

Non-Invasive Prenatal Genetic Diagnosis (NIPD)



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TABLE OF CONTENTS

<u>Introduction</u>	3
<u>The Science Behind NIPD</u>	4
<u>Advertising Accuracy</u>	6
<u>Current Clinical Uses of NIPD</u>	10
<u>NIPD and Informed Consent/Decision-making</u>	13
<u>Disability Rights and NIPD</u>	17
<u>Less than Life-altering Genetic Conditions & NIPD</u>	21
<u>Reshaping Reproductive Freedom: NIPD and Abortion</u>	23
<u>Prenatal Genetics and Eugenics: A Slippery Slope</u>	27
<u>Conclusion</u>	30
<u>Footnotes</u>	31

INTRODUCTION

Forty-years ago, prenatal genetic diagnosis was still in its beginning stages.ⁱ Since then, the invasive procedures of amniocentesis and chorionic villus sampling (CVS) have been adopted as the standard methods for testing *in utero* fetal tissue.ⁱⁱ Although reaching a standard of 98-99% accuracy,ⁱⁱⁱ the risk of miscarriage associated with these procedures has held the science of prenatal genetic diagnosis at a plateau. That level of stagnation has recently been overcome.

Non-invasive prenatal genetic diagnosis, or NIPD, has no associated risk of miscarriage.^{iv} Results have been obtained as early as seven weeks of gestation,^v utilizing 10 milliliters of blood from a pregnant woman. There appears to be no end to the possible uses or clinical applications of NIPD. In fact, the only plateau foreseeable for prenatal genetic diagnosis, now, will be policy based.

The ethical implications of NIPD arise from the same aspects of the procedure that make it so scientifically groundbreaking. The lack of a risk of miscarriage; the turnaround speed of the results; the earlier testing capacity; the minimal stress imposed on a pregnant woman; the increasing utility of molecular DNA analysis; as well as the potential to test for chromosomal aneuploidy, X-linked and late-onset conditions, single-gene diseases and disorders, as well as multiple diseases and disorder simultaneously, fosters an image of the future in which it becomes ethically imperative to ask about purpose and impact.

In this article, seven major issues regarding NIPD are discussed. First, detailed background about the development of NIPD and its contrast to other prenatal genetic techniques is provided. The next section considers the accuracy of NIPD as currently

promoted, and questions the verification of NIPD results and its predictive value.

Following, the impact of the two most common clinical uses of NIPD are compared and the issues arising from non-medical uses of NIPD in the clinic, as well as the direct-to-consumer market, are explored. The third issue explored is the impact of NIPD on current ethical issues regarding informed consent. This section also questions whether NIPD test results are actually useful in making medical decisions. The next two sections consider the tension between disability rights and prenatal diagnostics contrasting the impact of NIPD on conditions such as Down's Syndrome or cystic fibrosis, from conditions such as hereditary deafness or polydactylysm. Finally, it explores the impact of NIPD on reproductive freedom and the overlying concern of institutionalized eugenics.

THE SCIENCE BEHIND NIPD

After four years of parenting Peter Jr., who has Down's syndrome, Peter and Susan are ready to have another child. Reasonably, Peter and Susan are concerned about having another child with Down's syndrome. Perhaps Peter believes that the family cannot handle two children with this condition, financially, or emotionally. Perhaps Susan worries that all her children will be born with Down's syndrome, and she would consider adoption if that were true.

When Susan was pregnant with Peter Jr., she underwent CVS, an invasive and risky procedure that allows the testing of fetal cells for genetic diagnosis and screening. . The procedure could not be performed until 12 weeks after Susan's last menstrual period, near the beginning of her second trimester. The test was painful; and the doctors warned Peter and Susan that going through the procedure would increase the risk of miscarriage

Now, Peter and Susan are told that a new test is available. The test is not invasive. It requires only 10ml of blood from Susan. It can provide results very early in the pregnancy. It will tell Peter and Susan whether the mutation for Down's syndrome is present in the child's chromosomal profile. But that is not all

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Non-invasive prenatal genetic diagnosis, or NIPD, is based on the 1997 discovery of cell-free

fetal DNA (cffDNA) in the maternal blood stream.^{vi} Accounting for about 5-10% of the total free-floating DNA present in maternal blood,^{vii} cffDNA is easier to isolate and can be used for the same diagnostic purposes as cellular fetal DNA. Requiring, only 10 milliliters of blood from the pregnant mother, reliable diagnosis may be performed as early as seven weeks post-conception.^{viii}

Once the fetal DNA is isolated it must also be analyzed. The three most common methods of analysis for all prenatal genetic diagnostics are (1) karyotyping; (2) florescent *in situ* hybridization, or FISH; and (3) polymerase chain reaction, or PCR, analysis.^{ix} Karyotyping generally takes 10-12 days to achieve results, and provides a full map of the fetal genetic material. With karyotyping results, a clinician can determine whether the fetal chromosomes exist in the correct number, shape, and size. Both FISH and PCR take about 2-3 days to complete. FISH analysis may be used to diagnose both chromosomal and single-gene abnormalities, while PCR analysis is capable of diagnosing signal-gene abnormalities.^x

Before NIPD, prenatal diagnosis was based entirely upon the isolation of cellular fetal DNA from either the amniotic sac (amniocentesis) or samples of the placenta (chorionic villus sampling, or CVS). Both procedures require invasive surgery. Both procedures increase the risk of miscarriage.^{xi} And neither procedure provides means of guaranteeing that isolated fetal cells are from the current pregnancy.^{xii} In comparison, NIPD has no associated risk of miscarriage, and because cffDNA clears shortly after the end of a pregnancy, direct relevance to the current pregnancy is almost certain.^{xiii} Moreover, although current NIPD procedures target specific chromosome abnormalities, e.g. trisomy 21, the chromosomal mutation associated with Down's syndrome, developers predict that NIPD will be capable of monogenic disease identification (directed at specific disease-causing mutations or linked polymorphisms) and complete fetal

genome mapping within the next 10 years.^{xiv}

Not everyone is enthusiastic about the introduction of NIPD in the clinical setting, however. Scholars and advocates from various fields argue that NIPD will not only exacerbate current ethical issues in prenatal diagnostic and screening, but it will also create entirely new issues. NIPD, some contend, will erode informed consent, blur the line between medically necessary and non-medical fetal testing, obviate the disability rights movement, undermine disability treatment efforts, and reshape consideration of reproductive freedom. Some scholars have gone so far as to call NIPD a sham and a cover-up for modern-day eugenics.^{xv}

ADVERTISING ACCURACY

Non-invasive testing has long been a goal in the prenatal diagnostic field.^{xvi} Prenatal genetic diagnosis, thus far, has been made more complicated by the risk of miscarriage. While over 95% of pregnant women choose some form of prenatal screening,^{xvii} less than 2% undergo CVS or amniocentesis.^{xviii} The American College of Obstetricians and Gynecologists (ACOG) recommends screening prior to all diagnostic testing for all pregnant women, in part because of the risk of losing non-affected fetuses in unscreened populations.^{xix} Some studies have shown, however, that many women refuse even prenatal screening to avoid the likelihood of subsequent prenatal diagnosis.^{xx}

The background rate of miscarriage during the first trimester is about 3%. During the second trimester, the background rate of miscarriage is about 1%. Thus, out of every 100 pregnancies, 3 miscarriages in the first trimester, and 1 miscarriage in the second trimester, are likely to occur naturally.^{xxi} CVS, which is generally performed in the late first trimester, increases the rate of first trimester miscarriages to about 4-4.5%; amniocentesis, generally performed during the

second trimester, increases the rate of miscarriages from about 1% to about 1.5%. NIPD completely eliminates the significant procedural risks of spontaneous fetal loss, as well as the discomfort and stress related in invasive prenatal diagnosis.^{xxii}

Yet, despite confident promotion by NIPD developers and providers, NIPD may not be as ready for clinical implementation as it may seem. First, maternal cell-free DNA outnumbers cffDNA at a rate of about 20:1, thus, “[d]istinguishing—or ideally isolating—fetally derived cell-free DNA . . . [is] a significant technical challenge.”^{xxiii} Second, NIPD testing methods are not fully diagnostic - limited to identifying only paternally derived, or *de novo* genetic mutations, and cannot be used for the diagnosis of single-gene diseases or disorders.^{xxiv} Neither is NIPD associated with a clinically applicable means of verification, since its researchers verify their results by the very techniques that NIPD intends to replace.^{xxv} Verification by invasive procedures, however, would directly negate the benefit of using NIPD, and will therein not transition with NIPD to a clinical setting. Additionally, the technology has yet to reach the diagnostic-level of accuracy set by amniocentesis and CVS,^{xxvi} and unlike these prenatal diagnostic procedures, NIPD, as envisioned, does not involve confirmatory verification later in the pregnancy.

Whether or not the technology reaches diagnostic-level accuracy, many believe that NIPD will become the standard of care for prenatal diagnosis.^{xxvii} For one thing, novel diagnostic tests can be introduced into the clinical setting without outside regulatory requirements, as long as they are developed and validated by the original providers.^{xxviii} Some applications of NIPD may bypass clinical validation completely – offered as direct-to-consumer products. It follows that much of the concern over NIPD accuracy and verification is based on concerns about its developers and providers.

Traditionally the transition from research into clinical practice is generally carried out in academic settings and involves proof of the underlying scientific concepts, objective clinical trials, peer review and publication of the developments. But the participation of the private sector works to diminish this process^{xxxix} - details of testing may be kept secret as a matter of proprietary secrets; companies using testing as the basis of company investments may rush clinical application; and clinical trials are conducted internally by interested companies without regulation or outside verification.^{xxx} The development of NIPD in recent years has been primarily funded by the private sector,^{xxxi} and the false reporting discovered by the FDA on the accuracy of NIPD testing for Down's syndrome in 2007, is a fitting example of why publications of private research in this area should be viewed with skepticism.^{xxxii}

Finally, of particular import is the predictability of NIPD. Like other prenatal diagnostic tests, NIPD provides "predictive," not "certain" tests results. What separates NIPD is its projected use for varying types of genetic conditions,^{xxxiii} and its current and projected use in the direct-to-consumer (DTC) market. Currently, NIPD is limited to specific paternally-derived mutations or polymorphisms, chromosomal aneuploidy, and genotypic deviating from the maternal genome. Future developments of NIPD will be adapted to identify markers for complex genetic disorders, polygenic inheritance, as well as multiple disorders simultaneously (as required for a whole fetal genome).^{xxxiv} If any of these forms of NIPD testing fail to reach diagnostic-level accuracy, then such tests are "more akin to current screening tests that require additional diagnostic testing before any clinical action is warranted."^{xxxv} Similarly, the use of NIPD for multiple genetic disorders is more akin to current DTC genetic testing.

Early sex identification through NIPD is already offered as a DTC product, and as many note, there is no reason to stop NIPD at sex determinations.^{xxxvi} But the predictive value of

current DTC genetic tests is already highly debated, especially when the tests are used for multiple diseases simultaneously. The implications of adding NIPD to this market are best explained by analogy to current DTC genetic tests.

Genetic diagnosis is based on preselected genetic variants and uses preselected genetic markers, for which no cross-industry standard has been established. Regardless of the variants chosen, other variants and environmental factors not tested for or assessed may greatly affect any predicted risk.^{xxxvii} Additionally, all genetic testing requires statistical inferences based on such factors as race or ethnicity. In 2010, investigations by the United States Government Accountability Office (GAO) found that “identical DNA samples yield contradictory results,” leading to their conclusion that DTC test results are misleading and of little or no practical value.^{xxxviii} Results received from an earlier GAO investigation, predicted that fictitious consumers were at risk for “a myriad of medical conditions. These predictions were similar for all of our fictitious consumers, no matter which DNA or lifestyle description we used.”^{xxxix} Additionally, the GAO found that DTC testing companies often failed to provide adequate information along with test results. Expert advice promised by companies failed to be provided; limitations on testing results for non-Caucasian test-takers were not explicitly disclosed.

NIPD as a DTC product is likely to encounter similar difficulties, in part because of the lack of adequate regulation of genetic testing via DTC mediums. It is also concerning that NIPD is likely to enter the DTC market as a “diagnostic test,” whether or not it reaches diagnostic-level accuracy. One of the most common critiques of current genetic testing is that the tests are not for diagnostic purposes. Many DTC companies provide statements indicating that the information provided is not for diagnostic, predisposition, or even screening purposes.^{xl} Nevertheless scholars and investigators agree that most consumers will interpret tests results as diagnoses,

after all, “[t]he overriding impression from all the results is that . . . [consumers] are at risk for developing a variety of medical conditions”^{xli} NIPD carries even greater ability to mislead DTC consumers, if for no other reason than because of the impression of accuracy that submitting blood (as opposed to saliva) carries. Moreover, “[p]rospective parents are vulnerable, and many, when made aware of genetic screening’s possibilities, will seek a conclusive determination as to whether they are going to have a healthy baby.”^{xlii} The prospect of pregnant woman making irreversible decisions based on inconclusive information is alarming. In light of the issues regarding NIPD verification and accuracy, it is troubling that the public and policy makers have until next year to respond before, some estimate, routine application of NIPD will begin.

CURRENT CLINICAL USES OF NIPD

This new test is able to tell Peter and Susan about many more potential complications with the new pregnancy. It can be used to tell the sex of the child; or whether the child is likely to manifest sex-linked genetic conditions. Some applications of NIPD have been used to predict late-onset genetic conditions. Eventually developers envisage that NIPD will be able to provide an entire chromosomal profile of the fetus within the first few months of the pregnancy . . .

If, however, the predicted consequences of NIPD are at all accurate, then the clinical implementation of NIPD is riddled with ethical and societal concerns that go far beyond its scientific accuracy. Currently, the two most notable clinical applications of NIPD are for fetal sex determinations, and fetal Rhesus D (Rh D) status determinations. Unlike fetal Rh D status determinations, however, fetal sex determination is generally not used for medical reasons. On the contrary, sex determinations are often based on fetal sex preferences. The potential for additional applications of NIPD in the clinical setting are growing; as is the concern over certain uses of NIPD.

First, the routine use of NIPD for fetal Rh D provides a demonstrable advantage over current Rh D detection. Briefly, Rh D is a protein on the surface of red blood cells, which is present in an overwhelming percentage of the population. For those pregnant women who do not have the Rh D protein, or are Rh D negative, the consequences can be severe. The pregnant woman's immune system will produce antibodies against the fetal blood, especially during a second or later pregnancy, causing such life-threatening or fatal conditions as jaundice, brain damage, or heart damage. NIPD allows for faster determinations of the Rh factor status of the mother and fetus.^{xliii} It lessens misdiagnosis (where both the mother and fetus are Rh D negative), and the unnecessary exhaustion of medical resources. Additionally, because invasive prenatal screening and diagnostic techniques may allow fetal blood to enter the maternal blood stream needlessly, NIPD decreases the risk of anti-Rh D antibody production.

The use of NIPD for fetal sex determinations is generally *not* based on any medical grounds.^{xliv} Sex determination was the first application of NIPD. Because the Y chromosome is absent in the genome of the pregnant woman, detection and measurement of fetal-derived paternally inherited DNA was the first focus of researchers in the prenatal screening field. While, detection and identification of fetal sex-linked or sex-limited conditions is considered a legitimate medical reason for NIPD testing of sex, the more common use of pre-conception and prenatal technology for sex-determination is based on preference.^{xlv}

The ethical implications of sex-selection are well documented. Sex selective breeding and sex selective abortion are most commonly associated with the nations of India and China, whose overpopulations concerns have led to growth control policies,

generally targeting girl children.^{xlvi} Most studies on sex preferences in the US concluded that the majority of Americans prefer either the same number of either sex, or have no preference at all.^{xlvii} One particular study, while concluding that Americans do not display fetal sex preferences, also showed the affect that technology could have on these *currently* held values.

Confronted by a hypothetical pill that would simplify and ensure fetal sex, respondents in this study changed their considerations on using preconception sex-selection technologies. While a majority of the respondents did not change their responses,^{xlviii} those who did reveal an affect that is very likely to be seen with the widespread use of NIPD. Other scholars have also noted the “. . . fundamental dynamic between technology and culture . . .”, and the ability of technology to “coax cultures one way or the other by making it easier . . .”.^{xlix} Certainly the cumbersome nature of prenatal genetic screening and diagnostics has acted as a “checkpoint” – providing a reason to consider whether the sex of the child, or any other trait for that matter, was really worth the additional procedures, associated risks, and expense. Current and future envisages of NIPD are likely to eliminate that checkpoint, both nationally and internationally.

NIPD in the DTC market will likely affect the frequency of prenatal decisions based on non-medical rationales. One reason for this is that in the DTC market a starkly different ideology is likely to govern prenatal care: “The ideology of medicine requires physicians to set professional standards and adhere to them, while the ideology of the market says that physicians (providers) are just conduits to provide services to consumers, whatever services the consumers want.”²¹ Although misleading consumers is not legitimate in either the clinic or the open market, prenatal diagnostics as a DTC

product is not governed by the same considerations. In the DTC market, the use of genetic testing tends to be swallowed by consumer choice and consumer protection concerns.^{li} Whether one agrees or disagrees, the notion that genetic tests are “just like any other product,”^{lii} is a valid argument in the market place, and the affects on patient-consumers are only *beginning* to be a required consideration for DTC genetic testing companies. The ethical implications of DTC genetic products has prompted calls for greater regulation, but the FDA has yet to come to a decision regarding how best to regulate these medical “products”.^{liii}

Whether or not, genetic testing is a product, the ability of these products to “intrinsically mislead customers,”^{liv} must be addressed. Like many direct-to-consumer genetic tests offered today, future applications of NIPD are predicted to cover whole genome and multi-disease detection. If regulation of DTC genetic testing remains as it is, many expectant parents may find themselves changing their views on what trait preferences they have and what technology they are willing to use; without any guidance from clinicians.

NIPD AND INFORMED CONSENT/DECISION-MAKING

As Susan listens to her doctor’s account of the plethora of information that will be provided with such ease, her face goes from fascination to apprehension. “And then what?” she says to her doctor. “Well,” the doctor replies, “because the test can be conducted so early in the pregnancy, you’ll have the information to make medically relevant decisions about your pregnancy.”

No consensus exists on the definitions of informed consent and informed decision-making; still both principles are established cornerstones of medical care and medical research.^{lv} Along with patient self-determination and patient autonomy, the notion of informed consent

creates a trilogy^{lvi} that shapes the modern clinician-patient relationship. Legally, clinicians are obligated to provide pregnant women with all sufficient information necessary to make informed reproductive decisions. For patients to be sufficiently “informed” prior to consenting to NIPD testing, it should be disclosed that NIPD has yet to reach diagnostic-level accuracy. Additionally, prior to consenting to NIPD, patients should be aware of the negative implications of having NIPD information. Part of being “informed” is being prepared for what you *may* be told. Before NIPD, family history was a major factor in determining eligibility for prenatal genetic testing.^{lvii} Without such prior knowledge, patients are more susceptible to anxiety post-testing. Whether, and how, clinicians will discuss with patients the issue of whether they *want* to know the information revealed by NIPD is not yet established.

This aspect of informed consent is most difficult to facilitate with multi-disease and multi-trait testing. Like direct-to-consumer genetic testing, NIPD is envisaged to cover multiple diseases and, eventually, to be capable of whole fetal genetic profiling. But multiple-disease testing only “militat[es] against adequate preparation . . .”^{lviii} In a recent case study conducted by Donna Messner, Gordon Cain Fellow at the Chemical Heritage Foundation, one patient who underwent a direct-to-consumer test for diabetes, also received positive genetic markers for Alzheimer’s disease and was led to psychological counseling to “deal with his distress over how to cope with this information . . .”^{lix} Another patient reported “controlling” her fate by taking 50 supplements daily, exercising, and “if she gets diagnosed in the future [with Alzheimer’s], she plans to commit suicide . . .”^{lx} Many people may face similar difficulties accepting and internalizing predictive genetic results; and it is from this difficult position that a patient is expected to make medically sound choices.

Moreover, to enjoy the benefits of NIPD, patients may be expected to make these

decisions fairly immediately. After all, one of the major advantages of NIPD is earlier testing and the ability to make earlier decisions therefrom. Although little concrete data exists to support the contention that “reflection time” enhances informed consent/decision-making,^{lxi} one small sample study did show that patients of prenatal genetic diagnosis “did not reflect the amount of information they were given, leading [researchers] to wonder if they were not sometimes overwhelmed by the quantity of information they had been presented.”^{lxii} Reflection time may, at least, be required for absorption of provided information. It seems quite apparent that NIPD will encourage the *faster* consent and decision-making, however, whether or not, it encourages informed consent/decision-making.

One of the reasons why scholars have argued that “[i]n most cases, the results of genetic testing cannot be used for practical decisions about health care”^{lxiii} is because patients, in fact, have the same options before, as after, genetic tests are performed. Yes, the medical information available has changed; but the medical actions that can be pursued have not. As Erik Parens & Adrienne Asch so astutely note, “researchers have enjoyed only minimal success in using gene therapy to correct such conditions, and no researcher has yet even attempted to use gene therapy to correct genetic impairments in a fetus.”^{lxiv} The current focus in prenatal technological development is not to provide patients with additional or alternative medical courses of action. So what benefit ensues from providing patients with earlier, inconclusive information?

To a great extent the benefit of NIPD testing is based on the ability of clinicians to facilitate informed consent and informed decision-making. For “informed” decision-making, testing results should only be *part* of the considerations used to make medical decisions. A patient should also consider their own values, in order to make value-consistent decision, and should feel, as though more than one option is available to them.^{lxv}

Because NIPD is new, especially in the clinical context, few studies on the impact of NIPD on informed consent and informed decision-making have been conducted. One such study, performed in the UK, showed that health professionals are more likely to follow the informed consent practice associated with prenatal screening as opposed to invasive prenatal diagnosis, when using NIPD.^{lxvi} So, how well are we doing with regards to facilitating informed consent/decision-making for prenatal screening?

Numerous studies have shown poor or unsatisfactory levels of knowledge about tests received in prenatal care.^{lxvii} From her overview of information presented about prenatal disabling traits, Adrienne Asch concluded that the information provided about targeted prenatal conditions were generally too negative, tending not to recognize that disabling conditions do not lead to lower quality of life.^{lxviii} Other researchers have shown that information provided to parents at the prenatal testing stage is more negative than information provided at other times, and more negative than information provided to parents who already have an affected child.^{lxix}

Service delivery, or the way in which test taking is presented and/or offered, also affects choice. Researchers have found that patients are more willing to undergo tests when part of a routine visit, rather than separate visit.^{lxx} But the “routinization” of prenatal testing is associated with lower rates of informed choice, as compared to when the test is presented as “optional.”^{lxxi} In some cases, informed consent is completely absent; as patients receive results of blood screening tests without even knowing they consented to such testing.^{lxxii} Few methods for facilitating informed consent have been *proven* to ensure that the decisions made by patients are “informed”, and the current difficulties with providing information and counseling to prenatal patients will carry over to the clinical use of NIPD.

It has also been suggested that NIPD may improve informed consent by reducing the risk

of miscarriage.^{lxxiii} In this way, NIPD may foster, rather than undermine, value-consistent choices, since the risk of miscarriage will no longer be a confounding concern. Still, others consider this difference – the lack of associated miscarriage risks – to be *the* reason why informed consent is likely to be eroded by NIPD – “[c]onfronted with a long needle or a trans vaginal probe, few, if any, women will undergo either procedure without understanding that something serious is happening. But if NIPD requires just one more tube of blood from the mother — and just one more signature on one more form — how can we ensure that parents understand what they are consenting to?”^{lxxiv} The exact impact of NIPD on current issues regarding informed consent can only be postulated, but “[t]hirty years after the routine introduction of prenatal diagnostic tests we remain unaware of how women are counseled, the information and support they receive, and how this affects the quality and type of the quality and type of decisions they make.”^{lxxv} In light of the current difficulties with prenatal screening and diagnostics, and the unique issues raised by NIPD, it is more likely that the “information explosion from NIPD,”^{lxxvi} will only bombard the public with early term information that it is difficult to interpret, hard to accept, and even harder to use as the basis for medically sound decisions.

NIPD AND DISABILITY RIGHTS

Not only does NIPD provide Peter and Susan with earlier information to prepare for a child with Down’s syndrome; it provides them with the choice to avoid having another child with a disability completely . . .

The thought of never having a child with a genetic-based condition, such as Down’s syndrome, or Tay-Sachs, or sickle-cell anemia, may sound appealing to some at first. But the consequences for those with these conditions; the effect on parents making these decisions; and

the impact on clinicians prompting such selection creates a different picture.^{lxxvii} To begin, the tensions between prenatal diagnostics and disability existed long before the introduction of NIPD. The so-called “disability rights critique of prenatal testing” involves three major contentions, including: (1) that prenatal diagnosis to detect disabling traits reinforces the medical model that disability is a problem to be solved, and in so doing, overshadows the more important issue of societal discrimination against people with disabilities; (2) supports parental expectations of “perfect” children^{lxxviii}; and (3) selective abortions based on predicted disability is too often associated with misinformation about living with and raising a child with a disability.^{lxxix} As discussed above, NIPD effectively works to eliminate the “checkpoints” that currently exist with regards to the use of prenatal genetic diagnosis (i.e. cost, associated risks, additional strain and frustration for surgical procedures); and as such, NIPD threatens to exacerbate and make “routine” the issues that disability advocates are most concerned about.

The history of discrimination against people with disabilities instructs many arguments made by advocates with regards to prenatal diagnostics.^{lxxx} In the nineteenth century, social policy for persons with disabilities, whether mental, mobile, vision, or any other impairment, involved labeling them all “feeble-minded” and separating them from the rest of societal activities.^{lxxxi} In 1846, the first efforts to aid persons with disabilities was carried out by Dr. Samuel Gridley Howe, employed by the Massachusetts legislature “to study the problem of the feeble-minded and recommend policies for their relief.”^{lxxxii} Through Howe’s work, the first school for disabled children – the Massachusetts School for Idiotic Children and Youth - was established. Yet as the twentieth century neared, Howe’s model of education and reintegration of persons with disabilities into the rest of society, gave way to institutionalized custodial care.^{lxxxiii} By the 1920s,^{lxxxiv} scholarly calls for involuntary sterilization and institutionalization

were commonplace, and in 1927 the US Supreme court made these policies into law when it upheld a Virginia compulsory sterilization statute on the rationale that “three generations of imbeciles is enough.”^{lxxxv} From the 1920’s until the mid-1960s, involuntary sterilizations continued. Thousands were subjected to compulsory sterilization for “genetically related reasons.”^{lxxxvi}

Since the 1970s society has taken many steps forward with regards to the rights of disabled persons, including the passing of the American Disabilities Act. Still a contradiction in contemporary goals exists. While discrimination against persons living with disabilities is no longer tolerated, the termination of diseased/disabled pregnancies is not only promoted, it threatens to become common practice.^{lxxxvii} While no scholar has argued in the affirmative for diminishing the rights of persons of protected classes, many have argued for sex selection and prenatal genetic trait selection. John A. Robertson, for example, has argued that preconception gender/sex selection is ethically acceptable in certain situations.^{lxxxviii} For Robertson, “[i]f a practice is not motivated by judgments or evaluations that one gender is superior to the other, or does not lead to discrimination against one gender, it is not sexist.” In these situations, according to Robertson and others, preconceived parental dreams based on the presence of certain traits may be based on “legitimate” and studied rationales, such as sexual similarity, sexual complementarity, and family balancing.^{lxxxix} Disability advocates, however, argue that prenatal detection technology reinforces, rather than causes discriminatory preconceptions; that notions of superiority and inferiority are already engrained, not brought out by specific reproductive choices. As such, “[t]hat prospective parents do not intend to send a hurtful message does not speak to the fact that many people with disabilities receive such a message and are pained by it,”^{xc} and the particular motives of expectant patients fail to change the impact on disability

rights, and felt by persons with disability.

Furthermore, disability advocates argue that NIPD developers, providers, supporters, and the patients who use this technology, are often misinformed about the undesired traits selected against. Living with a disabling condition does not eliminate an individual's quality of life, and families including children with disabilities are more similar to families without than society is willing to recognize.^{xci} Disability rights advocates often target statements such as:

“[p]rebirth selection of offspring characteristics . . . in most instances does not harm offspring or other important interests. In most cases, the purpose of the selection action is to produce a child that will be healthier and happier than the child born without selection . . .”^{xcii}

for the unexamined and unjustified attitude that it reflects about children with disabilities.^{xciii}

The personal views of clinicians, and the manner in which clinicians provide genetic information, may also contribute to misinformation on the impact of disabling traits. To this affect, Clarke argues that “acceptance of responsibility for the consequences,” including the potential discriminatory implications for persons affected with genetic conditions, is part of the “*full price*” of intervening in prenatal care/decisions^{xciv}. Despite the concepts of patient autonomy and nondirectiveness (a principle of genetic counseling), in practice the personal views of clinicians often work to “steer women” towards (or away from) prenatal screening and diagnostics.^{xcv} Informed consent and informed decision-making cannot occur if “information about what disability is really like for children with disabilities and for their families” is not provided – information based on experience, from families that have children with disabilities.^{xcvi}

Many, if not most, of us would have trouble with the notion that “someone like you will never be born again,” whatever our genetic condition may be. But whether Down's syndrome and other disabling conditions are traits which the public is ready to be “rid” of must be addressed. Furthermore, to what extent the difficulties faced by persons with disabilities are

societal – and therein not a “problem” that should or can be addressed through NIPD – must be considered.^{xcvii} Is “the last child with Down syndrome” more like “the last child with glasses”, “the last child with polio”, or “the last child with black skin?” For persons with disabilities and disability advocates, it is not mere inconvenience,^{xcviii} or disease that the implementation of NIPD threatens. It is their identity.

LESS THAN LIFE-ALTERING GENETIC CONDITIONS & NIPD

The implications of NIPD for such conditions as Down’s syndrome, Tay-Sachs, or cystic fibrosis will continue to be debated. But what about conditions such as polydactylism (the addition of digits on the hands and feet), hereditary deafness, cleft lip, or any other condition that may be deemed a “minor” disability? Do these conditions justify prenatal detection? How will NIPD affect the perspectives of traits that are less-than life altering?

In their two-year investigation, Erik Parens and Adrienne Asch took a close look at the impact of prenatal diagnosis on “minor” disabling traits.^{xcix} They note, among other things, our current lack of consensus with regard to the definition of “serious” medical conditions. A study of 1,481 certified genetic professionals^c showed substantial overlap among what genetic/congenital conditions were considered “lethal”, “serious but not lethal”, and “not serious”.^{ci} Sixty-four percent of the conditions listed as lethal by some respondents were considered “serious but not lethal” by others. Of the two hundred and sixty seven conditions listed as “not serious,” forty-six percent of respondents listed the same as “serious.” Fifty-one conditions appeared in all three categories. These conditions included Down’s syndrome, cystic fibrosis, and Huntington disease, as well as,

ectrodactyly, and hereditary deafness.^{cii}

The last two conditions are distinct from others, at least in their severity. Still, future applications of NIPD may be used to detect and select against pregnancies with such seemingly minor genetic conditions as a missing finger (ectrodactyly). Recall the controversial account of Bree Walker Lampley,^{ciii} whose decision to have children carrying her genetic trait for ectrodactyly (a genetic condition causing a deletion in the digits of the hands and feet) caused public backlash. Radio talk-show host, Jane Norris spent two hours of her show questioning whether it was *fair* of Lampley to risk having more “deformed” children, and taking calls from listeners who suggested it was “irresponsible” to bear a child with such traits.^{civ} The impact that NIPD will have on the already contentious issues regarding “minor” disabling conditions is difficult to determine. What can be said is that NIPD will allow for faster, and perhaps rash, decisions about all fetal characteristics that may diverge from the “norm.”

Often, the argument against the birth of children with “minor” disabilities is the difficulty that these children will experience. But living with a disability “need not be detrimental either to an individual’s prospects of leading a worthwhile life, or to the families in which they grow up, or to society at large.”^{cv} The Smith family, celebrating 180 years of hereditary deafness, provided stories to this effect; recalling how “the doctor broke the news by saying that he was sorry to tell them the children were deaf. For us, there is nothing to be sorry about. We're deaf and we don't mind.”^{cvi} Of course hardships may be encountered, but for a woman named Deidre, born with bilateral cleft lip and cleft palate: “why, you ask, am I glad to have gone through all that torture? I believe that any person who has to go through any hardship as a child or adolescent has an advantage over

those that don't. We have an ability to sympathize that others don't, we become much stronger people and develop much more close-knit support systems.”^{cvi} Before the controversy over her decision to birth children with her same genetic condition, Bree Walker Lampley was “mostly” a legendary news anchor and activist, known for “taking her less-than-perfect hands out of her lap and placing them on the news anchor's desk where they could be seen by millions, in a medium where every blemish is magnified.”^{cvi}. What legitimate concerns, if any, does NIPD address, especially when technological advances in other fields have show such success in increasing access and opportunities for persons with “minor” disabilities?^{cix} More importantly, is society ready and willing to trade character – the strength and originality in a person’s nature – in order to normalize characteristics?

RESHAPING REPRODUCTIVE FREEDOM:

NIPD AND ABORTION

As Susan listens to the doctor’s information on NIPD, she recalls her pregnancy with Peter Jr., and the CVS procedure that she went through before. When the results of the CVS procedure revealed that Peter and Susan would have a child with Down’s syndrome, they prepared for the disability their child was to have. Peter began researching Down’s syndrome, and Susan enrolled them as members of the National Down’s Syndrome Society. Together they looked over the information about state and federal benefits for a child with disabilities, and so on. NIPD provides Peter and Susan with a new set of considerations. Now Peter and Susan can begin preparing much earlier, or not . . .

First, it must be noted that the legally recognized right to abortion is not at issue in this article. As Parens and Asch note, “[p]eople who make policy concerning the dissemination of genetic information have reached a consensus that the purpose of prenatal testing is to enhance reproductive choice for women and families – not to decrease the number of children with

disabilities who are born. Some have acknowledged, however, that there is 'a tension between the goals of enhancing reproductive choice and preventing the births of children who would have disabilities.’^{cx} The tension that these scholars discuss is a very real and practical concern. As well, the connection between NIPD and abortion is a matter of fact. As one commentator notes,

“ . . . from a dollars-and-cents perspective, [prenatal screening] is an unnecessary expense. Developers of prenatal testing, however, have justified these unnecessary expenses by demonstrating through cost-effectiveness studies that such costs can be offset to the private insurer or the public healthcare system, provided that enough children prenatally identified with Down syndrome are terminated.”^{cx}

Information for information’s sake cannot be the ultimate goal of NIPD in the clinical setting.

Developers and supporters of NIPD have acknowledged as much, often describing prenatal diagnostic information as a corollary right or obligation flowing from the right to an abortion.

“[P]rospective parents have the right to obtain preconception or prenatal information about the genetic characteristics of offspring, so that they may decide in a particular case whether or not to reproduce.”^{cxii} NIPD raises new and complex issues for both pro-life and pro-choice supporters. Before NIPD becomes standard practice, such issues require public discourse.

The association between NIPD and abortion has also informed the insurance standpoint: “[e]ach accurate detection presents the possibility of aborting a very sick fetus, which, if born, could cost its parents (and its parents' insurer) large amounts of money. Thus, the medical necessity standard may be a moot point when it comes to coverage of [NIPD].”^{cxiii} Under current insurance law, “medically necessity” – a concept of contentious definition – guides determinations of health care coverage. A procedure, which has been deemed “medically necessary,” is distinguished from experimental procedures, which are either not covered, or require more financial responsibility on the part of the insured. Although currently NIPD is as expensive as other prenatal diagnostic procedures,^{cxiv} further developments with sequencing and

DNA analysis techniques will probably allow NIPD to become the least expensive form of prenatal diagnosis within the next ten years.^{cxv} As a consequence, the cost of bringing a child to term with predicted disabled traits may very well be disfavored over covering NIPD tests, whether medically necessary or not.^{cxvi}

A woman's right to choose to continue a pregnancy is the cornerstone of the pro-choice movement. More so, "pro-choice" may be defined as the recognition and defense of a woman's right to self-determination regarding sex, sexuality, reproduction, and motherhood; and the promotion of equal access to abortive services, reproductive services, and sex education. The National Abortion and Reproductive Rights Action League (NARAL) webpage advertises its belief "in reducing the need for abortion" by way of "improving access to birth control and teaching young people comprehensive sex education." The incorporation of NIPD is likely to have an effect on many of the tenants of the pro-choice movement .

For instance, if women will be routinely confronted with decisions based on prenatal genetic information, will sex education now include genetic inheritance and disability? Will the routine use of NIPD transform the issue of choosing to have *this* pregnancy, into choosing to have *this particular* pregnancy^{cxvii}? To what extent does trait-selection abortion coincide with being pro-choice ? Is a "healthy pregnancy" destined to become a list of wanted versus unwanted traits? Will NIPD results provide a woman with information that she can use to make her decisions, or information that makes the decision for her?

The last questions is of great import to both the pro-life and pro-choice communities, because it considers the affect that health care professionals and other third-party persons will have on a woman's choice when NIPD information is available. As George Annas notes, "[w]hen non-invasive prenatal genetic testing is available and reasonably priced, there will be

tremendous pressure from many sources to use them.”^{cxviii} As well, as Erik Parens and Adrienne Asch note, “in a health care delivery system ever more intent on keeping down costs, things are likely to get worse rather than better when it comes to fostering the dialogue and the counselor-patient relationship that ideally accompany prenatal testing.”^{cxix} For pregnant women to make informed *choices*, they must be provided with information and *alternatives*. Health insurers, both private and public, will have a great deal of influence on the alternatives that women are given, and the information that clinicians feel required to provide. Clinicians, including physicians, medical geneticists, genetic counselors, and others will also have a great affect on the alternatives that women feel they have. Currently the accounts of women who felt their decision was supported by professional third parties^{cxx} are as numerous as the accounts of women who felt that their decision was ignored or opposed.^{cxxi} For the right to choice and for the right to life to be real options, pregnant women cannot be pressured by third parties towards the choice of whether or not to terminate a pregnancy.

For the pro-life community, NIPD brings to the forefront the question of whether one *should* bear children with life-altering or life-threatening genetic conditions. It may also shift the pro-life focus (i.e. raising awareness and promoting adoption choices for low-income mothers), since NIPD will most often be used by expectant mothers of higher income, whose motivation for considering abortion will not be “whether she can raise this child,” but rather if this is “the child she wants to raise.” The usual adoption alternative (i.e. bringing the pregnancy to term and putting the child up for adoption) will no longer suffice. Additionally, NIPD may “normalize” abortions based on prenatal diagnostics. Will such routine decisions trivialize the significance of terminating a pregnancy? According to some, the benefits of NIPD do not outweigh the risk that “[e]very pregnancy becomes a ‘tentative pregnancy’ pending the results of prenatal

screening.”^{cxxii} How the pro-life community will handle the impact of NIPD on the frequency of abortion decisions has yet to be discussed.

Prior to NIPD, prenatal testing was already associated with high termination rates.^{cxxiii} But unlike these prior tests, NIPD provides more than an estimated likelihood that a fetus will be affected by the condition at issue (i.e. the limitation of prenatal screening)^{cxxiv}, and can be performed as early as the end of the first trimester of the pregnancy (i.e. the limitation of invasive prenatal diagnosis). The fact is, “[i]n contrast to the great volume of research on women’s decisions about prenatal testing, there is a dearth of research on women’s decision following the diagnosis of a fetal abnormality,”^{cxxv} and only a few studies have shown an association between prenatal information and subsequent abortions decisions.^{cxxvi} The routine implementation of NIPD may impose a trade-off – the increased risk of miscarriage *for* the increased likelihood of choosing to have an abortion. It seems eerily ironic that the means chosen to prevent the loss of pregnancies through prenatal genetic diagnosis are the same means likely to increase selection against pregnancies. However expansive one believes reproductive rights should be, NIPD is an impetus to reconsider and reevaluate these issues in light of a technological advance which promises to normalize genetic-based selective abortion.

PRENATAL GENETICS AND EUGENICS: A SLIPPERY SLOP

NIPD is part of a medical model of prenatal genetic care, which focuses on earlier, and more accurate detection of genetic impairments, not correction. In this way, prenatal genetic diagnosis is not designed to protect or promote healthy pregnancies, but may lead to institutionalized eugenics.^{cxxvii} In essence, there is a crucial difference between “preventing children from being born with Down’s Syndrome,” and “preventing children with Down’s

Syndrome from being born.” As well, although it may seem puzzling that our treatment of pregnancies with potential disabilities could express or threaten persons living with disabilities, “[w]hether and to what degree we respect someone depends not only on how we do treat him, but also on how we would treat him were circumstances different.”^{cxxviii} Any impact that NIPD could have on promoting or institutionalizing eugenic-style elimination must be addressed.

The association of eugenics with prenatal care is not new. In the 1920s, sterilization was the policy of choice and widely enforced by law.^{cxxix} Based on imprecise and generally incorrect concepts of inheritance, “old eugenic” techniques targeted those whom it was presumed would transmit undesirable traits to their offspring.^{cxxx} According to many scholars, the “new eugenic” movement focuses on the offspring directly. Unlike “old eugenics” techniques, now eugenics is based on individual choice instead of governmental policy. Rather than involuntary sterilization, new eugenic techniques include screening, diagnosing, and selectively terminating potentially affected fetuses. More accurate predictions of inheritance are constantly developed on the bases of molecular genetic principles. Finally, the scope of targeted conditions and traits has narrowed to pregnancies with predicted disability or disease.^{cxxxi} These differences aside, many recognize that prenatal genetic diagnosis is very much part of a modern science aimed at “[t]he perfect baby – a wide grin, ten fingers, ten toes, and the potential to become a doctor, Olympic athlete, or President of the United States”,^{cxxxii} or at giving “parents power over their children that parents cannot exercise once the children are born”,^{cxxxiii} or at providing “discretion to select – or not – the characteristics of [one’s] offspring”^{cxxxiv} – all of which are difficult to separate from “improving the human population by controlled reproduction and decreasing the occurrence of undesirable characteristics and conditions”^{cxxxv} – the very definition of eugenics.

On the other hand, it has been argued that the use of genetics in reproduction should not

be unnecessarily associated with “public forms” of eugenics.^{cxxxvi} Since procreative liberty provides for the right *not* to use reproductive genetics, as well as the right to use reproductive genetics and “prebirth” selection,^{cxxxvii} we are not in a situation of forced genetic selection. Additionally, “the harms thought to flow from prebirth selection decisions” do not justify legal and policy interference.^{cxxxviii} Finally, in light of the diverse individual attitudes towards offspring, reproduction, family and disability, and as long as public support of genetic selection does not transform into public coercion, widespread pressure or compelled prebirth selection is unlikely.^{cxxxix} A more immediate concern is individual procreative liberty, and “there may be no way to avoid recognizing the prebirth liberty of parents to exercise control over offspring characteristics,” in a society where reproductive choice is taken seriously.^{cxl}

But the association of eugenics and prenatal genetic diagnosis is not just a matter of deciding between governmental interference and individual freedom. Insurers, health professionals, advocacy groups, as well as other private individuals all have a stake in these decision, and will have a part in determining the extent to which “prebirth selection” remains voluntary. As one critic of the clinical implementation of NIPD notes, “[i]f, as seems likely, respect for autonomy continues, prospective parents will have to be *persuaded* that eugenic solutions are in their best interest.”^{cxli} Thus, whether continuing developments in the prenatal diagnosis field will led to institutionalized eugenics cannot be simplified to a question of “is there governmental force or not.” Rather, the public and policy-makers need to address eugenics concerns *way before* we get to the question of governmental force.

The delicate balance between individual reproductive freedom and social policy will continue to be a difficult area to navigate. Nevertheless, the ways in which NIPD and other forms of genetic diagnostics threaten our preservation of a non-eugenic society cannot be taken lightly.

And each step taken towards more controlled forms of reproduction, especially when premised on the detection and selection against assumed “bad” traits, must be implemented with caution, if implemented at all.

CONCLUSION

Stories by expectant and new mothers confronting the decision to test for disabling traits, and to make decision based on that information, are filling the Internet and other outlets.^{cxlii} Some expectant parents will want to use the NIPD plus abortion option, others will use NIPD results to prepare for the child they are going to have, and some will refuse the test. These individual choices are not what the public and policy makers should focus on. Instead, the issues raised in this article should encourage the public and policy makers to put NIPD into context; to consider whether the current context with regards to informed consent, direct-to-consumer regulation, the disagreement on “serious” medical conditions, *sufficiently* supports faster, predictive results.

NIPD raises certain issues and makes others more complicated. The introduction and continuing development of NIPD puts policy makers and the public to the task. Not only is technology developing quickly, but it also allows, for the first time, quick, easy, and perhaps rash pre-birth selection decisions. As prenatal genetic technology continues to develop and become commercialized, each incremental step will have to be justified in light of the risk of institutionalized eugenic practices. The development of NIPD requires us to question: at what point is “controlled breeding to increase the occurrence of desirable heritable characteristics” no longer just a matter of individual reproductive

choice.

Regardless of where one stands on abortion, or how one perceives “medical necessity”, we must question what standards should be adopted for prenatal care. We must recognize that all the issues raised in this article require us to answer “the question of what objectives the medical profession or society is pursuing through prenatal diagnosis.”^{cxliii} The concerns raised by NIPD are difficult; on the one hand, disease-free is the epitome of medical success. On the other hand, what we mean by “disease” and what efforts we take to become “free” of such conditions demands a great deal of discussion among the public and policymakers alike.

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- i. F. Lucy Raymond, *Molecular Prenatal Diagnosis: the Impact of Modern Technologies*, 30 *Prenatal Diagnosis* 674, 674 (2010); Michael J. Malinowski, *Coming into Being: Law, Ethics, and the Practice of Prenatal Genetic Screening*, 45 *HASTINGS L. J.* 1435, 14^{**} (1993-1994).
 - ii. Carolyn J. Chachkin, *What Potent Blood: Non-Invasive Prenatal Genetic Diagnosis and the Transformation of Modern Prenatal Care*, 33 *AM. J. L. & MEDICINE* 9, 9 (2007).
 - iii. Id.
 - iv. Id.
 - v. Id.
 - vi. Y.M. Dennis Lo et al., *Digital PCR for the Molecular Detection of Fetal Chromosomal Aneuploidy*, 104 *Proc. Nat’l. Acad. Sci.* 13116 (2007); see also H.C. Fan et al., *Noninvasive Diagnosis of Fetal Aneuploidy by Shotgun Sequencing DNA from Maternal Blood*, 105 *Proc. Nat’l. Acad. Sci.* 16266 (2008).
 - vii. Y.M. Dennis Lo, *Noninvasive prenatal diagnosis in 2020*, 30 *PRENATAL DIAGNOSIS* 702 (2010) (hereinafter *NIPD 2020*).
 - viii. Melissa Hill et al., *Incremental Cost of Non-invasive Prenatal Diagnosis Versus Invasive Prenatal Diagnosis of Fetal Sex in England*, 31(3) *PRENATAL DIAGNOSIS* 267 (Mar. 2011); Laura Clout, *Simple Blood Test for Down’s Syndrome Raises Prospect of Screening for Expectant Mothers*, *THE TELEGRAPH* (posted on Jun 21, 2008, 2:26AM BST); Chachkin, *supra* note 2, at 9. In contrast, amniocentesis is generally performed 14 to 20 weeks after pregnancy is confirmed. CVS is generally performed 10 – 13 weeks after the last menstrual cycle. Amniocentesis can also be performed later in the third trimester, unlike CVS. CVS can be used to collect larger samples, and provides faster results. *See also* Malinowski, *supra* note 1, at 1448, n.48.
 - ix. Chachkin, *supra* note 2, at 12.
 - x. Chachkin, *supra* note 2, at 12.

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- xi. CVS is associated with a risk of miscarriage, resulting in 1 out of every 100 pregnancies. For amniocentesis the risk of miscarriage ranges from 1 in 400 to 1 in 200. *See* Linda M. Hunt, *The Routine and the Traumatic in Prenatal Genetic Diagnosis*, 56 *PATIENT EDUCATION AND COUNSELING* 302, 302 (2005).
- xii. Henry T. Greely, Comment, Get Ready for the Flood of Fetal Gene Screening, *NATURE*, Jan. 20, 2011 at 289.
- xiii. Neil D. Avent et al., *Cell-Free Fetal DNA in the Maternal Serum and Plasma: Current and Evolving Applications*, 21 *CURRENT OPINION IN OBSTETRICS AND GYNECOLOGY* 175, 176 (2009).
- xiv. NIPD 2020, *supra* note 2 at 702-703.
- xv. Mark W. Leach, Abortions on Disabled Babies: The Prenatal Testing Sham, *LIFENEWS.COM*, available at <http://www.lifenews.com/2011/05/25/abortions-on-disabled-babies-the-prenatal-testing-sham/> (May 25, 2011, 11:59 AM).
- xvi. Avent, *supra* note 13, at 175.
- xvii. Avent, *supra* note 13, at 175.
- xviii. Greenly, *supra* note 12, at 289.
- xix. American College of Obstetricians and Gynecologists, Clinical Management Guidelines for Obstetrician-Gynecologists, Screening for Fetal Chromosomal Abnormalities, *OBSTETRICS & GYNECOLOGY* 217, 219 no. 77 (Jan. 2007).
- xx. *See* Susan Markens et al., 'Because of the risks': How US Pregnant Women Account for Refusing Prenatal Screening, 49 *SOC. SCIENCE & MED.* 359 (1999).
- xxi. Center for Disease Control & Prevention, *Draft Genetic Test Review: Cystic Fibrosis: Clinical Utility*, 4-26 (2002) [hereinafter *Draft Genetic Test Review*], available at <http://www.cdc.gov/genomics/gtesting/fiIe/print/FBR/CFCiIiUti.pdf>.
- xxii. Chachkin, *supra* note 2, at 14.
- xxiii. Caroline F. Wright, *The Use of Cell-Free Fetal Nucleic Acids in Maternal Blood for Non-invasive Prenatal Diagnosis*, 15 *HUMAN REPRODUCTION UPDATE* 139, 140 (2009).
- xxiv. F. Lucy Raymond, *Molecular Prenatal Diagnosis: the Impact of Modern Technologies*, 30 *Prenatal Diagnosis* 674, 677 (2010). As a consequence of fetal DNA accounting for only 5-10% of the DNA in the maternal serum, current technology is best equipped at isolating fetal DNA by distinguishing paternally derived genes in fetal DNA, not found in the maternal DNA.
- xxv. Lo, *supra* note 1; Chachkin, *supra* note 2, at 11.
- xxvi. CVS and amniocentesis are the adopted standard of care methods for prenatal genetic diagnostic and both procedures are held to 98-99% accuracy standards. Chachkin, *supra* note 2, at 35.
- xxvii. Chachkin, *supra* note 2, at 37.
- xxviii. Peter A. Been and Audrey R. Chapman, Ethical Challenges in Providing Noninvasive Prenatal Diagnosis, 22 *CURRENT OPINION IN OBSTETRICS AND GYNECOLOGY* 128, 129 (2010); *see also* THE GENETICS AND PUBLIC POLICY CENTER JOHN HOPKINS UNIVERSITY, *Reproductive Genetic Testing: A Regulatory Patchwork*, ("In the United States, there is no uniform or comprehensive system for the regulation of assisted reproductive technologies, including reproductive genetic testing. The federal government does not have direct jurisdiction over the practice of medicine. Moreover, it has banned all federal funding for research involving the creation or destruction of embryos. Consequently, the
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- regulatory framework for reproductive genetic testing in the United States is characterized by a patchwork of federal and state regulation.”), *available at* http://www.dnapolicy.org/policy.international.php?action=detail&laws_id=63 (January 2004).
- xxix. Peter A. Been and Audrey R. Chapman, Ethical Challenges in Providing Noninvasive Prenatal Diagnosis, 22 CURRENT OPINION IN OBSTETRICS AND GYNECOLOGY 128, 129 (2010).
- xxx. Been, *supra* note 27, at 129; *see also* Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past – Present and Future?*, 36 CONN. L. REV. 125, 171 (2003-2004) (“... the prevalence of academic-industry collaborations and general integration of academia and industry in contemporary biomedical research and development necessitate higher standards of disclosure to prevent and manage conflicts of interest that threaten research integrity and patient safety.”) (“The accuracy and methods used in a direct-to-consumer NIPD sex test have been raised but not answered in a scientific or medical forum.”)
- xxxi. The Lo group is working with and funded by Sequenom of San Diego, California; the Quake group by Artemis Health of Menlo Park, California. *See* Greenly, *supra* note 2, at 290; and Leach, *supra* note 8, at 1.
- xxxii. Been, *supra* note 27, at 129-30; *see also* Leach, *supra* note 8, at 2 (“Once available, it is expected that the testing will have almost universal uptake. Indeed, the test developers are banking on this—literally, in the case of Sequenom, a publicly traded company whose stock price is rebounding after plummeting from earlier, false reports about its testing.”).
- xxxiii. As discussed *supra*, p. 3, DNA analysis is limited in its ability to diagnosis certain conditions. Karyotyping, which requires physically isolated cells to culture, is used to detect fetal chromosomal conditions; PCR, to detect signal-gene abnormalities; and FISH, to diagnose both chromosomal and single-gene abnormalities. NIPD, on the contrary, is projected to detect all of the above as well as multiple genetic conditions simultaneously, as well as complete fetal genome sequencing. *See* Y.M. Dennis Lo, *Noninvasive Prenatal Diagnosis in 2020*, 30 PRENAT. DIAGN. 702 (2010).
- xxxiv. Lo, *supra* note, at 702-703; Been, *supra* note 27, at 129.
- xxxv. Been, *supra* note 27, at 129.
- xxxvi. Benn, *supra* note 27, at 129, 132.
- xxxvii. United States Government Accountability Office, *Nutrigenetic Testing – tests purchased from Four Web Sites Mislead Customers* 13, GAO-06-977T (July 27, 2006) (hereinafter *Nutrigenetic*).
- xxxviii. United States Government Accountability Office, *DIRECT-TO-CONSUMER GENETIC TESTS: Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices* (Thursday, July 22, 2010)
- xxxix. *Nutrigenetic*, *supra* note 37, at 7.
- xl. Id.
- xli. Id. at 8.
- xlii. Michael J. Malinowski, *Coming into Being: Law, Ethics, and the Practice of Prenatal Genetic Screening*, 45 HASTINGS L. J. 1435, 1494 (1993-1994).

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- xliii. Diana W. Biachi, et. al., Noninvasive Prenatal Diagnosis of Fetal Rhesus D: Ready for Prime(r) Time, 106 OBSTETRICS & GYNECOLOGY 841 (Oct. 2005).
- xliv. Many legitimate reasons for sex selection exists, including adherence to certain religious beliefs and cultural traditions, John A. Robertson, *Preconception Gender Selection*, 1 A. J. BIOETHICS 1, 3 (Winter 2001), but these are often not medically motivated rationales.
- xlv. T. Mukherjee, et al., Unexpected Gender Bias Found in IVF Cycles for Sex Selection, 88 FERTILITY & STERILITY (Supplement 1) S134 (2007). (A 2007 study found that only 4 of 30 reviewed *in vitro* fertilizations with pre-implantation genetic diagnosis procedures were conducted to avoid sex-linked diseases. The rest were performed for elective sex selection.)
- xlvi. See Dorothy Wertz, *Ethical and Legal Implications of the New Genetics: Issues for Discussion*, 35 SOC. SCI. MED. 495, 501 (1992); John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U.L. Rev. 421, 446 (1996) (hereinafter *Genetic Selection of Offspring*); American Society for Reproductive Medicine, *Preconception Gender Selection for Nonmedical Reasons*, 82 FERTILITY AND STERILITY (Supplement) S232, S233 (2001).
- xlvii. Edgar Dahl, et al., Preconception Sex Selection Demand and Preferences in the United States, 85 FERTILITY AND STERILITY 468, 473 (Feb. 2006) (Researchers noted that patients dealing with infertility conditions expressed much greater desire for sex selection, at an observed rate of 40.8% as compared to 8% for patients not dealing with infertility.).
- xlviii. Their results showed that of the 1,197 respondents surveyed, only 8% would use preconception sex selection technology, 74% were opposed to the technology, and less than 20% were undecided about its use. In that study the researchers asked whether respondents would be willing to use sex selection technology if it required taking a simple pill to ensure a certain sex of the fetus, many answered differently. Respondents willing to use sex selection technology increased by 10%, and the number of respondents who answered undecided rose to above 20%
- xliv. William Saletan, *Fetal Subtraction: Sex Selection in the United States*, SLATE.com, available at www.slate.com/id/2188114 SLATE (posted Thursday, Apr. 3, 2008, at 7:59AM ET)
- i. George J. Annas, *Ethical aspects of non-invasive prenatal diagnosis: medical, market, or regulatory model?*, 47 Early Human Development (Supplement) S5, S8 (1996).
- ii. Saletan, *supra* note 49.
- iii. Annas, *supra* note 50, at S8.
- liii. Dan Vorhaus, *The FDA and DTC: Time to Set the Record Straight*, www.genomicslawreport.com, available at <http://www.genomicslawreport.com/index.php/2011/03/31/the-fda-and-dtc-time-to-set-the-record-straight/> (posted on Mar. 31, 2011) (hereinafter *FDA and DTC*).
- liv. Kat Zambon, *Case Studies Illustrate the Dilemmas of Genetic Testing*, American Association for the Advancement of Science, www.aaas.org (posted April 29, 2011) (last visited June 28, 2011) (quoting Donna Messner, Gordon Cain Fellow at the Chemical Heritage Foundation).
- lv. Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past – Present and Future?*, 36 CONN. L. REV. 125, 133 (2003-2004).

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- lvi. Malinowski, *supra* note 40, at 170.
- lvii. Chachkin, *supra* note 2, at 14 (“Because of the fetal and maternal hazards . . . medical professionals recommend the procedures almost exclusively for women aged 35 and older, unless the fetus is at particular risk for genetic disease or abnormality (e.g. because of a positive family history).”).
- lviii. Zambon, *supra* note 55.
- lix. Id.
- lx. Id.
- lxi. Heuvel, *supra* note 65, at 27 (“Despite the fact that separating test offer and uptake provides time for reflection, there is no empirical evidence to support or indeed refute the implicit assumption that this period of reflection actually facilitates informed choice. Whilst conducting counseling and testing on the same day has been associated with higher uptake rates, immediate choices to undergo screening are not necessarily less well informed.”) (citing RP Lorenz et al., *Encouraging Patients to Undergo Prenatal Genetic Counseling Before the Day of Amniocentesis: Its Effect on the Use of Amniocentesis*. 30 J REPROD. MED. 933 (1985).).
- lxii. Hunt, *supra* note 11, at 311 (noting that further research is required to “to draw any conclusions beyond our small sample.”)
- lxiii. *New Diagnostic Guidelines*, *supra* note 24 (quoting David Litwack).
- lxiv. Erik Parens & Adrienne Asch, *The Disability Rights Critique of Prenatal Genetic Testing: Reflections and Recommendations*, 29 THE HASTINGS CENTER REPORT (SPECIAL SUPPLEMENT) S1, S3 (Sep. - Oct., 1999).
- lxv. Parens, *supra* note 44, at 33 (“Based on respect for persons, and as articulated in the National Society of Genetic Counselors Code of Ethics, genetic counselors are committed to helping individuals understand genetic information and act on that information in accordance with their own values.”) (internal citation omitted).
- lxvi. Ananda van den Heuvel et al., *Will the Introduction of Non-invasive Prenatal Diagnostic Testing Erode informed Choices? An Experimental Study of Health Care Professionals*, 78 PATIENT EDUCATION AND COUNSELING 24 (2010). (“[H]ealth care professionals are likely to approach counseling and service provision of non-invasive diagnostic tests in a clinically significantly different way to invasive procedures.”) In this study, three aspects of informed consent were compared, including written consent, reflection time, and the information considered important to communicate during counseling session. Only 68% of the respondents indicated that NIPD testing should be preceded by written consent, compared to 96% of respondents who indicated that written consent should precede invasive prenatal diagnosis. Similarly, only 74% of the respondents who received the NIPD or blood screening vignettes considered time for reflection before conducting the test as an important clinical practice. In comparison, 94% of the respondents who received the invasive prenatal diagnosis vignette indicated that the presentation of test information and the actual testing should take place on different days. For both timing preferences and perceived need to sign a consent form, the results showed no significant difference between the NIPD vignettes and prenatal blood screening vignettes.
- lxvii. Theresa M. Marteau & Eliabeth Dormandy, *Facilitating Informed Choice in Prenatal Testing: How Well Are We Doing?*, 106 AMERICAN JOURNAL OF MEDICAL GENETICS 185, 186 (2001).

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- lxviii. Adrienne Asch, *Prenatal Diagnosis and Selection Abortion: A Challenge to Practice and Policy*, 89 AM. J. PUB. HEALTH 1649 (1999) (hereinafter Asch – *Practice and Policy*).
- lxix. Wilfond A. Lipmman, Twice-told Tales: stories about Genetic Disorders, 51 AMERICAN J. HUMAN GENETICS 936 (1992); G.L. Loeben et al., Mixed Messages: Presentation of Information in Cystic Fibrosis Screening Pamphlets, 63 AMERICAN J. HUMAN GENETICS 1181 (1998).
- lxx. Elizabeth Dormandy et al., Informed Choice to Undergo Prenatal Screening: A Comparison of Two Hospitals Conducting Testing either as part of a Routine Visit or Requiring a Separate Visit, 9 J. MED. SCREEN. 109 (2002).
- lxxi. Matthis van den Berg, et al., Are Pregnant Women Making Informed Choices About Prenatal Screening? 7 GENETICS IN MEDICINE 332 (2005).
- lxxii. Greenly, *supra* note 4, at 291; *see also* Theresa M. Marteau, et al., Screening for Downs' Syndrome, 297 B.M.J. 1469 (1988) (describing the psychological effects on people who received false positive results and suffering high levels of anxiety, even after subsequent testing showed no signs of the disease.)
- lxxiii. Heuvel, *supra* note 65, at 27.
- lxxiv. Greenly, *supra* note 4, at 291
- lxxv. Marteau, *supra* note 58, at 189.
- lxxvi. NIPD 2020, *supra* note 2 a
- lxxvii. *See* HELGA KUHSE, PREVENTING GENETIC IMPAIRMENTS: DOES IT DISCRIMINATE AGAINST PEOPLE WITH DISABILITIES?, *in* GENETIC INFORMATION: ACCESS, ACQUISITION, AND CONTROL 17, 17 (eds. Thompson & Chadwick, 1999) (“On the face of it, the avowed goal of the new genetics – “to deliver today’s children and future generations from genetic disease” – would seem unobjectionable [T]here is a cluster of distinct dissenting voices – voices found in the critical disability rights literature – which charge that the very endeavour that seeks to prevent genetic disability and disease is morally flawed because it discriminates against, and devalues the lives of, disabled people.”)(internal citation omitted).
- lxxviii. The actual formulation of point number two is, “In rejecting an otherwise desired child because they believe that the child’s disability will diminish their parental experience, parents suggest that they are unwilling to accept any significant departure from the parental dreams that a child’s characteristics might occasion.” Parens, *supra* note 44, at S13. In explaining this tenant, the authors discuss how prenatal testing may foster “a ‘fantasy and fallacy’ that “parents can guarantee or create perfection” for their children.” *Id.* at S17 (referencing Caroline Moon, unpublished paper of file with Luce Program at Wellesley College, 1999.)
- lxxix. Parens, *supra* note 44, at S13; Adrienne Asch, *Disability Equality and Prenatal Testing: Contradictory or Compatible?*, 30 FL. ST. UNIV. L. REV. 315, 316 (2003).
- lxxx. Parens, *supra* note 44, at 4 (“If one thinks for even a moment about the history of our society’s treatment of people with disabilities, it is not difficult to appreciate why people identified with the disability rights movement might regard such testing as dangerous.”)
- lxxxi. David Pfeiffer, *Overview of Disability Movement: History, Legislative Record, and Political Implications*, 21 POL’Y STUDIES J. 724, 724-25 (1993).
- lxxxii. *Id.*
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- lxxxiii. Id.
- lxxxiv. Id.
- lxxxv. Buck v. Bell, 274 U.S. 200, 207 (1927).
- lxxxvi. Pfeiffer, *supra* note at * 725-26.
- lxxxvii. Joan Retsinas, *The Impact of Prenatal Technology Upon Attitudes Toward Disabled Infants*, 9 RES. SOC. HEALTH CARE 75, 89-90 (1991).
- lxxxviii. *Genetic Selection of Offspring*, *supra* note 46, *passim*.
- lxxxix. Robertson, *supra* note 44, at 5 (quoting CHRISTINE OVERALL, ETHICS AND HUMAN REPRODUCTION 27 (Allen and Unwin, eds., Boston 1987)).
- xc. Parens, *supra* note 44, at S15.
- xcii. Parens, *supra* note 44, at 20-22 (“Three disability researchers in the Hastings Center group, Philip M. Ferguson, Alan Gartner, and Dorothy K. Lipsky – analyzed empirical data on the impact of children with disabilities on families. Their review, surprising to many, concludes that the adaptational profiles of families that have a child with a disability basically resembles those of families that do not.”) (citing National Down Syndrome Congress, *Position Statement on Prenatal Testing and Eugenics: Families’ Rights and Needs*, available at <http://members.carol.net/ndsc/eugenics.html>; Little People of America, *Position Statement on Genetic Discoveries in Dwarfism*, available at http://www2.shore.net/~dkennedy/dwarfism_genetics.html.)
- xciii. *Genetic Selection of Offspring*, *supra* note 46, at 464.
- xciv. See Asch, *supra* note 65, at 1650 (“Less often discussed by clinicians is the view, expressed by a growing number of individuals, that the technology is itself based on erroneous assumptions about the adverse impact of disability on life.”)
- xcv. Gerhard Wolff & Christine Jung, *Nondirectiveness and Genetic Counseling*, 4 J. GENETIC COUNSELING 3, 17-18 (1995).
- x cvi. Neil A. Holtzman, *Eugenics and Genetic Testing*, 11 SCI. IN CONTEXT 397, 408 (1998).
- x cvii. *Practice and Policy*, *supra* note 49, at 1654 (arguing that if the rights of persons with disabilities are to be respected and protected in prenatal diagnostics, then “the tone, timing, and content of the counseling process cry out for drastic overhaul.”).
- x cviii. Kuhse, *supra* note 74, at 20 (“ . . . if I lived in a society where being in a wheelchair was no more remarkable than wearing glasses and if the community was completely accepting and accessible, my disability would be an inconvenience and not much more than that. It is Society which handicaps me, far more severely and completely than the fact that I have spina bifida.”) (quoting Allison Davis, *From Where I Sit*, 19 (Triangle, 1989).)
- xcix. Id.
- c. Parens, *supra* note 44, at 8-10.
- c. Including individuals certified by the American Board of Medical Genetics, the American Board of Genetic Counseling, the European Society of Human Genetics, the Canadian College of Medical Genetics, or the Ibero-American Society of Human Genetics (an organization of professionals from Spanish and Portuguese-speaking nations). The majority of the respondents were members of the Canadian College of Medical Genetics, with less than 40% of the respondents were from Spanish or Portuguese-speaking nations. Dorothy C. Wertz & Bartha Maria Knoppers, *Serious Genetic Disorders: Can or*

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- Should They be Defined*, 108 AM. J. OF MEDICAL GENETICS 29 (2002) (hereinafter *Serious Genetic Disorders*).
- ci. *Serious Genetic Disorders*, *supra* note 89, at 31-33.
- cii. Id.
- ciii. Carole Ashkinaze, *Trampling on Anchorwoman's Right to Give Life*, CHICAGO SUN-TIMES SECTION:EDITORIAL 39 (Aug. 25, 1991); Parens, *supra* note 52, at S9-S10.
- civ. Ashkinaze, *supra* note 92, at 39; Parens, *supra* note 52, at S9-S10.
- cv. Parens, *supra* note 44, at S4.
- cvi. Sarah Tavner, *Celebrating 180 Years of Deafness*, www.guardian.co.uk, available at <http://www.guardian.co.uk/lifeandstyle/2008/may/31/familyandrelationships.disability> (posted on May 31, 2008).
- cvii. Living with Cleft Lip and Palate, <http://deeanddall2.tripod.com/index.htm> (last visited June 30, 2011).
- cviii. Ashkinaze, *supra* note 92, at 39
- cix. See Tayner, *supra* note 100 (“Technology has changed the experience of deafness over the generations, even in my lifetime. We didn't have a telephone when I was growing up. It was before the invention of the minicom textphone or fax or mobile texting, so deaf people had no access to telecommunications.”); see also [Dailymail.co.uk](http://www.dailymail.co.uk), Schoolboy with 31 fingers and toes has surgery to remove his extra digits, available at <http://www.dailymail.co.uk/news/article-1260245/Schoolboy-31-fingers-toes-surgery-remove-extra-digits.html> (last updated on Mar. 24, 2010).
- cx. Parens, *supra* note 44, at 6.
- cxii. Leach, *supra* note 8 at 2.
- cxiii. Robertson, *supra* note 44, at 4.
- cxiiii. Chachkin, *supra* note 2, at 40.
- cxv. Hill, *supra* note 3, at *passim*;
- cxvi. See Lo, *supra* note 8, at 702- 703.
- cxvii. Chachkin, *supra* note 2, at 40.
- cxviii. See Parens, *supra* note 44, at S15 (“According to Asch, most abortions reflect a decision not to bring any fetus to term at this time; selective abortions involve a decision not to bring this particular fetus to term because of its traits. Pro-choice individuals within and outside the disability community agree that it is morally defensible for a woman to decide [against an unwanted pregnancy] The question is whether that decision is morally different from a decision to abort an otherwise-wanted fetus.”)
- cxix. Annas, *supra* note 50, at S11.
- cxix. Parens, *supra* note 44, at S11.
- cxix. See Malinowski, *supra* note 1, at 1472 – 1475 (Recalling her decision to terminate a pregnancy predicted to have spina bifida, this patient found “[m]y family, genetic counselor, and the doctor who performed the procedure got me through it all. They were all great.”)
- cxix. See Parens, *supra* note 44, at S6-S7 (providing one example from a “study designed to understand the experience of mothers who received a prenatal diagnosis of Down syndrome and chose to continue the pregnancy”, wherein “one of the mothers who received a diagnosis of Down syndrome reported the following exchange:

Obstetrician: *You have to move quickly. There is a doctor at [Hospital X] who does late-term abortions.*

Mother: *No, I told you I'm not going to have an abortion.*

Obstetrician: *Talk to your husband. You might want to think about it.'*

. . . . Advising a patient to discuss a major life decision with her spouse is not prima facie problematic, much less discriminatory. According to their interpretation, however, these words reveal the physician's *unwillingness or inability to respect this woman's already stated decision* to continue the pregnancy with the fetus carrying a disabling trait.” (emphasis added) (referencing David T. Helm, Sara Miranda, & Naomi Angoff Chedd, *Prenatal Diagnosis of Down Syndrome: Mothers' Reflections on Supports Needed from Diagnosis to Birth*, 36 MENTAL RETARDATION 55, 57 (1998).).

- cxxii. Mitchell CB. THE CHURCH AND THE NEW GENETICS in GENETIC ETHICS (Kilner JF, Pentz RD, Young FE, eds., WM B Eerdmans Publish'g Co.) (1997).
- cxxiii. Leach, *supra* note 8 at 1 (“Already, existing prenatal testing is followed by high termination rates, exceeding 70 percent in California, and 90 percent in England and Europe. At this high percentage, it is more accurate to call it an “elimination rate.” With each advance in prenatal testing, the next generation of children born with Down syndrome is smaller, so much so that there are close to 50 percent fewer children born with Down syndrome than if all were carried to term.”);
- cxxiv. Chachkin, *supra* note 2, at 10-11 (“Screening test impose a lower threshold of accuracy and merely help identify an at-risk population for additional testing . . .”)
- cxxv. Theresa M. Marteu & Elixable Dormandy, *Facilitating Informed Choice in Prenatal Testing: How Well Are We Doing?*, 106 AMERICAN JOURNAL OF MEDICAL GENETICS 185 (2001).
- cxxvi. Sue Hall et al., *Health Professionals' reports of information given to parents following the Prenatal Diagnosis of Sex Chromosome Anomalies and Outcomes of Pregnancies: A Pilot Study*, 23 PRENATAL DIAGNOSIS 535 (2003); Caroline M. Ogilvie et al., *The Future of Prenatal Diagnosis: Rapid Testing or Full Karyotype? An Audit of Chromosome Abnormalities and Pregnancy Outcomes for Women Referred for Down's Syndrome Testing*, 112 B.J.O.G.: AN INTERNATIONAL JOURNAL OF OBSTETRICS & GYNECOLOGY 1369 (Oct. 2005).
- cxxvii. Mark W. Leach, *Abortions on Disabled Babies: The Prenatal Testing Sham*, LIFE NEWS.COM, available at <http://www.lifenews.com/2011/05/25/abortions-on-disabled-babies-the-prenatal-testing-sham/> (May 25, 2011, 11:59 AM).
- cxxviii. Rebeca Stangl, *Selective Terminations and Respect for the Disabled*, 35 J. MED. AND PHILOSOPHY 32 – 45 (2010) (concluding, “respecting the disabled community while at the same time advocating for the selective termination of disabled fetuses or infants” creates moral issues with regards to respect, and “should at least give us pause before advocating selective terminations on the basis that disabled infants should be replaced with normal ones.”)
- cxxix. Holtzman, *supra* note 84, at 398.
- cxxx. Id.
- cxixxi. Id.
- cxxxii. Malinowski, *supra* note 1, at 1436.

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- cxxxiii. *Genetic Selection of Offspring Characteristics*, *supra* note 46, at 480.
- cxxxiv. Id. at 479.
- cxxxv. "eugenics." Oxford American Dictionaries. (Oxford University Press, 1999).
- cxxxvi. *Genetic Selection of Offspring Characteristics*, *supra* note 46, at 468-69.
- cxxxvii. Id.
- cxxxviii. Id. at passim.
- cxxxix. Id. at 479.
- cxl. *Genetic Selection of Offspring Characteristics*, *supra* note 46, at 482.
- cxli. Holtzman, *supra* note 84, at 397 (emphasis added).
- cxlii. Suzy Evans, Who's Afraid of Down's Syndrome, <http://whosafraidofdownsyndrome.blogspot.com/> (last visited Jun. 7, 2011) (A woman's account of her difficulty dealing with the positive prenatal results for Down's syndrome and subsequent birth of her child.) http://www.pregnancy-info.net/forums/Possible_Complications/Blood_test_came_out_postive_for_downs_syndrome_only_21_yrs/ (follows a dialogue between numerous expectant and new mothers dealing with positive blood tests for Down's syndrome.); http://www.cafemom.com/answers/837519/Down_Syndrome_testing_Positive; Poll: Non-Invasive Prenatal Testing, http://community.babycenter.com/post/a27877103/poll_non_invasive_prenatal_testing?cpg=3&csi=2347974870&pd=2 (last visited Jun. 7, 2011).
- cxliii. Wolff, *supra* note 85, at 18.