NOTE

Screening for Children: Choice and Chance in the "Wild West" of Reproductive Medicine

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While the struggle over abortion rights in the United States continues vociferously,[1] as recently highlighted by the passage of nationalized health care,[2] a new type of reproductive medical procedure has arrived, unnoticed and unregulated. Preimplantation genetic screening ("PGS")[3] and *in vitro* fertilization ("IVF")[4] provide parents who can afford them[5] with a new, powerful, and potentially dangerous

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1 *See* William Wan, *Marchers' Focus: Life, Legislation*, WASH. POST, Jan. 23, 2010, at B1.

2 *See* Bart Stupak, *Why I'm Proud of My Health Bill Vote*, WASH. POST, Mar. 27, 2010, at A13.

3 PGS and preimplantation genetic diagnosis (PGD) are two terms that refer to the same technology. PGS covers all types of genetic screening, whereas PGD encompasses screening for therapeutic reasons only, e.g., disease prevention. *See* Jaime King, *Duty to the Unborn: A Response to Smolensky*, 60 HASTINGS L.J. 377, 379 n.15 (2008).

4 PGS is the process through which embryos are evaluated for certain genetic markers known to manifest into human characteristics. IVF is the process through which those embryos are implanted in the womb. *See infra* Part I.

5 IVF with PGD costs average between $17,000 and $22,000, according to one estimate.

choice: rather than taking the chance of conceiving traditionally, parents can now create a limitless number of candidate embryos in a laboratory, analyze the characteristics of each, and select which embryo will become their future child. As PGS is a reproductive medical procedure, some have argued that regulations on the technology would unconstitutionally infringe on parents' reproductive liberty and autonomy, rights that are sacrosanct in the United States.[6] However, PGS differs materially from other reproductive medical procedures both in its procedures—because it takes place outside of the human body—and its potential for abuse—because it deals with more than mere creation of life, as it allows for the selection and creation of life with expected specific attributes.[7]

PGS raises certain ethical implications that have led several countries to ban it and others to heavily regulate it. These ethical implications range from the destruction of unused embryos[8] to the selection of designer babies and the elimination of unpopular communities.[9] And yet, somewhat mysteriously, the United States has refused to regulate.[10] Although scholars have proposed changes in this area, these

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PGD and IVF Costs, ADVANCED FERTILITY CENTER CHI., http://www.advancedfertility.com/pgd-costs.htm (last visited May 16, 2011).

6 *See, e.g.*, JOHN A. ROBERTSON, CHILDREN OF CHOICE 22–23 (1994); John A. Robertson, *Assisting Reproduction, Choosing Genes, and the Scope of Reproductive Freedom*, 76 GEO. WASH. L. REV. 1490, 1491 (2008).

7 *See infra* Part I.

8 *Id.*

9 *See infra* Part III.C.

10 PGS is not specifically regulated in the United States. There are, however, some federal and state laws that relate to PGS research and procedures. *See* FRANCIS FUKUYAMA & FRANCO FURGER, BEYOND BIOETHICS: A PROPOSAL FOR MODERNIZING THE REGULATION OF HUMAN BIOTECHNOLOGIES 117–33 (2006), *available at* http://www.biotechgov.ch/images/uploads/aggregated/FinalReport.pdf; PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 51–54 (2004) [hereinafter PCBE], *available at* http://bioethics.georgetown.edu/pcbe/reports/reproductionandresponsibility/_pcbe_final_reproduction_and_responsibility.pdf. The federal Clinical and Laboratory Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903 (codified as amended at 42 U.S.C. § 263a (2006)), "imposes minimal requirements on the professional qualifications of laboratory personnel"; this would "presumably extend to [PGS]" performed in a clinical setting, but not in a research laboratory. FUKUYAMA & FURGER, *supra*, at 122. Outside the federal context, there are a variety of state laws that relate to research on and disposition of human embryos. For example, Louisiana state law defines an embryo as a "juridical person," restricts the purposes of research on embryos to that which leads to implantation, and prohibits the intentional destruction of embryos. LA. REV. STAT. ANN. § 9:122, :123, :129 (2008 & Supp. 2011). Because multiple embryos must be created as part of PGS, *see infra* Part I, those embryos would need to either be implanted or frozen. *Id.* § 9:129. By contrast, California's legislature attempted to regulate embryonic research in 2003, but a direct democracy initiative reversed these regulations, and in fact, requires the state to raise funds for embryonic research "free of virtually any public oversight."

proposals have not been implemented, and time has grown short. One of President Obama's first actions upon entering office was the signing of Executive Order 13,505, "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells," which reversed an eight-year presidential ban on federal funding for embryonic stem cell ("ESC") research.[11] Although the congressional Dickey-Wicker Amendment[12] still prohibits federal funding for the creation of human embryos,[13] President Obama's action will hasten the scientific progress in this unregulated area described by some as the "Wild West" of American medicine.[14]

Expanded federally sanctioned ESC research will likely lead to an increased use of PGS because the technologies are complementary. For example, ESC research led to the discovery that individuals with certain diseases can be treated with stem cells from genetically similar humans; PGS can be used to select embryos that can become those humans (so-called "savior siblings").[15] PGS is now used frequently for this purpose.[16] Also, although federal law still prohibits the creation of embryos for use in stem cell research,[17] President Obama's order now permits federally funded researchers to obtain embryos from other sources. Discarded embryos created by PGS, but not selected

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FUKUYAMA & FURGER, *supra*, at 132–33. In sum, there are no federal or state laws directly on point with regards to PGS, but some related laws may burden or otherwise affect PGS procedures.

11 Exec. Order No. 13,505, 3 C.F.R. 229 (2010); Thomas F. Schaller, *For Obama, a Frenetic First 50 Days*, BALT. SUN, Mar. 10, 2009, at 15. As of this writing, however, regulations promulgated under the Order are the subject of litigation. The United States District Court for the District of Columbia entered a temporary injunction barring all research using embryonic stem cells, citing the Dickey-Wicker Amendment. Sherley v. Sebelius, 704 F. Supp. 2d 63, 72–73 (D.D.C. 2010). The United States Court of Appeals for the District of Columbia Circuit stayed the injunction pending expedited appeal, Sherley v. Sebelius, No. 10-5287 (D.C. Cir. Sept. 28, 2010), and recently vacated the injunction, Sherley v. Sebelius, No. 10-5287 (D.C. Cir. Apr. 29, 2011).

12 Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 509(a)(2), 123 Stat. 524, 803.

13 Sheryl Gay Stolberg, *New Stem Cell Policy to Leave Thorniest Issue to Congress*, N.Y. TIMES, Mar. 9, 2009, at A1 ("[The] Dickey-Wicker amendment[ ] first became law in 1996, and has been renewed by Congress every year since. It specifically bans the use of tax dollars to create human embryos—a practice that is routine in private fertility clinics.").

14 Marsha Garrison, *Regulating Reproduction*, 76 GEO. WASH. L. REV. 1623, 1623 (2008).

15 *See infra* note 239.

16 SUSANNAH BARUCH ET AL., GENETICS & PUB. POLICY CTR., GENETIC TESTING OF EMBRYOS: PRACTICES AND PERSPECTIVES OF U.S. IVF CLINICS 5 (2006) [hereinafter PRACTICES AND PERSPECTIVES], *available at* http://www.dnapolicy.org/resources/PGDSurveyReportFertilityandSterilitySeptember2006withcoverpages.pdf (stating that nearly a quarter of clinics surveyed performed this service).

17 *See* Stolberg, *supra* note 13.

for implantation, represent a source for these researchers.[18] Thus, ESC research and the use of PGS are inextricably connected: increased ESC research causes an increase in PGS, which in turn, provides researchers with the resources to conduct additional ESC research.[19]

The United States should take immediate action to ensure that a regulatory framework is in place to address this advancing technology. Although technological limitations prevent some of the most controversial uses of this technology, serious ethical questions surround what is currently possible and will soon be possible. Part I of this Note provides a basic overview of the technology at issue. Part II examines the increasing demand for the service. Part III discusses the necessity of some form of regulation, and Part IV examines the worldwide array of PGS regulation. Part V proposes a unique combination of legislation, regulation, and state engagement to suit the needs and interests of the United States. Finally, Part VI concludes that this unique combination is the best course of action for the United States to take given time constraints and other concerns.

I. PGS: THE TECHNOLOGY

Preimplantation genetic screening is a technology that allows doctors to evaluate the genetic characteristics of embryos.[20] As the name suggests, this process occurs outside of the mother's body and prior to implantation of the embryo in her womb.[21] The basic steps

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18 *See, e.g.*, Michelle N. Meyer & James W. Fossett, *The More Things Change: The New NIH Guidelines on Human Stem Cell Research*, 19 KENNEDY INST. ETHICS J. 289, 291 (2009). Previously, researchers could only use stem cells derived from embryos that were destroyed (through the process of collecting stem cells) before 2001. *Id.*

19 In addition to driving increased use of PGS, further ESC research could eventually lead to a type of technology that is even more advanced than PGS: human germline genetic modification (HGGM). *See, e.g.*, SUSANNAH BARUCH ET AL., GENETICS & PUB. POLICY CTR., HUMAN GERMLINE GENETIC MODIFICATION: ISSUES AND OPTIONS FOR POLICYMAKERS 13 (2005), *available at* http://www.dnapolicy.org/images/reportpdfs/HumanGermlineGeneticMod.pdf. Rather than selecting an embryo for certain criteria among several created through PGS, HGGM would actually allow the modification of an embryo to meet the specified criteria. *See id.* Thus, parents could literally design their embryo, rather than selecting one from several created through chance. *Id.* at 31. Although this does not directly bear on PGS per se, the regulatory structure proposed here could easily adapt, once created, to regulate HGGM. *See infra* Part V.

20 GENETICS & PUB. POLICY CTR., PREIMPLANTATION GENETIC DIAGNOSIS: A DISCUSSION OF CHALLENGES, CONCERNS, AND PRELIMINARY POLICY OPTIONS RELATED TO THE GENETIC TESTING OF HUMAN EMBRYOS 3 (2004) [hereinafter CHALLENGES], *available at* http://www.dnapolicy.org/images/reportpdfs/PGDDiscussionChallengesConcerns.pdf.

21 *Id.*

are as follows[22]: First, a woman is given drugs to stimulate egg production.[23] Next, her eggs are extracted;[24] this process is painful.[25] After extraction, the eggs are fertilized, thereby creating one or more embryos.[26] Several days later, each embryo is biopsied and genetic tests are performed on the sample material.[27] On the basis of these test results, the woman chooses which embryos, if any, to implant.[28]

The technology was originally created to screen for diseases.[29] Thus, early characteristics that could be identified through PGS included the likelihood of conditions such as Tay-Sachs,[30] cystic fibrosis,[31] sickle cell anemia,[32] Huntington's disease,[33] Alzheimer's disease,[34] and breast cancer.[35] More recently, the list of characteristics

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22 The scientific details of the process are complicated and need not be included for the purposes of this Note.

23 CHALLENGES, *supra* note 20, at 4.

24 *Id.*

25 Supriya Kakkar, Note, *Unauthorized Embryo Transfer at the University of California, Irvine Center for Reproductive Health*, 24 HASTINGS CONST. L.Q. 1015, 1019 (1997). The process of egg extraction, fertilization, and implantation is referred to generally as *in vitro* fertilization (IVF). *Id.* at 1018–19.

26 CHALLENGES, *supra* note 20, at 4.

27 *Id.*

28 *Id.*

29 *Id.* at 3. This is the reason that the technology was initially termed "preimplantation genetic diagnosis." *See supra* note 3.

30 Tay-Sachs is a fatal neurological disorder that kills most affected children by the age of four. *Tay-Sachs Disease Information Page*, NAT'L INST. NEUROLOGICAL DISORDERS & STROKE, http://www.ninds.nih.gov/disorders/taysachs/taysachs.htm (last updated Feb. 14, 2007).

31 Cystic fibrosis is a serious pulmonary condition that leads to compromised lung function, and frequently, death through respiratory failure; some, but not all, will live until their forties. *What Is Cystic Fibrosis?*, NAT'L HEART LUNG & BLOOD INST., http://www.nhlbi.nih.gov/health/dci/Diseases/cf/cf_what.html (last updated Mar. 2009).

32 Sickle cell anemia is a serious condition that affects red blood cells. *What Is Sickle Cell Anemia?,* NAT'L HEART LUNG & BLOOD INST., http://www.nhlbi.nih.gov/health/dci/Diseases/Sca/SCA_WhatIs.html (last updated Feb. 2011). If left untreated, it can lead to organ failure between ages twenty and forty; when treated, affected people can live into their fifties and beyond, though they will experience painful episodes called "crises" that may require hospitalization. *Sickle Cell Anemia*, MEDLINEPLUS, http://www.nlm.nih.gov/medlineplus/ency/article/000527.htm (last updated Jan. 31, 2010).

33 Huntington's disease is a severe and irreversible neurological disorder that leads to "uncontrolled movements, loss of intellectual faculties, and emotional disturbance." *Huntington's Disease Information Page*, NAT'L INST. NEUROLOGICAL DISORDERS & STROKE, http://www.ninds.nih.gov/disorders/huntington/huntington.htm (last updated Aug. 13, 2010).

34 Alzheimer's disease is an irreversible brain disorder that leads to a decline of cognitive function and eventually death. *Alzheimer's Disease Information Page*, NAT'L INST. NEUROLOGICAL DISORDERS & STROKE, http://www.ninds.nih.gov/disorders/alzheimersdisease/alzheimersdisease.htm (last updated Nov. 19, 2010).

35 Breast cancer is a disease that causes abnormal cell growth and tumors in breast tissue. *Breast Cancer*, GENETICS HOME REFERENCE, http://ghr.nlm.nih.gov/condition=breastcancer (last

for which there are genetic tests has grown substantially. As of 2006, a study identified over 1000 characteristics that could theoretically be screened using PGS.[36] A new technology exists on the horizon that could expand that number to over 15,000.[37] Nearly any genetic test that currently exists can be performed on the biopsied matter.[38] Consequently, the technology is no longer limited to screening for serious diseases alone.

In considering the types of characteristics for which PGS can screen, it is helpful to characterize them into three groups: (1) life-threatening diseases, (2) manageable but disabling conditions, and (3) all remaining characteristics. For example, the diseases listed above could fairly be categorized as life-threatening diseases. As treatments for these diseases improve, however, they may no longer threaten—or threaten as seriously—a person's life.[39] At that point, they may be more fairly categorized into a second group of lifelong conditions with potentially disabling effects.

Hereditary deafness is an example of a characteristic in this second group.[40] Deafness is by no means a life-threatening condition, but neither is it medically inconsequential.[41] Sensitivity in defining this second group is warranted; where some people without these characteristics see them as a disability, those with these characteristics often see them as a component of their identity.[42] A similar characteristic

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visited Mar. 31, 2011). Hereditary breast cancer (the type for which PGS can screen) often occurs earlier in life. *Id.*

36 PRACTICES AND PERSPECTIVES, *supra* note 16, at 4.

37 Amber Angelle, *Made-to-Order Offspring*, POPULAR MECHANICS, Jan. 2010, at 20, 20 (discussing karyomapping, a "new procedure [that] compares the genetic maps of parents and embryos").

38 PRACTICES AND PERSPECTIVES, *supra* note 16, at 4.

39 For example, thirty years ago, approximately twenty-five percent of women who were diagnosed with breast cancer did not survive for more than five years. NAT'L INST. OF HEALTH, FACT SHEET: BREAST CANCER 1 (2006), *available at* http://report.nih.gov/NIHfactsheets/Pdfs/BreastCancer(NCI).pdf. Today, that number has fallen to ten percent. *Id.*

40 PRACTICES AND PERSPECTIVES, *supra* note 16, at 4.

41 The federal government defines deafness as a disability. ADA Amendments Act of 2008, Pub. L. No. 110-325, sec. 4, § 3, 122 Stat. 3553, 3555 (codified at 42 U.S.C. § 12102) (defining "disability" to include a "physical or mental impairment that substantially limits one or more major life activities of [an] individual," and defining "major life activity" to include hearing).

42 A large community of deaf individuals existed on Martha's Vineyard in Massachusetts for more than 250 years. NORA ELLEN GROCE, EVERYONE HERE SPOKE SIGN LANGUAGE: HEREDITARY DEAFNESS ON MARTHA'S VINEYARD 106 (1985). Because of the significant population, both nonhearing and hearing members of society alike used sign language, thus leading the author to conclude that "these deaf men and women . . . were *not* handicapped, because no one perceived their deafness as a handicap." *Id.* at 107, 110.

for which PGS can screen is dwarfism.[43] Both deafness and dwarfism are especially notable traits within this discussion, as parents have, somewhat controversially, screened for the *presence* (as opposed to the absence) of these traits.[44]

Beyond screening for life-threatening diseases and for lifelong conditions that are manageable but disabling, PGS technology can be used to screen for a third category of characteristics—those characteristics that are not linked to a life-threatening or disabled condition.[45] For example, a widespread use of the technology today is sex selection.[46] Although sex selection can be used as an avoidance strategy for some life-threatening diseases,[47] clinics today already offer parents the ability to choose the sex of their child for nonmedical reasons.[48] As of 2006, nearly half of the clinics in the United States providing sex

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43 Darshak M. Sanghavi, *Wanting Babies like Themselves, Some Parents Choose Genetic Defects*, N.Y. TIMES, Dec. 5, 2006, at F5.

44 PRACTICES AND PERSPECTIVES, *supra* note 16, at 5; Sanghavi, *supra* note 43. The process of selecting embryos *for* the characteristic has been controversial. *See, e.g.*, William Saletan, *Deformer Babies: The Deliberate Crippling of Children*, SLATE (Sept. 21, 2006, 9:15 AM), http://www.slate.com/id/2149854 (referring to the matter as the "deliberate crippling of children"). There has been a lively academic debate on the subject; for a truly fascinating introduction, see Kirsten Rabe Smolensky, *Creating Children with Disabilities: Parental Tort Liability for Preimplantation Genetic Interventions*, 60 HASTINGS L.J. 299 (2008). With all of the arguments in this area, defining disability is a difficult exercise in line drawing. *See, e.g.*, Karen E. Schiavone, Comment, *Playing the Odds or Playing God? Limiting Parental Ability to Create Disabled Children Through Preimplantation Genetic Diagnosis*, 73 ALB. L. REV. 283, 308–09 (2009). Schiavone concludes that the government should be able to cite the "social rejection" of a child and accompanying psychological effects in barring parents from choosing a characteristic such as dwarfism. *Id.* at 309. She continues, "Worse yet are the parents who suffered emotionally when they were children as a result of their own disabilities, but nevertheless decide to create children just like them." *Id.* at 318. A liberal interpretation of these arguments could potentially include gay parents that used PGS to create a gay child, were that possible, despite the fact that homosexuality is not a disability; children often experience "social rejection" and suffer emotionally owing to their actual or perceived sexuality. *See* JOSEPH G. KOSCIW ET AL., THE 2009 NATIONAL SCHOOL CLIMATE SURVEY, at xvi (2010) (finding that 84.6% of lesbian, gay, bisexual, and transgender teenaged students were harassed or threatened at school).

45 Again, line drawing between a disability or disease and "cosmetic" traits can be extremely difficult. *See, e.g.*, Sonia M. Suter, *A Brave New World of Designer Babies?*, 22 BERKELEY TECH. L.J. 897, 936 (2007) ("On a societal scale, the more we use technology to select against lesser conditions and traits, the more perfectionist we may become as a culture, and the more demanding we may become with respect to what is acceptable, normal, or healthy. The distinction between disease and normalcy may evolve. If enhancement and trait selection are widely used, it is easy to imagine that what was once normal will start to seem abnormal and perhaps disease-like.").

46 PRACTICES AND PERSPECTIVES, *supra* note 16, at 5.

47 For example, some diseases (called "X-linked" diseases) can be avoided by selecting a gender for which the condition does not manifest. *See id.*

48 *Id.*

selection offered parents this option.[49] Because of this expansive offering, nonmedical sex selection screening was performed in nearly ten percent of all PGS procedures in 2005.[50] Other nonmedical characteristics for which screening is available include eye color and hair color.[51]

Finally, although genetic tests exist for more than 1000 characteristics,[52] so much of what makes up a human being still remains unknown. One characteristic discussed frequently in academic literature relating to PGS is sexual orientation.[53] At this point there is no genetic test for sexuality, but it is widely believed that sexuality is, at least in part, a genetically determined attribute.[54] Other characteristics, such as height, are similarly recognized as "strongly genetic trait[s]," although currently the complexity of the human genome has put a genetic test outside the reach of scientists.[55] However, the pace at which new genetic tests are discovered may be increasing.[56]

It is clear that PGS provides the technological potential to reshape the process of reproduction in this country. The technology now exists for parents to choose among any number of embryos, screened to their standards, subject only to the limits of their financial ability and desire to continue the process further. Before concluding that such a paradigm shift is imminent, however, it is important to investigate the current demand for the technology.

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49 *Id.*

50 *Id.* Parents can seek PGS treatment to screen for the gender of their child independently, or in addition to screening for other characteristics. *Id.*

51 One U.S. clinic briefly provided these services before changing course due to negative public reactions. Daniel MacArthur, *"Designer Baby" Doctor No Longer Offering Embryo Screening for Cosmetic Traits*, GENETIC FUTURE, WIRED.COM (Mar. 5, 2009, 1:05 PM), http://www.wired.com/wiredscience/2009/03/designer-baby-doctor-no-longer-offering-embryo-screening-for-cosmetic-traits/.

52 *See supra* text accompanying note 36.

53 *See, e.g.*, Edgar Dahl, *Ethical Issues in New Uses of Preimplantation Genetic Diagnosis*, 18 HUM. REPROD. 1368, 1368–69 (2003) (arguing that parents should be allowed to use PGD to choose the sexual orientation of their children).

54 *See, e.g.*, Sven Bocklandt et al., *Extreme Skewing of X Chromosome Inactivation in Mothers of Homosexual Men*, 118 HUM. GENETICS 691, 691 (2006) (concluding that "[v]ariation in human sexual preference has a substantial genetic component").

55 Daniel MacArthur, *Predicting Height: The Victorian Approach Beats Modern Genomics*, GENETIC FUTURE, WIRED.COM (Mar. 3, 2009, 7:30AM), http://www.wired.com/wiredscience/2009/03/Predicting-height:-the-Victorian-approach-beats-modern-genomics (discussing Yurii S. Aulchenko et al., *Predicting Human Height by Victorian and Genomic Methods*, 17 EUR. J. HUM. GENETICS 1070, 1070–75 (2009)).

56 *See supra* notes 11–19 and accompanying text (discussing the circular and interrelated nature of the relationship between stem cells and PGS technology).

II. An Increasing Demand: How Parents Use PGS Today and Why

Given the sheer power of the technology just described, it would be natural for a person to dream up any number of possibilities, and perhaps to categorize them into "good" and "bad." But value systems differ across all types of people, and imagination is not a sound basis for policy change. Hard data provides a better foundation, and for better or worse, the totally unregulated marketplace can provide a snapshot of the increasing demand for this technology. It is well known that parents want what is best for their children,[57] but data can quantify this. Additionally, recent surveys can provide a macro perspective on how people categorize (and to some extent, moralize) current uses of the technology. Between the data and the surveys, a trend has emerged: despite financial and moral barriers to PGS, use of the technology is increasing substantially.

First, a discussion of the current volume of testing is warranted. Because the United States lacks a formal regulatory system to track and research PGS technology, details are scant, but reports that do exist conclude that "[PGS] use appears to be growing rapidly."[58] In the first ten years of the commercial availability of PGS, 6500 screening cycles were performed worldwide, with more than 1000 babies born.[59] One year later, in the United States alone, a survey found that

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57 Consider, as an anecdotal entry point to this discussion, the oft-cited "Mozart Effect" that leads parents to play classical music for their children in hopes of increasing their intelligence. Frances H. Rauscher et al., *Music and Spatial Task Performance*, 365 Nature 611 (1993). Consider also the fact that millions of parents purchased movies from Disney's *Baby Einstein* series, which purported to have the same effect (although Disney has since been forced to give refunds to dissatisfied parents). Chris Ayres, *Disney Offers Refund Amid Outcry over TV Baby Brain Training*, Times (London), Oct. 27, 2009, at 36. Finally, consider the frantic nature of preschool admissions in some parts of the country. *See, e.g.*, Jane Ridley, *Toddlers as Scholars: Parents Learn that Preschools Can Be as Competitive as Harvard & Yale*, N.Y. Daily News, Apr. 19, 2009, at 15; Nursery University (Docurama Films 2008). Although these anecdotes may not seem representative of the general population, they do show that millions are willing to spend money if they think it will augment their children's attributes; at least one scholar recognizes the link between a parent willing to bear the expense of private school and one willing to bear the expense of PGS to select for a "superstar" child. Vicki G. Norton, Comment, *Unnatural Selection: Nontherapeutic Preimplantation Genetic Screening and Proposed Regulation*, 41 UCLA L. Rev. 1581, 1598–99 (1994); *see also* Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past—Present, and Future?*, 36 Conn. L. Rev. 125, 205 (2003) (concluding that "assuming availability, prospective parents will utilize [PGS] to the fullest extent their financial means allow"); Suter, *supra* note 45, at 934–35 (examining current ways that parents are pressured and concluding that "it is hard to imagine that many parents wouldn't feel subtle, or perhaps not so subtle, pressures to seek such advantages for their children").

58 Practices and Perspectives, *supra* note 16, at 1.

59 Challenges, *supra* note 20, at 3; Esther Landhuis, *Pre-Implantation Genetic Diagnosis*

more than 3000 screening cycles were performed.[60] The survey identified 415 assisted reproductive technology clinics within the United States and collected data from approximately half of them (those which voluntarily responded to the survey requests).[61] Thus, the actual number of screenings performed in the United States in 2005 was likely much greater than 3000.

Clearly, the technology for screening embryos is widely available and increasing in scope and magnitude. Mere availability and use statistics, however, do not provide the whole picture; it is of critical importance to know how parents want to use PGS and how parents perceive various uses of the technology. Any regulation will founder without support. Several recent surveys address this matter.[62] Two surveys conducted in the past twelve years conclude that members of the general population, after being provided with information on genetic testing, favored access to more reproductive testing than was currently available.[63]

In the first study, surveying a cross-section of the mainstream population, conclusive majorities supported the use of PGS when used to screen for embryos less at risk for fatal diseases or more likely to be a genetic match for blood or tissue donations to a sibling.[64] Perhaps most importantly for the discussion here, when asked about the statement, "Parents ought to do everything technologically possible to prevent their child from suffering including using reproductive genetic technologies," a majority of respondents agreed or strongly agreed.[65]

Offers Hope but Prompts Ethical Concerns, STANFORD REP. (Mar. 3, 2004), http://news.stanford.edu/news/2004/march3/invitro-33.html.

60 PRACTICES AND PERSPECTIVES, *supra* note 16, at 2.

61 *Id.* at 1–2.

62 *See, e.g.*, GENETICS & PUB. POLICY CTR., REPRODUCTIVE GENETIC TESTING: WHAT AMERICA THINKS (2004) [hereinafter WHAT AMERICA THINKS], *available at* http://www.dnapolicy.org/images/reportpdfs/ReproGenTestAmericaThinks.pdf; Feighanne Hathaway et al., *Consumers' Desire Towards Current and Prospective Reproductive Genetic Testing*, 18 J. GENETIC COUNSELING 137 (2009); Karen K. Milner et al., *Attitudes of Young Adults to Prenatal Screening and Genetic Correction for Human Attributes and Psychiatric Conditions*, 76 AM. J. MED. GENETICS 111 (1998).

63 Hathaway, *supra* note 62, at 138 (discussing the WHAT AMERICA THINKS and Milner studies).

64 WHAT AMERICA THINKS, *supra* note 62, at 11 fig.3.1.

65 *Id.* at 14 tbl.3.1. A majority or near-majority of most demographics surveyed agreed or strongly agreed. The lone demographic to deviate from this trend was fundamentalist/evangelical Christians, of whom thirty-five percent of respondents agreed or strongly agreed. *Id.* This is still quite extraordinary, given the strong views this group typically holds in regards to the sanctity of the reproductive process. *See, e.g.*, Tom Krattenmaker, *A Model of Faith*, USA TODAY, June 5, 2006, at 13A (discussing evangelical megachurch pastor (and Obama inauguration speaker) Rick Warren's opposition to stem cell research and abortion—"divisive issues that have

Nearly half approved of screening for sex selection.[66] A substantial minority (slightly more than a quarter) of respondents favored screening for characteristics like intelligence and strength.[67] These results indicate that a majority of the general population believes parents *should* use these techniques for the vague purpose of "preventing suffering."[68] A later survey, specifically targeting parents who were already engaged in the genetic screening process, provides an interesting contrast.[69] Ultimately, it is evident that majorities support screening for certain characteristics.

The problem is clear. Parents want what is best for their children, and have demonstrated time and again a desire to do what is within their means to ensure the best opportunities for their children. A clear majority believes this mandate should extend to the use of assisted reproductive technologies, including PGS technology. However, the decreasing level of support for screening of certain characteristics—in some cases amounting to substantial majority disapproval—indicates that respondents also approve of limits.

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come to define the Christian right"); Rick Warren, *Why Every U.S. Christian Must Vote in the Election*, RICK WARREN'S MINISTRY TOOLBOX (Oct. 27, 2004), http://www.pastors.com/blogs/ministrytoolbox/archive/2004/10/27/Why-every-U.S.-Christian-must-vote-in-this-election.aspx (describing stem cell research and abortion as two of "five issues that are nonnegotiable").

66 WHAT AMERICA THINKS, *supra* note 62, at 11 fig.3.1.

67 *Id.* It is important to note that intelligence and strength are presently not characteristics for which PGS can screen. *Id.* at 11 (showing that this was merely a hypothetical question).

68 *Id.*

69 Although both groups ordered the characteristics for which they felt screening was acceptable in a similar way (for example, both groups found it more acceptable to screen for disabilities than for enhancements), the group already engaged in genetic screening was uniformly less supportive of the screening process. *Compare* Hathaway, *supra* note 62, *with* WHAT AMERICA THINKS, *supra* note 62. For example, although approximately two-thirds of the mainstream population supported PGS screening for fatal childhood diseases, WHAT AMERICA THINKS, *supra* note 62, at 11 fig.3.1, only about half of those already involved in screening supported such tests, Hathaway, *supra* note 62, at 140 tbl.3. Whereas more than a quarter of the mainstream population supported screening for enhancements (e.g., intelligence, strength), WHAT AMERICA THINKS, *supra* note 62, at 11 fig.3.1, only about one eighth of those already involved in screening supported such tests, Hathaway, *supra* note 62, at 140 tbl.3. It is not clear why parents were less supportive, but one can imagine a variety of possibilities. Perhaps potential parents who have taken sufficient time to learn about genetic screening and go to a clinic to seek services are more likely to have thought critically about the process, as compared to members of the general population who may be learning about the technology for the first time and have not yet considered some of the potential implications. Perhaps current consumers of genetic testing fear that their own treatments will be curtailed through regulation if they answer survey questions in a way that makes them appear interested in criticized screening practices. It is ultimately impossible to know for certain why these consumers are less in favor of screening, but large percentages still support screening. *See generally* Hathaway, *supra* note 62.

Beyond concern over specific characteristics, respondents also had more generalized concerns. Two-thirds of the general population polled in the first survey feared that the technology would be used for the "wrong purposes," or be akin to "playing God."[70] More than eighty percent feared that using PGS would result in discrimination against the disabled.[71] A full seventy percent feared that genetic testing on this scale would lead to children being treated like products.[72] Perhaps because of these fears, eighty-four percent expressed concern that, if unregulated, the technology would get out of control.[73] In light of the demand for PGS and, more importantly, public concern with the ethics and scope of PGS testing, regulation is necessary.

III. BEYOND WHAT PARENTS WANT: WHY REGULATION IS NECESSARY

Beyond what the general population fears, there are additional reasons that weigh in favor of regulation. Although many commentators have attempted to answer why and how regulation is necessary,[74] none do so more thoroughly than Professor Jaime King.[75]

Professor King argues that the trend of medical regulation in this country has generally followed the libertarian principle that people should be able to make their own decisions, free of interference.[76] However, society will assert authority over that person when he makes a decision that negatively affects the interests of others, including potentially interfering with that decision.[77] In evaluating the existing condition of the federal and state regulatory system, Professor King concludes that there is a "reluctan[ce] to interfere in individual medical decisions," and intervention has occurred "only when it has been necessary to protect the patient or society."[78]

The general population has perceived that there is risk in a system that does not regulate PGS technology,[79] and Professor King

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70 WHAT AMERICA THINKS, *supra* note 62, at 29 fig.5.1.

71 *Id.* at 36 fig.6.1.

72 *Id.* at 40 fig.6.2.

73 *Id.* at 51 fig.8.1.

74 *See infra* Parts IV.B.1–2.

75 Jaime King, *Predicting Probability: Regulating the Future of Preimplantation Genetic Screening*, 8 YALE J. HEALTH POL'Y L. & ETHICS 283 (2008).

76 *Id.* at 301–02 (discussing the libertarian views of John Stuart Mill as applied to medical decisions).

77 *Id.*

78 *Id.* at 302.

79 *See supra* note 73 and accompanying text.

agrees.[80] Objectively, there are three categories of risk associated with PGS technology: (1) risks to offspring born with PGS technology that occur as a result of the IVF system, (2) risks to the prospective parents that will occur through their use of the technology, and (3) risks to society that that will occur through the use of PGS technology.[81] Professor King concludes that the ultimate solution is to regulate.[82]

A. Risks to the Offspring

Risks to offspring screened with PGS can be serious. As discussed previously, PGS is by no means an easy procedure.[83] The risk to the potential child through the use of PGS (and IVF) is threefold: First, a biopsy procedure that is performed on the embryo at a particularly early stage could "theoretically involve a risk of impaired development of the embryo and a potential risk to the offspring."[84] Second, to improve the chances of a successful IVF procedure, doctors have historically implanted multiple embryos, which can, and often does, result in multiple births (e.g., twins, triplets, or quadruplets).[85] Multiple births are associated with a variety of risks,[86] including premature birth and low birth weight,[87] cerebral palsy,[88] and stillbirth.[89] Regula-

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80 *See* King, *supra* note 75, at 303.

81 *Id.* at 303–12; *see also* PCBE, *supra* note 10, at 93–98.

82 King, *supra* note 75, at 354.

83 *See supra* Part I.

84 Sirpa Soini et al., *The Interface Between Assisted Reproductive Technologies and Genetics: Technical, Social, Ethical and Legal Issues*, 14 EUR. J. HUM. GENETICS 588, 608 (2006).

85 King, *supra* note 75, at 304.

86 *See* Suzanne C. Tough et al., *Effects of in vitro Fertilization on Low Birth Weight, Preterm Delivery, and Multiple Birth*, 136 J. PEDIATRICS 618, 620–21 (2000); Kate Devlin, *Technique to Screen Embryos 'Increases Risks in Multiple Pregnancies*,' THE TELEGRAPH (London) (Dec. 22, 2009, 7:30 AM), http://www.telegraph.co.uk/journalists/kate-devlin/6860443/Technique-to-screen-embryos-increases-risks-in-multiple-pregnancies.html. Beyond multiple pregnancies, there are also risks inherent to IVF. *See* Gina Kolata, *Picture Emerging on Genetic Risks of IVF*, N.Y. TIMES, Feb. 17, 2009, at D1 (stating that some studies indicate a possible increase in genetic disorders associated with IVF).

87 Madison Park, *Extreme Multiple Births Carry Tremendous Risks*, CNNHEALTH.COM (Jan. 28, 2009, 4:04 PM), http://www.cnn.com/2009/HEALTH/01/28/octuplet.risks/index.html (stating that "[m]ultiples have higher health risks because of their likelihood to be born premature" and are born "much smaller").

88 *Cerebral Palsy: Hope Through Research*, NAT'L INST. NEUROLOGICAL DISORDERS & STROKE, http://www.ninds.nih.gov/disorders/cerebral_palsy/detail_cerebral_palsy.htm (last updated May 6, 2010) ("Twins, triplets, and other multiple births—even those born at term—are linked to an increased risk of cerebral palsy. The death of a baby's twin or triplet further increases the risk.").

89 Rebecca Smith, *Concerns Raised over IVF Stillbirth Risk*, THE TELEGRAPH (London) (Feb. 24, 2010, 7:15 AM), http://www.telegraph.co.uk/health/healthnews/7297960/Concerns-

tions could potentially improve safety here; for example, recently completed studies indicate that the risk created by biopsying the embryo is reduced if only a single embryo is implanted.[90] Despite the lowered success rate of a single implantation and the potential time and cost of needing to endure multiple rounds, regulation could ensure greater safety and the knowledge that the burden to the parents is worth the risk to the potential child.[91]

A third threat to the potential child is psychological in nature.[92] No technology is perfect; a full one-fifth of clinics reported seeing inconsistencies between the results they obtained through PGS technology, and later, separate genetic testing.[93] Scientists have acknowledged that "the possibility of misdiagnosis obviously has significant medical, psychological, and economic implications."[94] PGS procedures, which exact a physical and financial toll on the parents, could result in a child different than the one the potential parents expected. The psychological consequences of carrying this burden, should the child learn of it, could be severe.

Even if the procedure goes as planned, some commentators believe that PGS would lead to the commodification of children.[95] Participants in focus groups and town hall meetings feared that PGS would lead to parents "put[ting] even more pressure on children to live up to unrealistic expectations"; seventy percent feared that children would be treated like products.[96] A 2004 report by the President's Council on Bio-Ethics came to the same conclusion—that the child would, in some cases, be treated "as a means to the parents' ends," particularly "should the reasons for embryo screening move from 'medical' purposes to nonmedical or enhancement purposes."[97]

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raised-over-IVF-stillbirth-risk.html (quoting Professor Philip Steer as saying, "Multiple pregnancy remains the single biggest risk of fertility treatment. Twins face an increased risk of preterm birth, low birthweight, and serious health problems. When possible, couples undergoing IVF should be encouraged to opt for single embryo transfer in order to reduce the risk of multiple pregnancy.").

90 Todd Neale, *Preimplant Embryo Biopsy Appears Safe for Singleton Babies*, MEDPAGE TODAY (Dec. 22, 2009), http://www.medpagetoday.com/Endocrinology/Infertility/17651.

91 King, *supra* note 75, at 304, 307.

92 *Id.* at 307–08.

93 *Id.*

94 PRACTICES AND PERSPECTIVES, *supra* note 16, at 4.

95 *See* MICHAEL J. SANDEL, THE CASE AGAINST PERFECTION 82–83 (2007); King, *supra* note 75, at 307 (citing JÜRGEN HABERMAS, THE FUTURE OF HUMAN NATURE 75 (Polity Press 2003) (2001)).

96 WHAT AMERICA THINKS, *supra* note 62, at 39.

97 PCBE, *supra* note 10, at 95; *see also* Norton, *supra* note 57, at 1606 (likening parents' selection of a child through PGS to the selection of a thoroughbred horse).

B. Risks to the Parents

Just as there are risks to the potential child, there are also physical and psychological risks to the potential parents. As discussed previously, the procedure women must endure in order to produce an egg as part of IVF is painful.[98] The procedure is also dangerous; Professor King describes several complications that can occur as a result of the procedure, including ovarian hyperstimulation—which can lead to "nausea, vomiting, shortness of breath—distended abdomen, and hospitalization."[99] In some particularly severe cases, women will develop blood clots, kidney failure, and serious bleeding.[100] As discussed previously, multiple embryo implantations also pose a greater risk to the mother than a single implantation.[101] Again, due to the cost and difficulty of the procedure, mothers may feel compelled, absent any regulation, to engage in multiple implantations to improve the chances of success.[102] Professor King concludes that mothers who plan to engage in IVF are particularly at risk, as they "are often willing to accept almost any personal risk to have a healthy child."[103] Absent any regulations, mothers will engage in unnecessary risk, and it is not clear that all (or any) clinics will stop them.[104]

Psychological conditions occurring as a result of PGS may also impact parents. As discussed previously, there is the potential for error in PGS technology, and the embryo implanted may not develop into the child expected by the parents.[105] The risk of error is aggravated by the lack of regulation of the testing procedures and of the personnel employed by these clinics.[106] There are no requirements for any "accreditation or approval process[es]," and this is made all the more alarming in the face of evidence that participants believe that these tests are, in fact, government regulated.[107] Professor King concludes that government regulation could mitigate many of these risks

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98 *See supra* Part I.

99 King, *supra* note 75, at 308.

100 *Ovarian Hyperstimulation Syndrome (OHSS): Complications*, MAYO CLINIC, http://www.mayoclinic.com/health/ovarian-hyperstimulation-syndrome-ohss/DS01097/DSECTION=complications (last visited Apr. 1, 2011).

101 King, *supra* note 75, at 308.

102 *Id.* at 304.

103 *Id.* at 309.

104 *See infra* note 220 and accompanying text.

105 *See supra* notes 93–94 and accompanying text.

106 King, *supra* note 75, at 309–10.

107 *Id.* (citing *Genetic Testing Quality Initiative*, GENETICS & PUB. POL'Y CENTER, http://www.dnapolicy.org/policy.gt.php (last updated Sept. 2006) (discussing study results indicating that the public believes there is government regulation in this area)).

by improving the safety of the procedure, initiating research on long-term risks, and providing information on risks to the users of the technology.[108]

C. Risks to Society

Finally, unregulated PGS technology presents a risk to society. The presence of PGS technology will, sooner rather than later, force Americans to grapple with some very difficult ethical questions. The speed at which this process will occur is only likely to increase as a result of increased ESC research.[109]

Professor King first highlights the problem of access to the technology, owing to financial, cultural, and educational barriers.[110] Professor King indicates that different demographic groups responded to the availability of the technology in widely varying ways.[111] These different responses have the potential to "increase health disparities" by ensuring that children who are screened for serious conditions with this technology, and future generations who engage in the same screening, will accrue health advantages over those families who do not participate.[112] Over time, "the burden of disease [will] be placed on those least able to afford care."[113]

The specter of a return to eugenics is also a cause for concern and is discussed regularly in the academic debate surrounding PGS technology.[114] Indeed, the history of eugenics in at least one country may have shaped legislative policy there.[115] In the United States, past practices regarding selective sterilization are demonstrated by an infamous quote from an otherwise exceptionally talented jurist: "Three generations of imbeciles is enough."[116] With these words, the United States Supreme Court—by an 8–1 vote—affirmed the right of the Commonwealth of Virginia to sterilize a woman in *Buck v. Bell*.[117] The Court reasoned that the woman was "the probable potential parent of socially inadequate offspring" and that her sterilization would promote

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108 *Id.* at 312.

109 *See supra* note 11.

110 King, *supra* note 75, at 313–14.

111 *Id.*

112 *Id.* at 314–15.

113 *Id.* at 315.

114 *Id.* at 316; *see also* Suter, *supra* note 45, at 898 (distinguishing between modern practices ("neoeugenics") and classic eugenics, the latter of which now calls to mind "injustice, abrogation of basic liberties, and poor science" due to historical abuses).

115 *See infra* Part IV.A.1.

116 Buck v. Bell, 274 U.S. 200, 207 (1927) (Holmes, J.).

117 Buck v. Bell, 274 U.S. 200, 207–208 (1927).

the welfare of society.[118] The legacy of *Buck* is the 60,000 Americans who were sterilized against their will, out of fear of the genetic material they would contribute to society.[119] The power of PGS technology is that it gives the decisionmaking power granted to states in *Buck v. Bell* to individual members of society.[120] Absent any regulation, potential parents would have to decide from a selection of offspring which they deem "socially inadequate." The aggregate effects of such decisions could have a seriously detrimental impact on society as it currently exists.[121]

Consider, as an example, the aggregate effect of individual decisionmaking on the gay community. Despite strides that the gay community has made over the last few decades, many gays, particularly youths, still struggle to persevere in a heteronormative society.[122] Gay and bisexual men are three times as likely as their heterosexual peers to experience major depression.[123] Gay men are more than five times as likely as heterosexual men to attempt suicide.[124] Lesbian, gay, and bisexual youths are twice as likely as heterosexual youths to abuse substances.[125] The hypothesized reason for these behaviors is that gays are a "marginalized group . . . oppressed [and without] equal opportunities and equal rights."[126] These studies provide evidence that gay youths still struggle in ways that their heterosexual counterparts do not. As discussed previously, there is majority support for the idea that parents should use reproductive technology to prevent their children from suffering.[127] If gay youths suffer more than heterosexual youths, and if parents would use PGS technology to prevent suffering, it seems evident that, given the choice, some parents would choose not to have a gay child. In 1992, as scientists began to pose questions

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118 *Id.* at 207.

119 *See* King, *supra* note 75, at 316 (discussing Judith F. Daar, *ART and the Search for Perfectionism: On Selecting Gender, Genes and Gametes*, 9 GENDER RACE & JUST. 241, 260–62 (2005)).

120 *See id.*

121 *See id.* (citing Malinowski, *supra* note 53, at 204).

122 *See* KOSCIW, *supra* note 44, at xvi.

123 Susan D. Cochran et al., *Prevalence of Mental Disorders, Psychological Distress, and Mental Health Services Use Among Lesbian, Gay, and Bisexual Adults in the United States*, 71 J. CONSULTING & CLINICAL PSYCHOL. 53, 55 (2003).

124 Susan D. Cochran & Vickie M. Mays, *Lifetime Prevalence of Suicide Symptoms and Affective Disorders Among Men Reporting Same-Sex Sexual Partners: Results from NHANES III*, 90 AM. J. PUB. HEALTH 573, 576 tbl.2 (2000).

125 *Gay Youth Report Higher Rates of Drug and Alcohol Use*, MED. NEWS TODAY (Mar. 26, 2008, 2:00 PM), http://www.medicalnewstoday.com/articles/101682.php.

126 *Id.*

127 *See supra* note 65 and accompanying text.

about the possibility of a "gay gene," Laurie Coburn, program director of the Federation of Parents and Friends of Lesbians and Gays, confirmed as much: "No parent would choose to have a child born with any factor that would make life difficult for him or her."[128] In considering the aggregate effect of parents choosing against having gay children, it is easy to reach "the nightmare scenario" where "[t]he gay population simply fades away."[129]

It is clear that Americans both embrace and fear PGS technology. Objectively, PGS is an innovative medical technology, but it is also one that creates many risks. Unregulated, these risks could have a serious impact on the offspring conceived using PGS technology, on the potential parents of those children, and on society at large. As the pace of PGS innovation increases, the need for regulation becomes increasingly urgent.

IV. Potential Frameworks for Regulation: Foreign Implementations and Domestic Proposals

The practical and ethical considerations explored thus far—as well as the desires of the electorate[130]—present a compelling case that the United States must regulate PGS technology. However, determining exactly how PGS technology should be regulated is a difficult question to answer. According to survey results, the public feels very strongly that PGS technology should be regulated, but the public is also concerned about the government intruding upon very personal

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128 David Gelman et al., *Homosexuality: Born or Bred?*, Newsweek, Feb. 24, 1992, at 46, 48. The Federation of Parents and Friends of Lesbians and Gays is today called Parents, Families and Friends of Lesbians and Gays, Inc., and is better known by its acronym, PFLAG. *About PFLAG*, PFLAG, http://community.pflag.org/Page.aspx?pid=267 (last visited Apr. 2, 2011). The idea for the organization began in 1972 when a mother marched along her son in New York's Pride Day Parade. *Id.* Ms. Coburn's statement inspired this Note, because it so clearly and compellingly presents the anguishing choice PGS may soon offer. For the last forty years, PFLAG parents have fought tirelessly for their children's right to be who they are: gay. These parents love their children and want to change the world's viewpoint on their children's characteristic. But soon, they might be able to change their child, instead of the world. Which would a parent choose?

129 Gelman, *supra* note 128, at 46. It is important to note, however, that some would select *for* a given characteristic, even if it is viewed by the majority as unpopular. *See, e.g.*, John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 Am. J.L. & Med. 439, 467 (2003) (proposing that gays might use PGS to select for a gay child should that option become available); *see also supra* notes 43–44. But consider also proposals that would allow the state to intervene to prevent parents from selecting for an unpopular characteristic. *See* Schiavone, *supra* note 44, at 309.

130 What America Thinks, *supra* note 62, at 51 fig.8.1 (showing that eighty-four percent of respondents felt that PGS should be regulated).

decisions. For example, in a 2004 survey of the general public, only seventeen percent of those surveyed believed that PGS should not be regulated, but the remaining respondents who favored control were split on exactly how to do so.[131] Twenty percent of respondents felt that PGS technology should be banned outright; twenty-four percent believed that only the safety of the technology, but not ethical matters, should be regulated; and thirty-seven percent believed that both the safety and the ethics of technology should be regulated.[132] Seventy percent of those surveyed expressed concern over government regulators "invading private reproductive decisions."[133]

One probable reason for the variability in opinions on the subject is that no formal regulatory system exists in the United States for PGS and other similar technologies.[134] It is therefore helpful to look abroad for ideas about how to regulate in the field of PGS. Indeed, most other peer countries of the United States have extensive regulations relating to PGS technology and *in vitro* fertilization, the technology underlying PGS.[135] The same is true for other procedures relating to reproduction.[136] The United States is, with its extreme lack of regulation, an outlier in this area—primarily due to the premium placed on reproductive rights in the last forty years.

In addition to examining foreign regulations, a consideration of current proposals in this area is also instructive. PGS technology was first advanced in 1990[137] and is an offshoot of IVF technology, which originated in 1978.[138] Thus, the academic community (including both medical and legal ethicists) has considered the ethical issues surrounding PGS for at least two decades. This Part first examines how other countries have opted to regulate (or not regulate) this technology and then turns to a brief evaluation of the many proposals for the United States.

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131 *Id.* at 52 fig.8.2.

132 *Id.*

133 *Id.* at 51 fig.8.1.

134 *See* Aaron R. Fahrenkrog, Note, *A Comparison of International Regulation of Preimplantation Genetic Diagnosis and a Regulatory Suggestion for the United States*, 15 TRANSNAT'L L. & CONTEMP. PROBS. 757, 758 (2006).

135 *See id.* at 762–68.

136 For example, European nations have more extensive regulations related to abortion. *See, e.g.*, *Europe's Abortion Rules*, BBC NEWS (Feb. 12, 2007, 1:18 AM), http://news.bbc.co.uk/2/hi/europe/6235557.stm (featuring a clickable map displaying Europe's abortion laws).

137 Susannah Baruch, *Preimplantation Genetic Diagnosis and Parental Preferences: Beyond Deadly Disease*, 8 HOUS. J. HEALTH L. & POL'Y 245, 246 (2008).

138 CHALLENGES, *supra* note 20, at 3.

A. Foreign Law: How Other Countries Regulate PGS

There are three main tactics used by countries that have regulated PGS technology.[139] First, some countries have completely banned PGS technology.[140] Second, some countries leave the decisionmaking to professional organizations or other nongovernment entities.[141] Finally, many countries have provided a regulatory framework that authorizes or licenses PGS technology, tests, or methods.[142]

1. Complete Ban

Germany is an example of a country that has completely banned PGS technology.[143] The foundation of this ban rests upon provisions in the German Constitution and the statutory Embryo Protection Law that confer upon all embryos the right to life.[144] This differs from American constitutional law jurisprudence, in which the Supreme Court has held that an embryo is not a human being under the law.[145] Some scholars have theorized that Germany has banned the technology as a result of atrocities committed during the Nazi era, when eugenics abuses were rampant.[146] Switzerland,[147] Austria,[148] Italy,[149] Ireland,[150] Norway,[151] and Poland[152] similarly maintain total bans on the procedure. Germany's ban is enforced by the criminal law, and

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139 *See* Fahrenkrog, *supra* note 134, at 762. *See also* Lori P. Knowles, *The Governance of Reprogenetic Technology: International Models*, *in* REPROGENETICS: LAW, POLICY, AND ETHICAL ISSUES 127, 128 (Lori P. Knowles & Gregory E. Kaebnick eds., 2007); *Preimplantation Genetic Diagnosis*, BIOPOLICYWIKI, http://www.biopolicywiki.org/index.php?title=Preimplantation_genetic_diagnosis (last updated June 24, 2009, 6:30 PM) (user-generated website attempting to list all PGS-related regulations worldwide).

140 Fahrenkrog, *supra* note 134, at 763.

141 *Id.* at 767–68.

142 *Id.* at 765–67; *see also* Knowles, *supra* note 139, at 132.

143 *Id.* at 763–65.

144 *Id.* at 763.

145 Roe v. Wade, 410 U.S. 113, 158 (1973) (holding that "the word 'person,' as used in the Fourteenth Amendment, does not include the unborn").

146 Fahrenkrog, *supra* note 134, at 764–65; *see also* King, *supra* note 75, at 318 (proposing that the ban is "ostensibly to avoid any implications of eugenic practices").

147 King, *supra* note 75, at 318.

148 *Id.*

149 *Id.*

150 Silvia Camporesi, *Choosing Deafness with Preimplantation Genetic Diagnosis: An Ethical Way to Carry on a Cultural Bloodline?*, 19 CAMBRIDGE Q. HEALTHCARE ETHICS 86, 87 (2010).

151 Knowles, *supra* note 139, at 128.

152 *Id.*

punishments for the improper use of reproductive technology include fines and prison terms.[153]

A total ban on the procedure in the United States is not the best solution to the problem. First, a total ban on the procedure is not likely to be politically popular. As demonstrated by the studies discussed previously, Americans are generally comfortable with the technology when it is used to address serious medical conditions, particularly life-threatening conditions; Americans, as individuals, would not favor a ban.[154] Moreover, private industry would clearly not support a total ban; there are hundreds of clinics across the country performing thousands of PGS cycles annually that would be forced to close. At a time when the economy is struggling, a total ban would also have the effect of eliminating jobs. It is simply too late for a ban; to do so now would have serious consequences. Second, as a practical matter, a total ban would not stop Americans with the resources to engage in medical tourism.[155] Those who can afford to travel to a country without a total ban will do so; this is currently the case in the United States, which receives couples from all over the world who seek to take advantage of the lack of regulation in our "free-wheeling, Wild West system."[156] This will only serve to widen the potential economic disparities Professor Jaime King discusses.[157] Some regulation is needed in the United States, but a total ban is not appropriate.

2. Professional Organizations

In some countries, a ban effectively exists, but exceptions can be made by private professional licensing or accreditation organizations. Japan provides one of the few examples of this approach.[158] In Japan, all requests for the use of PGS technology must be vetted by an organization called the Japan Society of Obstetrics and Gynecology ("JSOG").[159] JSOG's regulations, which are similar to the regulations in the United Kingdom, allow the use of PGS technology only for "se-

153 Embryonenschutzgeset [ESchG] [Embryo Protection Act], Dec. 13, 1990, BUNDESGESETZBLATT, Teil I [BGBL. I] at 2746 (Ger.), *translated in* 6 HUM. REPROD. 465, 605 (1991).

154 *See supra* notes 64–68 and accompanying text.

155 Garrison, *supra* note 14, at 1629 (stating that "State A's citizens will simply flock to State B and feather the nests of its reproductive technology centers").

156 *Id.* at 1629 (pointing out that British women sometimes travel to the United States to avoid U.K. regulations); Adam Wolfson, *Getting Serious About IVF*, NEW ATLANTIS, Spring 2004, at 78, 81, *available at* http://www.thenewatlantis.com/publications/getting-serious-about-ivf.

157 King, *supra* note 75, at 314–15.

158 Fahrenkrog, *supra* note 134, at 767–68.

159 *Id.*

rious hereditary disorders."[160] However, despite the apparent provisioning of guidelines for PGS technology, it does not appear that JSOG has actually authorized any screening under those guidelines.[161] A similar process exists in Israel, where, for example, the government has banned the use of PGS for nonmedical sex selection, but gives a professional committee discretion to waive this ban in "exceptional, unusual and rare cases" (defined at least in part by an example of parents with a "deep emotional need" for a child of a given sex after bearing four children of the opposite sex).[162]

Leaving regulations in the hands of professional societies would not work in the United States because, unlike Japan and Israel, membership in American medical professional societies is voluntary.[163] Having professional societies provide educational information to members and proposed guidelines would, of course, be better than nothing at all, but it remains unclear as to how effective this process would be. As for actual regulations, they would need to be imposed by the government to reach all clinics, whether or not they belonged to professional organizations.

3. Regulatory Framework

Finally, in contrast to total bans and regulation by professional organizations, some countries, such as the United Kingdom, have implemented comprehensive regulatory frameworks. In the early 1990s, the United Kingdom created a regulatory agency called the Human Fertilisation and Embryology Authority ("HFEA").[164] The agency has two areas of responsibility concerning PGS technology. First, HFEA is responsible for the licensing of all assisted reproductive technologic clinics within the country.[165] Second, HFEA reviews and considers requests made by clinics for any new characteristic for which a clinic would like to test.[166] This has permitted, for example, the government of the United Kingdom to walk the delicate line between the categories of characteristics discussed previously.[167] As of this writing,

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160 *Id.* at 767 (citing Naoki Takeshita & Harumi Kubo, *Regulating Preimplantation Genetic Diagnosis—How to Control PGD*, 21 J. ASSISTED REPROD. & GENETICS 19, 20 (2004)).

161 *Id.* at 768.

162 Ruth Zafran, *Non-Medical Sex Selection by Preimplantation Genetic Diagnosis: Reflections on Israeli Law and Practice*, 9 N.C. J.L. & TECH. 187, 189 (2008).

163 *See, e.g.*, *infra* text accompanying note 216.

164 Fahrenkrog, *supra* note 134, at 766.

165 *Id.*

166 *Id.*

167 *See supra* notes 37–51 and accompanying text (categorizing characteristics into fatal diseases, lifelong conditions with possibly disabling effects, and nonmedical conditions).

HFEA has only permitted screening for "deleterious, heritable genetic conditions."[168] However, the focus of the agency is expanding. When HFEA was created and initially provided guidelines for PGS technology, the only characteristics for which screening was available were those that were certain to manifest early on and be fatal.[169] In 2004, however, HFEA began permitting screening for cancers that would appear later in life.[170] In late 2005, HFEA requested public consultations on further widening the scope of available tests.[171] By 2006, HFEA concluded that it would widen the scope of available tests, permitting tests for hereditary conditions on a case-by-case basis.[172]

Canada has acted similarly in the arena, enacting legislation that created the Assisted Human Reproduction Canada federal regulatory agency,[173] which shares responsibility for assisted human reproduction with the Health Canada agency.[174] It appears, at least initially, that Canada's regulatory regime will be stricter than its counterpart in the United Kingdom.[175] Other countries also have limits on the types of tests for which PGS may be used: Spain, Belgium, and France limit PGS technology to screening for disorders.[176]

A regulatory approach similar to that enacted by the United Kingdom and Canada is the best of the foreign models from which the United States should derive its regulatory stance. In addition to receiving widespread support from commentators in the United States,[177] the United States can learn from the lessons that other coun-

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168 Fahrenkrog, *supra* note 134, at 766 (citing HUMAN FERTILISATION AND EMBRYOLOGY AUTH., CODE OF PRACTICE § 14.1 (6th ed. 2003), *available at* http://www.hfea.gov.uk/docs/Code_of_Practice_Sixth_Edition.pdf).

169 Jesse Reynolds, *UK's HFEA Lowers the Bar, Again*, BIOPOLITICAL TIMES (Apr. 30, 2007), http://www.biopoliticaltimes.org/article.php?id=3161.

170 *HFEA Approves Embryo Screening for Cancer*, PHG FOUND. (Nov. 2, 2004), http://www.phgfoundation.org/news/1444.

171 Philippa Brice, *HFEA Announces Policy Position on PGD for Late-Onset Hereditary Conditions that Are Not Completely Penetrant*, PHG FOUND. (May 9, 2006), http://www.phgfoundation.org/news/2493.

172 Jess Buxton, *HFEA Approves Embryo Tests for Hereditary Cancer*, BIONEWS (May 11, 2006), http://www.bionews.org.uk/page_12715.asp.

173 King, *supra* note 75, at 318 n.175.

174 *Assisted Human Reproduction*, HEALTH CAN., http://www.hc-sc.gc.ca/hl-vs/reprod/index-eng.php (last updated Feb. 1, 2008). Health Canada develops policy and regulations, while Assisted Human Reproduction Canada administers and enforces the regulations. *Id.*

175 Erin L. Nelson, *Comparative Perspectives: Regulating Preimplantation Genetic Diagnosis in Canada and the United Kingdom*, 85 FERTILITY & STERILITY 1646, 1649 (2006).

176 Camporesi, *supra* note 150, at 87.

177 *See infra* Part IV.B.

tries have faced over the past two decades.[178] A national model would provide uniformity in regards to regulations, would have the benefit of avoiding the evils of economic disparity and medical tourism that would occur either through a total ban or a state-by-state regulatory infrastructure, and would also address the lack of meaningful enforcement authority that would occur were regulations left in the hands of voluntary professional organizations.

After evaluating the state of foreign regulations of PGS technology, it is clear that the United States is an outlier.[179] Many countries have opted to regulate, and those that have done so have each done so to the exclusion of the third category of characteristics discussed previously (nonmedical traits).[180] The United States, by contrast, has done nothing, despite the fact that popular opinion generally disapproves of screening technologies for nonmedical traits.[181] Furthermore, as new tests are created for new characteristics through increased ESC research,[182] regulation is necessary to avoid PGS technology from spinning out of control. The United States must act now to resolve this lack of regulation. As discussed previously, the United States has already experienced a horrific past: over 60,000 people were sterilized against their will.[183] President Obama's executive order, which loosens the controls on ESC research,[184] and the current lack of any regulation as to PGS technology could lead to a similar future—this time, with eugenics occurring through the action of the people, rather than the government.

B. Existing Proposals:

As discussed previously, PGS technology has existed now for over two decades,[185] and many scholars have proposed solutions that address the lack of regulation in the United States. This Section is not an exhaustive inquiry of all proposals ever made; such a compilation is beyond the scope of this Note. Instead, this Section presents a brief

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178 HFEA was established in the 1990s. *See supra* text accompanying note 164; *see also* Human Fertilisation and Embryology Act, 1990, c. 37 (U.K.), *available at* http://www.opsi.gov.uk/Acts/acts1990/Ukpga_19900037_en_1.htm.

179 FUKUYAMA & FURGER, *supra* note 10, at 11 (concluding that the United States is an outlier).

180 Fahrenkrog, *supra* note 134, at 767; *see also* Camporesi, *supra* note 150, at 87; King, *supra* note 75, at 318; *Preimplantation Genetic Diagnosis*, *supra* note 139.

181 *See supra* Part II.

182 *See supra* notes 11–19 and accompanying text.

183 *See supra* text accompanying note 119.

184 Exec. Order No. 13,505, 3 C.F.R. 229 (2010).

185 *See supra* note 139 and accompanying text.

inquiry into the themes that have arisen, and from those themes, synthesizes a regulatory proposal that is appropriate in light of the recent executive order that will enhance opportunities for ESC research using federal funds.[186] It is important to recognize that the scholars who authored these proposals did so prior to Executive Order 13,505, and thus did not take into account increased federal funding or the consequences of that order on the development of PGS technology.

The proposals in regards to PGS (or similar) technology generally fall into the following categories: (1) mirroring, to some extent, the United Kingdom in creating an independent regulatory agency or advisory board at the national level; (2) adapting existing federal agencies to the task of regulating; (3) passing federal legislation that bans certain testing procedures; (4) delegating federal authority to professional societies which would, in turn, regulate; or (5) delegating federal authority to states or other federally funded entities, contingent on restrictions.

1. Mirroring the United Kingdom's System of Comprehensive Regulation

The majority of commentators who have addressed this issue appear to favor the creation of a national regulatory system with varying levels of similarity to that which was enacted in the United Kingdom. Indeed, with over twenty years of experience,[187] the United Kingdom is a leader in the area of PGS regulation. Professors Francis Fukuyama, Franco Furger, and Jaime King have proposed detailed regulatory systems that have their genesis in Britain's HFEA organization.[188] Professors Fukuyama and Furger argue compellingly that a national agency is needed because there is "little to be learned from the states," and what is to be learned is that the few states that have regulated have done so to the extremes.[189] Professors Fukuyama and Furger's proposal, in essence, is a three-level proposition that would (1) involve a congressional delegation of authority to create an independent agency modeled after HFEA, (2) create a permanent advi-

186 Exec. Order No. 13,505, 3 C.F.R. 229.

187 *Twenty Years Since the Human Fertilisation and Embryology Act Receives Royal Assent*, HUM. FERTILISATION & EMBRYOLOGY AUTHORITY (Nov. 1, 2010), http://www.hfea.gov.uk/6166.html.

188 *See* FUKUYAMA & FURGER, *supra* note 10, at 14; King, *supra* note 75 at 344.

189 FUKUYAMA & FURGER, *supra* note 10, at 131–33 (contrasting Louisiana's total ban on nontherapeutic embryonic research with California's "radical departure from pre-existing legislation" in its Proposition 71, a direct-democracy initiative which repealed a legislature-enacted system that he otherwise finds "preliminary but promising"); *see also supra* note 10.

sory board that would guide policy in this area, and (3) propose clear and open processes for public consultation in a rulemaking process that would be able to adapt quickly to new and changing technology.[190]

Professor King's proposal is similar in its stance, calling for the creation of a regulatory agency that she terms the Assisted Reproductive Technology Authority ("ARTA").[191] This agency would initially be tasked with implementing popular proposals, such as implementing regulations to improve safety, collecting data, and providing information.[192] Thereafter, the agency would address thornier issues, such as which screening tests should be permitted.[193] ARTA would address these issues by balancing the interests of all stakeholders, including the individual participants in PGS, the government, the medical community, and society at large.[194]

Many other commentators agree that this is the appropriate path to follow.[195] Other variations on the proposal include temporarily expanding the role of the Food and Drug Administration ("FDA") in the interim while the new agency is established (or temporarily inviting state participation)[196] and narrowing the focus of the new agency to avoid some of the intractable problems that have arisen through the "entanglement of [assisted reproduction] and human embryonic stem cell research."[197]

As discussed during the review of foreign regulations, a regulatory framework is the best starting point for action in the United

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190 FUKUYAMA & FURGER, *supra* note 10, at 16.

191 King, *supra* note 75, at 289.

192 *See id.*

193 *See id.* (recommending that ARTA balance the desire to use certain procedures against the procedures' potential harm to the public).

194 *See id.*

195 *See, e.g.*, Erik Parens & Lori P. Knowles, *Reprogenetics and Public Policy: Reflections and Recommendations*, HASTINGS CENTER REP., July–Aug. 2003, at S1, S18–S19 (concluding, based on HFEA's success, that a new agency should be implemented with a focus on addressing the abortion debate that is problematic here but not in the United Kingdom); Jason Christopher Roberts, *Customizing Conception: A Survey of Preimplantation Genetic Diagnosis and the Resulting Social, Ethical, and Legal Dilemmas*, 2002 DUKE L. & TECH. REV. 0012, ¶¶ 49–50, http://www.law.duke.edu/journals/dltr/articles/2002dltr0012.html (calling for an agency that would place the burden on clinics to justify new tests, similar to HFEA); Fahrenkrog, *supra* note 134, at 779 (calling for a licensing system similar to HFEA).

196 Lindsey A. Vacco, Comment, *Preimplantation Genetic Diagnosis: From Preventing Genetic Disease to Customizing Children. Can the Technology Be Regulated Based on the Parents' Intent?*, 49 ST. LOUIS U. L.J. 1181, 1126–27 (2005).

197 Michael J. Malinowski, *A Law-Policy Proposal to Know Where Babies Come from During the Reproduction Revolution,* 9 J. GENDER RACE & JUST. 549, 566 (2006).

States. However, prior suggestions are deficient for several reasons. First, as a practical matter, many proposals simply cannot be enacted quickly, preventing an immediate response to increased federal and private investment and scientific innovation. Second, some proposals do not begin with direct federal legislation that would both limit the types of testing currently available and provide for an exceptions-based approach for critical needs. Third, some proposals for a national regulatory agency ignore the role of the states or otherwise lightly define it, not taking into account the states' role in medical licensing and ethics. Thus, to the extent that the prior proposals lack these elements, they are inadequate.

2. Adapting Existing Regulatory Agencies

Some commentators have proposed that existing agencies could self adapt or be adapted through increased delegations of congressional authority to regulate PGS technology. Professor Michael Malinowski discusses the role of the FDA, which currently controls the market entry of drugs and medical devices and regulates laboratory conditions subject to the Clinical Laboratory Improvements Act of 1988,[198] and the Centers for Disease Control ("CDC"), which developed a voluntary model state certification program for assisted reproduction technology clinics.[199] Professor Malinowski proposes that the FDA's current oversight of human tissue products be expanded to cover techniques like PGS, or that the CDC's voluntary program be made mandatory, or both.[200] Jason Roberts makes a similar proposal but believes the Recombinant DNA Advisory Committee, located within the National Institutes of Health, should be the regulating agency.[201] The committee, which currently sets guidelines for federally funded projects that involve recombinant DNA techniques, would have expanded jurisdiction to cover the accreditation of clinics performing PGS testing.[202]

Other commentators suggest that existing agencies may be able to enforce meaningful controls on PGS technology without a congressional expansion of authority. Professor Jaime King highlights three

198 Clinical Laboratory Improvements Act of 1988, 42 U.S.C. § 263a (2006).

199 Malinowski, *supra* note 57, at 182–84 (summarizing current state of FDA and CDC regulation). Professor Malinowski notes that no state has adopted the CDC's model program. *Id.*

200 *Id.* at 218–22.

201 Roberts, *supra* note 195, at ¶ 49.

202 *Id.*

agencies.[203] First, the CDC is tasked with data collection related to the subject of pregnancies in assisted reproductive technology clinics;[204] publication of this data (including clinics which refuse to respond) could perhaps have a meaningful impact on consumer activity. For example, if consumers had easy access to the data, they could avoid clinics with shoddy or nonexistent records. The Centers for Medicaid and Medicare Services, though unable to regulate PGS procedures, can regulate the diagnostic tests performed by clinics to include the requirement that they meet certain proficiency standards; it has not yet done so, which has resulted in criticism.[205] Finally, the FDA has the authority to regulate the efficacy of specific genetic tests, though it has not done so.[206] Professor Lars Noah goes further, suggesting that the FDA could either assert new (but dubious) authority to regulate techniques using human reproductive tissue, or existing authority to restrict access to the drugs necessary in IVF procedures (which, Noah acknowledges, would likely subject the FDA to constitutional litigation).[207]

The major problem with these proposals is that it would be extremely complicated, both legally and practically, to implement these major regulatory changes by repurposing existing agencies. Creating a new agency is far simpler. If agencies begin to regulate in a new area without specific congressional approval, it is likely that litigation will needlessly delay further the implementation of PGS regulation.[208] One cure to that problem is for Congress to explicitly expand the scope of a regulatory agency, but it is clear from the above discussion that no current agency presents an immediately obvious target for such expansion; nor is there evidence that any of the agencies would be well suited to the change. A new agency specifically focused on the

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203 King, *supra* note 75, at 333 (stating that "the CDC, the Centers for Medicare and Medicaid Services (CMS), and the FDA" already "possess authority to regulate a portion of PGS practice"); *see also* Nicole C. Schuppner, *Preimplantation Genetic Diagnosis: A Call for Public Sector Implementation of Private Advocacy Regulation*, 14 MICH. ST. U. J. MED. & L. 443, 453 (2010) (calling for the FDA and CDC, in particular, to assert their existing authority more aggressively).

204 *Id.*

205 *Id.* at 334–35.

206 *Id.* at 335–36.

207 Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 651–65 (2003).

208 This is particularly true given that clinics already in existence would be prevented under this proposal from performing nonmedical PGS testing.

use of reproduction technology would be better suited, particularly as new technology becomes available.[209]

3. Passing Federal Legislation

At least one commentator has bypassed the need for new or existing agency efforts in favor of direct legislation.[210] Vicki Norton, in one of the first articles to discuss regulation for PGS technology, called for an explicit ban at federal and state levels on any use of the technology for nontherapeutic purposes (defined, in the framework presented in this Note, as the third category of characteristics, where no life-threatening condition or disability is implicated).[211] It is not entirely clear why others have not advocated for a similar position, but it may be for familiar reasons, articulated in the field of administrative law: Congress lacks the expertise and the resources to adequately and timely address the intricacies of medical science and the frequently changing nature of technology.[212]

4. Delegating Authority to Professional Societies

At least one commentator has considered the possibility of (temporarily) delegating federal authority to a professional organization that would regulate PGS technology.[213] In proposing that existing agencies eventually regulate PGS technology,[214] Professor Michael Malinowski suggests an interim measure in which the government would delegate certification and inspection responsibilities to professional medical societies, such as the Society for Assisted Reproductive Technology ("SART").[215] Critically—and Professor Malinowski acknowledges this—his proposal would "require significantly changing the essence of [SART] from a voluntary professional society that strongly encourages data reporting by members to an entity that enforces technical government requirements or standards and imposes

209 *See, e.g.*, *supra* note 19 (discussing human germline modification).

210 Norton, *supra* note 57, at 1648.

211 *Id.*

212 Common justifications supporting regulation by administrative agencies (as opposed to congressional legislation) typically include the speed, efficiency, and focus possible in a specialized agency as opposed to Congress, which is perhaps not as well structured to act quickly or in regard to new, complex technologies. *See generally* PETER L. STRAUSS ET AL., GELLHORN AND BYSE'S ADMINISTRATIVE LAW (10th ed. 2003); King, *supra* note 75, at 332 (concluding that "[r]eaching a legislative majority" in Congress would "likely prove extremely time-consuming, if not impossible").

213 Malinowski, *supra* note 57, at 221.

214 *Id.* at 218–22.

215 *Id.* at 221.

sanctions for noncompliance."[216] In this way, SART would become much like the professional societies discussed previously in Japan and Israel.[217] It is unclear how the professional society would make this transition from voluntary data requests to mandatory condition enforcement. Even more to the point, it is unclear how it would change from an organization offering voluntary membership to one where membership is compulsory.

Moreover, self-regulation has its own potential flaws (however unwilling lawyers, who are also part of a self-regulated practice, might be to admit it). As an example, Professors Fukuyama and Furger discuss the period prior to the Enron collapse where industry groups believed that self-regulation was providing sufficient protections—when in reality there were massive abuses requiring government intervention, which led to the enactment of the Sarbanes-Oxley Act.[218] He concludes his discussion by stating that there is "considerable evidence" that "absent powerful . . . incentives, [professional societies] are reluctant to take measures that could be interpreted by their members as policing activities."[219] Professor Sonia Suter makes similar observations about the fertility industry thus far, citing past examples of clinics misleading people regarding success rates.[220]

5. *Conditioning Federal Funding*

Still other commentators suggest that the best solution to regulation in this area is to place conditions on federal funds granted to states or other entities. Professor Michael Malinowski briefly discusses a system where implementation of PGS regulation responsibilities are delegated to the state with enforcement carried out "through funding of state Medicare and Medicaid programs."[221] Professor Malinowski's previous work suggests that industry would prefer strengthening of requirements in this way—particularly through the incorporation and adoption of the recommendations of voluntary professional societies (such as the American Society of Human Genetics)

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216 *Id.*

217 *See supra* Part IV.A.3.

218 Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745; FUKUYAMA & FURGER, *supra* note 10, at 13.

219 *Id.*

220 Sonia M. Suter, *Giving In to Baby Markets: Regulation Without Prohibition*, 16 MICH. J. GENDER & L. 217, 253–54 (2009) ("[W]ithout adequate oversight and regulation of the fertility industry, profit motives may drive self-interested and unethical providers toward practices that are unsafe or unethical . . . .").

221 Malinowski, *supra* note 57, at 221.

to avoid direct regulation.[222] Again, this might be a plausible solution if the technology were still in its infancy and required government funding to advance. However, the technology is significantly advanced and has become so largely in the private sector because of the federal funding ban.[223] If the conditions placed on federal money were too onerous, the money would be essentially as unavailable as it was before the signing of Executive Order 13,505.[224] Progress would be slowed, but not significantly. In the meantime, the private sector would remain totally unregulated.

A *Harvard Law Review* note appears to reach the same conclusion, seeing the idea of conditioned federal funds (with the private sector able to operate freely) as an improvement over no federal funds (which is no longer the case, due to Executive Order 13,505).[225] The note identified the ban on federal funding as creating a situation of "unexpected dynamics for new research while eliminating a valuable means of imposing safeguards to ameliorate many key ethical concerns."[226] Indeed, given the extent to which the private sector has developed during the partial freeze on federal funding, it would be well suited to continue on that path, leaving such regulations essentially purposeless but for slowing the pace of research.

Between existing foreign regulations and the spirited discussions within the American academic community, there are quite a large number of policy proposals for the United States to regulate PGS technology. These proposals, however, were made at a time when federal policy was more hostile toward research on embryos; with Executive Order 13,505, new research opportunities became immediately available, and the impact of those opportunities on PGS is likely to increase in scope and magnitude.[227] Although some of these proposals suggest the same relaxation of federal funding policies that has occurred through the passage of Executive Order 13,505, they do so with the understanding that some kind of regulation will take its place;

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222 Michael J. Malinowski & Erica Rose, *Clinical Laboratory Regulations*, *in* BIOTECHNOLOGY: LAW, BUSINESS AND REGULATION § 10.02[A][2][d], at 10-25 to 10-26 (1999).

223 Suter, *supra* note 220, at 252 ("[T]he [assisted reproductive technologies] industry in this country is a $3 billion industry, which is highly privatized [and] motivated largely by profit . . . .").

224 Exec. Order No. 13,505, 3 C.F.R. 229 (2010).

225 Note, *Guiding Regulatory Reform in Reproduction and Genetics*, 120 HARV. L. REV. 574, 589–90 (2006).

226 *Id.* at 589.

227 *See supra* note 11.

however, this has not happened. The United States should act immediately to remedy this situation.

V. Proposal: A Multipronged Regulatory Approach Combining Immediate Action with Long-Term Development

PGS is a powerful technology, but one with major potential for abuse. There are subjective and objective reasons why regulation is necessary in the United States. Foreign regulations present a wide variety of options currently in place, and scholarly proposals for the United States similarly provide additional ideas for regulation.[228] It is unacceptable that the United States has failed to regulate in this area and it should do so immediately because of "the mushrooming, rapidly burgeoning cloud of innovation categorically referred to as the 'genetics revolution.'"[229] Already a multibillion-dollar industry,[230] assisted reproduction, which includes PGS procedures, is growing; it will continue to grow as PGS technology becomes more sophisticated through unrestricted, privately funded research and increasingly less restricted publicly funded research. Although there are some relatively acceptable uses of the technology, the United States must place meaningful constraints on the use of PGS to put the United States in line with the international community and to avoid some of the potential ethical abuses described throughout this Note.[231] This Note's proposal also takes into account the American people's desire to have PGS regulated in a manner that does not excessively interfere with personal decisions.[232]

The United States should engage in a multipronged approach that simultaneously reins in the excesses of technology and encourages development, as it plays regulatory catch-up in a game that started over two decades ago. First, Congress should pass a law temporarily banning the use of PGS technology for nonfatal conditions (the second and third categories of characteristics discussed in this Note), with the possibility for exceptions.[233] Second, Congress should charter a temporary advisory board with the dual function of evaluat-

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228 *See supra* Part IV.

229 Malinowski, *supra* note 57, at 132.

230 Liza Mundy, Everything Conceivable 4 (2007) (estimating that the industry conducts $3 billion worth of business per year by selling drugs and products related to assisted reproductive technologies).

231 *See supra* Part III.C.

232 *See supra* Part IV.

233 See *infra* note 239 for examples of permissible exceptions.

ing requests for exceptions to this law and formulating the groundwork for a new regulatory agency that would permanently make policy and regulations in this area. Third and finally, Congress should impose two requirements onto state medical licensing boards: (1) that they provide greater availability of data and statistics regarding the use of PGS technologies and (2) that state licensors meet amongst themselves and with state industry representatives in furtherance of possible state policies.

States would not be required to form a policy, but any policy enacted would be subject to a ceiling requirement—that they not ban PGS for use for life-threatening medical conditions—and a floor requirement—that any new PGS test not already approved by the federal regulatory agency be submitted to that agency for preapproval. The net effect of this policy would be to give states the ability to permit or ban federally approved screening procedures as they wish, so long as bans retain an exception for the screening of life-threatening conditions and proposed tests are submitted for review by the federal body.

This proposal is an amalgamation of several other proposals with additional novel elements. The proposal, as a whole, is designed with a multipart rationale of (1) responding quickly to Executive Order 13,505 and increasing private investment that will speed the development of PGS testing; (2) creating federal policy that begins where most Americans believe it should—helping avoid serious fatal conditions while protecting against "playing God"; (3) developing that policy initially, and temporarily, at the federal level, and eventually at a combined federal/state level; and (4) ultimately creating a structure in which medical technology can flourish but in which meaningful controls help avoid the potential for abuse. This Part will conclude with a discussion of each parameter and why it is the preferable solution to alternate suggestions in place abroad or in scholarly works.

A. Federal Legislation

The first prong of the proposal involves the United States banning the use of PGS technology except in cases of tests for life-threatening conditions. Such a proposal was made shortly after the development of PGS technology and the rationale for this proposal still stands.[234] The United States is engaged in a culture war, and has been for decades. Questions of abortion and procreative liberty

234 Norton, *supra* note 57, at 1598–99, 1648.

abound, and regulation in this area is anticipated by many to be difficult.[235] As demonstrated by polling, however, much of the country is comfortable with the use of PGS technology to screen for serious, life-threatening conditions.[236] Moreover, this would place the United States at parity with other countries that only permit testing under those circumstances.[237]

As discussed previously, a full ban on the procedures along the lines of those in Germany and Italy would be inappropriate. A complete prohibition would not honor the spirit of procreative liberty in this country, it would not recognize that these procedures are already in place and frequently used, and it would cause needless suffering by banning a technique that most seem to support.[238] Moreover, it would halt continued research into preventing life-threatening conditions in a way that benefits only those few who fundamentally object to any use of it. Finally, a complete ban would aggravate economic disparities by permitting those with means to engage in medical tourism to use PGS abroad, while leaving those without means without options. The proper course of action is to permit PGS screening for life-threat-

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235 As discussed in the Introduction, *see supra* text accompanying notes 6–7, regulating PGS is on some (surface) level analogous to regulating abortion, in that general prohibitions on reproductive techniques interfere with choice and parental autonomy. At least one scholar has argued, more or less, that the debate should end there. *See* ROBERTSON, *supra* note 6, at 1491–92. The problem with Professor Robertson's reasoning, however, is that PGS and abortion differ significantly in their procedures and their end goals. PGS concerns conception and testing that is wholly removed from the body, and is moreover always an optional medical procedure. Abortion, by contrast, concerns conception that has already implanted inside of a human being, and abortion may be necessary for the health or the life of the mother. Constitutional law concerning the subject of abortions should not automatically be seen as controlling over PGS because the locus of the regulation has changed. Regulation of PGS does not infringe on a woman's right to control what is happening inside her body; regulation of PGS concerns what doctors may do, quite apart from a woman's body, in a laboratory. The majority of scholars appear to be in agreement. *See, e.g.*, Garrison, *supra* note 14, at 1626 ("[F]ederal courts are highly unlikely to adopt [Professor Robertson's] expansive interpretation . . . ."); King, *supra* note 75, at 327–29 (acknowledging Professor Robertson's eloquence, but concluding that he applies his proposals too broadly in light of the Supreme Court's recent decision in *Gonzales v. Carhart*, 550 U.S. 124 (2007)); Radhika Rao, *Equal Liberty: Assisted Reproductive Technology and Reproductive Equality*, 76 GEO. WASH. L. REV. 1457, 1481 (2008) (concluding that a flat ban on PGS would be constitutional); Norton, *supra* note 57, at 1648 (concluding after an exhaustive review that a ban on PGS for nontherapeutic purposes would be constitutional). There is little guidance from the federal judiciary at the moment; one district court judge has held that a woman has a presumptive right to *postimplantation* testing on a fetus, but for the above reasons, this does not necessarily extend to an embryo outside the body. Lifchez v. Hartigan, 735 F. Supp. 1361, 1377 (N.D. Ill. 1990).

236 *See supra* Part II.

237 *See supra* Part IV.A.2. (discussing the United Kingdom and Canada).

238 *See supra* Part II.

ening conditions, but *temporarily* ban the technology for all other uses.

B. Temporary Regulatory Structure, then a Permanent Regulatory Structure

The United States should next begin to lay the groundwork for a federal agency that would set policy and guidelines in the PGS arena. Establishing an agency will likely take time, so a temporary advisory board, or steering committee, should be created to deal with PGS-related issues in the interim and guide the creation of a fully functioning federal agency. While the regulatory agency is being created, and before it issues comprehensive policy and regulations, this interim body should play a quasi-appellate role in governing the acceptable uses of PGS technology. The interim body should operate to enforce the ban on PGS testing for non-life-threatening conditions, but have the flexibility to make exceptions in extreme circumstances.[239] This solution would aid in ameliorating some of the practical problems that could arise through Congress's flat ban on screening for non-life-threatening conditions. In making decisions, the interim body could examine the nearly two decades of thoughts and proposals from foreign and domestic sources. As a practical matter, the interim body might best take shape through a temporary expansion of authority of the National Institution of Health, as one commentator has proposed.[240]

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239 For example, one current use of PGS technology that would be banned by default under this proposal is the creation of savior siblings. A savior sibling results from a successful pregnancy using an embryo that, through the use of PGS, is on some level genetically compatible with an existing child whose health is threatened. *See, e.g.*, B.M. Dickens, *Preimplantation Genetic Diagnosis and 'Savior Siblings,'* 88 INT'L J. GYNECOLOGY & OBSTETRICS 91, 93–94 (2005). Then, substances that would normally be byproducts of the pregnancy (e.g., blood from the umbilical cord or placenta that contains stem cells) are transplanted into the sick child. *Id.* The proposal in this Note would, by default, prohibit the use of PGS to create a savior sibling because PGS initially would only be permitted for the selection of an embryo without a serious medical condition. *See supra* Part V.A. With respect to savior siblings, by contrast, PGS would be used to select for an embryo with a certain condition that is beneficial to a third-party child, but has no bearing on the "savior" embryo itself. The procedure is, of course, controversial; it exemplifies some of the risks discussed previously relating to psychological and physiological risk factors for parents and children born through the use of PGS technology. However, the procedure can save the life of a sick child with a fatal disease, and thus cannot be dismissed easily (and furthermore, garners majority support in polling, *see supra* text accompanying note 64); the exception to the interim policies proposed in this Note exist to allow some limited flexibility in cases such as these.

240 Roberts, *supra* note 195, at ¶ 49.

C. State Engagement

Finally, the states should be engaged in this process in their typical role as overseers of medical procedures and licensing within their borders. States are often discussed as "laboratories" of policy, and the balance of federalism is cited as providing for innovation in a way that one central federal government could not accomplish.[241] Regrettably, current state action in the PGS area has not been incredibly helpful in resolving regulatory problems in the United States; California's wide-open Proposition 71 is as problematic, if not more problematic, than Louisiana's restrictive treatment of embryos. Both of these policies initially would be swept under the table by federal actions proposed above, but these two states, and indeed all others, would be invited to meaningfully contribute. States would have the choice of participating passively, by not enacting any PGS regulations, at which point federal law would control private work within the state. Alternatively, states could participate positively, by submitting proposals to the new federal agency regarding which tests and procedures should be permitted. Finally, states could also participate negatively, by barring the use of the technology for all but those screenings that could identify life-threatening conditions. In this way, states could meaningfully contribute to national regulations.

VI. Why a Combination, and Why This Combination?

The international community and academic contributors have presented a wide variety of policies, some of which provide the foundation on which this Note's proposal is built. Other policies, however, are not included, and the reasons for those exclusions were discussed previously. The reason that the proposed amalgamation is well suited for the United States rests on several considerations. First, colloquially speaking, the United States is very late to the party. More than two decades have elapsed since PGS technology was advanced and since other countries have implemented successful regulatory approaches. The United States, regrettably, cannot operate in a vacuum—PGS technology has exploded in the past decades, and, not coincidentally, that explosion has largely occurred within the United States. Moreover, that explosion will only continue because of augmented private-sector and federal funding. The United States cannot afford to follow some of the more idealized approaches proposed that

241 New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments . . . .").

would involve long-term studies absent meaningful constraints in the meantime. The progress in this area has been, and is, unacceptable. A carefully calibrated ban combined with a process for exceptions will create time for the formation of appropriate policy, and the political process will provide a check on policymakers if studies languish too long.

Second, the engagement of the states, cast aside by many commentators, is also necessary. Although some commentators say there is "little to be learned from the states,"[242] all commentators calling for action on the federal level are forced to acknowledge that, currently, decisions regarding medical procedures and medical licensing are typically in state hands. Although current state action can be criticized for being at the polar extremes of the policy debate, such action is still more than the federal government has been able to accomplish. This proposal would create opportunities to limit state extremism but leverage state innovation. State engagement is essential to this proposal and to continued medical innovation in the United States.

Third, there is a longstanding tradition of reproductive liberty in the United States. Thus, the European proposals must be modified to work from that default rule. This modification requires balancing the interests of the American public, who want regulation of PGS but who also do not want excessive government interference, with these extremely personal decisions. The default posture of this proposal provides that states cannot interfere with PGS testing for serious medical conditions. This policy provides a balance between avoiding the dangerous excesses of the technology and ensuring that the American people have access to the types of PGS tests that they most support. Furthermore, the exceptions-based approach will provide the people with an opportunity to appeal if they feel that they should have access to a certain type of test in an extreme case. This compromise should satisfy the majority of concerns expressed by respondents.

CONCLUSION

The United States has lagged unacceptably far behind in regulating in this critical arena. The silver lining in this cloud, however, is the extensive and rich development of policy surrounding PGS technology, whether policy as implemented in foreign countries or policy discussed in medical, ethical, and legal journals. It is a sorry state of

242 FUKUYAMA & FURGER, *supra* note 10, at 131; *see also* Garrison, *supra* note 14, at 1629 (concluding that problems of medical tourism and consistent standards counsel for a national solution based in "[f[ederal, instead of state, regulation").

affairs that the United States has not been a leader in this arena, but the benefit is that it can learn from the extensive proposals and contributions that others have advanced. The United States must take action to regulate PGS technology now, before it is too late.