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Protecting Health Information In Utero: A Radical Proposal

Luke Isaac Haqq

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PROTECTING HEALTH INFORMATION IN UTERO: A RADICAL PROPOSAL

*Luke Isaac Haqq**

*This Article introduces an underappreciated space in which protected health information (“PHI”) remains largely unprotected, a fact that will become only more problematic as clinical medicine increasingly turns to genomics. The past decade has seen significant advances in the prevention of birth defects, especially with the introduction of clinical preconception, prenatal, and neonatal genomic sequencing.¹ Parental access to the results of embryonic and fetal clinical sequencing is critical to reproductive autonomy; results can provide parents with important considerations for determining whether to seek or avoid conception, as well as for deciding whether to carry a pregnancy to term.² The information can also prepare parents for the anticipated accommodations necessary for raising a child affected by complications from congenital disease.³ PHI retrieval in the perinatal context, however—from prenatal testing to state-run newborn screening programs—raises important concerns, especially in light of growing reliance on genomic data: *Roe v. Wade* clearly recognizes*

* History of Medicine Program, University of Minnesota, Twin Cities; haqq0004@umn.edu. I am grateful to Vanessa Laird, Susan Wolf, Gabriella Manduca, Rachel DiBenedetto, and several editors of the Journal for their helpful comments on earlier drafts.

¹ Luke Haqq, Note, *Of Mosquitoes, Adolescents, and Reproductive Rights: Public Health and Reproductive Risks in a Genomic Age*, 101 MINN. L. REV. 827, 829–30 (2016) [hereinafter Haqq, *Of Mosquitoes, Adolescents, and Reproductive Rights*].

² *Id.*

³ *Id.* (“With such reproductive choice-generating technologies available in the U.S., parents can now access much of their child’s health information from sources including routine maternal serum tests during pregnancy visits, specific tests parents may request be done on the fetus prior to birth or the infant after birth, and state-run newborn screening programs. This increased access to information offers parents reproductive choices, helps prevent the existence of birth defects, and can mitigate their effects if they do occur.”).

that individuals critically accrue legal rights only upon birth,⁴ and neither federal law nor the law in most states recognizes that children have any inviolable privacy or autonomy rights to their PHI.⁵ This Article notes potential tensions between protecting PHI from the embryonic stage onward and the federal reproductive rights and federal and state statutory conceptions of PHI, but ultimately emphasizes that protecting PHI in utero adds an important layer of ex post protection for individuals who are actually born that need not conflict with a parent’s reproductive autonomy ex ante. The concerning lack of protection of PHI in utero is mounting in light of biotechnological advancements in genomic sequencing generating large quantities of data and as a genomic healthcare system built on such information becomes a reality. This Article proposes protecting PHI as early on as embryonic stages by keeping it within a black box, opaque to unauthorized parties but transparent in relevant part when authorized parties request information relevant to decisions like abortion or childcare in minority. Such a proposal for a greater role of a best-interests standard in PHI protections merits discussion as a first step in imagining a landscape that protects PHI throughout an individual’s lifetime.

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⁴ *Roe v. Wade*, 410 U.S. 113, 158 (1973) (“[Our historical and jurisprudential analysis] persuades us that the word ‘person,’ as used in the Fourteenth Amendment, does not include the unborn.”).

⁵ Illustratively, in most states, unemancipated minors have no presumptive rights to refuse a parent’s decision to sequence the child’s genome, and if parents do request sequencing, “prevailing medical recommendations permit parents to choose that the results not be returned to the child, with the exception of results revealing a life-threatening condition.” Haqq, *Of Mosquitoes, Adolescents, and Reproductive Rights*, *supra* note 1, at 830; *see, e.g.*, Laurence B. McCullough et al., *Professionally Responsible Disclosure of Genomic Sequencing Results in Pediatric Practice*, 136 *PEDIATRICS* e974, e979, e981 (2015); Laine Friedman Ross et al., *Technical Report: Ethical and Policy Issues in Genetic Testing and Screening of Children*, 15 *GENETICS MEDICINE* 234, 236, 239–40 (2013).

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INTRODUCTION

The past several decades have seen numerous valuable efforts at the federal and state levels to keep people’s data and health information private and secure, from the Health Information Portability and Accountability Act of 1996 (“HIPAA”),⁶ the Genetic Information Nondiscrimination Act of 2008 (“GINA”),⁷ and the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”),⁸ to a complex net of “federal protections for [protected] health information” (“PHI”).⁹ PHI exists in many constructed forms—a folder containing one’s medical chart, a prescription with one’s diagnosis or treatment on it, or a computer

⁶ Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996).

⁷ Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (2008).

⁸ Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 155 (2009) (codified in scattered sections of 42 U.S.C.).

⁹ U.S. Dep’t Health & Human Servs., *What is PHI?*, HHS.GOV, <https://www.hhs.gov/answers/hipaa/what-is-phi/index.html> (content last reviewed Feb. 26, 2013).

screen providing a return of results.¹⁰ However, PHI importantly and fundamentally also exists in deconstructed, unanalyzed, bodily, or physical form—as with an individual’s genome.¹¹ For the entirety of this recent history in which PHI has existed as a distinct space of federal and state regulation, there has been little discussion on the permissibility of parents accessing genetic information in the prenatal context, yet newborn screening and prenatal testing and screening are the major points for parents to access their children’s PHI. While there are therapeutic reasons for parental access to fetal information, including screening for disease and disability as part of the parents’ informed decision on whether to bring the pregnancy to term, an increasing reliance on genomic sequencing as part of

¹⁰ U.S. Dep’t of Health & Human Servs., *Your Rights Under HIPAA*, HHS.GOV, <https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html> (content last reviewed Feb. 1, 2017).

¹¹ It is worth questioning whether an individual’s genome, left fully unanalyzed, counts as information at all. On the one hand, it can clearly be described as information about nucleic acid sequences of adenine, cytosine, thymine, and guanine (as well as uracil, found in RNA rather than DNA). *What’s a Genome?*, NAT’L HUM. GENOME RES. INST., <https://www.genome.gov/About-Genomics/Introduction-to-Genomics> (last updated Oct. 11, 2019). On the other, it also makes sense not to think of this large quantity of data as “information” since it is not clear what exactly one would *do* with this mapping of over three million base pairs. As one historian of science noted in 2000 (when the Human Genome Project was imminently about to achieve its primary goal),

A decade ago, many biologists spoke as if sequence information would, by itself, provide all that was necessary for an understanding of biological function. [The biochemist Walter Gilbert would write in this vein,] “Three billion bases of sequence can be put on a single compact disc (CD), and one will be able to pull a CD out of one’s pocket and say, ‘Here is a human being; it’s me!’” Today, almost no one would make such a provocative claim. [Another possibility is to] liken the human genome sequence to the Phaestos Disk: an as yet undeciphered set of glyphs from a Minoan palace . . . [.] With regard to understanding the A’s, T’s, G’s, and C’s of genomic sequence, by and large, we are functional illiterates. [There remains a large] gap between genetic “information” and biological meaning.

EVELYN FOX KELLER, *THE CENTURY OF THE GENE* 6, 8 (2000) (quoting Walter Gilbert, *Visions of the Grail*, in *THE CODE OF CODES* 84–85 (Daniel J. Kelves & Leroy Hood eds., 1992)).

today's healthcare system and the actualizing possibility of gene editing raise issues that will pose new questions with regard to the extent to which third parties, including parents, should be permitted to access genomic data at embryonic and fetal stages of development. This Article adds a layer of discussion to the highly permissive approach of the U.S. healthcare and legal systems with respect to disclosing genetic information to parents, and it primes the legal discussion over the extent to which and the contexts in which third-party access to certain genetic PHI should be permissible.

Parents can shape their reproductive decisions with regard to their concerns about conceiving children with genetic conditions, diseases, or disorders through an abundance of options that do not implicate this concern—for instance, carrier testing for conditions like cystic fibrosis or Tay Sachs disease—as such methods do not involve accessing fetal or embryonic DNA, just the PHI of the prospective parents.¹² Sampling fetal DNA, in contrast, is done for the specific purposes of obtaining PHI that can be individuated from and is distinct from each parent's own PHI.¹³ Perinatal testing and

¹² That is, unlike gene editing or selection in utero, parents in some populations might be able to garner rough information about risks of the HEXA gene mutation underlying Tay Sachs, for example, by having their own genomes sequenced prior to conception. This method of informing reproductive decisions thus relies fully on the parents' own PHI. Given that the disease is invariably lethal by infancy or early childhood, professional recommendations are that couples considering pregnancy should be offered screening if one of them is in a high-risk population. See Committee on Genetics, *Carrier Screening for Genetic Conditions: Committee Opinion No. 691*, AM. C. OBSTETRICIANS & GYNECOLOGISTS (Mar. 2017), <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Genetics/Carrier-Screening-for-Genetic-Conditions?IsMobileSet=false>.

¹³ For example, amniocentesis can extract fetal information and was the earliest of today's methods for extracting PHI prenatally. Around the midcentury, this route made it possible to test for conditions linked to allosomes like erythroblastosis fetalis, hemophilia, and Duchenne muscular dystrophy. See *infra* p. 35 and the discussion therein. Chorionic villus sampling ("CVS"), available beginning in the 1980s, offered a less invasive prenatal option for detecting fetal abnormalities earlier in pregnancy by extracting information from the chorion (the outermost fetal membrane) rather than the amnion (the inner membrane). Options like preimplantation genetic diagnosis, of course, would become increasingly available beginning in the 1990s. See ZARKO ALFIREVIC ET AL., AMNIOCENTESIS

screening have grown to become widespread since the 1960s, giving rise to a default of returning potentially overabundant results of a fetus or newborn individual's PHI to parents without the individual's prior consent (though, of course, it is not possible to obtain it in this context).¹⁴ While beneficial in many respects, this practice has problematically supported a widespread grant of access for parents, both in terms of the quantity of PHI initially divulged, and in terms of continued parental access to adolescent children's PHI until the child seeks emancipation or pursues sexual activity.¹⁵ This Article emphasizes that current legal protections for PHI noticeably fail to give individuals adequate protection for their PHI from conception and birth into adolescence and create controversial precedent in the rapidly evolving field of biotechnology, a domain in which privacy continues to prove a mounting concern.

AND CHORIONIC VILLUS SAMPLING FOR PRENATAL DIAGNOSIS 6 (2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6483702/pdf/CD003252.pdf>.

Within the past decade, consumers have also had noninvasive prenatal screening and testing options relying on genomic sequencing, like the MaterniT 21, originally offered in 2011. See *Early Risk Assessment of Down Syndrome and Other Conditions*, INTEGRATED GENETICS, <https://www.integratedgenetics.com/patients/pregnancy/maternit21plus> (last visited Oct. 26, 2019). Today, the home page for the MaterniT 21 PLUS advertises that the tool offers “[e]arly risk assessment of Down syndrome and other conditions.” The company offering the test goes on to advertise,

Did you know that information on your baby's health can be found in your own bloodstream? The MaterniT 21 PLUS test analyzes genetic information that enters your bloodstream from the placenta. It screens for certain chromosomal abnormalities that could affect your baby's health and development—such as trisomy 21 (Down syndrome) and sex chromosome aneuploidies (SCAs, abnormal numbers of X or Y chromosomes)—and can also detect if you're having a boy or a girl.

Id.

¹⁴ See *infra* Part V (suggesting a black box approach that releases PHI to comport with the law but otherwise adds a more nuanced perspective of the informed consent of the conceptus into the discussion).

¹⁵ See *infra* notes 53–69 and accompanying text (describing the existence of such rights created through HIPAA, Title X, and Supreme Court precedent on minor reproductive rights).

Protecting PHI in utero would involve reforms in the direction of recognizing that a blood sample containing fetal DNA, for example, contains the PHI of two genetically distinct individuals, not one.¹⁶ At the same time, this Article acknowledges that there is only a potential for unauthorized or unjustified access to embryonic and fetal PHI if the embryo or fetus is actually brought to term. This discussion thus proposes reforms that comport with the tenets of *Roe v. Wade* but also raise new questions that the future of reproductive rights will have to confront as genomics and biotechnology continue to advance. Rather than accepting the present landscape in which the PHI of children belongs to and is returned to parents from conception to majority, this Article defends the importance of protecting PHI throughout an individual's lifetime, only indirectly releasing an individual's PHI to parents if doing so is antecedently justified with respect to a best-interests-of-the-child or presumed-consent standard, and only releasing PHI in limited and relevant doses. This standard could be particularly relevant for shaping discussions about gene editing options like CRISPR-Cas9 and the even newer "prime" genomic editor,¹⁷ especially with uses in the direction of creating designer babies and away from advancing the best interests of the child.

Part I begins to paint a picture in broad brushstrokes of the current regulatory regime over PHI in laws like HIPAA and the

¹⁶ See *infra* Parts IV and V. *Contra* 45 C.F.R. § 160.103 (2018) (defining the conceptus as PHI of pregnant women, rather than a distinct entity with PHI, by defining "genetic information" protected by HIPAA to include "[a] fetus carried by the individual or family member who is a pregnant woman.").

¹⁷ One of its potential advantages over CRISPR-Cas9 is that the newer "prime" option only needs to break one rather than both strands of DNA. Andrew V. Anzalone et al., *Search-and-Replace Genome Editing Without Double-Strand Breaks or Donor DNA*, *NATURE* (Oct. 21, 2019), <https://www.nature.com/articles/s41586-019-1711-4>; see also Karen Zusi, *New CRISPR Genome Editing System Offers a Wide Range of Versatility in Human Cells*, *SCIENCE DAILY* (Oct. 21, 2019), <https://www.sciencedaily.com/releases/2019/10/191021124511.htm> ("The new prime editing system involves coupling Cas9 to a different protein called reverse transcriptase. The molecular complex uses one strand of the target DNA site to 'prime,' or initiate, the direct writing of edited genetic information into the genome.").

HITECH Act. Part II takes a closer look at the individual privacies protected in these laws to explain how such regulations governing PHI thus far have balanced parental and children's interests, from the return of results in fetal sequencing and newborn screening programs to protections for PHI in adolescence. Part III expands the discussion of keeping the PHI of individuals private to encompass the proposal of maintaining it private from parents in utero as well, as a failure to do so would largely eviscerate much of the instrumental value of regulations seeking to protect PHI later in life. Part IV contextualizes why this proposal comes as a radical one by highlighting how it intersects with key elements of the federal regime of reproductive rights and prenatal tort actions. Finally, Part V offers solutions and presents the idea of a "black box" framework that stages return of results as authorized, suggesting some potential paths forward that could do better in protecting the PHI of individuals across their lifetimes.

I. DEFINING PROTECTED HEALTH INFORMATION

The most obvious and direct uses of PHI arise in adulthood, in a "typical" doctor-patient relationship that does not involve the added element of intermediating parents making healthcare decisions for their children as patients.¹⁸ The brief canvassing of PHI law below makes clear that the adult is the archetypical or standard patient.¹⁹ This focus only on the PHI of adults has led to the marginalization of persons on either side of adulthood. For example, recent scholarship has explored the reasons for and against returning a person's PHI after the person has deceased and, in particular, when the decedent's PHI would be material to the health and reproductive

¹⁸ See note 29 and accompanying text (describing how HIPAA's "individual" generally only begins to exist in adulthood, with aspects of the protections that the statute offers even extending beyond the individual's death).

¹⁹ Compare notes 27–29 and accompanying text (describing the meaning of "individual" under HIPAA), with Section II.A (describing that HIPAA's default is that minors are not to be treated as such individuals independently, but rather that their parents are to be treated as personal representatives responsible for making the minors' healthcare decisions).

decisions of family members.²⁰ A considerably smaller body of literature has raised problems with PHI in adolescence, childhood, infancy, and in utero.²¹

Federal health information privacy law charts the relevant terrain. Most centrally, this terrain has been defined within HIPAA. Passed under the Clinton administration in 1996, the HIPAA statute is broken into five titles: “Healthcare access, portability, and renewability” (Title I), “Preventing health care fraud and abuse; administrative simplification; medical liability reform” (Title II), “Tax-related health provisions” (Title III), “Application and enforcement of group health plan requirements” (Title IV), and

²⁰ See, e.g., Laura Amendola et al., *Patients’ Choices for Return of Exome Sequencing Results to Relatives in the Event of Their Death*, 43 J.L. MED. & ETHICS 476 (2015); Carmen R. Breitkopf et al., *Preferences Regarding Return of Genomic Results to Relatives of Research Participants, Including After Participant Death: Empirical Results from a Cancer Biobank*, 43 J.L. MED. & ETHICS 464 (2015); Susan M. Wolf et al., *Returning a Research Participant’s Genomic Results to Relatives: Analysis and Recommendations*, 43 J.L. MED. & ETHICS 440 (2015).

²¹ See, e.g., DENA DAVIS, *GENETIC DILEMMAS: REPRODUCTIVE TECHNOLOGY, PARENTAL CHOICES, AND CHILDREN’S FUTURES* (2001); Jeffrey R. Botkin et al., *Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents*, 97 AM. J. HUM. GENETICS 6 (2015); Ellen Wright Clayton, *How Much Control Do Children and Adolescents Have over Genomic Testing, Parental Access to Their Results, and Parental Communication of Those Results to Others?*, 43 J.L. MED. & ETHICS 538 (2015); Dena Davis, *Genetic Dilemmas and the Child’s Right to an Open Future*, 27 HASTINGS CTR. REP. 7 (1997) (noting the need for a parental autonomy versus child autonomy paradigm by explaining, in sum, that “most genetic counselors enter the profession with certain assumptions about health and disability—for example, that it is preferable to be a hearing person than a deaf person. [Such assumptions, in turn, can affect how such counselors view couples who want to create children sharing conditions that parents have, like deafness or dwarfism.] This ethical challenge benefits little from viewing it as a conflict between beneficence and autonomy. The challenge is better recast as a conflict between parental autonomy and the child’s future autonomy.”); Loretta Kopelman, *Using the Best Interests Standard to Decide Whether to Test Children for Untreatable, Late-Onset Genetic Diseases*, 32 J. MED. & PHIL. 375 (2007); Mianna Lotz, *Feinberg, Mills, and the Child’s Right to an Open Future*, 37 SOC. PHIL. 537 (2006); Haqq, *Of Mosquitoes, Adolescents, and Reproductive Rights*, *supra* note 1, at 837.

“Revenue offsets” (Title V).²² Protections concerning the use, disclosure, privacy, and security of a person’s PHI all fall within Title II.²³ More specifically, these protections fall within the federal regulations implementing a component of the statute now known as the Privacy Rule, one of six rules that Title II directed the Department of Health and Human Services to promulgate in furtherance of the title’s purposes of “administrative simplification” (the others being the Transactions and Code Sets Rule, the Security Rule, the Unique Identifiers Rule, Breach Notification Rule, and the Enforcement Rule).²⁴ The Privacy Rule was opened to public comment in 1999 and published as a final regulation in 2000,²⁵ with some modifications made two years later.²⁶

²² Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

²³ *See id.* at 1937.

²⁴ *Id.* Tit. II, 110 Stat. at 1991; U.S. Dep’t of Health & Human Servs., *Combined Regulation Text of All the Rules*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/combined-regulation-text/index.html> (last visited Oct. 26, 2019).

²⁵ Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462 (Dec. 28, 2000); U.S. Dep’t of Health & Human Servs., *The HIPAA Privacy Rule*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/privacy/index.html> (last visited Oct. 26, 2019) [hereinafter *The HIPAA Privacy Rule*] (describing how the HIPAA Privacy Rule changed over time).

²⁶ Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53182 (2002).

The HIPAA Privacy Rule establishes national standards to protect individuals’ medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections.

The HIPAA Privacy Rule, *supra* note 25.

The Privacy Rule defines PHI as any information held by a “covered entity” that concerns the health status or the provision or payment of healthcare services that can be linked to an individual.²⁷ Under the statute’s language, an “[i]ndividual means the person who is the subject of the protected health information.”²⁸ Thus, HIPAA envisions a specific archetypical individual—its “default person”—as the type of person the statute protects. This individual only extends so far. Those who have been dead for more than fifty years, for example, fall outside the ambit of HIPAA’s protections for PHI.²⁹ Though HIPAA offers even this afterlife of protections, it is not as generous in the opposite direction; the more one falls under the guardianship of another (i.e., often the further one moves back into childhood), the fewer protections it accords, eventually offering none at all. HIPAA’s default person, then, lies between these extremes—it is neither the individual possessing limited protections earlier in life, nor the postmortem individual also with limited rights, but rather exists in the middle.

“Health information” under HIPAA “means any information, including genetic information, whether oral or recorded” that is “created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse” (HIPAA’s “covered entities”) and “relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.”³⁰ “Protected health information” more specifically means “individually identifiable health information,” where “individually identifiable” is defined as “a subset of health information . . . [t]hat identifies the individual” or “[w]ith respect to which there is a reasonable basis to believe the information can be used to identify the individual.”³¹ A covered entity might permissibly use health information for research, for

²⁷ Public Welfare, 45 CFR § 160.103 (2018).

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

instance, if it has been stripped of all identifiers that could link the information to a specific person.

A few of HIPAA's standard protections under the Privacy Rule are relevant to the regulation of PHI in the perinatal and childhood contexts. The regulations implementing HIPAA require covered entities and business associates, when using or disclosing PHI, to "make reasonable efforts to limit protected health information to the minimum necessary to accomplish the purpose of the use, disclosure, or request."³² This "minimum necessary" requirement does not apply to disclosures to the individual who is the subject of the PHI.³³ In short, the requirement seeks to prevent PHI from being disclosed beyond what is necessary for a particular function or purpose. It thus comports well with this Article's recommendation to adopt a similar attitude towards PHI at embryonic and fetal stages, permitting it to be disclosed for authorized purposes but otherwise keeping it private from third parties.

While they preclude certain uses of PHI, HIPAA regulations also accord substantial permissions to covered entities and business associates with respect to allowing public authorities access to PHI for a variety of reasons. These permissions include disclosures to public authorities "for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions,"³⁴ as well as disclosures to public authorities investigating child abuse and neglect,³⁵ instances in which the persons are subject to the jurisdiction of the Food and Drug Administration,³⁶ and those in which the person poses a risk of spreading a communicable disease.³⁷ This permission to deviate from the minimum-necessary requirement therefore countenances several circumstances in which

³² Public Welfare, 45 C.F.R. § 164.502(b) (2018).

³³ § 164.502(b)(2).

³⁴ § 164.512(b)(1)(i).

³⁵ § 164.512(b)(1)(ii).

³⁶ § 164.512(b)(1)(iii).

³⁷ § 164.512(b)(1)(iv).

public authorities can access PHI without needing consent from the individual who is the subject of that PHI.³⁸

A similar regime of broad disclosure without a consent requirement was carried over into the HITECH Act of 2009, which strengthened many of HIPAA's protections.³⁹ To this end, the HITECH Act offers incentives and eventual penalties for non-implementation to institutions to adopt systems of electronic health records for meaningful uses.⁴⁰ Under the Act, one permissible meaningful use is articulated as one to "improve population and public health."⁴¹ Despite the requirement that data be sufficiently anonymized, this regime is especially concerning because of the enormous potential in harnessing large quantities of aggregated health information for the purposes of helping fuel a genomic healthcare system running on analysis of big data.⁴² Indeed, on the one hand, the more that PHI is stripped of all identifying information, the less use it has for public health authorities—for instance, allowing zip codes to remain attached to the PHI could facilitate research and prevent risks endemic to populations in

³⁸ See notes 32–37 and the sources therein.

³⁹ Howard Burde, *The HITECH ACT—An Overview*, 13 AM. MED. ASS'N J. ETHICS 172, 173 (2011).

⁴⁰ *Id.* at 174.

⁴¹ *Public Health and Promoting Interoperability Programs (Formerly, Known as Electronic Health Records Meaningful Use): Introduction*, CENTERS FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/ehrmeaningfuluse/introduction.html> (content last reviewed Sept. 9, 2019); see Public Health, 42 C.F.R. § 495.40 (2011); *Public Health and Promoting Interoperability Programs (Formerly, Known as Electronic Health Records Meaningful Use): Program Description and History*, CENTERS FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/ehrmeaningfuluse/index.html> (last reviewed Oct. 9, 2019).

⁴² In part, the production of this data has been fueled by a "dramatic drop" in the cost of sequencing over the past few years. Rita Rubin, *Precision Medicine: The Future or Simply Politics?*, 313 JAMA 1089, 1089 (2015). Such developments, in turn, were catalysts encouraging President Obama to allocate federal funds to precision healthcare. *Remarks by the President in the State of the Union Address*, OBAMA WHITE HOUSE (Jan. 20, 2015), <https://obamawhitehouse.archives.gov/the-press-office/2015/01/20/remarks-president-state-union-address-January-20-2015>.

particular geographic locations.⁴³ On the other, researchers now claim that it is already feasible to locate a person based only on a zip code data point and an otherwise deidentified genome.⁴⁴

For the present purposes, the possibility that federal laws like the HITECH Act and HIPAA⁴⁵ are ill-equipped for horizons of personalized medicine and genomic healthcare is of secondary importance. The above provides a glimpse of what PHI is: information possessed by a covered entity about an identifiable individual's healthcare payment, services, or health status. The above also gives a view of what some of the protections of this information offer—including rights that such data will not be disclosed to third parties without the patient's consent, unless it is sufficiently deidentified.⁴⁶ Disclosure to third parties, however, is one of the central issues implicated by the lack of protections that laws like the HITECH Act and HIPAA⁴⁷ provide today to children regarding their own PHI being accessed by parents.

⁴³ E.g., Khaled El Emam, *Methods for the De-identification of Electronic Health Records for Genomic Research*, 3 *GENOME MED.* 1, 2 (2011) (identifying “geographic indicators” as a method that “can be used to probabilistically identify an individual” using otherwise deidentified information); Daniel S. W. Tan et al., *Cancer Genomics: Diversity and Disparity Across Ethnicity and Geography*, 34 *J. CLINICAL ONCOLOGY* 91, 98 (2016); Tanya Yatsunenko et al., *Human Gut Microbiome Viewed Across Age and Geography*, 486 *NATURE* 222, 222 (2012).

⁴⁴ See LATANYA SWEENEY ET AL., IDENTIFYING PARTICIPANTS IN THE PERSONAL GENOME PROJECT BY NAME 2–4 (2013), <https://arxiv.org/pdf/1304.7605.pdf>.

⁴⁵ Health Information Technology for Economic and Clinical Health Act of 2009 of the American Recovery and Reinvestment Act of 2009, Pub L. No. 111-5, 123 Stat. 155 (2009) (codified in scattered sections of 42 U.S.C.); Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

⁴⁶ Public Welfare, 45 C.F.R. § 160.103 (2018) (“Individually identifiable information is information that is a subset of health information.”); see also note 31 and accompanying text (explaining how health information is protected by HIPAA when it is individually identifiable, that is, identifying a particular individual).

⁴⁷ Health Information Technology for Economic and Clinical Health Act of 2009, 123 Stat. 155; Health Insurance Portability and Accountability Act of 1996, 110 Stat. 1936.

II. THE RIGHTS OF CHILDREN TO THEIR OWN PHI: THE CURRENT LANDSCAPE

Despite the background presumption in federal laws like HIPAA that people have considerably robust protections for their PHI once adults, and then even extending decades after death,⁴⁸ this Part explains how there are far fewer protections available for the PHI of minor children. First, Section II.A works backwards from adolescence, the period during which the most robust protections for PHI are available for minors. Second, Section II.B places these limited protections for PHI during minority—which appear to extend primarily to minors who become emancipated, who are sexually active, or who otherwise reveal another heightened category of PHI—in contrast with the default position that has been reflected by state-run newborn screening programs for over half a century, namely, of returning results of the child’s PHI to parents, presuming that they are the owners or caretakers of their child’s PHI.⁴⁹

A. Minor Rights to PHI and the Requirement of Emancipation

Parental rights under HIPAA are covered in the section on “personal representatives.”⁵⁰ That section provides that “[i]f under applicable law a person has authority to act on behalf of . . . an unemancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative.”⁵¹ The default position in HIPAA’s implementing regulations therefore is that treating parents as the personal representatives of their children in healthcare decisions—which inevitably involves

⁴⁸ Health Insurance Portability and Accountability Act of 1996, 110 Stat. 1936.

⁴⁹ *See infra* Part IV. While it denies that parents are owners of this PHI, this Article supports giving parents access to a limited range of the child’s PHI when it is based on ideal informed consent, as would be the case with several aspects of PHI revealed in newborn screening results.

⁵⁰ §164.502(g)(1).

⁵¹ § 164.502(g)(2) (emphasis added).

disclosing the child's PHI to parents so that they can make those decisions—is mandatory, not permissive.⁵²

At the same time, HIPAA states that, with regard to PHI pertaining to a healthcare service, parents “may” not be representatives when “minor[s] may lawfully obtain such health care service[s] without the consent of a parent.”⁵³ In other words, HIPAA requires that parents be treated as representatives who act on behalf of their child in making healthcare decisions, but the statute recognizes that this default might be overridden if there is judicial precedent or other applicable federal or state law giving the minor rights to access healthcare without parental involvement. This provision is a key wedge in HIPAA that permits minor informational privacy rights to be encompassed by the statute. It both speaks to the statute's overarching authority—namely, in defining what PHI is and the extent to which it is protected, but also speaks to its aim of comporting with state and other federal laws.⁵⁴

Other applicable federal and state laws can carve out considerable exceptions (i.e., permitting direct minor access rather than the default of treating parents as representatives), especially by way of granting minors reproductive rights. For example, covered entities and business associates could not require parents to be decisionmakers if this violated Supreme Court precedent granting unemancipated minors the right to access contraception and abortion privately from parents. The Court has recognized the right of minors to access contraception since 1977, including their right to access it without parental consent.⁵⁵ It had also found a state law unconstitutional that required all minors to obtain parental consent prior to obtaining an abortion a year earlier,⁵⁶ indirectly affirming this line of precedent again in a 1979 decision upholding a law facially including a parental consent requirement, so long as the law simultaneously contained provisions offering minors judicial bypass

⁵² *Id.*

⁵³ § 164.502(g)(3)(i)(B).

⁵⁴ *Id.* (permitting deviation from the default of treating parents as representatives where the “minor[s] may lawfully obtain such health care service[s] without the consent of a parent”).

⁵⁵ *Carey v. Population Servs.*, 431 U.S. 678, 694 (1977).

⁵⁶ *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 56, 72 (1976).

as an option in lieu of parental consent.⁵⁷ Such recognitions of minor rights to privacy comported with one function of the contraception and abortion rights generally: protecting privacy in the doctor-patient relationship.⁵⁸

Title X of the Public Health and Safety Act (“Title X”), the only source of federal funding dedicated exclusively to family planning,⁵⁹ is another (albeit limited) source of reproductive rights for minors, one which does not contain as strong a parental default as HIPAA.⁶⁰ Rather, recipients of Title X funds are required to

⁵⁷ *Bellotti v. Baird*, 443 U.S. 622, 647 (1979).

⁵⁸ *Planned Parenthood v. Casey*, 505 U.S. 833, 884 (1992) (“Whatever constitutional status the doctor-patient relation may have as a general matter, in the present context, it is derivative of the woman’s position,” a position which includes a right to privacy). At the same time, the Court refrained from granting minors the same scope of abortion right as adults, stressing their “inability to make critical decisions in an informed and mature manner and the importance of the parental role in child rearing.” *Bellotti*, 443 U.S. at 634.

⁵⁹ *Title X*, NAT’L FAM. PLAN. & REPROD. HEALTH ASS’N (2019), https://www.nationalfamilyplanning.org/title_x. As I have emphasized elsewhere, the Emergency Medical Treatment and Labor Act (“EMTALA”) is another source of limited protections for services related to family planning—namely, labor and delivery services, and only when labor presents hospital personnel with an “emergency medical condition.” 42 U.S.C. § 1395dd (2018); Public Welfare, 42 C.F.R. § 489.24(b)(1) (2018); Luke Haqq, *Expanding Reproductive Rights to Indigent Noncitizens: A Prioritarian View*, 11 ASIA PAC. J. HEALTH & ETHICS 139, 156 (2018) [hereinafter Haqq, *Expanding Reproductive Rights to Indigent Noncitizens*]; see also *Owens v. Nacogdoches Cty. Hosp. Dist.*, 741 F. Supp. 1269, 1280 (E.D. Tex. 1990) (finding a hospital liable for violating the state’s Anti-Dumping Act after instructing a woman in labor to drive to another hospital but failing to provide her with the transportation as stipulated in the transfer requirement of the statute).

⁶⁰ Compare ANGELIA NAPILI, CONG. RESEARCH SERV., RL33644, TITLE X (PUBLIC HEALTH SERVICE ACT) FAMILY PLANNING PROGRAM 24 (2017) (“Title X projects may not require written consent of parents or guardians for the provision of services to minors.”), with U.S. Dep’t of Health & Human Servs., *Summary of the HIPAA Privacy Rule*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html> (last visited Oct. 26, 2019) (“In most cases, parents are the personal representatives for the minor children.”). “The federal government provides grants for family planning services through the Family Planning Program, Title X of the Public Health Service Act (42 U.S.C. §§300 to 300a-6). Enacted in 1970, it is the only domestic federal program devoted solely to family planning and related preventive health services. In 2015, Title X-funded clinics served 4.0 million clients.” NAPILI, *supra* note 60. Given

certify that they “encourage family participation” in instances where minors request family planning services.⁶¹ In most cases, obviously the most relevant family participation would be that of parents, but this language is still permissive rather than mandatory in that encouraging family participation is not a *requirement* that family participate. Indeed, regulations implementing the statute explicitly direct Title X grantees to maintain strict confidentiality of the information of minors who access reproductive services.⁶² Institutions offering such services and drawing on Title X funds thus balance a requirement to certify that they encourage family participation on the one hand⁶³ against a concomitant obligation to protect the minor’s PHI on the other. This balancing can generally be justified by reference to Title X’s standard that family participation need only be encouraged “to the extent practical,”⁶⁴ terms granting minors more direct control over accessing clinical services than the parental default of HIPAA.⁶⁵ Given Title X’s aim of serving low-income families, minors requesting family planning services are to be “considered on the basis of their own resources,” rather than including the income of parents.⁶⁶

Minors seeking to access options like contraception and abortion therefore can find ample refuge in their protected federal reproductive rights and can obtain protection of their PHI if it relates to their desire to use family planning services. Of course, a minor would have to be sexually active—or at least broach the subject of sexual activity or family planning during a doctor’s visit—to access these protections for PHI, an incentive that federal PHI protections thus give in favor of protecting teenagers engaged in sexual

Title X’s aim of serving low-income families, minors requesting family planning services are to be “considered on the basis of their own resources,” rather than including the income of parents. Public Welfare, 42 C.F.R. § 59.2 (2018).

⁶¹ 115 Pub. L. 31, 131 Stat. 538 (2019). “Grantees continued to be required to certify that they encourage ‘family participation’ when minors seek family planning services and to certify that they counsel minors on how to resist attempted coercion into sexual activity.” NAPILI, *supra* note 60, at 1.

⁶² Public Welfare, 42 C.F.R. § 59.11 (2018).

⁶³ H.R. 6157, 115th Div. B, § 207 (2017–2018).

⁶⁴ 42 U.S.C. 300(a) (2017).

⁶⁵ See *supra* notes 50–54 and the sources therein.

⁶⁶ Public Welfare, 42 C.F.R. § 59.2 (2018).

activity.⁶⁷ If the services that a minor wishes to access are merely general healthcare services (and not those related to heightened categories of PHI), in other words, the entrenched default is that the minor's PHI can be disclosed to parents, whereas if the services pertain to reproductive rights, then federal and state protections are triggered to preserve the confidentiality of the minor's PHI.⁶⁸ In addition to federal law on reproductive rights, all states have statutes permitting minors access to certain clinical services without parental permission, such as services related to sexual activity, drug and alcohol abuse, and mental health.⁶⁹

⁶⁷ Such PHI might, for example, involve reproductive health (e.g., sexually transmitted diseases, pap smear results), or it might pertain to what can be distinguished as information of reproductive significance—that is, information that guides and informs reproductive autonomy (e.g., carrier screening and prenatal testing results, pregnancy warnings on pharmaceuticals, signage posted at grocery stores or airports about possible teratogenic risks to pregnancies in the environment, etc.). Cf. Haqq, *Of Mosquitoes, Adolescents, and Reproductive Rights*, *supra* note 1, at 829 n.12 (emphasizing the difference between reproductive health information and information of reproductive significance).

⁶⁸ That is, doctors are to follow HIPAA and treat parents as representatives as the default, unless the minor can otherwise obtain such services “lawfully.” Public Welfare, 45 C.F.R. § 164.502(g)(3)(i)(B). A minor requesting services related to abortion, for example, can lawfully obtain those services without parental involvement according to Supreme Court precedent. *Bellotti v. Baird*, 443 U.S. 622, 647 (1979); *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 75 (1976).

⁶⁹ See generally ABIGAIL ENGLISH ET AL., STATE MINOR CONSENT LAWS: A SUMMARY (2010), <https://www.freelists.org/archives/hilac/02-2014/pdf/Ro8tw89mb.pdf> (discussing the enactment of statutes in each state for minors to obtain certain services without a parent's consent). See also Abigail English, *Health Care for Adolescents: Ensuring Access, Protecting Privacy*, 39 CLEARINGHOUSE REV. 253, 264 (2005) (describing adolescents as having “experienced increased opportunities to receive confidential health care services, particularly for concerns related to sexual activity, pregnancy, sexually transmitted infections (STIs), HIV, substance abuse, and mental health”). Advisory opinions by the American Medical Association (“AMA”) also elaborate on a physician's duty in such respect under the Code of Ethics, stating that “[p]hysicians . . . have a responsibility to protect the confidentiality of minor patients, within certain limits.” *Confidential Health Care for Minors*, AM. MED. ASS'N, <https://www.ama-assn.org/delivering-care/ethics/confidential-health-care-minors> (last visited Oct. 26, 2019). Those limits arise in situations where unemancipated minors “request[] confidential care and the law does not grant the minor decision-

Beyond a minor's potential interests in keeping some PHI private from parents by keeping it strictly within the minor's own doctor-patient relationship, minors also have legitimate interests in ensuring parents do not disclose the child's PHI to others, including instances of disclosures to third parties, even on parents' social media accounts without the minor's consent (a form of what has been called "sharenting").⁷⁰ Granted, if minors obtained clinical services without notifying parents, some of their PHI might nevertheless be conveyed to parents if billing for the service is processed through their insurance policy; the AMA's guideline is that physicians are required to warn minors of such a possibility if they request confidential care, including clinical encounters that the law does not explicitly recognize as appropriate for minor decision-making.⁷¹ If parents did obtain and disclose such information, children might try to seek recourse in various tort claims.⁷²

making authority," in which case the physician must provide information to the minor, including a statement through which the physician will "encourage the minor patient to involve his or her parents and offer to facilitate conversation between the patient and the parents In some jurisdictions, the law permits minors who are not emancipated to request and receive confidential services relating to contraception, or to pregnancy testing, prenatal care, and delivery services." The AMA goes on to explain that, "[s]imilarly, jurisdictions may permit unemancipated minors to request and receive confidential care to prevent, diagnose, or treat sexually transmitted disease, substance use disorders, or mental illness." *Id.*

⁷⁰ *E.g.*, Anya Kamenetz, *The Problem with 'Sharenting'*, N.Y. TIMES (June 5, 2019), <https://www.nytimes.com/2019/06/05/opinion/children-internet-privacy.html>; Gabriel Snyder, *One Day, All of This Will Be Embarrassing*, THE ATLANTIC (June 11, 2019), <https://www.theatlantic.com/family/archive/2019/06/sharenting-its-way-becoming-old-fashioned/591361/>.

⁷¹ *Confidential Health Care for Minors*, *supra* note 69.

⁷² An unauthorized, nonconsensual disclosure of an individual's PHI to parents is not something that can be undone, short of them forgetting the information. Thus, for example, liability from an invasion of privacy tort might arise sometime well into the child's adulthood, after, say, parents disclose certain PHI that the individual finds embarrassing. If parents qua guardians of their children's PHI were treated as having informational stewardship obligations in a similar manner as "covered entities" under HIPAA, such parental obligations not to disclose PHI might also last as long as half a century after their child has died. Public Welfare, 45 C.F.R. § 160.103.

Penultimately, aside from the access and privacy concerns canvassed above, increasing reliance on genetic and genomic information also presses issues regarding a minor's right to refuse such testing.⁷³ On this front, with respect to genomic and genetic testing, "unemancipated minors have virtually no access to the courts to enjoin parental behavior."⁷⁴ In part, this is because child protection agencies would be unlikely to intervene to uphold a minor's refusal to be tested because, given that it is unlikely to impose a risk of serious harm to the child, such non-invasive testing might not qualify as neglect or abuse that is sufficiently severe to necessitate enjoining parental behavior. Still, physicians have discretion to refuse to perform procedures they deem "morally illicit,"⁷⁵ which could plausibly include obtaining samples for sequencing from a teenager who expressly objects to this being done. Indeed, professional ethical standards hold that clinicians should not perform testing on minors who object if they are "older school-age children."⁷⁶

Finally, professional pediatric recommendations support return of genomic results to adolescent individuals.⁷⁷ The American Academy of Pediatricians and American College of Medical Genetics ("ACMG") jointly issued a policy statement in 2013 supporting the initiation of pediatric genomic testing if parents know of a family history of mutations but otherwise not favoring pre-symptomatic genomic screening of minors.⁷⁸ In a separate policy statement that year, the ACMG recommended that, if parents obtain pediatric whole genome or exome sequencing for a targeted

⁷³ In the words of the U.S. National Library of Medicine, "Genetic testing is voluntary. Because testing has benefits as well as limitations and risks, the decision about whether to be tested is a personal and complex one." *What is Genetic Testing?*, U.S. NAT'L LIBR. MEDICINE (Oct. 15, 2019), <https://ghr.nlm.nih.gov/primer/testing/genetic-testing>.

⁷⁴ Clayton, *supra* note 21, at 539.

⁷⁵ Susan T. Rouse, *Professional Autonomy in Medicine: Defending the Right of Conscience in Health Care Beyond the Right to Religious Freedom*, 79 LINACRE Q. 155, 156 (2012).

⁷⁶ Arthur Kohrman et al., *Informed Consent, Parental Permission, and Assent in Pediatric Practice*, 95 PEDIATRICS 314, 316 (1995).

⁷⁷ Haqq, *Of Mosquitoes, Adolescents, and Reproductive Rights*, *supra* note 1, at 842–44.

⁷⁸ Ross et al., *supra* note 5, at 234.

purpose, incidental findings should be returned to parents if they reveal conditions in the child that are life-threatening unless ameliorated in childhood.⁷⁹ The ACMG initially recommended that parents should not be permitted to opt out from the analysis of incidental findings but released a policy update that reversed on that point in 2014,⁸⁰ after receiving criticism for the initial recommendation.⁸¹

The National Institute of Health's Clinical Sequencing Exploratory Research Pediatric Working Group ("CSER-PWG") similarly encourages returning results of PHI from genomic sequencing to minors.⁸² For example, the working group provides recommendations directed at the return of results that have reproductive significance for minor subjects.⁸³ It articulates that pediatricians have a "prima facie, autonomy-based ethical obligation to provide adolescent patients, ideally before they become sexually active, with reproductive risk assessment results."⁸⁴ Minors, CSER-PWG goes on, should be permitted "to refuse to learn or to act on the results of reproductive risk assessment[s]."⁸⁵ Similar in nature to the ACMG's 2014 update allowing parents to opt out of analysis of incidental findings, however, the CSER-PWG maintains that parents do not violate a prima facie ethical obligation to their child by choosing not to tell the child of non-life-threatening incidental findings.⁸⁶

In sum, the clearest route to having rights to one's PHI as a minor is to become emancipated, which triggers state law

⁷⁹ Robert C. Green et al., *ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing*, 15 GENETICS MEDICINE 565, 568 (2013).

⁸⁰ Am. Coll. of Med. Genetics & Genomics, *ACMG Updates Recommendations on "Opt Out" for Genomic Sequencing Return of Results*, CISION PR NEWSWIRE (Apr. 1, 2014, 10:00 AM ET), <https://www.prnewswire.com/news-releases/acmg-updates-recommendation-on-opt-out-for-genome-sequencing-return-of-results-253369641.html>.

⁸¹ Wylie Burke et al., *Recommendations for Returning Genomic Incidental Findings? We Need to Talk!*, 15 GENETICS MEDICINE 854, 857 (2013).

⁸² McCullough et al., *supra* note 5, at e978.

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.* at e979.

⁸⁶ *Id.*

protections according them autonomy and confidentiality in medical treatment and eliminates the status of parents as personal representatives for the minor's healthcare decisions.⁸⁷ Alternatively and more indirectly, minors can seek to extend their protected state or federal reproductive rights to the privacy of the doctor-patient relationship and any PHI within that relationship, though this primarily extends protection to minors for their PHI only if they purport to be engaged in or interested in sexual activity or raise certain other heightened categories of PHI. As shown above, these limited routes to direct access by minors have some support in federal laws like HIPAA (and even the Emergency Medical Treatment and Labor Act ("EMTALA")),⁸⁸ in state laws recognizing heightened protections for certain categories of PHI, and in the recommendations of national organizations within professional medicine. If the minor is neither emancipated nor asserting a reproductive right or otherwise raising a heightened category, then the default view, made explicit in HIPAA, is that

⁸⁷ See Ann McNary, *Consent to Treatment of Minors*, 11 INNOVATIONS IN CLINICAL NEUROSCIENCE 43, 44 (2014) (providing examples of court ordered and situational emancipation and explaining that, "[w]hile the law has traditionally considered minors to be incompetent to give consent for medical treatment, most states now have statutes that give minors the right to consent to treatment in specific situations," the most straightforward of which is emancipation).

⁸⁸ For instance, suppose the clinical encounter involves a pregnant teenager who has run away from home and has gone into labor within the meaning of EMTALA when she presents herself at the hospital. The EMTALA statute (passed as part of the Consolidated Omnibus Budget Reconciliation Act ("COBRA") of 1985 to address the problematic phenomenon of hospitals engaged in "patient dumping"), as a first matter, ought to provide her with the initial foot in the door, guaranteeing that she will receive treatment and care in the form of labor and delivery services. EMTALA requires hospitals and clinics to do this if they are capable, only releasing her after they have "stabilized" her within the meaning of the statute, or alternatively transferring her if they are incapable of providing the care themselves. As a second matter, once in the healthcare system via EMTALA, it would seem she would be entitled to any of the aforementioned federal, state, and professional protections for her PHI. See Haqq, *Expanding Reproductive Rights to Indigent Noncitizens*, *supra* note 59 (discussing available venues for indigent noncitizens to obtain protections for their reproductive interests).

parents have wide latitude in accessing their child's PHI without the child's consent.⁸⁹

B. PHI in Newborn Screening and the Threat of Genomics

On the one hand, federal guidance on Title X has noticed that “multiple professional medical associations have emphasized the importance of providing confidential services to adolescents,” since a failure to protect confidentiality can dissuade them from using those services.⁹⁰ On the other, such a recommendation still operates within a landscape that gives parents nearly complete control over the healthcare of their children before adolescence.⁹¹ Such parental control might be limited to some extent if it poses an imminent threat to the child's health.⁹² The return of results in newborn screening programs constitutes one of the more widespread examples of sharing expansive PHI data in practice, which raises concerns as

⁸⁹ See notes 50–52 and accompanying text (describing HIPAA's mandatory language providing that parents must be treated as personal representatives of their children).

⁹⁰ Loretta Gavin et al., *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Department of Population Affairs*, 63 MORTALITY & MORBIDITY WKLY. REP. 1, 13 (2014).

⁹¹ See *supra* Section II.A; see also *People v. Rippberger*, 283 Cal. Rptr. 111, 113, 122 (Cal. Ct. App. 1991) (discussing Christian Science parents convicted of felony child endangerment); Richard J. Brenneman, *Nestling's Faltering Flight: The Short Life and Death of Seth Ian Glaser*, in *DEADLY BLESSINGS: FAITH HEALING ON TRIAL* (1990) (death of child from bacterial meningitis, born to Christian Science parents). *But see* *Commonwealth v. Twitchell*, 617 N.E.2d 609, 609, 614, 517 (Mass. 1993) (involving an involuntary manslaughter claim against parents who relied on prayer to heal their child who died of peritonitis).

⁹² See *Prince v. Massachusetts*, 321 U.S. 158, 166–67 (1944) (recognizing a governmental authority to regulate parents over their treatment of their own children if it is in the best interests of the child). The Supreme Court has not ruled on the constitutionality of state regulations that contravene parental wishes to pursue medical treatment in the best interests of the child. The majority of states provide exemptions from child neglect laws for parents who rely on “faith healing,” though more than half of these states have judicial bypass options that permit judges to compel medical treatment against parental wishes when the child's life is endangered. See *supra* note 91 and the sources therein.

such programs envisage the use of newborn genomic sequencing in the near future.⁹³

Newborn screening programs first arose in the 1960s to identify infants born with phenylketonuria (“PKU”), after Robert Guthrie’s development of an assay that measured phenylalanine levels using the blood from a heel prick placed onto filter paper, also known as “Guthrie cards.”⁹⁴ Given their efficacy in staving off the highly debilitating effects of congenital diseases like PKU through early detection and treatment, these programs quickly spread across the U.S. and abroad and are now mandated by law in all fifty states and the District of Columbia.⁹⁵ Newborn screening expanded beyond solely PKU testing to include a panel of numerous congenital diseases and disorders, and today such screenings identify thousands of children annually with metabolic, endocrine, hematologic, or functional disorders.⁹⁶ If clinically significant results arise, state laboratories notify clinicians, who relay the information to parents to enable them to seek diagnostic confirmation and treatment options.⁹⁷

In this context of newborn screening, a panoply of the child’s PHI is returned to parents, with some states requiring parents to opt in regarding the analysis of incidental findings and others giving them the choice to opt out.⁹⁸ The list of conditions on screening

⁹³ Michelle Huckaby Lewis & Aaron J. Goldenberg, *Return of Results from Research Using Newborn Screening Dried Blood Samples*, 43 J.L. MED. & ETHICS 559, 560 (2015).

⁹⁴ Robert Guthrie & Ada Susi, *A Simple Phenylalanine Method for Detecting Phenylketonuria in Large Populations of Newborn Infants*, 32 PEDIATRICS 338, 338 (1963).

⁹⁵ E.g., Jeffrey Brosco & Diane B. Paul, *The Political History of PKU: Reflections on 50 Years of Newborn Screening*, 132 PEDIATRICS 987, 987 (2013) (“In the early 1960s, parents of children with intellectual disability began to advocate for state laws to test all newborns in the United States, and the first state laws for universal newborn screening (NBS) were implemented 50 years ago. By 1965, 32 American states had enacted screening laws, all but 5 making the test compulsory. By the mid-1970s, NBS for PKU had become routine in nearly every industrialized nation, and had even extended to many poorer countries.”).

⁹⁶ Lewis & Goldenberg, *supra* note 93, at 560.

⁹⁷ *Id.*

⁹⁸ E.g., Michelle Huckaby Lewis et al., *State Laws Regarding the Retention and Use of Residual Newborn Screening Blood Samples*, 127 PEDIATRICS 703,

panels varies state to state, but their inclusion is based on factors such as the severity of the condition detected and the clinical validity of the results.⁹⁹ It is important to reiterate that the vast majority of the time, parental access to children's PHI through newborn screening is easily justified with reference to the best interests of the child.¹⁰⁰ Most often, the motivation for parents who seek to have their children's PHI disclosed to them is in furtherance of the laudable pursuit of doing their best to ensure the child's health and wellbeing by preparing themselves with the knowledge and resources necessary to care for and nurture their child's development.¹⁰¹ What is more, as PKU exemplifies, parents can be faced with the need to make healthcare decisions on behalf of their children within a relatively short span of time, and certainly well before it could be possible to seek and receive the affected child's consent.¹⁰²

707 tbl. 1 (2011) (providing a national overview on return of results in state newborn screening programs); Lewis & Goldenberg, *supra* note 93, at 564 ("Most states allow parents to opt-out of mandatory screening, but few states require that parents be informed of their option to refuse.").

⁹⁹ Lewis & Goldenberg, *supra* note 93, at 566.

¹⁰⁰ In the U.S., the best-interests standard emerged in the twentieth century within broader conceptualizations of the *parens patriae* role of the state. In the early twentieth century this concept could be found in the "tender years" doctrine in divorce law (which gave mothers greater custody rights for young children). By the latter half of the twentieth century, the tender years doctrine was displaced in most states by the language of the best-interests standard, which could be found applying in a range of contexts—from child protection, children born out of marriage, and divorce and custody, to wills and trusts, grandparent visitation rights, and immigration law. Globally, the best-interests standard into the twenty-first century has been articulated most centrally in the UN Convention on the Rights of the Child, which the U.S. has conspicuously never ratified. See G.A. Res. 44/25, Convention on the Rights of the Child (Nov. 20, 1989).

¹⁰¹ *E.g.*, *What Happens If A Newborn Screening Test Comes Back Positive?*, U.S. NAT'L LIB. MEDICINE, <https://ghr.nlm.nih.gov/primer/newbornscreening/nbpositive> (last reviewed July 2015) (advising, if parents receive positive results from screening, to seek further testing to ascertain whether treatment or management options, like a special diet, are necessary).

¹⁰² *Id.* (emphasizing the role of newborn screening results—which are returned "[w]ithin 2 to 3 weeks"—in enabling "quick follow-up" so that any necessary treatments can be initiated "very soon after birth" (emphasis added)).

These reasonable justifications for accessing a child's PHI without consent are important to bear in mind, but they should not be taken as a dispositive reason against reforms that strengthen the minimum-necessary principle of PHI disclosure. To the contrary, given the effectiveness of early treatment, the ability of parents to access PHI through newborn screening results could be justified with respect to notions of what the child would reasonably be presumed to consent to, an equivalent standard to one reflecting the best interests of the child.¹⁰³ The point is that such accessing of PHI without the subject's consent is something that demands justification,¹⁰⁴ a justification that is perhaps implied in screening for serious diseases or disorders (it might be implied, for instance, as to congenital diseases like Tay Sachs, PKU, congenital rubella, and cystic fibrosis, some of the central congenital conditions that had motivated structural changes to state and federal laws beginning in the 1960s).¹⁰⁵ However, justification based on implied consent would become increasingly difficult to maintain if newborn screening relies less on targeted and more on full genomic sequencing, as this would involve returning far more PHI data than would be necessary for parents to make healthcare decisions about therapy or treatment on behalf of their child.

¹⁰³ See, e.g., Aaron J. Goldberg & Richard R. Sharp, *The Ethical Hazards and Programmatic Challenges of Genomic Newborn Screening*, 307 JAMA 461 (2012); Muin J. Khoury et al., *Population Screening in the Age of Genomic Medicine*, 348 NEW ENGL. J. MEDICINE 50 (2003); Bartha M. Knoppers et al., *Return of Genetic Testing Results in the Era of Whole-Genome Sequencing*, 16 NATURE REV. GENETICS 553 (2015); Bartha M. Knoppers et al., *Whole Genome Sequencing in Newborn Screening Programs*, 6 SCI. & TRANSLATIONAL MED. 229 (2014).

¹⁰⁴ There are substantial discussions about the ethics of the return of results stage, especially with respect to the treatment of "incidental findings." See, e.g., Burke et al., *supra* note 81; Mildred K. Cho, *Understanding Incidental Findings in the Context of Genetics and Genomics*, 36 J.L. MED. & ETHICS 280 (2008); Robert C. Green et al., *supra* note 79; Susan M. Wolf et al., *Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data Sets*, 14 GENETICS MEDICINE 361 (2012); Susan M. Wolf, *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 26 J.L. MED. & ETHICS 219 (2008); Susan M. Wolf et al., *Patient Autonomy and Incidental Findings in Clinical Genomics*, 340 SCI. 1049 (2013).

¹⁰⁵ See *infra* notes 130–138 and accompanying text.

For similar reasons, the question of parental access to the panoply of results returned from genetic sequencing in the newborn and fetal contexts suggests ethical questions that may eventually arise if embryonic gene editing joins the armory of acceptable clinical tools.¹⁰⁶ As with too broad a return of results, so also might it be difficult to justify PHI access for the purpose of selective creation of desired types of children (i.e., “designer babies”) from a best-interests standard. Justification for unnecessarily broad return of results may also be difficult because of the role of that such selection is playing in leading to the obsolescence of people with certain conditions from the human population.¹⁰⁷ The possibility of

¹⁰⁶ It is worth noting that the goal of protecting PHI at embryonic and fetal stages does not fall prey to a challenge posed by the reality that there are many repositories storing numerous frozen embryos. If PHI were protected at the embryonic stage even prior to implantation, the reason for doing so does not rest on ascribing moral status or personhood to embryos categorically. Rather, again, accessing PHI becomes problematic in the scenario in which an embryo is brought to term. Still, this can legitimately mean limiting access *ex ante* to the PHI of *all* embryos created (unless there is a therapeutic, best-interests reason to divulge it), even ones that will otherwise be discarded or frozen and never used. Even in the context of *in vitro* fertilization (“IVF”) and preimplantation genetic diagnosis (“PGD”), parents could exercise the ability to discard unhealthy embryos without knowing everything about them; PHI could be protected in such an example even where the embryos end up being discarded not because of any moral status of those embryos, but rather because it is an overinclusive consequence of a regime protecting the PHI of those which *are* brought to term.

¹⁰⁷ For some sources troubling this consequence of selection, see, for example, Nat Hentoff, *Down Syndrome Genocide*, CATO INST. (Nov. 29, 2011), <https://www.cato.org/publications/commentary/down-syndrome-genocide>; Jonathan Lange, *People with Down Syndrome Deserve Our Love, Not Genocide*, THE FEDERALIST (Mar. 21, 2018), <https://thefederalist.com/2018/03/21/people-syndrome-deserve-love-not-genocide/>; Mayrav Saar, *The End of Down Syndrome*, N.Y. POST (Nov. 13, 2011, 5:00 AM), <https://nypost.com/2011/11/13/the-end-of-down-syndrome/>; Kavin Senapathy, *Down Syndrome Screening Is Not About Eliminating A Group of People*, FORBES (Jan. 25, 2016, 11:05 AM), <https://www.forbes.com/sites/kavinsenapathy/2016/01/25/down-syndrome-screening-is-not-about-eliminating-a-group-of-people/#3a5a13372811>; Brian Skotko, *Will America Cull People with Down Syndrome?*, USA TODAY (Nov. 16, 2011), <https://www.pressreader.com/usa/usa-today-international-edition/20111116/282>

accessing PHI for the purposes of genetic enhancement helps suggest how the best-interests standard exists on a spectrum: sometimes accessing PHI can be used to prevent a person from coming into existence with debilitating pain, and sometimes it can be accessed for non-therapeutic reasons like a parental preference for eye color. The further on the spectrum in the direction of the latter of these, the less justified would any given PHI access be from a best-interests standard.¹⁰⁸

The likely incorporation of genomic sequencing into newborn screening programs on near horizons further speaks to the need for reform in the direction of limiting disclosures to parents of their child's PHI. *Bearder v. State*, a case reaching the Minnesota Supreme Court in 2011, exemplifies how states might move to protect PHI in the context of newborn screening.¹⁰⁹ The case involved plaintiffs raising the issue of whether the state's retention of Guthrie cards without the consent of parents constituted unauthorized use of the subject infants' PHI within the meaning of the state's privacy law.¹¹⁰ In *Bearder*, nine families sued the state of Minnesota and its Department of Health over its collection, use, storage, and dissemination of the blood samples and test results of

694748959166; Tim Stanley, *Down's Syndrome People Risk 'Extinction' at the Hands of Science, Fear and Ignorance*, TELEGRAPH (Jan. 18, 2016, 9:45 AM), <https://www.telegraph.co.uk/news/2016/03/22/downs-syndrome-people-risk-extinction-at-the-hands-of-science-fe/>; Chen Wang et al., *Gene-Edited Babies: Chinese Academy of Medical Sciences' Response and Action*, THE LANCET (Dec. 3, 2018), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)33080-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)33080-0/fulltext); George F. Will, *Questioning the 'Final Solution' for Down Syndrome People*, N.Y. POST (Mar. 16, 2018, 9:24 PM), <https://nypost.com/2018/03/16/questioning-the-final-solution-for-down-syndrom-e-people/>.

¹⁰⁸ At the same time, it could be argued that even some enhancements would be justifiable or justified from the perspective of a best-interests standard. See, e.g., ALLEN BUCHANAN ET AL., FROM CHANCE TO CHOICE: GENETICS AND JUSTICE (2000); Julian Savulescu, *In Defence of Procreative Beneficence*, 33 J. MED. ETHICS 284, 287–88 (2007) (arguing in favor of certain germline enhancements in the interests of future children); Julian Savulescu & Guy Kahane, *The Moral Obligation to Create Children with the Best Chance of the Best Life*, 23 BIOETHICS 274 (2009).

¹⁰⁹ See *Bearder v. State*, 806 N.W.2d 766, 766 (Minn. 2011).

¹¹⁰ *Id.*

their newborn infants without the parents' written consent.¹¹¹ Minnesota state law allowed for the screening of newborns for certain metabolic disorders, which:

[1] require[d] the Commissioner of Health to prescribe the manner of testing, recording, and reporting . . . newborn screening results; [2] require[d] those who perform[ed] screenings to inform parents that the blood samples and test results may be kept by the Department of Health; and [3] allow[ed] parents to either decline having their infants tested or require the blood samples and test results be destroyed after the screening.¹¹²

Without a specific request for a blood sample's destruction by the subject newborn's parent, part of the sample would be retained.¹¹³

The Department of Health had entered into contracts with Mayo Medical Laboratories to perform screening on the subject samples, where the contractual arrangement also permitted Mayo to use excess blood samples "for studies unrelated to the newborn screening program if, and in addition to other requirements, the samples ha[d] been de-identified or Mayo ha[d] obtained the written consent from the children's parent or legal guardian."¹¹⁴ At issue was the State Genetic Privacy Act of 2006, which provided that "genetic information" about an individual:

(1) may be collected by a government entity . . . or any other person only with the written informed consent of the individual; (2) may be used only for purposes the individual gave written informed consent for; (3) may be stored for only a short time which the individual gave written informed consent; and (4) may be disseminated only: (i) with the individual's written informed consent; or (ii) if necessary in order to achieve purposes described by clause.¹¹⁵

¹¹¹ *Id.* at 769.

¹¹² *Id.* at 770 (citations omitted).

¹¹³ *Id.*

¹¹⁴ *Id.* at 771.

¹¹⁵ MINN. STAT. § 13.386(3) (2019).

The Genetic Privacy Act defined “genetic information” broadly:

- (a) “Genetic information” means information about an identifiable individual derived from the presence, absence, alteration, or mutation of a gene, or the presence or absence of a specific DNA or RNA marker, which has been obtained from an analysis of: (1) the individual’s biological information or specimen; or (2) the biological information or specimen of a person to whom the individual is related. (b) “Genetic information” also means medical or biological information collected from an individual about a particular genetic condition that is or might be used to provide medical care to that individual or the individual’s family members.¹¹⁶

The plaintiffs argued that the Genetic Privacy Act required that the Department of Health obtain informed consent before it was permitted to collect, use, store, or disseminate the newborns’ blood samples after the completion of their newborn health screenings.¹¹⁷

The Department of Health countered that the Genetic Privacy Act did not control its handling of newborn blood samples because the blood samples were not “genetic information” under the Act, and because “the newborn screening statutes ‘expressly provide[d]’ that the Department of Health [could] use, store, and disseminate the genetic information without first [having] obtain[ed] written informed consent.”¹¹⁸

The court found that the DNA contained in the infants’ blood samples brought the blood samples within the ambit of the state’s Genetic Privacy Act, rendering the state’s practices of retaining these samples for further research and study without consent to be unlawful, at least without *parental* consent.¹¹⁹ The court then considered whether the Department of Health was exempt from the Genetic Privacy Law’s restrictions and determined that the newborn screening statutes expressly provided the agency with such an exception to the consent requirement in its collection and use of

¹¹⁶ MINN. STAT. § 13.386(1) (2019).

¹¹⁷ *Bearder v. State*, 806 N.W.2d 766, 769 (Minn. 2011).

¹¹⁸ *Id.* at 771–72.

¹¹⁹ *Id.* at 770.

genetic information, but only to the extent that the Department was authorized to “(1) administer newborn screening by testing samples for heritable and congenital disorders, (2) record and report test results, (3) maintain a registry of positive cases for follow-up services, and (4) store test results as required by federal law.”¹²⁰ In other words, the court noted important limitations on the scope of the state’s access to PHI without express parental consent.¹²¹

On the one hand, therefore, *Bearder* exemplifies ways in which newborn screening programs treat the newborn as a distinct person with unique PHI recognized to be deserving of privacy from third parties, implicating an obligation on the part of public authorities holding that information at least to solicit and receive affirmative consent of the subject’s parents in collection, use, storage, and dissemination of that information. On the other, the consent that the court found missing in *Bearder* was not the presumed consent of the child, but rather that of parents.¹²² That is to say, the court did not question the default view that there is little to no need to ensure privacy from parents as third parties, and in fact, several state statutes explicitly grant parents control over their children’s newborn screening results.¹²³

In contrast with the current terrain, this Article posits that newborn genetic information should be better protected against all third parties, including parents when parental access to and disclosure of that PHI is not justified in the best interests of the child. Clinical applications of genomics in prenatal, neonatal, and pediatric care raise the risk that parents will soon be entitled to access unprecedented amounts of their child’s PHI. The National Institute

¹²⁰ *Bearder*, 806 N.W.2d at 776; MINN. HOUSE OF REPRESENTATIVES, GENETIC PRIVACY LAW AND THE *BEARDER* CASE 5, <https://www.house.leg.state.mn.us/hrd/pubs/genprivlaw.pdf>.

¹²¹ *See Bearder*, 806 N.W.2d at 776.

¹²² *Id.* at 774–75, 779 (Anderson, J., concurring) (describing the statute as creating an informed consent “requirement that responsible parties inform parents of their right to object to the tests or have their infant’s blood samples and test results destroyed,” while the newborn’s own consent to the return of the newborn’s PHI to parents is an “implied rather than express authorization”).

¹²³ *E.g.*, CAL. HEALTH & SAFETY CODE § 124975 (West 2019); N.H. REV. STAT. ANN. §132:10-a (2019); OLKA. STAT. TIT. 21, § 21-1165 (2019); TEX. HEALTH & SAFETY CODE ANN. § 33.0111 (West 2019).

of Child Health and Human Development, for instance, is currently exploring the possibility of newborn genomic screening through initiatives like BabySeq in Boston, PediSEQ in Philadelphia, and Basic3 in Houston.¹²⁴ As the medical community's capacity to screen, sequence, and collect data continues to expand, it becomes apparent that the return of genomic results could easily extend, for example, to knowledge about late-onset health conditions like Huntington's disease—PHI that arguably has little to nothing to do with healthcare decisions that parents would need to make on behalf of their children during minority such that disclosure thereof is not justified by parents planning to act in the child's best interests.¹²⁵

The perinatal context thus appears to be one of the most consequential points in an individual's lifetime with respect to third-party access to their PHI. Beyond fetal sequencing and neonatal screening, parents may again seek to gain access to a child's genomic information if a child exhibits symptoms of an undiagnosed condition in infancy and early childhood. Beyond early childhood, though, genomic testing of children is less common.¹²⁶ Unless genome sequencing is done for a precise, targeted reason through partial sequencing, prevailing medical guidelines recommend that parents receive results of diagnoses and risk assessments for conditions that are life-threatening or can be ameliorated only in childhood.¹²⁷ Professional recommendations of organizations like the American Society of Human Genetics and

¹²⁴ *NIH Program Explores the Use of Genomic Sequencing in Newborn Healthcare*, NAT'L INSTITUTES HEALTH (Sept. 4, 2013), <http://www.nih.gov/news-events/news-releases/nih-program-explores-use-genomic-sequencing-newborn-healthcare>; see Carey Goldberg, *Baby DNA: Boston Researchers Find Childhood Genetic Risks in 9 Percent of Newborns*, WBUR (Jan. 3, 2019), <https://www.wbur.org/commonhealth/2019/01/03/deep-dna-testing-babyseq>; Ian Krantz & Nancy Spinner, *Applying Genomic Sequencing in Pediatrics*, CLINICAL SEQUENCING EXPLORATORY RES., <https://cser1.cser-consortium.org/projects/29> (last visited Oct. 26, 2019); Sharon Plon et al., *KidsCanSeq*, CLINICAL SEQUENCING EVIDENCE-GENERATING RES., <https://cser-consortium.org/projects/27> (last visited Oct. 26, 2019).

¹²⁵ *But see The Week Unwrapped: War Guilt, Genetics, and the Decline of the Pub* (Nov. 30, 2018) (downloaded using Apple Podcasts). I am grateful to Kate Olson for bringing this to my attention.

¹²⁶ Ross et al., *supra* note 5, at 234.

¹²⁷ McCullough et al., *supra* note 5, at e978.

American College of Medical Genetics and Genomics since 1995 have generally supported a nuanced approach to the return of results to minors in accordance with their ability to handle the results individually.¹²⁸

III. PHI IN THE WOMB: A PRECURSOR TO MINORS' RIGHTS TO THEIR OWN PHI AND PROSPECTIVE ISSUES WITH PARENTAL REPRODUCTIVE RIGHTS

The previous Parts have revealed how few protections minors have with regard to their own PHI. While some professional recommendations at least seem cognizant of the danger that this problem will become amplified in a healthcare system increasingly relying on genomics, the default view nevertheless remains that a child's PHI broadly belongs to parents unless the child is either emancipated or is sexually active and seeking refuge under the federal reproductive rights system.

In many respects, as mentioned, a failure to protect PHI anytime in childhood can be a failure with consequences that reverberate throughout a lifetime. Examination of a child's *entire* genomic sequencing analysis is a stark example of access that seems unnecessary or disproportionate to the purposes of detecting issues that manifest in minority and thus lend themselves to parental decision-making, but it is a possibility that could become not only more common but even routinized within the context of newborn screening unless safeguards are enacted. It is surprising that, given the likely direction of healthcare and pediatrics toward incorporating genomics, there have been very few voices in the legal literature willing to press the matter back one step further: if unlimited access of PHI in the neonatal context seems problematic, it would seem that accessing fetal PHI in utero would be problematic for similar reasons and remain as such under *Roe v. Wade's* regime that critically defines legal personhood only to begin after a mother decides to give birth.

Much like newborn screening, people have utilized this mode of accessing PHI since at least the 1960s.¹²⁹ The advent of

¹²⁸ See Botkin et al., *supra* note 21.

¹²⁹ See *infra* notes 132–138 and the sources therein.

amniocentesis was a catalyst that first made it possible to obtain parts of a person's health information before birth; the procedure had been used in the late-nineteenth century to reduce pressure from excess amniotic fluid, but it was only after the discovery of "Barr bodies" by the 1950s that researchers less than a decade later were able to use amniocentesis to determine the sex of a fetus.¹³⁰ Tests revealing fetal sex also soon enabled screening against sex-chromosome-linked defects like erythroblastosis fetalis, hemophilia, and Duchenne muscular dystrophy. Further discoveries in 1959 and 1966 enabled the procedure to be used to test for trisomy 21.¹³¹

The 1960s in many ways generally signaled the new role in the law of a "science of the unborn," as it were, especially in federal administrative law, centrally motivated not only by developments in science but also by the ability to harness scientific tools to respond to two widely publicized spikes in serious birth defects—one caused by contraction of German measles during pregnancy,¹³² and another

¹³⁰ Malcolm Ferguson-Smith, *Amniocentesis*, in *ENCYCLOPEDIA GENETICS* 60, 60–61 (Sydney Brenner & Jeffrey Miller eds., 2001).

¹³¹ Wiley H. Finely, *Normal/21-Trisomy Mosaicism: Report of Four Cases and Review of the Subject*, 11 *AM. J. DIS. CHILD.* 444, 444–47 (1996); Jérôme Lejeune et al., *Étude des chromosomes somatiques de neuf enfants mongoliens*, 248 *C.R. SEANCES ACAD. SCI.*, 1721, 1721–22 (1959).

¹³² In addition to the outbreak of congenital rubella syndrome ("CRS") births in the U.S. and elsewhere during the 1960s, defects were also brought into the national spotlight as a result of the media personality and reporter Sherri Finkbine. After using pills containing thalidomide that her husband had obtained while in Europe, it was not until her pregnancy had significantly advanced that either of them learned of the risks that the drug posed to the unborn fetus. It likely would have been legal for her to have obtained a therapeutic abortion on the grounds of medical necessity, the only reason for which abortions were permitted in Arizona at the time. However, in addition to a flurry of public backlashes and threats, she was turned down by several physicians in the U.S. who feared prosecution for performing an abortion. Given what she knew about the devastating effects of CRS, Mrs. Finkbine reflected in a *Life* magazine interview, "There is life there[.] . . . But is it life when you can't dress yourself, run, walk, dance, play games, have dates? If I had no choice, I would have the baby. But I have a way to prevent this tragedy, this sadness." LESLIE REAGAN, *DANGEROUS PREGNANCIES: MOTHERS, DISABILITIES, AND ABORTION IN MODERN AMERICA* 86 (2010) (quoting *Abortion—With the Future Dim, Should the Unborn Die?*, 53 *LIFE* 33 (1962)). Moreover, she noted that she "could be only a partial mother to the other

as a side-effect of the recently available pharmaceutical, thalidomide (often prescribed at the time for morning sickness).¹³³ One of the profoundest changes that took place after these spikes in birth defects was the creation of the FDA's efficacy standards in 1962. The Kefauver-Harris amendment to the Food, Drug, and Cosmetic Act, enacted by Congress in response to public concerns regarding thalidomide births, began requiring pharmaceuticals not only to demonstrate that they were safe at the pre-market stage, but also that they were effective.¹³⁴ After the implementation of these standards and FDA's new labeling requirements, pharmaceuticals that carried teratogenic risks would have to be clearly labeled "Category D" or "Category X" before they could be marketed.¹³⁵ Further, before they could be marketed, they would have to be run through the "Segment I" (fertility and general reproduction),

four" children, so bringing the fetus to term would mean "the others would be cheated of part of their birthright." Mrs. Finkbine ultimately traveled to Sweden to obtain an abortion, expressing her "belief that God had offered her 'the power to prevent' the birth of a 'malformed baby.'" *Id.* at 89 (quoting Sherri Finkbine, *The Baby We Didn't Dare to Have*, 120 REDBOOK 99 (1963)).

¹³³ The effects of thalidomide on the fetus depend on when in the pregnancy it is taken, and it is unclear how many children were affected in the 1960s. Some have suggested the drug affected between 10,000 and 20,000 births globally. Carl Zimmer, *Answers Begin to Emerge on How Thalidomide Caused Birth Defects*, N.Y. TIMES (Mar. 15, 2010), <http://news.bbc.co.uk/2/hi/health/8458855.stm>. During the period from 1958 to 1961 when thalidomide was licensed in the United Kingdom, 2,000 babies were born with defects; of these, half died within a few months, and at least 466 had survived until 2010. Nick Triggle, *Apology to Thalidomide Survivors*, BRIT. BROADCASTING CORP. (Jan. 14, 2010, 13:13 GMT), <http://news.bbc.co.uk/2/hi/health/8458855.stm>. Numerous wrongful life and wrongful birth actions would be brought on behalf of children a decade after the above birth defect outbreaks from the 1960s, most often for CRS. *E.g.*, *Gleitman v. Cosgrove*, 227 A.2d 689, 692–93 (N.J. 1967); *Stewart v. Long Island Coll. Hosp.*, 283 N.E.2d 616, 616 (N.Y. 1972); *Jacobs v. Theimer*, 507 S.W.2d 288, 290 (Tex. Civ. App. 1974); *Dumer v. St. Michael's Hospital*, 233 N.W.2d 372, 373 (Wisc. 1975).

¹³⁴ *Kefauver-Harris Amendments Revolutionized Drug Development*, FDA, <https://www.fda.gov/consumers/consumer-updates/kefauever-harris-amendments-revolutionized-drug-development> (last updated Sept. 10, 2012).

¹³⁵ FOOD & DRUG ADMIN., THE CODE OF FEDERAL REGULATIONS OF THE UNITED STATES OF AMERICA 22–23 (1983).

“Segment II” (teratogenicity), and “Segment III” (perinatal) protocols instituted by the FDA in 1966.¹³⁶

Abortion reforms before *Roe* also signaled a growing acceptance of using access to fetal PHI in tandem with abortion to prevent someone from living with serious or severe congenital disease. In 1962, the American Law Institute (“ALI”) published the Model Penal Code, for example, which included a recommendation that abortions be allowed in cases of a severe fetal defect.¹³⁷ “Colorado became the first state to reform its abortion law based on the ALI’s recommendation[.] . . . and by 1972, [thirteen] states had so called ALI statutes.”¹³⁸ Thus, well before *Roe*, it began to be possible for prospective parents to learn about fetal PHI for purposes of making informed abortion decisions.¹³⁹ Similarly, well before *Griswold v. Connecticut* and *Eisenstadt v. Baird*, the FDA had begun approving new oral contraceptives, i.e., “the Pill.”¹⁴⁰

As the next Part explores further, it is clear that the idea of fetal PHI immediately suggests that protecting PHI in utero might seem to clash with some of the more central values of the Court’s abortion jurisprudence upholding or expanding on *Roe*. However, there is nothing about this Article’s defense of the need to protect PHI in utero that must come into conflict with the Court’s jurisprudence of reproductive rights. To the contrary, it emphasizes that the issue of an entity having its rights violated only arises if it is in fact *not*

¹³⁶ See J.W. Kille, *Regulatory Toxicology*, in A COMPREHENSIVE GUIDE TO TOXICOLOGY IN NONCLINICAL DRUG DEVELOPMENT 525 (Ali S. Faqi ed., 2016).

¹³⁷ MODEL PENAL CODE § 230.3 (AM. LAW INST., Proposed Official Draft 1962).

¹³⁸ Rachel Gold, *Lessons from Before Roe: Will Past Be Prologue?*, 6 GUTTMACHER INST. REP. ON PUB. POL’Y 8, 9 (2003).

¹³⁹ But see Luke Mintz, ‘Are We Entering a New Era of Eugenics in Which People Like Me Will be Edited from the Population?’, TELEGRAPH (Oct. 9, 2019, 4:30 PM), <https://www.telegraph.co.uk/health-fitness/body/entering-new-era-eugenics-people-like-will-edited-population/> (providing a perspective of a disability rights activist with neurofibromatosis on the possibility of the condition being genetically edited from the human population); see also note 107 and the sources therein (problematizing the elimination of people with Down Syndrome from the population through selective abortion).

¹⁴⁰ PLANNED PARENTHOOD FED’N OF AM., THE BIRTH CONTROL PILL: A HISTORY 8 (2015), https://www.plannedparenthood.org/files/1514/3518/7100/Pill_History_FactSheet.pdf.

aborted. In the scenario of making an informed abortion decision, an abundance of PHI could be returned to pregnant women without it being necessary to divulge the *entirety* of the information generated about the fetal genome, as this would include ample information beyond that which is useful in such a decision. Today, even divulging the entire fetal genome does not become problematic as a matter of law if it motivates the decision to abort, since in such a case, no legal person would come into existence with violated rights.¹⁴¹

The possibility of protecting legal rights in the womb has centuries-old origins,¹⁴² extending as far back as Blackstone and Coke in the contexts of probate and criminal law.¹⁴³ U.S. courts by the outset of the nineteenth century would follow the English common law in according rights to the unborn—for example, in cases where a testator died before the birth of a child identified to take under a will.¹⁴⁴ Succinctly put, in all of these contexts, such

¹⁴¹ To emphasize, as mentioned, gaining access to three billion base pairs on its own hardly amounts to information (indeed, many regions of sequences are intronic DNA, regions identified as not synthesizing any proteins), unless a sequencing company analyzed it or one had the right equipment and wherewithal to compare it against published results of sequences that have been associated with particular risks, diseases, or other characteristics. *See supra* note 11.

¹⁴² Many of the cases creating this precedent involve scenarios in which an heir under a will was not born until after the testator died. *E.g.*, *Thellusson v. Woodford* (1799) 4 Ves. 227, 227; *Wallis v. Hodson* (1740), 2 Atk. 114, 114; *Doe v. Clark* (1795) 2 H BI 399, 399.

¹⁴³ If “the childe be born alive and dyeth of the potion, battery, or other cause, this is murder,” Coke had noted, yet he and Blackstone held the same view that prenatal injury causing stillbirth is not murder but rather “merely [] a heinous misdemeanor.” The crime was thus a lesser one if the prenatal injury did enough damage that it killed the fetus before birth. Cases as early as the eighteenth century reflected that courts followed the English common law, requiring that prenatally injured fetuses first be born before dying for their deaths to be treated as murder. WILLIAM BLACKSTONE, *COMMENTARIES ON THE LAWS OF ENGLAND*, vol. 1, bk. 1, 126 (1765); EDWARD COKE, *THE THIRD PART OF THE INSTITUTES OF THE LAWS OF ENGLAND: CONCERNING HIGH TREASON; AND OTHER PLEAS OF THE CROWN, AND CRIMINAL CAUSES* 58 (1644).

¹⁴⁴ *E.g.*, *Biggs v. McCarty*, 86 Ind. 352, 363 (Ind. 1882) (treating a fetus as a tenant in common with its mother); *Hall v. Hancock*, 32 Mass. 255, 258 (Mass. 1834) (extending legal personhood to the unborn in a case where the testator died nearly nine months before the child was born, i.e., the legal person judicially

rights only materialize in those instances in which the fetus is born and thereby recognized as a legal person. Even the condition of being born, Judge Oliver Wendell Holmes, Jr. would conclude on the Massachusetts Supreme Court, is insufficient on its own. Rather, under the doctrine of “prospective conditional liability” (“prospective” in the sense of forward-looking, and “conditional” in the sense of being dependent on a plaintiff being born alive) that he introduced into tort law, the person born must additionally stay alive long enough to maintain standing in any litigation asserting the person’s rights.¹⁴⁵

This born-alive prong of the doctrine of prospective conditional liability would be fatal to prenatal tort claims for over half a century (that is, often the prenationally injured plaintiff would die from the injuries before litigation had concluded),¹⁴⁶ from the first time a court entertained such an action in 1884. Indeed, while Holmes recognized the first prenatal tort in *Dietrich v. Inhabitants of Northampton*, this novelty was of little use to the infant plaintiff, the case being dismissed because the infant had already died from the prenatal injuries.¹⁴⁷ The national terrain of the prenatal tort only

recognized and allowed to take under a will was a conceptus that had barely been conceived); *Aubuchon v. Bender*, 44 Mo. 560, 569 (Mo. 1869) (recognizing a contingent remainder could vest in the unborn); *Hill v. Moore and Watters*, 5 N.C. 233, 234 (N.C. 1809) (finding the distributive share of the unborn child vested in the child’s mother).

¹⁴⁵ This doctrine articulated that “an injury transmitted from the actor to a person through his own organic substance, or through his mother, before he became a person” could theoretically stand “on the same footing as an injury transmitted to an existing person through other intervening substances outside him . . . *the argument would not be affected by the degree of maturity reached by the embryo* at the moment of the organic lesion or wrongful act.” *Dietrich v. Inhabitants of Northampton*, 138 Mass. 14, 16 (Mass. 1884) (emphasis added).

¹⁴⁶ See, e.g., *Smith v. Luckhardt*, 19 N.E.2d 446, 447–48 (Ill. App. Ct. 1939) (The plaintiff died at age thirteen as the result of an x-ray her mother underwent when she was a pre-viable fetus, and the court found it dispositive that she was not viable at the time.); *Nugent v. Brooklyn Heights Railroad Company*, 139 N.Y.S. 367, 371 (N.Y. App. Div. 1916) (implying that the defendant could not reasonably have known the plaintiff’s mother to have been pregnant).

¹⁴⁷ *Dietrich*, 138 Mass. at 15 (“There was testimony, however, based upon observing motion in its limbs [after premature birth], that it did live for ten or fifteen minutes The court below ruled that the action could not be maintained; and we are of opinion that the ruling was correct.”). In other words,

began in 1946, when the first federal court allowed recovery,¹⁴⁸ spurring state courts across the country to follow suit in recognizing the action.¹⁴⁹ Therefore, by the mid-twentieth century, a legal framework already existed recognizing the importance of protecting some rights in utero, including the original prenatal tort claim (one in which an injury to a fetus could become the basis of a tort action committed against the fetus if it is later born alive), and also, beginning in the 1960s, extending to the “wrongful life” action as well (a malpractice claim alleging that a child born alive would never have been born but for the negligent advice or treatment given to the parents by a healthcare provider—such as a failure to warn parents about risks of serious congenital disease).¹⁵⁰

One of the important social conditions behind this development of prenatal torts was the transition of childbirth from homes to hospitals,¹⁵¹ a crucial change propelled by federal efforts from the

Judge Holmes created the doctrine of prospective conditional liability as a two-pronged doctrine—a defendant may only be held liable where (1) doing so would be in the interests of a born person, and (2) a person is in fact born alive—but the infant who was the plaintiff of *Dietrich* (brought ad litem by parents) was no longer alive to have interests that could be benefited by holding the defendant liable, and arguably did not even live long enough after birth to constitute being “born alive” within the meaning of the doctrine. *Id.* at 15–17.

¹⁴⁸ *Bonbrest v. Kotz*, 65 F. Supp. 138, 143 (D.C.C. 1946) (“The law is presumed to keep pace with the sciences and medical science certainly has made progress since 1884.”).

¹⁴⁹ Cases showing states choosing not to recognize the prenatal tort include: *Stanford v. St. Louis-San Francisco Ry. Co.*, 108 So. 566 (Ala. 1926); *Smith v. Luckhardt*, 19 N.E.2d at 446, 451, 477; *Bliss v. Passanesi*, 95 N.E.2d 206, 207 (Mass. 1950); *Newman v. City of Detroit*, 274 N.W. 710, 711 (Mich. 1937); *Buel v. United Rys. Co. of St. Louis*, 154 S.W. 71, 72–73 (Mo. 1913); *Drabbels v. Skelly Oil Co.*, 50 N.W.2d 229, 223 (Neb. 1951); *Stemmer v. Kline*, 26 A.2d 489, 491 (N.J. 1942); *Drobner v. Peters*, 133 N.E. 567, 568 (N.Y. 1921), *overruled by* *Woods v. Lancet*, 102 N.E.2d 691 (N.Y. 1951); *Berlin v. J.C. Penney Co., Inc.*, 16 A.2d 28, 28 (Pa. 1940); *Gorman v. Budlong*, 49 A. 704 (R.I. 1901); *Magnolia Coca Cola Bottling Co. v. Jordan*, 78 S.W.2d 944, 950 (Tex. Comm’ m App. 1935); *Lipps v. Milwaukee Electric Ry. & Light Co.*, 159 N.W. 916, 917 (Wis. 1916).

¹⁵⁰ See *Zepeda v. Zepeda*, 190 N.E.2d 849, 852–53 (Ill. App. Ct. 1963); *Williams v. State of New York*, 223 N.E.2d 343, 343 (N.Y. 1966).

¹⁵¹ *E.g.*, CHARLOTTE BORST, *CATCHING BABIES: THE PROFESSIONALIZATION OF CHILDBIRTH, 1870–1920* 91 (1995); JUDITH WALZER LEAVITT, *BROUGHT TO BED: CHILDBEARING IN AMERICA, 1750–1950* 171 (1986).

New Deal era into the postwar Hill-Burton grants of the Truman administration,¹⁵² among other causes. Within broader goals of addressing the national healthcare system, these grants were critical in facilitating and promoting hospital renovation and construction. Of course, with scientists in the early twentieth century rediscovering Mendelian inheritance, unpacking the chromosome, identifying the function and location of the gene, and discovering a host of disease-causing microorganisms, many had turned to hospitals viewing them as a bastion of the promises of scientific medicine.¹⁵³

This new context of childbirth involving medical professionals and hospital patients outside the home gave rise to the first cases in which a plaintiff alleging prenatal injury prevailed on the claim, but a system of formal prenatal tort recovery had yet to solidify. For over half a century since *Dietrich* in 1884, courts were either unwilling to adopt the doctrine of prospective conditional liability,¹⁵⁴ or they found other reasons for denying recovery in cases of prenatal injury—for example, finding that the defendant could not reasonably have known that the plaintiff’s mother was pregnant at the time of the prenatal injury.¹⁵⁵ When the first courts finally

¹⁵² Hospital Survey and Construction Act, Pub. L. No. 725, 60 Stat. 1040, ch. 958 (1946) (codified as amended at 42 U.S.C. § 291o (1976)).

¹⁵³ See JOEL HOWELL, *TECHNOLOGY IN THE HOSPITAL: TRANSFORMING PATIENT CARE IN THE EARLY TWENTIETH CENTURY* 5 (1995) (describing “shiny new machines” like x-ray and equipment found in hospital laboratories as incentives hospitals offered to draw in consumer patients); see also JAMES MOHR, *LICENSED TO PRACTICE: THE SUPREME COURT DEFINES THE AMERICAN MEDICAL PROFESSION* 12–13 (2013) (noting how the term “regular” was one that the AMA’s physicians applied to their own healing practices that emphasizes laboratory findings, systematic study, and peer-review and replication of results, in contrast with alternative schools of healing like Thomsonianism, botanism, hydrophathy, homeopathy, and eclecticism).

¹⁵⁴ The concept of prospective conditional liability, not accepted by courts, posited that, in some circumstances, fetuses are owed a civil duty. *Smith v. Luckhardt*, 19 N.E.2d 446 (Ill. App. Ct. 1939) (the plaintiff having died at age thirteen as the result of an x-ray her mother underwent when she was a pre-viable fetus, and the court finding it dispositive that the injury occurred before the plaintiff was a viable fetus).

¹⁵⁵ See *Nugent v. Brooklyn Heights R.R. Co.*, 139 N.Y.S. 367, 371 (N.Y. App. Div. 1913) (“But it is not the duty of a carrier to scrutinize its passengers for the detection of unborn children, to the end that they, although latent, may be

recognized the prenatal tort, this latter excuse would have been unavailing, as the relevant actions arose as the result of prenatal injuries (like cerebral palsy) sustained by use of forceps during professional medical deliveries.¹⁵⁶

Despite the initiation of this jurisprudence recognizing prenatal physical injuries as cognizable legal harms to living individuals, the next step never occurred, namely, of recognizing an individual's right to seek compensation for prenatal *informational* injury.¹⁵⁷ One reason this is somewhat surprising is because the legal doctrine of informed consent was already well-developed by the time that states across the country began recognizing the right to seek recovery for one's own prenatal physical injuries from the 1950s onwards.¹⁵⁸

regarded as passengers . . . [Y]et it would not be liable to the child for mere negligence in the carriage of the mother, as it would owe its duty as a carrier to the mother and not to the child.”)

¹⁵⁶ *Scott v. McPheeters*, 92 P.2d 678, 679 (Cal. Dist. Ct. App. 1939); *see Bonbrest v. Kotz*, 65 F. Supp. 138, 143 (D.C.C. 1946).

¹⁵⁷ Though considerably different, the “wrongful life” action might be argued to be capable of protecting something approximating this—e.g., the prenatal informational injury being a failure to disclose information to *parents* that would have meant the plaintiff would not have come into existence. This is a stretch from the present context, however, as wrongful life would only construe a *failure* to divulge PHI as a legal wrong (e.g., failing to return fetal PHI to parents indicating fetal anomalies that would have led parents to choose abortion), rather than *divulging* fetal PHI as a wrong.

¹⁵⁸ *See Canterbury v. Spence*, 464 F.2d 772, 786 (D.C. Cir. 1972). As I have discussed elsewhere,

Shack v. Holland exemplifies how the concept of informed consent would start to be applied in the context of prenatal injuries, revealing the transition away from battery in favor of negligence actions. Even though some new forceps had been available by the 1930s that were designed to protect the fetal head, and even with the Caesarean section as a safer option obviating the need to use forceps, the case also indicates that this source of prenatal injury had not been eradicated. The plaintiff in *Shack* was alleged to have been injured by the defendant obstetrician during childbirth and left “permanently maimed and deformed.” Given that the plaintiff was twenty-two years old at the time of the lawsuit, however, a central issue was whether the statute of limitations had already run. That question, in turn, depended on whether the plaintiff's claim was a battery or a negligence action, since the latter had a longer

Consequently, people were left without protections or the possibility of recovery for injury to their PHI in the perinatal context as parents simultaneously started to have greater access to that information through venues like diagnostic uses of amniocentesis. While the majority view is that parental access to such fetal information is guaranteed as a right subsumed within their federal reproductive rights,¹⁵⁹ born individuals have generally been left without recourse in terms of unjustified perinatal informational injuries.

statute of limitations. Without needing to create a new definition of informed consent from whole cloth, the court was able to rely on the state's statutorily provided definition: Lack of informed consent means the failure of the person providing the professional treatment or diagnosis to disclose to the patient such alternatives thereto and the reasonably foreseeable risks and benefits involved as a reasonable medical practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation.

Luke Haqq, *The Impact of Roe on Prenatal Torts: On the Public Policy of Unexpected Children*, 13 J. TORT L. 1, 30 (forthcoming 2020) [hereinafter Haqq, *The Impact of Roe on Prenatal Torts*] (citing *Shack v. Holland*, 389 N.Y.S.2d 988, 993 (N.Y. Sup. Ct. 1976)). Applying *Dietrich*, the court found "that a conditional prospective liability to a fetus is created when an unborn child's mother is not sufficiently informed of the risks, hazards, and alternatives of the delivery procedure administered." *Shack*, 389 N.Y.S.2d at 993. The court then brought this statutory definition of informed consent to bear in the context of childbirth:

Having concluded that the unborn plaintiff has a cause of action and that the duty to disclose the reasonable foreseeable risks involved is grounded in negligence, the immediate question is whether this plaintiff has a cause of action against this defendant for lack of informed consent to the mother of the child here involved The court finds that although the obligation to disclose runs to the mother, plaintiff, Neil Shack, then unborn but within his mother's womb, comes within the area of persons to be protected. The lack of informed consent of the mother would have its effect upon the fetus to be born for good or ill. A child in its mother's womb is a foreseeable circumstance. Conduct, which creates a risk of harm to a woman, includes also a risk of harm to her unborn child.

Id.

¹⁵⁹ Haqq, *The Impact of Roe on Prenatal Torts*, *supra* note 158, at 43–44 (providing national maps of prenatal torts, which show how most states recognize the wrongful birth action, and nearly all have recognized the tort for wrongful conception as well). These actions recognize abortion and contraception as

These decades are the timeframe within which parents also became capable of accessing the PHI of their children through newborn screening programs. However, the failure to protect their PHI was—and continues to be—more palpably problematic in the in utero context than in newborn screening programs. This is true as a matter of pure quantity: a sole condition, PKU, was a key catalyst for the emergence of newborn screening programs.¹⁶⁰ By contrast, even at that time in the 1960s, there were already more conditions than could be tested for in utero with clinical applications—several types of trisomies, retinitis blastoma, and hemophilia, for instance.¹⁶¹ It is also true as a matter of function: the overriding purposes of newborn screening programs are to screen for conditions that can be effectively treated in infancy or early childhood to save children born with such conditions from lifelong debility.¹⁶² Accessing PHI in utero, by contrast, is more relevant to

informed consent rights to be apprised of risks that are material or germane to reproductive decision-making. *Id.*

¹⁶⁰ See, e.g., DIANE B. PAUL & JEFFREY P. BROSCO, *THE PKU PARADOX: A SHORT HISTORY OF GENETIC DISEASE* 54–59 (2013) (describing other relevant developments to include tests for congenital syphilis risks in the early twentieth century, growing consumer confidence in scientific medicine from sulfa drugs, penicillin, the Salk and Sabin vaccines, and increased attention given to diseases causing mental impairment under the Kennedy administration).

¹⁶¹ See generally Malcolm Ferguson-Smith, *supra* note 130 (discussing uses of amniocentesis to identify such conditions by the midcentury).

¹⁶² At the same time, newborn screening panels also extend to many conditions that are less severe than PKU. While highly effective treatments for otherwise highly debilitating congenital conditions seems to be a clear case where the minor's consent could be presumed, routine aural screening for deafness, by contrast, seems much more problematic or complex, since it is not necessarily the case that giving parents this PHI of their children is in the best interests of the child. If both options could be grounded in presumed consent—e.g., if cochlear implants with partial hearing and total deafness are incommensurable, but equally reasonable options (that is, assuming that neither can be said to be worse than the other with respect to the child's expected wellbeing)—then it could be argued that parents should be given access to this PHI. See e.g., Mara Mills, *Do Signals Have Politics? Inscribing Abilities in Cochlear Implants*, in *OXFORD HANDBOOK OF SOUND STUDIES* 321, 237 (Trevor Pinch & Karin Bijsterveld eds., 2011). *But see infra* Part V (suggesting only releasing PHI from newborn screening that is necessary to avert serious, severe, or lethal congenital conditions).

fulfilling parental wishes about what kind of child they want to have.¹⁶³

The differences between accessing PHI in newborn screening programs for specific detection purposes versus conducting broad genomic sequencing in utero are exacerbated by the possibility that prenatal PHI will not only continue to be used for analysis of disease and deformity in order to inform abortion decisions, but also with new ways of editing of genes at the embryonic stage. It is true that today's newborn screening panels do screen for and return results about numerous conditions,¹⁶⁴ but again, the overwhelming purpose of these programs is to improve the health and wellbeing of the children born with regard to problems that would otherwise affect them in childhood. For this reason, such accessing of the PHI of newborns is easily justified in that implied consent from the subject of the PHI can be presumed because accessing information about propensity to disease is materially within the child's best interests. Even though the later-born child is incapable of consent at the time of PHI access, the fact that such unauthorized access to PHI can be needed to stave off lifelong debilitating health concerns suggests the child would offer "retrospective" consent once rationally capable of doing so. This might even include retrospective consent in the prenatal context not to come into existence with a lethal disease like Tay Sachs.

The interests of the unborn and prospective parents begin to decouple, however, since fetal genomic information in this context serves an important function in a parent's right to choose, and indeed

¹⁶³ See *infra* note 182 (explaining the Supreme Court's definition of abortion as a liberty, autonomy, and privacy right, protected by the "life" and "health" exceptions carved out by *Roe* and *Bolton*); see also Lawrence B. Finer et al., *Reasons U.S. Women Have Abortions: Quantitative and Qualitative Perspectives*, 37 PERSP. ON SEXUAL & REPROD. HEALTH 110, 112 (2005) (describing personal inconvenience as the motivation behind almost three-quarters of abortions reported). Since *Roe*, any best-interests standard has not existed (some would argue it entered with the undue-burden standard of *Casey*, but this fails to account for the expanse of the health and life exceptions mandated by *Roe* and *Bolton*) because priority is given to the pregnant woman's liberty, autonomy, and privacy interests, as well as her mental and physical health interests.

¹⁶⁴ See Lewis & Goldenberg, *supra* note 93, at 560 (explaining how newborn screening identifies over 12,000 individuals annually with congenital conditions necessitating further specialized care).

studies have shown sustained trends over several decades that women will be more likely to obtain an abortion if the PHI that they access indicates fetal pathology than if they never had such information. In the U.S. and elsewhere, these studies indicate the vast majority of women who obtain testing and receive negative results choose abortion.¹⁶⁵ By contrast, it is difficult to conceptualize how the access of certain PHI in utero (as, for instance, with the disclosure of an entire fetal genome) could similarly be grounded in the presumed informed consent of the later-born child when that information does not serve a purpose of disease prevention but instead becomes increasingly relevant to new potentials regarding gene editing and parental decision to create designer babies. In such a case, the best interests served in something like a newborn screening program are no longer present.

IV. THE IMPACT OF FEDERAL REPRODUCTIVE RIGHTS ON PHI IN CHILDHOOD

The decades showing high rates of selective abortion after PHI is accessed in utero for informative purposes speaks to how this Article's proposal does not negate the abortion right but also presses the need for reform with respect to limiting the potentially abundant PHI disclosures in utero to information relevant either to abortion decisions or childcare factors that are justified by a best-interests standard. Nevertheless, as mentioned, this Article's recommendations do not require a fundamental reworking of *Roe v. Wade*.¹⁶⁶ This Part considers how the proposal to protect PHI in

¹⁶⁵ See, e.g., Tamsen Caruso et al., *Impact of Prenatal Screening on the Birth Status of Fetuses with Down Syndrome at an Urban Hospital 1972-1994*, 1 GENETICS MEDICINE 22 (1998); Mathias B. Forrester & Ruth D. Merz, *Epidemiology of Down Syndrome*, 65 TERATOLOGY 207 (2002); Ralph Kramer et al., *Determinants of Parental Decisions After the Prenatal Diagnosis of Down Syndrome*, 79 AM. J. MED. GENETIC 172 (1998); Caroline Mansfield et al., *Termination Rates After Prenatal Diagnosis for Down Syndrome, Spina Bifida, Anencephaly, and Turner and Klinefelter Syndromes: A Systematic Literature Review*, 19 PRENATAL DIAGNOSIS 808 (1999); Jaime L. Natoli et al., *Prenatal Diagnosis of Down Syndrome: A Systematic Review of Termination Rates (1995-2011)*, 32 PRENATAL DIAGNOSIS 142, 150 (2012).

¹⁶⁶ To reiterate, any informational right would follow the model of *Dietrich* and thereby comport with *Roe*'s notion of personhood. That is, *Dietrich* took legal

utero might be *thought* to be incompatible with abortion, specifically with the Supreme Court's framework that defines it as a woman's liberty right, as her right to bodily integrity, and as a right to privacy, but suggests that none of these rights conceptualizations provides a knock-down reason against protecting PHI in utero because of its legal importance to born individuals.

First, it is worth reemphasizing why abortion is the most pertinent of the federal reproductive rights. As mentioned, with regard to PHI at the juncture of parental avoidance of birthing children with certain diseases or disorders, parents reasonably have considerable power prior to conception to select which children to avoid creating by taking into account factors like carrier status, workplace teratogenic risks,¹⁶⁷ threats from mosquito-borne diseases in possible vacation destinations,¹⁶⁸ and parental age. Any such information that parents use prior to conception to inform their sexual and reproductive choices draws either on the parents' own PHI or on exogenous, environmental factors. Unlike the case of selective abortion, such options do not involve accessing genetic or

rules from probate law (the "for the interests" rule) and criminal law (the "born alive" rule) and merged them into the two-pronged doctrine of prospective conditional liability. While this doctrine introduced liability for prenatal injuries into tort law (i.e., protections for the unborn), it only extended legal rights to the subset of the unborn who are eventually born and stay alive. In this way, the *Dietrich* model does not challenge *Roe*'s principle of the non-personhood of the conceptus prior to birth; if the route of abortion is taken, then no legal person is in fact born alive (failing the born-alive prong) with interests that could be furthered by holding a third-party liable for prenatal injuries (failing the for-the-interests prong). If abortion is chosen, then *Dietrich* ascribes no legal personhood to the unborn because the situation cannot satisfy both prongs of the doctrine of prospective conditional liability, but if abortion is *not* chosen, the *Dietrich* model permits a range of rights to be accorded to the unborn.

¹⁶⁷ *E.g.*, *Peters v. Texas Instruments, Inc.*, C.A. No. 10C-06-043 (JRJ), 2011 WL 4686518, at *1 (Del. Super. Ct. 2011) (plaintiff seeking recovery under his state's worker's compensation statute for an "insult to his reproductive system" that resulted from exposure to toxic substances at work and led to his child's birth with retinoblastoma); *Catherwood v. American Sterilizer Co.*, 498 N.Y.S.2d 703, 704 (N.Y. Sup. Ct. 1986) (discussing preconception chromosomal damage claimed to have been caused by the plaintiff's mother's exposure to ethylene oxide).

¹⁶⁸ *See* Haqq, *Of Mosquitoes, Adolescents, and Reproductive Rights*, *supra* note 1, at 828.

genomic information that can be individuated from that of parents (i.e., prior to any unique combination of sperm and egg). Possibilities like IVF, PGD, and embryonic gene editing do highlight, though, that sometimes, individuated PHI can exist even before implantation.¹⁶⁹

Here, one anticipated objection becomes apparent: even if such genetic or genomic information can be claimed to be that of an individuated entity, perhaps it should not be considered to be distinct in utero because this would be incompatible with upholding abortion as a bodily integrity right, since any conceptus—short of being kept alive by an incubator—obviously falls entirely within the body of the pregnant woman carrying it. Indeed, the Court was explicit in recognizing abortion as a bodily integrity right.¹⁷⁰ If abortion *qua* a bodily integrity right could be interpreted to encompass the genetic or genomic information of the conceptus, and thus the PHI of a later-born individual, one implication is that it would extend the abortion right as a bodily integrity right reaching far beyond birth in time and far beyond the bodies of pregnant women. Under this line of thinking, *fully grown adults* who learn that their PHI was accessed or disclosed in utero would be denied full protections for their PHI because it would be considered part of their mothers' bodies. This is deeply implausible, as it would effectively deny adults a right to the inviolability of their own PHI on the grounds that their PHI and bodies once existed in utero.¹⁷¹ This Article, in contrast, has

¹⁶⁹ See Giulia Cavaliere, *Genome Editing and Assisted Reproduction: Curing Embryos, Society or Prospective Parents?*, 21 MED. HEALTH CARE & PHIL. 215, 216 (2018).

¹⁷⁰ *Planned Parenthood v. Casey*, 505 U.S. 833, 835 (1992) (“[I]f *Roe* is seen as stating a rule of personal autonomy and bodily integrity, akin to cases recognizing limits on governmental power to mandate medical treatment or to bar its rejection, this Court’s post-*Roe* decisions accord with *Roe*’s view that a State’s interest in the protection of life falls short of justifying any plenary override of individual liberty claims.”). *But see* *Roe v. Wade*, 410 U.S. 113, 154 (1973) (the Court citing to its prior rulings permitting vaccination and involuntary sterilization as suggestive that it has never found that “one has an unlimited right to do with one’s body as one pleases”).

¹⁷¹ Nevertheless, HIPAA effectively treats fetuses themselves as the PHI of pregnant women: the statute defines “genetic information” to include not only an individual’s genetic tests and the genetic tests of family members, but also “[a] fetus carried by the individual or family member who is a pregnant woman.”

emphasized the importance of protecting an individual’s PHI—whether (later-born) conceptus, child, or adult—throughout the entirety of the individual’s lifetime; a failure to take a nuanced, minimum-necessary approach (divulging information only if relevant for informing the rights to contraception and abortion) would expand abortion right far outside the context of pregnancy, affecting the informational privacy rights of children and adults.

Another line of argument that it is permissible to gain nonconsensual access to PHI in utero might be rooted in the conceptualization of abortion as a privacy right, rather than as a bodily integrity right. Continuing the line of precedent begun by *Griswold v. Connecticut*,¹⁷² this might be argued to be the privacy of parents to the decisions they make in the bedroom. More often, especially after *Planned Parenthood v. Casey*,¹⁷³ it is less a general privacy of sexually active people but rather specifically the privacy of pregnant women—privacy in their sexual, reproductive, and personal choices, and privacy in their doctor-patient relationships. Indeed, before *Casey*, one state’s supreme court declared in recognizing the wrongful conception action, “The United States Supreme Court in *Roe* and *Griswold* has recognized that a woman has the right to plan the size of her family,” even though nothing about the latter limited its protections just to women.¹⁷⁴ In this way,

Public Welfare, 45 C.F.R. § 160.103 (2018). First, as suggested below, such a recognition in HIPAA might be necessary for it to comport with the federal reproductive rights, so it would be conclusory to take the matter to be settled as a reason to ignore any arguments that challenge the federal reproductive rights. *See* notes 13, 28, and accompanying text (explaining that an “individual” under HIPAA simply means the “subject” entity of the PHI, and providing examples of technologies like fetal genomic sequencing in which the individual that is the subject of the PHI arguably seems more to be the conceptus rather than the pregnant woman). Second, this definition in HIPAA is unsurprising, given its dearth of protections for minors generally, as already discussed. *See supra* Part II.

¹⁷² *Griswold v. Connecticut*, 381 U.S. 479 (1965).

¹⁷³ *See generally Casey*, 505 U.S. 833 (finding spousal consent and spousal notification requirements to be unconstitutional under *Roe*).

¹⁷⁴ *Fulton-DeKalb Hosp. Auth. v. Graves*, 314 S.E.2d 653, 653 (Ga. 1984) (citing *Roe*, 410 U.S. 113 and *Griswold*, 381 U.S. 479).

state courts began to expand the abortion right in a gendered direction even before the Court explicitly did so in *Casey*.¹⁷⁵

This line of argumentation used against protecting fetal PHI in utero would be somewhat implausible because it presupposes what it sets out to establish. It asserts that a given act is permissible by claiming that the Constitution contains a right of individuals to privacy, but then leverages that assertion for the precise purpose of claiming that born individuals do not have any right to privacy of their PHI in utero. If there indeed is a right to privacy found within the Constitution, then surely a question arises as to balancing interests, as a compelling justification for refusing to keep any PHI private in utero must be based on some reason other than the fact that pregnant women have a recognized right to privacy over the abortion decision. At the very least, such reasoning would need to articulate why one individual's right to privacy (the mother's) outweighs another individual's countervailing privacy (that of the later-born individual with PHI).

Still, it could be argued that there are different kinds or degrees of privacy interests at stake. This seems more promising, as the Court has gestured towards recognizing a constitutionally protected right to informational privacy but has not explicitly recognized it. It first suggested this in two cases from 1977, *Whalen v. Roe* and *Nixon v. Administrator of General Services*, but fell short of articulating that such a right exists.¹⁷⁶ The Court revisited the issue in 2011 in *NASA v. Nelson*, a case in which contract employees at Caltech brought suit against the university, NASA, and the Department of Commerce, claiming such an informational privacy right was violated by NASA's open-ended background check, which required an effectively comprehensive release of personal information to avoid termination.¹⁷⁷ Similar to the argumentation it employed in *Whalen*, the Court in *NASA* supposed such a right existed for the sake of argument, but ultimately skirted the question by finding that

¹⁷⁵ See *Casey*, 505 U.S. at 878, 901 (striking down spousal consent and spousal notification requirements for abortions as unconstitutional).

¹⁷⁶ See generally *Nixon v. Adm'r of General Servs.*, 433 U.S. 425 (1977) (failing to recognize a constitutional right to informational privacy); *Whalen v. Roe*, 429 U.S. 589 (1977) (determining that the case before the Court did not create an "invasion of any [privacy] right").

¹⁷⁷ *NASA v. Nelson*, 562 U.S. 134, 138–39 (2011).

the state possessed a sufficiently compelling interest anyway to gain access to this personal information.¹⁷⁸

If the Court does recognize an informational right to privacy within the Constitution, this issue would return to the need to balance competing privacy interests. While the right to privacy over abortion decisions is required under the Court's reproductive rights jurisprudence, a born individual should also have a right with respect to informational privacy over PHI in utero; complete denial of PHI protection in utero is not narrowly tailored to accommodate both privacy interests. This concern will continue as genetic and genomic information becomes increasingly accessible and therefore increasingly capable of becoming un-private. The black box metaphor, discussed in the final Part, suggests a balance recognizing the privacy interests of pregnant mothers, especially in their abortion decisions, as well as the interests of born individuals.

The most plausible and direct approach for claiming that protecting PHI in utero is incompatible with the abortion right is the argument that it conflicts with abortion as a liberty and autonomy right. Though the Court focused on abortion as a privacy right in *Roe*, it made its status as a liberty and autonomy right clear in its subsequent abortion jurisprudence.¹⁷⁹ In later abortion cases, it explicated that this constitutionally protected liberty guarantees not just privacy but also decisional autonomy, including a pregnant woman's freedom to "determine her life's course"¹⁸⁰ and exercise "control over her destiny"¹⁸¹ by opting to terminate the pregnancy.

¹⁷⁸ Compare *id.* at 155 (recognizing the "regulatory duty to avoid unwarranted disclosures" while acknowledging the government's interest), with *Whalen*, 429 U.S. at 605–06 ("We therefore need not, and do not, decide any question which might be presented by the unwarranted disclosure of accumulated private data—whether intentional or unintentional—or by a system that did not contain comparable security provisions. We simply hold that this record does not establish an invasion of any right or liberty protected by the Fourteenth Amendment.").

¹⁷⁹ *E.g.*, *Roe v. Wade*, 410 U.S. 113, 113–54 (1973) (the majority opinion only mentioning "liberty" four times—but each time as part of finding a right of *privacy* within such a constitutional guarantee of liberty—and ruling, "We, therefore, conclude that the right of personal privacy includes the abortion decision.").

¹⁸⁰ *Gonzales v. Carhart*, 550 U.S. 124, 172 (2007) (Ginsburg, J., dissenting).

¹⁸¹ *Planned Parenthood v. Casey*, 505 U.S. 833, 869 (1992).

Certainly, part of *Roe*'s social significance lay in the recognition of the abortion right as a venue for promoting greater de facto equality in the labor market, by giving sexually active women greater control over choices like whether to have children, when to have them, and what sorts of children they want to raise.¹⁸² From this perspective, the ability to gain access to the PHI of a conceptus has long been assumed to be a right shrouded in the federal reproductive rights and their intersection with informed consent doctrine,¹⁸³ a view created in large part by state courts and legislatures and by legal academics.¹⁸⁴ Moreover, in addition to this federal precedent, there is ample state law that has similarly identified abortion as a personal liberty and right to autonomy; most relevantly, as mentioned, this

¹⁸² See *Roe*, 410 U.S. at 153 (“Maternity, or additional offspring, may force upon the woman a distressful life and future. Psychological harm may be imminent. Mental and physical health may be taxed by child care. There is also the distress, for all concerned, associated with the unwanted child, and there is the problem of bringing a child into a family already unable, psychologically and otherwise, to care for it.”). To understand the scope of the abortion right since *Roe*, an element continuing after *Casey*, it is essential to take the mandated health exception at all stages of pregnancy in light of how the Court defined “health” in *Roe*'s companion case, released on the same day. See *Doe v. Bolton*, 410 U.S. 179, 192 (1973) (defining “health” in the abortion context such that the exception permits that “medical judgment may be exercised in the light of all factors—physical, emotional, psychological, familial, and the woman’s age—relevant to the wellbeing of the patient. All these factors relate to health.”). The Court explained in *Bolton* that this broad understanding of the health exception permits physicians “the room [they need] to make [their] best medical judgment. And it is room that operates for the benefit, not the disadvantage, of the pregnant woman.” *Id.*

¹⁸³ See generally *Canterbury v. Spence*, 464 F.2d 772, 804–06 (D.C. Cir. 1972) (mentioning the intersection between reproductive rights and informed consent).

¹⁸⁴ A casebook on tort law from 1977, for example, would contend that *Roe*'s protection of first-trimester abortions for any reason “should constitute a forceful argument against any decision denying recovery for wrongful birth based on public policy.” JAMES A. DOOLEY, *MODERN TORT LAW: LIABILITY AND LITIGATION* 353 (1977). Similarly, a law review article from 1982 would declare that “all decisions since *Roe v. Wade* that deny recognition of the action [for wrongful birth of a healthy child] are ignoring the Supreme Court rulings regarding the individual’s right not to have children.” Donna K. Holt, *Wrongful Pregnancy*, 33 S.C. L. REV. 759, 793 (1982).

jurisprudence at the state level has developed through over half a century of wrongful conception and wrongful birth litigation.¹⁸⁵

Informed consent affected the original prenatal tort, and it also was a central impetus behind the emergence of three new actions—the wrongful life, wrongful birth, and wrongful conception torts.¹⁸⁶ The wrongful birth tort first arose in 1967,¹⁸⁷ one of several cases arising after the birth of infants suffering from congenital rubella

¹⁸⁵ Nearly every state recognizes a parental right to recover in tort for wrongful conception, over half recognize wrongful birth, and fewer than half a dozen recognize wrongful life. See Haqq, *The Impact of Roe on Prenatal Torts*, *supra* note 158, at 43–45 (providing fifty-state maps of the current terrain of wrongful conception, wrongful birth, and wrongful life claims). For a stark, recent example of the public policy forged within these cases, in 2015, a Washington couple obtained a \$25,000,000 award of general damages in their wrongful birth action. *Wuth v. LabCorp*, 359 P.3d 841, 846–47 (Wash. Ct. App. 2015) (involving a child born with a chromosomal translocation rather than having been aborted, a child who had already been awarded \$25,000,000 in special damages for accommodations and expenses necessitated by the associated impairments (experienced over his anticipated seventy-year lifespan), which was possible because Washington is one of only a handful of states that recognizes the claim for wrongful life, while most other states ban it). See *Harbeson v. Parke-Davis, Inc.*, 656 P.2d 483, 494 (Wash. 1983) (recognizing the wrongful life action for the first time).

¹⁸⁶ See generally Haqq, *The Impact of Roe on Prenatal Torts*, *supra* note 158 (describing prenatal torts alongside the rise of informed consent doctrine). For a recent example, the Iowa Supreme Court first recognized the wrongful birth action in 2017, recognizing that “the woman must be informed of all material facts, including the likelihood the child will be born with a severe birth defect.” *Plowman v. Fort Madison Cmty. Hosp.*, 896 N.W.2d 393, 405 (Iowa 2017) (the court curiously citing fetal *protective* statutory requirements about disclosing information about fetal pain before an abortion, offering an ultrasound, and other measures as justifying the creation of this informed consent aspect of the state’s interpretation of the abortion right). The court did consider the possibility that “allowing wrongful-birth claims will stigmatize the disabled community,” but it quickly found that any such stigma was outweighed by the importance of not “closing the courthouse door” to women’s rights guaranteed by *Roe*. *Id.* at 406. The court additionally considered the expressive impact not on the disabled community but rather on the disabled child at issue in the lawsuit, but dismissed this too, finding that “given Z.P.’s severe cognitive disabilities, there is nothing in the record to indicate he will someday understand his parents sued over their lost opportunity to avoid his birth.” *Id.* at 407.

¹⁸⁷ *Gleitman v. Cosgrove*, 227 A.2d 689 (N.J. 1967).

syndrome (“CRS”).¹⁸⁸ This variant of action is brought by parents and alleges that medical malpractice precluded their ability to make an informed choice about whether or not to abort.¹⁸⁹ In other words, wrongful birth cases involve parents as plaintiffs claiming they were denied certain information, i.e., relevant parts of the PHI of their child while a conceptus—a denial of information to which they would not have consented at the time.¹⁹⁰ In one of the early wrongful birth cases involving CRS, the mother of a child born with CRS stated in her deposition, “I would have done the kindest thing that I

¹⁸⁸ *Stewart v. Long Island Coll. Hosp.*, 283 N.E.2d 616 (N.Y. 1972); *Jacobs v. Theimer*, 507 S.W.2d 288 (Tex. Civ. App. 1974); *Dumer v. St. Michael’s Hosp.*, 233 N.W.2d 372 (Wis. 1975).

¹⁸⁹ The wrongful conception and wrongful life actions are somewhat less germane than wrongful birth actions to questions about accessing another individual’s PHI in utero or otherwise. Pre-conception, as mentioned, it seems clear especially from the contexts of IVF and PGD that no identifiable individual exists prior to conception, but rather reproductive material most plausibly seems to be fully under the ownership of each parent individually. The wrongful life action is brought by or on behalf of a child alleged to be injured by an infringement of this informational right—before or after conception—that the plaintiff alleges was the cause of the harm of facing life with serious congenital disease. Since it concerns the child’s own right to otherwise avoid existence (and thus avoid the protections of genetic privacy laws like HIPAA), it is less germane to this Article’s focus directly on those individuals that are in fact born.

¹⁹⁰ These actions raise problems even when they do not access the PHI of the conceptus. The vast majority of abortions in the U.S. are not for the purposes of selecting against disease, disorder, or impairment but rather for prudential or socio-economic reasons—i.e., because the timing of pregnancy or prospect of having a child was incongruent with personal preferences, professional ambitions, or financial means. In other words, most abortions are of fetuses that otherwise presumably would have been born healthy, rather than for the motives of preventing someone from being born with congenital disease. Several states permit parents to seek general damages for the pain and suffering of being denied the chance to abort their child who was born healthy, furthering what many consider to be an odious public policy. *See e.g., Azzolino v. Dingfelder*, 337 S.E.2d 528, 536 (N.C. 1985) (describing the wrongful birth action as furthering a public policy of “medical paternity suit[s]”); Haqq, *The Impact of Roe on Prenatal Torts*, *supra* note 158, at 72–73 (“The scope of recovery [might encompass recovery for infliction of extreme emotional distress,] roughly proportional to the severity and lethality of the congenital condition.”).

could have known to have done for her [counterfactually], and that would have been to terminate the pregnancy.”¹⁹¹

Grounding justifications for gaining access to another individual’s PHI on the abortion right *qua* a liberty and autonomy right, though initially seeming to provide the most plausible justification, ends in circularity as well. First, there is an obvious circularity in claiming that a failure to get consent or even presumed consent (regarding PHI access) is justified with respect to the importance of protecting consent (of prospective parents). If consent merits protection, then it makes little sense to fail to protect it in the name of protecting consent. Second, if reproductive rights were the central value being protected, then the circularity would be a failure to protect them in the name of protecting them—much of the PHI that parents currently are able to access in utero is information that would be material or germane to their child or prospective child’s *own* sexual and reproductive choices in the future. As such, PHI germane to those future choices could be argued to be protected by Supreme Court jurisprudence granting minors reproductive rights.¹⁹²

Third, it would be circular to ground any justification of accessing PHI in utero without implied consent or best-interests justifications on the availability of the wrongful birth action. State precedent on reproductive rights piggybacks on the federal reproductive rights, the former precedent depending on the latter. While some federal courts have recognized the action for wrongful birth, the Supreme Court has never addressed the issue of whether or not the ability to pursue that claim is found within the Constitution. Moreover, even if it did find a wrongful birth action to exist as a facet of the abortion right, wrongful birth is an informational right; as such, it seems circular to claim that it is permissible to deny protection for one individual’s informational rights (privacy and non-disclosure of one’s PHI in utero) on the grounds of upholding another individual’s informational rights (parents’ rights to make an informed abortion decision, enforced through wrongful birth claims).

¹⁹¹ *Jacobs v. Theimer*, 519 S.W.2d 846, 847 (Tex. 1975).

¹⁹² See notes 55–57 and the sources therein.

Of course, a few parries to the above points could be anticipated. One might argue that there is no circularity because all these matters have already been established by the federal reproductive rights and parental rights jurisprudence.¹⁹³ In other words, for example, the argument could be made there are no informational rights infringed in utero because fetuses are not legal persons. If this were taken as a categorical statement, it would be misplaced, since courts have long been willing to accord fetuses an abundance of rights of legal persons retroactively—e.g., in the mentioned probate context and property law (as when a testamentary gift requires the interpretation that a fetus be treated as a tenant in common with its mother),¹⁹⁴ and eventually through prenatal tort actions, so long as they are born alive (and not aborted spontaneously or through induced means, or otherwise killed by prenatal injury).¹⁹⁵ More centrally, the riposte is simply that claiming that the Court's reproductive rights jurisprudence has already settled the matter is to squelch any conversations or discussions, such as those in this Article, that might be interpreted to problematize that jurisprudence.¹⁹⁶ While this Article's thesis on the importance of protecting PHI in utero does not necessitate any fundamental reworking of the federal reproductive rights, and in fact does not even arise in terms of legal rights until a decision whether or not to abort has been made, it still provides one narrow set of reasons for understanding why that jurisprudence might be incapable of protecting PHI as healthcare increasingly turns to genetics and genomics.

Another parry might emphasize that most of these problems can be explained in terms of a difference in degree, though not in nature, of the rights to be protected. That is, it could be argued that a conceptus itself both has its own PHI and is also itself the PHI of the pregnant woman carrying it, such that a reflective choice to uphold

¹⁹³ On the latter, see, for example, *Wisconsin v. Yoder*, 406 U.S. 205, 214 (1972); *Pierce v. Soc'y of the Sisters*, 268 U.S. 510, 534–35 (1925); *Myer v. Nebraska*, 262 U.S. 390, 400 (1923).

¹⁹⁴ E.g., *Biggs v. McCarty*, 86 Ind. 352, 362 (Ind. 1882).

¹⁹⁵ See notes 142–155 and accompanying text (describing early prenatal torts); see also note 164 (explaining how *Dietrich's* model comports with legal personhood as defined in *Roe*).

¹⁹⁶ See, e.g., notes 178–181 and accompanying text (discussing the jurisprudential development of abortion as an autonomy interest).

implied consent or a best-interests standard in reasonably disclosing and protecting PHI in utero involves a choice between incompatible or incommensurable goals—respect for the PHI of the conceptus and respect for the conceptus as a pregnant woman’s PHI.¹⁹⁷ This reasoning seems plausible because it does not ignore the issue of nonconsensual PHI access. Rather, it acknowledges it but emphasizes that such access might be excused or justified by the very same value of protecting an individual’s PHI (i.e., the conceptus understood as the pregnant woman’s own PHI), on the grounds that this value that is more efficiently furthered by favoring treatment of the conceptus as a pregnant woman’s PHI rather than an independent subject of PHI. To reify this objection, suppose that a pregnant woman opts to have the fetal genome sequenced within the first few months of pregnancy and then chooses to abort because of the PHI she accesses—which is taken *arguendo* to be her own PHI and also that of a distinct individual. The obvious reason that the failure to protect the PHI of the conceptus is less legally problematic, wrong, or bad is that the conceptus was aborted before it ever learned that its own PHI had been accessed; no legal person with rights ever comes into existence so the issue of access is not problematic in the way it would be in cases in which a living person with that PHI is born. Further, plausible arguments can be marshaled that access for purposes of selective abortion can often be justified from a best-interests standard (as with *Tay Sachs*). In contrast to any harm in failing to bring someone with *Tay Sachs* or a non-lethal but still serious condition into existence (e.g., perhaps one might argue that there is a harm in not being able to experience existence), a greater harm might be said to exist in a failure to respect and protect the pregnant woman’s own PHI, given how life-altering the prospect of raising a child with serious congenital disease would be, and given that she can exercise control over such outcomes if she accesses the PHI of the conceptus and forestalls the possibility by choosing to abort.

¹⁹⁷ For an introduction to the relation of incommensurability theory to practical reason and ethics, see generally RUTH CHANG, *INCOMMENSURABILITY AND INCOMPARABILITY* (2013) (discussing if, and how, values can be compared to one another).

Perhaps the most significant problem with this definitional or attributional analysis of PHI is that it is in tension with the notion of rights as absolute—generally, it seems that it is wrong to violate the rights of another, and this wrongness is not premised on a degree of harm measured by the other individual knowing that such rights were violated. With the amount of PHI and other personal information generated and stored today, it is precisely the fact that people might otherwise be unaware when third parties like marketing companies or hackers gain access to their information that underscores the need for protecting and regulating PHI. If a healthcare institution gave a marketing company unauthorized access to a person's PHI for financial gain, certainly this would remain objectionable even if both actors assured that the person whose PHI was accessed never knew about it.

A final challenge might problematize any *ex ante* attempt to demarcate that individualized PHI exists *in utero*, and that it only makes sense to claim this *ex post*. This challenges the underlying problem about referring to two “individuals” who are reasonably distinct recipients of protections like those of HIPAA. The challenge in the prior paragraph accepts two sources of PHI but insists that the value of protecting PHI *in utero* is usually or always outweighed by the ends that are furthered through giving pregnant women access to that PHI. This challenge, by contrast, denies that there are two sources of PHI during pregnancy but rather only after birth, such that there never were two sources of PHI if the conceptus was not brought to term. Again, as this Article has shown, one clear reason for not recognizing the conceptus as a distinct individual is that this might create tension with *Roe* and related reproductive rights jurisprudence. Still, it has also emphasized that *both* goals can be accomplished—the rights to contraception and abortion could be left uninhibited in terms of parents having access to information that reasonably could inform their reproductive decisions, while still cabining off some PHI from disclosure, namely, information that is not salient for reproductive choices or healthcare decisions in childhood.

Further, as a matter of legal personhood, this Article has also shown that U.S. courts since the eighteenth century have recognized that human life during its embryonic stages can have a panoply of legal rights, though they can only be enforced after birth, thus

recognizing two sources of rights rather than one.¹⁹⁸ Protecting PHI in utero additionally does not depend on insisting that reproductive material before conception ought to have distinct rights; to the contrary, as mentioned, any PHI would belong to each parent individually. It is certainly true that this means they could learn a fair amount about their future child's PHI at this stage through testing and analysis, for example, at a clinic offering IVF and PGD. This possibility does not dissipate value of protecting PHI in utero, since the actual PHI of the child will be unique, not fully predictable from the prospective parents' own PHI that they can access prior to conception. Finally, knowing prior to conception that one's future children will have certain PHI, like hereditary diseases, is something that could also plausibly be justified with respect to presumed consent, since any extent to which this constitutes accessing the PHI of one's future child is generally done with the best interests of the future child in mind.

This point is a descriptive rather than a normative one: many people opt to abort out of compassion and being humane—indeed, as mentioned, an early abortion (in tandem with nonconsensual PHI access in utero) that thwarts the birth of a child with severe congenital anomalies can plausibly be justified with respect to presumed consent and best interests of the child.¹⁹⁹ Given that most abortion decisions are not premised on decisions made with regard to fetal health anyway,²⁰⁰ an argument favoring protection of PHI in

¹⁹⁸ As one court after *Dietrich* would recognize, even without the new possibility of alleging prenatal injuries in tort, it had already been well-established that a conceptus “may be appointed an executor, is capable of taking as legatee or under a marriage settlement, may take specifically under a general devise as a child, and may obtain an injunction to stay wastes.” *Nugent v. Brooklyn Heights R.R. Co.*, 139 N.Y.S. 367, 369 (N.Y. App. Div. 1916); *see also* note 13 (providing an example of how some PHI extraction methods seem more clearly than others to be culling PHI from the conceptus more than the pregnant woman).

¹⁹⁹ Here, the wrongful life becomes somewhat relevant, since it insists that life with congenital impairment is a legally compensable harm; if this is accepted, it would provide justification for accessing PHI and abortion for these reasons grounded in compassion or humaneness. *Cf.* note 155 and the discussion therein (suggesting that the wrongful life claim could be interpreted as encompassing at least some prenatal informational injuries).

²⁰⁰ *See supra* note 182 (describing the broad scope of abortion recognized in *Roe* and *Bolton*, and continuing after *Casey*). The Guttmacher Institute further

utero comes as radical because it seems to challenge the present perspective from which this unauthorized access is justified. Again, however, the best-interests standard is irrelevant in cases of selective abortion because no recognizable legal rights ever come to fruition in such cases. Currently, broad access to fetal PHI without even considering best interests in cases of selective abortion is justified under the Court's abortion jurisprudence,²⁰¹ state interpretations of that jurisprudence most centrally in wrongful birth suits,²⁰² and

reports personal inconvenience, not humane selection, as the primary reason behind abortion in the U.S.:

The three most common reasons [abortions are chosen in the U.S.]—each cited by three-fourths of patients—were concern for or responsibility to other individuals; the inability to afford raising a child, and the belief that having a baby would interfere with work, school or the ability to care for dependents.

Laurence B. Finer et al., *supra* note 163, at 112.

²⁰¹ *Roe v. Wade*, 410 U.S. 113, 158 (1973) (“[Our historical and jurisprudential analysis] persuades us that the word ‘person,’ as used in the Fourteenth Amendment, does not include the unborn.”).

²⁰² *E.g.*, ARIZ. REV. STAT. ANN. § 12-719 (A), (C) (D) (2019); ARK. CODE ANN. § 16-120-902 (a), (c) (2010); IDAHO CODE § 5-334 (1) (2019); KAN. STAT. ANN. 60-1906 (a), (b) (2019); ME. REV. STAT. ANN. tit. 24 § 2931(1) (2019); MINN. STAT. ANN. § 145.424, Subd. 2 (2019); N.D. CENT. CODE § 14-02.1-04.1 (2019); OKL. STAT. tit. 63 § 63-1-741.12 (A)–(D) (2014); 42 PA. CONS. STAT. ANN. § 8305 (a) (1988); S.D. CODIFIED LAWS §§ 21-55-2, 21-55-3 (1981); *Phillips v. United States*, 575 F. Supp. 1309 (D.S.C. 1983); *Keel v. Banach*, 624 So. 2d 1022 (Ala. 1993); *Turpin v. Sortini*, 643 P.2d 954 (Cal. 1982); *Linger v. Eisenbaum*, 764 P.2d 1202 (Colo. 1988); *Rich v. Foye*, 976 A.2d 819 (Conn. Super. Ct. 2007); *Garrison v. Med. Ctr. of DE*, 581 A.2d 288 (Del. 1989); *Haymon v. Wilkerson*, 535 A.2d 880 (D.C. 1987); *Kush v. Lloyd*, 616 So. 2d 415 (Fla. 1992); *Atlanta Obst. & Gyn. v. Abelson*, 398 S.E.2d 557 (Ga. 1990); *Siemieniec v. Lutheran Gen. Hosp.*, 512 N.E.2d 691 (Ill. 1987); *Bader v. Johnson*, 732 N.E.2d 1212 (Ind. 2000); *Nanke v. Napier*, 346 N.W.2d 520 (Iowa 1984); *Arche v. United States*, 798 P.2d 477 (Kan. 1990); *Grubbs v. Barbourville Health Ctr.*, 120 S.W.3d 682 (Ky. 2003); *Pitre v. Opelousas Gen. Hosp.*, 530 So. 2d 1151 (La. 1988); *Reed v. Campagnolo*, 630 A.2d 1145 (Md. 1993); *Viccaro v. Milunsky*, 551 N.E.2d 8 (Mass. 1990); *Taylor v. Kurpati*, 600 N.W.2d 670 (Mich. Ct. App. 1999); *Wilson v. Kuenzi*, 751 S.W.2d 741 (Mo. 1998); *Azzolino v. Dingfelder*, 337 S.E.2d 528 (N.C. 1985); *Greco v. United States*, 893 P.2d 345 (Nev. 1995); *Smith v. Cote*, 513 A.2d 341, 348 (N.H. 1986); *Schroeder v. Perkel*, 432 A.2d 834 (N.J. 1981); *Becker v. Schwartz*, 386 N.E.2d 807 (N.Y. 1978); *Schirmer v. Mt. Auburn Obstetrics & Gynecologic Assocs.*, 844 N.E.2d 1160 (Ohio 2006); *Zehr v. Haugen*, 855 P.2d 1127 (Or. App. 1993); *Speck v. Finegold*, 439 A.2d 110 (Pa.

federal regulations like the terms of HIPAA.²⁰³ Reform is therefore needed to do better at protecting the informational rights of born individuals. Under the current terrain, there is virtually no justification assumed to be needed for any nonconsensual access. A reformed terrain could still permit parental access to PHI in a range of cases, but such PHI should be disclosed only if the disclosure is justified to inform the rights to contraception and abortion and broader parental rights from the perspective of best interests or presumed consent of the later-born child. The final Part suggests that such PHI in this reformed terrain should be contained in a “black box” that is accessible only through the doctor-patient relationship by the child, or by parents only selectively, namely, only if disclosure is antecedently justified based on the child’s presumed consent and best interests.

V. A BLACK BOX: PHI UNDER A “RIGHTS-IN-TRUST” FRAMEWORK

Though this Article has centered on the possibility of protecting and respecting PHI in utero, it has also emphasized this option as part and parcel of protecting PHI over an individual’s lifetime, since unauthorized disclosure to a third party generally cannot be undone. This final Part makes initial gestures in describing what reform in this arena of public policy might look like, providing a theoretical framework and practical examples of giving children greater ownership and control over their own PHI.

The previous Parts have shown that some of a future child’s PHI can be ascertained before conception (e.g., through IVF and PGD), that federal and state reproductive rights generally give parents full access to it in utero, that all states routinely return some elements of

1981); *Schloss v. Miriam Hosp.*, No. 98-2076 (RJH), 1999 WL 41875 (R.I. Super. Jan. 11, 1999); *Jacobs v. Theimer*, 519 S.W.2d 846 (Tex. 1975); *Naccash v. Burger*, 290 S.E.2d 825 (Va. 1982); *Harbeson v. Parke-Davis, Inc.*, 656 P.2d 483 (Wash. 1983); *James G. v. Caserta*, 332 S.E.2d 872 (W. Va. 1985); *Dumer v. St. Michael’s Hosp.*, 233 N.W.2d 372 (Wis. 1975); *Beardsley v. Wierdsma*, 650 P.2d 288 (Wyo. 1982).

²⁰³ Public Welfare, 45 C.F.R. § 160.103 (2018) (defining the conceptus as PHI of pregnant women, rather than a distinct entity with PHI, by defining “genetic information” protected by HIPAA to include “[a] fetus carried by the individual or family member who is a pregnant woman.”).

the child's PHI to parents in newborn screening programs, and that HIPAA and other privacy laws regulating PHI continue this regime up to the age of majority.²⁰⁴ The reasons for gaining unauthorized, nonconsensual access to the PHI of another individual in utero seem most plausible when they can be grounded in presumed consent, carving out a limited exception to the background importance of otherwise protecting this information. For the rest of the PHI, this nonconsensual access becomes problematic.

In computing and engineering, a "black box" denotes a system, process, or object that can be understood in terms of inputs and outputs without fully knowing the internal workings.²⁰⁵ Legal scholars have recently borrowed this concept to speak of a turn to "black box medicine" in a healthcare system dealing with increasingly opaque algorithms and large quantities of raw PHI data.²⁰⁶ Authors have also applied the concept in biology and genetics, discussing the human body as existing within the history of genetics as an "organism [that originally] remained a black box," one "being quickly opened up by modern biology."²⁰⁷ Such data is generated not only from clinical visits but also from wearable devices, internet activity, and consumer purchases, with reliance on big-data PHI further increasing significantly with growing reliance on genomic sequencing.²⁰⁸ In the present context of protecting PHI

²⁰⁴ See *supra* Section II.A (explaining the default of treating parents as personal representatives of their children in the child's healthcare decisions).

²⁰⁵ With some related descriptions and methodology arising in circuitry and computing in the early twentieth century, it appears the black-box term first started to be applied to such processes by the 1950s and 1960s. See, e.g., NORBERT WEINER, *CYBERNETICS: OR CONTROL AND COMMUNICATION IN THE ANIMAL AND THE MACHINE* vii-x, xi n.1 (1961); ASHBY ROSS, *AN INTRODUCTION TO CYBERNETICS* 86 (1956); Vitold Belevitch, *Summary of the History of Circuit Theory*, 50 *PROC. INST. RADIO ENGINEERS* 848, 848-49 (1962).

²⁰⁶ See Roger A. Ford & W. Nicholson Price, *Privacy and Accountability in Black-Box Medicine*, 23 *MICH. TECH. L. REV.* 1 (2016). See generally W. Nicholson Price, *Regulating Black-Box Medicine*, 116 *MICH. L. REV.* 421, 429-30 (2017) (providing an in-depth discussion of black box medicine).

²⁰⁷ JOHN GERHART & MARC KIRSCHNER, *CELLS, EMBRYOS, & EVOLUTION* 613 (1997).

²⁰⁸ See Joshua S. Talboom & Matthew J. Huentelman, *Big Data Collision: The Internet of Things, Wearable Devices and Genomics in the Study of Neurological Traits and Disease*, 27 *HUM. MOLECULAR GENETICS* R35, R35-R39

from nonconsensual disclosure to parents (or other third parties), such opaque PHI processing and analyzing will continue to increase the role of physicians and other clinical actors as gatekeepers for PHI access.

In this gatekeeper role, as well as being a central target of regulation by laws like HIPAA, clinical actors working with PHI are those responsible for disclosing or not disclosing it to parents, prospective parents, and minors. For the same reason, they also are the most relevant actors interpreting the medical-necessity, presumed-consent, or best-interests exceptions—the actors who decide whether or not a given disclosure of PHI is permissible. Relevant data computing and processing systems themselves could also be designed in the clinical context to grant access to PHI only when authorized in actuality (like when minors seek to access their own PHI) or could be justified according to presumed informed consent (e.g., a return of results to parents indicating PKU in a neonate).²⁰⁹

In short, the proposal to keep PHI private throughout a lifetime, and not just in adulthood, could be realized by working to ensure that an individual's PHI is kept within a metaphorical black box—one that is otherwise opaque to unauthorized parties but provides a return of relevant results for those who are authorized. Granted, it could be the case that minors who gain access to results about their genome would be too immature to know what to do with the information.²¹⁰ Beyond the benign possibility that such information would not be useful to minors, it is also possible that providing it

(2018). See generally Morris W. Foster & Richard R. Sharp, *The Contractual Genome: How Direct-to-Consumer Genomic Services May Help Patients Take Ownership of Their DNA*, 5 PERSONALIZED MED. 399 (2008) (compiling and analyzing patients' DNA outside of the clinical context).

²⁰⁹ See generally Jennifer Kulynych & Henry T. Greely, *Clinical Genomics, Big Data, and Electronic Medical Records: Reconciling Patient Rights with Research When Privacy and Science Collide*, 4 J.L. & BIOSCIENCES 94 (2017) (discussing the problematic intersections of big data and electronic medical records with HIPAA-covered entities' use of genomic data).

²¹⁰ Cf. *Bellotti v. Baird*, 443 U.S. 622, 634 (1979) (granting minors a more limited right to abortion than adults, citing to their "inability to make critical decisions in an informed and mature manner and the importance of the parental role in child rearing.").

could even come as a harm, thus potentially running in tension with the best-interests standard and presumed consent.

For example, the Presidential Commission for the Study of Bioethical Issues describes one person's experience who learned from his ophthalmologist at age thirteen that he would, at some point in his life, go blind from retinitis pigmentosa.²¹¹ "It was like having a time bomb inside of me," he remarked about the prognosis.²¹² His vision did steadily deteriorate after college, and he lost the majority of his eyesight by the time he was thirty-three.²¹³ "The irony," he concluded in retrospect, "is the anticipation was much worse than the actual loss. It was a relief to stop worrying about when the loss would occur."²¹⁴ Though this may reflect the experiences of some, systematic reviews have found "insufficient evidence to inform a nuanced understanding of how children respond to genetic testing."²¹⁵

What is more, some PHI like genomic results might be hard for adults to understand as well, in which case difficulty in understanding is less of an objection to allowing minors to access their own genomic PHI. As one genetic counselor recently recounted of an adult patient, "He had highlighted the consent form very carefully and he highlighted the word 'genome' and he kept saying 'gnome' . . . he was like 'What's a gnome? What does that mean? . . . Is that in my body? Can you take it out of me?'"²¹⁶ The integration in recent years of user-friendly technologies like iPads into both public education and clinical medicine can support

²¹¹ PRESIDENTIAL COMM'N FOR THE STUDY BIOETHICS ISSUES, PRIVACY AND PROGRESS IN WHOLE GENOMIC SEQUENCING 23 (2013).

²¹² *Id.*

²¹³ *Id.* at 22.

²¹⁴ *Id.*

²¹⁵ Christopher H. Wade, *Effects of Genetic Risk Information on Children's Psychosocial Wellbeing: A Systematic Review of the Literature*, 12 GENETICS MEDICINE 317, 317 (2010); see also Kathrine James et al., *Impact of Direct-to-Consumer Predictive Genomic Testing on Risk Perception and Worry Among Patients Receiving Routine Care in a Preventive Health Clinic*, 86 MAYO CLINIC PROC. 933, 934 (2011) (conducting a test study involving in-depth interviews, recording office visits, and providing a genetic counselor if requested).

²¹⁶ Ashley N. Tomlinson et al., "Not Tied up Neatly with a Bow": Professionals' Challenging Cases in Informed Consent for Genomic Sequencing, 25 J. GENETIC COUNSELING 62, 67 (2016).

comprehension during childhood and into adulthood of key concepts like DNA and genetics.²¹⁷ The Integrative Genomics Viewer, for example, allows individuals who have their genome sequenced to view the entire sequence on an iPad, with interactive features enabling them to zoom in to particular segments and variants, with explanations of their significance.²¹⁸ In high school, topics like genetics can further be incorporated into classes in the natural sciences, for example, through discussions of inheritance in biology.²¹⁹

Reasons of public health could also recommend against return of PHI to the individual subjects of that PHI inasmuch as knowledge of one's genetic and genomic information reinforces unhealthy life choices that impose a public burden. For example, public health genomic policies could attempt to identify genotypes that modulate smoking status, initiation, cessation, and treatments.²²⁰ While using such an initiative to identify individuals who have a high susceptibility to cancer might motivate them to quit, it could also "enable[] those who are unsuccessful in quitting to blame genetic factors, which would thereby decrease motivation."²²¹ Facilitating such genetic fatalism affects the public interest not only because of smoking-related disabilities, but also because the testing itself would be an inefficient use of resources if it did change individual behaviors.²²² Further, inasmuch as knowledge of one's genetic

²¹⁷ See Helga Thorvaldsdóttir et al., *A Genomic Data Viewer for iPad*, 16 GENOME BIOLOGY 46, 46 (2015).

²¹⁸ *Id.*

²¹⁹ E.g., Sherree Kassuba, *Environmental Causes of Birth Defects*, YALE-NEW HAVEN TEACHERS INST., <http://www.yale.edu/ynhti/curriculum/units/1982/7/82.07.07.x.html> (last visited Oct. 26, 2019) (detailing a unit on birth defects designed for ninth-grade students).

²²⁰ See, e.g., Evy Cleeran et al., *Public Health in the Genomic Era: Will Public Health Genomics Contribute to Major Changes in the Prevention of Disease?*, 69 ARCHIVES PUB. HEALTH 1, 6–7 (2011).

²²¹ Clarissa Allen et al., *Defining the Scope of Public Engagement: Examining the "Right Not to Know" in Public Health Genomics*, 42 J.L. MED. ETHICS 11, 16 (2014).

²²² E.g., Chris Carlsten & Wylie Burke, *Potential for Genetics to Promote Public Health: Genetics Research on Smoking Suggestions Caution About Expectations*, 296 JAMA 2480, 2480–81 (2006) (discussing studies regarding the extent to which genetic knowledge improves personal and social interventions).

information can cause anxiety about one's health,²²³ the predictive, prognostic role of genomics (its role in providing risk assessments rather than diagnoses) could contribute to unnecessary surveillance and further testing.²²⁴

The idea of storing a child's PHI within a black box is similar to legal philosopher Joel Feinberg's argument that children possess a set of moral rights to an "open future," that is, rights not to have important life choices like personal healthcare decisions determined by others.²²⁵ He also recommends against imposing important healthcare decisions on individuals when they are too young to possess the necessary maturity and decisional autonomy to make those decisions wisely, a reason potentially against giving minors more direct access to their own PHI.²²⁶ Feinberg's claim is that it is the autonomy of adults to make informed choices that is valuable, and their "rights-in-trust" should be protected in childhood.²²⁷ Numerous authors since the 1990s have applied Feinberg's argument in the context of genetic testing, namely, for the proposition that it is generally better to delay until adulthood the decision of whether or not to view one's genetic results.²²⁸

In contrast to this focus on the rights of adults, this Article has emphasized the need for a secure, private repository for an individual's PHI from conception up to majority. In practical

²²³ Though not focusing on adolescent populations, recent surveys have found mixed results, with some people experiencing anxiety from knowing genomic results, others equanimity, and others enthusiasm. See, e.g., Jacqueline Duffour et al., *Reproductive Decision-Making in MMR Mutation Carriers After Results Disclosure: Impact of Psychological Status in Childbearing Options*, 25 J. GENETIC COUNSELING 432, 433–34 (2015) (finding that twelve percent of participants experienced initial stress from learning results, but that stress decreased over time).

²²⁴ See LAURINDA HARMAN & FRANCES CORNELIUS, *ETHICAL HEALTH INFORMATICS* 470, 713 (2015).

²²⁵ Joel Feinberg, *The Child's Right to an Open Future, in WHOSE CHILD? CHILDREN'S RIGHTS, PARENTAL AUTHORITY, AND STATE POWER* 124, 125–26 (William Aiken & Hugh LaFollette eds., 1980).

²²⁶ *Id.*

²²⁷ *Id.*

²²⁸ See generally Joseph Millum, *The Foundation of the Child's Right to an Open Future*, 45 J. SOC. PHIL. 522 (2014) (providing a review of contexts in which authors have applied the open-future concept).

implementation, a black box might draw on analogue principles that have already been developed in the research rather than the clinical context. Discussions about the professional ethics of “biobanking,” for example—the reposition and use of biological samples for research purposes—have addressed the storage of PHI taken from minors.²²⁹ As with the recommendations in pediatrics canvassed above,²³⁰ research principles for the treatment of an individual’s biological material and information have recognized that “older minors,” unlike “small children,” have greater and perhaps sufficient capacities “to understand the meaning and implications of the research and to give a documented agreement to it.”²³¹ In the clinical context, similarly, professional recommendations consider informed consent to be possible in older children and adolescents.²³² It therefore may be useful, especially given other mentioned risks of returning PHI,²³³ for the algorithms and analyses underlying a black box of an individual’s PHI to stage results as appropriate to the individual’s age and the nature of the PHI.

Other analogue principles in research could further be used for clinical ethics concerning the return of a minor’s PHI not just to the minor but also to public authorities. Adhering to a commitment to proportionality, for example, might justify access if great harm to

²²⁹ E.g., Kristien Hens et al., *Developing a Policy for Paediatric Biobanks: Principles for Good Practice*, 21 EUR. J. HUM. GENETICS 2, 2–3 (2013); Heidi C. Howard et al., *Whole-genome Sequencing in Newborn Screening? A Statement on the Continued Importance of Targeted Approaches in Newborn Screening Programmes*, 23 EUR. J. HUM. GENETICS 1593, 1593 (2015) (“The primary objective of NBS [newborn screening programs] should be the targeted analysis and identification of gene variants conferring a high risk of preventable or treatable conditions, for which treatment has to start in the newborn period or in early childhood.”).

²³⁰ See generally *supra* Part II (discussing the recommendations of professional organizations including the AMA, American College of Obstetricians and Gynecologists (“ACOG”), American Academy of Pediatrics (“AAP”), and Clinical Sequencing Exploratory Research Pediatric Working Group (“CSER-PWG”)).

²³¹ Hens et al., *supra* note 229, at 2.

²³² See generally *supra* Part II (discussing a professional attitude favorable toward greater control of PHI in later childhood and adolescence).

²³³ See *supra* notes 209–227 and accompanying text (considering reasons in favor of withholding rather than disclosing PHI).

others could be avoided through nonconsensual access to the minor's PHI.²³⁴ As this Article has suggested, however, such a principle seems to be violated unless the return of results from genomic sequencing is limited only to necessary genomic PHI.²³⁵ Further, "great harm to others" risks being an exception that swallows the rule, given the real benefits to present people and future generations that could be gained by allowing public authorities to access a minor's full genomic PHI.²³⁶ A more restricted permission for limited access within the clinical context, supported by legal precedent,²³⁷ might allow release of otherwise confidential information only when this could avert serious harm or death to another (presently existing) individual. Finally, such a balancing could also be grounded on independent ethical or moral considerations—such as a commitment to respect other persons, including future people, by acting in relation to others on grounds to which they could not reasonably object.²³⁸

²³⁴ Hens et al., *supra* note 229, at 2.

²³⁵ Even with targeted sequencing, many of the same underlying ethical issues about the return of PHI arise about the return of incidental findings. *See supra* note 104 and the sources therein.

²³⁶ A balancing of these competing values might be possible, for example, by making a considerable financial contribution that is placed in trust and released once minors reach the age where they are reasonably capable of managing their finances, which could potentially be grounded on their anticipated informed consent.

²³⁷ *Cf. Tarasoff v. Regents of California*, 551 P.2d 334, 347 (Cal. 1976) (finding a duty to disclose otherwise confidential personal information within a professional duty to warn third parties of risk serious harm or death).

²³⁸ In contemporary philosophy, T.M. Scanlon's notion of respect as grounded in reasonable objection has been particularly influential. *See generally* T.M. SCANLON, *WHAT WE OWE EACH OTHER* 153 (2000) (proffering a theory of normative reasoning and moral justification in which respect for others is understood in terms of "principles for the general regulation of behavior that no one could reasonably reject as a basis for informed, unforced, general agreement"). Perhaps most relevantly, Scanlonian contractualism has been applied in the context of duties owed to people before they exist. *See, e.g.,* Rahul Kumar, *Wronging Future People: A Contractualist Proposal*, in *INTERGENERATIONAL JUSTICE* 251 (Axel Gosseries & Lukas Meyers eds., 2009). For more on this literature of duties to future people, see, for example, Jan Narveson, *Future People and Us*, in *OBLIGATIONS TO FUTURE GENERATIONS* 85 (Richard I. Sikora & Brian M. Barry eds., 1978); DEREK PARFIT, *REASONS AND*

With PHI stored inside a metaphorical black box, staged access according to authorization could certainly be more nuanced than the brief sketches canvassed above. If PHI were of reproductive significance, for instance, there could be public health reasons for a physician to reveal it to a minor, say, in early adolescence,²³⁹ though such a possibility might encounter opposition by people who believe disclosing it to minors implicitly and objectionably endorses sexual activity prior to majority. Indeed, if a child's PHI is given to parents, they might forget to inform their child (e.g., if the results were revealed in infancy), or they might be motivated by personal convictions not to return results to children out of a concern that the information will raise the chances that the minor will consider abortion. Rather than taking a position on this issue, it is enough to say that it is likely that this domain will become a much more contested space between the political right and left over abortion politics.

CONCLUSION

The topic of regulating PHI in the perinatal context will continue to pose vexing questions and speaks to the necessity of substantial reforms to personal privacy laws governing healthcare data and even abortion law, as medicine turns to genomic healthcare and as gene editing sparks the imagination with possibilities of new frontiers. This Article has introduced a space that raises new considerations that will inevitably arise in the context of reproductive healthcare. It thus emerges as radical because *Roe v. Wade* is the law, but law which does not respond to concerns over PHI of children, neonates, and fetuses, especially outside the context of making of an abortion decision. Reforms are still possible regardless of whether federal reproductive rights are revisited. Keeping an individual's PHI in a black box and recognizing informational rights thereto not only

PERSONS 4 (1984); R. M. Adams, *Existence, Self-interest, and the Problem of Evil*, 13 NOÛS 53, 53 (1979); Caspar Hare, *Voices from Another World: Must We Respect the Interests of People Who Do Not, and Will Never, Exist?*, 117 ETHICS 498, 498 (2007); Seana V. Shiffrin, *Wrongful Life, Procreative Responsibility, and the Significance of Harm*, 5 LEGAL THEORY 117, 117 (1999); J. David Velleman, *Persons in Prospect*, 36 PHIL. & PUB. AFF. 221, 221 (2008).

²³⁹ McCullough et al., *supra* note 5, at e978.

throughout childhood but also as far back as conception is a proposal that could begin to shift the conversation in this direction, taking an individual's PHI away from the absolute ownership of parents, away from the parental default in HIPAA, and away from the informational rights of parents asserted in wrongful birth lawsuits. Though this reformed regime might look similar and countenance many of the same disclosures of PHI to parents that already occur in the current landscape, by reframing the perspective to be one of a black box mediated by clinicians that stages results and limits PHI disclosures to parents only to those rooted in the presumed consent or best interests of the later-born child, such a reformed terrain would provide a more deliberative, intentional, and concerted framework for protecting PHI throughout an individual's lifetime. In this way, it sets better foundations for personal privacy for the future.