lead to adverse patient outcomes.¹²¹ Second, many CPGs are vague and based on generalities, thus providing limited assistance for diagnosing or treating a particular patient.¹²² Third, significant credibility problems may also arise where the recommended guidelines are biased by the self-interests of the standard-setting organizations.¹²³ Finally, and perhaps most importantly, CPGs will invariably lag

and endorsement of practice guidelines as response to "apparent lack of coordination between technology assessment and clinical practice").

114. See Williams, *supra* note 38, at 489 n.53 (noting that CPGs can help "articulate consensus on acceptable practice" and "disseminate information on the consensus" (internal quotation marks omitted)).

115. See Leahy, *supra* note 113, at 1487–91 (explaining how explosion of medical information necessitates CPGs).

116. See Noah, *supra* note 100, at 418 ("If nothing else, practice guidelines provide a handy abridgement of the burgeoning biomedical literature.").

117. *Id.* ("[CPGs] also serve a signaling function, reflecting the judgments of leading experts in the field").

118. See Linda L. LeCraw, *Use of Clinical Practice Guidelines in Medical Malpractice Litigation*, 3 J. ONCOLOGY PRAC. 254 (2007); Timothy K. Mackey & Bryan A. Liang, *The Role of Practice Guidelines in Medical Malpractice Litigation*, 13 VIRTUAL MENTOR 36, 37–38 (2011). The use of CPGs as exculpatory evidence of malpractice has been given special scrutiny due to its use in Maine's Medical Liability Demonstration Project in the 1990s. Mello, *supra* note 111, at 674–77. Under the reform, physicians who complied with the twenty state-adopted CPGs were provided an affirmative defense against medical malpractice claims. *Id.* at 675. Unfortunately, the project did not show significant reductions in defensive medicine practices or in malpractice claims, and the law's provisions had low utilization in court. *Id.* at 676.

119. INST. OF MED., *supra* note 112, at 24 ("[M]any physicians, especially those longer in practice, see guidelines as a challenge to clinical judgment and resist them as a threat to the most fundamental element of professional autonomy.").

120. See Williams, *supra* note 38, at 491 n.65 ("Substantial regional variations exist in the use of many procedures, with no apparent differences in outcome." (internal quotation marks omitted)).

121. Mackey & Liang, *supra* note 118, at 39.

122. See E. Haavi Morreim, Commentary, *From the Clinics to the Courts: The Role Evidence Should Play in Litigating Medical Care*, 26 J. HEALTH POL. POL'Y & L. 409, 422 (2001) ("[E]ven the best CPGs cannot possibly dictate each patient's course of care. They are based on generalities that hold true on average, but have only limited room to accommodate the natural variations among individuals in any population.").

123. See Noah, *supra* note 100, at 422 ("When specialty medical societies sponsor clinical practice guidelines, the financial interests of their members may influence the resolution of contested issues.").

behind current advances in medical science because professional associations can take years to formulate and codify guidelines.¹²⁴ CPGs cannot always reflect the current best evidence. “Even if a guideline reflects current best evidence when written, medical advances could soon render such a guideline obsolete.”¹²⁵ “[G]uidelines may [thus] have the effect of freezing the standard of care, thereby discouraging further research and innovation in areas [where] the experts have reached a consensus.”¹²⁶ This inherent lack of dynamism perpetuates inconsistencies within the standard of care analysis for emerging technologies, thereby weighing against a legal framework that is solely based on CPGs.

Given the problems associated with the CPG standard, it would be unwise for courts to demand lockstep adherence to any given CPG.¹²⁷ Instead, an optimal standard of care is one that encourages physicians to keep informed of current medical knowledge and practice accordingly. This is not to say that CPGs lack *any* significance. Rather, physicians should not only be aware of CPG recommendations, but also of how other evidence alters those recommendations.¹²⁸ In other words, while CPGs can reflect current best evidence at the time that they are promulgated, subsequent advances in medical science may interpret, refine, or overturn them.¹²⁹ Thus, while CPGs remain a significant factor in the standard of care analysis, they are not dispositive of a physician’s liability for malpractice.

D. *Informed Consent: The Duty to Inform of Alternative Treatments*

The doctrine of informed consent is part of the general evolution of attitudes about the doctor-patient relationship, including “the growing belief that patients are entitled to more information about their health, as well as a real and informed role in decisions about their medical treatment.”¹³⁰ One aspect of the informed consent doctrine is the duty to inform the patient of appropriate alternative treatments.¹³¹ To prove a medical malpractice claim due to negligent nondisclosure of an alternative treatment plan, the plaintiff must establish: (a) a duty on the part of the physician to know of an alternative treatment,¹³² and (b) a duty to disclose the alternative treatment plan “by evidence establishing that a reasonable person in what the physician knows or should have known to be the patient’s position would likely attach significance to that . . . alternative in

124. See Mark Kadzielski et al., *Peer Review and Practice Guidelines Under Health Care Reform*, 16 WHITTIER L. REV. 157, 176 (1995) (identifying the concern that CPGs will be outdated before adopted).

125. Williams, *supra* note 38, at 487–88.

126. Noah, *supra* note 100, at 425.

127. Morreim, *supra* note 122, at 422.

128. Williams, *supra* note 38, at 525–26.

129. *Id.*

130. Prillaman, *supra* note 72, at 46.

131. *Id.*

132. This duty parallels the duty to stay abreast described *infra* in Part II.B.

formulating his decision to consent to treatment.”¹³³ Unlike a typical medical malpractice claim, the injury sustained under an informed consent claim is not necessarily an injury resulting from negligent medical treatment.¹³⁴ The critical factor is whether the injury would have been avoided if the plaintiff had chosen an undisclosed alternative treatment.

Courts adopt one of two approaches to the duty to obtain informed consent. Some jurisdictions apply a “professional” standard of informed consent, which requires a physician to inform the patient of alternatives to the recommended medical treatment as would other physicians practicing in the community.¹³⁵ Thus, under the professional standard, the defendant physician’s conduct is measured in relation to the level of care given by other practitioners in the relevant community. Other states apply the “lay” standard of informed consent, where the physician has a duty to inform the patient of all the information a reasonable patient would wish to know in making an informed decision as to whether to undergo the proposed treatment.¹³⁶ Thus, the driving force behind the lay standard is protecting the patient’s rights of self-determination and bodily autonomy.

Under either the professional or lay approach to informed consent, the physician has the duty to inform the patient of appropriate alternative treatments, and to describe the risks and benefits of those treatments.¹³⁷ Of course, this duty does not require a physician to disclose every possible alternative to every detail of the proposed treatment. Rather, the physician must engage in a dialogue that “involves choosing among *medically acceptable* options, not simply accepting or rejecting the medically preferable option.”¹³⁸ For instance, in *Keogan v. Holy Family Hospital*, a physician gave a resting electrocardiogram (EKG) to a thirty-seven-year-old patient with chest pain, but did not inform him of a treadmill EKG or an angiography as medically acceptable options.¹³⁹ The court held that the physician had a duty to disclose alternative diagnostic procedures once he had knowledge of a physical abnormality in the patient, and that the physician was negligent as a matter of law for his failure to disclose the alternative diagnostic procedures.¹⁴⁰ Thus, the duty to inform patients of alternative treatments has a profound effect

133. Prillaman, *supra* note 72, at 44 (quoting *Cornfeldt v. Tongen*, 295 N.W.2d 638, 640 (Minn. 1980)).

134. In fact, the injury may even be a fully expected outcome of the recommended medical treatment.

135. *E.g.*, *Ziegert v. S. Chi. Cmty. Hosp.*, 425 N.E.2d 450 (Ill. App. Ct. 1981).

136. *E.g.*, *Neal v. Lu*, 530 A.2d 103, 111 (Pa. Super. Ct. 1987). Some courts apply an objective test, which requires a showing that a reasonable person would have made a different choice if informed of the alternative. *Duff v. Yelin*, 721 S.W.2d 365, 372 (Tex. Ct. App. 1986), *aff'd*, 751 S.W.2d 175 (Tex. 1988). Whereas other courts require the patient to prove subjectively that disclosure of the alternative would have altered her decision to consent to the proposed treatment. *Spencer v. Seikel*, 742 P.2d 1126, 1129 (Okla. 1987).

137. Prillaman, *supra* note 72, at 46–47.

138. APPELBAUM ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 54 (1987) (emphasis added).

139. *Keogan v. Holy Family Hosp.*, 622 P.2d 1246, 1249 (Wash. 1980).

140. *Id.* at 1252–53.

on the doctor-patient relationship because it effectively obligates the physician to defend her choice of treatment, compared to other medically acceptable alternatives, to the patient.¹⁴¹ The rule goes beyond ensuring that the patient is made aware of the dangers of the recommended treatment and effectively reserves a role for the patient in the clinical decision-making process.¹⁴²

The case law makes clear that the touchstone for determining whether an alternative treatment must be disclosed is that the treatment be “medically acceptable.” Thus, courts are confronted with the task of defining (a) what makes a particular treatment, especially a new one, acceptable; and (b) to whom it must be acceptable. To this end, scholars have enumerated several criteria to evaluate when a new treatment becomes sufficiently “acceptable” to trigger the duty to disclose.¹⁴³ These criteria include (a) approval of a drug or device by the FDA for a particular indication, (b) official acceptance of a new medical treatment by a professional medical society,¹⁴⁴ (c) whether the effectiveness of the new treatment has been demonstrated through articles in peer-reviewed medical journals or leading textbooks of the relevant specialty,¹⁴⁵ (d) whether the new treatment is accepted as appropriate by a substantial percentage (or respectable minority) of practitioners in the relevant specialty, and (e) whether the physician has individual knowledge of a new treatment. All of the enumerated factors potentially could be used by experts in formulating their opinions as to whether the practitioner was reasonable in her assessment of whether the alternative treatment was medically acceptable.

Some courts, including those applying the lay standard of informed consent, have implicitly recognized that the standard for “medical acceptability” should be based on the perceptions of the reasonable practitioner.¹⁴⁶ Thus, the relevant

141. Prillaman, *supra* note 72, at 47.

142. Some courts believe that improved access to information may broaden the physician’s duty of informed consent. *Harnish v. Children’s Hosp. Med. Ctr.*, 439 N.E.2d 240, 243 (Mass. 1982) (stating that a doctor must “disclose in a reasonable manner all significant medical information that the physician possesses or *reasonably should possess* that is material to an intelligent decision by the patient whether to undergo a proposed procedure” (emphasis added)).

143. Prillaman, *supra* note 72, at 53–57.

144. However, this approach would lead to a conflict between the patients’ interests and the professional organization’s interest in protecting its own members. It would also exclude recommended treatments by reputable groups dissenting from the professional society’s view.

145. There are several caveats with the leading textbook approach. It is practically impossible to keep textbooks up to date given the rapidly changing realm of modern medical science. No leading, general textbook is updated on more than a yearly basis and many specialty textbooks are updated far less frequently.

146. *See, e.g., Steele v. St. Paul Fire & Marine Ins. Co.*, 371 So. 2d 843, 849 (La. Ct. App. 1979), *cert. denied*, 374 So. 2d 658 (La. 1979); *see also Sard v. Hardy*, 379 A.2d 1014, 1025 (Md. 1977); *Getchell v. Mansfield*, 489 P.2d 953, 957 (Or. 1971); *Neal v. Lu*, 530 A.2d 103, 112 (Pa. Super. 1987). Expert testimony is necessary to establish that an alternative treatment is “feasible” but not to establish whether it must be disclosed. *Miller v. Kennedy*, 522 P.2d 852, 861 (Wash. App. 1974) (“There is no need to prove what other doctors might tell their patients in similar circumstances.”), *aff’d*, 530 P.2d 334 (Wash. 1975), *superseded by statute*, Wash. Rev. Code Ann. § 7.70.050 (West 2011), *as recognized in Stewart-Graves v. Vaughn*, 170 P.3d 1151, 1155 (Wash. 2007).

inquiry is whether the *reasonable physician* would believe that the treatment was accepted as an appropriate treatment by a substantial percentage of reputable experts in the field, rather than whether the individual physician believes that the treatment is feasible. Under this standard, a physician could avoid the danger of having to disclose treatments that are either suspect or too new to have a track record, but would still be obligated to keep up with the relevant literature and other sources of information, and to inform patients of new treatments as they meet the criteria for medical acceptance.

III. APPLICATION OF EXISTING LEGAL FRAMEWORKS TO A PHYSICIAN'S DUTY TO OFFER AND PROVIDE OPTIMIZED PGS-ANEUPLOIDY SCREENING SERVICES

A. The Inadequacy of a Custom-Based Standard of Care for PGS

As an initial matter, this Note contends that it is illogical for courts to apply a custom-based standard in determining a physician's standard of care for adopting technological advances in PGS-aneuploidy screening. As mentioned earlier, the malpractice standard of care is evolutionary because it assumes and depends upon changes in medical knowledge and the innovation of new technologies. Because emerging technologies differ from traditional modalities of treatment, most practitioners have not yet adopted them. Therefore, one consequence of maintaining a custom-based standard of care is that physicians may be reluctant to incorporate state-of-the-art procedures and devices that offer new or improved clinical benefits since, generally, these technologies have not yet been accepted by the medical community.¹⁴⁷ This dilemma is exacerbated by the fact that there is significant lag time between discovery and general acceptance by the profession.¹⁴⁸

Adhering to a custom-based standard of care makes little sense where high-grade scientific evidence suggests deviating from a customary medical practice that is ineffective or poses unnecessary clinical risks to patients. In the context of PGS-aneuploidy screening, FISH has traditionally been the method of choice used to examine chromosomal abnormalities in biopsied material retrieved from cleavage-stage embryos,¹⁴⁹ and various FISH protocols only permit physicians to screen five to nine chromosomes per embryo, as opposed to the whole chromosome complement.¹⁵⁰ Thus, FISH would inherently yield a certain number of false-negative results because the abnormalities may be present on chromosomes that

147. See Amy Jurevic Sokol & Christopher J. Molzen, *The Changing Standard of Care in Medicine*, 23 J. LEGAL MED. 449, 471 (2002).

148. See *id.* at 485 ("Acceptance of new practice approaches engendered by new technology takes time . . .").

149. Fragouli & Wells, *supra* note 2, at 290.

150. E.g., Pere Colls et al., *Increased Efficiency of Preimplantation Genetic Diagnosis for Infertility Using "No Result Rescue,"* 88 FERTILITY & STERILITY 53 (2007); A. Mantzouratou et al., *Variable Aneuploidy Mechanisms in Embryos from Couples with Poor Reproductive Histories Undergoing Preimplantation Genetic Screening*, 22 HUM. REPROD. 1844 (2007).

are not scored. The procedure is further complicated by the fact that cleavage-stage embryos tend to be mosaic, which can lead to additional errors in classification.¹⁵¹ Over the past five years, several randomized clinical trials have reported that the use of FISH-based screening methods at the cleavage stage can negatively impact the likelihood of establishing a clinical pregnancy.¹⁵² Subsequent studies demonstrated that comprehensive molecular cytogenetic methodologies have superior diagnostic potential on account of their high accuracy and precision rates.¹⁵³ For instance, CGH-based screening detects forty-two percent more chromosomal errors in cleavage-stage embryos than the most sensitive FISH-based protocol,¹⁵⁴ and yields significantly lower error rates compared to FISH analysis.¹⁵⁵ Additionally, improved biopsy procedures are less likely to damage the embryos, thereby increasing the likelihood of establishing a clinical pregnancy via the preferential transfer of viable, normal embryos. Under these circumstances, a physician may reasonably believe that she can serve the patient's best interests by deviating from traditional PGS-aneuploidy screening techniques and employing optimized strategies that yield more promising results. But under a custom-based standard of care, a physician might not act in accordance with her best judgment because she realizes that departure from custom would leave her vulnerable to malpractice liability. Indeed, the physician may be inclined to adhere to outdated, and often harmful, customary medical practices until the new technologies are generally accepted in the profession.¹⁵⁶

151. Mastenbroek et al., *supra* note 16, at 16.

152. See, e.g., Christophe Blockeel et al., *Prospectively Randomized Controlled Trial of PGS in IVF/ICSI Patients with Poor Implantation*, 17 REPROD. BIOMEDICINE ONLINE 848, 848–54 (2008); Sophie Debrock et al., *Preimplantation Genetic Screening for Aneuploidy of Embryos After In Vitro Fertilization in Women Aged at Least 35 Years: A Prospective Randomized Trial*, 93 FERTILITY & STERILITY 364, 364–73 (2010); Hardarson et al., *supra* note 16, at 2806–12; Mastenbroek et al., *supra* note 16, at 9–17; Jennifer E. Mersereau et al., *Preimplantation Genetic Screening to Improve In Vitro Fertilization Pregnancy Rates: A Prospective Randomized Controlled Trial*, 90 FERTILITY & STERILITY 1287, 1287–89 (2008); Liza R. Meyer et al., *A Prospective Randomized Controlled Trial of Preimplantation Genetic Screening in the “Good Prognosis” Patient*, 91 FERTILITY & STERILITY 1731, 1731–38 (2009); William B. Schoolcraft et al., *Preimplantation Aneuploidy Testing for Infertile Patients of Advanced Maternal Age: A Randomized Prospective Trial*, 92 FERTILITY & STERILITY 157, 157–62 (2009); C. Staessen et al., *Preimplantation Genetic Screening Does Not Improve Delivery Rate in Women Under the Age of 36 Following Single-Embryo Transfer*, 23 HUM. REPROD. 2818, 2818–25 (2008).

153. See *supra* note 30.

154. Cristina Gutiérrez-Mateo et al., *Validation of Microarray Comparative Genomic Hybridization for Comprehensive Chromosome Analysis of Embryos*, 95 FERTILITY & STERILITY 953, 955 (2011).

155. *Id.* at 955 (demonstrating that error rates for optimal CGH protocol were generally lower compared with those reported with the use of FISH).

156. Kacmar, *supra* note 37, at 621 (“Ordinarily, until the medical community adopts a particular procedure, technique, or methodology, a physician is not negligent for failing to discover, consider, or adopt it.”). It is possible that physicians practicing in some custom-based jurisdictions might find safe harbor under the “respectable minority” or “two schools of thought” rule. But the mere existence of this safe harbor might not be enough to persuade physicians to depart from customary practices because jurisdictions vary widely in the language used to define the standard. See Michael Kowalski, *Applying the “Two Schools of Thought” Doctrine to the Repressed Memory Controversy*, 19 J. LEGAL MED. 503, 505–23 (1998).

The status quo of PGS-aneuploidy screening in reproductive medicine mirrors the factual circumstances described in *Burton v. Brooklyn Doctors Hospital*, where the medical-community custom was clearly lagging behind a recognized, scientifically reliable trend, and the defendant physician was fully aware of the dangers of following the harmful customary practice.¹⁵⁷ This is precisely the sort of situation where courts have been willing to disregard custom and resolve the predicament by judicial fiat.¹⁵⁸ A custom-based standard of care is thus inappropriate in the context of PGS-aneuploidy screening because it decreases physician autonomy with respect to incorporating state-of-the-art procedures, hinders the pace of innovation, and perpetuates a substandard level of care that can lead to adverse patient outcomes.

B. *A Standard of Care Based Solely on CPGs Is Insufficient*

The ASRM's existing CPGs on PGS-aneuploidy screening should not serve as the sole barometer in evaluating good medical practice. Presently, the ASRM offers no guidance on preferred PGS-aneuploidy screening protocols,¹⁵⁹ but specifies that PGS is an experimental procedure "that should be performed only with the specific review of a properly constituted Institutional Review Board."¹⁶⁰ In fact, blind reliance on the ASRM's current recommendations against the "routine [use of] preimplantation embryo aneuploidy screening"¹⁶¹ for infertile patients is no longer justified because the guidelines no longer reflect the current best evidence.¹⁶² The ASRM's existing guidelines were formulated based on research studies that used FISH-based screening methods in cleavage-stage embryos,¹⁶³ and the ASRM has yet to issue guidelines that consider recent advances in PGS-aneuploidy screening, including CGH, CCS, SNP microarrays, and improved embryo biopsy procedures. Additionally, physicians would not be fulfilling their fiduciary obligations by merely searching for updates in PGS-aneuploidy screening practice guidelines because, apart from the most remarkable discoveries, there is always a delay before a professional society endorses any promising innovative technology.¹⁶⁴ This is largely due to the fact that many

157. See *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875, 879–80 (App. Div. 1982).

158. See *Toth v. Cmty. Hosp. at Glen Cove*, 239 N.E.2d 368 (N.Y. 1968); *Burton*, 452 N.Y.S.2d at 879–80; *Helling v. Carey*, 519 P.2d 981 (Wash. 1974); *Nowatske v. Osterloh*, 543 N.W.2d 265, 272 (Wis. 1996), *abrogated by* *Nommensen v. Am. Cont'l Ins. Co.*, 629 N.W.2d 301 (Wis. 2001).

159. See SART & ASRM, *supra* note 3; ASRM, *supra* note 5.

160. Practice Comm. of the Am. Soc'y for Reprod. Med., *Definition of "Experimental Procedures,"* 92 FERTILITY & STERILITY 1517, 1517 (2009).

161. ASRM, *supra* note 5, at 1105.

162. *Id.*

163. See, e.g., M.T.M. Franssen et al., *Reproductive Outcome After PGD in Couples with Recurrent Miscarriage Carrying a Structural Chromosome Abnormality: A Systematic Review*, 17 HUM. REPROD. UPDATE 467 (2011); Jennifer Hirshfeld-Cytron et al., *Management of Recurrent Pregnancy Loss Associated with a Parental Carrier of a Reciprocal Translocation: A Systematic Review*, 29 SEMINARS REPROD. MED. 470, 470–81 (2011).

164. For example, the ASRM waited almost twenty years before removing the "experimental" label from embryo freezing protocols. *Fertility Experts Issue New Report on Egg Freezing: ASRM Lifts*

CPGs, like customary practices, are based on current medical consensus.¹⁶⁵ Thus, ART physicians should not solely rely on the ASRM's existing CPGs concerning PGS-aneuploidy screening, because doing so may actually compromise the best interests of their existing patients.

*C. The "Reasonable Physician" Standard: The Optimal Framework
for Defining a Physician's Duty to Adopt Emerging PGS Technologies*

The "reasonable physician" standard is the most suitable approach to defining the standard of care owed by ART physicians in the context of providing optimized PGS-aneuploidy screening. Usually, the reasonable physician standard is informed by reference to what other physicians would do when confronted with similar circumstances. But the reasonable physician standard takes on an added layer of complexity when the use of a new medical technology is implicated, particularly where the technology involves a transformation in related procedures or processes of medical care.¹⁶⁶ Under such circumstances, physicians are expected to take steps to ensure that the new technology is appropriate for a particular patient, thereby mitigating their risk of liability.¹⁶⁷ These steps include (a) acquiring knowledge about the safety and effectiveness of the new technology and of the scientific evidence base that supports it, (b) obtaining appropriate training and expertise prior to actually using the technology, (c) evaluating any specific risks posed by the technology in connection with particular types of procedures or patients, and (d) receiving informed consent from their patients prior to undertaking medical procedures on a nonemergency basis.¹⁶⁸ Simply put, the reasonable physician standard would essentially incorporate a cost-benefit analysis whenever a new treatment modality is involved.¹⁶⁹

The seminal case of *Helling v. Carey* is one such example that integrates cost-benefit analysis into the reasonable physician standard.¹⁷⁰ In *Helling*, the plaintiff sued her ophthalmologist for failing to give her a simple, painless, and inexpensive test that would have detected her glaucoma before her symptoms got worse.¹⁷¹ The defendant argued that his decision was consistent with the customary norms of the profession, which did not require the routine administration of the test to

'Experimental' Label from Technique, ASRM (Oct. 19, 2012), <http://www.asrm.org/news/article.aspx?id=10358>.

165. Williams, *supra* note 38, at 524.

166. Greenberg, *supra* note 39, at 432.

167. *Id.* at 434–37.

168. These criteria are identical to the ones courts consider when assessing whether a physician has breached the standard of care by adopting a noncustomary medical practice. *See* Bergero v. Univ. of S. Cal. Keck Sch. of Med., No. B200595, 2009 WL 946874, at *9–14 (Cal. Ct. App. Apr. 9, 2009) (finding that defendant physician was not liable for malpractice for recommending and providing PGD via PCR instead of FISH).

169. *See* Williams, *supra* note 38, at 519–21 (integrating both cost-benefit analysis and the reasonable physician standard as a potential standard of care for evidence-based medicine).

170. *Helling v. Carey*, 519 P.2d 981, 981 (Wash. 1974).

171. *Id.* at 981–82.

patients her age.¹⁷² The plaintiff contended that adherence to the medical custom of not administering routine pressure tests was not dispositive of reasonableness.¹⁷³ The court found the physician liable and held that the reasonable standard of care that should have been followed was to administer the inexpensive, harmless, and effective glaucoma pressure test, regardless of what was customary at the time.¹⁷⁴ Since *Helling*, glaucoma pressure tests have become “a routine part of every eye examination,” regardless of age.¹⁷⁵ Like the glaucoma pressure test in *Helling*, optimized PGS-aneuploidy screening techniques involving trophoctoderm biopsy and comprehensive chromosomal screening methods, such as array-CGH, SNP microarrays, and qPCR, also have the ability to transform related procedures in reproductive medicine. Optimized PGS-aneuploidy screening methods are highly predictive of the reproductive potential of human embryos,¹⁷⁶ and may be used to increase pregnancy rates and decrease risks of spontaneous abortion and chromosomal syndromes in infertile patients.¹⁷⁷ Furthermore, the high embryo implantation rates achieved through optimized PGS-aneuploidy screening techniques mark an extremely significant milestone for IVF clinics attempting to circumvent the problem of multiple births via single embryo transfer.¹⁷⁸ These promising results also signal that the rate of misdiagnosis is much lower with optimized methodologies than when compared to traditional PGS-aneuploidy screening techniques. Unlike the traditional embryo biopsy procedure at the cleavage stage, which requires a high degree of technical proficiency,¹⁷⁹ and is associated with some risk of reduced implantation

172. *Id.* at 982.

173. *Id.*

174. *See id.* at 983–84.

175. Veronica M. O’Hern, *Medicolegal Rounds*, 230 JAMA 1577, 1578 (1974).

176. R.T. Scott, Jr. et al., *Comprehensive Chromosome Screening Is Highly Predictive of the Reproductive Potential of Human Embryos: A Prospective, Blinded, Nonselection Study*, 97 FERTILITY & STERILITY 870, 870–75 (2012).

177. Studies using optimized PGS-aneuploidy screening report significantly higher implantation rates and ongoing pregnancy rates compared to unscreened control groups, despite disparities in maternal age or poor medical history. Forman et al., *supra* note 30, at 1217; Schoolcraft et al., *supra* note 21, at 1700; Scott, Jr. et al., *supra* note 30, at S2.

178. *See* Forman et al., *supra* note 31, at S49; William B. Schoolcraft & Mandy G. Katz-Jaffe, *Comprehensive Chromosome Screening of Trophoctoderm with Vitrification Facilitates Elective Single-Embryo Transfer for Infertile Women with Advanced Maternal Age*, 100 FERTILITY & STERILITY 615, 617–18 (2013) (reporting higher implantation rates, higher ongoing pregnancy rates, and lower spontaneous miscarriage rates in advanced maternal age (AMA) patients following blastocyst CCS with vitrification and frozen single embryo transfer compared with AMA patients in the non-CCS group that underwent single embryo transfer. AMA patients in the CCS group had reproductive outcomes similar to their younger counterparts following blastocyst CCS with vitrification and frozen embryo transfer); Yang et al., *supra* note 31, at 24.

179. King, *supra* note 19, at 307 (“[I]mprecise or unskilled embryo biopsy can substantially harm the embryo, preventing implantation and development.”). For instance, PGS practitioners have questioned the quality of the embryo biopsy procedures performed in the seminal Mastenbroek study, as approximately twenty percent of embryos in the PGS group had “undetermined” chromosomal status compared with five percent in experienced laboratories. *See* Mastenbroek et al., *supra* note 16, at 16 tbl.4; *PGD Pioneers*, *supra* note 21.

potential,¹⁸⁰ almost every cultured blastocyst subjected to trophoctoderm biopsy survives the procedure.¹⁸¹ Thus, trophoctoderm sampling is a much simpler, safer alternative. Lastly, improvements in DNA sequencing have made it increasingly practical to generate large amounts of sequence data with the use of high-throughput next-generation sequencing (NGS) machines, for which the cost per reaction is falling drastically.¹⁸² Studies are currently underway to evaluate the feasibility of NGS for preimplantation embryo assessment, which, if successful, would significantly lower the costs of optimized PGS-aneuploidy screening.¹⁸³

One caveat of the optimized technology is that it disadvantages patients who suffer from diminished ovarian reserve (DOR).¹⁸⁴ DOR patients produce poor-quality oocytes and embryos, and only have a small number of embryos available for trophoctoderm biopsy.¹⁸⁵ Thus, women with DOR cannot be expected to derive outcome benefits from day-five blastocyst transfers compared to day-three cleavage-stage embryo transfers.¹⁸⁶ However, even under this scenario, a physician who is leaning toward providing optimized PGS-aneuploidy screening would still be able to mitigate the risk of liability. First, the physician must receive the patient's informed consent *after* disclosing the risks and benefits of both the recommended treatment and the medically acceptable alternatives. Second, the physician would still have to exercise his or her best judgment and alter the course of treatment in the event that early warning symptoms arise. For instance, the physician would suspect that a patient suffers from DOR based on the low numbers of cleavage-stage embryos. At that moment, the physician could point the patient toward other medically acceptable alternatives (such as day-three embryo transfer without PGS screening or oocyte donation) and alter the course of treatment accordingly. Given these circumstances, a reasonable physician may conclude that the risk of liability for adopting optimized PGS-aneuploidy screening is not as daunting as it would seem at first blush. The reasonable physician standard thus eliminates the hurdles that a custom-based standard places on ART physicians desiring to disregard customary practices, and allows the standard of care to evolve in response to medical advances.

180. Cohen et al., *supra* note 20; Cohen & Grifo, *supra* note 21.

181. See studies cited *supra* note 31. In fact, critics question the value of retaining traditional PGS-aneuploidy screening methods given the technical proficiency barriers. See Fragouli & Wells, *supra* note 2, at 291 (“[E]ven if it is true that FISH-based analyses can be beneficial, the fact that so few laboratories are able to demonstrate any efficacy is indicative of a technology that is not sufficiently robust, leading to problems applying it in different laboratories.”).

182. Julio Martin et al., *The Impact of Next-Generation Sequencing Technology on Preimplantation Genetic Diagnosis and Screening*, 99 FERTILITY & STERILITY 1054, 1055 (2013).

183. XuYang Yin et al., *Massively Parallel Sequencing for Chromosomal Abnormality Testing in Trophoctoderm Cells of Human Blastocysts*, 88 BIOLOGY REPROD. 69 (2013).

184. Norbert Gleicher & David H. Barad, *A Review of, and Commentary on, the Ongoing Second Clinical Introduction of Preimplantation Genetic Screening (PGS) to Routine IVF Practice*, 29 J. ASSISTED REPROD. & GENETICS 1159, 1163 (2012).

185. *Id.*

186. *Id.*

C. *Dismissing Objections to the Proposed Standard of Care*

One may contend that physicians have no duty to offer patients optimized PGS-aneuploidy screenings because the treatment is still experimental. Indeed, some courts have held that experimental treatments are not therapies that fall within the definition of medically acceptable alternatives.¹⁸⁷ This Note contends that optimized PGS-aneuploidy screening no longer fits within the ASRM's definition of "experimental procedures," and thus should not be classified as such. According to the ASRM, "[p]rocedures (including tests, treatments, or other interventions) for the diagnosis or treatment of infertility will be considered experimental or investigational until the published medical evidence regarding their risks, benefits, and overall safety and efficacy is sufficient to regard them as established medical practice."¹⁸⁸ The ASRM states that "relevant medical evidence can derive only from appropriately designed, peer-reviewed, published studies performed by multiple independent investigators, including a description of materials and methods sufficient to assess their scientific validity and to allow independent verification."¹⁸⁹ Several influential studies demonstrate that comprehensive molecular cytogenetic methodologies are highly predictive of the implantation potential of human embryos,¹⁹⁰ and that blastocyst biopsy is safer and thus preferable to cleavage-stage embryo biopsy.¹⁹¹ Numerous clinical trials have since combined blastocyst biopsy with comprehensive molecular cytogenetic methodologies to assess their overall efficacy in improving reproductive outcomes.¹⁹² Implantation rates and ongoing pregnancy rates using optimized PGS-aneuploidy screening are significantly higher compared to untreated controls, a trend that has been consistent across multiple studies from independent groups, regardless of age or medical prognosis.¹⁹³ Another recent study has revealed that qPCR-based CCS is comparable with the current standard of care (double unscreened embryo transfer), and eliminates the problem of multiple pregnancy.¹⁹⁴ As of August 2012, optimized PGS-aneuploidy screening methods have been used in more than 3000 IVF cycles at nine centers in the United States.¹⁹⁵ This trend

187. *Garrett v. United States*, 667 F. Supp. 1147, 1162–63 (W.D. La. 1987) ("This court will not find malpractice in the treating physician's failure to adopt a 'controversial' treatment modality which is not commonly accepted in the medical profession. . . . This court would violate the long-established standard of care for physicians if it held a doctor liable for failing to use experimental and unproven treatment on one of his patients."); *Del Valle Rivera v. United States*, 630 F. Supp. 750, 755–56 (D.P.R. 1986).

188. Practice Comm. of the Am. Soc'y for Reprod. Med., *supra* note 160, at 1517.

189. *Id.*

190. Scott, Jr. et al., *supra* note 176, at 870.

191. McArthur et al., *supra* note 29, at 1628; N.R. Treff et al., *Cleavage Stage Embryo Biopsy Significantly Impairs Embryonic Reproductive Potential While Blastocyst Biopsy Does Not: A Novel Paired Analysis of Cotransferred Biopsied and Nonbiopsied Sibling Embryos*, 96 FERTILITY & STERILITY S2 (2011).

192. See studies cited *supra* notes 29–31.

193. Forman et al., *supra* note 30, at 1217; Schoolcraft et al., *supra* note 21, at 1700; Scott, Jr. et al., *supra* note 30, at S2; Yang et al., *supra* note 31, at 24.

194. Forman et al., *supra* note 31, at S49.

195. Nathan R. Treff & Richard T. Scott, Jr., *Four-Hour Quantitative Real-Time Polymerase Chain*

also suggests that there is a substantial percentage of reputable experts within the field of reproductive medicine that favor optimized PGS-aneuploidy screening methodologies over generally accepted methods involving FISH and cleavage-stage biopsy. Furthermore, a few scholars have expressed optimism about universally applying improved PGS-aneuploidy screening techniques with routine IVF procedures for patients in all age groups.¹⁹⁶ The well-designed, peer-reviewed, published studies referenced above represent the accuracy, safety, and clinical efficacy of optimized PGS-aneuploidy screening techniques. Therefore, under the ASRM's own guidelines, PGS should no longer be classified as an experimental procedure.

And even if optimized PGS-aneuploidy screening retains the “experimental” classification, a physician is still not absolved of the duty to inform patients of the existence of the experimental treatment if it is accepted as an appropriate treatment by some substantial percentage of practitioners in the relevant specialty.¹⁹⁷ In *Wachter v. United States*, the physician failed to inform the patient of the possibility to use the internal mammary artery for a coronary bypass operation instead of the saphenous vein.¹⁹⁸ Applying the lay standard of informed consent, the court held that the internal mammary artery procedure was not a “medically significant alternative” because the procedure was not a choice among treatment modalities.¹⁹⁹ The court explained that the procedure was not in general use, not then known among surgeons to produce better results, and not the subject of any definitive study showing it would be better to use than a saphenous vein graft in a coronary bypass operation.²⁰⁰ Unlike *Wachter*, optimized PGS-aneuploidy screening techniques are medically acceptable alternatives because they have been repeatedly scrutinized during numerous clinical trials, and were found to be safer, more accurate, and more efficacious than traditional PGS screening methods.²⁰¹ Indeed, specialists who make a good-faith effort to keep abreast of current advances in ART would know that the application of these optimized techniques results in superior clinical outcomes, regardless of the patient’s age or poor

Reaction-Based Comprehensive Chromosome Screening and Accumulating Evidence of Accuracy, Safety, Predictive Value, and Clinical Efficacy, 99 FERTILITY & STERILITY 1049, 1052 (2013).

196. *Id.* (“Together these data suggest that it is feasible to universally apply blastocyst qPCR-based CCS without compromising transfer rates and significantly improving overall clinical outcomes, reducing miscarriage rates, and nearly eliminating multiple gestations in all age groups.”); see also Joe Leigh Simpson, *Preimplantation Genetic Diagnosis to Improve Pregnancy Outcomes in Subfertility*, 26 BEST PRAC. & RES. CLINICAL OBSTETRICS & GYNAECOLOGY 805, 805 (2012) (“Current recommendations are for obligatory 24 chromosome testing, most readily using array comparative genome hybridisation.”).

197. *Archer v. Galbraith*, 567 P.2d 1155, 1161 (Wash. Ct. App. 1977) (holding that a patient has the right to be informed about an alternative “means of therapy pursued by a respectable segment of the medical profession”).

198. *Wachter v. United States*, 689 F. Supp. 1420 (D. Md. 1988), *aff’d*, 877 F.2d 257 (4th Cir. 1989).

199. *Id.* at 1423–24.

200. *Id.* at 1423.

201. See *supra* text accompanying notes 29–31, 176–181.

medical prognosis.²⁰² Moreover, the fact that optimized PGS-aneuploidy screening is not yet a general practice in the ART field does not shield a physician from liability for failing to inform patients of the experimental therapy. Because these improved methodologies are accepted as treatment modalities that are supported by some substantial percentage of reputable and respected experts in reproductive medicine,²⁰³ these treatments fall within the definition of “medically acceptable” alternatives. Thus, ART physicians still have the duty to inform their patients of the existence of optimized PGS-aneuploidy screening, notwithstanding its experimental classification.

CONCLUSION

Modern medicine is largely a product of innovation grounded in empirical science. But any time a physician adopts an emerging technology that can transform the nature or delivery of clinical care, there is always the potential for a new set of malpractice risks. This uncertainty can be so unsettling to physicians that it may actually deter them from adopting new technologies that would best serve the interests of their patients. The proposed standard of care in this Note comports with the Learned Hand formula in *United States v. Carroll Towing Co.*, which defines negligence as failing to take precautions whose costs do not exceed the potential loss, multiplied by the probability of that loss.²⁰⁴ The reasonable physician standard is the optimal framework for assessing the standard of care for adopting emerging medical technologies because it is dynamic and easy to administer, and is not over- or underinclusive. Many jurisdictions are already quite familiar with judging physicians by standards of reasonable prudence,²⁰⁵ and courts have had over half a century of experience applying the Hand formula.²⁰⁶ The reasonable physician standard also remedies problems of over- and underinclusiveness that exist under a custom-based standard by liberating courts from having to “hold every physician who deviates from custom liable and from having to exonerate every physician who follows custom.”²⁰⁷ Most importantly, the reasonable physician standard is dynamic because it allows the standard of care to evolve in light of current medical advances by reducing the chilling effects that a “custom-based standard places on physicians desiring to disregard customary practice.”²⁰⁸

202. See *supra* text accompanying notes 30–31.

203. See studies cited *supra* notes 29–31, 176–181.

204. See *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947). As applied here, a standard of care is overinclusive where physicians are penalized for using their best judgment and deviating from questionable customary norms in favor of emerging technologies that improve patient welfare. Conversely, a standard of care is under-inclusive where physicians can escape liability by asserting that they were merely adhering to customary, albeit harmful, medical practices.

205. Peters, Jr., *supra* note 37, at 187–88 (arguing that courts are shifting away from a custom-based standard in favor of a reasonable physician standard).

206. Williams, *supra* note 38, at 521.

207. *Id.* at 520.

208. *Id.* at 521.

Under the reasonable physician standard, courts would hold physicians accountable for the failure to recommend, or provide patients with, optimized PGS-aneuploidy screening, to the extent that not doing so violates Hand's formula, which is essentially the same standard employed in *Helling v. Carey*. Imposing such a duty on physicians advances compelling policies, including protecting the health and safety of vulnerable ART patients; encouraging physician and patient autonomy in clinical decision making; promoting the reproductive autonomy of individuals with recurring, but surmountable, fertility issues; and facilitating the rapid development of state-of-the-art techniques and devices in reproductive medicine.