

Refuting the Right Not to Know

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REFUTING THE RIGHT NOT TO KNOW

BENJAMIN E. BERKMAN*

While promising to eventually revolutionize medicine, the capacity to cheaply and quickly generate an individual's entire genome has not been without controversy. Producing information on this scale seems to violate some of the accepted norms governing the practice of medicine, norms that evolved during the early years of genetic testing when a targeted paradigm dominated. One of these widely accepted norms was that an individual had a right not to know genetic information about him or herself. Prompted by evolving professional practice guidelines, the right not to know has become a highly controversial topic. The medical community and bioethicists are actively engaged in a contentious debate about the extent to which individual choice should play a role (if at all) in determining which clinically significant findings are returned.

This paper explores the extent to which it is legally and ethically necessary to respect the so-called right not to know genetic information about oneself. Challenging the majority view that the right not to know is sacrosanct, I push back against that vigorously held (although not always rigorously defended) position, in defense of the idea that we should abandon the notion of a strong right not to know. Drawing on the fields of law, philosophy and social science, I provide an extended argument in support of a default for returning high value genetic information without asking about a preference not to know. I conclude by offering some recommendations about how best to balance individual autonomy and professional beneficence as the field of genomic medicine continues to evolve.

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I. INTRODUCTION

The past decade has seen almost unimaginable advances in genomic sequencing capabilities.¹ In the field's early days, generation of sequence data was the primary bottleneck; it took more than a decade and billions of dollars to produce the first full map of the human genome.² In the years since the Human Genome Project was completed, however, the cost and efficiency of sequencing technology has improved dramatically.³ Massively parallel sequencing platforms began appearing in 2005, and as this new technology continued to evolve, the previously unimaginable goal of a \$1000 genome is now nearly obtainable.⁴ As a result, genomic sequencing has become a powerful tool for researchers⁵ and is emerging as an important component of clinical medicine.⁶

While promising to eventually revolutionize medicine,⁷ the capacity to cheaply and quickly generate an individual's entire genome has not been

1. See Elaine R. Mardis, *A Decade's Perspective on DNA Sequencing Technology*, 470 NATURE 198, 198 (2011) (discussing the advancements in sequencing technology from 2001 to 2011 and analyzing the impacts of these advancements in various fields).

2. Francis S. Collins et al., *The Human Genome Project: Lessons from Large-Scale Biology*, 300 SCIENCE 286, 286–89 (2003) (detailing the timeline and cost of sequencing the first human genome).

3. Mardis, *supra* note 1, at 198–99, 201.

4. See Kris Wetterstrand, *DNA Sequencing Costs: Data from the NHGRI Genome Sequencing Program (GSP) – Cost Per Genome*, NAT'L HUM. GENOME RES. INST. (Oct. 2, 2015), <http://www.genome.gov/sequencingcosts> (including a graph showing the decreasing cost of genome sequencing since 2001); see also Francis S. Collins & Margaret A. Hamburg, *First FDA Authorization for Next-Generation Sequencer*, 369 NEW ENG. J. MED. 2369, 2369 (2013) (“[A] human genome can be sequenced in about 24 hours for . . . less than \$5,000.”); see also W. Gregory Feero et al., *Genomic Medicine — An Updated Primer*, 362 NEW ENG. J. MED. 2001, 2008, 2010 (2010) (discussing advances in technology that are driving down the costs of genome sequencing).

5. See Jamie K. Teer & James C. Mullikin, *Exome Sequencing: The Sweet Spot Before Whole Genomes*, 19 HUM. MOLECULAR GENETICS R145, R147 (2010) (explaining the wide range of purposes for which genomic sequencing can be used, from “disease causation and diagnosis to evolutionary comparison of ancient genomes”).

6. See Francis S. Collins, *Medical and Societal Consequences of the Human Genome Project*, 341 NEW ENG. J. MED. 28, 29–31, 33–34, 36 (1999) (discussing potential clinical applications of human genomic sequencing); see also Teri A. Manolio et al., *Implementing Genomic Medicine in the Clinic: The Future is Here*, 15 GENETICS MED. 258, 258, 266 (2013) (noting that many medical institutions have implemented genomic information into their clinical care); Katherine Johansen Taber et al., *The Promise and Challenges of Next-Generation Genome Sequencing for Clinical Care*, 174 JAMA INTERN. MED. 275, 275–79 (2014) (discussing examples of how human genomic sequencing information can be applied in a clinical setting).

7. See, e.g., Eric D. Green et al., *Charting a Course for Genomic Medicine From Base Pairs to Bedside*, 470 NATURE 204, 204, 205, 207, 209, 211 (2011) (explaining the current and future impact of genomics on medicine); Editorial, *Human Genome at Ten*, 464 NATURE 649, 649

without controversy.⁸ The problematic characteristic of large-scale genomic sequencing is the thing that makes it such a powerful tool: the ability to quickly and cheaply produce massive amounts of genomic information about an individual. Producing information on this scale seems to violate some of the accepted norms governing how to practice medicine— norms that evolved during the early years of genetic testing when a targeted paradigm dominated. Traditionally, doctors would only order a targeted test designed to elucidate specific information about a particular medical problem.⁹ Similarly, researchers generally only collected the targeted data necessary to answer their well-defined scientific questions.¹⁰ Genetic counselors focused on conveying the risks and benefits associated with the testing of a single gene or genes, with the goal of learning more about one highly penetrant disease.¹¹

Genomic sequencing, in contrast, is not targeted and produces massive amounts of extraneous information, some of which can have relevance for an individual's health.¹² This mismatch between the specific indication that led to ordering the test and the breadth of results that the test produces has ignited an ongoing debate about the ethics of managing what have become known as *incidental* or *secondary findings*.¹³ Incidental or secondary

(2010) (mentioning a White House press statement discussing the remarkable scientific advances and clinical applications that will be afforded by human genome sequencing).

8. See Holly K. Tabor et al., *Genomics Really Gets Personal: How Exome and Whole Genome Sequencing Challenge the Ethical Framework of Human Genetics Research*, 155 AM. J. MED. GENETICS 2916, 2917 (2011) (discussing how genome sequencing has created controversy by altering the standard ethical framework of researchers); see also Amy L. McGuire et al., *Research Ethics and the Challenge of Whole-Genome Sequencing*, 9 NAT. REV. GENETICS 152, 152, 155 (2008) (discussing ethical controversies created by cost-efficient genome sequencing technologies).

9. See Isaac S. Kohane et al., *The Incidentalome: A Threat to Genomic Medicine*, 296 JAMA 212, 212 (2006) (noting that, generally, doctors order tests for specific purposes only if “such tests will result in a change in [patient] management”).

10. See Susan M. Wolf et al., *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36 J.L. MED. & ETHICS 219, 219 (2008) (defining “incidental findings” and explaining that because such findings are only discovered during the course of conducting research, they are usually outside the scope of the initial research protocol); see also Erik Parens et al., *Incidental Findings in the Era of Whole Genome Sequencing?*, 43 HASTINGS CTR. REP. 16, 18 (2013) (explaining that in conducting a search for pathologic variants, genomic researchers “restrict their analyses to . . . the focus of their study”).

11. Parens, *supra* note 10, at 16.

12. See Wylie Burke et al., *Seeking Genomic Knowledge: The Case for Clinical Restraint*, 64 HASTINGS L.J. 1649, 1650 (2013) (discussing how genomic tests “generate unprecedented amounts of information, much of it extraneous”); see also Wolf et al., *supra* note 10, at 226 (noting that “approximately 10% of [incidental findings] have . . . potential medical significance needing further clinical response.”).

13. PRESIDENT'S COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, ANTICIPATE AND COMMUNICATE: ETHICAL MANAGEMENT OF INCIDENTAL AND SECONDARY FINDINGS IN THE CLINICAL, RESEARCH, AND DIRECT-TO-CONSUMER CONTEXTS 22, 27–28 (Dec. 2013) [hereinafter

findings are pieces of information (often clinically significant and medically actionable) that arise from a test or procedure but that are beyond the original purpose for which the test or procedure was conducted.¹⁴ The problem of incidental or secondary findings has been a major source of contention in the research ethics and science policy realms for the past decade.¹⁵

Much of this vigorous debate has centered on defining the contours of the obligation towards patients and research participants whose genomes are being sequenced. For example, given that researchers and clinicians have different obligations to participants and patients,¹⁶ to what extent is it required that researchers devote time and resources towards the return of clinical information unrelated to their scientific aims?¹⁷ Is there a duty to actively interrogate sequencing data to look for incidental findings as the difficulty of doing so decreases?¹⁸ Does an obligation to disclose clinically relevant information extend to relatives of participants or patients, particularly after the death of the proband?¹⁹ Is there any risk of liability for failure to disclose clinically relevant incidental findings?²⁰

PCSBI, ANTICIPATE AND COMMUNICATE], http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf. The President's Commission for the Study of Bioethical Issues draws a useful terminological distinction between incidental and secondary findings. *Incidental findings* represent a broad category of information unrelated to the aim of the test or research. They can be anticipatable ("Practitioner aims to discover A, but learns B, a result known to be associated with the test or procedure at the time it takes place") or unanticipatable ("Practitioner aims to discover A, but learns C, a result not known to be associated with the test or procedure at the time it takes place"). In contrast, *secondary findings* represent the narrow category of unrelated findings that are actively sought ("Practitioner aims to discover A, and also actively seeks D per expert recommendation").

14. Wolf et al., *supra* note 10, at 226. I have adapted my definition from Wolf's commonly cited definition of incidental finding: "[A] finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research but is beyond the aims of the study." Wolf's definition is simultaneously too narrow (only applying to the research setting) and too broad (accepting an expansive view of what constitutes an important finding).

15. Leigh Jackson et al., *Incidental Findings in Genetic Research and Clinical Diagnostic Tests: A Systematic Review*, 158A AM. J. MED. GENETICS 3159, 3160, 3166 (2012).

16. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAV. RES., THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR PROTECTION OF HUMAN SUBJECTS OF RESEARCH, 1, 2–3 (1978).

17. Gail P. Jarvik et al., *Return of Genomic Results to Research Participants: The Floor, the Ceiling, and the Choices In Between*, 94 AM. J. HUM. GENETICS 818, 818–19, 823 (2014).

18. Catherine Gliwa & Benjamin E. Berkman, *Do Researchers Have an Obligation to Actively Look for Genetic Incidental Findings?*, 13 AM. J. BIOETHICS 32 (2013).

19. See Ben Chan et al., *Genomic Inheritances: Disclosing Individual Research Results From Whole-Exome Sequencing to Deceased Participants' Relatives*, 12 AM. J. BIOETHICS 1, 1, 6 (2012) (concluding that limited relevant information should be passively disclosed to relatives unless it is unduly burdensome to the research team).

20. See Elizabeth R. Pike et al., *Finding Fault?: Exploring Legal Duties to Return Incidental Findings in Genomic Research*, 102 GEO. L.J. 795, 798–99, 815, 843 (2014) (advocating for a

While these are all important questions, I wish to bracket them in order to explore a different and increasingly controversial issue: the extent to which it is legally and ethically necessary to respect the so-called right not to know (“RNTK”) genetic information about oneself. As the field of genetic medicine has emerged over the past few decades, the RNTK has been a persistent and widely accepted bioethical tenet.²¹ Simply put, it involves the idea that an individual should be able to control the genetic information about themselves to which they are exposed.²² The idea came to particular prominence in the early research protocols that were looking for genetic variants predictive of breast cancer.²³ In a world where breast cancer was still fairly stigmatizing, and treatment options were much less successful, it was certainly understandable why women might want to be given the opportunity to make a reasoned decision about whether or not to receive this information.²⁴ Similar arguments were often made about other devastating conditions, such as Huntington’s disease and Alzheimer’s disease.²⁵

In a rapidly moving field like medical genetics, the standard of care will often naturally be in a state of flux. As sequencing capacity has exploded, and as the breadth and depth of predictive genetic knowledge has grown, questions about the ongoing appropriateness of a strong RNTK have emerged. Medical genetics providers and bioethicists have been engaged in a contentious debate about the extent to which individual choice should play a role in determining which clinically significant findings are returned. Autonomy is a core principle of clinical ethics, but the rapid expansion of sequencing power is challenging conventional wisdom in uncomfortable ways and is forcing a reexamination of what an appropriate standard of care looks like in a genomic era. Are traditional conceptions about non-directive counseling still appropriate? Are there any circumstances where it might be ethically appropriate to override an individual’s expressed wish not to know

policy requiring researchers to explicitly disclose which of three ethically acceptable approaches they will employ).

21. See discussion *infra* Part II.

22. See Kirke D. Weaver, *Genetic Screening and the Right Not To Know*, 13 ISSUES L. & MED. 243, 270 (1997) (defining the RNTK as “the individual decision whether or not to undergo genetic screening or monitoring”).

23. See discussion *infra* Part II.B.4.

24. See, e.g., Litanja Lodder et al., *Psychological Impact of Receiving a BRCA1/BRCA2 Test Result*, 98 AM. J. MED. GENETICS 15 (2001) (assessing psychological distress in women at risk of hereditary breast cancer).

25. See, e.g., Ruth Chadwick et al., *The Right to Know and the Right Not to Know: The Emerging Debate*, in *THE RIGHT TO KNOW AND THE RIGHT NOT TO KNOW: GENETIC PRIVACY AND RESPONSIBILITY* 18 (Ruth Chadwick et al. eds., 2014) (discussing a British woman who refused predictive testing for Alzheimer’s disease so she could retain hope for the future).

genetic information about him or herself? How, if at all, should the RNTK be reflected in informed consent and return of results policies?

To make these questions more concrete, imagine the following scenario: P is having her genome sequenced as part of a diagnostic work-up for what is suspected to be a rare genetic disorder. During the informed consent process, she clearly checks the box opting not to receive any incidental genetic results. While analyzing P's genomic data, her physicians happen to find evidence of high genetic risk for Hereditary Non-Polyposis Colon Cancer ("HNPCC"). HNPCC is treatable if found early, but is nearly always fatal if discovered in its late stages. They believe that this information will prevent serious disease and perhaps even save P's life because it would direct her to seek enhanced screening for a cancer that is very difficult to pick up with normal colonoscopies. Should they disclose the finding, even though P indicated that she did not want to receive any secondary findings?

Instincts about whether or not to honor P's RNTK vary widely, pointing to the contentiousness of this debate.²⁶ The emerging controversy about the RNTK highlights two of the classic problems in bioethics. First, it focuses us on the frequent tension between autonomy and beneficence.²⁷ We place an extremely high value on empowering and honoring an individual's choices, particularly in the medical realm.²⁸ On the other hand, cases like the one outlined above present a clear dilemma for physicians who want to act in a way that provides the highest prospect of benefit for their patients. When someone chooses not to know beneficial information about him or herself, it forces doctors to address an extremely difficult decision: not honoring a clearly stated choice, or forgoing the opportunity to take advantage of potentially beneficial medical information.

The RNTK also highlights a second commonly observed problem in the field of bioethics: the difficulty with rights language. Rights are generally seen as having "special normative force"²⁹ with the power to trump other interests.³⁰ But the use of rights language can be criticized

26. See discussion *infra* Part V.A.

27. See, e.g., David E. Ost, *The "Right" Not to Know*, 9 J. MED. PHIL. 301, 303–04, 310 (1984) ("The question of refusal of information is an important one in medical ethics because it brings into direct confrontation two value orientations which are often conflated in ordinary experience: the humane and the humanistic.").

28. See *id.* at 301, 303 (advocating for a right to refuse important medical information). See also Roberto Andorno, *The Right Not to Know: An Autonomy Based Approach*, 30 J. MED. ETHICS 435, 435–37 (2004) (interpreting the right to not know the results of genetic tests as part of a patient's freedom to make choices regarding medical decisions).

29. Leif Wenar, *Rights*, in THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY § 5.1 (Edward N. Zalta ed., 2011), <http://plato.stanford.edu/archives/fall2011/entries/rights/>.

30. See Ronald Dworkin, *Rights as Trumps*, in THEORIES OF RIGHTS 153 (Jeremy Waldron ed., 1984).

because rights are inherently absolute, effectively “inhibit[ing] dialogue that might lead toward consensus, accommodation, or at least the discovery of common ground.”³¹ This has the effect of enabling people to pre-emptively short-circuit discussion, thereby avoiding the necessity of making actual arguments, and often resulting in a move “toward confrontation instead of negotiation, as each side escalates an arms race of rights assertions that can only be resolved by a superior authority like a court.”³²

As genomic sequencing technology continues to drive a re-examination of ethical norms and standards of care, there needs to be serious deliberation about the appropriateness of the RNTK in a genomic era, given the obvious and inevitable conflict between autonomy and beneficence that such a right creates. Because the ability to control what genetic information is revealed has been imbued with the power of a right, the debate thus far has been unduly focused on the seemingly absolute nature of an individual’s autonomy.³³ The majority view seems to be that the RNTK continues to be of paramount importance and should not be abrogated in any way.

A case can be made, however, that genomic medicine is holding too tightly to an outdated conception of the RNTK. My goal in this article is to push back against that vigorously held (although not always rigorously defended) position in defense of the idea that we should abandon the notion of a **strong** RNTK. I will provide an extended argument in support of a default for returning high value genetic information **without asking** about a preference not to know. To be clear, I do not intend to argue that there is no role for patient preferences in determining the kind of genetic information to be disclosed. Rather, I will be focusing only on the extent to which there is a RNTK genetic information associated with conditions where medical action can mitigate or prevent mortality or serious morbidity, and where there is strong evidence of the link between genotype and significant disease risk.

In Part II, I will describe the apparent early consensus around the RNTK, and the subsequent controversy that erupted upon publication of the American College of Medical Genetics and Genomics Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing. Parts III and IV will dissect and critique the common arguments made in favor of a RNTK. Part III will explore the foundational philosophical literature that established the RNTK. In this section, I will

31. MARY ANN GLENDON, RIGHTS TALK: THE IMPOVERISHMENT OF POLITICAL DISCOURSE 14 (1991).

32. See Wenar, *supra* note 29, at §7.2.

33. See Andorno, *supra* note 28, at 435–37 (arguing that individuals may have a RNTK and that this right, while not absolute, strengthens autonomy and cannot be assumed).

argue that the RNTK does not enjoy the overwhelming support that modern commentators assert. Rather, a detailed analysis of the literature reveals that the legitimacy and coherence of the RNTK has actually been quite contested. Furthermore, even the more ardent supporters in this early literature qualify the right as being quite limited, in that it only applies in certain contexts and can be overridden with relative ease. Part IV will argue against a commonly asserted legal claim that the constitutional right to refuse medical treatment clearly also implies a right not to know medical information about oneself. Part V will then shift to a series of novel empirical and normative arguments, drawing on a range of psychological constructs (i.e., affective forecasting bias, identified victim effect) and areas of bioethical debate (i.e., moral distress, genetic exceptionalism) to suggest reasons why we should be skeptical of a strong right RNTK. I conclude by providing some recommendations about how best to balance individual autonomy and professional beneficence as the field of genomic medicine continues to evolve.

II. EMERGENCE OF THE RIGHT NOT TO KNOW CONTROVERSY

A. *Early Views on the Right Not To Know*

Researchers and bioethicists have been grappling with the problem of genetic incidental findings for over a decade. The National Bioethics Advisory Commission (“NBAC”) originally examined this issue in 1999, well before sequencing technology took its monumental leap forward.³⁴ Focusing on the research setting, the NBAC concluded that the default should be to not return individual research results, except in “exceptional circumstance[s].”³⁵ Specifically, disclosure was only allowable if “a) the findings are scientifically valid and confirmed, b) the findings have significant implications for the subject’s health concerns, and c) a course of action to ameliorate or treat these concerns is readily available.”³⁶

Once next-generation sequencing technology became available, sentiment began shifting.³⁷ Still focusing on the use of sequencing in research settings (since clinical adoption lagged a few years behind), scholars and researchers started debating whether researchers should have

34. 1 NAT’L BIOETHICS ADVISORY COMM’N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE (1999).

35. *Id.* at 72.

36. *Id.*

37. Teri A. Manolio, *Taking Our Obligations to Research Participants Seriously: Disclosing Individual Results of Genetic Research*, 6 AM. J. BIOETHICS 32, 33 (2006).

an obligation to disclose incidental findings,³⁸ and later whether there should be a further positive obligation to search for certain high value variants.³⁹ While there is still no consensus, the field seems to be moving towards accepting the view that researchers have some obligation to disclose incidental findings, although the precise limits of that obligation, and the circumstances under which it attaches, remain murky.⁴⁰

Although the incidental findings debate has been protracted and often quite heated, there was one issue that at least initially seemed

38. See, e.g., Paul Affleck, *Is It Ethical to Deny Genetic Research Participants Individualised Results?*, 35 J. MED. ETHICS 209 (2009); Laura M. Beskow, *Considering the Nature of Individual Research Results*, 6 AM. J. BIOETHICS 38 (2006); Ebony B. Bookman et al., *Reporting Genetic Results in Research Studies: Summary and Recommendations of an NHLBI Working Group*, 140A AM. J. MED. GENETICS 1033 (2006); Mildred K. Cho, *Understanding Incidental Findings in the Context of Genetics and Genomics*, 36 J. L. MED. ETHICS 280 (2008); Ellen Clayton & Lainie Ross, *Implications of Disclosing Individual Results of Clinical Research*, 295 JAMA 37 (2006); Lynn G. Dressler & Eric T. Juengst, *Thresholds and Boundaries in the Disclosure of Individual Genetic Research Results*, 6 AM. J. BIOETHICS 18 (2006); Conrad V. Fernandez & Charles Weijer, *Obligations in Offering to Disclose Genetic Research Results*, 6 AM. J. BIOETHICS 44 (2006); Morris W. Foster & Richard R. Sharp, *Ethical Issues in Medical-Sequencing Research: Implications of Genotype–Phenotype Studies for Individuals and Populations*, 15 HUM. MOL. GENETICS R45 (2006); Bartha M. Knoppers et al., *The Emergence of an Ethical Duty to Disclose Genetic Research Results: International Perspectives*, 14 EUR. J. HUM. GENETICS 1170 (2006); Fiona A. Miller et al., *Duty to Disclose What? Querying the Putative Obligation to Return Research Results to Participants*, 34 J. MED. ETHICS 210 (2008) [hereinafter Miller et al., *Duty to Disclose?*]; Franklin G. Miller et al., *Incidental Findings in Human Subjects Research: What Do Investigators Owe Research Participants?*, 36 J.L. MED. ETHICS 271 (2008); Pilar N. Ossorio, *Letting the Gene Out of the Bottle: A Comment on Returning Individual Research Results to Participants*, 6 AM. J. BIOETHICS 24 (2006); Vardit Ravitsky & Benjamin S. Wilfond, *Disclosing Individual Genetic Results to Research Participants*, 6 AM. J. BIOETHICS 8 (2006); Henry S. Richardson & Leah Belsky, *The Ancillary-Care Responsibilities of Medical Researchers: An Ethical Framework for Thinking about the Clinical Care that Researchers Owe Their Subjects*, 34 HASTINGS CENTER REPORT 25 (2004); David I. Shalowitz & Franklin G. Miller, *Disclosing Individual Results of Clinical Research: Implications of Respect for Participants*, 294 JAMA 737 (2005); Susan M. Wolf, *Introduction*, 36 J.L. MED. ETHICS 216 (2008); Wolf et al., *supra* note 10.

39. Gliwa & Berkman, *supra* note 18, at 33.

40. See, e.g., *id.* (arguing that “opinion seems to be moving toward the idea that there is some obligation to offer to disclose a limited set of findings, generally understood as findings that meet an exacting standard of validity, severity, and actionability” but that “[e]ven among those who support the existence of an obligation to disclose, however, the contours of that obligation remain murky”); Lisa Eckstein et al., *A Framework for Analyzing the Ethics of Disclosing Genetic Research Findings*, 42 J.L. MED. ETHICS 190, 190 (2014) (“There appears to be an emerging (but disputed) view that researchers have some obligation to disclose some genetic findings to some research participants. The contours of this obligation, however, remain unclear.”); Ellen Wright Clayton & Amy L. McGuire, *The Legal Risks of Returning Results of Genomics Research*, 14 GENETICS MED. 473, 473–74 (2012) (“There is substantial consensus that people should be offered results that could trigger interventions that are lifesaving or that could avert serious adverse health outcomes; there is somewhat less consensus about whether people should be offered results that may have reproductive implications or that could be personally meaningful.”); PCSBI, ANTICIPATE AND COMMUNICATE, *supra* note 13, at 23 (“In fact, there seems to be an emerging consensus in some contexts that practitioners have a duty to return some incidental findings—even if there is little consensus as to precisely which ones.”).

uncontroversial: the right not to know.⁴¹ While commentators were arguing about the circumstances under which there was an obligation to return individual findings, and which findings to return, there seemed to be broad support for the view that findings should only be returned when the research participant desires them.⁴² To the extent that there was an obligation on the part of researchers, that obligation was to *offer* individual findings to research subjects, which they could then elect to receive or refuse.⁴³ Accordingly, there was wide agreement that researchers should discuss the RNTK with potential subjects, and should prospectively solicit subject preferences.⁴⁴ Foreshadowing the impending controversy, some commentators voiced a concern that medical professionals would have difficulty not returning highly relevant medical information, but the

41. See PCSBI, ANTICIPATE AND COMMUNICATE, *supra* note 13, at 59 (“The autonomous patient also has a right *not* to know selected information and should be able to exercise this right (to the extent possible).”); see also BIOBANKS FOR RESEARCH, OP. GERMAN NATIONAL ETHICS COUNCIL 59 (2004) (“Finally, as a precaution, donors would have to be informed in advance of the possible results, so that they could exercise their right not to know.”).

42. See e.g., Richard R. Fabsitz et al., *Ethical and Practical Guidelines for Reporting Genetic Research Results to Study Participants Updated Guidelines From a National Heart, Lung, and Blood INST. Working Group*, 3 CIRCULATION CARDIOVASCULAR GENETICS 574, 575–76 (2010). While there was some dissent among the authors of that paper, they ultimately recommended to honor an individual’s decision not to know genetic information. *Id.* (“Although the Working Group was highly supportive of the right of study participants to opt-out of receiving genetic results, some Working Group members argued there may be exceptional circumstances where . . . the potential for reducing the harm associated with the finding is so compelling that . . . there is an ethical basis to override the wishes of the participant Because of the strong arguments in favor of respecting research participant choices and the lack of consensus in our group on overriding the participant’s decision in some circumstances, we recommend that when the participant has opted-in or opted-out of receiving results, the investigators honor that decision”). See also Timothy Caulfield et al., *Research Ethics Recommendations for Whole-Genome Research: Consensus Statement*, 6 PLOS BIOLOGY 430 (2008) (recommending that the informed consent process “should acknowledge the participants’ right not to know certain results.”); PCSBI, ANTICIPATE AND COMMUNICATE *supra* note 13, at 59 (“The autonomous patient also has a right *not* to know selected information and should be able to exercise this right (to the extent possible).”); GERMAN NAT’L ETHICS COUNCIL, BIOBANKS FOR RESEARCH 59 (2004), http://www.ethikrat.org/files/ner_opinion_biobanks.pdf (“Finally, as a precaution, donors would have to be informed in advance of the possible results, so that they could exercise their right not to know.”).

43. See, e.g., Wolf et al., *supra* note 10, at 231 (“The literature on returning research results cautions that such results should be offered to research participants, not foisted upon them. This is consistent with the literature on genetic testing in particular, which recognizes a right not to know results.”); see also Bartha M. Knoppers, *Introduction: From the Right to Know to the Right Not to Know*, 42 J.L. MED. ETHICS 6, 6 (2014) (“Respect for the autonomy of research participants recognizes that all individuals have the right to make their own decision.”).

44. See, e.g., Fabsitz et al., *supra* note 42, at 575 (arguing that incidental findings should only be offered “during the informed consent process or subsequently, [where] the study participant has opted to receive his or her individual genetic results.”); Knoppers, *supra* note 43, at 6.

prevailing view was that rigorous informed consent could ameliorate this problem.⁴⁵

Buttressing this apparent early consensus was a set of international instruments that increasingly seemed to provide legal recognition for the RNTK. The UNESCO Universal Declaration on the Human Genome and Human Rights (1997) gave individuals the right “to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.”⁴⁶ Similarly, the European Convention on Human Rights and Biomedicine (1997) declared that “the wishes of individuals not to be so informed shall be observed” because “[p]atients may have their own reasons for not wishing to know about certain aspects of their health.”⁴⁷ Individual countries also passed laws specifically recognizing an individual’s right not to know diagnostic (genetic) information.⁴⁸

B. *The Right Not to Know Controversy*

These early views on the RNTK were expressed in the nascent days of genomic medicine, before large-scale genomic sequencing had emerged.⁴⁹ As sequencing technology advanced, and particularly as it moved from the research setting into the clinical realm, the debate began to slowly shift away from the clear consensus view that an individual has a strong RNTK genetic information about oneself.⁵⁰ There were two related reasons for this shift. First, the utility of genomic sequencing was improving.⁵¹ An increasing number of genetic variants had been strongly linked to a range of phenotypes where knowledge of one’s genetic status could have a profound

45. Wolf et al., *supra* note 10, at 231 (discussing the fact that “researchers may understandably be hesitant to accept a research participant’s waiver of information about an IF likely to be life-threatening or grave and ameliorable, unless the participant appreciates that the information being waived may be of high health importance.”).

46. Universal Declaration on Human Genome and Human Rights, G.A. Res. 31, ¶ 16, 29th Sess., U.N. Doc. A/RES/29/31, at 43 (Oct. 21, 1997).

47. Convention on Human Rights and Biomedicine, Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Apr. 4, 1997, CETS No. 164, 4, 11, <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>.

48. See, e.g., TRI-COUNCIL WORKING GROUP, TRI-COUNCIL POLICY STATEMENT: ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS 183 (2010), http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf (“Since the right to privacy includes a right not to know, researchers shall give participants options for receiving or refusing different types of information.”).

49. See, e.g., Jarvik et al., *supra* note 17, at 818 (examining how next-generation sequencing affects the process of returning results to patients).

50. See, e.g., *id.*

51. See *id.* (discussing how the advancements in sequencing technology created a need to address questions about the RNTK).

impact on treatments for (or prevention of) serious disease.⁵² Second, a growing number of patients were being sequenced,⁵³ leading to reasonable projections about the important role that genomic sequencing would have as a regular part of clinical care.⁵⁴

It was in response to this new reality that the American College of Medical Genetics and Genomics (“ACMG”) issued their “ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing.”⁵⁵ Their goal was to start a conversation about clinical standards for managing the predictable onslaught of medically relevant incidental findings.⁵⁶

The Recommendations contained a number of more and less controversial elements. On the less disputed end, they articulated a “minimum list” of fifty-seven (later reduced to fifty-six) genes, and a subset of variants that predispose to twenty-four disorders that “would likely have medical benefit for the patients and families of patients undergoing clinical sequencing.”⁵⁷ Considering both the weight of the scientific evidence and the clinical implications of knowing the genetic information, they limited the list to “unequivocally pathogenic mutations in genes where pathogenic variants lead to disease with very high probability and where evidence

52. See, e.g., Leslie G. Biesecker, *Opportunities and Challenges for the Integration of Massively Parallel Genomic Sequencing into Clinical Practice: Lessons from the ClinSeq Project*, 14 GENETICS MED. 393, 395–96 (2012) (considering the clinical practicalities of genomic sequencing and how it affects the RNTK); Jonathan S. Berg et al., *Deploying Whole Genome Sequencing in Clinical Practice and Public Health: Meeting the Challenge One Bin at a Time*, 13 GENETICS MED. 499, 499 (2011) (discussing the impact of new technology for whole genome sequencing on clinical practice and public health).

53. See Manolio et al., *supra* note 6, at 259 (articulating how the acceptance of genomic medicine has caused an increase in participating sites for clinical application).

54. See Green et al., *supra* note 7, at 209 (“Genomic discoveries will increasingly advance the science of medicine in the coming decades, as important advances are made in developing improved diagnostics, more effective therapeutic strategies, an evidence-based approach for demonstrating clinical efficacy, and better decision-making tools for patient and providers.”); see also Editorial, *The Human Genome at Ten*, 464 NATURE 649, 650 (2010) (asserting that genomic sequencing has been accompanied by unprecedented success in the scientific community that will have powerful applications to human health in the coming decades).

55. Robert C. Green et al., *ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing*, 15 GENETICS MED. 565, 565–66 (2013) [hereinafter *ACMG Recommendations*].

56. Their recommendations were explicitly limited to the clinical context; they intentionally bracketed genomic sequencing done for research purposes, although there is an ongoing debate about the influence that clinical recommendations and guidelines should have in the research realm. See, e.g., Jarvik et al., *supra* note 17, at 817–19 (recognizing that the ACMG Recommendations, which specifically address incidental findings in clinical settings, provided researchers with new considerations in their ongoing debate on reporting genetic results).

57. *ACMG Recommendations*, *supra* note 55, at 567; see also Anastasia Richardson, *Incidental Findings and Future Testing Methodologies: Potential Application of the ACMG 2013 Recommendations*, 28 J.L. BIOSCIENCES 378, 381 (2014).

strongly supports the benefits of early intervention.”⁵⁸ While other researchers and organizations would certainly disagree about the variants that were and were not included, the Working Group did not intend for this to be a definitive list.⁵⁹ Acknowledging there was insufficient data to make confident “evidence-based recommendations,” the ACMG working group used the best available literature and clinical consensus to derive their product.⁶⁰ In addressing the limitations of this approach, the committee explicitly articulated an expectation that this list would actively evolve over time.⁶¹

More controversially, the Working Group recommended that the laboratory should actively seek the variants on the list.⁶² This directly contradicted much of the early incidental findings literature that argued against the need to actively interrogate genomic data looking for incidental findings.⁶³ They characterized this approach as “opportunistic screening,” asserting that even if there was insufficient evidence of cost-effectiveness to warrant population-level screening for these variants, disclosure is justified by the fact that a patient has presented him or herself to a physician who is in a position to provide an important medical benefit.⁶⁴

Most controversially,⁶⁵ the Working Group argued against soliciting patient preferences about receiving (or not receiving) incidental findings.⁶⁶

58. *ACMG Recommendations*, *supra* note 55, at 567.

59. *Id.* See also Laura M. Amendola et al., *Actionable Exomic Incidental Findings in 6503 Participants: Challenges of Variant Classification*, 25 *GENOME RES.* 305, 305–06 (2015) (recognizing limitations of the pathogenic variants identified in the ACMG Recommendations and finding additional genes associated with medically actionable disorders in individuals with European and African ancestries).

60. See *ACMG Recommendations*, *supra* note 55, at 567.

61. See *id.* (acknowledging that the ACMG Recommendations are based on clinical experience from “patients with disease symptoms or family histories” and will likely change as evidence becomes available from “persons without symptoms or family history”).

62. See *id.*

63. Gliwa & Berkman, *supra* note 18, at 33 (“In other words, when researchers generate and interrogate sequence data, do they have any obligation to actively look within the data for potential variants associated with severe or life-threatening diseases? The standard view has been that ‘researchers generally have no obligation to act as clinicians and affirmatively search for IFs,’ but this assumption seems to be relatively unexamined.”) (quoting Wolf et al., *supra* note 10, at 236)). See also, Cho, *supra* note 38, at 283 (questioning whether researchers are obliged to sift through and analyze all collected samples to uncover findings that are unrelated to their research); Miller et al., *Duty to Disclose?*, *supra* note 38, at 212 (suggesting that basing differential obligations to disclose on the veracity of the genomic data analysis will render unfavorable outcomes); Brian Van Ness, *Genomic Research and Incidental Findings*, 36 *J.L. MED. ETHICS* 292, 296 (2008) (arguing against the necessity of a directed effort to find genetic variation unrelated to the goals of the study).

64. *ACMG Recommendations*, *supra* note 55, at 572.

65. While not within the scope of this article, it should be noted that the Working Group also controversially recommended the disclosure of adult-onset conditions to pediatric patients, which

They did not think that it was appropriate to give patients a choice not to learn about clinically important and actionable findings, advancing the claim that clinicians have a fiduciary duty to warn patients about high-risk variants where an intervention is available.⁶⁷ They were also concerned that it would be unduly burdensome to translate the rigorous informed consent procedures used in targeted genetic testing to the enormous range of results that genomic sequencing could produce.⁶⁸ The Working Group contended that this did not remove a patient's opportunity to make an autonomous choice; if patients were uncomfortable with the prospect of learning about incidental findings, they maintained the right to refuse the test altogether.⁶⁹

The recommendation against soliciting patient preferences for not knowing genetic information ignited an extended (and often quite spirited) debate within the research ethics community.⁷⁰ A relatively small set of commentators tried to defend the call for mandatory disclosure of high value incidental findings.⁷¹ The overwhelming majority view, however,

represented a substantial break from the prevailing view, arguing that benefit to parents and other family members outweighed concerns about protecting the child's future autonomy. *See id.* at 568.

66. *Id.*

67. *Id.* The ACMG Recommendations do concede that findings would be delivered to the ordering clinician, who could manage the information in the context of the patient's specific circumstances. *See id.* at 567 ("It was expected that this clinician would contextualize any incidental findings for the patient in light of personal and family history, physical examination, and other relevant findings. This places responsibility for managing incidental findings with the ordering clinician, because we believe that the clinician-patient interaction is the appropriate place for such information to be explained and discussed."). While this language could be read to imply that patient preferences should be sought within the context of the doctor-patient relationship, the ACMG Recommendations do not make this point explicitly, and the overwhelming weight of the documents arguments suggest another reading, as will be discussed below.

68. *Id.* at 568.

69. *ACMG Recommendations, supra* note 55, at 568 ("Patients have the right to decline clinical sequencing if they judge the risks of possible discovery of incidental findings to outweigh the benefits of testing.")

70. *See* James P. Evans, *Finding Common Ground*, 15 *GENETICS MED.* 852, 852 (2013) ("[H]aving read (way too many) positions on this matter, listened to strong (but thankfully, largely polite) debate, and obsessed (way too much) about it.")

71. *See, e.g.,* Benjamin E. Berkman & Sara Chandros Hull, *The "Right Not to Know" in the Genomic Era: Time to Break From Tradition?*, 14 *AM. J. BIOETHICS* 28, 29–30 (2014) (advocating for mandatory disclosure by undermining the RNTK paradigm); Effy Vayena & John Tasioulas, *Genetic Incidental Findings: Autonomy Regained?*, 15 *GENETICS MED.* 868, 868–69 (2013) (proposing mandatory disclosure of incidental findings to provide valuable, life-shaping and life-saving choices that ultimately enhance the patient's autonomy); Amy L. McGuire et al., *Ethics and Genomic Incidental Findings*, 340 *SCIENCE* 1047, 1047–48 (2013) (arguing in favor of the ACMG Recommendations as they likely promote patient health, contain ethical standards that actually exceed the legal standards in most states, and afford safeguards for patients deciding against receiving incidental finding information); Leslie G. Biesecker, *Incidental Variants Are Critical for Genomics*, 92 *AM. J. HUM. GENETICS* 648, 648–49 (2013) (claiming that the potential advances in healthcare posed by reporting incidental findings will not be realized if researchers are not obligated to identify and return results to patients with life-threatening predispositions to diseases); James P. Evans, *Finding Common Ground*, 15 *GENETICS MED.* 852, 853 (2013)

was extremely critical of the recommendation, holding that patients have a strong RNTK, and that any abrogation of that right was inappropriate.⁷² As one paper put it, the ACMG statement was “an instance of paternalistic overreach” that should be “widely rejected as inconsistent with the ethical and legal duties of clinicians.”⁷³

The arguments against the recommendations generally focused on patient autonomy, appealing to the long history of shared medical decision-making and respect for patient preferences. For example, as an impressively credentialed group of bioethicists forcefully argued:

However, choice matters. Patients may wish to decline the additional analysis on a number of grounds Concepts of shared decision making and respect for patient preferences argue for offering meaningful choices wherever possible, with appropriate information to allow patients to choose the best option for themselves If patients decline additional testing, it follows that the laboratory should not perform the additional analyses.⁷⁴

(advocating for the examination of the fifty-six variants described in the ACMG recommendation by default, yet expressing discomfort in the illusory degree of autonomy afforded to patients in allowing them to opt of examination). The arguments advanced in these articles will be examined in more detail in Part V.

72. See, e.g., Wylie Burke et al., *Recommendations for Returning Genomic Incidental Findings? We Need to Talk!*, 15 GENETICS MED. 854 (2013); Susan M. Wolf et al., *Patient Autonomy and Incidental Findings in Clinical Genomics*, 340 SCIENCE 1049 (2013) [hereinafter Wolf et al., *Patient Autonomy*]; David S. Rosenblatt, Commentary, *Who's on First in Exome and Whole Genome Sequencing? Is it the Patient or the Incidental Findings?*, 110 MOLECULAR GENETICS METABOLISM 1 (2013); Lainie F. Ross et al., *Mandatory Extended Searches in All Genome Sequencing: "Incidental Findings," Patient Autonomy, and Shared Decision Making*, 310 JAMA 368 (2013); Megan Allyse & Marsha Michie, *Not-So-Incidental Findings: The ACMG Recommendations on the Reporting of Incidental Findings in Clinical Whole Genome and Whole Exome Sequencing*, 31 TRENDS BIOTECH. 439 (2013); Nat'l Soc'y of Genetic Counselors, *NSGC Responds to ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing*, NSGC.ORG (Mar. 27, 2013), <http://nsgc.org/p/bl/et/blogid=45&blogaid=18>; Anne Townsend et al., *Paternalism and the ACMG Recommendations on Genomic Incidental Findings: Patients Seen But Not Heard*, 15 GENETICS MED. 751 (2013); Robert Klitzman et al., *Return of Secondary Genomic Findings vs. Patient Autonomy: Implications for Medical Care*, 310 JAMA 369 (2013); Susan M. Wolf, *Return of Individual Research Results and Incidental Findings: Facing the Challenges of Translational Science*, 14 ANN. REV. GENOMICS & HUM. GENETICS 557 (2013); Neil A. Holtzman, *ACMG Recommendations on Incidental Findings are Flawed Scientifically and Ethically*, 15 GENETICS MED. 750 (2013); Jarvik et al., *supra* note 17; Gabriel Lázaro-Muñoz et al., *Looking for Trouble: Preventive Genomic Sequencing in the General Population and the Role of Patient Choice*, 15 AM. J. BIOETHICS 3 (2015); Susan B. Trinidad et al., *Looking for Trouble and Finding It*, 15 AM. J. BIOETHICS 15 (2015); Annelien L. Bredenoord et al., *Next Generation DNA Sequencing: Always Allow an Opt Out*, 15 AM. J. BIOETHICS 28 (2015).

73. Trinidad et al., *supra* note 72, at 15.

74. Burke et al., *supra* note 72, at 857.

The support for this line of reasoning was extensive,⁷⁵ and critics often further supported their argument by claiming that there is good reason to think that many people do not want to learn certain kinds of genetic information about themselves.⁷⁶

Even more interesting was the fact that these autonomy-focused views were often couched in relatively absolute terms.⁷⁷ Commentators were not blind to the fact that strongly preferencing the RNTK meant that some patients might not receive information that could save their lives.⁷⁸ Although not expressed in exclusively principlistic language, these arguments essentially seem to advance the view that autonomy should trump beneficence in RNTK situations. For example, as one commentator put it: “Patients have the right to refuse testing and findings, even if potentially lifesaving. Just because many patients might want this information does not mean that it can or should be imposed on all.”⁷⁹ Similarly, a number of commentators cited the legal right to refuse medical

75. See Wolf et al., *Patient Autonomy*, *supra* note 72, at 1049 (“Informed consent is a well-established legal requirement designed to protect patient autonomy – not a matter susceptible to modification by experts in human genetics, no matter how learned.”); Ross et al., *supra* note 72, at 368 (“Implementing mandatory testing for conditions beyond the scope of the original request is in conflict with key ethical principles of patient autonomy and shared decision making.”); Allyse & Michie, *supra* note 72, at 439 (“[T]he implication that individual autonomy should be overridden by physicians for the patient’s ‘own good’ is weakly supported in modern clinical ethics.”); Nat’l Soc’y of Genetic Counselors, *supra* note 72 (“The recently published ACMG recommendations represent a break from past practices, which prioritized a patient’s right not to know genetic information that was predictive rather than diagnostic in nature.”); Townsend et al., *supra* note 72, at 751 (“The traditionally paternalistic model of medicine, underpinned by values and assumptions about passive patient and authoritative physician roles, is increasingly criticized by patients, advocacy groups, health policy makers, and many physicians.”); Klitzman et al., *supra* note 72, at 370 (“A balance between beneficence and paternalism would seem to be optimal, but striking such a fine balance may prove to be difficult.”); Jarvik et al., *supra* note 17, at 820 (“Participants should have the right to refuse any results that are offered. Potential research participants . . . should be provided proper informed consent that respects autonomy, including the right to refuse participation in research.”).

76. Rosenblatt, *supra* note 72, at 1 (“In the experience of this physician, it is not common practise [sic] for the patient or parent to want to know about all health issues unrelated to the reason they are consulting their health professional.”); Townsend et al., *supra* note 72, at 752 (“In a qualitative study, we explored patient, public, and professional views of disclosing genomic incidental findings They emphasized having ‘the power’ to choose disclosure or not, and that patients no longer accept medical paternalism.”); Klitzman et al., *supra* note 72, at 369 (“Currently, many well-informed individuals with known family histories of cancer syndromes . . . choose to forgo or defer genetic testing, given that disease manifestations and timing cannot be predicted.”); Jarvik et al., *supra* note 17, at 822 (“Participant preferences might play a role in the choice of which research results should be returned in that all participants might not choose the same options as those deemed to be clinically significant.”).

77. See Townsend et al., *supra* note 72, at 752.

78. See Burke et al., *supra* note 72, at 857. See also Wolf et al., *Patient Autonomy*, *supra* note 72, at 1050 (explaining that allowing patients the right not to know means that they may not receive potentially lifesaving findings).

79. Wolf et al., *Patient Autonomy*, *supra* note 72, at 1050.

interventions, arguing that an individual's ability to place limits on treatments also implies a legal right to refuse medical information.⁸⁰

In addition to the primary autonomy argument, critics of the ACMG Recommendations discussed a number of other concerns. First, some took issue with ACMG's claim that patients still had a choice, namely whether or not get their genome sequenced.⁸¹ Critics worried that it would be coercive to make clinically indicated genomic sequencing contingent on agreement to analyze and disclose incidental findings.⁸² Relatedly, some raised concerns that this forced choice would cause some patients to forgo medically necessary sequencing to avoid learning unwanted genetic information.⁸³

Second, many critics pointed to a variety of ways in which unwanted genetic information could harm patients.⁸⁴ Most prominent were

80. See *infra* Part IV.

81. See Wolf et al., *Patient Autonomy*, *supra* note 72, at 1049 (explaining that patients had no opportunity to decline unwanted information because the ACMG makes clinicians "report the results of the deliberate search for incidental findings to the patient . . . [thus] [t]he patient's only choice is to decline sequencing altogether . . ."); see also Ross et al., *supra* note 72, at 368 (stating that the ACMG Recommendations violate patient autonomy because they leave patients with an all-or-nothing decision); Klitzman et al., *supra* note 72, at 369 (explaining how proponents claim that patients have a choice whether to undergo exome sequencing, while opponents argue that patients may require testing for diagnosis and treatment of their specified conditions but may not wish to be tested for other conditions).

82. See Rosenblatt, *supra* note 72, at 1 ("Were the ACMG guidelines to reach the level of 'standard of care,' many clinicians, including myself, would avoid clinical exome sequencing to spare both my patients and me the added strains of coerced screening."); Allyse & Michie, *supra* note 72, at 440 ("The assertion that 'patients have the right to decline clinical sequencing if they judge the risks of possible discovery of incidental findings to outweigh the benefits of testing' borders on the coercive."); Townsend et al., *supra* note 72, at 752 ("Another key concern prompted by the ACMG recommendations is the notion of coercive consent to testing and disclosure for vulnerable patients desperate to find the cause of a serious disorder."); Jarvik et al., *supra* note 17, at 822 ("Participation in research studies should be as noncoercive and respectful of participants as possible . . . Framing the conversation as 'if we find . . . would you want' avoids the potentially coercive 'we have . . . do you want.'").

83. Burke et al., *supra* note 72, at 857 (explaining that without the option to refuse additional findings, patients may refuse genomic testing when it is recommended); Ross et al., *supra* note 72, at 368. ("Mandating analysis and reporting beyond that recommended by the ordering clinician may lead to harm if patients and clinicians decide to avoid testing in order to avoid unwanted information."); Townsend et al., *supra* note 72, at 752 ("Some patients who prefer nondisclosure may decline whole-genome sequencing even though by doing so they lose the opportunity to end their diagnostic odyssey.").

84. See, e.g., Wolf et al., *Patient Autonomy*, *supra* note 72, at 1049 (recognizing that unwanted information may harm the patient by causing anxiety as well as unnecessary procedures and interventions); see also Burke et al., *supra* note 72, at 858 (noting that the classification of healthy people as "sick" may cause them to undergo expensive and unnecessary procedures); Klitzman et al., *supra* note 72, at 369 (identifying children as "at-risk" may harm their development).

psychosocial concerns such as stigma, discrimination, and anxiety.⁸⁵ There were also worries about the iatrogenic and economic impact of unnecessary follow-up procedures and interventions, both on the individual and population levels.⁸⁶

Finally, critics claimed that there was not adequate evidence to support the recommendation to engage in opportunistic screening.⁸⁷ Critics worried that our knowledge about the link between genotypes and phenotypes is not yet robust enough to make the specific claims contained in the ACMG recommendations.⁸⁸ There were concerns about the prior predictive value problem; since existing evidence was based on studies involving affected families, critics argued that it is premature to assume similar penetrance in families without a history of the disease because there could be as yet unidentified mitigating genetic features that could reduce or eliminate risk.⁸⁹ Invoking the precautionary principle, these critics argued that we should avoid returning incidental information until we can be more certain that doing so will help rather than harm patients.⁹⁰ Finally, critics pointed to the lack of scientific validity and reliability in existing sequencing platforms and the resultant risk of false negatives.⁹¹

As the academic community was vigorously critiquing the ACMG recommendations, a growing body of evidence indicated that genetics professionals shared many of these concerns. In one national survey of

85. See, e.g., Klitzman et al., *supra* note 72, at 369 (arguing that incidental findings will cause anxiety and stigma in certain communities); Lazaro-Muñoz et al., *supra* note 72, at 11 (concluding that incidental findings will increase the chances of genetic discrimination).

86. Burke et al., *supra* note 72, at 858 (“[C]areful consideration must be given to potential harms, both to the individual tested and to the health-care system. These harms include adverse labeling of health people as ‘sick,’ unnecessary health-care expenditures, and iatrogenic complications.”); Wolf et al., *Patient Autonomy*, *supra* note 72, at 1049 (“Inflicting unwanted information on patients carries its own risks, as unwanted information may lead to anxiety, further clinical workup, and potentially burdensome interventions.”); Ross et al., *supra* note 72, at 368 (“Mandating analysis and reporting beyond that recommended by the ordering clinician may lead to harm if patients and clinicians decide to avoid testing in order to avoid unwanted information.”); Allyse & Michie, *supra* note 72, at 439–40 (arguing that “extra testing will place an added burden on laboratories” that could lead to increased costs that might not be covered by insurance); Klitzman et al., *supra* note 72, at 369 (“Such erroneous classification could cause anxiety and lead patients to inappropriately seek expensive medical screening . . . or unwarranted procedures such as prophylactic mastectomy.”);

87. Klitzman et al., *supra* note 72, at 369 (“Until well-curated human mutation databases are available, patients may be told about many mutations that, because of incomplete penetrance and misclassification of benign variants as mutations, are likely neither to cause disease nor confer substantial risk when ascertained in the general population.”); Holtzman, *supra* note 72, at 750 (“The evidence to support these beliefs is insufficient to constitute reporting them as ‘the standard of care.’”).

88. Klitzman, *supra* note 72, at 369.

89. Holtzman, *supra* note 72, at 750.

90. *Id.*

91. *Id.*

genetics professionals, 81% of respondents thought that individual patient preferences should be honored when deciding which results to return.⁹² Another qualitative study found consensus support for the view that autonomy and informed consent were of vital importance when returning results.⁹³ In response to the mounting criticism of their recommendations, ACMG published a policy statement that clarified their position without making any substantive changes.⁹⁴ Eventually, however, ACMG retreated from their position.⁹⁵ Citing a “consensus among ACMG members,” the organization refined their position to state that before the sample is sent for analysis “patients should have an opportunity to opt out of the analysis of medically actionable genes when undergoing whole exome or genome sequencing.”⁹⁶

It should be noted that in the course of this debate, the President’s Commission for the Study of Bioethical Issues published a report on incidental findings, broadly considering the issue across a range of contexts (i.e., research, clinical, direct to consumer testing) and technologies (e.g., genetics, imaging, etc.).⁹⁷ While the Commission did not go into extensive detail about the RNTK, the report did briefly address whether or not there should be limits on a clinician’s obligation to respect a patient’s preference not to know genetic information.⁹⁸ The Commission rightly pointed out that grappling with incidental findings requires balancing two competing principles, respect for persons and beneficence.⁹⁹

Consistent with the majority view, however, there is an emphasis throughout the document on soliciting and respecting patient preferences for managing incidental findings, including the RNTK.¹⁰⁰ The Commission did nevertheless seem to leave room to override an autonomous choice.

92. Joon-Ho Yu et al., *Attitudes of Genetics Professionals Toward the Return of Incidental Results from Exome and Whole-Genome Sequencing*, 95 AM. J. HUM. GENETICS 77, 79 (2014).

93. Megan E. Grove et al., *Views of Genetics Health Professionals on the Return of Genomic Results*, 23 J. GENETICS COUNSELING 531, 532–33 (2013).

94. AMERICAN COLLEGE OF MEDICAL GENETICS & GENOMICS, *Incidental Findings in Clinical Genomics: A Clarification*, 15 GENETICS MED. 664, 664–65 (2013).

95. See ACMG Updates Recommendation on “Opt Out” for Genome Sequencing Return, AMERICAN COLLEGE OF MEDICAL GENETICS & GENOMICS (Apr. 1, 2014), https://www.acmg.net/docs/Release_ACMGUpdatesRecommendations_final.pdf.

96. *Id.*

97. See PCSBI, ANTICIPATE AND COMMUNICATE, *supra* note 13, at 22.

98. *Id.* at 59.

99. *Id.* at 61 (“Beneficence demands that a physician use professional judgment to determine whether disclosure would do more harm than good for the particular patient, and respect for persons requires that a patient’s preferences be ascertained, preferably before testing.”).

100. PCSBI, ANTICIPATE AND COMMUNICATE, *supra* note 13, at 4, 5, 10, 30, 44, 59, 61, 63, 64, 66, 78, 83 (2013) (recognizing the importance of patient autonomy and consistently asserting that respect for persons requires that the autonomous individual should be encouraged to express preferences regarding secondary and incidental findings before testing).

Specifically, the Commission recommended that “clinicians should respect a patient’s preference not to know about incidental or secondary findings to the extent consistent with the clinician’s fiduciary duty.”¹⁰¹ Similarly, they assert that “if patients wish to opt out of receiving incidental or secondary findings that are clinically significant, actionable, and of serious importance to their health, then clinicians should exercise discretion.”¹⁰²

Overall, while the Commission’s position on the RNTK seems to be much less strident than many of the other commentators in the contemporaneous literature, they also did not firmly defend the ACMG view. While representing a step away from the majority view, the Commission did not challenge the underlying appropriateness of the RNTK in a genomic era, given the obvious and inevitable conflict between autonomy and beneficence that such a right creates. Nor do they rigorously explore when and why it might be acceptable to override a patient’s RNTK, and whether it would be appropriate to abandon the consensus position that preferences have to be proactively solicited. I take up these challenges in the subsequent sections.¹⁰³

101. *Id.* at 64.

102. *Id.*

103. *See infra* Parts III, IV, V.

III. THE PHILOSOPHICAL ORIGINS OF THE RNTK: AN UNEXPECTEDLY CONTESTED CONCEPT

The RNTK genetic information is a relatively new idea, first appearing in the literature in the 1970s and 80s¹⁰⁴ but not really gaining traction until the 1990s.¹⁰⁵ A substantial body of work developed in the subsequent decade, concurrent with the gradual incorporation of genetic testing into clinical medicine.¹⁰⁶ While there appears to be significant recent support for the RNTK, a robust examination of the concept must begin with an analysis of the idea's philosophical origins. Contemporary RNTK advocates have had a tendency to present their views in the absence of this historical perspective, seemingly arguing that a strong, autonomy-based RNTK is self-evident.¹⁰⁷ In contrast to this assumption, I believe that a close examination of the earlier RNTK literature reveals a much more controverted and nuanced history.¹⁰⁸ Specifically, I will demonstrate that acceptance of a strict RNTK is far from universal in the philosophical

104. Robert M. Veatch, *Three Theories of Informed Consent: Philosophical Foundations and Policy Implications*, in THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, APPENDIX II 6, 8–9, 50 (Nat'l Comm'n for the Protection of Human Subjects of Biomedical & Behavioral Research ed., 1978); Ost, *supra* note 27.

105. See, e.g., Torleiv Austad, *The Right Not to Know—Worthy of Preservation Any Longer? An Ethical Perspective*, 50 CLIN. GENETICS 85, 86 (1996) (explaining that the RNTK gained significant traction in the 1990s after studies found that the burden of genetic information had the potential to cause serious psychological harm); see Juha Räikkä, *Freedom and a Right (Not) to Know*, 12 BIOETHICS 49, 50 (1998) (analyzing the relationship between the moral right to know and the RNTK genetic information to prevent “harmful personal consequences”); Weaver, *supra* note 22, at 243 (1997); Rosamond Rhodes, *Genetic Links, Family Ties, and Social Bonds: Rights and Responsibilities in the Face of Genetic Knowledge*, 23 J. MED. PHIL. 10, 11 (1998) (examining the moral responsibilities and effects that exercise of the RNTK has on third parties); Graeme Laurie, *In Defence of Ignorance: Genetic Information and the Right not to Know*, 6 EUR. J. HEALTH L. 119, 130 (1999) [hereinafter Laurie, *In Defence of Ignorance*] (concluding that the field of bioethics is witnessing a new era which expressly recognizes an interest in not knowing genetic information); Graeme Laurie, *Protecting and Promoting Privacy in an Uncertain World: Further Defences of Ignorance and the Right Not to Know*, 7 EUR. J. HEALTH L. 185, 188 (2000) [hereinafter Laurie, *Privacy in an Uncertain World*] (arguing that the RNTK can be circumvented by medical practitioners, either internationally, or unintentionally, by disclosing information before an individual unequivocally elects to exercise this right); Tuija Takala, *The Right to Genetic Ignorance Confirmed*, 13 BIOETHICS 288, 289 (1999) (examining the psychological benefits of genetic ignorance, and the harm it can have on others).

106. See Chadwick et al., *supra* note 25, at 13, 19 (explaining that since 1997, the emergence of genetic testing in clinical medicine greatly contributed to the developments in RNTK); see also Rhodes, *supra* note 105, at 11 (analyzing the responsibilities and rights of individuals with respect to the emergence of genetic testing and genetic knowledge).

107. See, e.g., Andorno, *supra* note 28, at 435.

108. In this section, I will exclusively be analyzing the earlier RNTK literature, drawing a line at 2007, around the advent of next-generation sequencing. This new technology is ethically relevant because it changed the magnitude and likelihood of concerns that before that point had been primarily theoretical. See Tabor et al., *supra* note 8, at 2917.

literature, and that even staunch proponents recognize that the RNTK can be easily overridden by competing considerations.

A. *The Arguments for a Strong RNTK*

Most commonly, scholars ground the RNTK in autonomy, arguing that one's right to self-determination implies a right to make decisions about learning (or not learning) sensitive medical information.¹⁰⁹ These authors typically build their argument on a foundational assertion that genetic information has the potential to cause psychological and economic harm.¹¹⁰ While often granting that more information can allow for improved decision-making regarding future plans, they stress that for some individuals, this information can lead to anxiety, depression, stigma and even discrimination.¹¹¹ Therefore, an individual should be afforded the freedom to weigh the risk of psychosocial and economic harms against the potential benefit that the knowledge might provide.¹¹²

Beyond this basic argument, RNTK proponents often focus their reasoning on a number of specific themes. Most commonly, a number of scholars cite concerns about paternalism in medical care, making claims it has no place in modern medicine, even if justified by seemingly reasonable considerations.¹¹³ For example, Tuija Takala argues that:

109. See, e.g., Andorno, *supra* note 28, at 435 (2004) (“This paper argues that ‘autonomy,’ understood in a wide sense, provides a theoretical basis for a right not to know one’s genetic status.”); Jonathan Herring & Charles Foster, “*Please Don’t Tell Me*”, 21 CAMBRIDGE Q. HEALTHCARE ETHICS 20, 28 (2012) (finding that although the RNTK enhances personal autonomy, the right is not absolute because “it can and sometimes should be outweighed by other considerations”); Austad, *supra* note 105, at 86 (denoting that the RNTK has been predominately motivated by the severe psychological consequences that can arise from an individual’s cognition of their genetic abnormalities); Weaver, *supra* note 22, at 270, 273 (explaining that the RNTK ensures an individual has complete autonomy in their decision regarding the disclosure of their genetic information); Takala, *supra* note 105, at 292 (reasoning that a truly autonomous decision “implies a duty of self-determination,” and that an individual must consider all of the relevant information regarding the disclosure of the genetic defect).

110. See Austad, *supra* note 105, at 86 (“There is reason to believe that increasing knowledge about genetic predispositions could be an extra burden, at least for some.”); see also Weaver, *supra* note 22, at 243 (“[S]uch knowledge can lead to anxious preoccupation with the ever present disease potential within, and discrimination by employers, insurers, governmental agencies, and health care providers without.”); see also Andorno, *supra* note 28, at 435 (“[O]ne has to consider that the burden of knowledge may become unbearable for them, leading to a severe psychological depression and having a negative impact on their family life and on their social relationships in general.”).

111. See Andorno, *supra* note 28, at 435 (noting that the burden of knowledge that coalesces with the acquiring of genetic information can lead to negative psychological consequences).

112. *Id.* at 437.

113. See, e.g., Tuija Takala, *Genetic Ignorance and Reasonable Paternalism*, 22 THEORETICAL MED. BIOETHICS 485, 490 (2001).

If a person's own judgment can be overridden by considerations of the "reasonable," as defined by the profession, or by ethicists for that matter, we must forget the principle of autonomy at the outset, or at least find its applications extremely limited. It seems that by accepting the rhetorics of "what the reasonable person would do," we re-introduce the practice of paternalism to medical ethics.¹¹⁴

Takala clearly dismisses the idea of requiring a person to obtain knowledge that can be used to benefit him or herself, labeling such a practice as "reasonable paternalism."¹¹⁵ She draws a distinction between preventing harm and creating benefit, arguing that knowing one's genetic status offers the possibility of a benefit, but not knowing about a genetic defect does not directly harm the person, since the defect is present regardless.¹¹⁶ If forced provision of information poses a risk of harm, and there is only a possibility of creating benefit (rather than prevention of harm) unwanted provision of genetic information is indefensibly paternalistic.¹¹⁷ According to her view, it is paternalistic to overrule individual choice, even if a choice differs from our conception of what is "reasonable."¹¹⁸ This paternalism may be understandable, but that does not make it acceptable.¹¹⁹

Roberto Andorno also argues that individuals may have a legitimate interest in not knowing their genetic makeup in order to avoid serious psychological consequences.¹²⁰ Not only does he endorse the commonsense view that it is respectful of autonomy to comply with an individual's stated preference, he goes further to say that honoring the RNTK should be seen as an enhancement of an individual's autonomy "because the decision to know or not to know is not taken out of the hands of the patient by the doctor."¹²¹ Furthermore, he makes a non-maleficence argument, claiming that if the information is likely to cause psychological harm, the medical

114. *Id.*

115. *Id.* at 490 (explaining that "reasonable paternalism" essentially disregards individual autonomy for a more objective standard that looks solely to "what a reasonable person would do" in similar circumstances).

116. *Id.*

117. *Id.*

118. Takala, *supra* note 113, at 490 (finding that individual autonomy should be insulated from societal judgment and paternalistic limitations guided by the objectivity of "what a reasonable person would do").

119. Takala, *supra* note 105, at 288 (arguing that "liberal societies should acknowledge people's right to remain in ignorance" unless "grave harm would follow if people were allowed to make these self-regarding decisions").

120. Andorno, *supra* note 28, at 435–37.

121. *Id.* at 436.

principle of *primum non nocere* (do no harm) justifies honoring the RNTK.¹²²

Others make an argument based on scientific uncertainty, pointing out that genetic information is often less probative than people realize.¹²³ Indeed, there are many conditions where genetics simply reveal a risk factor, rather than anything of diagnostic certainty.¹²⁴ In some cases “since being a carrier is not something that can be *averted* by informing, it is not clear why there should be an onus on individuals to know, or to facilitate others being told, about their genetic constitution.”¹²⁵ These authors also highlight how reproductive issues give genetic information a unique valence, as genetic knowledge may present a constraint on autonomous reproductive choices if people change their decisions due to the genetic information.¹²⁶

Interestingly, there does not seem to be overwhelming support in the foundational RNTK literature for a strict, autonomy-based RNTK.¹²⁷ The limited number of scholars discussed above support such a view, but the weight of the literature is squarely against an expansive view of the RNTK. As I will discuss in the next few sections, most scholars either argue for a much narrower conception of the RNTK, or dismiss the idea entirely.

B. *The Arguments Against a Strong RNTK*

1. *Autonomy Misapplied*

There are a number of lines of reasoning challenging the notion of a strong, autonomy-based RNTK. One main strain of criticism asserts that the concept of an autonomy-based RNTK is too broad and that the principle has been misapplied.¹²⁸ As Rhodes has argued, “Misunderstandings about the nature and moral force of autonomy have led some in the genetics

122. *Id.* at 437.

123. *See, e.g.*, Weaver, *supra* note 22, at 252 (“Because of the varied causal nature of many ‘genetic’ diseases or conditions, it seems highly unlikely that any one test or series of tests would be able to incorporate the numerous factors that influence the development of the illness.”).

124. *See id.* at 251–52.

125. Jane Wilson, *To Know or Not to Know? Genetic Ignorance, Autonomy and Paternalism*, 19 *BIOETHICS* 492, 502 (2005).

126. *See id.* at 498; *supra* Part III.A.

127. I’m defining the foundational literature as the articles published prior to the emergence of genomic sequencing technology in approximately 2007. Compare Andorno, *supra* note 28, at 435 (arguing that the RNTK genetic information is deeply grounded in the theoretical concept of autonomy); with Laurie, *Privacy in an Uncertain World*, *supra* note 105, at 190 (advocating that the foundational basis for the RNTK is grounded in privacy as opposed to autonomy).

128. *See* Wilson, *supra* note 125, at 502.

community to a false conclusion about genetic ignorance.”¹²⁹ The concern with an autonomy-based RNTK stems from the commonly held view that rights are “pre-emptive and value-laden” and therefore the content of a right must be carefully articulated and defended.¹³⁰

On Laurie’s account, autonomy fails as a basis for doing so for a number of reasons.¹³¹ First, a strong, autonomy-based RNTK is inappropriate because that line of reasoning unrealistically requires ignoring the fact that there is no such thing as an unfettered choice.¹³² There are lots of things that people would like to do (or not do), or to know (or not know), but one sometimes must make non-ideal choices. Second, there is no basis for the idea that information alone is autonomy-constraining, because a clear distinction can be drawn between obtaining relevant information and making subsequent decisions on the basis of that information.¹³³ Finally, autonomy is not boundless; there are certain actions that are prohibited as a matter of public policy, like suicide or selling oneself into slavery.¹³⁴

Instead of autonomy, Laurie argues in favor of a RNTK grounded in privacy.¹³⁵ Distinguishing his reasoning from the more common autonomy claims, he states that the RNTK is “better characterized as a privacy issue that is related to, and yet distinct from, autonomy claims that we each might have as individuals worthy of respect.”¹³⁶ He prefers the principle of privacy because it provides a “neutral basis from which arguments about the merits and demerits of non-disclosure can be advanced and assessed.”¹³⁷ He builds his theory on the idea of spatial privacy, or the notion that we have a right to ensure that an individual is in “in a state of non-access.”¹³⁸ Spatial privacy includes both the familiar notion of physical separateness, but also “encompasses separateness of the individual’s psyche.”¹³⁹ The latter form of privacy entitles an individual to protect his or

129. Rhodes, *supra* note 105, at 26. *See also* Matti Häyry & Tuija Takala, *Genetic Information, Rights, and Autonomy*, 22 THEORETICAL MED. BIOETHICS 403, 403 (2001).

130. *See* Graeme Laurie, *Recognizing the Right Not to Know: Conceptual, Professional, and Legal Implications*, 42 J.L. MED. ETHICS 53, 56 (2014) (rejecting the characterization of non-knowledge as a “right”).

131. *See id.* at 55–56.

132. *See id.* at 56 (“no choice in life is unfettered by circumstantial influence . . .”); *see also* John Harris & Kirsty Keywood, *Ignorance, Information and Autonomy*, 22 THEORETICAL MED. BIOETHICS 415, 418 (2001) (stating that all choices have an effect on autonomy to some extent).

133. Laurie, *supra* note 130, at 56.

134. Harris & Keywood, *supra* note 132, at 420.

135. Laurie, *supra* note 130, at 53.

136. *Id.*

137. *Id.* at 56.

138. *See* Laurie, *In Defence of Ignorance*, *supra* note 105, at 119 (explaining that this right is violated when one’s physical sphere is invaded).

139. *Id.*

her own sense of self.¹⁴⁰ As a result, it can be an invasion of one's "psychological spatial privacy" to receive information about oneself that was not already possessed.¹⁴¹

Ultimately, in basing his conception of a RNTK in privacy rather than autonomy, he calls into question the view that the RNTK is actually a strong right.¹⁴² Rather, he acknowledges that a decision to violate someone's psychological privacy involves a number of competing factors and must be holistically assessed instead of being held up as a strict ethical rule.¹⁴³ Using a privacy lens, Laurie demonstrates that an unwanted disclosure can be a violation, as it represents an incursion into the private sphere.¹⁴⁴ But even if disclosure constitutes a violation of privacy, it can be justifiable under certain circumstances.¹⁴⁵ Ultimately, he argues for a *prima facie* presumption in favor of non-violation of the sphere of privacy.¹⁴⁶ This presumption can be rebutted, however, in a range of clinical cases.¹⁴⁷ When considering the justifiability of violating someone's psychological integrity, a number of factors should be relevant, including: availability of a cure or intervention, severity of the condition, and the likelihood of disease manifestation.¹⁴⁸

Wilson, like Laurie, is a RNTK proponent who does not see autonomy as the correct supporting principle.¹⁴⁹ She acknowledges that it is possible to view the provision of genetic information as an attack on autonomy, particularly when such information "impinges on the range of choices that an individual has to make, and on the conditions of autonomy required to make them."¹⁵⁰ However, she thinks that a RNTK should exist in a much more limited form than an autonomy-based view would require.¹⁵¹ While she concedes that there should be a RNTK in certain obvious circumstances

140. *Id.*

141. *See id.* at 119–20.

142. *See id.* at 123–24, 127, 129 (suggesting that autonomy cannot explain the RNTK because there is simply no way to exercise the choice of not knowing, while privacy, on the other hand, suggests the idea that individuals can be protected from unwarranted information about themselves).

143. *Id.* at 127

144. *See* Laurie, *In Defence of Ignorance*, *supra* note 105, at 124 (explaining that sharing unwanted information diminishes the amount of control that one has over their own private sphere, as it coerces an individual into self-reflection and re-evaluation).

145. *See id.* at 121 (arguing that in order for an action to be justifiable, there must be a high likelihood that the harm will be avoided by the revelation of the information).

146. *Id.* at 127.

147. *Id.*

148. *Id.* at 127–28.

149. Wilson, *supra* note 125, at 503–04.

150. *Id.* at 502.

151. *See id.* at 503–04 (arguing that greater consideration should be given to potential harms and benefits to welfare).

(such as when there is nothing that can be done with the information, or there is clear evidence of psychological harm that will result) her primary claim is that an autonomy-based RNTK is unjustifiably broad, and that we should only be talking about a narrow RNTK in limited situations when it can be justified by a clear demonstration that welfare costs to an individual outweigh associated benefits.¹⁵²

Räikkä similarly explores whether autonomy is the correct theoretical grounding for a RNTK, arguing that while self-determination can technically support a RNTK to know, such a position relies on a number of problematic assumptions.¹⁵³ In particular, he is concerned about our ability to determine when people are making competent, authentic decisions and whether one can ever make a solely self-regarding choice to refuse genetic information.¹⁵⁴ Given the controversies inherent in asserting an autonomy-based RNTK, he worries about its persuasive rigor when appealed to in concrete cases where the RNTK is in question.¹⁵⁵ He argues that when:

there are disagreements about whether a person has a right to know or a right not to know, it may be unhelpful to refer to a right to personal determination. To argue for example that a person has a right not to have information concerning her own genes, since she has a moral right to self-determination, is nowhere near enough to convince and give a rational warrant to believe she has such a right.¹⁵⁶

Ultimately, he concludes that proponents of controversial claims, like the RNTK, should avoid appealing to autonomy and instead find “values that allow for a shorter, less controversial route to shedding light on the problem.”¹⁵⁷

Given the views of scholars like Laurie, Wilson, and Räikkä, there is clearly a school of thought comprised of people who generally accept a form of the RNTK, but who reject a broad, autonomy-based view. Interestingly, these scholars are clear that we should anticipate the circumstances where the RNTK can be overridden.¹⁵⁸ For example, Laurie

152. *Id.* at 499–500, 502–04 (arguing for an alternative to an autonomy-based RNTK, which considers harms and values to welfare, and whether disclosure of the information will be useful in light of the specifics of the genetic disease).

153. Räikkä, *supra* note 105, at 61, 62.

154. *Id.* at 62.

155. *Id.*

156. *Id.*

157. *Id.* at 63.

158. *See, e.g.*, Herring & Foster, *supra* note 109, at 28. (“We do not say that this is or should be an absolute right. We accept that, like most other recognized rights, it can and sometimes should be outweighed by other considerations.”); Räikkä, *supra* note 105, at 57 (“If a person has a weak right to self-determination, there are cases in which it is justified to override the right to self-determination In a given situation we should always first consider the circumstances and only

argues that the RNTK should be balanced against a number of clinical considerations, including the availability of a treatment for a severe disease that is likely to manifest.¹⁵⁹ Herring and Foster agree that there should be exceptions to any RNTK, presenting criteria similar to those endorsed by Laurie.¹⁶⁰ These exceptions echo the idea that I will defend in more detail in the sections below, namely that we should reject a RNTK that is so broad as to include conditions where medical action can mitigate or prevent mortality or serious morbidity, and where there is strong evidence of the link between genotype and significant disease risk.

2. *The Incoherence Objection*

In addition to challenging the notion that the principle of autonomy plausibly supports a RNTK, some critics make an even more forceful argument, calling into question the very coherence of the RNTK as a viable concept. These scholars make an autonomy claim of their own, but in the opposite direction, advancing the idea that knowledge is necessary in order to exercise autonomy.¹⁶¹ One needs to know that there is a question in order to make a decision; so not knowing undermines one's ability to make an

then decide whether a right to self-determination should be respected.”); Andorno, *supra* note 28, at 437 (arguing that it is appropriate to consider overriding the RNTK if there is serious risk to other individuals; if there are reasonable and effective treatments/cures for the condition being tested for; or for broader public health reasons).

159. Laurie, *supra* note 130, at 59 (listing a number of other relevant considerations: “The availability of a cure or effective intervention; the severity of the condition and likelihood of onset; the nature of the health condition itself, e.g., genetic or otherwise; the nature of any further testing or intervention that might be required; the nature of the information to be disclosed; the nature of the request (e.g., testing for an individual’s health or for diagnostic purposes for a relative); the question of whether and how far disclosure can further a legitimate public interest, which can include familial interests; and the question of how the individual might react if offered unsolicited information (e.g., whether any advance decision has been made and is applicable in the circumstances).”).

160. Herring & Foster, *supra* note 109, at 27 (listing: “The availability of cures or preventive measures[;] The severity of the disease and likelihood of onset; The nature of the disorder[;] The availability of genetic testing and its accuracy in assessing the risk[;] The relative’s likely emotional reaction when given the information[;] The effect any decision (to disclose or not to disclose) will have on the familial relationship and on the dynamics of the particular family.”).

161. See, e.g., Phillipa Malpas, *The Right to Remain in Ignorance About Genetic Information—Can Such a Right Be Defended in the Name of Autonomy?*, 118 N. ZEALAND MED. J. 71, 72 (2005) (“Respecting self-determination requires that individuals have access to information so that they can make informed decisions.”); Laurie, *supra* note 130, at 55 (“[I]n order for us to choose meaningfully, we must be informed about the parameters within which we are being invited to exercise choice. The entire consent mechanism is constructed around informed choice.”); Rhodes, *supra* note 105, at 17 (“[R]espect for autonomy actually leads to the opposite conclusion, the obligation to pursue genetic knowledge.”).

autonomous choice.¹⁶² Rather, autonomy demands “critical reflection,” which includes thoughtful, informed decision-making, and deliberation.¹⁶³ This is made impossible if one deprives one’s self of information.¹⁶⁴ Without relevant information, it is impossible to make informed decisions about future plans, and ill-informed decisions may even frustrate one’s future self, as an individual may make choices that are ultimately self-defeating.¹⁶⁵ As one scholar argued, a refusal of relevant knowledge is so irrational as to be “directly opposed to human rights philosophy and to ethics.”¹⁶⁶

Some have gone as far as saying that autonomy requires rationality, and freedom of will, but patients who deny themselves readily available information are not acting rationally, as they are depriving themselves of relevant health information.¹⁶⁷ If someone is so fixed in their intentions that no amount of relevant information would change their mind, this would be tantamount to an irrational obsession.¹⁶⁸ Similarly, it is logically impossible for someone to claim to know *a priori* that information will not be relevant to his or her decision.¹⁶⁹

This line of reasoning not only rejects a RNTK, but also seems to imply a moral duty to be informed about information that would make a difference in decisions (at least when it can be obtained without undue effort).¹⁷⁰ For example, Rhodes argues that the concept of autonomy may actually create a duty to know, as people cannot make autonomous choices without relevant information.¹⁷¹ Therefore, rather than respecting autonomy, the RNTK allows willful blindness that stymies autonomous decision-making.¹⁷² This duty to know is activated when “genetic

162. See, e.g., Veatch, *supra* note 104, at 26–33 (“If the human is ethically responsible for decisions about his or her own medical future, it can be seriously questioned at the ethical level whether one is justified in waiving information necessary to make a consent informed.”).

163. Malpas, *supra* note 161, at 75 (“When autonomy (as self-determination) is understood as involving critical self-reflection, deliberation, and thoughtful and informed decision-making, it becomes clear that one must have relevant information at ones [sic] disposal to be autonomous.”).

164. *Id.*

165. *Id.*

166. Gilbert Hottois, *A Philosophical and Critical Analysis of the European Convention of Bioethics*, 25 J. MED. & PHILOS. 133, 140 (2000).

167. Ost, *supra* note 27, at 306.

168. *Id.*

169. *Id.* (“But to claim to know what you cannot know is contradictory, i.e., irrational.”)

170. *Id.* at 309 (“[W]e can say that the right of informed consent is a mandatory right, and that receiving information about one’s diagnosis, alternative treatments, etc., is both a right and a duty.”). See also Rhodes, *supra* note 105, at 18.

171. Rhodes, *supra* note 105, at 18.

172. Harris & Keywood, *supra* note 132, at 418 (2001) (arguing that the right not to know is “inimical to liberty rights”).

information is likely to make a significant difference in my decisions and when the relevant information is obtainable with reasonable effort.”¹⁷³

If there is no such thing as a right to remain ignorant of true genetic information about oneself, the RNTK must compete on equal terms with others’ rights. Harris and Keywood propose two rights in particular, that might reasonably defeat a desire to remain in ignorance.¹⁷⁴ First, they present an argument for the right of free speech, particularly in the context of doctors exercising their free speech right to warn patients about medical risks, and to provide patients with a fully informed understanding of their health conditions.¹⁷⁵ Second, they argue for the right to decline to accept responsibility for others’ decisions; doctors should not be forced to make certain decisions for patients who are willfully ignorant of their true health status.¹⁷⁶ I will explore these and other possible relevant considerations in Section V below.

3. *Effects on Third Parties*

A third objection to a strict, autonomy-based RNTK is founded on a concern about the effect of maintaining one’s ignorance on others. On this line of reasoning, genetic information unavoidably involves relatives, and one has an obligation to learn readily available information about your health in order to allow relatives to have an opportunity to act on that knowledge.¹⁷⁷ Relatives that hadn’t previously known about a familial genetic risk would be able to benefit from knowing by taking a variety of actions, such as seeking their own genetic testing, changing risk-associated behaviors, pursuing prophylactic treatment options, engaging in rigorous screening, etc.¹⁷⁸

Austad articulates this kind of view clearly, arguing that the RNTK does not actually rise to the level of a human right because genetic information does not only implicate a single individual.¹⁷⁹ Rather, genetic information, and information about genetic risks, implicates the individual, their family members, their practicing physician, and, potentially, scientific research into genetics in general.¹⁸⁰ An individual’s desire to say no to genetic information may conflict with the duty of care (i.e., duty to warn) a

173. Rhodes, *supra* note 105, at 18.

174. Harris and Keywood, *supra* note 132, at 418.

175. *Id.* at 431.

176. *Id.* at 431–32.

177. See Austad, *supra* note 105, at 87.

178. See, e.g., *id.*; Maria C. Bottis, *Comment on a View Favoring Ignorance of Genetic Information: Confidentiality, Autonomy, Beneficence and the Right Not to Know*, 7 EUR. J. HEALTH L. 173, 174, 179–80 (2000).

179. Austad, *supra* note 105, at 87.

180. *Id.*

potentially affected family member.¹⁸¹ This does not mean that the RNTK should not be respected if possible, but that there are clear situations where other competing ethical principles might cause one to disregard a desired RNTK.¹⁸² On this view, the RNTK should not be viewed as a strict right¹⁸³ and when there is a conflict between the RNTK and the right of relatives to sensitive genetic information concerning their own health, the RNTK must yield, due to the very real risk of harm to the family members.¹⁸⁴ Andorno advances a similar, but somewhat weaker claim, calling the RNTK a “relative right, in the sense that it may be restricted when disclosure to the individual is necessary in order to avoid serious harm to third parties, especially family members.”¹⁸⁵

4. *Outdated Examples*

Thus far, I have shown that the foundational RNTK literature substantially challenges the notion of a strong, autonomy-based right. Even if one finds the critiques presented above to be unconvincing, there is an additional, novel argument to be made against those asserting a strong RNTK. Specifically, the examples used by scholars to support a RNTK are extremely limited and, I would argue, have not kept pace with evolution of genomic technologies. A close reading of the literature demonstrates an almost exclusive reliance on three primary examples: Huntington’s disease (“HD”), Alzheimer’s disease (“AD”), and breast cancer (“BRCA”).¹⁸⁶

Starting with HD and AD, defenders of RNTK often point to concerns about testing for these two conditions, citing data on people’s reluctance to get tested.¹⁸⁷ Similarly, the illustrative cases are typically about one of

181. *Id.* (“If somebody objects to being informed and prevents relatives from being informed, this person is rejecting his/her duty to inform those who may really want this information and may also need it.”)

182. *See id.* (noting conflicts between individuals who may not want to know and relatives who would prefer to have that information).

183. *Id.* at 88 (“[T]he right not to know is not to be considered as an absolute ethical principle, especially when dealing with very sensitive genetic information.”)

184. *Id.* (“If somebody objects to being informed and prevents relatives from being informed, this person is rejecting his/her duty to inform those who may really want this information and may also need it.”)

185. Andorno, *supra* note 28, at 439.

186. *See e.g., id.*, at 435; Bredenoord, *supra* note 72, at 29.

187. *See, e.g.,* Tarja-Brita Robins Wahlin, *To Know or Not to Know: A Review of Behavioral and Suicidal Ideation in Pre-Clinical Huntington’s Disease*, 65 *PATIENT EDUC. & COUNSELING* 279, 281–82 (2007) (noting that several recent studies indicated that 3 to 21 percent of at-risk persons enter predictive testing programs; a vast majority feared the negative consequences of a potential positive result).

these three examples.¹⁸⁸ RNTK proponents cite these kinds of studies and cases to illustrate the potential anxiety that people feel when faced with negative genetic information, and to support the claim that there is a very real risk of harm associated with unwanted provision of one's genetic status.¹⁸⁹

But both examples come out of the targeted genetics era, and I would argue that they have limited utility as valid comparators in the modern genomic era. HD and AD are devastating and presently intractable neurological conditions.¹⁹⁰ As such they are *sui generis*, since they present the possibility of psychological harm without any corresponding clinical benefit.¹⁹¹

When these kinds of examples are utilized by scholars, they should only be used to make a claim about the RNTK genetic information associated with commensurate diseases. But this isn't the case; commentators consistently use these limited examples to make broader claims. For example, Andorno appropriately starts by arguing that "for many people, the discovery that they have a genetic condition that places them at a high risk of suffering certain **untreatable** diseases could so depress them that the quality, joy, and purpose of their lives would literally evaporate" (emphasis added).¹⁹² But this qualification that the RNTK only applies in this subset of conditions falls away thereafter and most other authors don't even follow Andorno's initial token wave at this important limitation.¹⁹³

The field of genomic medicine has moved beyond these two limited examples; the current iteration of the RNTK debate should really be about whether individuals have the right to refuse information regarding conditions where medical action can mitigate or prevent mortality or

188. See, e.g., Andorno, *supra* note 28, at 435 (citing examples of individuals with a genetic predisposition to Alzheimer's and breast cancer); Bredenoord et al., *supra* note 72, at 29 (providing research on breast cancer testing in at-risk patients).

189. See, e.g., Andorno, *supra* note 28, at 435 (presenting examples of situations where at-risk patients reject genetic testing for fear of negative consequences); Bredenoord et al., *supra* note 72, at 29 (noting that a high percentage of people refuse genetic testing to avoid psychological harm); Austad, *supra* note 105, at 86 (stating that the RNTK is motivated by the psychological pressures that individuals may face).

190. See Wahlin, *supra* note 187, at 279 ("HD is an autosomal dominant neurodegenerative disorder characterized by irreversible physical and mental deterioration, personality change, and increased susceptibility to mental disorder."); *What is Alzheimer's?*, ALZ.ORG, http://www.alz.org/alzheimers_disease_what_is_alzheimers.asp (last visited Nov. 23, 2015) (noting that AD is the sixth-leading cause of death in the United States and has no cure).

191. See Wahlin, *supra* note 187, at 280 (noting that because there is no cure or adequate treatment for HD, there may be no legitimate benefit in predictive testing; instead, the psychological risk associated may result in injury to the patient).

192. Andorno, *supra* note 28, at 435.

193. *Id.*

serious morbidity, and where there is strong evidence of the link between genotype and significant disease risk. Citing to evidence of concern about being tested for HD or AD is irrelevant to this important debate, since the real empirical and normative questions relate to whether people would or should refuse to learn about potentially life-saving genetic information.

BRCA is a somewhat harder case. BRCA testing does offer clinical benefit, but it was commonly used to illustrate why we needed a RNTK because of concerns about stigma and discrimination.¹⁹⁴ Although it would be an exaggeration to claim that these worries have completely dissipated, our society seems to be moving away from worries about psychosocial harms associated with BRCA. Rather, we seem to be moving towards the view that BRCA testing might offer positive public health benefits, so much so that Dr. Mary-Claire King has argued for population level screening.¹⁹⁵ Dr. King dismissed concerns about psychosocial harms of knowing one's BRCA status, arguing that "women do not benefit by practices that 'protect' them from information regarding their own health."¹⁹⁶

In this section, I have taken a close look at the philosophical origins of the RNTK. Contrary to what contemporary commentators have been arguing, the notion of a strong, autonomy-based RNTK rests on an unstable conceptual foundation. Only a handful of philosophers have endorsed such a position, with the majority either arguing for a much more limited, non-autonomy-based conception, or even against the whole concept entirely. In the next section, I address another commonly advanced (but poorly defended) argument in favor of a strong RNTK: that the legal right to refuse medical treatment includes a right to refuse medical information.

194. See Bredenoord, *supra* note 72, at 29 (referencing research that supports the notion that a large percentage of people refuse genetic testing for the BRCA gene for fear of discrimination).

195. Mary Claire King et al., *Population-Based Screening for BRCA1 and BRCA2*, 312 JAMA 1091 (2014), available at <http://jama.jamanetwork.com/article.aspx?articleid=1902783>.

196. *Id.* at 1092.

IV. IS THERE A CONSTITUTIONALLY PROTECTED RIGHT NOT TO KNOW?

When thinking about legal rights in the medical realm, courts must often confront a difficult conflict between autonomy and beneficence. The principle of autonomy demands that an individual gets to control one's own body according to one's own preferences and desires, free from imposition by other people or institutions.¹⁹⁷ The principle of beneficence, on the other hand, is only concerned with achieving what is best for a person, both by avoiding harm and by doing positive good.¹⁹⁸ These principles can come into tension when a person does not want something that others would reasonably perceive to be in an individual's best interest (or the interests of third parties).¹⁹⁹

Courts have struggled with this tension in end-of-life cases as medical technology has advanced, expanding the ways in which doctors can help people by creating new, but often invasive, methods for extending life.²⁰⁰ A number of commentators have drawn a direct link between the well-established legal right to refuse medical treatments and the RNTK genetic information about oneself.²⁰¹ Either directly or implicitly, these scholars seem to be asserting that a patient's constitutionally protected autonomous right to place limits on the medical interventions to which they are subjected also includes the ability to broadly limit the medical information to which they are exposed.²⁰² As one group of prominent bioethics scholars put it:

197. See TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 57–58 (5th ed. 2001).

198. *Id.* at 166.

199. See *id.* at 176 (noting that proponents of benevolence believe a “physician’s primary obligation is to act for the patient’s medical benefit, not to encourage autonomous decision-making.”).

200. See *id.* at 142–43 (noting that “legal liability should not be imposed on physicians and surrogates unless they have an obligation to provide or continue the treatment.”); see also *id.* at 176–86 (noting that the role of paternalism persists in the government sector when medical advances are involved). See generally *Bouvia v. Superior Court*, 179 Cal. App. 3d 1127 (Cal. Ct. App. 1986) (holding that a patient had the right to remove a nasogastric tube that had been inserted against her will).

201. See, e.g., Burke et al., *supra* note 72, at 856–57 (noting that patients decline gene analysis for a number of reasons, including limited evidence on test performance and outcomes); Lázaro-Muñoz et al., *supra* note 72, at 4 (stating that individuals have the right to control the medical test performed, rooted in a right to bodily autonomy); Wolf et al., *Patient Autonomy*, *supra* note 72, at 1049–50 (stating that patients have the right to refuse testing and findings, even if potentially lifesaving).

202. See Wolf et al., *Patient Autonomy*, *supra* note 72, at 1050 (explaining that medical information should not be imposed upon patients since they have the right to refuse medical testing and findings); see also Burke et al., *supra* note 72, at 856–57 (explaining that adult patients

Competent adult patients have an established right to refuse medical interventions recommended by their health-care providers. This right is present even when medical interventions are immediately life-saving Unless patients' decision-making capacity is impaired . . . their right to refuse is virtually unlimited. The ACMG recommendations propose, however, that any patient accepting WES/WGS [whole genome sequencing] for a clinical indication must also accept analysis of the 56 genes²⁰³

None of these authors have actually engaged in a rigorous legal analysis of this claim. I do so below, concluding that the right to refuse medical treatment cannot easily be expanded to include a right to refuse medical information.

A. *The Right to Refuse Medical Treatment*

The right to refuse medical treatment can primarily trace its roots to common-law informed consent jurisprudence²⁰⁴ and Fourteenth Amendment substantive due process liberty interests.²⁰⁵ Building on these areas of law, courts have found a constitutionally protected privacy interest in refusing medical treatment.²⁰⁶ This right has been firmly based on views

have an unlimited right to refuse doctor-recommended treatment and undergo further analysis of their health conditions).

203. See Burke et al., *supra* note 72, at 856–57; see also Lázaro-Muñoz et al., *supra* note 72, at 11 (“Informed consent implies that the individual must freely consent in advance to medical intervention; its negative logical corollary is that the individual is free to refuse. It is widely recognized that the doctrine of informed consent applies to medical examinations; thus, clinicians routinely obtain [them] before ordering genetic tests. The application of the informed consent doctrine to genetic testing implies that individuals have a legal right to refuse genetic tests.”) (citation omitted); see Wolf et al., *Patient Autonomy*, *supra* note 72, at 1049 (“Informed consent is a well-established legal requirement designed to protect patient autonomy—not a matter susceptible to modification by experts in human genetics, no matter how learned. Circumstances in which clinicians can test without consent are rare exceptions However, this does not apply when laboratories and clinicians perform clinical sequencing, because they are not responding to a medical emergency threatening imminent harm and preventing them from seeking consent.”).

204. See, e.g., *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1890) (“No right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestioning authority of the law.”); *Schloendorff v. Soc’y of New York Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) (“Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without the patient's consent commits an assault, for which he is liable in damages.”); *In re Brown*, 478 So. 2d 1033, 1040 (Miss. 1985) (“The informed consent rule rests upon the bedrock of this state’s respect for the individual’s right to be free of unwanted bodily intrusions no matter how well intentioned.”).

205. See *Griswold v. Connecticut*, 381 U.S. 479 (1965) (establishing the Constitutional right to privacy).

206. See *Brown*, 478 So.2d at 1040 (stating that Mississippi’s Chancery Court could not compel a woman to receive a blood transfusion after she refused one); see also *In re Quinlan*, 355

about the sanctity of bodily integrity.²⁰⁷ As I will argue, bodily integrity is clearly distinct from psychological integrity, therefore undermining the claim that the right to refuse medical treatment also includes the RNTK.

One of the earliest prominent end-of-life cases was that of Karen Quinlan.²⁰⁸ Ms. Quinlan was admitted to the hospital after she became unconscious and ceased breathing for an extended period.²⁰⁹ Though stable, she had experienced significant brain damage and was diagnosed as being in a persistent vegetative state.²¹⁰ As her condition deteriorated, she eventually required artificial respiration and nasogastric feeding to survive.²¹¹ With no prospect for improvement, her father petitioned the court to remove the ventilator.²¹² His petition was opposed by a number of parties, including Ms. Quinlan's doctors, the hospital, and the State of New Jersey.²¹³ After lower courts initially denied the family's request, the New Jersey Supreme Court eventually found in their favor.²¹⁴ They held that Ms. Quinlan had a constitutionally protected right to privacy that would have permitted her to refuse medical treatment if competent, and that allowed her family to act as her surrogate since she was not competent.²¹⁵

In finding an individual right to privacy, the court extensively relied on the notion of bodily integrity. They argued that the State's interest in preserving life "weakens and the individual's right to privacy grows as the degree of bodily invasion increases and the prognosis dims."²¹⁶ In many cases, the importance of an individual's right to bodily integrity can supersede the State's interest in preserving life.²¹⁷

The Quinlan case was widely followed,²¹⁸ but ultimately the Supreme Court directly addressed the right to die in the case of Nancy Cruzan.²¹⁹

A.2d 647, 663 (N.J. 1976) (explaining that the individual's right to privacy against bodily invasion can overcome the state's interest)

207. See S. Elizabeth Malloy, *Beyond Misguided Paternalism: Resuscitating the Right to Refuse Medical Treatment*, 33 WAKE FOREST L. REV. 1035, 1048–49 (1998) (stating that the right to make medical decisions is established in the right to one's own bodily integrity which is derived from informed consent).

208. *Quinlan*, 355 A.2d 647.

209. *Id.* at 653–54.

210. *Id.* at 654.

211. *Id.*

212. *Id.* at 651.

213. *Id.* at 650.

214. See *Quinlan*, 355 A.2d at 671 (holding that Quinlan's father has "full power to make decisions" regarding his daughter's medical treatment).

215. *Id.* at 665–66.

216. *Id.* at 664.

217. See *id.* (noting the strength of one's right to privacy over a State's own interests).

218. George J. Annas, "Culture of Life" Politics at the Bedside — The Case of Terri Schiavo, 352 NEW ENG. J. MED. 1710, 1711 (2005) (explaining that the Quinlan case encouraged states to

Cruzan was severely injured in a car accident.²²⁰ Although she was discovered without a heartbeat or respiration, paramedics were able to restore these functions, but she remained unconscious.²²¹ It was estimated that her brain had been without oxygen for twelve to fourteen minutes, well beyond the six-minute window when permanent brain damage is thought to occur.²²² Once it became clear that Cruzan would not recover, her parents asked the medical staff to terminate artificial nutrition and hydration.²²³ The hospital refused, prompting Cruzan's parents to seek authorization from the courts.²²⁴ After an initial ruling in favor of the parents at the trial court level, the Supreme Court of Missouri reversed. Ultimately, the Supreme Court of the United States granted certiorari.²²⁵

Much of Chief Justice Rehnquist's majority opinion focused on explaining why the United States Constitution does not bar states from setting evidentiary requirements about an incompetent person's desire to be withdrawn from life-sustaining treatments,²²⁶ which is beyond the scope of this article. What is relevant, however, was the justification for holding that competent individuals have a constitutionally protected liberty interest under the due process clause in refusing medical treatment.²²⁷ Like the Court in *Quinlan*, the Supreme Court relied extensively on the concept of bodily integrity. Chief Justice Rehnquist's reasoning built on informed consent jurisprudence, which was in turn based on common law ideas of battery (unwanted, offensive touching).²²⁸ He suggested that if bodily

provide legal immunity to hospitals that feared they would be sued for following advanced directives of patients that later became incompetent).

219. *Cruzan v. Dir. Mo. Dep't of Health*, 497 U.S. 261 (1990).

220. *Id.* at 266.

221. *Id.*

222. *Id.*

223. *Id.* at 267.

224. *Id.* at 268.

225. *Cruzan*, 497 U.S. at 268 (1990) (detailing the back and forth decisions by the Missouri court on the issue of informed consent).

226. *Id.* at 280 (explaining that the Constitution allows states to set evidentiary requirements and that whether a state's requirements align with the law depends on the interest the state is seeking to protect. Additionally, a state should not have to remain neutral when an informed person voluntarily chooses to take actions that cause her death—for example, willful starvation.).

227. *Id.* at 278.

228. *Id.* at 277 (“As these cases demonstrate, the common law doctrine of informed consent is viewed as generally encompassing the right of a competent individual to refuse medical treatment.”); *see also* *Jacobson v. Massachusetts*, 197 U.S. 11, 39 (1905) (acknowledging that the requirement of a vaccine for certain individuals could be cruel and inhumane and thus an overreaching of government power); *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251–52 (1891) (holding “[n]o right is held more sacred or is more carefully guarded by the common law than the right of every individual to the possession and control of his own person, free from restraint or interference of others unless by clear and unquestionable authority of law”); *Schloendorff v. Soc’y of N.Y. Hosp.*, 211 N.E. 92, 95 (N.Y. 1914) (holding “a surgeon who

integrity requires that one must give consent to receive medical treatment, it follows that patients also possess the right to refuse medical treatment.²²⁹

Justice O'Connor wrote a concurring opinion to further clarify why she believed that there is a constitutionally protected liberty interest in refusing unwanted medical treatment.²³⁰ Echoing the majority opinion, she stressed the connection to bodily integrity.²³¹ Even more than Chief Justice Rehnquist, however, she painted a picture of the physical imposition that life-sustaining treatment might entail:

Whether or not the techniques used to pass food and water into the patient's alimentary tract are termed "medical treatment," it is clear they all involve some degree of intrusion and restraint. Feeding a patient by means of a nasogastric tube requires a physician to pass a long flexible tube through the patient's nose, throat and esophagus and into the stomach. Because of the discomfort such a tube causes, "[m]any patients need to be restrained forcibly, and their hands put into large mittens to prevent them from removing the tube." . . . Requiring a competent adult to endure such procedures against her will burdens the patient's liberty, dignity, and freedom to determine the course of her own treatment. Accordingly, the liberty guaranteed by the Due Process Clause must protect, if it protects anything, an individual's deeply personal decision to reject medical treatment, including the artificial delivery of food and water.²³²

Although the three dissenting justices did not agree with the ultimate holding of the Court, they joined in strongly asserting that there is a

performs an operation without his patient's consent commits an assault for which he is liable in damages").

229. *Cruzan*, 497 U.S. at 270 ("The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment."). Although the three dissenting justices did not agree with the ultimate holding of the Court because they assert that the right to refuse medical treatment is fundamental, their reasoning also clearly relies on one's autonomous right to bodily integrity. *See id.* at 305 (Brennan, J., dissenting) ("The right to be free from medical attention without consent, to determine what shall be done with one's own body, is deeply rooted in this Nation's traditions . . .").

230. *See id.* at 287 (O'Connor, J., concurring).

231. *Id.* at 287 ("[T]he liberty interest in refusing medical treatment flows from decisions involving the State's invasions into the body. Because our notions of liberty are inextricably entwined with our idea of physical freedom and self-determination, the Court has often deemed state incursions into the body repugnant to the interests protected by the Due Process Clause.") (citation omitted).

232. *Id.* at 288–89.

fundamental right to refuse medical treatment, flowing from one's autonomous right to bodily integrity.²³³

These cases involved adults who lacked capacity to make decisions themselves, but similar language is found in cases where competent patients refused life-saving medical treatment. For example, in *Bouvia v. Superior Court*, the court affirmed the petitioner's right to remove a nasogastric tube that had been inserted over her objections for the purpose of providing life-sustaining nutrition.²³⁴ Ms. Bouvia was a college educated twenty-eight-year-old woman with severe cerebral palsy and quadriplegia.²³⁵ Because of her deteriorating condition and quality of life, she repeatedly expressed a desire to die, and intended to refuse food to accomplish that aim.²³⁶ Concerned about her weight loss, the medical staff began forced feedings, prompting Ms. Bouvia to petition the court to intervene.²³⁷ The court found that she did have a right to refuse medical treatment, using language clearly focused on her right to bodily integrity like that seen in *Quinlan* and *Cruzan*.²³⁸

Taken together, these and related cases clearly demonstrate that the right to refuse medical treatment is specifically rooted in the idea of an individual's autonomous right to *bodily integrity*.²³⁹ This makes sense given the strong history and legal tradition of protecting people against physical invasion.²⁴⁰ In contrast, RNTK cases would raise questions about the distinct concept of *psychological integrity*.²⁴¹ As I will illustrate in the next section, there are a number of domains where courts have been willing to forcibly impose sensitive medical information on individuals, suggesting that courts would have difficulty finding a comparable history and tradition of protecting psychological integrity.

233. See *id.* at 305 (Brennan, J., dissenting) (“The right to be free from medical attention without consent, to determine what shall be done with one's own body, is deeply rooted in this Nation's traditions . . .”).

234. *Bouvia v. Superior Court*, 179 Cal. App. 3d 1127, 1146 (Cal. Ct. App. 1986).

235. *Id.* at 1135–36.

236. *Id.* at 1136.

237. *Id.* at 1136–37.

238. *Id.* at 1137 (“A person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment.”).

239. For an extensive list of similar cases, see RONALD B. STANDLER, LEGAL RIGHT TO REFUSE MEDICAL TREATMENT IN THE USA at 33–39 (2012), <http://www.rbs2.com/trmt.pdf>.

240. Cass R. Sunstein, *The Right to Die*, 106 YALE L.J. 1123, 1125 (1997).

241. See Laurie, *supra* note 130, at 58 (explaining psychological integrity as the non-connectedness with others, including “being in a state of ignorance about one's own health”).

B. Judicial Imposition of Medical Information

There are a number of prominent areas of law that can be used to demonstrate the fact that the American judiciary has historically been quite willing to impose sensitive health information on individuals who might reasonably prefer not to know that information. While these cases are not directly about the RNTK, taken together this jurisprudence strongly suggests that courts would not be sympathetic to an argument that there is a clear history and legal tradition of honoring the RNTK in the United States.

1. Mandatory Disclosure of Information to Women Seeking an Abortion

Over the past two decades, opponents of abortion rights have advocated for a series of state laws requiring women seeking abortions to be given various kinds of medical information.²⁴² Many of these disclosure laws are generic, in the sense that they require physicians to relay standard information relating to pregnancy, and the purported risks (physical and psychological) of seeking an abortion.²⁴³ However, there have also been a series of laws requiring women to be given specific information about their fetus, including gestational age, and the (scientifically contested) fact that an early fetus can feel pain.²⁴⁴ These mandatory disclosure laws are generally seen as creating a barrier to abortion; in a sense, the state is imposing potentially unwanted sensitive medical information on a woman for the purpose of dissuading her from continuing with the abortion.²⁴⁵ Without delving too far into the contentious realm of abortion politics, I will show that partial judicial acceptance of these laws suggests that there are at least some cases where state interest in preserving life has been used to justify the forced imposition of unwanted medical information by the state.

This trend began with *Planned Parenthood v. Casey*.²⁴⁶ The law at issue in *Casey* required, among other provisions, that doctors provide women with certain information beyond that which would have been required under standard informed consent jurisprudence.²⁴⁷ The Court in

242. GUTTMACHER INST., STATE POLICIES IN BRIEF: COUNSELING AND WAITING PERIODS FOR ABORTION, http://www.guttmacher.org/statecenter/spibs/spib_MWPA.pdf (last updated Nov. 1, 2015).

243. *See id.* (describing various states laws requiring women to hear general information about their pregnancy including risks of an abortion or counseling for receiving an abortion); Erin Bernstein, *The Upside of Abortion Disclosure Laws*, 24 STANFORD L. & POL'Y REV. 171, 174 (2013).

244. GUTTMACHER INST., *supra* note 242.

245. Bernstein, *supra* note 243, at 174.

246. *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992).

247. *Id.* at 844.

Casey concluded that provisions entailing truthful, non-misleading information relevant to the decision of whether or not to go through with the abortion did not impose an undue burden on the woman seeking an abortion.²⁴⁸ They argued that although all pre-viability regulations burden a woman's ability to obtain an abortion to some degree, an abortion law is not rendered unconstitutional just because it may make getting an abortion more difficult or more expensive, as long as the burden isn't too substantial.²⁴⁹ Subsequent laws have expanded disclosure requirements, requiring doctors to provide scientifically questionable information, not to enhance informed consent, but to advance the state's interest in preserving life or mitigating abortion's negative effects.²⁵⁰

In the past two decades, these abortion laws have begun to evolve and expand, recently adding provisions that require women to receive and view ultrasound images²⁵¹ and hear the fetal heartbeat,²⁵² even if they would prefer otherwise. Since they have been the most controversial, I will focus on mandatory ultrasound laws. As of 2015, three states mandate that women seeking an abortion view an ultrasound image of the fetus.²⁵³ Another ten states require the provider to perform the procedure and offer an opportunity for the women to see the image.²⁵⁴ An additional fourteen states require that women be given an opportunity to see an ultrasound image under certain circumstances.²⁵⁵

These laws have been challenged, and the judicial response has been split. In *Stuart v. Camnitz*, the Fourth Circuit struck down a law requiring narration of ultrasounds.²⁵⁶ The law at issue was North Carolina's

248. *Id.* at 882 ("If the information the State requires to be made available to the woman is truthful and not misleading, the requirement may be permissible.").

249. *Id.* at 874 ("Numerous forms of state regulation might have the incidental effect of increasing the cost or decreasing the availability of medical care, whether for abortion or any other medical procedure. The fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it. Only where state regulation imposes an undue burden on a woman's ability to make this decision does the power of the State reach into the heart of the liberty protected by the Due Process Clause.").

250. Bernstein, *supra* note 243, at 173.

251. GUTTMACHER INST., STATE POLICIES IN BRIEF: REQUIREMENTS FOR ULTRASOUND, http://www.guttmacher.org/statecenter/spibs/spib_RFU.pdf (last updated Oct. 1, 2015) (noting that twenty-five states currently have such provisions).

252. *See, e.g.*, *Planned Parenthood Minn. v. Rounds*, 653 F.3d 662, 665 (8th Cir. 2011) (considering a South Dakota law on informed consent); *Karlin v. Foust*, 188 F.3d 446, 497 (7th Cir. 1999) (concluding that the physician should advise women how to obtain the services of ultrasound imaging and auscultation of the fetal heartbeat if she chooses to do so).

253. GUTTMACHER INST., *supra* note 251 (Louisiana, Texas, and Wisconsin).

254. *Id.* (Alabama, Arizona, Florida, Indiana, Kansas, Mississippi, North Carolina, Ohio, Oklahoma, and Virginia).

255. *Id.*

256. 774 F.3d 238, 242 (4th Cir. 2014).

Woman's Right to Know Act,²⁵⁷ which set forth a real-time viewing mandate requiring physicians to perform an ultrasound, display the image, and describe the fetus to a woman seeking an abortion.²⁵⁸ The law stipulated that the description must continue, even if the woman turns away or otherwise attempts to avoid hearing what the doctor is saying.²⁵⁹ Providers brought suit, arguing that this violated their free speech rights.²⁶⁰ The court struck down the law under the First Amendment, holding that it was impermissible compelled speech because it "is ideological in intent and in kind."²⁶¹

In contrast, the Fifth Circuit has ruled that a similar law does not violate providers' First Amendment rights.²⁶² Like *Stuart*, the law in this case compelled doctors to take and display sonogram images of the fetus, play the sound of the fetal heartbeat, and explain the results of both exams to the woman seeking an abortion.²⁶³ Furthermore, the woman had to certify that the physician complied with the law's requirements, forcing her to acknowledge the unwanted information that had been conveyed.²⁶⁴ Equating these requirements with those upheld in earlier cases, the court argued that "required disclosures of a sonogram, the fetal heartbeat, and their medical descriptions are the epitome of truthful, non-misleading information."²⁶⁵

Without engaging with the fundamental appropriateness of these laws, we can take three tentative lessons from the forced ultrasound controversy. First, though controversial, there appears to be significant political support for forcing or strongly encouraging women to view ultrasound images. The fact that a significant number of states have been willing to pass these laws undermines any claim that there is unwavering support for a broad RNTK unwanted medical information. Second, the circuit split suggests that some courts are willing to entertain the idea that the state's interest in preserving life overrides an individual's right to make decisions about the kind of medical information that is revealed to them. Notably, the Supreme Court

257. North Carolina Women's Right to Know Act, N.C. Gen. Stat. §§ 90-21.80 to -21.92 (2011).

258. *Stuart v. Camnitz*, 774 F.3d 238, 242 (4th Cir. 2014).

259. *Id.*

260. *Id.* at 243.

261. *Id.* at 242. *See also* *Pruitt v. Nova Health Sys.*, 134 S. Ct. 617 (2013) (striking down a mandatory ultrasound law pursuant to *Casey*).

262. *Tex Med Providers Performing Abortion Services v. Lakey*, 667 F.3d 570, 580 (5th Cir. 2012).

263. *See id.* at 573; *see also* TEX. HEALTH & SAFETY CODE ANN. § 171.012(a)(4) (West 2014).

264. *Tex Med Providers Performing Abortion Services v. Lakey*, 667 F.3d 570, 573 (5th Cir. 2012).

265. *Id.* at 577-78.

has refused to resolve the existing circuit split.²⁶⁶ Finally, it should be stressed that the courts that overturned the mandatory ultrasound laws did so on the basis of First Amendment jurisprudence rather than an individual RNTK.²⁶⁷ If protecting an individual's RNTK was clearly included in the well-established right to refuse treatment, it stands to reason the courts would have at least partially relied on that as a component of their reasoning.

2. *Court-Ordered Genetic Testing in Toxic Tort Cases*

Toxic torts are civil actions arising from alleged harm suffered by a plaintiff who was exposed to a “chemical substance, emission, or product.”²⁶⁸ In order to recover, the plaintiff must demonstrate that he or she was exposed to the relevant chemical, and that the exposure resulted in demonstrable, significant, and lasting physical or psychological harm.²⁶⁹ A paradigmatic case might involve an individual with a cancer diagnosis (e.g., lung cancer) who claims to have been exposed to a carcinogenic chemical (e.g., asbestos) in an industrial setting.²⁷⁰

Since many medical conditions can be mediated by genetic susceptibility to illness, parties to toxic torts cases, particularly defendants, have reason to seek relevant genetic testing of the plaintiff, particularly as genetic tests have become more sophisticated.²⁷¹ Under the Federal Rules of Civil Procedure, courts have the power to “order a party whose mental or physical condition—including blood group—is in controversy to submit to a physical or mental examination by a suitably licensed or certified examiner.”²⁷²

Legal scholars have recognized, however, that court-mandated genetic testing can be intrusive and can lead to individual harm.²⁷³ For example, Anthony Niedwiecki has criticized Rule 35, arguing:

266. Adam Liptak, *Supreme Court Refuses to Hear Cases on Pre-Abortion Ultrasounds*, N.Y. TIMES, June 15, 2015.

267. See David Orentlicher, *Abortion and Compelled Physician Speech*, 43 J.L. MED. & ETHICS 9, 9 (2015) (explaining that states impose mandates on abortion providers based on the First Amendment and the doctrine of informed consent).

268. KAREN A. GOTTLIEB, TOXIC TORTS PRACTICE GUIDE 5 (Spring ed. 2015).

269. *Id.*

270. *Id.*

271. Randi B. Weiss et al., *The Use of Genetic Testing in the Courtroom*, 34 WAKE FOREST L. REV. 889, 889 (1999) (“as testing methodologies become more sophisticated, the use of genetic test results is likely to expand, particularly in toxic tort litigation, to provide evidence of causation.”).

272. FED. R. CIV. P. 35(1).

273. See Mark A. Rothstein, *Preventing the Discovery of Plaintiff Genetic Profiles by Defendants Seeking to Limit Damages in Personal Injury Litigation*, 71 IND. L.J. 877, 888–89 (1996) (arguing that genetic testing should never be compelled because of concerns about non-

These risks become even more prevalent when the genetic information reveals a disease or disorder that is incurable or untreatable. Without an analysis of the informational risks, courts fail to fully understand the depth of intrusiveness caused by the Rule 35 examination. Analyzing the informational risks associated with the test requires a close examination of the potential impact that the information garnered from the test could have on the individual being tested. The impact may be psychological trauma to the individual tested, as well as a violation of privacy through disclosure of the results to sources outside of the litigation.²⁷⁴

Nevertheless, Rule 35 has been widely interpreted as allowing a compelled test if there is “good cause” to seek the medical information, and if the information is relevant to the individual’s health status that is “in controversy” due to litigation.²⁷⁵ As a result, examples of compelled genetic testing abound.²⁷⁶

Furthermore, Hoffmann and Rothenberg conducted a survey of judges, asking whether they would compel genetic testing in a variety of scenarios.²⁷⁷ Judges were sensitive to the psychosocial concerns associated with forced genetic testing, particularly “the psychological impact of receiving unwanted information about a lethal and incurable genetic condition.”²⁷⁸ Nevertheless, approximately 80% of the judges surveyed indicated that they would still compel genetic testing to determine whether a genetic condition either made the plaintiff especially sensitive to pain or was the most likely cause of the plaintiff’s injury. Further, over 70% said they would order such testing to determine whether the plaintiff had a genetic condition necessary for a given toxic exposure to produce disease.²⁷⁹

maleficence and autonomy); Gary E. Marchant, *Genetic Data in Toxic Tort Litigation*, 14 J.L. & POL’Y 7, 35–36 (2006) (raising concerns about the privacy and discrimination risks to plaintiffs whose genetic information is placed into evidence); Jennifer M. Champagne, *Genetic Testing and Testimony in Toxic Tort Litigation: “Admissibility and Evaluation”*, 13 N. C. J.L. & TECH 1, 24 (2011) (“[g]iven the highly personal and sensitive nature of genetic data, there is a strong need to take precautions to prevent others from gaining access to such information.”).

274. Anthony S. Niedwiecki, *Science Fact or Science Fiction? The Implications of Court-Ordered Genetic Testing Under Rule 35*, 34 U.S.F. L. REV. 295, 339 (2000).

275. *Id.* at 301–02.

276. *See id.* at 299–300 (stating that Rule 35 and similar state rules have provided courts with wide authority to order genetic testing).

277. Diane E. Hoffmann & Karen H. Rothenberg, *Judging Genes: Implications of the Second Generation of Genetic Tests in the Courtroom*, 66 MD. L. REV. 858, 873–74 (2007).

278. *Id.* at 908.

279. *See id.* at 880–84 (observing that judges appreciated the objectiveness of genetic testing in these scenarios where the results can either rule out alternate causes or validate the plaintiff’s allegations to help make the decision process easier and more accurate). *See also* Diane E. Hoffmann & Karen H. Rothenberg, *When Should Judges Admit or Compel Genetic Tests?*, 310

3. *Duty to Warn Cases*

There have been a number of significant cases about medical professionals' duty to warn others about information revealed in the course of treating a patient.²⁸⁰ These cases are instructive because they bring into focus the tension between a patient's rights (e.g., privacy, confidentiality, autonomy) and third-party interests. What becomes apparent through an examination of this jurisprudence is the fact that courts appear quite willing to override the former when sufficient justification exists, often for reasons that sound very much like those that would be used to override a RNTK (e.g., preventing harm to third parties, preservation of life).²⁸¹

Since clinical genetic testing is relatively new, there haven't been many cases directly addressing the obligations of physicians vis-à-vis disclosure of hereditary health risk information to relatives.²⁸² The two most prominent cases, however, seem to suggest that courts believe that physicians have a duty to consider the interests beyond those of their specific patient.²⁸³ In *Pate v. Threlkel*, the plaintiff was diagnosed with a late stage form of medullary thyroid carcinoma, a hereditary disease that her mother had been treated for three years earlier.²⁸⁴ Pate sued her mother's physicians arguing that they had possessed a duty to educate their patient about the genetic nature of her disease, so that she could have an opportunity to pass that information on to her children.²⁸⁵ The court found

SCIENCE 241, 241–42 (2005) (confirming the results of judges' preferences to compel a test "to establish that the defendant's negligence was not the cause of the plaintiff's injury" because confirming a diagnosis is more objective than predicting one).

280. See, e.g., *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334, 347–48 (Cal. 1976); *Safer v. Estate of Pack*, 677 A.2d 1188, 1192 (N.J. Super. Ct. App Div. 1996).

281. See, e.g., *Tarasoff*, 551 P.2d at 345–48 (holding that a psychologist has an obligation of confidentiality to his or her patients, but under reasonable circumstances where a third party is most likely to become a potential victim of the patient, the psychologist has a duty to warn the third party); *Safer*, 677 A.2d at 1192 (holding that a physician owes a duty to warn patient's family member(s) of genetic disorders that can be avoidable or treated properly if addressed early-on).

282. Hoffmann & Rothenberg, *supra* note 277, at 865–66, n.16 (recognizing that newer genetic testing that goes beyond simple DNA fingerprinting has been slow to become a viable resource in litigation).

283. See, e.g., *Pate v. Threlkel*, 661 So.2d 278, 282 (Fla. 1995) ("[W]hen the prevailing standard of care creates a duty that is obviously for the benefit of certain identified third parties and the physician knows of the existence of those third parties, then the physician's duty runs to those third parties."); *Safer v. Estate of Pack*, 677 A.2d 1188, 1192 (N.J. Super. Ct. App Div. 1996) (recognizing that duty is owed not only to the patient himself but that it also "extend[s] beyond the interests of a patient to members of the immediate family of the patient who may be adversely affected by a breach of that duty") (quoting *Schroeder v. Perkel*, 432 A.2d 834, 839 (N.J. 1981)).

284. *Pate*, 661 So.2d at 279.

285. *Id.*

that there was a duty to warn about the genetic component of a disease, but that simply informing the patient could discharge this duty.²⁸⁶

A year later, in *Safer v. Estate of Pack*, a New Jersey appellate court went further, ruling that physicians have an even broader duty to warn third-party relatives about genetic information.²⁸⁷ This case had similar facts to *Pate*, in that a parent was diagnosed with a hereditary disease (colorectal cancer), which his daughter (the plaintiff) also subsequently acquired.²⁸⁸ The patient's daughter argued that her father's physician had a duty to warn at-risk relatives so that they could seek out early monitoring and/or treatment to mitigate the course of the disease.²⁸⁹ Pushing well past the holding in *Pate*, this court found that simply disclosing the information to the patient might not discharge the physician's duty to warn.²⁹⁰ Arguing that genetic risk is analogous to an infectious public health threat,²⁹¹ the court required that "reasonable steps be taken to assure that the information reaches those likely to be affected or is made available for their benefit."²⁹² Recognizing that this expanded duty entails making trade-offs, the court acknowledged that sometimes the wishes of the patient might have to be overridden for the benefit of their relatives.²⁹³ Speculating about a case where there was evidence that a patient explicitly requested not to disclose genetic risk to relatives, the court made it clear that they were willing to consider asking "whether, as a matter of law, there are or ought to be any limits on physician-patient confidentiality."²⁹⁴

Without a strong line of comparable cases, it is hard to know exactly how far courts will be willing to push this issue. *Safer* was subsequently overturned by the New Jersey legislature, and has not been widely followed. Subsequent academic commentary was generally negative

286. *Id.* at 280–82 (holding that a physician has an indirect duty to significant third parties who are within the "zone of foreseeable risk" of harm or danger, thus the physician only needs to inform his or her patient of this harm or danger in hopes that the patient will relay the information to the pertinent third parties).

287. *Safer*, 677 A.2d at 1192.

288. *Id.* at 1189–90 (identifying multiple polyposis as a hereditary disease that can develop into colorectal cancer if left untreated); *see also Pate*, 661 So.2d at 279 (Fla. 1995) (identifying medullary thyroid carcinoma as the genetic disease that was transferred to the patient's daughter).

289. *Safer*, 677 A.2d at 1190.

290. *Id.* at 1192 ("We decline to hold as the Florida Supreme Court did in *Pate v. Thelkel*, that, in all circumstances, the duty to warn will be satisfied by informing the patient.").

291. *Id.* ("In terms of foreseeability especially, there is no essential difference between the type of genetic threat at issue here and the menace of infection, contagion or a threat of physical harm.").

292. *Id.*

293. *See id.* at 1192–93 ("It may be necessary, at some stage, to resolve a conflict between the physician's broader duty to warn and his fidelity to an expressed preference of the patient that nothing be said to family members about the details of the disease.").

294. *Id.* at 1193.

(presaging many of the arguments that would be made more than a decade later in the RNTK debate),²⁹⁵ though a major genetic professional society issued guidance that physicians should be permitted to breach a patient's confidentiality under limited circumstances.²⁹⁶ At the very least, it is reasonable to say that these cases suggest that courts might be willing to consider placing limits on patient control over their own genetic information. To say something more definitive, we have to look to a better-developed area of law with very clear parallels to genetic testing: forced HIV testing and/or disclosure of HIV-status.

The forced HIV testing jurisprudence provides strong evidence that courts are readily willing to override individual preferences about receiving or disclosing sensitive medical information.²⁹⁷ The validity of compelled testing and disclosure has been regularly disputed, but these challenges

295. See, e.g., Kenneth Offit et al., *The "Duty to Warn" a Patient's Family Members About Hereditary Disease Risks*, 292 JAMA 1469, 1472 (2004) (arguing that "physicians are in no position to undertake the primary responsibility for identifying and communicating with an untold number of their patients' relatives who might be at some unspecified risk from genetic predispositions" because it would create impractical burdens that "discourage physician involvement in the merging subspecialty of genetic medicine"); Faith Lagay, *A Physician's Role in Informing Family Members of Genetic Risk*, 7 AMA J. ETHICS, June 1, 2005 (concluding that the AMA guideline for medical ethics "does not—explicitly or implicitly—encourage physicians to breach patient confidentiality."); Lisa S. Lehmann et al., *Disclosure of Familial Genetic Information: Perceptions of the Duty to Inform*, 109 AM. J. MED. 705, 709 (2000) (finding that the majority of women surveyed "did not believe that physicians should breach the confidentiality of genetic information"); Gary N. McAbee et al., Commentary, *Physician's Duty to Warn Third Parties About the Risk of Genetic Diseases*, 102 PEDIATRICS 140, 141–42 (1998) (arguing that these cases have necessitated overriding legislation "to establish more appropriate guidelines").

296. See AM. SOC'Y HUMAN GENETICS SOCIAL ISSUES SUBCOMM. ON FAMILIAL DISCLOSURE, PROFESSIONAL DISCLOSURE OF FAMILIAL GENETIC INFORMATION, 62 AM. J. HUM. GENETICS 474, 474 (1998) (stating that disclosure should be allowed when "attempts to encourage disclosure on the part of the patient have failed; where the harm is highly likely to occur and is serious and foreseeable; where the at-risk relative(s) is identifiable; and where either the disease is preventable/treatable or medically accepted standards indicate that early monitoring will reduce the genetic risk," and when "[t]he harm that may result from failure to disclose should outweigh the harm that may result from disclosure."). But see AMA Code of Med. Ethics, Op. 2.131 (2003) (stressing the physician's duty of confidentiality and limiting the physician's role to facilitating the disclosure by the patient); Sara Taub et al., *Managing Familial Risk in Genetic Testing*, 8 GENETICS TESTING 356, 358 (2004) (citing two different guidelines for familial disclosure—The American Society of Human Genetics (ASHG) and The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research—to demonstrate that breach of confidentiality would only be justified in rare situations); AM. SOC'Y OF CLINICAL ONCOLOGY, *American Society of Clinical Oncology, Policy Statement Update: Genetic Testing for Cancer Susceptibility*, 21 J. CLINICAL ONCOLOGY 2397, 2397 (2003) (counseling providers to "remind patients of the importance of communicating test results to family members . . .").

297. Robin C. Miller, Annotation, *Validity, and Propriety Under Circumstances, of Court-Ordered HIV Testing*, 87 A.L.R. 5th 631, § 1(2)(a) (2001) (demonstrating that some courts have used their inherent authority to mandate HIV testing regardless of the preferences of the parties).

have nearly always been dismissed.²⁹⁸ It should be noted that the courts have not imposed HIV testing blindly, recognizing that, like genetic information, there can be very real psychosocial risks associated with unwanted disclosure of an individual's HIV status.²⁹⁹ Despite readily recognizing these concerns, courts have still compelled testing, arguing that concerns about the RNTK are outweighed by a range of legitimate justifications.³⁰⁰ While these cases have predominantly been brought in the criminal context,³⁰¹ there are also a number of civil decisions that demonstrate courts' willingness to consider interests beyond those of patient autonomy.³⁰²

In addition to case law, there are a number of federal and state HIV non-disclosure laws that also provide evidence of our political willingness to override an individual's ability to control their own sensitive health information.³⁰³ These laws generally prohibit disclosure of someone's HIV

298. *Id.* (noting that several courts have reasoned and held that mandated HIV testing does not violate an individual's right to equal protection, prohibition of *ex post facto* laws, freedom of religion, due process, or privacy).

299. *See, e.g.,* Agosto v. Trusswal Systems Corp., 142 F.R.D. 118, 120 (E.D. Pa. 1992) ("The Court is aware of the delicate nature of HIV and AIDS-related information. Given the nature of the disease and the public's attitudes towards those who contract AIDS or test positive for the HIV virus, Plaintiff's desire to protect the confidentiality of this information is understandable."); *Virgin Islands v. Roberts*, 756 F. Supp. 898, 901–02 (V.I. 1991) (recognizing that although blood testing is innocuous and commonplace for routine health screening, revealing whether an individual has HIV has more "devastating consequences" due to "prejudice and apprehension that its diagnosis typically signifies a social death as concrete as the physical one which follows"); *State v. Superior Court*, 930 P.2d 488, 493 (Ariz. Ct. App. 1996) (acknowledging that when testing an adolescent for HIV, "a positive test result would likely be psychologically traumatic, given the absence of a present cure for AIDS").

300. Miller, *supra* note 297, at II(B)(1)6 §11(a) (noting that courts use a balancing test, weighing the interests of opposing parties, to justify testing in a range of situations). *See, e.g.,* Agosto, 142 F.R.D. at 120 (holding that although plaintiff has privacy rights to protect his HIV status, if plaintiff is to continue with a suit in order to recover for pain and suffering from his employer, it would be necessary to disclose his health status, including his HIV diagnosis); *Virgin Islands*, 756 F. Supp. at 904 (stating that "the Government has a substantial interest in curbing the transmission of HIV" because "[t]he outcome of a potential source's test affects the degree to which a person should undertake precautionary measures to ensure the virus is not spread to others," which in effect outweighs the defendant's right to privacy); *State*, 930 P.2d at 493 (concluding that "the State's interest in assisting victims [of sexual crimes] significantly outweighs the privacy interest of the juvenile" in resisting HIV testing).

301. *See* Miller, *supra* note 297, at I §2(a), II(A)(1) §3, §6 (demonstrating that courts have been willing to impose HIV testing in a range of criminal contexts, including sexual assault, prostitution, and intravenous drug use).

302. *Id.* at III.B (demonstrating that courts have been willing to impose HIV testing in a range of civil cases, even in the face of a number of challenges, such as Fourth Amendment unreasonable search and seizure, Equal Protection, *ex post facto* laws, freedom of religion, substantive Due Process, and the right to privacy).

303. *See State Statutes or Regulations Expressly Governing Disclosure of Fact That Person Has Tested Positive for Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS)*, A.L.R. 5th 149, 159–60, 169–70.

status, but typically contain a set of exceptions. Most commonly, HIV-status can be revealed when there is a “compelling need” or “good cause.”³⁰⁴ While these terms have been subject to judicial interpretation, courts have interpreted them broadly, allowing disclosure in a wide range of contexts.³⁰⁵ Similarly, the Health Insurance Portability and Accountability Act (“HIPAA”) Privacy Rule contains a public interest exception, which allows medical professionals to disclose “individually identifiable health information” when there is a “serious and imminent threat to the health or safety of a person or the public.”³⁰⁶

The cases establishing a right to refuse medical treatment are explicitly rooted in our history and tradition of protecting bodily integrity, never mentioning the distinct concept of psychological integrity. In a RNTK case of first impression, the question is whether courts would readily expand established protection of bodily integrity to incorporate protection of an individual’s psychological integrity. This seems unlikely. Given the controversial debate about the scope and propriety of substantive due process jurisprudence,³⁰⁷ courts seem to have become reluctant to haphazardly expand constitutionally protected liberty interests.³⁰⁸ The current judicial approach appears to involve carefully “identifying a narrow category of liberty interests that are deemed sufficiently ‘fundamental’ to warrant heightened scrutiny”³⁰⁹

There appears to be enough judicial acceptance of infringement on psychological integrity that one can reasonably predict that courts would find purchase in the distinction between physical and psychological integrity. It is unlikely that courts would be willing to independently establish psychological integrity as a right requiring constitutional protection, given the lack of a clear history and legal tradition of such protections, and the fact that it would be monumentally difficult to establish the contours of protection for a concept as amorphous and potentially

304. *Id.* at 159–60.

305. *Id.* (demonstrating that courts have upheld exceptions for mandatory disclosure of HIV-status in a range of contexts, including for surgeons, defendant in prostitution cases, and where there is a “clear and imminent danger to individual’s health”).

306. 45 C.F.R. § 164.512 (2014).

307. Ryan C. Williams, *The One and Only Substantive Due Process Clause*, 120 YALE L.J. 408, 411 (2010) (“Critics of substantive due process have condemned the doctrine as, among other things, a “contradiction in terms,” an “oxymoron,” a “momentous sham,” a “made-up, atextual invention,” and the “most anticonstitutional branch of constitutional law.” Substantive due process “has been criticized both as textually implausible and as contrary to basic principles of democratic self-government.”).

308. *See id.* at 510–11 (noting the controversy and opposition in some circles to modern substantive due process decisions such as *Lawrence v. Texas* and *Roe v. Wade*).

309. *Id.* at 427.

expansive as psychological integrity. Having critically argued against the philosophical and legal arguments for a strong RNTK, in the next section I marshal social science and psychology data to demonstrate that the RNTK is a malleable concept, and to make a series of positive arguments against the status quo position of honoring a strong RNTK.

V. MOVING AWAY FROM A STRONG RNTK

In Part II, I described the various arguments that recent commentators and scholars have made in favor of honoring a strong RNTK. While these voices represented a clear majority position, I believe that there are a number of compelling arguments in defense of a more skeptical view about the RNTK. In this Part, I begin by presenting data suggesting that the strength of people's views about the RNTK is much softer than one might believe, leading us to reconsider the propriety of instinct to frame the RNTK as such a strong right. I then reframe the debate away from an autonomy-dominated perspective, providing a *comprehensive* analysis of the harms and benefits that result from adhering to a strong RNTK position. From this analysis, I conclude that the potential health benefits of abandoning a strong RNTK greatly outweigh the concomitant harms, thereby challenging the idea that psychosocial concerns should automatically get to trump the prospect of life-saving intervention. Finally, I end by exploring two additional considerations that are relevant to any rigorous discussion of the RNTK: moral distress and genetic exceptionalism.

A. *The Identified Life Effect*

There seems to be overwhelming support for the RNTK in the genetics community.³¹⁰ In a survey of genetics professionals, when asked how they would respond to a patient that declined to receive results from the ACMG list, only 19% said that they would return findings regardless of the patient's preferences.³¹¹ Qualitative data similarly supports the claim that the RNTK is held to be of paramount important.³¹²

310. See generally Yu et al., *supra* note 92, at 79 (stating that “[t]he vast majority of genetics professionals agreed that the preferences of a patient or family should guide which incidental results are offered for return”).

311. *Id.*

312. See Grove et al., *supra* note 93, at 6–7; ACMG, *supra* note 94, at 664–65

These studies are informative, but potentially misleading because of a psychological bias known as the identified life (or victim) effect.³¹³ This phenomenon is related to people's greater willingness to help specific, identified people, relative to abstract or theoretical ideas of people in need.³¹⁴ Functionally, the idea is that people aren't very good at understanding tradeoffs in the abstract, but are much better at weighing costs and benefits in a specific, concrete scenario.³¹⁵ Schelling, in his seminal work on the economics of preventing human death, highlighted the distinction between individual and aggregate lives, arguing that people do not feel an emotional tie to a "statistical life" and are therefore less motivated to provide help to unidentified victims.³¹⁶ For example, stories about specific victims elicit significantly higher levels of charitable donations compared to anonymous victims.³¹⁷ There is often a substantial spike in emergency aid donations in the months after a major disaster, even though there is perpetual chronic need for such assistance.³¹⁸ In the medical realm, there is evidence that physicians make different decisions when evaluating an individual patient than when considering an anonymous group of comparable patients.³¹⁹ It appears that physicians give more weight to patients' individual concerns when considering them on their own and more weight to general criteria of effectiveness when considering them as a group.³²⁰

It shouldn't be surprising then, that while there is certainly strong support for the RNTK in the abstract, there is reason to believe that support is softer than it appears. Asking about the RNTK in the abstract unduly

313. Tehila Kogut & Ilana Ritov, *The "Identified Victim" Effect: An Identified Group, or Just a Single Individual?*, 18 J. BEHAV. DECISION MAKING 157, 158 (2005).

314. *See id.* at 164–65.

315. Karen E. Jenni & George Loewenstein, *Explaining the Identifiable Victim Effect*, 14 J. RISK UNCERTAINTY 235, 236 (1997); Deborah A. Small & George Loewenstein, *Helping a Victim or Helping the Victim: Altruism and Identifiability*, 26 J. RISK UNCERTAINTY 5, 11 (2003) (arguing that identifiable victims seem to produce a greater empathic response, accompanied by greater willingness to make personal sacrifices to provide aid); George Loewenstein et al., *Statistical, Identifiable, and Iconic Victims*, in BEHAVIORAL PUBLIC FINANCE at 34–35, 44 (Edward J. McCaffery & Joel Slemrod eds., 2006) (showing that people respond more strongly to identifiable rather than statistical victims even when identification provides absolutely no information about the victims).

316. Thomas C. Schelling, *The Life You Save May Be Your Own*, in PROBLEMS IN PUBLIC EXPENDITURE ANALYSIS 127, 129–30 (Samuel B. Chase ed., 1968).

317. Kogut & Ritov, *supra* note 313, at 161–62.

318. Deborah A. Small et al., *Sympathy and Callousness: The Impact of Deliberative Thought on Donations to Identifiable and Statistical Victims*, 102 ORGANIZATIONAL BEHAV. AND HUM. DECISION PROCESSES 143, 143–44, 152 (2007).

319. Donald A. Redelmeier & Amos Tversky, *Discrepancy Between Medical Decisions for Individual Patients and for Groups*, 322 NEW ENG. J. MED. 1162, 1162 (1990).

320. *Id.*

focuses the respondent solely on respect for autonomy. Conversely, real world cases that highlight a tension between autonomy and beneficence can cause support for the RNTK to drop significantly.

Take the scenario outlined in the introduction: P is having her genome sequenced as part of a diagnostic work-up for what is suspected to be a rare genetic disorder. During the informed consent process, she clearly checks the box opting not to receive any incidental genetic results. During their analysis of her genomic data, her physicians happen to find evidence of high genetic risk for Hereditary Non-Polyposis Colon Cancer (“HNPCC”). They believe that this information will prevent serious disease and perhaps even save P’s life. Should they disclose the finding, even though P indicated that she did not want to receive any secondary findings?

A survey of 800 Institutional Review Board (“IRB”) members and staff about their views on genetic incidental findings (“GIFs”) demonstrates how malleable views on the RNTK can be.³²¹ Respondents were first asked about the RNTK in the abstract: “Do research participants have a right not to know their own genetic information? In other words, would it be acceptable for them to choose not to receive any GIFs?”³²² When presented in this abstract manner, an overwhelming majority (96%) endorsed the RNTK.³²³ But when asked a version of the above case where a specific patient has chosen not to receive incidental findings, only 35% indicated that the individual’s RNTK should definitely be respected, and 28% said that they would probably honor the request not to know.³²⁴ Interestingly, the percentage of respondents who indicated that they did not support the RNTK increased from 2% at baseline to 26% when presented with the specific case.³²⁵ The percentage of people who are unsure similarly jumps, from 1% to 11%.³²⁶

These data demonstrate that support for a strong RNTK is soft; while autonomy and the RNTK may seem sacrosanct in isolation, forcing people to confront the tradeoffs inherent in real world scenarios changes many minds. This suggests that practical conceptions about the RNTK are less absolute than some of the recent literature would have us believe.

321. Catherine Gliwa et al., *Institutional Review Board Perspectives on Obligations to Disclose Genetic Incidental Findings to Research Participants*, GENETICS MED., Nov. 19, 2015 (advance online publication).

322. *Id.*

323. *Id.* at 4.

324. *Id.*

325. *Id.*

326. *Id.*

B. Analyzing the Impact of a Strong RNTK

If views on the RNTK are less settled than one might have previously believed, and if people are open to considering tradeoffs between autonomy and beneficence, then it becomes important to rigorously examine what those tradeoffs might entail. This kind of analysis has thus far been absent from the RNTK debate. The focus on an autonomy-based RNTK has had the unfortunate effect of short-circuiting discussion of the topic.³²⁷ Specifically, the autonomy-dominated conversation has focused on the harms associated with not honoring individual preferences.³²⁸ That focus has not allowed for a comprehensive analysis of the harms **and** benefits of honoring **or** ignoring the RNTK. The reality is any policy will have potential negative consequences. Whichever option is chosen, we will necessarily be making a mistake in one of two directions: unwanted disclosure, or lost opportunity for medical intervention. In this section, I lay out the full set of relevant considerations, and explore some of the relevant empirical data that can help us to fully assess the overall impact of any RNTK policy.

Specifically, there are three empirical questions that should be carefully considered. The first two questions are necessary to understand the scope and magnitude of harms that would result from a decision to create policies that de-emphasize a strong RNTK, asking about the frequency and magnitude of possible harms from unwanted disclosure: (1) How many people genuinely don't want to know genetic information about themselves if it could have a profound impact on morbidity or mortality? (2) If people were given genetic risk information that they would have preferred not to know, what is the magnitude of the harm they actually experience? The third question explores the possible negative ramifications of honoring a strong RNTK: (3) If we actively solicit patient preferences for knowing or not knowing, how many people undergoing genomic sequencing would erroneously or accidentally fail to be notified of potentially lifesaving information?

1. *How many people genuinely don't want to know genetic information about themselves if it could have a profound impact on morbidity or mortality?*

Available data support the reasonable claim that the overwhelming majority of people would want to be given genetic risk information that will

327. *Supra* Part III.B.

328. *Supra* Part III.B.1.

have a direct impact on their health.³²⁹ For example, in one study, nearly all respondents wanted to learn about a range of genetic risk factors, with 90% wanting to learn about non-actionable health risks and 96% wanting to learn about actionable genetic risk factors.³³⁰ Similarly, in the largest study to date of views toward the return of incidental findings resulting from sequencing research, nearly 5,000 members of the public were surveyed and nearly all of them (98%) wanted to learn about genetic risk for life-threatening conditions that can be prevented.³³¹ A strong majority even wanted to know about life-threatening conditions that cannot be treated.³³² So as a baseline, it seems fair to say that the vast majority of people would actively want to know high-value health information, which I'm defining as genetic findings associated with conditions where medical action can mitigate or prevent mortality or serious morbidity, and where there is strong evidence of the link between genotype and significant disease risk.

Of course, that leaves some very small subset of the population who might not want to know this information. Although this is an empirical question that requires further study, it seems reasonable to assume that this small set of people who would not want to know is primarily comprised of individuals for whom clinical action might not be indicated (e.g., patients with a terminal illness, the elderly, people with a religious objection to receiving medical treatment, etc.).³³³ Proponents of the RNTK point to these kinds of examples in defense of their views.³³⁴ My counter-argument, which I will develop in more detail below, is that these relatively rare examples should not drive the RNTK debate; we should not be creating a broad RNTK policy based on a limited set of cases where the medical

329. See, e.g., David Kaufman et al., *Subjects Matter: A Survey of Public Opinions About a Large Genetic Cohort Study*, 10 GENETICS MED. 831, 836–38 (2008); Anna Middleton et al., *Attitudes of Nearly 7000 Health Professionals, Genomic Researchers and Publics Toward the Return of Incidental Results from Sequencing Research*, EUR. J. HUM. GENETICS 1, 5 (2015); Martha F. Wright et al., *Preferences for Results Delivery from Exome Sequencing/Genome Sequencing*, 16 GENETICS MED. 442, 443–44 (2014); Nedal Arar et al., *Preferences Regarding Genetic Research Results: Comparing Veterans and Nonveterans Responses*, 13 PUB. HEALTH GENOMICS 431, 432–47 (2010); Juli M. Bollinger et al., *Public Preferences Regarding the Return of Individual Genetic Research Results: Findings from a Qualitative Focus Group Study*, 14 GENETICS IN MED. 451, 452, 455 (2012); Tineke M. Meulenkamp et al., *Communication of Biobanks' Research Results: What Do (Potential) Participants Want?*, 152A AM. J. MED. GENETICS 2482, 2486, 2488 (2010); Juli Murphy et al., *Public Expectations for Return of Results from Large-Cohort Genetic Research*, 8 AM. J. BIOETHICS 36, 38, 41 (2008); Layla Shahmirzadi et al., *Patient Decisions for Disclosure of Secondary Findings among the First 200 Individuals Undergoing Clinical Diagnostic Exome Sequencing*, 16 GENETICS MED. 395, 397 (2014).

330. Kaufman et al., *supra* note 329, at 835.

331. Middleton et al., *supra* note 329, at 1.

332. *Id.* at 4, 6.

333. See Wright et al., *supra* note 329, at 444–47.

334. See *supra* Part II.B.

information actually has little or no value to the individual. Rather, these cases can be addressed separately, because they represent scenarios where doctors can reasonably anticipate a need to actively solicit preferences.

2. *If people were given genetic risk information that they would have preferred not to know, what is the magnitude of the harm they actually experience?*

- a. *Psychological harms*

If the vast majority of people would want to know important genetic risk information, and if most of those who wouldn't want to know can be bracketed, we are arguably left with an exceedingly small set of people. More empirical research is needed to ascertain the exact size and composition of this group, but whatever that number turns out to be, the next task is to examine the magnitude of harm that this small group will experience if given information that they would have preferred not to know. As discussed above, RNTK proponents frequently make claims about the danger of psychological harms flowing from disclosure of negative genetic information.³³⁵ These claims rely on limited data related to a few poorly-targeted examples like HD and AD.³³⁶ What can the broader psychological literature tell us about our reactions to unfortunate genetic information?

The short answer is that psychological research has demonstrated that people are terrible at affective forecasting, or predicting our future emotional reaction to both positive and negative events.³³⁷ For example, recent lottery winners typically overestimate the length and duration of their spike in happiness.³³⁸ Similarly, but in the opposite direction, people who have recently lost a loved one overestimate the length and duration of their negative emotional response to the traumatic event.³³⁹ In both cases, after an initial spike, people gradually tend to return to their previous baseline

335. *See supra* Part III.A.

336. *See supra* Part III.B.4.

337. *See, e.g.*, Elisabeth W. Dunn & Simon M. Laham, *Affective Forecasting: A User's Guide to Emotional Time Travel*, in *AFFECT IN SOCIAL THINKING AND BEHAVIOR* 177, 177–78 (Joseph P. Forgas ed., 2006); Timothy D. Wilson & Daniel T. Gilbert, *Affective Forecasting*, in 35 *ADVANCES IN EXPERIMENTAL SOC. PSYCHOLOGY* 345, 346, 401 (James M. Olson & Mark P. Zanna eds., 2003); Timothy D. Wilson & Daniel T. Gilbert, *Affective Forecasting Knowing What to Want*, 14 *CURRENT DIRECTIONS IN PSYCHOL. SCI.* 131, 131, 134 (2005).

338. Brett Pelham, *Affective Forecasting: The Perils of Predicting Future Feelings*, *PSYCHOL. SCI. AGENDA* (Apr. 2004), <http://www.apa.org/science/about/psa/2004/04/pelham.aspx>.

339. *Id.*

level of happiness.³⁴⁰ It appears that individuals are generally much more emotionally adaptable than they might realize.

This is also true in the medical realm, where the literature suggests that an individual's predictions concerning the emotional consequence of learning about genetic disease risk do not square with people's actual ability to adapt to negative health information.³⁴¹ In a broad range of medical contexts, there are data showing that the affective forecasting bias is particularly pronounced when healthy people are asked to assess the negative emotional impact of (theoretical) future health problems.³⁴² Specifically, people generally assume that receiving negative genetic information will be devastating, but research demonstrates that people are much better at coping with negative information than they think they will be.³⁴³ In reality, the negative psychological effect of receiving positive risk information for many untreatable conditions is generally transient and mild.³⁴⁴

Of particular interest are the concepts of immune neglect and focal illusion. Immune neglect deals with "the failure to anticipate how easily and quickly we make sense of and adapt to negative events."³⁴⁵ Essentially, the body has a sort of psychological immune system, which helps people deal with negative information, often making the actual impact of negative information significantly smaller than the expected negative impact.³⁴⁶ However, when making a prediction about future emotional responses, we disregard our ability to cope, thereby overestimating the negative impact of information.³⁴⁷ Relatedly, the focal illusion bias "is the tendency to focus on the affective consequences of a single, focal future event, while ignoring the emotional impact of non-focal events on well-being."³⁴⁸ This bias causes us to pay more attention to the negative implications of the topic at hand (i.e., the genetic test result that was just returned) while ignoring the

340. Wilson & Gilbert, *Affective Forecasting*, *supra* note 337, at 369, 393 (finding that people's emotional reactions become less intense with time, in a phenomenon called emotional evanescence).

341. Jodi Halpern & Robert M. Arnold, *Affective Forecasting: An Unrecognized Challenge in Making Serious Health Decisions*, 23 J. GEN. INTERNAL MED. 1708, 1708, 1710 (2008) (finding that people fail to predict their own ability to adapt to declines in health).

342. S.A. Peters et al., *The Future in Clinical Genetics: Affective Forecasting Biases in Patient and Clinician Decision Making*, 85 CLINICAL GENETICS 312, 313–14 (2014).

343. *Id.*

344. *See id.* (describing studies in which patients' emotional responses were less extreme than anticipated).

345. *Id.* at 313.

346. *Id.*

347. Peters et al., *supra* note 342, at 313–14 (2014).

348. *Id.* at 313.

positive mitigating effects that other aspects of life might offer (e.g., family, hobbies, etc.).³⁴⁹

While the field hasn't "systematically considered such biases in clinical genetics,"³⁵⁰ there is a growing body of data supporting the claim that concerns about psychological reactions to negative genetic results are likely overblown.³⁵¹ One systematic review of 15 published papers on predictive genetic testing for a range of conditions found "no increased distress (general and situational distress, anxiety, and depression) in carriers or non-carriers at any point during the 12 months after testing."³⁵² Furthermore, both carriers and non-carriers actually showed decreased distress after testing.³⁵³ Similarly, a review of the literature on responses to genetic testing of cancer susceptibility found that there was very little evidence of adverse psychological effects observed among people who learn that they have a genetic predisposition to certain cancers.³⁵⁴

Even when the testing is for a condition like HD (an untreatable and devastatingly progressive neurological disorder) the evidence suggests that while carriers experience some short-term distress, long-term psychological distress is comparable to that of non-carriers.³⁵⁵ Reactions to learning about risk for other neurodegenerative disorders, such as AD, seem to follow a similar trajectory.³⁵⁶ One review article examined the health-related quality

349. *Id.*

350. *See id.*

351. *See, e.g.,* Bettina Meiser, *Psychological Impact of Genetic Testing for Cancer Susceptibility: An Update of the Literature*, 14 *PSYCHO-ONCOLOGY* 1060, 1060 (2005) (claiming that "[m]ost studies on the psychological impact of genetic testing among individuals" without cancer have revealed no adverse psychological effects among carriers of the cancer-predicting BRCA1/2 gene who undergo the testing, while non-carriers generally receive a net psychological benefit from the test).

352. Marita Broadstock et al., *Psychological Consequences of Predictive Genetics Testing: A Systematic Review*, 8 *EUR. J. HUM. GENETICS* 731, 731 (2008).

353. *Id.*

354. Meiser, *supra* note 351.

355. *See* Bettina Meiser & Stewart Dunn, *Psychological Impact of Genetic Testing for Huntington's Disease: An Update of the Literature*, 69 *J. NEUROLOGY NEUROSURGERY PSYCHIATRY* 574, 576–77 (2000) (finding that in a study of individuals who underwent genetic testing for Huntington's disease, the psychological outcomes among carriers and non-carriers "differed significantly" seven to ten days after the test but measured similarly six to twelve months after the test). *See also* Sandi Wiggins et al., *The Psychological Consequences of Predictive Testing for Huntington's Disease*, 327 *NEW ENG. J. MED.* 1401, 1404 (1992) (finding that both people testing positive for an "increased risk" and those found to have a "decreased risk" reported the same psychological effects twelve months after the genetic testing); Aad Tibben et al., *Psychological Effects of Presymptomatic DNA Testing for Huntington's Disease in the Dutch Program*, 56 *PSYCHOSOMATIC MED.* 526 (1994).

356. Robert C. Green et al., *Disclosure of APOE Genotype for Risk of Alzheimer's Disease*, 361 *NEW ENG. J. MED.* 245, 245 (2009) (reporting no significant difference in anxiety levels between those who reviewed their test results and those who did not after being tested for a genetic predisposition to Alzheimer's).

of life for patients after learning about increased risk for a range of neurodegenerative diseases, finding that 1) severe responses are rare; 2) to the extent that patients do experience anxiety or depression, it is generally transient; 3) and most patients do not experience regret.³⁵⁷

The literature tells a similar story about the limited psychological impact of learning that one is at an increased risk of developing breast cancer or colon cancer.³⁵⁸ For example, one study demonstrated that while BRCA mutation carriers reported higher incidence of depression and other negative psychological effects at one and six months post-test, their psychological state returned to baseline levels by 12 months.³⁵⁹ A meta-analysis echoed the theme that people are capable of adapting over time, concluding that the overall literature suggests that there is a brief period of increased distress after receiving a positive result, but that distress levels returned to a pre-test baseline over time.³⁶⁰ The literature for hereditary non-polyposis colon cancer also lends credence to the view that people may manifest short-term distress but do not generally experience long-term adverse psychological outcomes as a result of learning about their genetic risk status.³⁶¹

One must be careful when evaluating these data, as some of the studies have methodological limitations. Nevertheless, it is striking that RNTK proponents continue to make claims about the harmful psychological impact of genetic information when there is such limited empirical support for such concerns. More evidence about emotional reactions to genetic information would certainly be useful, but the existing literature at least raises important questions about whether we “systematically overestimate the durability and intensity of the affective impact of events on well-being,” thereby creating a “culture of risk-aversion in which patients may be opting out of potentially beneficial diagnostic and treatment regimes.”³⁶²

357. Jane S. Paulsen et al., *A Review of Quality of Life After Predictive Testing for and Earlier Identification of Neurodegenerative Diseases*, 110 PROGRESS NEUROBIOLOGY 1, 2 (2013).

358. Kathryn J. Schlich-Bakker et al., *A Literature Review of the Psychological Impact of Genetic Testing on Breast Cancer Patients*, 62 PATIENT EDUC. COUNSELING 13, 13 (2006).

359. Tammy M. Beran et al., *The Trajectory of Psychological Impact in BRCA1/2 Genetic Testing: Does Time Heal?*, 36 ANNALS BEHAV. MED. 107, 107 (2008).

360. Jada G. Hamilton et al., *Emotional Distress Following Genetic Testing for Hereditary Breast and Ovarian Cancer: A Meta-Analytic Review*, 28 HEALTH PSYCHOL. 510 (2009).

361. See Bettina Meiser et al., *Psychological Impact of Genetic Testing for Hereditary Non-polyposis Colorectal Cancer*, 66 CLINICAL GENETICS 502, 507 (2004) (finding that carriers tend to see an increase in negative psychological outcomes through two weeks after testing that returns to baseline after four to twelve months); see also Polymnia Galiatsatos et al., *Psychosocial Impact of Lynch Syndrome on Affected Individuals and Families*, 60 DIGESTIVE DISEASES SCI. 2246, 2246 (2015) (finding that while carriers suffer an increase in depression and anxiety immediately following testing, these same symptoms “seem to normalize” by six to twelve months).

362. Peters, *supra* note 342, at 312–13.

b. Economic harms

If psychological harms are likely to be minimal, that still leaves a question about economic harms (i.e., discrimination). The likelihood and magnitude of discrimination is somewhat more difficult to assess, but early experience with the Genetic Information Non-Discrimination Act (“GINA”) suggests that perhaps there is less cause for concern than previously thought. GINA was enacted in 2008, in response to concerns that public fears about genetic discrimination were inhibiting the adoption of clinical genetic testing.³⁶³ The law prohibited employers and health insurance companies from receiving genetic information (broadly defined) and from using genetic information as the basis for employment or actuarial decisions.³⁶⁴ GINA’s protections only apply when decisions are made on the basis of genetic risk information; once the disease has become manifest, GINA no longer applies (although other laws, such as the Americans with Disabilities Act might provide some protection).³⁶⁵

In the years since its passage, however, there have been remarkably few cases requiring the Equal Employment Opportunity Commission to exercise its enforcement power.³⁶⁶ Since 2010, there have only been an average of 278 claims filed per year.³⁶⁷ The majority of these claims were dismissed for lack of reasonable cause, with an annual average of merely 48 cases reaching merit resolution.³⁶⁸ Damages appear to be minimal, averaging less than \$1 million in total awards per year.³⁶⁹ These data suggest that while there are isolated incidents of genetic discrimination occurring in the employment and health insurance contexts, there is a significant gap between the fears that motivated GINA’s passage, and actual reality. This isn’t to say that genetic discrimination won’t become a more significant problem in the future. My claim is merely that there is little evidence of it being a widespread and egregious problem at the

363. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881, 881–83 (in their findings, Congress declared that establishing “a national and unified basic standard” for preventing genetic discrimination was “necessary to protect the public from discrimination” and “allay their concern about the potential for discrimination,” so that the country could better “take advantage of genetic testing, technology, research and new therapies”).

364. *See generally id.*

365. Mark A. Rothstein, *GINA, the ADA, and Genetic Discrimination in Employment*, 387 J.L. MED. & ETHICS 837, 839 (2008). *See also* Anya E.R. Prince & Benjamin E. Berkman, *When Does an Illness Begin: Genetic Discrimination and Disease Manifestation*, 40 J. LAW MED. ETHICS 655 (2012).

366. U.S. EQUAL EMPLOYMENT OPPORTUNITY COMM’N, GENETIC INFO. NON-DISCRIMINATION ACT CHARGES FY 2010-2014, <http://www.eeoc.gov/eeoc/statistics/enforcement/genetic.cfm> (last visited Nov. 3, 2015) (reporting a total of 1188 resolutions from FY 2010 through FY 2015).

367. *Id.*

368. *Id.*

369. *Id.*

moment. It is notable that the most highly publicized genetic discrimination case thus far involved employees being forced to submit to genetic testing in order to ascertain who was secretly leaving human excrement in their workplace.³⁷⁰

GINA has been criticized, however, for not covering other areas of potential genetic discrimination, such as life insurance and long-term care insurance.³⁷¹ These areas are difficult to assess in the absence of a GINA analog. It does appear that there are occasional instances of discrimination in these realms,³⁷² but that they are primarily associated with untreatable single gene conditions, like Huntington's disease,³⁷³ that I've argued carry little weight for purposes of determining whether there should be a broad RNTK.³⁷⁴ Even with some evidence of discrimination in these realms, a systematic review of existing data calls into question the need for a policy intervention.³⁷⁵ As one review article concluded, "With the notable exception of studies on Huntington's disease, none of the studies reviewed here (or their combination) brings irrefutable evidence of a systemic problem of GD that would yield a highly negative societal impact."³⁷⁶ Again, this isn't to suggest that genetic discrimination will never become a problem in life and long-term care insurance. Rather, my argument is that we should make a clear-eyed assessment of the frequency and magnitude of any economic harms flowing from disclosure of genetic risk information before automatically assuming a worst-case scenario. As we will explore in the next section, there are some potential negative effects associated with honoring a strong RNTK, which should be balanced against a rigorous evaluation of the harms associated with not doing so.

3. *If we actively solicit patient preferences for knowing or not knowing, how many people undergoing genomic sequencing would erroneously or accidentally fail to be notified of potentially lifesaving information?*

On one side of the scale, we have a very small group of people, who are arguably at very low risk of experiencing significant, lasting

370. Gina Kolata, 'Devious Defecator' Case Tests Genetics Law, N.Y. TIMES (May 29, 2015), <http://www.nytimes.com/2015/06/02/health/devious-defecator-case-tests-genetics-law.html>.

371. Rothstein, *supra* note 365, at 837.

372. See Mark A. Hall & Stephen S. Rich, *Laws Restricting Health Insurers' Use of Genetic Information: Impact on Genetic Discrimination*, 66 AM. J. HUMAN GENETICS 293, 295, 302 (2000) (noting instances of discrimination relating to life, disability and long-term care insurance).

373. Yann Joly et al., *Genetic Discrimination and Life Insurance: A Systematic Review of the Evidence*, 11 BMC MED. 25 (2013).

374. See *supra* Part III.B.4.

375. Joly et al., *supra* note 373, at 25, 36.

376. *Id.* at 36.

psychological or economic harm. On the other side, we would want to know the impact of adopting a robust RNTK policy that involved actively soliciting individual preferences. My argument is that such a policy would necessarily result in some loss of opportunity to provide people with valuable information because there is good reason to doubt our ability to accurately and reliably assess people's true preferences.

Any attempt to assess individual preferences will likely take place as part of the informed consent process. A typical model might look like this: Patients or research participants are given a written informed consent document that explains the risks and benefits of genomic sequencing, and includes discussion about the possibility of generating incidental findings. Perhaps after a conversation with the researcher or clinician (or perhaps not), the individual would be asked to indicate whether or not they are interested in learning about genetic risks unrelated to the condition under investigation. The choice might be binary ("Yes, I want to learning incidental findings" or "No, I don't want to learn incidental findings") or could present a menu of types of genetic findings any of which could be selected (e.g., serious/actionable, serious/non-actionable, late-onset, carrier status, etc.).

There are a number of reasons to be skeptical about our ability to reliably assess an individual's true preferences about knowing or not knowing genetic information. The first problem has to do with how people engage with informed consent documents. There are extensive data suggesting that people frequently do not carefully read consent forms, and when they do, that their understanding and appreciation of the content can often be lacking.³⁷⁷ These problems are acute enough that the research ethics community is continually trying to find ways to improve the process of obtaining informed consent.³⁷⁸

The research demonstrating these effects has been extensive; one review article that employed quantitative methods to examine whether research subjects actually comprehended the information contained in a consent form found that only forty-seven of 427 published medical studies met specific criteria for comprehensibility, demonstrating that

377. See Henry W. Riecken & Ruth Ravich, *Informed Consent to Biomedical Research in Veterans Administration Hospitals*, 248 JAMA 344, 346 (1982) (pointing to data indicating that "most of the consent forms are written in language that requires reading ability at the college level" and only "27% of the patients [in the study] had more than a high school education").

378. See Ezekiel J. Emanuel & Jerry Menikoff, *Reforming the Regulations Governing Research with Human Subjects*, 365 NEW ENG. J. MED. 1145, 1147 (2011) (proposing to simplify consent documents so that they are more understandable).

comprehension varied widely and was often quite minimal.³⁷⁹ For example, one specific study showed that more than 25% of the participants had no idea about the purpose of the research, and only 10% could describe its goals completely.³⁸⁰ Other studies similarly demonstrated that a substantial proportion of subjects could not name study risks/side effects without prompting, and often did not understand basic research characteristics such as randomization and use of placebos.³⁸¹ In one study of patients enrolled in cancer clinical trials, 74% did not recognize that they would be receiving non-standard treatment, 63% did not understand that they were at potential risk for increased harm from participation, 70% did not comprehend the experimental nature of the treatment, 29% did not internalize the fact that they might not receive any clinical benefits, and 25% did not appreciate that research trials are done mainly to benefit future patients.³⁸²

If subjects are signing consent forms with such incomplete understanding of the important details contained therein, it seems questionable to have confidence in the infallibility of any process designed to solicit preferences about knowing genetic incidental findings. This is particularly true given the inherent complexity of genetic information, and the associated difficulty patients will have in making a choice in that context. Many commentators have expressed a concern that the wide range of types of genomic findings will be overwhelming and could become a significant barrier to implementing truly informed consent.³⁸³ For example, as Holm and colleagues have argued:

379. Amulya Mandava et al., *The Quality of Informed Consent: Mapping the Landscape. A Review of Empirical Data from Developing and Developed Countries*, 38 J. MED. ETHICS 356, 356–57 (2012).

380. Riecken & Ravich, *supra* note 377, at 345.

381. See, e.g., Mandava et al., *supra* note 379, at 357, 362 (showing that multiple studies have found that a small percentage of subjects actually understand the randomization process and the concept of a placebo); Jan M. Howard & David DeMets, *How Informed is Informed Consent? The BHAT Experience*, 2 CONTROLLED CLINICAL TRIALS 287, 290–92 (1981) (finding that many subjects did understand basic information about their clinical trial, but overall, informed consent did not provide a robust and full understanding. For example, 47% of research participants did not know that they were assigned to treatment or placebo by chance, and only a minority of subjects were aware of all of the possible side effects); Margriet van Stuijvenberg et al., *Informed Consent, Parental Awareness, and Reasons for Participating in a Randomised Controlled Study*, 79 ARCHIVES DISEASE CHILDHOOD 120, 120 (1998) (finding that while 73% of parents were aware of the major study characteristics, some had difficulty understanding the information provided).

382. Steven Joffe et al., *Quality of Informed Consent in Cancer Clinical Trials: A Cross-Sectional Survey*, 358 LANCET 1772 (2001).

383. See, e.g., Bredenoord et al., *supra* note 72, at 29 (“Most if not all patients will have difficulties with making a reasonable selection out of the wide array of possible genetic findings. The quantity, significance, and ambiguity of the genetic data generated by NGS will make any reasonable choice beforehand highly complex.”); Knoppers, *supra* note 43, at 9 (“Unless the time period and the content of the right not to know are well laid out in the consent process, the emerging requirements for the return of results in genomics may rapidly become

To understand the implications of [preventive genome sequencing], a person will have to be informed about and (at least to some degree) understand the prevalence of each MAG [medically actionable gene], the relation between each MAG and its linked disease, including mode of inheritance and degree of penetrance, details about the disease, and details about the possible prevention and treatment options Thus, if we have problems informing people adequately about the relevant probabilities, risks, and benefits relevant to screening for one disease, how are we going to do this for 10, 20, or (in the future) many more diseases? And these are diseases that because of their genetic nature, furthermore, have potential implications not only for the person but also for his or her relatives. Even with the best patient support systems in the world we are unlikely to get anything approaching “informed consent.”³⁸⁴

In the pre-genomic era when targeted genetic testing was the norm, patients could reasonably absorb the range of information they might receive; a single gene test typically only revealed information associated with the relevant condition.³⁸⁵ But when employing genome sequencing, it is impossible to know what kind of results will be generated, making the informed consent process that much more difficult.³⁸⁶ Ensuring patient comprehension and managing expectation becomes increasingly difficult as the amount of genomic data generated grows.

Furthermore, it will even be difficult to adequately describe the variety of genomic information categories because of terminological confusion. Terms like “actionability,” “clinical utility,” and “clinical significance” are typically used to describe the kinds of findings someone might or might not desire, but there is a lack of conceptual clarity about exactly what those

unmanageable.”); Bredenoord et al., *Disclosure of Individual Genetic Data to Research Participants: The Debate Reconsidered*, 27 *TRENDS GENETICS* 41–47 (2011); Amy L. McGuire & Laura M. Beskow, *Informed Consent In Genomics and Genetic Research*, 11 *ANN. REV. GENOMICS HUM. GENETICS* 361 (2010) (arguing that there are unique ethical issues raised by genetic research, both in the way research is conducted and the level of understanding of the participants, that make obtaining informed consent more difficult); ACMG BOARD OF DIRECTORS, *Points to Consider for Informed Consent for Genome/Exome Sequencing*, 15 *GENETICS MED.* 748 (2013) (arguing that genomic sequencing poses heightened challenges for obtaining informed consent relative to the process of informed consent for other types of genetic testing); Ashley N. Tomlinson et al., “*Not Tied Up Neatly with a Bow*”: *Professionals’ Challenging Cases in Informed Consent for Genomic Sequencing*, *J. GENETICS COUNSELING* 1 (2015); Gail E. Henderson, *Is Informed Consent Broken?*, 342 *AM. J. MED. SCI.* 267 (2011); Erika Check Hayden, *Informed Consent: A Broken Contract*, 486 *NATURE* 312 (2012).

384. Søren Holm & Thomas Ploug, *Patient Choice and Preventive Genomic Sequencing—More Trouble Upstream*, 15 *AM. J. BIOETHICS* 24, 25 (2015).

385. Eckstein et al., *supra* note 40, at 193.

386. *See id.* at 190, 193–94 (stating that the results of secondary findings are often “unanticipated” and “unforeseen by either party at the time of consent”).

terms mean.³⁸⁷ For example, there seem to be at least two different conceptions of “actionability.”³⁸⁸ The narrow conception focuses on how the information can impact the individual’s clinical care by informing therapies or preventative interventions.³⁸⁹ The expanded view is more broadly patient-centered, including impact on clinical care, as well as somewhat more nebulous considerations like importance to the person’s life choices.³⁹⁰ If scholars in the field cannot agree on a unified definition of the terms used to describe the categories of genetic information presented, how can we be confident that patients will have a consistent and predictable understanding of the same?³⁹¹

There are also concerns about how preferences can shift over time.³⁹² Life events and the passage of time can change one’s views; the answer given as a single young adult might be different than the one that same person would give once they are married with children. But unless the medical world can develop a process for actively re-soliciting preferences (an unrealistic proposition) there is the very real risk that a binding decision made at a single point in time could become inconsistent with future desires.

Informed consent is a cornerstone of bioethics, and with good reason. In its ideal form, it allows doctors and researchers to demonstrate respect for persons, and allows competent individuals to make autonomous choices about their engagement with medicine. The arguments made above should not be read as a wholesale indictment of informed consent. Rather, my point is that we should be skeptical about our capacity to adequately and accurately assess individual preferences about knowing or not knowing specific categories of genetic information. In particular, I question the validity of automatically privileging broad, hypothetical checkbox answers collected during a demonstrably imperfect informed consent process. While more empirical research would be helpful in determining the full extent of the problem, there is a very real risk that a policy of actively soliciting preferences about knowing or not knowing genetic information could result in people making choices that do not reflect their true values and

387. *Id.* at 190.

388. *Id.* at 197.

389. *Id.*

390. *Id.*

391. See, e.g., Kristi D. Graves et al., *Public Perceptions of Disease Severity But Not Actionability Correlate with Interest in Receiving Genomic Results: Nonalignment with Current Trends in Practice*, 18 PUB. HEALTH GENOMICS 173, 181 (2015).

392. See, e.g., Jeffrey R. Botkin, *Informed Consent for Genetic Research*, in CURRENT PROTOCOLS IN HUMAN GENETICS (Nicholas Dracopoli et al. eds., 2001).

preferences, thus erroneously or accidentally not receiving potentially lifesaving information.³⁹³

C. Moral Distress

I've argued that patient autonomy is not the only relevant value in this debate, and that it is important to seek out other possibly relevant considerations. In the last section, I examined the full range of effects that honoring or not honoring the RNTK would have on individual patients or research subjects. Now I turn to an examination of other relevant considerations, namely those raised by the interests of medical professionals. The RNTK can place researchers and clinicians in a difficult position. It is a vexing problem to possess genetic information that one deems to be clinically important, but to be precluded from disclosing it because a patient has exercised their RNTK. These medical professionals are apt to experience what we can colloquially call the "I-can't-sleep-at-night" problem. More technically, they are experiencing a phenomenon known as moral distress.³⁹⁴

A concept that originated from the field of nursing, moral distress refers to the situation where one knows the morally correct course of action, but is constrained from taking it.³⁹⁵ Unlike a classic ethical dilemma, where there are two ethically justifiable, but non-optimal choices, moral distress involves feeling like there is a clearly correct, but unavailable choice to make.³⁹⁶ In normal clinical care, moral distress can be found in a range of situations where structural, legal, or institutional barriers prevent someone from doing what they feel would be right. These barriers can arise out of "clinical situations, factors internal to the individual professional, and factors present in unit cultures, the institution, and the larger health care

393. The obvious response to my argument is to suggest that when patients have chosen not to know, and their doctors find something that they think justifies revisiting that decision, just ask a second time. But if one truly wants to honor an expressed desire not to know, it seems practically impossible to ask the person in a way that doesn't implicitly alert them to the fact that there has been a significant result. See Dorothy C. Wertz & John C. Fletcher, *Privacy and Disclosure in Medical Genetics Examined in an Ethics of Care*, 5 *BIOETHICS* 212, 221 (1991) ("There is no way . . . to exercise the choice of not knowing, because in the very process of asking 'Do you want to know whether you are at risk?' the geneticist has already made the essence of the information known.").

394. Pauline W. Chen, *When Doctors and Nurses Can't Do the Right Thing*, N.Y. TIMES (Feb. 6, 2009), <http://www.nytimes.com/2009/02/06/health/05chen.html>.

395. ANDREW JAMETON, *NURSING PRACTICE: THE ETHICAL ISSUES* (1984). See also Elizabeth G. Epstein & Sarah Delgado, *Understanding and Addressing Moral Distress*, 15 *ONLINE J. ISSUES NURSING Manuscript* 1 (2010).

396. Epstein & Delgado, *supra* note 395, at 1–2.

environment.”³⁹⁷ For example, a doctor or nurse might feel moral distress when an institution has decided to keep a patient on life support, even though he or she firmly believes that doing so is not in the patient’s best interest.³⁹⁸ While most commonly discussed in the context of nursing, moral distress is experienced by a range of medical specialties.³⁹⁹ Medical geneticists and genetic counselors seem to be at particular risk. One study of genetic service providers found that 18% were considering leaving patient care because of distress.⁴⁰⁰ As the authors of that study noted, “[b]ecause of the emphasis on patient autonomy and nondirective counseling, genetic service providers also may experience moral distress when patients are making morally charged decisions, especially in prenatal genetic settings.”⁴⁰¹

From a professional perspective, the worry is that experiencing moral distress can have a lasting detrimental effect on medical practitioners, which some have termed “moral residue.”⁴⁰² As Epstein and Delgado explain:

In situations of moral distress, one’s moral values have been violated due to constraints beyond one’s control. After these morally distressing situations, the moral wound of having had to act against one’s values remains. Moral residue is long-lasting and powerfully integrated into one’s thoughts and views of the self. It is this aspect of moral distress—the residue that remains—that can be damaging to the self and one’s career, particularly when morally distressing episodes repeat over time.⁴⁰³

Given that a patient’s exercise of their RNTK presents a potential risk to medical professionals, the question then is how much weight we should give this concern. Stated another way, when is it permissible for a doctor’s moral interests (i.e., an orientation towards trying to prevent or ameliorate disease) to trump patient autonomy?

397. Ann B. Hamric, *Empirical Research on Moral Distress: Issues, Challenges, and Opportunities*, 24 HEC FORUM 39, 39 (2012).

398. Mary C. Corley, *Nurse Moral Distress: A Proposed Theory and Research Agenda*, 9 NURSING ETHICS 636, 638–39 (2002).

399. See, e.g., Wendy J. Austin et al., *The Balancing Act: Psychiatrists’ Experience of Moral Distress*, 11 MED. HEALTH CARE & PHIL. 89, 89 (2007). See also Epstein & Delgado, *supra* note 395, at 2 (citing to literature documenting moral distress in a range of healthcare professions).

400. Barbara A. Bernhardt et al., *Distress and Burnout Among Genetic Service Providers*, 11 GENETICS IN MED. 527, 532 (2009).

401. *Id.* at 527.

402. Epstein & Delgado, *supra* note 395, at 2, 4.

403. *Id.* at 4.

This notion of beneficence trumping autonomy has been a frequent topic of exploration in the bioethics literature.⁴⁰⁴ For example, Edmund Pellegrino has argued that while autonomy is certainly an important principle, beneficence and autonomy should be complementary.⁴⁰⁵ Physician autonomy should also be respected, as the physician has a claim to follow her own “conscience about what is good medicine and what is morally acceptable as a person.”⁴⁰⁶ Similarly, others have concluded that the morality associated with the medical profession sometimes makes it permissible to violate a patient’s autonomy.⁴⁰⁷

This isn’t to say that a medical professional’s interests generally, and moral distress in particular, are sufficiently weighty to carry an argument against the RNTK. But considered in the overall context of a rigorous debate about whether or not we should honor an individual’s RNTK important medical information about him or herself, it certainly seems like moral distress is at least another relevant consideration in favor of arguing that it is appropriate to be skeptical about a broad, strong RNTK.

D. Genetic Exceptionalism

It has been popular to argue that genetic information requires special treatment, such as extra privacy protections, enhanced pre-test education and a distinct informed consent process.⁴⁰⁸ This position was supported by the strongly held notion that there is something different about genetic information.⁴⁰⁹ People have an instinct that genetic information is special, perhaps because genetic information can uniquely shed light on our familial

404. See Edmund D. Pellegrino, *Patient and Physician Autonomy: Conflicting Rights and Obligations in the Physician-Patient Relationship*, 10 J. CONTEMP. HEALTH. L. POL’Y 47, 58 (1994) (discussing conflicts that arise out of the potential incompatibility of beneficence and autonomy).

405. *Id.* at 47.

406. *Id.* at 51.

407. Ost, *supra* note 27, at 310–11 (“Underlying medicine is another, humanistic value-orientation which calls upon the physician to do what he can to help the patient make autonomous decisions It is an insight of this sort, I suspect, that leads Beauchamp and Childress to the conclusion that it is sometimes permissible to violate the patient’s autonomy (in the sense of freedom from external coercion) in order to promote autonomy.”).

408. Michael J. Green & Jeffrey R. Botkin, “Genetic Exceptionalism” in *Medicine: Clarifying the Differences between Genetic and Nongenetic Tests*, 138 ANNALS INTERNAL MED. 571, 571 (2003).

409. See, e.g., Miguel Ruiz-Canela & J. Ignacio Valle-Mansilla, *What Research Participants Want to Know about Genetic Research Results: The Impact of “Genetic Exceptionalism”*, 6 J. EMPIRICAL RES. ON HUM. RES. ETHICS 39 (2011) (showing study results in which participants considered genetic data to be riskier than other types of medical data).

or ancestral relationships, or maybe because people (erroneously) subscribe to genetic determinism.⁴¹⁰

Beyond popular instincts, scholars have also made a number of more rigorous attempts to argue about the ways in which genetic information is unique.⁴¹¹ First, genetic exceptionalists have argued that genetic information is often predictive, rather than diagnostic, and thus can be used to predict an individual's future health in ways that other kinds of non-genetic medical information cannot.⁴¹² Genetic exceptionalists have also focused on the fact that since genetic information is an immutable part of your identity and cannot be altered, we should be careful to guard against the psychosocial and economic effects of disclosing genetic risk information.⁴¹³ Finally, genetic information has implications for third parties; any genetic diagnosis or risk information is not just relevant to the patient, but also to their blood relatives.⁴¹⁴

Nevertheless, as the field of medical genetics has evolved, genetic exceptionalism has been subject to significant criticism.⁴¹⁵ As Evans and Burke have argued:

410. Jim Evans & Wylie Burke, *Genetic Exceptionalism: Too Much of a Good Thing?*, 10 *GENETICS IN MED.* 500, 501 (2008).

411. *See, e.g.*, Patricia A. Roche & George J. Annas, *Protecting Genetic Privacy*, 2 *NATURE REV. GENETICS* 392, 393 (2001) (arguing that DNA sequence information is unique because it has information beyond medical history and current health status such as future conditions and traits shared with family members); Gail Geller et al., *Genetic Testing for Susceptibility to Adult-Onset Cancer*, 277 *JAMA* 1467, 1468 (1997) (warning that genetic information affects other family members, our future behavior, and can put a healthy patient in an "at-risk" category); Barbara Biesecker et al., *Genetic Counseling for Families with Inherited Susceptibility to Breast and Ovarian Cancer*, 269 *JAMA* 1970 (1993) (reporting that it is now possible to identify family members who carry a gene that predisposes women to breast and ovarian cancer).

412. Green & Botkin, *supra* note 408, at 572.

413. *Id.* at 572–73.

414. *Id.* at 572.

415. *See, e.g.*, Thomas H. Murray, *Genetic Exceptionalism and Future Diaries: Is Genetic Information Different from Other Medical Information?*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 60, 71 (Mark Rothstein ed., 1997) (proposing that genetic exceptionalism is an "overly dramatic view of the significance of genetic information in our lives"); Soren Holm, *There is Nothing Special About Genetic Information*, in *GENETIC INFORMATION: ACQUISITION, ACCESS AND CONTROL* 97, 102 (Alison K. Thomson & Ruth Chadwick eds., 1999) (arguing that there is no distinction between genetic information and other types of health-related data); Lawrence O. Gostin & James G. Hodge, *Genetics Privacy and the Law: An End to Genetics Exceptionalism*, 40 *JURIMETRICS* 21 (1999) (asserting that genetic exceptionalism impairs the achievement of public health goals because genetic information is no different from other health data); Lainie F. Ross, *Genetic Exceptionalism vs. Paradigm Shift: Lessons from HIV*, 29 *J.L. MED. & ETHICS* 141, 141 (2001) (advocating that health care policy should not give rise to a principle of genetic exceptionalism); Jon Beckwith & Joseph S. Alper, *Reconsidering Genetic Antidiscrimination Legislation*, 26 *J.L. MED. & ETHICS* 205 (1998) (urging the legislature to redraft antidiscrimination laws for genetic medical information in the same manner as those for non-genetic medical information).

If our field of medical genetics realizes the bright future, often predicted for it, genetic and genomic information will increasingly aid medical decision-making in many clinical arenas. This promise calls into question—in our view appropriately—a core assumption of our field: that genetic information is qualitatively different from other types of medical information and thus must be treated in a different way.⁴¹⁶

Accompanying this sort of view has been an increasingly powerful chorus of arguments refuting the basic claims of genetic exceptionalists. While genetic information can often predict distant future health (sometimes with high accuracy) there are many examples of non-genetic health information possessing comparable predictive power.⁴¹⁷ For example, a test revealing high blood pressure can predict one's chance of developing heart disease.⁴¹⁸ Similarly, non-genetic health information can also have a profound impact on family members, and can cause psychosocial or economic harm.⁴¹⁹

This strong refutation of genetic exceptionalism is relevant in the RNTK debate. Proponents of the RNTK are effectively arguing that the return of any genetic information requires explicitly soliciting patient consent. Since it is standard practice in many clinical situations to disclose certain kinds of non-genomic medical findings without asking for explicit permission, it seems fair to ask whether this instance of genetic exceptionalism is warranted.

Autonomy is obviously an important value in medical ethics; modern social norms have clearly and enthusiastically moved away from medicine's paternalistic history. However, it isn't true that patients are asked to make decisions about every single aspect of their health care. If a patient undergoes a specifically indicated scan (e.g., to check on the healing of a broken bone), but that scan incidentally reveals a potentially cancerous tumor, a doctor isn't going to ask the patient if they want to learn about the unexpected but important result. Similarly, if a patient receives a routine blood panel to check for a specific indication (e.g., monitoring hypertension) but the panel returns a panic value indicating a serious acute

416. Evans & Burke, *supra* note 410, at 501.

417. See, e.g., Green & Botkin, *supra* note 408, at 572; Ross, *supra* note 415, at 143.

418. Green & Botkin, *supra* note 408, at 572.

419. See, e.g., *id.* at 572–73. See also GENETIC TESTING COMM. TO THE MEDICAL SECTION OF THE AMERICAN COUNCIL OF LIFE INSURANCE, THE POTENTIAL ROLE OF GENETIC TESTING IN RISK CLASSIFICATION 45, 45–46 (1989) (arguing that insurance underwriters routinely rely on information such as HIV status, serum cholesterol levels, alcohol or narcotic addiction, and even blood pressure to determine eligibility and rates for life or disability insurance); Angelo A. Alonzo & Nancy R. Reynolds, *Stigma, HIV and AIDS: An Exploration and Elaboration of a Stigma Trajectory*, 41 SOC. SCI. MED. 303, 312 (1995) (demonstrating that patients with AIDS and leprosy have been stigmatized).

problem (e.g., impending renal failure) the physician isn't going to ask before disclosing this urgent finding.

These analogies aren't perfect;⁴²⁰ genomic findings generally aren't associated with conditions that require immediate attention, nor is genetic predisposition always equivalent to a diagnosis of manifested disease.⁴²¹ But the question isn't whether genetic information is precisely analogous to the urgent cases presented above. Rather, the relevant question should be whether and why the kind of important genomic information being discussed here warrants special treatment. Given the thorough rejection of genetic exceptionalism, the burden of proof lies with RNTK proponents to make that case.

IV. CONCLUSION

The currently prevailing view about the RNTK involves an almost exclusive focus on the principle of autonomy. This pure autonomy view results in an environment where individual preferences must be actively sought and respected. At the other end of the spectrum, one can imagine an argument that completely relies on beneficence, justifying forced provision of genetic information whenever it could provide medical benefit to a given individual. In between, there seems to be a more centrist, qualified disclosure view. Embracing "libertarian paternalism,"⁴²² we could give patients a choice not to receive genetic information (even if that decision seems objectively unreasonable) but could also create a default package of recommended variants to disclose. This would function as a form of soft paternalism, helping to frame decision-making in a way that is thought to lead to more beneficial choices.

I reject the pure autonomy view for the reasons explored throughout this article. First, the philosophical basis for such a position seems shaky—susceptible to a range of at least plausible, if not convincing, challenges.⁴²³ Second, a legal analysis cannot support the claim that psychological integrity clearly deserves the same kind of protection afforded to bodily integrity.⁴²⁴ Third, there is reason to think people's instincts about the RNTK will shift away from a pure autonomy view as genomic medicine

420. See, e.g., Benjamin D. Solomon, *Incidentalomas in Genomics and Radiology*, 370 *NEW ENG. J. MED.* 988, 989 (2014) (explaining that the radiology analogy is flawed because after an incidental problem is discovered in that context, physicians can efficiently reach a diagnosis).

421. *Id.* at 990.

422. Cass Sunstein & Richard Thaler, *Libertarian Paternalism Is Not an Oxymoron*, 70 *U. CHI. L. REV.* 1159, 1160 (2003) (offering "libertarian paternalism" as acceptable to those who advocate freedom of choice on the grounds of welfare).

423. *Supra* Part III.

424. *Supra* Part IV.

becomes increasingly incorporated into everyday medical care.⁴²⁵ Fourth, there is a strong argument to make that a pure autonomy view could do more harm than good.⁴²⁶ Finally, if we widen the debate beyond a focus on autonomy, there are other considerations, such as moral distress and genetic exceptionalism that, while not dispositive on their own, weigh in favor of a more limited view of the RNTK.⁴²⁷

I cannot, however, endorse a pure beneficence view either. It seems too paternalistic to force information on someone who is actively resisting that knowledge. Libertarian paternalism is attractive, but partially fails because of concerns about our ability to accurately assess individual preferences for such a complex question. My view falls somewhere between the liberal paternalism and pure beneficence views. For high impact genetic information, I think that it is a mistake to actively solicit preferences. We should inform patients that there is a default set of high impact incidental findings that will be sought and returned. In the rare case that someone independently requests to not learn about this information, in-depth counseling should be provided to ensure that they fully understand the choice being made, but ultimately the decision should be honored if not knowing consistently remains their clearly stated preference. For high impact genetic information, any deviation from regular disclosure should be a clearly defined exception, rather than the basis for a broadly applied conception of the RNTK.

This approach should be relatively uncontroversial for the vast majority of people since most autonomous adults would want to know life-saving information. There are, however, a few predictable exceptions that should be anticipated and accommodated, namely, terminally ill patients, elderly individuals, and people with religious objections to treatment. These are all cases where clinical action would likely not be indicated, so it might be appropriate for medical providers to actively solicit preferences. These kinds of cases represent an important exception to my proposed approach, but I do not believe that we should institute a strong RNTK policy based on a small group that is relatively easy to bracket. The RNTK has become an ingrained part of our lexicon, and though I ultimately believe that we should abandon the term altogether, I recognize that this is unlikely. At the very least, a compelling case can be made that we should at least stop talking about the RNTK in such strong terms.

425. *Supra* Part V.A.

426. *Supra* Part V.B.

427. *Supra* Part V.C and V.D.