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A Life Worth Living? Implications of Noninvasive Prenatal Testing on the Down Syndrome Population

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Introduction

“I am a man with Down syndrome, and my life is worth living.”¹ Frank Stephens, actor, Special Olympian, and Down syndrome advocate, spoke these words to the United States House of Representatives in the Fall of 2017 to address the emergence of State laws either allowing or attempting to suppress the use of prenatal testing to identify Down syndrome in a fetus. “Why do I feel the need to make that point?”² Stephens went on to state. “Across the world, a notion is being sold that maybe we don’t need to continue to do research concerning Down syndrome. Why? Because there are pre-natal screens that will identify Down syndrome in the womb, and we can just terminate those pregnancies.”³ The identified probability of the presence of Down syndrome based on prenatal testing has a statistically high occurrence of inducing parent(s) to terminate otherwise wanted pregnancies.⁴

In many of these cases, the decision to terminate is prompted by misinformation and inaccurate stereotypes.⁵ Research indicates that individuals with Down syndrome and their families enjoy a quality of life that is happy, fulfilling, and purposeful.⁶ A better understanding of the quality of life attainable by those with Down syndrome could be grasped through better educational opportunities for those considering the decision to terminate based on the results of a prenatal indication of the presence of Down syndrome in the fetus. However, education is merely

¹ Frank Stephens: Hearing Before the Subcomm. on Lab., Health and Hum. Serv. & Educ., 115th Cong. 1 (2017), <https://docs.house.gov/meetings/ap/ap07/20171025/106526/hrg-115-ap07-wstate-stephensf-20171025.pdf>.

² *Id.*

³ *Id.*

⁴ Greg Stapleton, *Qualifying Choice: Ethical Reflection on the Scope of Prenatal Screening*, 20 MED. HEALTH CARE & PHIL. 195, 202 (2016).

⁵ *Id.* at 202.

⁶ See, e.g., Brian G. Skotko, Susan P. Levine & Richard Goldstein, *Self-perceptions from People with Down Syndrome*, 155 AM. J. OF MED. GEN. 2360, 2362 (2011) (pointing out that individuals with Down syndrome and their families perceive themselves as being happy and fulfilled).

a tool to address the underlying issue that individuals with Down syndrome should somehow be made to prove that their life is worth living. “I don’t feel I should have to justify my existence,” as Stephens would point out.⁷

This paper focuses on the emerging availability of noninvasive prenatal testing (NIPT) and its implications for the potential eradication of people with disabilities, particularly people with the chromosomal disorder trisomy 21, more commonly known as Down syndrome. This paper argues that the use of NIPT to identify trisomy 21, particularly in the absence of proper physician and parental education, leads to an increased termination rate in otherwise wanted pregnancies in which Down syndrome is prenatally diagnosed.

The reason for the focus on persons with Down syndrome is threefold. First, through life experience or perhaps media portrayals, most people can immediately recognize a person with Down syndrome. The characteristic almond-shaped eyes and the somewhat stunted speech patterns caused by low muscle tone allows instantaneous identification (and perhaps stigmatization).⁸

Second, among genetic anomalies occurring in humans, Down syndrome occurs the most frequently in the United States.⁹

Third, with the continuously evolving availability of genetic testing, the identification of Down syndrome in the fetus is one of the most common reasons for which expectant parent(s) will terminate an otherwise wanted pregnancy.¹⁰ The increasing availability of NIPT and the

⁷ Stephens, *supra* note 1.

⁸ *Facts about Down Syndrome*, CDC (Feb. 2, 2020, 3:42 PM), <https://www.cdc.gov/ncbddd/birthdefects/downsyndrome.html>.

⁹ See *Down Syndrome Facts*, NAT’L DOWN SYNDROME SOC., (Mar. 12, 2020, 1:52 PM), <https://www.ndss.org/about-down-syndrome/down-syndrome-facts/> (Down syndrome occurs in 1 out of every 700 live births in the United States.).

¹⁰ C. Lewis, C. Silcock & L.S. Chitty, *Non-Invasive Prenatal Testing for Down's Syndrome: Pregnant Women's Views and Likely Uptake*, 16 PUB. HEALTH GENOMICS 223, 225 (2013).

emerging possibility that it will become the norm for prenatal care (i.e., standard, insurance-covered care similar to an ultrasound) will have implications for the Down syndrome population in particular.

This paper argues that the ability to obtain a simple, noninvasive, diagnostic test that merely provides the name of the highly likely disease with which the fetus will be born has parallels with eugenics, potential disability discrimination implications, and potential reproductive rights implications. Studies have shown that parent(s) will choose to terminate an otherwise wanted pregnancy in nearly two-thirds of the cases in which they are presented with the results of a prenatal test indicating the presence of Down syndrome.¹¹ One of the key factors that leads to this decision to terminate is the unavailability or improper administration of person-first educational materials that provide adequate information on the realities of living with a person with Down syndrome.¹²

Part I provides an overview of NIPT, including its availability, accuracy, and potential for more widespread use in determining whether to terminate a pregnancy. Part II discusses the potential legal and regulatory issues associated with NIPT, including eugenics, reproductive rights, wrongful death and wrongful life claims, licensing, and disability discrimination. Part III discusses the potential for NIPT to become a means by which people with certain disabilities are essentially eradicated from our society and offers the proposed solutions of increased education and counseling for the expectant parent(s) first and foremost, as well as possible legal and regulatory remedies. Part IV concludes that NIPT has negative implications for people with Down syndrome and measures should be taken to ensure that expectant parents opting for the NIPT procedure are given adequate education and counseling on the accuracy rate and results of

¹¹ George F. Will, *The Real Down Syndrome Problem: Accepting Genocide*, WASH. POST, March 24, 2018, at A23.

¹² Lewis, *supra* note 3, at 229.

the testing, and that legal and regulatory measures should be formulated with the goal of minimizing the prevalence of pregnancy termination due to the diagnosis of a child with a disability, and specifically Down syndrome.

An important caveat to this conclusion is that any potential solutions should not impede a woman's Constitutional right to terminate her pregnancy; the goal is to ensure that expectant parents have the information necessary to make an informed decision before making the choice to terminate a previously wanted pregnancy upon learning that their child would likely be born with Down syndrome.

I. OVERVIEW OF NONINVASIVE PRENATAL TESTING (NIPT)

NIPT was first introduced in 2011.¹³ It is a method of testing for genetic anomalies in fetuses that is noninvasive to the pregnant woman, requiring only a blood draw which allows the lab to analyze the fetal DNA.¹⁴ It is available as early as the first trimester of pregnancy.¹⁵ It has a high detection rate for genetic anomalies in the fetus, including trisomy 21 (Down syndrome).¹⁶ In fact, NIPT has a 99% accuracy rate in identifying the presence of the extra chromosome that causes Down syndrome in a fetus.¹⁷

NIPT admittedly has certain benefits. NIPT is a noninvasive alternative to amniocentesis which, until the development of NIPT, was one of the only ways to test for preexisting conditions in a fetus.¹⁸ Amniocentesis is an invasive procedure that involves inserting a needle

¹³ Megan Allyse, et al., *Non-Invasive Prenatal Testing: A Review of International Implementation and Challenges*, 2015 INT'L J. OF WOMEN'S HEALTH 113, 114.

¹⁴ *Id.* at 114.

¹⁵ *Id.* at 115.

¹⁶ Jeffrey Wale, *Screening Human Life: The Legal and Ethical Implications of Noninvasive Prenatal Testing*, 2018 AMPS 25.

¹⁷ Giovanni Rubeis & Florian Steger, *A burden from birth? Non-invasive prenatal testing and the stigmatization of people with disabilities*, 33 BIOETHICS 91, 92 (2018).

¹⁸ *Id.* at 93.

into the uterus of a pregnant mother to collect and analyze the amniotic fluid.¹⁹ It carries with it certain risks, including an up to 0.3% chance of causing a miscarriage and the possibility of injuring the fetus with the test needle.²⁰ Another positive aspect of NIPT is that it provides doctors with the early diagnoses required to effectively treat curable diseases prenatally.²¹

As additional context, in fertility clinics, it is an emerging practice to offer a series of genetic testing prior to conception, from initial carrier screening, or “preconception genetic testing,” to preimplantation genetic testing.²² The initial carrier screening is performed prior to pregnancy to determine whether the parents are carriers for certain genetic disorders that could potentially be passed on to their child.²³ Similarly, preimplantation genetic testing is performed on the embryo itself prior to implantation in the mother’s uterus to determine the existence of any genetic disorder.²⁴ In both cases, the parents are offered extensive genetic education and counseling before making the decision whether to move forward with a pregnancy. Despite the availability of these preconception tests, NIPT remains the most common genetic test performed both in and outside of the fertility clinic setting.²⁵ Currently, administering NIPT does not typically accompany the same level of genetic education that the preconception tests do.²⁶

NIPT can provide the parent(s) with information that can help them decide whether to continue with or terminate the pregnancy. This is seen as a positive by some and a negative by others, depending on the viewpoint as well as the diagnosis.²⁷ Proponents of prenatal genetic

¹⁹ *Amniocentesis*, MAYO CLINIC (April 12, 2020, 2:15 PM), <https://www.mayoclinic.org/tests-procedures/amniocentesis/about/pac-20392914>.

²⁰ *Id.*

²¹ Stapleton, *supra* note 2, at 202.

²² *Id.* at 285

²³ *Id.* at 284

²⁴ *Id.* at 286

²⁵ *Id.* at 289

²⁶ *Wale*, *supra* note 16, at 25.

²⁷ *Wale*, *supra* note 16, at 25.

testing argue that it allows expectant parents to make an informed choice whether to proceed with a pregnancy in which the NIPT indicates a strong likelihood for a genetic disorder such as Down syndrome.²⁸ Part of this argument includes the question of whether the parents in fact have a moral duty to refrain from bringing a child into the world knowing its diagnosis beforehand.²⁹ Detractors argue that NIPT allows expectant parents to essentially become modern day eugenicists in deciding whether to terminate such a pregnancy and that it is wrongly using the field of genetics to “make a distinction between normality and abnormality.”³⁰

This article argues that even though NIPT is a positive step forward in terms of allowing expectant parents to have the ability to have more information about their unborn child, it has rapidly become a simpler means than the previously available amniocenteses of identifying genetic anomalies that induces expectant parents to terminate for the reason of Down syndrome. For example, a 2015 study revealed that live Down syndrome births in the United States were reduced by at least 30% between 2006 and 2010 due to termination resulting from prenatal diagnosis.³¹ Another study revealed that between 1995-2011, the termination rate for fetuses diagnosed with Down syndrome in the United States was 66.67%.³²

Even with the availability of preconception testing for parents who are trying to conceive, NIPT remains the most common prenatal genetic test, and it is performed during pregnancy.³³

Prenatal genetic testing has led to increased termination rates pregnancies in which the test

²⁸ Stapleton, *supra* note 11, at 200.

²⁹ *Id.*

³⁰ Heidi Mertes & Guido Pennings, *Bioethics in Human Reproduction*, 2020 HUM. REPROD. GENETICS 283, 285.

³¹ Gert de Graaf, Frank Buckley & Brian G. Skotko, *Estimates of the live births, natural losses, and elective terminations with Down syndrome in the United States*, 167 AM. J. OF MED. GENETICS 756, 760 (2015).

³² *See supra* note 11.

³³ Mertes, *supra* note 20, at 289.

revealed Down syndrome.³⁴ This reality presents several legal and ethical issues, which will be explored in the next section.

II. LEGAL & ETHICAL ISSUES

A. Regulatory bodies in the United States are important for regulation and licensing of NIPT but will not necessarily offer a workable solution for its implications for the Down syndrome population.

In the United States, three federal agencies play various roles in the regulation of genetic tests, each with a particular area of influence. These are the Federal Trade Commission (FTC), the Center for Medicare and Medicaid Services (CMS), and the Food and Drug Administration (FDA).³⁵ Although other controls lie in the “best practices” guidelines promulgated by professional and scientific societies, such as the American Medical Association, these are merely advisory and have no binding legal authority.³⁶

The FTC exercises its regulatory authority on how tests are advertised, and has the authority to regulate any advertisement that relates to health-related information that is directed at consumers to ensure that it is not false and misleading.³⁷ With the advent of NIPT, direct-to-consumer marketing or marketing to healthcare providers without specialized training in genetics may give rise to greater involvement of the FTC in its regulation, but the FTC currently plays a negligible role with regard to NIPT.³⁸

³⁴ See *supra* notes 31-2 and accompanying text.

³⁵ *Regulation of Genetic Tests*, GENOME (Feb. 11, 2020, 1:20 PM), [https://www.genome.gov/about-genomics/policy-issues/Regulation-of-Genetic-Tests#:~:text=Federal%20Regulation-,Two%20federal%20agencies%20have%20the%20primary%20authority%20to%20regulate%20genetic,and%20Medicaid%20Services%20\(CMS\).](https://www.genome.gov/about-genomics/policy-issues/Regulation-of-Genetic-Tests#:~:text=Federal%20Regulation-,Two%20federal%20agencies%20have%20the%20primary%20authority%20to%20regulate%20genetic,and%20Medicaid%20Services%20(CMS).)

³⁶ Audiey Kao, *The AMA's Code of Medical Ethics Serves as “Gold Standard,”* 4 AM. MED. ASSOC. J. OF ETHICS 11 (2002).

³⁷ 21 C.F.R. § 801.

³⁸ Sarah E. Gollust, *Limitations of Direct-to-Consumer Advertising for Clinical Genetic Testing*, 288 J. AM. MED. ASSOC. 1762, 1763 (2002).

The CMS has the authority to regulate clinical laboratories performing genetic tests to ensure there is compliance with the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”).³⁹ The primary objective of the CLIA is to certify the clinical testing quality and verify procedures, uses, and qualifications of the technical personnel processing the tests.⁴⁰ In general, the CLIA regulates the release of information.⁴¹ Therefore, only research laboratories that test human specimens but do not report patient-specific results for the diagnosis, prevention, or treatment of any disease, or the assessment of the health of individual patients are exempt.⁴² Requiring genetic counseling to accompany NIPT would likely not fall under the CMS’s regulatory purview.

The FDA has broad authority to regulate the safety and effectiveness of genetic tests as medical devices falling under the Federal Food, Drug, and Cosmetic Act (FFDCA).⁴³ They can therefore regulate genetic tests sold to laboratories. The FDA’s reach is guided by the intended use and the risks posed by an inaccurate NIPT result.⁴⁴ Of the three – FTC, CMS, and FDA – the FDA has the greatest potential to require genetic counseling as part of the administration of NIPT.

As discussed below, balancing Constitutionally protected reproductive rights with the parallels to eugenics often drawn by critics of NIPT presents an ethical conundrum which will not necessarily be addressed through regulation of the NIPT test in of itself.⁴⁵ However, requiring specialized genetic counseling and education to accompany NIPT could provide a

³⁹ 42 C.F.R. § 493.1-25.

⁴⁰ *Id.* § 493.1.

⁴¹ *Id.*

⁴² *Id.*

⁴³ 21 U.S.C. § 301, et seq. (2018).

⁴⁴ *Id.*

⁴⁵ See discussion *infra* Parts II.A-B.

positive step forward in mitigating the prevalence of terminating otherwise wanted pregnancies when Down syndrome is identified.⁴⁶

B. The decision to terminate a pregnancy based on the prenatal diagnosis of Down syndrome has implications of modern eugenics.

The term, eugenics, literally means “good birth.”⁴⁷ Modern eugenics was started by British scientist Francis Galton.⁴⁸ It focuses on the scientific management of selective breeding in order to promote “good births” and reduce or eliminate the existence of so-called “inferior individuals,” namely, those prone to mental illness, alcoholism, or “feeble-mindedness.”⁴⁹ In theory, this is accomplished by preventing certain groups from reproducing, commonly known as “negative eugenics.”⁵⁰

Eugenics grew in popularity around the world and even resulted in cooperative experiments between entities in the United States and Nazi Germany.⁵¹ A popular adherent to the eugenics movement, Margaret Sanger, also advocated for women’s reproductive rights, founding Planned Parenthood.⁵² Although eugenics practices as they were witnessed in the early 1900s are largely seen as discriminatory today, some of the principles and mindsets have presented themselves in new ways through the popular acceptance of prenatal genetic screening providing opportunities to screen out undesirable traits prior to birth.

⁴⁶ See discussion *infra* Part III.A.

⁴⁷ Sara Goering, *Eugenics*, STANFORD ENCYC. OF PHIL. (Mar. 11, 2020, 2:20 PM), <https://plato.stanford.edu/entries/eugenics/>.

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ U.S. Holocaust Mem., *The Biological State: Nazi Racial Hygiene: 1933–1939*, ENCYCLOPEDIA.USHMM.ORG (Apr. 17, 2020, 11:15 AM), <https://encyclopedia.ushmm.org/content/en/article/the-biological-state-nazi-racial-hygiene-1933-1939>.

⁵² Amita Kelly, *Fact Check: Was Planned Parenthood Started to Control the Black Population?*, NPR (Apr. 17, 2020, 10:52 AM), <https://www.npr.org/sections/itsallpolitics/2015/08/14/432080520/fact-check-was-planned-parenthood-started-to-control-the-black-population>.

While genetic tests to determine whether couples should reproduce have been available since the 1950s, prenatal testing did not become available until the 1960s.⁵³ With the legalization of abortion in the 1970s, prenatal genetic testing experienced a “major boom,” triggering a debate on the implications of genetic testing that continues to this day, namely, whether genetic testing that leads to the decision to terminate an otherwise wanted pregnancy is essentially a form of modern eugenics.⁵⁴ Ultimately, it is unhelpful to equate prenatal testing for genetic anomalies with the popularly held notion of eugenics (i.e., the Nazi Germany practices); however, it is important to note that when reproductive decisions are being made primarily on the basis of the results of a prenatal test, in particular, when combined with preconceived notions or negative attitudes towards disability in general, there can be a “eugenics outcome.”⁵⁵ Prenatal screening for Down Syndrome in particular, then, could be considered as a form of contemporary eugenics.⁵⁶

The most famous Supreme Court case involving modern eugenics is *Buck v. Bell*, in which the Court held a state statute permitting compulsory sterilization of mentally ill persons did not violate those persons’ substantive due process rights under the Fourteenth Amendment.⁵⁷ In doing so, the Court stated that

It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. ***Three generations of imbeciles are enough.***⁵⁸

⁵³ Rubeis, *supra* note 17, at 93.

⁵⁴ *Id.*

⁵⁵ Gareth M. Thomas & Barbara Katz Rothman, *Keeping the Backdoor to Eugenics Ajar?: Disability and the Future of Prenatal Screening*, 18 AM. MED. ASSOC. J. OF ETHICS 406, 407 (2016).

⁵⁶ *Id.* at 408.

⁵⁷ *Buck v. Bell*, 274 U.S. 200, 207 (1927).

⁵⁸ *Id.* at 207 (emphasis added).

The reasoning behind the decision in *Buck* revolved around the mindset that Carrie Buck “[was] the probable potential parent of socially inadequate offspring.”⁵⁹ This is similar to the reasoning some expectant parents use, whether consciously or unconsciously, when deciding to terminate a pregnancy based on an NIPT result of the likelihood of Down syndrome.⁶⁰

Buck v. Bell addressed the particular issue of sterilization, but the legal precedent was set to enable legislation on the State level to approve the expansion of the deplorable eugenics acts and experiments.⁶¹ The mindset of eugenicists was to create a better society through the purification of those considered to be “imbeciles,” among other undesirable traits. This idea led to the prevalence of forced sterilization based on race, poverty, and perceived intelligence.⁶² The regularity of prenatal screening can be used to do the same, and in fact has been used to do the same as the abortion rates of fetuses with Down syndrome just in the United States would indicate.⁶³ Entire people groups were targeted by individuals wishing to improve society.⁶⁴ It was common for males and females deemed subhuman in various parts of the United States to be told they needed a medical procedure, then to be sterilized without their knowledge.⁶⁵ The justification for committing such acts was that the individuals were a burden to the state and to society in general.⁶⁶ Eugenics practices were conducted to lessen the population of those not seen

⁵⁹ *Buck*, 274 U.S. at 207.

⁶⁰ See discussion *supra* Part II.B.

⁶¹ *Eugenic Sterilizations in Indiana*, U. VT. (Mar. 12, 2020, 4:13 PM) <https://www.uvm.edu/~lkaelber/eugenics/IN/IN.html>.

⁶² Allyse, *supra* note 13, at 115.

⁶³ *Id.*

⁶⁴ *Introduction to Eugenics*, GENETICS GENERATION (Apr. 15, 2020, 2:30 PM), <https://knowgenetics.org/history-of-eugenics/>.

⁶⁵ *Id.*

⁶⁶ See *supra* note 61.

as desirable.⁶⁷ Often, these forced sterilizations targeted those belonging to the minority population or living in mixed-race relationships and communities.⁶⁸

An additional issue is that targeting Down syndrome through NIPT can diminish the value of those children and adults who are living with Down syndrome.⁶⁹ If Down syndrome is deemed to be undesirable, in the eugenics sense, then it would be reasonable to think the argument may present itself that those with Down syndrome should be sterilized for their inability to care for offspring, or for the outcome of avoiding more individuals with Down syndrome being produced. This is not an unreasonable or abstract assumption, as it ties directly into the logic behind *Buck* in appealing to compassion and societal good.⁷⁰ The argument that Buck could be “sterilized without detriment to her general health and that her welfare and that of society will be promoted”⁷¹ by this act is not dissimilar to the reasoning behind NIPT testing. Individuals with qualities seen as detrimental to the betterment of society are able to be conveniently prevented from becoming a nuisance. Eugenics is based on the notion that life is only as valuable as its ability to contribute to society.⁷² Modern NIPT allows for the fulfillment of the goal of eugenicists through the reduction of individuals who, in their opinion, do not enhance societal good. Culture and society are constantly changing and evolving. Desirable and undesirable qualities are subject to change frequently as our knowledge changes.

Although modern notions of fairness and human rights have prompted State and Federal legislatures to create laws prohibiting forced sterilization,⁷³ *Buck v. Bell* has never been expressly

⁶⁷ See *supra* note 64.

⁶⁸ *Id.*

⁶⁹ Rubeis, *supra* note 17, at 95.

⁷⁰ *Buck*, 274 U.S. at 207.

⁷¹ *Id.*

⁷² See *supra* note 64.

⁷³ See, e.g., IND. S. RES. 91, 115TH GEN. ASSEMB., 1ST SESS., § 1 (2007) (expressing regret over Indiana’s 1907 sterilization law and its role in the eugenics movement).

overturned by the Supreme Court. As genetic screening becomes more routine and in-depth, there could be any number of disqualifying factors beyond the potential existence of Down syndrome by which a fetus may be terminated.

C. Reproductive rights are protected by the Constitution, but legislation to regulate reasons-based abortion is beginning to emerge.

It is widely known that the Supreme Court has held that the Fourteenth Amendment gives a woman the right to have an abortion, regardless of her reason for doing so. The decisions in landmark cases such as *Roe v. Wade* and *Planned Parenthood v. Casey* are justified as being grounded in personal liberty, privacy, and autonomy.^{74, 75} However, with the emergence of prenatal testing technology and its ability to predict an increasingly wider range of genetic traits, predispositions, diseases, and disabilities, questions have arisen as to the prevalence of decisions to terminate otherwise wanted pregnancies, and the implied implications for reproductive rights.

To date, the Supreme Court has said that States may restrict abortion-related activities for only two reasons: (1) when the statute or regulation is rationally related to a legitimate state interest and does not restrict a decision or activity that is protected by the Fourteenth Amendment,⁷⁶ and (2) when the statute or regulation does not interfere with or create an undue burden upon a woman’s right to exercise her right to choose to terminate her pregnancy.”⁷⁷

A few states have attempted to regulate reasons-based abortion due to the identification of a disability, and some have even specifically called out Down syndrome. For example, an Ohio law prohibits abortion providers from knowingly performing an abortion on a woman who “is seeking the abortion, in whole or in part, because of... a test result indicating Down

⁷⁴ *Roe v. Wade*, 410 U.S. 113 (1972).

⁷⁵ *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

⁷⁶ *Roe*, 410 U.S. at 166.

⁷⁷ *Casey*, 505 U.S. at 878.

syndrome in an unborn child.”⁷⁸ The Ohio law in fact makes it a fourth-degree felony to obtain an abortion under these circumstances.⁷⁹ Similarly, the State of Indiana makes it a felony to abort a fetus “solely because the fetus has been diagnosed with Down syndrome or has a potential diagnosis of Down syndrome.”⁸⁰ These laws were, in fact, prompted by the emerging availability of NIPT.⁸¹

To date, the Seventh Circuit has held such laws to be unconstitutional, and the Supreme Court has declined to rule on this specific issue.⁸² In finding the Indiana law unconstitutional, the Seventh Circuit noted that it was inconsistent with the Fourteenth Amendment’s right to privacy – to which the Supreme Court pointed in *Roe* and *Casey* – that the State can eliminate this right “if a woman later decides she wants to terminate her pregnancy for a particular purpose.”⁸³

Although this case made it all the way to the Supreme Court, the Court denied certiorari on the part of the Indiana code prohibiting reasons-based abortion, instead ruling on the part of the code related to the disposal of fetal remains following an abortion.⁸⁴ However, in his concurrence, Justice Thomas made it clear that undergoing or performing an abortion for the sole purpose of the prenatal diagnosis of a disability is not protected by the Constitution, and is in danger of “becoming a tool of modern-day eugenics.”⁸⁵ He went on to state that *Casey* could not be interpreted as a decision prohibiting States from disallowing eugenics abortions, and in light

⁷⁸ OHIO REV. CODE ANN. § 2919.10(B)(1) (West).

⁷⁹ *Id.* § (C).

⁸⁰ IND. CODE ANN. § 16-34-4-6 (West).

⁸¹ *Planned Parenthood of Indiana & Kentucky, Inc. v. Comm’r of Indiana State Dep’t of Health*, 888 F.3d 300 (7th Cir.), *reh’g en banc granted, judgment vacated*, 727 F. App’x 208 (7th Cir. 2018), *vacated*, 917 F.3d 532 (7th Cir. 2018), *and opinion reinstated*, 917 F.3d 532 (7th Cir. 2018), *and cert. granted in part, judgment rev’d in part sub nom.*, *Box v. Planned Parenthood of Indiana & Kentucky, Inc.*, 139 S. Ct. 1780 (2019).

⁸² *Id.* at 307.

⁸³ *Id.* at 307.

⁸⁴ *Box v. Planned Parenthood of Indiana & Kentucky, Inc.*, 139 S.Ct. 1780, 1782 (2019) (reversing the Seventh Circuit and holding that the State has a “legitimate interest in proper disposal of fetal remains”).

⁸⁵ *Id.* at 1783.

of the Court’s denial of certiorari on this specific question in the *Box* case, “the constitutionality of other laws like Indiana’s thus remains an open question.”⁸⁶

Whether they were intended, the consequences of the *Buck v. Bell* decision resulted in eugenics-minded atrocities that extended over six decades and destroyed countless lives.⁸⁷ The failure to define a legal standard for the NIPT screening of genetic traits could also have unintended consequences and result in further atrocities.

For example, the concept of after-birth abortion has been presented in some jurisdictions, because, “The moral status of an infant is equivalent to that of a fetus in the sense that both lack those properties that justify the attribution of a right to life to an individual.”⁸⁸ If certain traits are deemed undesirable or burdensome to a family or society, then “the same reasons which justify abortion should also justify the killing of the potential person when it is at the stage of a newborn.”⁸⁹ It is not a hypothetical “slippery slope” scenario to see how the failure to establish a legal standard not only regarding reasons-based abortion but also the education that must accompany a decision regarding genetic screening in pregnant women could lead to the freedom to once again fall into the eugenics mindset. Legal boundaries and requirements that provide an ethical approach to this issue must be enacted proactively. If we are to avoid repeating our failures in this recent history of our nation, then a legal precedent must be set to prohibit genetic experimentation that results in damage to human lives.

⁸⁶ *Id.* at 1792.

⁸⁷ *See supra* note 73.

⁸⁸ Alberto Giubilini & Francesca Minerva, *After-birth Abortion: Why Should the Baby Live?*, 39 J. OF MED. ETHICS 261, 262 (2012).

⁸⁹ *Id.* at 262.

D. The use of NIPT to prenatally diagnose Down syndrome can have negative implications for the children and adults currently living with it, i.e., perception, loss of programming and education, eradication, etc.

The Americans with Disabilities Act of 1990 (ADA) was revolutionary in terms of creating or enhancing the rights of persons with disabilities to seek employment without discrimination⁹⁰ and have access to public services⁹¹ and housing.⁹² Although the law was historic in the emergence and availability of programs to assist persons with recognized disabilities, it appears to have had unanticipated consequences. Although the ADA and other laws like it (e.g., Civil Rights laws) are intended to equal the playing field for the most disadvantaged in our society, this paper proposes that these laws' very existence means that the individuals they are meant to protect are perceived as "other." One consequence of the ADA, for example, is statistics showing that birthrates in children with Down syndrome in particular declined by 13-18% between 1989 and 2002, following the passage of the ADA in 1990.⁹³ This is due, at least in part, to the concept of ableism which the ADA, whether intentionally or not, tends to promote.⁹⁴

The concept of ableism, sometimes used interchangeably with the term disablism, is the idea that impairment or disability in a human being, is inherently negative in nature, and that every effort should be made to cure or eliminate these characteristics in an individual or in society as a whole.⁹⁵ It is a set of assumptions that can be either conscious or unconscious in which the individual with real or perceived disabilities is seen as "other," and is therefore

⁹⁰ 42 U.S.C.A. § 12111 (2018).

⁹¹ *Id.* § 12131.

⁹² *Id.* § 12102.

⁹³ Xuanqian Xie et al., *Noninvasive Prenatal Testing for Trisomies 21, 18, and 13, Sex Chromosome Aneuploidies, and Microdeletions in Average-Risk Pregnancies: A Cost-Effectiveness Analysis*, 42 J. OF OBSTETRICS AND GYNECOLOGY 740, 742 (2019).

⁹⁴ *Id.* at 743.

⁹⁵ KATIE ELLIS, *CONTOURS OF ABLEISM: THE PRODUCTION OF DISABILITY AND ABLEDNESS*, 638-640 (2010).

deserving of unequal treatment.⁹⁶ The idea is based on the proposition that there is a “normal” or “ideal” state for a human being, and anything less or other than this state should be treated, cured, or somehow eliminated.⁹⁷

These concepts tend to manifest themselves in today’s world, for the most part, as unconscious bias.⁹⁸ Without the proper education, this unconscious bias can lead to life-altering decisions when presented with the results of a NIPT report that lets expectant parents know, without any additional information whatsoever, that their fetus has a 99% likelihood of being born with a recognized disability such as Down syndrome.⁹⁹

The primary disability critique of NIPT technology is that it is *only* used to test for disability traits, and the fetus is aborted because of the presence of these traits.¹⁰⁰ The problem, then, is that personhood is reduced or eliminated altogether; the fetus is defined by the extra chromosome or the genetic anomaly, and the focus of the parent’s decision-making process is on these negative traits and not on the person as a whole.

A secondary argument is that prenatal genetic testing implies that procreation for the parent(s) can be optimized, much as shopping for a car can be optimized – children are not seen as a positive addition to the family that should be shown unconditional love, but as a product to be selected.¹⁰¹ Although it is routine practice in fertility clinics to make these types of decisions prior to implantation, it is worth noting that these types of tests and decisions are made prior to a viable pregnancy.¹⁰² It is also worth noting that these preconception tests are the subject of the same disability critiques as NIPT, i.e., the notion of “designer babies,” the potential for negative

⁹⁶ Anita Ghai, *Discourses of Ableism and Disablism*, CONF. PROC. (2017).

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ Rubeis, *supra* note 17, at 93.

¹⁰⁰ Stapleton, *supra* note 4, at 196.

¹⁰¹ *Id.* at 198.

¹⁰² Mertes, *supra* note 28, at 283.

consequences for existing persons with disabilities, or the use of genetics to “wrongly make a distinction between normality and abnormality.”¹⁰³

The third argument is societal – the mere existence of tests for disability traits implies that persons with disabilities are unworthy of life.¹⁰⁴ All three arguments treat prenatal testing in general and NIPT in particular as the product of societal misconceptions or deficits and general inhumane attitudes towards people with disabilities.¹⁰⁵

As previously mentioned, following the passage of the Americans with Disabilities Act (ADA) in 1990, the birthrates of children with Down Syndrome in particular declined significantly.¹⁰⁶ The results of the study indicated that the ADA may have paradoxically promoted selective abortion in the case of Down Syndrome if the parent(s)’ social interactions or media exposure following the implementation of ADA regulations in public spaces and the workplace reinforced any conscious or unconscious negative attitudes towards people with disabilities.¹⁰⁷ Parents of children with Down Syndrome could also be seen as subjecting themselves to the challenges that come with raising the children and subjecting the children to the same if they had the option of terminating the pregnancy.¹⁰⁸

Another potential consequence is a reduction in the amounts of money allocated for organization that provide assisted living or other benefits to persons with disabilities.¹⁰⁹ If children born with disabilities such as Down syndrome are systematically eradicated through

¹⁰³ *Id.* at 285.

¹⁰⁴ Rubeis, *supra* note 1, at 94.

¹⁰⁵ *Id.*

¹⁰⁶ Dov Fox, Christopher L. Griffin, Jr., *Disability-Selective Abortion and the Americans with Disabilities Act*, UTAH L. REV. 845 (2009).

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ E. J. Joanne Verweij, Dick Oepkes & Marjon A. de Boer, *Changing Attitudes Towards Termination of Pregnancy for Trisomy 21 with Noninvasive Prenatal Trisomy Testing: A Population-based Study in Dutch Pregnant Women*, 33 PRENATAL DIAGNOSIS 397, 398 (2013).

NIPT and selective abortion, it is logical to draw the conclusion that those currently living with it will have less and less access to necessary resources such as special education, vocational training, specialized housing, and the like.

The concept of ableism is inherent to any discussion about whether it is ethical to terminate a pregnancy based on the single fact of a prenatal test identifying a recognized disability in the fetus. It presupposes that there is something inherently “wrong” with a person who would have this or that diagnosis. In the case of Down syndrome, it presupposes that the person would have a diminished quality of life and be a burden on everyone around him or her.

E. The underlying assumption in “wrongful life” or “wrongful birth” claims is that certain lives have more value than others; but the recognition of these claims in tort law represents a balancing act for physicians and regulatory bodies in determining how to approach prenatal testing.

It would be remiss not to mention the existence of the legal remedy for parents to sue physicians under the theory of “wrongful life” or “wrongful birth.” An available remedy in tort law, wrongful birth claims allow parents to seek compensation for the costs associated with the care of a disabled child, including projected future medical expenses as well as the emotional pain associated with raising such a child.¹¹⁰ Similarly, wrongful life claims are brought by the parents on behalf of the child born with a disability. These claims arise out of the notion that, had the parents known about the disability prior to birth, they would have terminated the pregnancy.¹¹¹

Wrongful birth or wrongful life claims are typically brought to court by a parent or guardian on behalf of a minor child who has been born with a genetic or congenital disorder.¹¹²

¹¹⁰ *Wrongful-birth Action*, BLACK'S LAW DICTIONARY (10th ed. 2014).

¹¹¹ *Id.*

¹¹² *See, e.g.*, *Smith v. Saraf*, 148 F. Supp. 2d 504, 08 (D.N.J. 2001) (parents brought wrongful birth action on behalf of themselves and wrongful life action on behalf of their child, who was born with spin bifida).

The litigants seek to recover damages for the healthcare provider's alleged negligence in failing to identify the disability prior to birth.¹¹³ There are several examples across the United States in which courts have determined that physicians were negligent in failing to provide expectant parents with the option to terminate prior to the birth of the child with undesirable traits.¹¹⁴

Although recent wrongful birth and wrongful life causes of action regarding a child born with Down syndrome have been largely unsuccessful, they do exist. Parents bring suit on behalf of themselves and/or their child against physicians for either failing to perform a prenatal test that would have warned them of the child's chromosomal anomaly, or on behalf of the child born with it.¹¹⁵

Wrongful birth and wrongful life claims in of themselves have eugenics implications and diminish the value of life in the same way that deciding to terminate a pregnancy based on an NIPT result does. Their underlying premise is that the individual that is the subject of the lawsuit would have been better off never having been born. Although the focus of this paper is not these types of claims, it is not a leap in logic to presume that the underlying assumption in wrongful life and wrongful birth claims, namely, that the child was wrongfully allowed to live, could have infinite implications for any trait deemed "undesirable" by the parents. Where is the line drawn? At least regarding Down syndrome, medical literature has shown that both individuals with Down syndrome and their families believe that their quality of life is very positive.¹¹⁶ Where

¹¹³ *Id.*

¹¹⁴ Jay Bringman, *Challenging Underlying Assumptions of Wrongful Birth*, 19 NAT'L CATH. BIOETHICS Q. 37, 40 (2019).

¹¹⁵ *See, e.g.,* Maliton v. United States, 2016 WL 270213, 1 (D.N.J. Jan. 20, 2016) (unsuccessful wrongful life claim on behalf of child born with Down syndrome following tubal ligation of the mother); B.D.H. *ex rel.* S.K.L. v. Mickelson, 792 N.W.2d 169, 170 (N.D. 2010) (wrongful birth claim on behalf of parents and wrongful life claim on behalf of child born with Down syndrome due to doctor's failure to administer a prenatal test barred by State statute).

¹¹⁶ Bringman, *supra* note 114, at 40.

does the notion of undesirability regarding Down syndrome come from, if this is the case? This paper proposes it that it is lack of education and understanding.

In developing educational solutions to counteract the ethical implications of utilizing prenatal testing to identify undesirable traits in the fetus that would induce a parent to terminate, physicians, lawmakers, and regulators will also need to consider the legal implications for physicians who may choose to forego offering this type of test.¹¹⁷ Physicians can be held liable in wrongful birth and wrongful life claims for failing to offer sufficient prenatal testing.¹¹⁸ However, this paper proposes that proper education on the realities of a diagnosis of Down syndrome could help to counteract these types of claims as well as termination of the pregnancy in the first place.

III. PRACTICAL SOLUTIONS

a. Regulatory remedies could provide the requirement for genetic education and counseling in the short term; legal remedies for reasons-based abortion will not provide an immediate solution.

Potential legal and regulatory remedies generally fall under the category of medical testing device regulations and legislative actions.¹¹⁹

One potential remedy is for the FDA or FTC to require licensing provisions for NIPT that would require a certain level of education and counseling be provided before the test can even be administered. In fertility clinics, for example, prenatal genetic counseling is regularly offered by specialists to hopeful or expectant parents covering details such as the accuracy of the genetic testing (including the possibility of “false positives”) and the nature of the identified genetic

¹¹⁷ See Daniel W. Whitney & Kenneth N. Rosenbaum, *Recovery of Damages for Wrongful Birth*, 32 J. OF L. MED. 167, 168 (2011) (most U.S. jurisdictions recognize wrongful birth in tort law against physicians who fail to prenatally diagnose certain genetic conditions).

¹¹⁸ *Id.* at 169.

¹¹⁹ See *supra* note 35.

condition(s) prior to conducting preconception genetic testing or preimplantation genetic testing.¹²⁰ Offering this type of counseling prior to or even after undergoing NIPT would be a logical step, especially given that it is performed once the pregnancy is already viable.

Laws outlawing abortion for the purpose of a prenatal diagnosis – such as the ones created in Indiana and Ohio¹²¹ – have not gotten much traction. Although well-intentioned and with some very good arguments as to why they should fall outside of the Fourteenth Amendment’s right to privacy, they have thus far been held to be unconstitutional.¹²²

In his concurrence in *Box*, Justice Thomas made it clear that, “Enshrining a constitutional right to an abortion based solely on the... disability of an unborn child...,” and that “[t]he Court’s decision to allow further percolation [of the Indiana law prohibiting abortion based on a diagnosis of disability] should not be interpreted as agreement with the decisions below.”¹²³ The Court has, however, expressly condemned disability discrimination in other contexts.¹²⁴

Justice Thomas points out in *Box* that since the Supreme Court has made abortion a Constitutional right, it is “dutybound to address its scope.”¹²⁵ While a favorable Supreme Court ruling may be on the horizon if more and more states begin to enact laws that recognize the eugenics implications of allowing selective abortions for prenatal diagnoses of Down syndrome, the short-term solution of proper counseling and education remains the most viable option for stemming these termination decisions.

¹²⁰ Roberto Coco, *Genetic Counseling Prior to Assisted Reproductive Technology Procedures in the Era of Cytogenomics*, 22 J. ASSIST. REPROD. 375, 377 (2018).

¹²¹ See *supra* notes 30-2.

¹²² See *supra* note 33.

¹²³ *Box*, 139 S.Ct. at 1792.

¹²⁴ See, e.g., *Tennessee v. Lane*, 541 U.S. 509, 522 (2004) (condemning “irrational disability discrimination” against individuals seeking employment).

¹²⁵ *Box*, 139 S.Ct. at 1793.

b. Person-first education and counseling of physicians as well as expectant parents could provide valuable insights outside of the clinical diagnosis of Down syndrome when making a fully informed decision regarding termination of a pregnancy.

The most obvious, practical, and easily implemented solution is person-first education and counseling of prospective parents once they receive the results of an NIPT report indicating that their fetus has a 99% chance of having Down Syndrome.¹²⁶ Misperceptions about the cost, diminished quality of life, etc., are a primary driving force in the decision to terminate an otherwise wanted pregnancy on this basis alone. Studies have in fact shown that having a child with a disability affects the outlook of parents and siblings positively, thereby increasing their quality of life.¹²⁷

Down syndrome is the most common chromosomal disorder.¹²⁸ The number of babies born in the United States with Down syndrome increased by 30% between 1979 and 2003.¹²⁹ This increase largely coincided with an increase of pregnancies at a later age, due to better medical treatment available for expectant mothers.¹³⁰ In 2008 an estimated “250,700 children, teens, and adults were living with Down syndrome in the United States.”¹³¹ Improved medical treatment and technology has greatly increased both the quality of life and the lifespan of individuals living with Down syndrome.¹³²

In spite of any steps forward with regard to our knowledge and acceptance of the Down syndrome community, pressures to abort based on a prenatal diagnosis can come in the form of

¹²⁶ Rubeis, *supra* note 17, at 93.

¹²⁷ *Id.* at 96.

¹²⁸ *Facts About Down Syndrome*, CDC (Feb. 2, 2020, 12:32 PM), <https://www.cdc.gov/ncbddd/birthdefects/downsyndrome/data.html>.

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

the genetic counseling or informed consent discussions themselves.¹³³ Issues such as concern over legal liability¹³⁴ or misinformation among physicians and genetic counselors themselves can lead to pressure on the parent(s) to abort a fetus based on a prenatal diagnosis of Down syndrome.¹³⁵

It is important that the information made available to expectant parents is first made available to the medical providers themselves so that they can provide expectant parents with person-first education regarding the realities of raising a child with Down syndrome. Medical providers may have the same biases regarding Down syndrome, whether conscious or unconscious, that a layperson has. Person-first education would allow the physicians and the expectant parents to look past the clinical diagnosis and have some insight into the realities of living with Down syndrome.

For example, a 2011 study conducted by a Harvard physician concluded that most individuals with Down syndrome perceived themselves to be living “happy and fulfilling lives.”¹³⁶ The study was conducted in response to the correlation between prenatal tests indicating the likelihood of Down syndrome to abortions of otherwise wanted pregnancies. It revealed that individuals with Down syndrome, and their families, had generally loving and fulfilling lives, liked how they looked, and wanted “normal” things like education and marriage.¹³⁷

Requiring counseling and education prior to entering into a potentially life-altering medical decision is not without legal precedent, even within recognized abortion laws. The idea

¹³³ Darrin P. Dixon, *Informed Consent or Institutionalized Eugenics? How the Medical Profession Encourages Abortion of Fetuses with Down Syndrome*, 24 ISSUES IN L. & MED., 1, 3 (2008).

¹³⁴ See discussion *supra* Part II.E.

¹³⁵ Dixon, *supra* note 133, at 4.

¹³⁶ See *supra* note 6.

¹³⁷ *Id.*

of informed consent is explicitly called out in *Casey*, in which the Supreme court stated, “the State may take measures to ensure that the woman's choice is *informed*. Measures designed to advance this interest should not be invalidated if their purpose is to persuade the woman to choose childbirth over abortion.”¹³⁸ Although the key premise of the Court’s holding in *Casey* is that any State law surrounding a woman’s right to have an abortion should not impose an undue burden upon her, the Court did not contemplate the technological advances that would allow a simple blood test to identify genetic anomalies in a fetus that could inform a woman’s decision to terminate an otherwise wanted pregnancy. While the question of an individual’s right to abort an unwanted pregnancy has been settled, the issue raised of newer technological methods of providing selective abortion to produce desired traits has not.

Even so, informed consent is a recognized prerequisite for any medical procedure and is “fundamental in both ethics and law.”¹³⁹ Requiring the right level of education and counseling before expectant parents make the choice whether to abort based on a prenatal Down syndrome diagnosis would not require a change in the law. It would simply require physicians, advocates, and parents to work together to create information that would not merely focus on the genetic anomaly that leads to a diagnosis of Down syndrome and some of the associated medical risks. It could be formulated to create a full and accurate picture of what raising and living with an individual with Down syndrome is really like, using person-first, and not diagnosis-first, language.

¹³⁸ *Casey*, 505 U.S. at 737 (emphasis added).

¹³⁹ *Informed Consent*, AM. MED. ASSOC. (Feb. 16, 2020, 2:34 PM), <https://www.ama-assn.org/delivering-care/ethics/informed-consent>.

IV. CONCLUSION

“[People with Down syndrome] are giving the world a chance to think about the ethics of choosing which humans get a chance at life.”¹⁴⁰ This paper proposes that this type of thinking will necessarily result in the establishment of a legal framework by which issues impacting life are approached. NIPT has the potential to become the standard of care for any pregnancy. Its emerging popularity and the ease with which this test can be administered in the first trimester of pregnancy, the minimal risk of any health complications in the mother or the fetus, and its high degree of accuracy in identifying genetic anomalies in the fetus will likely make it an increasingly normal and routine procedure for all pregnant women. It will no longer be solely recommended for expectant mothers whose age, family history, or other risk factors make them likelier candidates for such a test.

Lawmakers, physicians, advocates, parents, and individuals living with Down syndrome should work together to ensure that misinformation and prejudice do not inform decisions about which humans get to be born. Although the practice of NIPT screening may currently seem isolated to concerns regarding a fetus with Down syndrome, an ethical approach is needed to ensure a standard is set that values human life as the inevitable expansion of the customization of genetic traits becomes the norm. The stakeholders mentioned above must explore the real concerns of the ethical implications of screening based on any undesired quality that results in the termination of a pregnancy.

First and foremost, this paper proposes that physicians and genetic counselors must provide person-first education for parent(s) who choose to undergo prenatal testing and receive a

¹⁴⁰ Stephens, *supra* note 1.

prenatal diagnosis of Down syndrome. This is the simplest way to ensure that misinformation is not underlying the decision to terminate an otherwise wanted pregnancy.

Secondly, this paper proposes that legislation should be enacted proactively to address the expanding ability of geneticists to screen for any number of desired or undesired traits in the fetus, and the Supreme Court must take on the question of the scope of the abortion laws as Justice Thomas has suggested.¹⁴¹ Furthermore, a comprehensive discussion regarding the question of the rights of individuals extending to the production of desirous traits in offspring should take place in order to establish a framework by which to consistently approach the expanding ability to genetically manipulate outcomes in the future.

¹⁴¹ *See supra* note 84.