

# The Genetic Information Nondiscrimination Act at Age 10: GINA's Controversial Assertion that Data Transparency Protects Privacy and Civil Rights

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## THE GENETIC INFORMATION NONDISCRIMINATION ACT AT AGE 10: GINA'S CONTROVERSIAL ASSERTION THAT DATA TRANSPARENCY PROTECTS PRIVACY AND CIVIL RIGHTS

BARBARA J. EVANS\*

### ABSTRACT

*The genomic testing industry is an edifice built on data transparency: transparent and often unconsented sharing of our genetic information with researchers to fuel scientific discovery, transparent*

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*sharing of our test results to help regulators infer whether the tests are safe and effective, and transparent sharing of our health information to help treat other patients on the premise that we gain reciprocity of advantage when each person's health care is informed by the best available data about all of us. Transparency undeniably confers many social benefits but creates risks to the civil rights of the people whose genetic information is shared. Touted as a major civil rights law at the time of its passage, the Genetic Information Nondiscrimination Act of 2008 (GINA) has endured ten years of criticism that its protections are ineffectual, insufficient, or even unethical and overtly unsafe for the people it aims to protect. At the center of this controversy are provisions of GINA that expand people's access to genetic information that others store about them—a heavily contested assertion that data transparency implies sharing data not just with third parties, but with the people whose data are being shared. This Article traces the decades-long roots of this assertion and explores pathways to resolve the controversy that engulfs it. It is important to resolve this controversy. As GINA enters its second decade, genomics is finally starting to gain sufficient predictive power to support discriminatory and other nefarious uses that GINA was designed to prevent. We are entering a positive feedback loop in which the genomic research that exposes us to risk of unwanted data disclosures simultaneously fuels discoveries that make such disclosures potentially more damaging.*

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INTRODUCTION: GINA'S FIRST DECADE AND THE CHALLENGES  
AHEAD

The Genetic Information Nondiscrimination Act of 2008 (GINA) was born with high expectations.<sup>1</sup> The late Senator Edward Kennedy, who cosponsored the legislation, billed it as “the first major new civil rights bill of the new century.”<sup>2</sup> However, GINA celebrated its tenth anniversary last year amid festering doubt about its significance as a civil rights law.<sup>3</sup> Scholars dismiss GINA as having attacked two problems—genetic discrimination in employment and in health insurance—that, as far as the available evidence shows, never actually existed.<sup>4</sup> GINA fails to address problems, such as genetic discrimination in long-term care insurance, that genuinely trouble people who undergo genetic testing.<sup>5</sup> The centerpiece of GINA’s civil rights protections—an expanded right of transparency allowing individuals to access genetic information that third parties store about them—remains mired in controversy.<sup>6</sup> This Article explores the individual access right GINA created and explains why it is a crucial tool to protect people’s civil rights as genomic testing grows more common and more informative in coming years. A convoluted rulemaking history obscured GINA’s role in creating this important right,<sup>7</sup> and GINA enters its second

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1. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (codified as amended in scattered sections of 26, 29, and 42 U.S.C.).

2. Kathy L. Hudson et al., *Keeping Pace with the Times—The Genetic Information Nondiscrimination Act of 2008*, 358 NEW ENGL. J. MED. 2661, 2662 (2008).

3. See Jessica L. Roberts, *Preempting Discrimination: Lessons from the Genetic Information Nondiscrimination Act*, 63 VAND. L. REV. 439, 441 (2010).

4. See, e.g., *id.* (“While some examples do exist, both GINA’s advocates and adversaries agreed that scant evidence indicated a significant history of genetic-information discrimination.”).

5. See Triangle Privacy Research Hub, *Genomics, Precision Medicine, and Privacy—Refining Privacy to Improve Health Outcomes Symposium*, YOUTUBE (Nov. 8, 2017), <https://www.youtube.com/watch?v=zpgXeSZWnmk> [<https://perma.cc/NZU4-BVCM>]. Misha Rashkin’s statement, which can be found at 00:19:00, discusses some of the deficiencies of GINA.

6. See Barbara J. Evans, Commentary, *HIPAA’s Individual Right of Access to Genomic Data: Reconciling Safety and Civil Rights*, 102 AM. J. HUM. GENETICS 5, 5-8 (2018) (summarizing this controversy briefly); see also *infra* Part VII.A (explaining the controversy in detail).

7. See *infra* Part VIII.A (explaining the complex rulemaking history that obscured the

decade like a misunderstood teenager, struggling to be taken seriously as a civil rights law.

If GINA's alleged shortcomings caused no widespread harm over the past decade, this fact lends itself to two possible explanations: The first is that GINA addressed frivolous problems that did not matter in 2008 and, by implication, may not matter now. The second is that GINA addressed important problems and was thwarted in its initial attempt to do so, but somehow we lucked out and escaped serious harm, which still awaits unless we take steps now to ensure that GINA's essential civil rights protections work as Congress intended. I disclose that I lean toward this second view.

Congress enacted GINA during a period of enthusiasm that followed the completion of the Human Genome Project in the year 2000.<sup>8</sup> Those were heady times. When announcing initial results of that project, renowned geneticist Francis Collins declared, "Today, we celebrate the revelation of the first draft of the human book of life,"<sup>9</sup> and President Bill Clinton gushed, "[t]oday, we are learning the language in which God created life."<sup>10</sup> Scholars of the era likened genetic information to a "future diary" that is "uniquely powerful and uniquely personal" and able to "predict an individual's ... medical future" and foretell the future of one's family members.<sup>11</sup> People worried that a drop of spit on a discarded coffee cup or a strand of hair they shed on the street might enable others to infer deeply personal secrets: where they came from (for example, is their

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provenance of the access right GINA created).

8. See Press Release, White House, Remarks by the President, Prime Minister Tony Blair of England (Via Satellite), Dr. Francis Collins, Director of the National Human Genome Research Institute, and Dr. Craig Venter, President and Chief Scientific Officer, Celera Genomics Corporation, on the Completion of the First Survey of the Entire Human Genome Project (June 26, 2000), [http://www.ornl.gov/sci/techresources/Human\\_Genome/project/clinton2.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/project/clinton2.shtml) [<https://perma.cc/JGS5-AA2N>].

9. *Id.*

10. *Id.*

11. George J. Annas et al., *Drafting the Genetic Privacy Act: Science, Policy, and Practical Considerations*, 23 J.L. MED. & ETHICS 360, 360, 365 (1995).

ostensible father really their father?),<sup>12</sup> their mental defects and behavioral shortcomings,<sup>13</sup> and how and when they will die.<sup>14</sup>

GINA, in many respects, was Congress's response to a mass delusion that genetic information is more informative than, at least to date, it has proved to be.<sup>15</sup> As we now know, and as cooler heads knew back then, "[t]he argument from genetic prophecy is not compelling."<sup>16</sup> As of 2014, of the roughly 10,000 mutations that each of us has in our genomes,<sup>17</sup> fewer than 130 could be conclusively linked to a clinically significant health impact.<sup>18</sup> Behavioral genetics, after years of explaining practically nothing,<sup>19</sup> is only now beginning to have predictive power, which remains limited. Basic physical traits like height are influenced by hundreds of interacting genes, such that viewing people's genomes usually reveals little about how tall they are.<sup>20</sup> A 2010 study found that simple metrics,

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12. See Georgia Lowe et al., *How Should We Deal with Misattributed Paternity? A Survey of Law Public Attitudes*, 8 *AJOB EMPIRICAL BIOETHICS* 234, 234 (2017), <https://www.tandfonline.com/doi/pdf/10.1080/23294515.2017.1378751?needAccess=true> [<https://perma.cc/2N6S-JVNS>] (discussing "misattributed paternity, where the assumed father is not the biological father" and noting it is an incidental finding encountered in genetic testing).

13. Jennifer Kulynych & Henry T. Greely, *Clinical Genomics, Big Data, and Electronic Medical Records: Reconciling Patient Rights with Research When Privacy and Science Collide*, 4 *J.L. & BIOSCIENCES* 94, 98 (2017) (noting the growing body of knowledge linking genetics with some mental and behavioral characteristics).

14. See Annas et al., *supra* note 11, at 360 (discussing the presumed predictive power of genetics as a "future diary").

15. See 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, 61 (Mark A. Rothstein ed., 1997) (citing the past belief, circa 1995, that genetic information is "uniquely powerful"); *supra* notes 8-11 and accompanying text.

16. Murray, *supra* note 15, at 64.

17. Isaac S. Kohane et al., *Taxonomizing, Sizing, and Overcoming the Incidentalome*, 14 *GENETICS MED.* 399, 403 (2012).

18. Frederick E. Dewey et al., *Clinical Interpretation and Implications of Whole-Genome Sequencing*, 311 *JAMA* 1035, 1040 (2014).

19. See, e.g., Glenn I. Roisman & R. Chris Fraley, *The Limits of Genetic Influence: A Behavior-Genetic Analysis of Infant-Caregiver Relationship Quality and Temperament*, 77 *CHILD DEV.* 1656, 1658, 1663 (2006) (finding that "the role of genetic variation among infants is trivial," and questioning the "ubiquity of heritability effects in all domains of psychological inquiry").

20. See *Is Height Determined by Genetics?*, U.S. NAT'L LIBR. MED. (Nov. 13, 2018), <https://ghr.nlm.nih.gov/primer/traits/height> [<https://perma.cc/R8YZ-8BG5>] (noting that more than 700 gene variants have been discovered that influence height and that more discoveries are expected).



such as a person's waist circumference, are better at predicting future diabetes risk than genetic "models based on 20 common independently inherited alleles."<sup>21</sup>

If GINA failed in its first decade to save us from genetic discrimination, it may have been a harmless error because the human genome was too poorly understood at the time to lend itself to very many discriminatory uses.<sup>22</sup> If GINA failed, then so did the science, and it all somehow worked out. This does not imply, however, that GINA's civil rights protections are unimportant: they may simply have been premature.

Genetic science is rapidly gaining power to explain and predict.<sup>23</sup> As it does so, the potential for genetic discrimination and other inappropriate uses of genetic information grows more real than it was ten years ago when Congress enacted GINA.<sup>24</sup> It is no longer "mere theory or science fiction" that a hacker who misappropriates our genetic information will be able to infer personal characteristics such as our height, ethnicity, hair color, eye color, and facial features.<sup>25</sup> The plan for advancing our understanding of the human genome, and thus our ability to draw such inferences, relies on research that uses large datasets of genetic and other personal data, often without individual consent.<sup>26</sup> We are entering a positive feedback loop in which the research that exposes us to risk of unwanted data disclosures simultaneously fuels the discovery process that makes disclosures all the more damaging.<sup>27</sup> As GINA enters its second decade, the civil rights protections it affords are starting to matter. The goal of this Article is to open a debate about possible solutions to controversies that have undercut GINA's protections during its first decade.

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21. See Philippa J. Talmud et al., *Utility of Genetic and Non-Genetic Risk Factors in Prediction of Type 2 Diabetes: Whitehall II Prospective Cohort Study*, 340 *BMJ* b4838 (2010), <http://www.bmj.com/content/340/bmj.b4838> [<https://perma.cc/8C8K-4732>].

22. See Murray, *supra* note 15, at 64-65 (commenting in the mid-1990s and noting the weakness of genetic "prophecy").

23. See, e.g., Kulynych & Greely, *supra* note 13, at 104.

24. See *id.* at 96 (noting the expanding predictive power of genetic testing).

25. *Id.* at 100.

26. See *id.* at 105 (predicting increased exposure of sensitive information, including genetic information, to privacy risks as a result of research that relies on large datasets).

27. See *id.*

These controversies reflect a clash of competing regulatory paradigms. Passage of GINA expanded the federal regulatory program for genetic and genomic testing.<sup>28</sup> The program had long included consumer health and safety regulations (for brevity, “safety regulations”) that aim to protect the physical health and safety of people who undergo genetic and genomic testing. Examples of safety regulations include the U.S. Food and Drug Administration’s (FDA’s) oversight of in vitro diagnostic testing products,<sup>29</sup> the Centers for Medicare and Medicaid Services’ (CMS’s) oversight of clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988<sup>30</sup> (CLIA) regulations,<sup>31</sup> as well as aspects of federal research regulations that minimize physical safety risks to research participants.<sup>32</sup> GINA added a second layer of regulations: civil rights laws that address the social consequences of genetic testing.<sup>33</sup> For example, GINA bans unjust discrimination,<sup>34</sup> strengthens privacy protections,<sup>35</sup> and protects rights that foster fruitful human interactions, such as the rights to speak freely,<sup>36</sup> to receive information relevant to one’s decisionmaking,<sup>37</sup> to associate and assemble with others, to engage in scientific inquiry, and to participate in political life.<sup>38</sup>

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28. *See infra* Part VI.

29. *See* 21 U.S.C. § 321(h) (Supp. IV 2016) (defining FDA-regulated devices); 21 C.F.R. § 809.3(a) (2018) (defining in vitro diagnostic products, a category of medical devices that includes genetic and genomic testing products).

30. *See* Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903 (codified as amended at 42 U.S.C. § 263a).

31. 42 C.F.R. § 493 (2018).

32. *See, e.g.*, 45 C.F.R. § 46.111(a)(1) (2018) (requiring Institutional Review Boards (IRBs) overseeing research under the Common Rule to ensure that “[r]isks to subjects are minimized”); *see also* 21 C.F.R. § 56.111(a)(1) (2018) (imposing this same requirement on IRBs reviewing FDA regulated research); 21 C.F.R. §§ 312, 812 (2018) (outlining FDA’s investigational new drug and investigational device exemption regulations, which protect research participants from exposure to unreasonable levels of risk from experimental drugs and devices used in research).

33. James Buchwalter et al., *Definition and Nature of Civil Rights*, 14 C.J.S. § 1 (2018) (“A civil right refers to rights arising under federal and state civil rights laws and the federal and state constitutions, embracing the rights due from one to citizen to another, pertaining to a person by virtue of citizenship in a state or community.”).

34. *See infra* Part III.

35. *See infra* Part IV.B.

36. *See infra* Part IV.D.

37. *See infra* Part IV.B.

38. *See infra* Part IV.D.

The transition to a broader federal regulatory program for genetic testing has not gone smoothly. GINA led to the creation, in 2014,<sup>39</sup> of a federally protected, individual right of access<sup>40</sup> to genetic information stored at laboratories covered by the Health Insurance Portability and Accountability Act of 1996<sup>41</sup> (HIPAA) Privacy Rule, which is a major federal medical privacy regulation.<sup>42</sup> The 2014 Privacy Rule amendments expanded individuals' access to laboratory-held data,<sup>43</sup> including genetic and genomic information as well as assorted other diagnostic test results that laboratories hold in their files.<sup>44</sup> Insofar as these amendments pertain to genetic information, they were implementing a congressional civil rights mandate stated in GINA.<sup>45</sup> Failing to appreciate this fact, safety regulators and some members of the bioethics and medical communities have opposed HIPAA's right of access to genomic information, citing safety concerns.<sup>46</sup> These safety concerns are most intense with respect to genomic information generated during research.<sup>47</sup> Research data, for various reasons, may fall short of the quality standard suitable for use in clinical healthcare, but can affect people's civil rights and they need access to it.<sup>48</sup>

The compliance date for HIPAA-covered laboratories<sup>49</sup> to provide access to laboratory-held data was October 6, 2014.<sup>50</sup> Four years

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39. CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. 7290 (Feb. 6, 2014) (codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164).

40. 45 C.F.R. § 164.524 (2018).

41. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29 and 42 U.S.C.).

42. 45 C.F.R. pts. 160, 164.

43. See CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7290.

44. See *infra* Part VI.B.2.

45. See *infra* Part VIII.A.

46. See *infra* Part VII.

47. See *infra* Part VII.A.1.

48. See *infra* Part II.

49. See 45 C.F.R. § 160.102 (2018) (providing that the HIPAA regulations, including the Privacy Rule, apply to healthcare providers such as physicians, clinics, hospitals, laboratories and various other entities, such as insurers, that transmit "any health information in electronic form in connection with a transaction covered by this subchapter [the Administrative Simplification provisions of HIPAA]" and to their business associates); see also *id.* § 160.103 (defining the terms "covered entity" and "business associate").

50. CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. 7290, 7292 (Feb. 6, 2014) (codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164).

later, many individuals face ongoing problems accessing their data.<sup>51</sup> Steven Keating, diagnosed with brain cancer while pursuing Ph.D. studies several years ago, has chronicled his saga to overcome the access barriers this Article discusses.<sup>52</sup> After surgery, he donated his tumor tissue to a research study, assuming he would have access to the genome sequencing results, but he was denied access based on concerns that the research laboratory was not certified under the CLIA regulations.<sup>53</sup> “I wanted to see my sequence and share it with the world to benefit science. Instead, the reward for donating valuable tumor tissue was a legal barrier preventing me from seeing my future.”<sup>54</sup>

Genomic research laboratories are caught in a crossfire of conflicting directives from three subagencies within the U.S. Department of Health and Human Services (HHS). The three are: (1) the FDA, which regulates medical devices including some genetic and genomic testing products;<sup>55</sup> (2) the CMS, which regulates clinical laboratories under its CLIA program;<sup>56</sup> and (3) the Office for Civil Rights (OCR), which administers the HIPAA Privacy Rule.<sup>57</sup> Many researchers additionally find themselves squeezed between HIPAA’s apparent directive to grant individual access and an

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51. See, e.g., Steven Keating, *Can a Hospital “Share” Button Save Us?*, GENOME MAG. (Mar. 13, 2017), <http://genomemag.com/can-a-hospital-share-button-save-us/> [<https://perma.cc/E2ZQ-G54R>]; see also Carolyn T. Lye et al., *Assessment of U.S. Hospital Compliance with Regulations for Patients’ Requests for Medical Records*, JAMA NETWORK OPEN (Oct. 5, 2018), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2705850> [<https://perma.cc/8J9J-QKM3>] (providing empirical data demonstrating the difficulty individuals experience exercising their HIPAA access rights).

52. See Keating, *supra* note 51; see also K. McGowan, *The Man Who Dissected His Own Brain*, WIRED (Feb. 11, 2016, 12:00 AM), <https://www.wired.com/2016/02/the-man-who-dissected-his-own-brain/> [<https://perma.cc/YLE7-FYSA>] (interviewing Keating).

53. See Keating, *supra* note 51.

54. See *id.*

55. See *Regulation of Genetic Tests*, NAT’L HUM. GENOME RES. INST. (Jan. 17, 2018), <https://www.genome.gov/10002335/regulation-of-genetic-tests/> [<https://perma.cc/9TGB-ET7W>].

56. See *id.*

57. Cf. *Genetic Information*, U.S. DEP’T HEALTH & HUM. SERV. (June 16, 2017), <https://www.hhs.gov/hipaa/for-professional/special-topics/genetic-information/index.html> [<https://perma.cc/8UAS-N2L4>].

Institutional Review Board (IRB)<sup>58</sup> that considers it unethical to do so under various federal research regulations.<sup>59</sup>

This Article ascribes these conflicts to growing pains within an evolving federal regulatory program for genomic testing.<sup>60</sup> As new civil rights protections were added after GINA, they were not adeptly<sup>61</sup> integrated into the fabric of preexisting safety regulations. The first step toward successful integration is to understand that HIPAA's access right is not a safety regulation and should not be judged as such.<sup>62</sup> Rather, it is a regulation that aims to balance privacy and transparency in a way that allows socially beneficial uses of genomic data while protecting people's civil rights.<sup>63</sup> It rests on legal precedents that date back to the 1970s and has clear ethical justifications enunciated in studies Congress commissioned at two critical junctures; first, as the modern information age started to unfold in the 1970s and, second, as the Human Genome Project began to bear fruit in the late 1990s.<sup>64</sup>

Recent debate about HIPAA's access right is often couched in bioethical and safety-related terms: Is individual access to genomic data normatively justified, consistent with bioethical standards, and safe? And if not, can consumer safety regulators like FDA and CMS find jurisdiction to block HIPAA access? This Article argues that these are not appropriate questions to ask about a federally protected civil right. Civil rights enjoy a special status in U.S. federal law. Public officials—including safety regulators—are obliged to respect people's civil rights.<sup>65</sup> The most fruitful way forward is to

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58. An Institutional Review Board is a private ethics review body that oversees the ethical conduct of research at institutions regulated by the Federal Policy for the Protection of Human Subjects (Common Rule). *See* 45 C.F.R. § 46.101(a) (2018).

59. *See supra* note 32 (listing examples of federal research regulations that prescribe the use of IRBs).

60. *See infra* Part VII.

61. *See infra* Part VII.

62. *See* Evans, *supra* note 6, at 5.

63. *See generally* Barbara J. Evans, *The Interplay of Privacy and Transparency in Health Care: The HIPAA Privacy Rule as a Case Study*, in *TRANSPARENCY IN HEALTH AND HEALTH CARE IN THE UNITED STATES: LAW AND ETHICS* (Holly Fernandez Lynch, I. Glenn Cohen, Carmel Shachar & Barbara J. Evans eds., forthcoming 2019) (reviewing HHS's efforts, when designing the Privacy Rule, to balance socially beneficial data uses with the individual's interest in privacy).

64. *See infra* Part VII.B.

65. *See, e.g.*, 18 U.S.C. § 242 (2012); *see also infra* Part VII.A.

look for approaches that affirm people’s civil rights while making the exercise of those rights as safe as it possibly can be—recognizing, however, that civil rights have never been cost-free, and autonomous individuals often embrace risks to claim their civil rights. This Article identifies legally workable options for advancing safety, bioethical values, and civil rights simultaneously, so that GINA can achieve its original promise, which was to protect genomic civil rights.<sup>66</sup>

### I. CIVIL RIGHTS IN BIOETHICAL DISCOURSE

After a recent article referred to HIPAA access as a civil right,<sup>67</sup> it drew protests from some scientists and bioethicists who regard such language as provocative.<sup>68</sup> No provocation is intended. Whatever special valence the term “civil right” may have in popular culture, it has a simple dictionary meaning, which is the intended meaning here.<sup>69</sup> Civil rights are legally enforceable rights and protections within the social and political spheres.<sup>70</sup> “Enforceable” means that people whose civil rights are violated can seek redress, such as monetary damages or an injunction to force others to respect their rights.<sup>71</sup> Civil rights are legal creations, protected by laws such as the U.S. Constitution, federal and state statutes, and regulations implementing those statutes.<sup>72</sup>

Civil rights differ from natural rights that inhere in the nature of persons, from moral and bioethical claims of right that are not legally enforceable, and from rights incidental to the ownership of property.<sup>73</sup> On this last point, civil rights generally attach to people,

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66. See *infra* Part VIII.

67. See Evans, *supra* note 6.

68. See, e.g., Jennifer C. Dreyfus & Mark E. Sobel, *Concern About Justifying the Release of Genomic Data as a Civil Right*, 103 AM. J. HUM. GENETICS 163, 163-65 (2018) (expressing concern, in a letter to the editor, about characterizing HIPAA’s access right as a civil right).

69. See, e.g., *Civil Rights*, BLACK’S LAW DICTIONARY (10th ed. 2014) (defining “civil right” as “Any of the individual rights of personal liberty guaranteed by the Bill of Rights and by the 13th, 14th, 15th, and 19th Amendments, as well as by legislation such as the Voting Rights Act. Civil rights include esp[ecially] the right to vote, the right of due process, and the right of equal protection under the law”).

70. See Buchwalter et al., *supra* note 33, § 1.

71. *Id.*

72. See *id.*

73. See *id.* § 3.

not to property.<sup>74</sup> Data ownership, if it existed, would grant rights for owners to use, access, and control their data, but these rights seemingly would evaporate when owners transfer their data to someone else: property rights generally run with the property and pass to the next owner.<sup>75</sup> Jessica Roberts correctly observes that a property right in one's own genetic information could be designed in a way that affords significant protection of individual rights.<sup>76</sup> Conceivably, genetic data ownership might be defined as including an ongoing right of access to one's data that endures even after the data are sold or transferred to another person. To date, however, this has not occurred. Several states have enacted laws granting individuals a property interest in their own genetic information,<sup>77</sup> and a few more states have considered such legislation.<sup>78</sup> But such laws are generally vague about what genetic property rights entail,<sup>79</sup> and none provides a right of ongoing access after transfer or sale.<sup>80</sup> Popular discourse about genetic data ownership often draws an analogy to fee simple ownership of a house.<sup>81</sup> The popular

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74. See *id.* (noting that civil rights “pertain originally and essentially to humans”).

75. Cf. *id.*

76. See Jessica L. Roberts, *Progressive Genetic Ownership*, 93 NOTRE DAME L. REV. 1105, 1148 (2018).

77. See SETH AXELRAD, AM. SOC'Y OF LAW, MED. & ETHICS, STATE STATUTES DECLARING GENETIC INFORMATION TO BE PERSONAL PROPERTY, [https://www.aslme.org/dna\\_04/reports/axelrad4.pdf](https://www.aslme.org/dna_04/reports/axelrad4.pdf) [<https://perma.cc/T2T2-7XGN>] (listing statutes in Alaska, Colorado, Florida, and Georgia that recognize individual property rights in genetic information); see also ALASKA STAT. § 18.13.010(a)(2) (2018); COLO. REV. STAT. § 10-3-1104.7(1)(a) (2018); FLA. STAT. § 760.40(2)(a) (2018); GA. CODE ANN. § 33-54-1(1) (2018).

78. See, e.g., H.B. 1220, 84th Legis. Sess. (Tex. 2015); H.B. 1260, 87th Legis. Assemb., Reg. Sess. (S.D. 2012); H.B. 2110, 82d Legis. Sess. (Tex. 2011).

79. See, e.g., Jennifer K. Wagner & Dan Vorhaus, *On Genetic Rights and States: A Look at South Dakota and Around the U.S.*, PRIVACY REP. (Mar. 20, 2012), <https://theprivacyreport.com/2012/03/20/on-genetic-rights-and-states-a-look-at-south-dakota-and-around-the-u-s/> [<https://perma.cc/JNX2-83N9>] (discussing the areas of ambiguity in South Dakota's proposed bill).

80. See ALA. CODE § 18.13.010 (2018); COLO. REV. STAT. § 10-3-1104.7 (2018); FLA. STAT. § 760.40 (2018); GA. CODE ANN. § 33-54-1 (2018).

81. See Barbara J. Evans, *Much Ado About Data Ownership*, 25 HARV. J.L. & TECH. 69, 89 (2011) (noting the vagueness of many data ownership proposals and suggesting that individual data ownership would differ from *fee simple* ownership of a house and might resemble riparian ownership or copyright); Roberts, *supra* note 76, at 1169-71; see also Mark A. Hall & Kevin A. Schulman, Commentary, *Ownership of Medical Information*, 301 JAMA 1282, 1283-84 (2009) (noting the popular tendency to liken data ownership to fee simple ownership but pointing out that data ownership would differ from familiar “[o]wnership of houses and cars”).

conception of home ownership has never included a right for former owners to enjoy ongoing access to sit in the living room after a sale. Thus, it seems unlikely that genetic data ownership, if it existed, would provide an inalienable, enduring right of access to one's own data wherever the data happened to be stored.

In a similar fashion, a bioethical right of informed consent offers few ongoing protections once consent is improvidently granted to a downstream data user who distributes one's data carelessly and widely.<sup>82</sup> Withdrawing consent may—but does not always—block recipients' further use of a person's data, nor is it an effective way to force privacy, data security, data destruction, and data transfer policies to guard consenters' civil rights.<sup>83</sup>

A law creating data-related civil rights, in contrast, could be drafted in a way that gives people ongoing access to, control over, and protections for their data even when the data are held by others. GINA's drafters appreciated the limits of consent and ownership as mechanisms to address the concerns people feel about storage, use, and disclosure of their genetic information.<sup>84</sup> GINA instead embraced a civil rights approach.<sup>85</sup> Civil rights are simply a different legal technique for protecting some of the same individual interests that many bioethicists and property theorists also seek to protect.<sup>86</sup>

The field of bioethics has always been attentive to civil rights-related issues—for example, privacy, stigmatization and discrimination, and the need to be informed when consenting to uses of one's data.<sup>87</sup> But bioethical literature rarely frames these issues in the

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82. See, e.g., Fred H. Cate, *Protecting Privacy in Health Research: The Limits of Individual Choice*, 98 CALIF. L. REV. 1765, 1797 (2010) (“Consent requirements [imposed by the HIPAA Privacy Rule] not only impede health research, but may actually undermine privacy interests.”).

83. See generally PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., EXEC. OFFICE OF THE PRESIDENT, REPORT TO THE PRESIDENT: REALIZING THE FULL POTENTIAL OF HEALTH INFORMATION TECHNOLOGY TO IMPROVE HEALTHCARE FOR AMERICANS: THE PATH FORWARD 2, 28 (2010), <https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf> [<https://perma.cc/33NN-9YMT>] (discussing the weakness of informed consent as a mechanism to protect data privacy and security).

84. See Hudson, *supra* note 2, at 2662 (noting weaknesses in the framework of genetic privacy protections prior to GINA).

85. See *id.* (characterizing GINA as a civil rights law); *infra* Part II.

86. See *supra* notes 73-81 and accompanying text.

87. See, e.g., SEC'Y'S ADVISORY COMM. ON GENETIC TESTING, NAT'L INST. OF HEALTH,



language of civil rights. This may reflect historical factors. The Secretary's Advisory Committee on Genetic Testing (SACGT), working in the late 1990s while the Human Genome Project was still a work in progress, identified four criteria for assessing the benefits and risks of genetic testing: analytic validity,<sup>88</sup> clinical validity,<sup>89</sup> clinical utility<sup>90</sup> (sometimes called "actionability"),<sup>91</sup> and social consequences.<sup>92</sup> Public comments confirmed that these criteria capture concerns people feel about the safety of genetic testing.<sup>93</sup>

The SACGT's formulation appended social consequences—a focus of civil rights law—to the end of a list of safety-related criteria.<sup>94</sup> This suggested a mindset that civil rights are subordinate to safety or—worse—it suggested a complete blurring of the two as if social consequences are part of the risk/benefit ratio safety regulators should use to assess whether genetic testing is safe.<sup>95</sup> In practice,

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ENHANCING THE OVERSIGHT OF GENETIC TESTS: RECOMMENDATIONS OF THE SACGT 8, 20 (2000), [https://osp.od.nih.gov/wp-content/uploads/2013/11/oversight\\_report.pdf](https://osp.od.nih.gov/wp-content/uploads/2013/11/oversight_report.pdf) [<https://perma.cc/83C3-MGK2>].

88. *See id.* at 15 n.10 (explaining that analytical validity is an indicator of how well a test measures the property or characteristic it is intended to measure and addresses such matters as the test's accuracy, rate of false positives and negatives, and reliability in the sense of repeatedly getting the same result).

89. *See id.* at 15 n.11 (explaining that clinical validity refers to the accuracy with which a test predicts the presence or absence of a clinical condition or predisposition, addressing whether there is a strong and well validated association between having a particular gene variant and having a particular health condition, and asking whether knowing that a person has the gene variant offers meaningful insight into the person's health or reproductive risks); *see also* 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 Institute Working Group*, 3 *CIRCULATION CARDIOVASCULAR GENETICS* 574, 575 (2010) (expressing this concept by stating that a test result has an "established" meaning).

90. *See* SEC'Y'S ADVISORY COMM. ON GENETIC TESTING, *supra* note 87, at 15 n.12 ("Clinical utility refers to the usefulness of the test and the value of the information to the person being tested. If a test has utility, it means that the results—positive or negative—provide information that is of value to the person being tested because he or she can use that information to seek an effective treatment or preventive strategy. Even if no interventions are available to treat or prevent the disease or condition, there may be benefits associated with knowledge of the result.").

91. *See* Fabsitz et al., *supra* note 89, at 575 ("Actionable means that disclosure has the potential to lead to an improved health outcome; there must be established therapeutic or preventive interventions available or other available actions that may change the course of the disease.").

92. *See* SEC'Y'S ADVISORY COMM. ON GENETIC TESTING, *supra* note 87, at 15.

93. *See id.*

94. *See id.*

95. *See, e.g.*, OFFICE OF TECH. ASSESSMENT, CONG. OF THE U.S., *ASSESSING THE EFFICACY*

consumer safety regulators like FDA and CMS have neither the legal authority nor appropriate staffing to address social aspects of technologies they regulate; separate federal agencies administer civil rights regulations.<sup>96</sup>

Bioethical discourse about safety and civil rights has been further blurred because the traditional Common Rule<sup>97</sup> (the longstanding federal research regulation, for which 2017 amendments took effect in January 2019)<sup>98</sup> combined both types of regulation. The traditional Common Rule engaged ethics review bodies, known as IRBs, in a safety regulatory function when minimizing the physical risks of research, but in a civil rights function when assessing privacy risks in informational research that stores, discloses, or uses people's data or when assessing the adequacy of informed consent.<sup>99</sup> These mixed oversight responsibilities perhaps made sense when the Common Rule was drafted in the late 1970s and 1980s because the HIPAA Privacy Rule did not yet exist.<sup>100</sup> The traditional Common Rule—the federal regulation that is most familiar to many bioethicists—was a muddle of safety and civil rights law.<sup>101</sup> This

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AND SAFETY OF MEDICAL TECHNOLOGIES 17-18 (1978) (conceiving medical product safety as a risk/benefit ratio with a product deemed “safe” if its risks are acceptable in relation to its benefits).

96. See *Office for Civil Rights (OCR)*, U.S. DEP'T HEALTH & HUM. SERVS., <https://www.hhs.gov/ocr/index.html> [<https://perma.cc/F6S6-NCMR>] (describing the separate subagency within HHS that is responsible for civil rights enforcement); see also *Civil Rights Enforcement Through Other Agencies*, U.S. DEP'T HEALTH & HUM. SERVS. (Dec. 15, 2015), <https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/enforcement-other-agencies/index.html> [<https://perma.cc/HH3L-TTRK>].

97. See Basic HHS Policy for Protection of Human Research Subjects (Common Rule), 45 C.F.R. pt. 46, subpt. A (2018).

98. See Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46 and in various other regulations of implementing agencies); see also Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects, 83 Fed. Reg. 2885 (Jan. 22, 2018) (extending the effective date of the new Common Rule until July 19, 2018); Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period, 83 Fed. Reg. 28,497 (June 19, 2018) (further delaying implementation until January 21, 2019).

99. See Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7149, 7154.

100. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164) (finalizing the HIPAA Privacy Rule in December 2000).

101. See 45 C.F.R. pt. 46.

may have suggested that blurring safety and civil rights is normal in regulatory practice when, in fact, it is not.

A major goal of the 2017 Common Rule revisions was to disentangle safety and civil rights by ceding civil-rights oversight to the HIPAA regulations and focusing the Common Rule on the physical risks of research—that is, on safety issues.<sup>102</sup> Under the revised Common Rule, uses and disclosures of data that are subject to HIPAA regulation as research, public health, or health care operations will be exempt from the Common Rule.<sup>103</sup> In other words, the Common Rule will no longer regulate these activities.<sup>104</sup> The preamble to the 2017 Final Rule explains that this exemption avoids duplication in cases where data privacy is already protected by HIPAA.<sup>105</sup> This change may help distinguish the concepts of safety and civil rights in future bioethical discourse. Common Rule IRBs will still have residual oversight responsibilities for data privacy in contexts where HIPAA does not apply, so some mixing of responsibilities will continue.<sup>106</sup>

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102. *See, e.g.*, Federal Policy for the Protection of Human Subjects: Notice of Proposed Rulemaking, 80 Fed. Reg. 53,933 (proposed Sept. 8, 2015); Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,514 (advance notice of proposed rulemaking provided July 26, 2011) (discussing the benefits of reducing Common Rule oversight of privacy risks in HIPAA-regulated informational research).

103. *See* Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7261-62 (adopting a new regulation at § 46.104(d)(4)(iii) which provides, “[e]xcept as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy: ... (4) Secondary research ... [t]he research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ‘health care operations’ or ‘research’ as those terms are defined at 45 CFR 164.501 or for ‘public health activities and purposes’ as described under 45 CFR 164.512(b)”).

104. *See supra* note 98.

105. *See* Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7194 (“HIPAA also provides protections in the research context for the information that would be subject to this exemption (e.g., clinical records), such that additional Common Rule requirements for consent should be unnecessary in those contexts.... This provision introduces a clearer distinction between when the Common Rule and the HIPAA Privacy Rule apply to research in order to avoid duplication of regulatory burden. We believe that the HIPAA protections are adequate for this type of research, and that it is unduly burdensome and confusing to require applying the protections of both HIPAA and an additional set of protections.”).

106. *See* 45 C.F.R. § 46.104(d)(4)(iii) (2018).

The historical blurring of safety and civil rights in bioethics disguised a problem that is glaringly evident after GINA. Safety and civil rights regulations are distinct bodies of law serving different objectives that sometimes call for conflicting policies on particular issues, such as “whether individual access to genomic data should be narrow or broad.”<sup>107</sup> This Article explores how—and why—safety and civil rights collided after GINA and possible ways to reconcile the two.

## II. FORMALIZING GENOMIC CIVIL RIGHTS AFTER GINA

GINA marked a shift to a more formal federal regulatory structure to address the social consequences of genetic testing.<sup>108</sup> Informal oversight, as opposed to governmental regulation, had long been part of the framework to protect individuals who undergo genetic and genomic testing. In the early 1990s, when Congress established the National Center for Human Genome Research,<sup>109</sup> Congress called for “not less than’ 5% of the [National Institutes of Health (NIH)] Human Genome Project budget to be set aside for research on the ethical, legal, and social implications of genomic science.”<sup>110</sup> The resulting Ethical, Legal, and Social Implications (ELSI) research program is estimated to have funded over 480 scholarly research projects costing more than \$300 million by 2014.<sup>111</sup> This program has been described as a mechanism through which Congress “legislatively instantiated” its commitment to address the social consequences of genetic and genomic testing.<sup>112</sup> “Instantiate” is not a legal term; it simply means to provide an

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107. See Evans, *supra* note 6, at 7.

108. See Hudson et al., *supra* note 2, at 2661-62 (summarizing GINA’s protections).

109. This Center is now known as the National Human Genome Research Institute within the National Institutes of Health (NIH). See *About the Institute*, NAT’L HUM. GENOME RES. INST. (Feb. 16, 2018), <https://www.genome.gov/27534788/about-the-institute/> [<https://perma.cc/325N-RWXC>].

110. Jean E. McEwen et al., *The Ethical, Legal, and Social Implications Program of the National Human Genome Research Institute: Reflections on an Ongoing Experiment*, 15 ANN. REV. GENOMICS & HUM. GENETICS 481, 482 (2014) (quoting the National Institutes of Health Revitalization Act of 1993 § 1521, Pub. L. No. 103-43, 107 Stat. 122, 180 (1993)).

111. *Id.* at 483.

112. *Id.* at 482.

example or a specific instance.<sup>113</sup> If it seemed that Congress was appointing ELSI scholars to regulate the social consequences of genetic testing, this was just a pleasant scholarly conceit. Congress had other plans.

GINA emerged in 2008 at a critical juncture when genomic testing was maturing from a research pursuit into a vibrant clinical and consumer testing industry that routinely stores, shares, and uses large volumes of personal data in ways that the tested individuals may not even be aware of.<sup>114</sup> GINA is most famous for addressing two narrow problems: genetic discrimination in employment and in health insurance.<sup>115</sup> Its broader significance as a genomic civil rights law lay in two low-key provisions in which Congress defined the types of genetic information that raise civil rights concerns<sup>116</sup> and appointed a federal regulator with broad rulemaking authority to address those concerns.<sup>117</sup>

Section 102 of GINA defines the “genetic information” that, in Congress’s view, has the potential to affect people’s civil rights.<sup>118</sup> This definition includes virtually any information that a genetic test may reveal about a person, as well as other genetic information that can be inferred from genetic tests and manifest disease of the person’s family members.<sup>119</sup> GINA’s definition pays no heed to whether the information is reliable or unreliable, clinically significant or

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113. See *Instantiate*, MERRIAM WEBSTER (2018), <https://www.merriam-webster.com/dictionary/instantiate> [<https://perma.cc/5V5Y-8PDS>].

114. See Kulynych & Greely, *supra* note 13, at 94-95 (noting “[w]idespread use of medical records for research, without consent” and noting the increased presence of genomic information in medical records (emphasis omitted)).

115. Jessica L. Roberts, *The Genetic Information Nondiscrimination Act as an Antidiscrimination Law*, 86 NOTRE DAME L. REV. 597, 632 (2011) (explaining that GINA took an anticlassification approach that “comprehensively prohibits health insurers and employers from considering genetic information”); *id.* at 597 (noting that GINA “protects individuals from any intentional differential treatment by health insurers or employers based on genetic information”).

116. Genetic Information Nondiscrimination Act of 2008 § 102(a)(4), 42 U.S.C. § 300gg-91(d)(15)-(19) (2012).

117. *Id.* § 105 (codified at 42 U.S.C. § 1320d-9).

118. See *id.* § 102(a)(4) (codified at 42 U.S.C. § 300gg-91(d)(16)(A)) (amending the Public Health Service Act at 42 U.S.C. § 300gg-91(d) to define genetic information as meaning, “with respect to any individual, information about—(i) such individual’s genetic tests, (ii) the genetic tests of family members of such individual, and (iii) the manifestation of a disease or disorder in family members of such individual”).

119. *Id.*

not, or whether it was generated in a research or clinical laboratory.<sup>120</sup>

This definition opened a gulf between consumer safety regulations and genomic civil rights regulations. Central tenets of safety regulation are that genetic information is potentially dangerous unless it meets quality standards appropriate for clinical health care,<sup>121</sup> and that data generated during research should be shared with individuals only if the information can be confidently traced to the individual and has analytic validity, clinical validity, and/or clinical utility/actionability.<sup>122</sup> Before GINA, there was ongoing

120. *See generally id.*

121. *See, e.g.*, FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., OPTIMIZING FDA'S REGULATORY OVERSIGHT OF NEXT GENERATION SEQUENCING DIAGNOSTIC TESTS—PRELIMINARY DISCUSSION PAPER (Dec. 29, 2014), <https://www.fda.gov/downloads/medicaldevices/newsevents/workshopsconferences/ucm427869.pdf> [<https://perma.cc/837T-BQLT>] (focusing on analytical performance and clinical performance—that is, analytic and clinical validity—as key aspects of whether genomic tests are safe for clinical uses and providing examples of misdiagnoses and other harms that might occur if tests lack these attributes).

122. *See, e.g.*, 1 NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE 71 (1999) (“Experts disagree about whether findings from research should be communicated to [research participants], although most do believe that findings should not be conveyed unless they are confirmed and reliable and constitute clinically significant or scientifically relevant information. Those who oppose revealing unconfirmed findings argue that the harms that could result from revealing preliminary data are serious, including anxiety or unnecessary (and possibly harmful) medical interventions.”); 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, 1037 (2006) (counseling “extreme caution” in returning results that are preliminary and not validated by other studies). Analytic validity is widely viewed as the bare minimum quality standard for return of results from research. *See, e.g.*, Susan M. Wolf, *The Role of Law in the Debate over Return of Research Results and Incidental Findings: The Challenge of Developing Law for Translational Science*, 13 MINN. J.L. SCI. & TECH. 435, 446 (2012) (noting “a near-universal demand [in the literature] for analytic validity as a precondition” for returning results and incidental findings). Many commentators would require, in addition, that the results should have some level of clinical significance (clinical validity and/or utility). *See, e.g.*, Karen J. Maschke, *Returning Genetic Research Results: Considerations for Existing No-Return and Future Biobanks*, 13 MINN. J.L. SCI. & TECH. 559, 559 (2012) (citing the fact that most genetic research results have uncertain clinical significance as a reason why many biobanks adopt a “no-return policy”); Susan M. Wolf et al., *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36 J.L. MED. & ETHICS 219, 235 (2008) (noting that many commentators call for results to be returned only if they have clinical validity, that is, a well-established clinical or reproductive significance); *id.* at 231 (“Disclosure should occur only when findings are valid and confirmed, have significant health implications, and the health problem can be treated.”); *see also* Fabsitz et al., *supra* note 89, at 578 (noting the controversy surrounding return of results that have personal utility but not clinical significance/validity/utility). *But see* Ingrid A. Holman & Patrick L. Taylor, *The Informed*

debate within the bioethics community about whether individual findings from genetic and genomic research even amount to genetic *information*.<sup>123</sup> An influential 1999 report by the National Bioethics Advisory Commission opined that “preliminary results do not yet constitute ‘information’ since ‘until an initial finding is confirmed, there is no reliable information’ to communicate to subjects.”<sup>124</sup> The perception that unreliable genetic findings are not genetic information reflects a consumer health and safety regulatory mindset.

GINA recognized that protecting civil rights requires a different mindset. People can be deprived of civil rights based on unreliable as well as reliable information that is attributed to them; indeed, unreliable data are sometimes the most damaging. If somebody else’s data are in your file as a result of a laboratory error, the data obviously are useless and potentially even dangerous from a medical standpoint,<sup>125</sup> but can also affect your civil rights. You could face genetic discrimination if a sicker person’s information is wrongly attributed to you. To discover and correct the error—and protect your civil rights—you need access to the data that are (rightly or wrongly) stored under your name. Variants with uncertain clinical significance (or no clinical significance at all) can imperil a person’s civil rights. For example, the Combined DNA Index System (CODIS) genetic markers that law enforcement agencies use to identify suspected criminals are from noncoding regions of the genome<sup>126</sup> and have no clinical validity or utility whatsoever.<sup>127</sup> Still, if a research

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*Cohort Oversight Board: From Values to Architecture*, 13 MINN. J.L. SCI. & TECH. 669, 676 (2012) (supporting disclosure of information even if its clinical significance is uncertain but requiring that it be analytically valid).

123. See NAT’L BIOETHICS ADVISORY COMM’N, *supra* note 122, at 71-72.

124. See *id.* at 71 (quoting Charles R. MacKay, *Ethical Issues in Research Design and Conduct: Developing a Test to Detect Carriers of Huntington’s Disease*, 6 IRB 1, 3 (1984)).

125. See FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 121 (noting that inaccurate genomic tests “can lead to patients receiving the wrong diagnosis, the wrong treatment or no treatment at all even when effective therapy is available” (internal citations omitted); see also Ellen Gabler, *Weak Oversight Allows Lab Failures to Put Patients at Risk*, J.SENTINEL (May 17, 2015, 12:00 PM), <http://archive.jsonline.com/watchdog/watchdog-reports/weak-oversight-allows-lab-failures-to-put-patients-at-risk-303445851.html> [<https://perma.cc/V3H4-KBMU>] (providing examples of medical harms that can occur as a result of mix-ups and misdiagnoses in the laboratory setting).

126. See *What Is CODIS?*, NAT’L INST. JUST. (July 16, 2010), <https://www.nij.gov/journals/266/Pages/backlogs-codis.aspx> [<https://perma.cc/2RJJ-JLWW>] (describing the FBI’s Combined DNA Index System and its uses).

127. See D.H. Kaye, *Please, Let’s Bury the Junk: The CODIS Loci and the Revelation of*

laboratory stores people's CODIS markers in their genome sequencing files, these data later could be used to link them (or one of their family members) to a crime.<sup>128</sup> Worse still, if someone else's CODIS markers are in their files because of a laboratory mix-up, they could be falsely accused.<sup>129</sup>

Section 105 of GINA ordered the Secretary of HHS to place all genetic information held at HIPAA-covered facilities under the protection of the HIPAA regulations.<sup>130</sup> Since it was first promulgated in December 2000,<sup>131</sup> the HIPAA Privacy Rule has provided privacy protections for "health information" (often referred to as protected health information or "PHI," the information that HIPAA protects).<sup>132</sup> However, the definition of "health information" has changed over time. The 1996 HIPAA statute supplied a definition of this term.<sup>133</sup> The problem with this 1996 definition was that it only seemed to include genetic information that had a well-established relationship to a health condition.<sup>134</sup> Genetic information with analytic validity, clinical validity, and clinical utility seemed to qualify

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*Private Information*, 102 NW. U. L. REV. COLLOQUY 70, 81 (2007).

128. See *What is CODIS?*, *supra* note 126.

129. See Sarah Rackley Olson, *CODIS: Combined DNA Index System*, FORENSIC SCI. N.C. (Sept. 13, 2011, 2:38 AM), <https://ncforensics.wordpress.com/2011/09/13/codis-combined-dna-index-system/> [https://perma.cc/6ZFP-MVQP].

130. See Genetic Information Nondiscrimination Act 2008 § 105(a), 42 U.S.C. § 1320d-9(a) (2012) (calling, in the section entitled "Application of the HIPAA Regulations to Genetic Information," for HHS/OCR to amend the definition of "protected health information" that HIPAA protects to include all of the genetic information within GINA's broad definition and ordering the Secretary of Health and Human Services to implement the change within one year); see also 42 U.S.C. § 1320d-9(b)(1) (stating, in a new section introduced by GINA's § 105, that Congress deems "genetic information," as broadly defined by GINA at 42 U.S.C. § 300gg-91, to be health information, for purposes of making it subject to HIPAA's privacy protections).

131. See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164) (promulgating the original HIPAA Privacy Rule).

132. 45 C.F.R. § 160.103 (2001).

133. See 42 U.S.C. § 1320d(4) (2012) ("The term 'health information' means any information, whether oral or recorded in any form or medium, that—(A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.").

134. See *id.*



as “health information” and enjoy HIPAA’s privacy protections.<sup>135</sup> This protected, for example, the fact that a person has a genetic variant known to be associated with diabetes, Huntington’s disease, cystic fibrosis, or high blood pressure. But genetic findings lacking clear associations with health conditions were not clearly subject to HIPAA’s privacy protections.<sup>136</sup> Thus, the original Privacy Rule did not seem to protect genetic information bearing on a person’s behavior, intellect, criminal tendencies, athletic prowess, or physical appearance, or the fact that a person has variants for which the significance is not yet understood.<sup>137</sup> This left an important gap in privacy protection as genomic testing grew more common in recent years.

Unlike traditional genetic tests that examine a discrete number of specific genes already known to have a clinically significant relationship to human health, genomic tests scan a large swathe of a person’s genome.<sup>138</sup> Each of us has on the order of three million genetic variants—the modern euphemism for mutations—in our whole genomes (the entirety of our genetic material), and we have about 10,000 variants in our exomes (the roughly 1.5 percent of the genome that contains our genes, manufactures proteins, and influences our physical characteristics).<sup>139</sup> For most of these variants, the clinical validity and utility are not yet known.<sup>140</sup> A 2014 study found that only 90 to 127 variants have a well-established clinical significance based on the science at that time.<sup>141</sup> These clinically significant variants seemingly amount to health information and would have received privacy protection under the original Privacy Rule, but the other 9875 or so variants that each of us carries are

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135. *See id.*; *supra* notes 88-90.

136. *See* § 1320d(4).

137. *See id.*

138. *See* FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 121 (“Unlike other laboratory tests that typically detect a single or a defined number of substances to diagnose a limited set of conditions, a single [genome sequencing] test can identify thousands—even millions—of genetic variants.”).

139. *See id.*; Kohane et al., *supra* note 17, at 400; Leah Eisenstadt, *What Is Exome Sequencing?*, BROAD INST. (Oct. 15, 2010), <https://www.broadinstitute.org/blog/what-exome-sequencing> [<https://perma.cc/4LQ5-ELCE>].

140. *See* Dewey et al., *supra* note 18, at 1039.

141. *Id.*

not necessarily health-related and did not qualify for privacy protection under that old standard.

Even now, genomic testing is only slowly moving into wide clinical use because it is still rare for health insurers to cover the cost of gene sequencing in clinical settings.<sup>142</sup> As a result, most of the gene sequencing test results currently stored in the United States—and thus in need of privacy protection—were generated during past research studies, and research studies continue to play a large role in generating new genomic information.<sup>143</sup> Data generated during research do not always meet the standards of quality needed for use in clinical health care.<sup>144</sup> These data were at risk of slipping through the protections of the original Privacy Rule—a problem that Congress addressed by passing GINA.<sup>145</sup>

There are two ways that research results can fail to meet the standards of quality that are expected of data destined for use in clinical healthcare. First, the data themselves may be of subclinical-quality in the sense of lacking analytic validity, clinical validity, and/or clinical utility/actionability.<sup>146</sup> This situation reflects a substantive problem with data quality: the data, while useful for research, are not sufficiently reliable and well-understood to qualify for use in healthcare settings. Second, the laboratory that generated the data may not have complied with regulatory standards required of laboratories that perform tests as part of clinical healthcare. In particular, some research laboratories do not comply with

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142. See generally Patricia A. Deverka & Jennifer C. Dreyfus, *Clinical Integration of Next Generation Sequencing: Coverage and Reimbursement Challenges*, 42 J.L. MED. & ETHICS 22 (2014) (discussing difficulties obtaining coverage for clinical genomic testing).

143. See Ryan L. Collins, *Strength in Numbers: Genetic Sequencing of Large Populations Is Shaping the Future of Medicine*, HARV. U. SCI. NEWS BLOG (June 5, 2017), <http://sitn.hms.harvard.edu/flash/2017/strength-numbers-genetic-sequencing-large-populations-shaping-future-medicine/> [<https://perma.cc/R4D6-3UHS>] (discussing the large number of gene sequencing tests that are generated in research studies).

144. See, e.g., Susan M. Wolf & Barbara J. Evans, *Return of Results and Data to Study Participants*, 362 SCIENCE 159, 159 (2018) (“Some research results will meet clinical standards of quality, but many will not, because research seeks to advance understanding.”); see also Wylie Burke et al., *Return of Results: Ethical and Legal Distinctions Between Research and Clinical Care*, 166 AM. J. MED. GENETICS PART C (SEMINARS MED. GENETICS) 105, 106-07 (2014) (distinguishing the goals and data quality requirements of research and clinical care).

145. See *infra* this Part.

146. See *supra* notes 88-91.

the federal CLIA regulations.<sup>147</sup> This situation is in the nature of a legal technicality and has only a weak relationship to the data's substantive quality.<sup>148</sup>

Research laboratories can, and often do, produce genomic results that have “clinical quality” in the sense of being analytically valid and having a well-understood clinical validity and utility.<sup>149</sup> Conversely, clinical genomic tests—tests performed at CLIA-compliant clinical laboratories for the purpose of informing healthcare decisions—reveal a lot of subclinical quality information, unsuitable for use in clinical care as a byproduct of detecting the few variants that have known clinical significance.<sup>150</sup> Whether test results have clinical quality or subclinical quality thus is not a function of where the results were generated, that is, at a clinical *versus* research laboratory.

The fact that a research laboratory complies with the CLIA regulations<sup>151</sup> provides no assurance that the data are of clinical quality.<sup>152</sup> Congress enacted the CLIA statute in response to reports of inaccurate results from tests used in cervical cancer screening, and the CLIA regulations play a useful role in enhancing the safety of laboratory tests used in clinical health care.<sup>153</sup> It is not an

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147. See 42 C.F.R. § 493.3(b)(2) (2018) (providing an exception that allows some research laboratories to operate without having to comply with the CLIA regulations).

148. See *infra* this Part.

149. See 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, 823 (2014) (noting that clinically “actionable information might be learned from assays that cannot easily be confirmed in a CLIA-compliant laboratory”).

150. See *generally* Dewey et al., *supra* note 18, at 1041 (discussing how few genetic variants currently have known clinical significance); Jarvik et al., *supra* note 149, at 818-23 (discussing data produced during genome sequencing).

151. A laboratory is considered CLIA-compliant if it either holds a CLIA certificate or is exempt from the CLIA regulations. See 42 C.F.R. § 493.2. A laboratory is CLIA-exempt if it has been licensed by a state whose laboratory requirements CMS has determined are equal to or more stringent than CLIA's requirements, and the state licensure program has been approved by CMS. See *id.* Two states—New York and Washington—currently meet these conditions. See *List of Exempt States Under the Clinical Laboratory Improvement Amendments (CLIA)*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ExemptStatesList.pdf> [<https://perma.cc/8ZRX-A7WS>].

152. See discussion *infra* this part.

153. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., CMS INITIATIVES TO IMPROVE QUALITY OF LABORATORY TESTING UNDER THE CLIA PROGRAM 1 (2006), <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/060630BackgrounderrlEG.pdf> [<https://perma.cc/6DL8-6WRY>].

indictment of the CLIA regulations to acknowledge that, like all laws, their protections are tailored to the context for which they were designed: in this instance, clinical laboratory testing.<sup>154</sup> These same protections may offer fewer benefits as applied in other contexts.<sup>155</sup> For example, one of CLIA's most important protections is its requirement for a laboratory to have a scientifically qualified laboratory director.<sup>156</sup> This guards against the possibility that a commercial clinical laboratory might hire a non-scientist business person to oversee its operations.<sup>157</sup> This same protection offers less incremental benefit in research contexts, where other mechanisms—such as grant sponsors' close scrutiny of the scientific bona fides of grant recipients—generally ensure that the person overseeing a research study has relevant scientific knowledge.<sup>158</sup>

Subjecting research laboratories to the CLIA regulations would not necessarily advance the goal of ensuring that test results have clinical quality—that is, that specimens and data are well-identified and results have analytic validity, clinical validity, and clinical utility.<sup>159</sup> The CLIA program only addresses analytic validity, but not clinical validity or utility.<sup>160</sup> The analytic validity of tests at a CLIA-regulated laboratory “is reviewed during its routine biennial survey—after the laboratory has already started testing.”<sup>161</sup> At clinical laboratories that use tests for many years, a biennial validation ensures that patients tested after the second year a new test is introduced will receive an analytically validated test.<sup>162</sup> At CLIA-certified research laboratories that use novel tests during short-term research projects, CLIA's biennial survey may or may not

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154. *Cf. id.*

155. *See id.* (describing CLIA's applicability to clinical settings).

156. 42 C.F.R. § 493.1443.

157. *Cf. id.* (detailing scientific qualifications required of laboratory directors).

158. *See Evans, supra* note 6, at 8.

159. *See supra* notes 88-90.

160. *See What Is CMS's Authority Regarding Laboratory Developed Tests (LDTs) and How Does It Differ from FDA's Authority?*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 22, 2013), [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/LDT-and-CLIA\\_FAQs.pdf](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/LDT-and-CLIA_FAQs.pdf) [<https://perma.cc/9P77-ARA4>] [hereinafter “*What Is CMS's Authority?*”] (“[U]nlike the FDA regulatory scheme, CMS' CLIA program does *not* address the clinical validity of any test.”).

161. *Id.*

162. *See Evans, supra* note 6, at 8.

happen in time to ensure analytic validity.<sup>163</sup> Adding to concerns about analytic validity, a 2006 report by the United States Government Accountability Office (GAO) documented lax enforcement of CLIA's proficiency-testing requirement—the process Congress viewed as central to ensuring the analytic validity of laboratory tests.<sup>164</sup> Even if CMS vigorously enforced CLIA's proficiency-testing requirements at CLIA-certified research laboratories, proficiency testing materials (the well-characterized biospecimens laboratories purchase in order to conduct their proficiency testing)<sup>165</sup> are not available for many genomic tests, and this is especially true of novel tests used in research: “For many genetic conditions that are either rare or for which testing is performed by one or a few laboratories, substantial challenges in developing formal proficiency testing programs have been recognized.”<sup>166</sup> Subjecting research laboratories to CLIA regulation thus may not always ensure analytic validity.

CLIA also offers only modest protection against laboratory mix-ups in which one person's test samples (biospecimens) or data are mistaken for another person's. The CLIA regulation calls for accurate sample and record identification, but its requirements are modest:

Laboratories that perform molecular genetic testing for heritable diseases and conditions should ensure that at least two unique identifiers are solicited on these test requests, which should include patient names, when possible, and any other unique identifiers needed to ensure patient identification. In certain situations (e.g., compatibility testing for which donor names are

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163. *See id.*

164. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-06-416, CLINICAL LAB QUALITY: CMS AND SURVEY OVERSIGHT SHOULD BE STRENGTHENED 33 (2006); *see also* Gabler, *supra* note 125 (“Even when serious violations are identified, offending labs are rarely sanctioned except in the most extreme cases. In 2013, just 90 sanctions were issued—accounting for not even 1% of the 35,000 labs that do high-level lab testing in the United States.”).

165. *See* Bin Chen et al., *Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions*, MORBIDITY & MORTALITY WKLY. REP., June 12, 2009, at 1, 5.

166. *Id.*; *see also* SECY'S ADVISORY COMM. ON GENETICS, HEALTH, & SOC'Y, U.S. DEP'T OF HEALTH & HUMAN SERVS., U.S. SYSTEM OF OVERSIGHT OF GENETIC TESTING: A RESPONSE TO THE CHARGE OF THE SECRETARY OF HEALTH AND HUMAN SERVICES (2008), [https://repository.library.georgetown.edu/bitstream/handle/10822/512822/SACGHS\\_oversight\\_report.pdf?sequence=1&isAllowed=y](https://repository.library.georgetown.edu/bitstream/handle/10822/512822/SACGHS_oversight_report.pdf?sequence=1&isAllowed=y) [<https://perma.cc/L45B-C3HA>].

not always provided to the laboratory), an alternative unique identifier is appropriate.<sup>167</sup>

CLIA's sample-identification requirements are disappointingly minimal, and mix-ups occurring at CLIA-regulated clinical laboratories sometimes have tragic consequences.<sup>168</sup> Many non-CLIA-regulated research laboratories implement sample-identification procedures that are as stringent as, if not more stringent than, CLIA's requirements.

For all of these reasons, CLIA-compliant facilities—whether they are clinical or research laboratories—may or may not produce clinical-quality genomic information. GINA draws no distinction between clinical and subclinical-quality genetic information, between data generated in research settings and clinical settings, between data from CLIA or non-CLIA laboratories, or between information that is correctly or incorrectly attributed to an individual as long as it purports to be the person's data.<sup>169</sup> This is as it should be because all such information affects a person's civil rights.

GINA's section 105 contains a congressional mandate that genetic information, as defined by GINA, shall be treated as "health information" that is protected by the HIPAA Privacy rule.<sup>170</sup> Even

167. Chen et al., *supra* note 165, at 10.

168. See, e.g., Gabler, *supra* note 125 (detailing mix-up errors at CLIA-regulated laboratories); Gina Kolata, *The Lab Says It's Cancer: But Sometimes the Lab Is Wrong*, N.Y. TIMES (June 26, 2017), <https://www.nytimes.com/2017/06/26/health/the-lab-says-its-cancer-but-sometimes-the-lab-is-wrong.html> [<https://perma.cc/A9XJ-6554>] (discussing cases of mix-ups at CLIA labs).

169. See *supra* note 118 (reciting the broad definition of "genetic information" that GINA's § 102(a)(4) inserted at 42 U.S.C. § 300gg-91(d)(16)); see also 42 U.S.C. § 300gg-91(d)(17) (2012) (defining "genetic test" as meaning "an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes" and thus clearly including non-clinically-significant information, such as raw genomic data, within the scope of information included in GINA's definition of "genomic information"); *id.* § 300gg-91(d)(18) (defining "genetic services" as including genetic tests and "genetic counseling (including obtaining, interpreting, or assessing genetic information)" and genetic information, such that information from testing, assessing, and counseling occurring during the course of genetic research is included in GINA's broad definition of "genetic information").

170. See Genetic Information Nondiscrimination Act of 2008 § 105 (adding a new § 1180 to the Social Security Act, codified at 42 U.S.C. § 1320d-9, providing that "[t]he Secretary shall revise the HIPAA privacy regulation" so that "[g]enetic information shall be treated as health information described in [section 1320d(4)(B)] of this title," which was the section of the Social Security Act added by the 1996 HIPAA statute in which Congress defined the "health information" that is subject to HIPAA's privacy protections); *supra* note 133.

though non-clinically-significant genetic information might not be viewed as health data for other medical and legal purposes (such as Medicare billing), Congress regards it as “health information” for purposes of receiving HIPAA’s privacy protections.<sup>171</sup> Section 105 also orders HHS to amend its HIPAA regulations to place all genetic information stored at HIPAA-covered facilities under the HIPAA protections.<sup>172</sup> On December 28, 2000, the day that HHS promulgated the original Privacy Rule, the Secretary of HHS delegated her HIPAA-related responsibilities to the OCR, which oversees civil rights within HHS.<sup>173</sup> Section 105 thus was a delegation of rule-making authority to OCR. GINA requires OCR to consult with other agencies like the Department of Labor and Department of Treasury, which have various GINA-related responsibilities,<sup>174</sup> but states that OCR “has the sole authority to promulgate such regulations.”<sup>175</sup> Together, GINA’s sections 102 and 105 are a Congressional delegation of authority for OCR to serve as America’s principal regulator for the protection of genomic civil rights.<sup>176</sup>

### III. GINA’S RELIANCE ON TRANSPARENCY TO PROTECT PRIVACY AND CIVIL RIGHTS

GINA expressly bans genetic discrimination in two private spheres—employment and health insurance<sup>177</sup>—that Congress clearly can regulate under its commerce power.<sup>178</sup> Yet people’s fears about genetic discrimination extend more broadly to private social relationships that lie outside the reach of federal regulation: will a prospective marriage partner reject you over a recessive variant

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171. See § 105.

172. *Id.*

173. Statement of Delegation of Authority, 65 Fed. Reg. 82,381 (Dec. 28, 2000); *see also About Us*, U.S. DEP’T HEALTH & HUM. SERVS., OFF. C.R., <https://www.hhs.gov/ocr/about-us/index.html> [<https://perma.cc/YM54-AA9D>].

174. Genetic Information Nondiscrimination Act of 2008 § 105(b); *see also The Genetic Information Nondiscrimination Act of 2008: “GINA,”* U.S. DEP’T LAB.: C.R. CTR., <https://www.dol.gov/oasam/programs/crc/finalGINAguidance.htm> [<https://perma.cc/AV6X-5362>].

175. § 105(b)(1).

176. See §§ 102, 105.

177. See Roberts, *supra* note 3, at 441.

178. See U.S. CONST. art. 1, § 8, cl. 3 (granting Congress the power “[t]o regulate Commerce with Foreign Nations, and among the several States, and with the Indian Tribes”); *see also* Roberts, *supra* note 3, at 484-87.

for offensive body odor, a clinically insignificant but undesirable trait that rational suitors may not wish to bestow on their offspring? The federal government cannot force your lover to marry you in spite of the variant. All it can do is arm people with information that empowers them to negotiate their own, private solutions. GINA embraced this approach to the broader problem of private genetic discrimination.

The HIPAA Privacy Rule already included an individual access right on the day Congress enacted GINA.<sup>179</sup> By placing genetic information under the Privacy Rule,<sup>180</sup> Congress seemingly intended to grant Americans a right of access to their own genetic information stored at HIPAA-regulated facilities.<sup>181</sup> A major challenge in fighting genetic discrimination is that people may never realize they belong to a genetic subclass that is being targeted for discrimination, making it hard to organize resistance to the discrimination. Invidious discrimination based on classifications like gender, sexual preference, race, or national origin is easier for its victims to detect, because people generally know they fall into, or could be perceived as falling into, those classes. Yet who among us knows whether we carry a particular genetic variant that may cause other people—not just employers and insurers, but neighbors and friends—to turn against us?

People can discriminate against us based on our genetic variants only if the people know we possess those variants. For this reason, when our genetic information is stored anywhere, we need privacy protections that limit others' access to it. Less obvious is the fact that we also need access to the data ourselves, because access to our own data empowers us to detect and address genetic discrimination if it is leveled at us. Individual data access challenges the assertion that good policy will emerge if people are kept behind a Rawlsian "veil of ignorance"<sup>182</sup> so that none of us knows which gene variants we possess and, therefore, none of us knows which forms of genetic discrimination potentially affect us.<sup>183</sup> A foundational assumption

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179. Evans, *supra* note 6, at 6; *see also* 45 C.F.R. § 164.524 (2018).

180. *See supra* note 130 and accompanying text.

181. Evans, *supra* note 6, at 6.

182. JOHN RAWLS, A THEORY OF JUSTICE 136-42 (1971).

183. *Id.* at 136-37 ("[Under the veil of ignorance, people] do not know how the various alternatives will affect their own particular case and they are obliged to evaluate principles



of genomic civil rights is that good policies can emerge only from a smart, informed population whose members know where their interests lie. The insistent civil rights assertion of Moses's "[l]et my people go!"<sup>184</sup> translates in the genomic era to "let my people have their data!"

Data privacy is often theorized as a condition in which individuals exercise full control over their own data and who has access to it.<sup>185</sup> GINA did not, by placing genetic information under the HIPAA Privacy Rule, grant people this brand of privacy. One way to protect genomic civil rights would have been to impose a strong consent regime that gave people ironclad control over all uses and disclosures of their genetic information, including control over any downstream redisclosures of their data.<sup>186</sup> Then, individuals could protect their own civil rights by restricting access to their data.<sup>187</sup> The Privacy Rule never embraced this approach.<sup>188</sup> It states a default rule that individuals can control access to their data by signing or refusing to sign "authorizations" (HIPAA's name for consents),<sup>189</sup> but it enumerates a long list of exceptions to this default rule.<sup>190</sup>

The Privacy Rule is widely—and unfairly—criticized for having broken its promise of privacy by allowing people's data to be shared

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solely on the basis of general considerations.").

184. *Exodus* 9:1.

185. See, e.g., Deborah C. Peel, *Written Testimony Before the HIT Policy Committee*, ELECTRONIC PRIVACY INFO. CTR. (Sept. 18, 2009), [http://epic.org/privacy/medical/Peel\\_PPR%20Written%20testimony%20HIT%20Policy%20Committee.pdf](http://epic.org/privacy/medical/Peel_PPR%20Written%20testimony%20HIT%20Policy%20Committee.pdf) [https://perma.cc/Q34X-GQZR] (framing privacy as "control of personal information" and "consumer control over [personal health information]"); see also Paul M. Schwartz, *Internet Privacy and the State*, 32 CONN. L. REV. 815, 820 (2000) (noting that individual control over one's data, rather than secrecy of the data, is key to the modern paradigm of data privacy).

186. Evans, *supra* note 63.

187. See *id.*; Evans, *supra* note 6, at 8.

188. See *infra* this Part.

189. See 45 C.F.R. § 164.508 (2018).

190. See *id.*; Letter from William W. Stead, Chair, Nat'l Comm. Vital & Health Statistics, to Honorable Sylvia M. Burwell, Secretary, U.S. Dep't of Health & Human Servs. app.A at 15-19 (Nov. 9, 2016), <https://www.ncvhs.hhs.gov/wp-content/uploads/2013/12/2016-Ltr-Privacy-Minimum-Necessary-formatted-on-ltrhead-Nov-9-FINAL-w-sig.pdf> [https://perma.cc/J7DF-X9VP] (listing various provisions allowing unconsented disclosure and use of data); see also Barbara J. Evans & Gail P. Jarvik, *Impact of HIPAA's Minimum Necessary Standard on Genomic Data Sharing*, 20 GENETICS MED. 531, 531-35 (2018) (discussing nonconsensual data sharing under HIPAA).

and used, in many instances, without their consent.<sup>191</sup> In reality, the Privacy Rule never made such a promise. It was designed, from its inception, to serve competing values of privacy and data transparency, giving considerable weight to the latter.

The 1996 HIPAA statute charged HHS with preparing recommendations on health data privacy and submitting them to Congress by 1997.<sup>192</sup> The statute envisioned that Congress would separately enact a national health privacy statute based on these recommendations.<sup>193</sup> The HIPAA statute contained a springing authority for HHS to promulgate the Privacy Rule if Congress had not enacted privacy legislation by August 21, 1999.<sup>194</sup> After reviewing HHS's recommendations,<sup>195</sup> Congress chose to let HHS proceed with rule-making—a signal that Congress endorsed the main contours of the 1997 recommendations.<sup>196</sup> Those recommendations unabashedly embraced the view that transparent sharing of health data offers societal benefits that, in some circumstances, outweigh individuals' desire to control access to their data:

A Federal health privacy law should permit limited disclosures of health information without patient consent for specifically identified national priority activities. We have carefully examined the many uses that the health professions, related industries, and the government make of health information, and we are aware of the concerns of privacy and consumer advocates about these uses. The allowable disclosures and corresponding restrictions we recommend reflect a balancing of privacy and other social values.<sup>197</sup>

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191. See, e.g., Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. REV. 1701 (2010) (criticizing the Privacy Rule).

192. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 264(a)-(b), 110 Stat. 1936, 2033.

193. *Id.* § 264(c).

194. *Id.*

195. *Confidentiality of Individually Identifiable Health Information: Recommendations of the Secretary of Health and Human Services, Pursuant to Section 264 of the Health Insurance Portability and Accountability Act of 1996*, U.S. DEP'T HEALTH & HUM. SERVS. § I.I (Sept. 11, 1997) [hereinafter *HHS Recommendations*], <https://aspe.hhs.gov/report/confidentiality-individually-identifiable-health-information> [<https://perma.cc/M9TK-YZQW>].

196. See OFFICE FOR CIVIL RIGHTS, U.S. DEP'T OF HEALTH & HUMAN SERVS., SUMMARY OF THE HIPAA PRIVACY RULE 1-2 (2003), <https://www.hhs.gov/sites/default/files/privacysummary.pdf?language=es> [<https://perma.cc/G8KE-4DLK>].

197. *HHS Recommendations*, *supra* note 195, § I.I.

In addition to disclosures to support medical treatment and healthcare payments, these national priority activities include: (1) supplying data to support regulatory oversight of the healthcare system; (2) allowing access to data for public health activities; (3) supplying data for health research; and (4) supporting data flows authorized by other laws and court orders for law enforcement, court proceedings, and various state governmental purposes.<sup>198</sup> Under the Privacy Rule, individuals have no right to block uses or disclosures of their data for these activities, and alternative, lesser privacy protections apply.<sup>199</sup>

The Privacy Rule's national priority activities map onto categories of transparency that Frederick Schauer once identified.<sup>200</sup> In Schauer's scheme, "[t]ransparency as regulation" empowers the recipient of information to regulate, monitor, or control the information provider.<sup>201</sup> This concept is exemplified by FDA's proposal to rely on large genomic databases, populated with data shared by genome testing laboratories, to infer whether their tests have clinical validity.<sup>202</sup> Schauer's second concept, "[t]ransparency as [e]fficiency," treats data flows as instrumental to efficient markets<sup>203</sup> and corresponds to the Privacy Rule's provisions allowing data to flow freely to support treatment and healthcare payment activities.<sup>204</sup> Schauer's third concept, "[t]ransparency as [e]pistemology," describes data flows that sustain the creation of nonmarket and public goods,<sup>205</sup> such as scientific discovery, public health, or the capacity of law enforcement agencies and courts to get at the

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198. *Id.*; see also I. Glenn Cohen, *Is There a Duty to Share Healthcare Data?*, in *BIG DATA, HEALTH LAW, AND BIOETHICS* 209, 209-22 (I. Glenn Cohen et al. eds., 2018) (discussing the role of data sharing in fostering scientific discovery).

199. See Letter from William W. Stead to Honorable Sylvia M. Burwell, *supra* note 190, app. A at 15-17 tbl.1 (summarizing the protections available under the Privacy Rule in situations where data are used without the individual's authorization); Evans & Jarvik, *supra* note 190.

200. Frederick Schauer, *Transparency in Three Dimensions*, 2011 U. ILL. L. REV. 1339, 1347-50.

201. *Id.* at 1347-48.

202. See FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 121 (proposing to leverage genetic databases to evaluate clinical performance of genomic tests).

203. Schauer, *supra* note 200, at 1350.

204. 45 C.F.R. § 164.506(a)-(c) (2018).

205. Schauer, *supra* note 200, at 1350.

truth.<sup>206</sup> These three concepts portray unconsented data flows as conferring broad benefits on society as a whole.<sup>207</sup> Individuals whose data are shared for the sake of transparency may reap some of these benefits, but many of the benefits presumably flow to others, setting up a potential conflict between privacy and transparency.

Relevant to this conflict, Schauer identified a fourth, and final concept, “[t]ransparency as [d]emocracy,” which describes the sharing of data with members of the public to enable the governed to monitor and manage their government.<sup>208</sup> By this view, individuals’ access to data promotes better governmental decisions by subjecting the government to oversight “by the people,” and, more deeply, it displays respect for public control as an end in itself.<sup>209</sup> In health-care settings, the phrase “[t]ransparency as [d]emocracy” is inapposite: the healthcare system is in a power relationship—but not governance relationship—with patients and research participants. The term “transparency as respect for autonomy” is more appropriate. The values served by Schauer’s fourth concept of transparency closely resemble the modern bioethical values of respect for autonomy, respect for persons, and informed consent<sup>210</sup> which promote accountability of healthcare providers to individuals, address imbalances of power between patients and medically trained personnel, and foster patient empowerment as an end in itself.<sup>211</sup>

The Privacy Rule gives special weight to this fourth type of transparency,<sup>212</sup> granting individuals a legally enforceable right to inspect and receive copies of data that HIPAA-regulated entities store about them.<sup>213</sup> A former HHS Secretary once characterized this right as

206. See generally BRETT M. FRISCHMANN, *INFRASTRUCTURE: THE SOCIAL VALUE OF SHARED RESOURCES* 61-90 (2012) (describing the role of infrastructure, including data infrastructure, in creating public and nonmarket goods).

207. See generally Schauer, *supra* note 200.

208. *Id.* at 1349.

209. See *id.*

210. See, e.g., NAT’L COMM’N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, U.S. DEP’T OF HEALTH, EDUC., & WELFARE, *THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH* pt. B (1979) [hereinafter *BELMONT REPORT*], [https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c\\_FINAL.pdf](https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf) [<https://perma.cc/99VW-5ZN6>] (listing “respect for persons” as the first of three “basic ethical principles”).

211. Evans, *supra* note 63, at 32-33.

212. *Id.* at 33.

213. See *HHS Recommendations*, *supra* note 195, § II.C.2 (calling for an individual access

the “cornerstone of the [HIPAA] Privacy Rule.”<sup>214</sup> Individual data access is the cornerstone, I argue, because—dating back to the dawn of the information age in the early 1970s—the U.S. federal government has embraced this form of transparency as its response to the central dilemma of privacy regulation. Individuals have strong claims for their sensitive data to remain strictly private and subject to their own control.<sup>215</sup> However, honoring those claims would inflict unacceptable costs to society because transparency fosters effective regulation, economic efficiency, and the creation of diverse public goods.<sup>216</sup> Transparency in service of these goals undeniably poses risks to individuals’ civil rights. U.S. federal law embraces a daring and somewhat counterintuitive approach to this dilemma: perhaps the way to address transparency’s risk to individual rights is to provide *even more transparency*, in this case, in the form of transparency as respect for autonomy.<sup>217</sup> Empowered by access to their own data, individuals can identify forms of discrimination and stigmatization to which they may be susceptible.<sup>218</sup> Armed with this knowledge, they can exercise various other federally protected civil rights, including their First Amendment protected rights to assemble and petition the government for redress of grievances.<sup>219</sup>

Embracing this approach, the Fair Credit Reporting Act of 1970 granted people a right to obtain all the information about themselves stored by consumer credit-reporting agencies.<sup>220</sup> In the sphere

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right in recommendations that the HIPAA statute required HHS to provide to Congress in 1997); *see also* 45 C.F.R. § 164.524 (2018) (implementing this right).

214. *See HHS Announces New Rule that Gives Patients Direct Access to Lab Test Results*, CAL. PHYSICIAN’S LEGAL HANDBOOK: NEWS (Feb. 6, 2014), <http://cplh.org/blog/detail/?article=hhs-announces-new-rule-that-gives-patients> [https://perma.cc/N4N3-QRGF] (alteration in original) (quoting then-HHS Secretary Kathleen Sebelius).

215. *See, e.g.,* Sandra Park, *Who Should Control Your Genetic Information—You or Corporate Laboratories?*, ACLU BLOG (May 19, 2016, 5:00 PM), <https://www.aclu.org/blog/privacy-technology/medical-and-genetic-privacy/who-should-control-your-genetic-information-you> [https://perma.cc/VXX7-TWW9] (discussing cancer patients’ interests in accessing their genetic information both to aid their family members and to be able to contribute the data to research).

216. *See supra* this Part; *see also* Schauer, *supra* note 200, at 1347-50.

217. *See infra* Part IV.A.

218. *See infra* Part IV.C.

219. *See* U.S. CONST. amend. I (protecting “the right of the people peaceably to assemble, and to petition the Government for a redress of grievances”); *infra* Part IV.D.

220. 15 U.S.C. § 1681b(a)(2) (2012); *see also* FED. TRADE COMM’N, A SUMMARY OF YOUR RIGHTS UNDER THE FAIR CREDIT REPORTING ACT, <https://www.consumer.ftc.gov/articles/pdf->

of health care, the Department of Health, Education, and Welfare Secretary's Advisory Committee on Automated Personal Data Systems developed a Code of Fair Information Practices in 1973 that stressed, "[t]here must be a way for an individual to find out what information about him is in a record and how it is used."<sup>221</sup> The Privacy Act of 1974, which governs the privacy of federal health record systems like CMS's Medicare databases, incorporated this recommendation, enabling access to government-held health data.<sup>222</sup> Before the Privacy Act, individuals sometimes invoked the Freedom of Information Act (FOIA) to obtain access to their own data,<sup>223</sup> but FOIA requests were cumbersome and often yielded incomplete access.<sup>224</sup> The Privacy Act's more streamlined access right later became the model for HIPAA's access right.<sup>225</sup>

The Privacy Act contains congressional findings that data privacy is a fundamental right protected by the Constitution<sup>226</sup> and that an individual right to inspect and obtain one's own data is necessary and proper to protect this privacy right.<sup>227</sup> These statements are enacted congressional findings of fact: findings that

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0096-fair-credit-reporting-act.pdf [https://perma.cc/JS6J-JYC5].

221. SECRETARY'S ADVISORY COMM. ON AUTOMATED PERS. DATA SYS., U.S. DEP'T OF HEALTH, EDUC., & WELFARE, RECORDS, COMPUTERS, AND THE RIGHTS OF CITIZENS 41 (1973), <https://www.justice.gov/opcl/docs/rec-com-rights.pdf> [https://perma.cc/LLS9-28EF] (announcing an influential Code of Fair Information Practices (FIPs) based on five principles); *see also* Fred H. Cate, *The Failure of Fair Information Practice Principles*, in CONSUMER PROTECTION IN THE AGE OF THE "INFORMATION ECONOMY" 341, 346 (Jane K. Winn ed., 2006) (tracing subsequent development of FIPs, including access rights, after the 1973 HEW Code of FIPs); *HHS Recommendations, supra* note 195, § II.C.2 (referring to this principle from the 1973 HEW Code of FIPs in the roadmap for the HIPAA Privacy Rule).

222. 5 U.S.C. § 552a(a), (d) (2012), *amended by* 5 U.S.C. § 552a (Supp. III 2016).

223. 5 U.S.C. § 552 (2012), *amended by* 5 U.S.C. § 552 (Supp. V 2018).

224. PRIVACY PROT. STUDY COMM'N, PERSONAL PRIVACY IN AN INFORMATION SOCIETY 508 (1977).

225. *See* Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,980-82 (proposed Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160-64) (explaining, in the preamble to the originally proposed HIPAA Privacy Rule, that HIPAA's access right was modeled on the similar provisions of the Privacy Act of 1974).

226. *See* Privacy Act of 1974 § 2(a), 5 U.S.C. § 552a note ("The Congress finds that ... the right to privacy is a personal and fundamental right protected by the Constitution of the United States, and ... it is necessary and proper for the Congress to regulate the collection, maintenance, use, and dissemination of information.").

227. *Id.* § 2(b)(3) (including, as a core element of data privacy protection, safeguards that "permit an individual to gain access to information pertaining to him ..., to have a copy made of all or any portion thereof, and to correct or amend such record").

received majority votes in both houses of Congress and were signed into law by President Gerald Ford and then recorded in the U.S. Code.<sup>228</sup> Enacted congressional findings of legal fact such as these are not binding on the courts, but courts do pay some attention to them and tend to give more weight to congressional findings that expand individual rights, as these do, than to those that reduce people's rights.<sup>229</sup> The Privacy Act codifies the principle that access to one's own data is necessary to enable the exercise of fundamental rights.

In the Privacy Act, Congress also established a Privacy Protection Study Commission (PPSC),<sup>230</sup> which issued an influential 1977 report supporting individual access to medical data held by nongovernmental healthcare providers, insurers, and other organizations.<sup>231</sup> Private-sector entities are not covered by the 1974 Privacy Act and thus are not subject to its access right,<sup>232</sup> nor are they subject to FOIA.<sup>233</sup> The United States relies heavily on private-sector healthcare providers and payers,<sup>234</sup> so individual health data access would never be effective without a right of access to privately stored health records. The opportunity to create such a right arose twenty years later, after passage of the HIPAA statute in 1996.<sup>235</sup>

The PPSC's 1977 report recognized that there are compelling reasons to share people's data, under certain circumstances, without

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228. See 5 U.S.C. § 552a note (codifying these findings). See generally DAVID L. FAIGMAN, *CONSTITUTIONAL FICTIONS: A UNIFIED THEORY OF CONSTITUTIONAL FACTS* (2008) (pointing out that Congressional findings of fact can include facts about the law); William D. Araiza, *Deference to Congressional Fact-Finding in Rights-Enforcing and Rights-Limiting Legislation*, 88 N.Y.U. L. REV. 878 (2013) (discussing enacted congressional findings of fact and the degree of deference courts accord to them).

229. See sources cited *supra* note 228.

230. See *Overview of the Privacy Act of 1974: Role of the Privacy Protection Commission*, U.S. DEP'T JUST. (July 16, 2015), <https://www.justice.gov/opcl/role-privacy-protection-study-commission> [<https://perma.cc/S39C-QG85>].

231. PRIVACY PROT. STUDY COMM'N, *supra* note 224, ch. 7.

232. 5 U.S.C. § 552a.

233. 5 U.S.C. § 552.

234. See Bradley Sawyer & Cynthia Cox, Kaiser Family Found., *How Does Health Spending in the U.S. Compare to Other Countries?*, PETERSON-KAISER HEALTH SYS. TRACKER (Feb. 13, 2018), <https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-u-s-increased-public-private-sector-spending-faster-rate-similar-countries> [<https://perma.cc/Z6ZR-PFGR>].

235. See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.).

their consent.<sup>236</sup> The PPSC cautioned, however, that if a person's data—including their research records—cannot be “totally protected against the possibility that individually identifiable information in them will be disclosed for any other purpose, the individual's concern is obvious and his access right highly relevant.”<sup>237</sup> By this view, individual access is ethically justified not merely because it is instrumental to better clinical health care. It is ethically necessary as a means of protecting people's civil rights in contexts where people's data privacy is imperfectly protected—which is to say, in virtually all healthcare and biomedical research contexts.<sup>238</sup>

#### IV. TRANSPARENCY AS A TOOL OF CIVIL RIGHTS

HIPAA's individual access right serves several stated regulatory objectives. The HHS and its component agencies such as CMS and OCR announced these purposes in various rulemakings creating or amending HIPAA's access right and in subsequent regulatory guidance documents.<sup>239</sup> Some of the purposes clearly relate to clinical data, rather than research data. For example, helping patients understand their health status and treatment options<sup>240</sup> and helping patients detect instances of misdiagnosis and medical malpractice<sup>241</sup> are pertinent to tests done in the clinical treatment setting. The remaining regulatory objectives, discussed below, are equally relevant to clinical and research data.

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236. PRIVACY PROT. STUDY COMM'N, *supra* note 224, at 281 (observing “how heavily a variety of institutions in our society have come to depend on the information in medical records in order to perform their basic functions”).

237. *Id.* at 597.

238. See *infra* Part VII.B.; see also Gina Kolata, *Poking Holes in Genetic Privacy*, N.Y. TIMES: NEWS ANALYSIS (June 16, 2013), <https://www.nytimes.com/2013/06/18/science/poking-holes-in-the-privacy-of-dna.html> [<https://perma.cc/M7WP-W9PN>] (discussing problems with the privacy, security, and reidentifiability of stored genetic information).

239. See *infra* Part IV.A-D.

240. See, e.g., CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. 7290 (Feb. 6, 2014) (to be codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164) (noting, in the preamble to final rule on laboratory data access, that barriers to individual data access “prevent[] patients from having a more active role in their personal health care decisions”).

241. See *id.* at 7293 (citing statistics that clinicians fail to inform patients of abnormal test results 7 percent of the time).



*A. Ensuring Respect for Individual Autonomy*

The primary purpose of HIPAA's access right is to force entities that store individually identifiable data to display respect for the individuals' autonomy. The preamble to the original Privacy Rule cites a "well-established principle" that an individual should have "access rights to the data and information in his or her health record and other health information databases."<sup>242</sup>

The 1979 Belmont Report—a foundational document in American bioethics—declared that "individuals should be treated as autonomous agents."<sup>243</sup> Legal standards of that decade, such as the 1974 Privacy Act and the 1973 Code of Fair Information Practices,<sup>244</sup> treated access to one's own information as an obvious appurtenance of autonomy.<sup>245</sup> Subsequent theorizations divorced the concept of individual autonomy from the right of access to information about oneself.<sup>246</sup> My research could not conclusively pinpoint when this shift occurred and others are invited to add their insights.

The Belmont Report's 1979 declaration of individual autonomy was hedged with a proviso that "persons with diminished autonomy are entitled to protection."<sup>247</sup> This proviso, however, seemed to envision a rare exception to protect prisoners, children, and others whose circumstances or decisional incompetence make it hard to exercise autonomy.<sup>248</sup> There was no suggestion, in the Belmont Report, that *all* research participants have diminished autonomy.<sup>249</sup>

At some point between 1979 and now, this proviso swallowed the rule that most people are entitled to be treated as autonomous, at least where data access is concerned. A recurring theme

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242. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,606 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164).

243. BELMONT REPORT, *supra* note 210, pt. B (listing "respect for persons" as the first of three "Basic Ethical Principles").

244. *See supra* Part III.

245. *See supra* notes 222-25 and accompanying text.

246. *See supra* note 122 (listing various recent scholarly works that have maintained that individuals' access to their own data should be subject to various restrictions, such as limiting return of results to information that has analytic validity, clinical validity and/or clinical utility).

247. BELMONT REPORT, *supra* note 210, pt. B.

248. *See id.*

249. *See id.*

in post-1990 ESLI studies is that genetic information is so complex that all who are not medically trained have diminished autonomy and need special protections when confronted with it.<sup>250</sup> These concerns are most intense with respect to one discrete class of individuals—research participants undergoing genomic testing in research laboratories—because research data may be unreliable and laypeople may fail to appreciate the unreliability.<sup>251</sup> Laypeople may suffer anxiety or psychological distress.<sup>252</sup> They may pursue harmful medical treatments to mitigate misunderstood genetic risks.<sup>253</sup> They may waste scarce research and healthcare resources asking follow-up questions and seeking follow-up medical evaluations.<sup>254</sup> They may make bad choices that harm themselves and society.<sup>255</sup>

While there is a diversity of bioethical views on this matter, a fairly broad consensus of bioethical opinion favors restricting people's access to their own genomic data.<sup>256</sup> Research regulators<sup>257</sup> call

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250. See, e.g., NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 122, at 71-72.

251. See *supra* note 122 and accompanying text (listing a number of scholarly works that have expressed concerns about broad, unrestricted access by individuals to information about themselves generated during the course of research).

252. See NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 122, at 71 (noting the existence of these concerns); Maschke, *supra* note 122, at 563 (same); Lisa S. Parker, *Returning Individual Research Results: What Role Should People's Preferences Play?*, 13 MINN. J.L. SCI. & TECH. 449, 470 (2012) (same); Sharon F. Terry, *The Tension Between Policy and Practice in Returning Research Results and Incidental Findings in Genomic Biobank Research*, 13 MINN. J.L. SCI. & TECH. 691, 713 (2012) (same).

253. See FOOD & DRUG ADMIN., U.S. DEPT OF HEALTH & HUMAN SERVS., *supra* note 121 (noting that uncertain or inaccurate genomic tests "can lead to patients receiving the wrong diagnosis, the wrong treatment or no treatment at all even when effective therapy is available" (internal citations omitted)).

254. See Thomas M. Morgan, *Genomic Screening: The Mutation and the Mustard Seed*, 46 J.L. MED. & ETHICS 541, 544 (2018) (discussing the workload involved when individuals turn to their physicians to seek clarification of low-quality or unconfirmed genetic findings).

255. See, e.g., Holman & Taylor, *supra* note 122, at 687 (noting these concerns, without necessarily agreeing that they are sufficient grounds to restrict individuals' access to their own genetic information).

256. See *supra* note 122 (citing examples of scholar works that recommend various restrictions on individuals' access to research data about themselves).

257. See, e.g., Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,514-15 (advance notice of proposed rulemaking provided July 26, 2011) (to be codified at 45 C.F.R. pts. 46, 160, 164 and 21 C.F.R. pts. 50, 56) (proposing that an Institutional Review Board (IRB) review is necessary in research where results will be returned to participants, even if the research is otherwise low-risk biospecimen research that would be excused from IRB review).

for ethics review bodies to filter genetic information before it is shared with research participants to assess “what information can be effectively communicated in a manner sensitive to [research] subjects’ health literacy.”<sup>258</sup> “Participant literacy, or lack thereof, causes a great deal of tension in the system.”<sup>259</sup> In a discussion paper, the U.S. National Academy of Medicine (formerly the Institute of Medicine) notes that “analyses of health literacy indicate that, on average, US adults have limited health literacy.”<sup>260</sup> The academy has published too many papers over the past thirty years with “health literacy” in the title to cite them all here.<sup>261</sup>

In some strands of modern ELSI scholarship, health illiteracy is seen as diminishing individuals’ autonomy in a way that disqualifies their right of access to their own data. Forty years ago, the Belmont Report conceived autonomy as the capacity of self-determining people to make *their own* decisions;<sup>262</sup> there was no requirement that they must make *good* decisions.<sup>263</sup> To borrow Frederick Schauer’s remark about democracy: “[Autonomy], after all, is not about the people necessarily being right, but about the

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258. Holman & Taylor, *supra* note 122, at 672-73 (quoting Isaac S. Kohane et al., *Reestablishing the Researcher-Patient Compact*, 316 *Sci.* 836, 837 (2007)).

259. Terry, *supra* note 252, at 709.

260. Kim Parson et al., *Health Literacy Insights for Health Crises 1-2* (Nat’l Acad. of Med., Discussion Paper, 2017), <https://nam.edu/wp-content/uploads/2017/07/Health-Literacy-Insights-for-Health-Crises.pdf> [<https://perma.cc/2EW6-QVA7>].

261. *See, e.g., id.* (“[T]he results of the 1992, 2003, and 2011 surveys of adult literacy in the United States indicate that literacy skills—reading, writing, speaking, listening, calculating, problem solving, and use of technology—are indeed quite problematic for a large proportion of adults. Furthermore, analyses of health literacy indicate that, on average, US adults have limited health literacy.”); *see also* NAT’L ACADEMIES OF SCIS. ENG’G & MED., HEALTH INSURANCE AND INSIGHTS FROM HEALTH LITERACY: HELPING CONSUMERS UNDERSTAND: PROCEEDINGS OF A WORKSHOP IN BRIEF (2016), <https://www.nap.edu/catalog/24613/health-insurance-and-insights-from-health-literacy-helping-consumers-understand> [<https://perma.cc/NDS4-C54N>]; NAT’L ACADEMIES OF SCIS. ENG’G & MED., RELEVANCE OF HEALTH LITERACY TO PRECISION MEDICINE: WORKSHOP IN BRIEF (2016), <https://www.nap.edu/catalog/23538/relevance-of-health-literacy-to-precision-medicine-workshop-in-brief> [<https://perma.cc/VA7A-HUPJ>]; Andrew Pleasant et al., *Considerations for a New Definition of Health Literacy* (Nat’l Acad. of Med., Discussion Paper, 2016), <http://nam.edu/wp-content/uploads/2016/04/Considerations-for-a-New-Definition-of-Health-Literacy.pdf> [<https://perma.cc/BZ3C-4GY2>]; Bhavna Sivanand et al., *Building Health Literacy and Family Engagement in Head Start Communities: A Case Study* (Nat’l Acad. of Med., Discussion Paper, 2017), <https://nam.edu/wp-content/uploads/2017/04/Building-Health-Literacy-and-Family-Engagement-in-Head-Start-Communities.pdf> [<https://perma.cc/UW3R-AM46>].

262. *See* BELMONT REPORT, *supra* note 210, pt. B.

263. *Cf. id.*

right of people to be wrong.”<sup>264</sup> At some point over the past four decades, a more paternalistic view gained ground.<sup>265</sup>

GINA, and the access right it created, reinstated two longstanding principles of U.S. federal law and Belmont-era bioethics: (1) individuals—even those whom an entrenched elite disparages as illiterate—are autonomous individuals,<sup>266</sup> and (2) autonomy implies certain basic civil rights, including a right of access to one’s own genetic information.<sup>267</sup>

### *B. Strengthening Privacy Protections*

When first proposing HIPAA’s access right in 1999, HHS noted that “[w]hile the right to have access to one’s information may appear somewhat different from the right to keep information private, these two policy goals have always been closely tied”<sup>268</sup> and the right to inspect and copy one’s data “is a fundamental aspect of protecting privacy.”<sup>269</sup> The Privacy Rule’s preamble notes that individuals’ confidence in the protection of their information requires that they have the means to know what is contained in their records.<sup>270</sup>

The existence of stored data contributes to a person’s reidentification risk: the risk that data held in anonymous form elsewhere might be reidentified via cross-correlation with the stored dataset.<sup>271</sup>

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264. Schauer, *supra* note 200, at 1349.

265. *Cf. id.* at 1353-54.

266. See BELMONT REPORT, *supra* note 210, pt. B.

267. See Privacy Act of 1974, 5 U.S.C. § 552a, amended by 5 U.S.C. § 552a (Supp. III 2016) (providing an individual access right to individually identifiable information held in governmental databases, including genetic information if it is stored with identifiers).

268. Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,980 (Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160, 164).

269. *Id.*

270. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,606 (citing NAT’L COMM. FOR QUALITY ASSURANCE & THE JOINT COMM’N ON ACCREDITATION OF HEALTHCARE ORGS., PROTECTING PERSONAL HEALTH INFORMATION: A FRAMEWORK FOR MEETING THE CHALLENGES IN A MANAGED CARE ENVIRONMENT 25 (1998)).

271. See Letter from William W. Stead, Chair, Nat’l Comm. Vital & Health Statistics, to Honorable Thomas E. Price, Secretary, Dep’t Health & Human Servs. 5 (Feb. 23, 2017), <https://www.ncvhs.hhs.gov/wp-content/uploads/2013/12/2017-Ctr-Privacy-DeIdentification-Feb-230Final-w-sig-pdg> [<https://perma.cc/C7EF-AQMB>] (“Even data properly de-identified under the Privacy Rule may carry with it some private information, and, therefore, poses some risk of re-identification, a risk that grows into the future as new datasets are released and as datasets are combined.”).

In an age when reidentification is a growing privacy threat, people need access to *all* of their stored genetic data, including data from non-CLIA-regulated research laboratories, in order to understand their privacy risks.<sup>272</sup> Even if a laboratory that stores genetic information does not share it, its files may be hacked and, when correlated with external data sets, become a tool for reidentifying people's data held in deidentified form elsewhere.<sup>273</sup>

The National Committee for Vital and Health Statistics, which advises on HIPAA issues,<sup>274</sup> recently noted that HIPAA-covered laboratories that store data in identifiable form can release it to others without individual consent if they first deidentify it according to HIPAA's rather lax deidentification standards.<sup>275</sup> The laboratory has no duty to provide the individual with an accounting for disclosures of deidentified data,<sup>276</sup> which have "expanded exponentially" in recent years.<sup>277</sup> The Common Rule also allows research data to be disclosed in deidentified form without consent.<sup>278</sup> If a research laboratory releases a person's deidentified data to a non-HIPAA-covered entity, the information will no longer be subject to HIPAA's privacy protections even if it is subsequently reidentified, which is increasingly done in order to assemble integrated, longitudinal databases.<sup>279</sup> A non-HIPAA-covered data aggregator, analytics company, or health applications business that receives and reidentifies a person's data is free—at least as far as HIPAA is concerned—to redisclose it in fully identified form.<sup>280</sup> The whole world potentially has

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272. See Kolata, *supra* note 238 (providing examples in which genetic information was successfully reidentified); see also Daniel Barth-Jones, *The Debate Over 'Re-Identification' of Health Information: What Do We Risk?*, HEALTH AFF. BLOG (Aug. 10, 2012) (discussing reidentifiability of health information more generally), <https://www.healthaffairs.org/doi/10.1377/hblog20120810.021952/full> [<https://perma.cc/DW9V-YTRR>].

273. See Letter from William W. Stead to Honorable Thomas E. Price, *supra* note 271, at 5.

274. See *About*, NAT'L COMM. FOR VITAL HEALTH STATISTICS, <https://ncvhs.hhs.gov/about/> [<https://perma.cc/PZR3-6KJ9>].

275. See Letter from William W. Stead to Honorable Thomas E. Price, *supra* note 271, at 5.

276. See *id.* at 7.

277. *Id.* at 5.

278. 45 C.F.R. pt. 46, subpt. A.

279. See Letter from William W. Stead to Honorable Thomas E. Price, *supra* note 271, at 9-10.

280. See *id.* at 5.

access to your fully identified research-quality genomic data, yet safety regulators and many bioethicists feel you should not have it.<sup>281</sup> GINA took the position that, at least as far as your genetic information is concerned, you deserve access, too.

### *C. Protecting Civil Rights in the Face of Incomplete Privacy Protections*

From the outset, the HIPAA statute was an imperfect vehicle for protecting people's health data privacy. HIPAA was primarily an insurance statute.<sup>282</sup> HIPAA's Administrative Simplification provisions<sup>283</sup> authorized HHS to regulate the electronic exchange of information to support payments and administrative transactions among healthcare providers, payers, and healthcare clearinghouses that transmit information electronically when conducting such transactions.<sup>284</sup> HHS's regulatory authority under the HIPAA statute extended only to these entities (the so-called "HIPAA-covered entities"), which are involved in the payment chain for healthcare services.<sup>285</sup> Privacy was just one aspect of these regulations.<sup>286</sup> HIPAA gave HHS no jurisdiction to regulate the multitude of other private companies and institutions (for example, drug manufacturers, research institutions that provide no healthcare services, companies that sell fitness-tracking devices, direct-to-consumer genetic testing services, and many others) that use and store people's health data in ways that affect their privacy.<sup>287</sup>

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281. *See supra* note 122 (citing bioethical studies that have recommended various restrictions on individuals' access to research results); *see also* Part VII.A.2 (discussing statements by CMS that have had the effect of impeding individuals' HIPAA right of access to data from non-CLIA-compliant research laboratories).

282. *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, pmb., 110 Stat. 1936, 1936.

283. *See id.* §§ 261-264 (codified at 42 U.S.C. § 1320d to § 1320d-8 (2012)) (enacting a new part C of title IX of the Social Security Act).

284. Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,920 (proposed Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160, 164).

285. *See supra* note 49.

286. *See* Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. at 59,920-21 (noting that HIPAA's privacy regulations are part of a package of regulations addressing the electronic interchange of health information more broadly).

287. *Cf.* 45 C.F.R. § 160.102 (defining the entities to which the HIPAA regulations apply and not including drug manufacturers, fitness device manufacturers, and many other entities

Congress knew that the HIPAA statute had not granted HHS the jurisdiction it really needed to be an effective health privacy regulator.<sup>288</sup> For this reason, HIPAA envisioned that Congress would enact follow-on privacy legislation by August 21, 1999.<sup>289</sup> HHS would gain authority to promulgate the HIPAA Privacy Rule only if Congress failed to legislate.<sup>290</sup>

Congress's self-imposed deadline passed, and it fell to HHS to try to regulate using the inadequate powers HIPAA had granted. HHS reluctantly proposed a draft Privacy Rule in 1999.<sup>291</sup> In the preamble, HHS exhorted Congress to pass legislation and expressed frustration that

the proposed regulation does not directly cover many of the persons who obtain identifiable health information from the covered entities.... [W]e are, therefore, faced with creating new regulatory permissions for covered entities to disclose health information, but cannot directly put in place appropriate restrictions on how many likely recipients may use and re-disclose such information.<sup>292</sup>

HHS seriously considered "limiting the type or scope of disclosures permitted" but felt forced to allow wide data sharing to promote "key public goals such as research, public health, and law enforcement."<sup>293</sup>

The PPSC's 1977 recommendations found an ethical duty to provide individual access if privacy protections are too weak to protect against unconsented disclosures of people's data.<sup>294</sup> Aware that the Privacy Rule was weak and would not protect people against unconsented disclosures of their data,<sup>295</sup> HHS followed the PPSC's

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that use and handle healthcare data).

288. See Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. at 59,923.

289. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-91, § 264(e)(1), 110 Stat. 1930, 2033.

290. *Id.*

291. See Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. at 59,923-24.

292. *Id.* at 59,923.

293. *Id.*

294. See *supra* notes 230-38 and accompanying text.

295. See Standards for Privacy of Individually Identifiable Health Information, 64 Fed.

recommendation to include an individual access right.<sup>296</sup> Access is a second-best solution that empowers people to assess the risks to their civil rights so that they can protect their rights as best they can when privacy law fails to do so.

#### *D. Enabling Other Federal Civil Rights*

For the vast majority of variants that genomic testing reveals, the clinical validity and utility are unknown.<sup>297</sup> Such data lack clinical significance but are relevant to civil rights.<sup>298</sup> In addition to empowering individuals to detect instances of genetic discrimination,<sup>299</sup> data access enables the exercise of various other federally protected civil rights, including people's First Amendment rights to assemble and petition the government for redress of grievances.<sup>300</sup>

Precision medicine scholar Matt Might has published “how-to” instructions for assembling social networks of people who share genetic variants associated with rare diseases.<sup>301</sup> Sharon Terry, President and CEO of the Genetic Alliance, agrees that access to genetic test information fosters formation of social networks among people who share particular gene variants.<sup>302</sup> This right of assembly has its greatest significance precisely in the circumstance when a person has a variant of unknown clinical significance.<sup>303</sup> Professor Might recounts a compelling story of having a son with a suspected deleterious variant that scientists had never seen before.<sup>304</sup> He used social networking to assemble a group of other people with that same variant, which enabled researchers to clarify the variant's

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Reg. at 59,923-24 (discussing the weaknesses of the proposed Privacy Rule).

296. *See id.* at 59,923.

297. *See* Dewey et al., *supra* note 18.

298. *See supra* notes 125-29 and accompanying text.

299. *See supra* Part III.

300. U.S. CONST. amend. I (protecting “the right of the people peaceably to assemble, and to petition the Government for a redress of grievances”).

301. *See* Matt Might, *Discovering New Diseases with the Internet: How to Find a Matching Patient*, MATT MIGHT, <http://matt.might.net/articles/rare-disease-internet-matchmaking/> [<https://perma.cc/2GSS-SSZV>].

302. *See* Terry, *supra* note 252, at 714-15.

303. *See* The White House, *White House Precision Medicine Initiative Summit*, YOUTUBE (Feb. 25, 2016), <https://www.youtube.com/watch?v=3AMq759psUM&feature=youtu.be&t=1h2m36s> [<https://perma.cc/3H46-UAB9>] (presentation of Matt Might).

304. *See id.*



significance.<sup>305</sup> Groups with a variant of unknown significance also can petition Congress and research funding agencies, such as the NIH, to direct more funding toward clarifying the significance of their variant.<sup>306</sup> These activities are expressly protected by the First Amendment,<sup>307</sup> and policies that limit people's genomic data access potentially deprive them of federally protected civil rights.

People have civil rights to engage in scientific inquiry themselves and to contribute their data for research by others. OCR noted, in a 2016 guidance document, that HIPAA's access right makes it possible for people to "directly contribute their information to research."<sup>308</sup> People wishing to contribute their stored data for use in research often find that the data holder will not cooperate in releasing their data, and HIPAA's access right empowers individuals to free their data from recalcitrant data-holders for research purposes.<sup>309</sup> Citizen-led groups, empowered by access to their own data, can attract researchers to study their condition.<sup>310</sup> There is also a growing citizen-science movement, and data access fosters this activity.<sup>311</sup> Policies by research funding agencies and professional

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305. *See id.*

306. *See Terry, supra* note 252, at 714; *see also* REBECCA DRESSER, WHEN SCIENCE OFFERS SALVATION: PATIENT ADVOCACY & RESEARCH ETHICS 5 (2001) ("Today, more than ever, biomedical research is a public affair.... A new breed of patient advocate sits at the table with scientists and policymakers, setting research agendas, planning studies, and considering how study results should affect clinical practice.").

307. U.S. CONST. amend I.

308. *See* OFFICE FOR CIVIL RIGHTS, U.S. DEP'T OF HEALTH & HUMAN SERVS., INDIVIDUALS' RIGHT UNDER HIPAA TO ACCESS THEIR HEALTH INFORMATION 45 CFR § 164.524 (Feb. 25, 2016) [hereinafter OCR, 2016 ACCESS GUIDANCE], <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html> [<https://perma.cc/N9YT-3DXU>].

309. *See* Barbara J. Evans, *Barbarians at the Gate: Consumer-Driven Health Data Commons and the Transformation of Citizen Science*, 42 AM. J.L. & MED. 651, 672-73 (2016).

310. *See, e.g.*, *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1067 (S.D. Fla. 2003) (discussing an effort by families affected by Canavan disease to assemble data and biospecimen resources to fuel research); *see also* PCORnet PPRN Consortium, *Patient-Powered Research Networks: Building Capacity for Conducting Patient-Centered Clinical Outcomes Research*, 21 J. AM. MED. INFORM. ASSOC. 583, 583-86 (2014), <https://academic.oup.com/jamia/article/21/4/583/2909240> [<https://perma.cc/QQG5-4956>] (discussing assembly of data resources by groups of individuals empowered by access to their data); Sharon F. Terry, *The Study Is Open: Participants Are Recruiting Investigators*, SCI. TRANSLATIONAL MED. (Jan. 4, 2017), <http://stm.sciencemag.org/content/9/371/eaaf1001.full.pdf> [<https://perma.cc/YLB8-UMSG>].

311. *See generally* Evans, *supra* note 6 (discussing HIPAA's access right as a tool to enable citizen science); Michael J. Madison, *Commons at the Intersection of Peer Production, Citizen Science, and Big Data: Galaxy Zoo*, in GOVERNING KNOWLEDGE COMMONS 209, 215 (Brett M.

scientists that block individual data access may reflect a judgment that citizen science is illegitimate, yet people have a right of scientific inquiry that potentially enjoys constitutional protection.<sup>312</sup>

Beyond citizen science, some people also desire a new citizen-led bioethics: a framework of data citizenship that gives them a meaningful voice in setting the privacy and data security standards that will govern research uses of their data.<sup>313</sup> The earlier discussion of risks of reidentification and redisclosure of deidentified data sheds light on why many people are disenchanted with the top-down, expert-led “protections” that bioethicists and regulators have fashioned for them.<sup>314</sup> HIPAA access helps foster data citizenship.<sup>315</sup>

### *E. Additional Non-Civil-Rights Objectives*

The remaining objectives of HIPAA’s access right sound in economic and data quality regulation. The Privacy Rule preamble in 2000 notes that access helps people detect and correct errors in their records,<sup>316</sup> which, in the clinical setting, helps avoid medical errors and in research settings helps ensure the integrity of data sets on which scientific conclusions are based.<sup>317</sup>

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Frischmann et al. eds., 2014) (discussing the citizen science movement).

312. See Lori B. Andrews, *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643, 661 (1998) (noting that while “there is no specifically enumerated right to research in the U.S. Constitution, certain commentators argue that support for such a right could be derived from the Fourteenth Amendment right to personal liberty and the First Amendment right to free speech” (footnote call number omitted)); see also Natalie Ram, *Science as Speech*, 102 IOWA L. REV. 1187, 1198 (2017) (arguing that scientific experimentation produces knowledge that is the basis for speech and that, therefore, “the First Amendment must also be concerned with the production of ideas and information”).

313. See generally Barbara J. Evans, *Power to the People: Data Citizens in the Age of Precision Medicine*, 19 VAND. J. ENT. & TECH. L. 243 (2016) (discussing data citizenship in which individuals who form data resources would exert meaningful governance control over decisions about permissible data uses, privacy standards, and database policies).

314. See *supra* Part IV.B.

315. See generally Evans, *supra* note 313.

316. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,606 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164).

317. See Danita Arrowood et al., *Integrity of the Healthcare Record: Best Practices for EHR Documentation (2013 Update)*, J. AHIMA (Aug. 2013), <http://library.ahima.org/doc?oid=300257#.W9yNOi2ZOCR> [<https://perma.cc/6BRC-G52Q>] (discussing data integrity problems in electronic health records and various harms they can cause).

The preamble to the 2014 Privacy Rule amendments notes that individual access to laboratory data promotes “certain health reform concepts” including personalized medicine, participatory medicine, disease management, and prevention.<sup>318</sup> It adds that individual access supports HHS’s goals and commitments regarding widespread adoption of electronic health records.<sup>319</sup>

The 2014 preamble emphasizes that individuals “have access to interpretative information on laboratory results from many sources, including the Internet.”<sup>320</sup> This suggests that one of HHS’s goals was to promote economic freedom and foster a competitive market in unbundled genome interpretation services—that is, stand-alone services that help people understand the significance of variants detected by tests performed at other laboratories.<sup>321</sup> Scholars note that denying people access to their genomic data locks them into an ongoing relationship with the same laboratory that administered the test, raising antitrust concerns and denying their economic freedom to seek variant reinterpretation and second opinions from other sources.<sup>322</sup>

A final, important role of HIPAA’s individual access right is to reduce pressure for passage of state laws granting individuals ownership rights in their data. Topol and Kish have cited the inadequacies of individual data access as grounds to favor individual data ownership.<sup>323</sup> This frustration reflects, in part, the fact that HIPAA’s access right has not yet been effectively enforced.<sup>324</sup> State data ownership laws could create a national patchwork of requirements that interfere with the assembly of nationally scaled data

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318. CLIA Program and HIPAA Privacy Rule; Patients’ Access to Test Reports, 79 Fed. Reg. 7290, 7290 (Feb. 6, 2014) (to be codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164).

319. *Id.*

320. *Id.* at 7295.

321. See Barbara J. Evans, *Economic Regulation of Next-Generation Sequencing*, 42 J.L. MED. & ETHICS (ISSUE 1 SUPPLEMENT) 51, 52-53 (discussing the unbundling of genomic testing and interpretive services).

322. See, e.g., *id.* at 51-66.

323. Leonard J. Kish & Eric J. Topol, Commentary, *Unpatients—Why Patients Should Own Their Medical Data*, 33 NATURE BIOTECHNOLOGY 921, 922 (2015) (arguing that individual ownership of data would serve important interests not being served by current rights of access and control); Eric J. Topol, Comment, *The Big Medical Data Miss: Challenges in Establishing an Open Medical Resource*, 16 NATURE REV. 253 (2015) (calling for data ownership).

324. See Kish & Topol, *supra* note 323, at 922; see also Lye et al., *supra* note 51 (documenting problems with HIPAA access).

sets and impede access to data for socially beneficial research and public health activities.<sup>325</sup> Blocking HIPAA access strengthens the case for individual data ownership. HHS did not state this rationale in its Privacy Rule preambles,<sup>326</sup> but the threat of state data ownership laws hangs heavily over the HIPAA access debate.

## V. DISPLACING STATE LAWS THAT BLOCK TRANSPARENCY

GINA set a deadline of 2009 to place genetic information under the HIPAA Privacy Rule and, by implication, to make genetic data subject to HIPAA's individual access right.<sup>327</sup> HHS met the deadline to extend basic privacy protections to all genetic information held at HIPAA-covered facilities through an interim policy, pending final Privacy Rule revisions in 2013.<sup>328</sup> Implementing HIPAA access to laboratory-held genomic data took even longer, until 2014.<sup>329</sup> Creating a federal civil right of access to laboratory data proved difficult because it required HHS to displace state law.<sup>330</sup>

### A. State Law Barriers to Laboratory Data Access

The Health Care Financing Administration (HFCA), precursor of today's CMS, promulgated regulations implementing the 1988 CLIA

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325. See AXELRAD, *supra* note 77 (discussing diverse state data ownership laws); see also Barbara J. Evans & Susan M. Wolf, *A Faustian Bargain That Undermines Research Participants' Privacy Rights and Return of Results*, 71 FLA. L. REV. (forthcoming 2019), <http://ssrn.com/abstract=3368555> [<https://perma.cc/C9C6-CBWP>] (warning that efforts to stymie HIPAA access could have the unintended consequence of adding to pressure for state data ownership legislation).

326. *Cf.* CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. 7290 (Feb. 6, 2014) (to be codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164).

327. See Genetic Information Nondiscrimination Act of 2008, Pub. L. 110-233, § 105(b)(1), 122 Stat. 881, 905 (2008).

328. See Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5566, 5568 (Jan. 25, 2013) (to be codified at 45 C.F.R. pts. 160, 164) (amending the Privacy Rule to protect genetic information as defined by GINA).

329. See CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7290 (amending the HIPAA and CLIA regulations to support the individual access right).

330. See *infra* Part V.A.

statute in 1992.<sup>331</sup> Those 1992 regulations, still in effect when the Privacy Rule was first developed, looked to the states to define who was an “authorized person” that could receive laboratory data.<sup>332</sup> States traditionally regulated the practice of medicine, including whether test results should be delivered directly to patients or to their physicians.<sup>333</sup> If a state failed to specify who was authorized to receive laboratory data, CLIA defaulted to a rule that the “authorized person” was the person who ordered the test—usually a healthcare provider rather than the tested individual.<sup>334</sup> Otherwise, state law governed.<sup>335</sup> If HIPAA’s access right required laboratories to release data to individuals, this would violate the laws of some states and, consequently, would violate the CLIA regulations.

HHS, writing in 2000, expressed frustration at this state of affairs<sup>336</sup> but was reluctant to preempt the state laws that were blocking individual access at that time.<sup>337</sup> Executive Order 13132<sup>338</sup> on federalism went into effect on November 4, 1999, one day after HHS first proposed the Privacy Rule.<sup>339</sup> HHS scrupulously complied with it when developing the final Privacy Rule published in December 2000.<sup>340</sup> Executive Order 13132 requires federal agencies to consult with states about new federal regulations,<sup>341</sup> and these consultations revealed that the states were alarmed that the Privacy Rule would preempt state laws.<sup>342</sup> The Privacy Rule was famously contentious:

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331. Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 57 Fed. Reg. 7002 (Feb. 28, 1992) (to be codified at 42 C.F.R. pts. 405, 410, 416, 417, 418, 440, 482, 483, 484, 485, 488, 491, 493, and 494).

332. *Id.* at 7013.

333. *See* Evans, *supra* note 6, at 6.

334. *See* Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,485 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164) (discussing, in the preamble to the original Privacy Rule, the role of state law in determining individual access to laboratory information).

335. *Id.*

336. *Id.* (commenting, “we believe individuals should be able to have access to their individually identifiable health information”).

337. *See id.* at 82,797.

338. Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999).

339. *Id.* at 43,259.

340. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,797-98.

341. Exec. Order No. 13,132, 64 Fed. Reg. at 43,256, § 3(a).

342. *See* Standards for Privacy of Individually Identifiable Health Information, 65 Fed.

the proposed rulemaking drew over 52,000 public comments.<sup>343</sup> The year 2000 was not an opportune moment for HHS to court avoidable conflicts with the states.<sup>344</sup> Only under GINA's prodding, eight years later, did HHS finally press forward in addressing state law barriers to HIPAA access.<sup>345</sup>

Even under the original, year-2000 HIPAA Privacy Rule, laboratories still had to comply with HIPAA's access right in states where the term "authorized person" included the tested individual.<sup>346</sup> Moreover, if the individual was the person who ordered the test, laboratories also had to allow HIPAA access.<sup>347</sup> But the laws of many states—and CLIA's deference to those laws—prevented many Americans from accessing their laboratory-held data.<sup>348</sup>

In 2000, HHS expressed hope that people would nevertheless be able to access their laboratory test results: "Although we are concerned about the lack of immediate access by the individual, we believe that, in most cases, individuals who receive clinical tests will be able to receive their test results or reports through the health-care provider who ordered the test for them."<sup>349</sup> In other words, HHS hoped that laboratory test results would find their way into physicians' files where individuals could access them because most physicians are HIPAA-covered and subject to the access right.<sup>350</sup>

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Reg. at 82,797-98.

343. Grace Ko, *Partial Preemption Under the Health Insurance Portability and Accountability Act*, 79 S. CAL. L. REV. 497, 500 & n.23. (2006).

344. *See generally id.* (discussing concerns with the Privacy Rule as it was being promulgated).

345. *See, e.g.*, Genetic Information Nondiscrimination Act of 2008, Pub. L. 110-233, § 105(b)(1), 122 Stat. 881, 905 (requiring amendments to ensure that genetic information, as broadly defined by GINA, would receive HIPAA's privacy protections, which include an access right).

346. Standard for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,485.

347. *Id.*

348. *See* CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. 7290, 7307-08 tbl.4 (Feb. 6, 2014) (codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164) (listing the states in which people were not able to access their laboratory-held data under the original HIPAA Privacy Rule).

349. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,485.

350. *See Health Information Privacy: Covered Entities and Business Associations*, U.S. DEP'T HEALTH & HUM. SERVS., <https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html> [<https://perma.cc/BYL8-LTEV>].

The shift to genomic testing after 2000 dashed this hope. The vast majority of genomic information—even from clinical genomic tests—lacks clinical significance<sup>351</sup> and is never reported to HIPAA-covered healthcare providers but remains stored at the laboratory.<sup>352</sup> Without a right of access to laboratory-held information, people lack an effective right of access to their genomic information, most of which never leaves the laboratory even when testing is performed at a CLIA-certified clinical lab.<sup>353</sup>

Lack of access is an even greater problem for data generated at research laboratories. As already noted, most gene sequencing to date has been performed as part of biomedical research, so research laboratories hold much of the genomic data now in storage.<sup>354</sup> Sequencing produces a vast amount of data about a person's gene variants, which are the thousands, even millions, of points at which the person's genes differ from an idealized human reference genome.<sup>355</sup> For most of these variants, nobody yet knows how they affect health, so the variant cannot be interpreted in the sense of explaining its clinical validity or utility (health impact).<sup>356</sup> Even if a variant's health impact is well understood, research laboratories may not bother to interpret it if the information is irrelevant to the focus of their research.<sup>357</sup> Thus, a study of cystic fibrosis may not take time to interpret nonfocal (unrelated) variants with known associations to diabetes risk.<sup>358</sup> A research lab may interpret just a handful of gene variants relevant to the research, but nevertheless

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351. See Dewey et al., *supra* note 18.

352. See CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7295 (noting that "test reports [i.e., the reports that laboratories convey to health-care providers] may be only part of a designated record set that a HIPAA-covered laboratory holds"); see also Barbara J. Evans et al., *Regulatory Changes Raise Troubling Questions for Genomic Testing*, 16 GENETICS MED. 799, 800 (2014) (discussing the types of data that laboratories develop in the course of conducting genetic testing, much of which lacks clinical significance and therefore may not be reported to healthcare providers).

353. See *supra* notes 351-52.

354. See *supra* notes 141-43 and accompanying text.

355. See FOOD & DRUG ADMIN., *supra* note 121; Kohane et al., *supra* note 17, at 400.

356. Dewey et al., *supra* note 18.

357. Susan M. Wolf et al., *Managing Incidental Findings and Research Results in Genomic Research Involving Biobanks and Archived Data Sets*, 14 GENETICS MED. 361, 364 (2012).

358. *Id.* (distinguishing findings "discovered in the course of research, when the finding is on the focal variables under study in meeting the stated aims of the research project" from nonfocal variables that do not advance the aims of the research).

keep files recording all of the person's variant data: the focal variants interpreted as part of the research, plus other variants that were uninterpreted or uninterpretable.<sup>359</sup>

All of this stored information presents potential risks to a person's privacy and civil rights, and people want access to it.<sup>360</sup> Many (although not all) research laboratories, including those affiliated with large academic medical centers, are subject to the HIPAA Privacy Rule.<sup>361</sup> Yet, under the year-2000 rule, HIPAA access to laboratory data was constrained by state law.<sup>362</sup> As of 2014, HHS found that only nine U.S. states and territories authorized direct individual access to laboratory test reports; seven allowed individual access with a doctor's approval; twenty-six were silent about individual access, and; thirteen only allowed healthcare providers to access a person's data.<sup>363</sup>

### *B. GINA as a Federal Civil Rights Intervention*

The February 2014 final rule creating HIPAA's right of access to laboratory data did two things. It eliminated the Privacy Rule's earlier access exceptions that placed most laboratory data outside HIPAA's access right,<sup>364</sup> and it made conforming changes to the CLIA regulation permitting laboratories to provide HIPAA access.<sup>365</sup> CLIA's general reporting rules continue to look to state law to define who is "authorized" to receive laboratory data,<sup>366</sup> but HHS emphasized that the HIPAA Privacy Rule preempts any state law that impairs people's HIPAA access right.<sup>367</sup>

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359. Evans et al., *supra* note 352, at 800 (describing the many types of data that laboratories generate as a byproduct of genomic testing).

360. See Parker, *supra* note 252, at 456 ("What appears rather consistent across most of these studies is the finding that a substantial proportion of people express a desire for receiving research results.").

361. See Evans et al., *supra* note 352, at 801 (explaining situations in which research laboratories may become HIPAA-covered entities).

362. See *supra* notes 331-35 and accompanying text.

363. CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. 7290, 7307 (Feb. 6, 2014) (to be codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164).

364. 45 C.F.R. § 164.524 (2018).

365. 42 C.F.R. § 493.1291(l).

366. 42 C.F.R. § 493.1291(f); 42 C.F.R. § 493.2.

367. CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7304.



Patients and patient advocates who commented on this rule-making uniformly supported direct patient access to laboratory test results, citing dignity, liberty, and even property interests in access to their data.<sup>368</sup> In contrast, comments by physicians emphasized laypeople's lack of sophistication and the alleged harms they might suffer if granted direct access.<sup>369</sup> State medical practice regulations that block individual access to laboratory data embody these concerns about the public's scientific illiteracy.<sup>370</sup>

GINA, like the Voting Rights Act of 1965,<sup>371</sup> was a federal intervention to displace state laws that were interfering with important civil rights.<sup>372</sup> "Like the right to vote, access to one's own data is a foundational civil right that empowers people to protect all their other civil rights."<sup>373</sup> Like the Voting Rights Act, GINA challenged deeply held establishment convictions that people's civil rights should be curtailed, both for their own good and for the good of society, based on a perception that they are illiterate<sup>374</sup>—in this case, medically and scientifically illiterate.

In 1959, the U.S. Supreme Court noted that nineteen states had laws requiring people to prove literacy before they could vote.<sup>375</sup> The right to vote is a federally protected civil right,<sup>376</sup> but states administer the process of voter registration.<sup>377</sup> Literacy tests have a certain rationale. In the nineteenth century, a Massachusetts literacy

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368. See Individual Comments, <http://www.regulations.gov> [<https://perma.cc/CV28-HR3Y>] (referencing rulemaking file CMS-2011-0145), at document references CMS-2011-0145-0022, CMS-2011-0145-0035, CMS-2011-0145-0039, CMS-2011-0145-0063, CMS-2011-0145-0073, CMS-2011-0045-0079, CMS-2011-0145-0090, CMS-2011-0145-0104, CMS-2011-0145-0105, CMS-2011-0145-0120, CMS-2011-0145-0166.

369. See Physician Comments, <http://www.regulations.gov> (referencing rulemaking file CMS-2011-0145), at document references, CMS-2011-0145-0042, CMS-2011-0145-0038, CMS-2011-0145-0007, CMS-2011-0145-0019.

370. See *supra* Part IV.A.

371. Voting Rights Act of 1965, Pub. L. No. 89-110, 79 Stat. 437 (codified as amended at 52 U.S.C. §§ 10101, 10301-10314, 10501-10508, 10701-10702 (Supp. III 2016)).

372. See *supra* Part IV; notes 323-26 and accompanying text.

373. Evans, *supra* note 6, at 6-7.

374. See *id.*; see also *supra* Part IV.A.

375. See *Lassiter v. Northhampton Cty. Bd. of Elections*, 360 U.S. 45, 52 n.7 (1959) (listing nineteen states that imposed literacy tests as a condition of voter registration).

376. See Voting Right Act of 1965, Pub. L. No. 89-110, 79 Stat. 437 (codified as amended at 52 U.S.C. §§ 10101, 10301-10314, 10501-10508, 10701-10702 (Supp. III 2016)).

377. U.S. CONST. art. 1, § 4 ("The Times, Places and Manner of holding Elections for Senators and Representatives, shall be prescribed in each State by the Legislature thereof.")

test was said to “insure an ‘independent and intelligent’ exercise of the right of suffrage.”<sup>378</sup> Literacy and intelligence are not necessarily correlated, but literacy does promote informed voting “in our society where newspapers, periodicals, books, and other printed matter canvass and debate campaign issues.”<sup>379</sup> An ethical person could conclude that letting illiterate people vote may lead them to make bad choices that harm themselves and society. In *Lassiter v. Northhampton County Board of Elections*, the Supreme Court did not “sit in judgment on the wisdom” of state literacy tests, and held that they were not, in themselves, unconstitutional.<sup>380</sup>

Justice Douglas, writing for the Court in *Lassiter*, spotted a problem and invited plaintiffs to raise it in future federal proceedings.<sup>381</sup> Literacy testing, however well-motivated it may sometimes be, can have discriminatory impacts that divest entire classes of people of important civil rights.<sup>382</sup> Several years later, Congress addressed this problem in the 1965 Voting Rights Act, which was “designed to attack the clear moral wrong of deliberate disfranchisement in the Jim Crow South.”<sup>383</sup> It did not single out Southern states, but it instead applied a two-pronged test.<sup>384</sup> States were covered by the legislation if they applied a literacy test and had total voter turnout (across all races) below 50 percent in the 1964 presidential election.<sup>385</sup> These covered states—which happened to be in the South—were placed under “federal receivership, with every change in any aspect of voting subject to pre-approval by either the [U.S. Department of Justice] or the U.S. District Court for the District of Columbia.”<sup>386</sup>

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378. *Lassiter*, 360 U.S. at 52 (quoting *Stone v. Smith*, 34 N.E. 521, 521 (Mass. 1893)).

379. *Id.*

380. *Id.* at 53.

381. *Id.* at 50 (“[The] issue of discrimination in the actual operation of the ballot laws of North Carolina has not been framed in the issues presented for the state court litigation. So we do not reach it. But we mention it in passing so that it may be clear that nothing we say or do here will prejudice appellant in tendering that issue in the federal proceedings which await the termination of this state court litigation.” (internal citation omitted)).

382. *See id.*

383. Abigail Thernstrom, *Section 5 of the Voting Rights Act: By Now, A Murky Mess*, 5 GEO. J.L. & PUB. POL’Y 41, 42-43 (2007).

384. *See id.* at 42.

385. *Id.* at 43.

386. *Id.* at 47.

The federal government thus stepped in to correct state laws that were divesting people of federally protected civil rights based on their perceived literacy.<sup>387</sup> Like today's scientific literacy standards that seemingly can be met only if a person has advanced training in medicine or science,<sup>388</sup> the literacy tests at issue in the Voting Rights Act were highly contrived to favor voter qualification of an entrenched elite.<sup>389</sup> The Voting Rights intervention was effective.<sup>390</sup> The percentage of African American adults registered to vote rose from 19.3 percent in March 1965 to 51.6 percent by September 1967 in Alabama and, in Mississippi, the figure rose from 6.7 percent to 59.8 percent in two years.<sup>391</sup>

In a tragic echo of the Voting Rights Act, the individual access right GINA created has elicited a strong resistance that—as the remainder of this Article explores—has included instances of public officials acting under the color of law to block the newly created civil right.<sup>392</sup> The Article concludes, however, that this resistance is not willful, but rather it is the product of misunderstanding about what the access right is. The access right is judged as if it were a consumer health and safety regulation, when in fact it is a civil rights law.<sup>393</sup>

## VI. INDIVIDUAL DATA ACCESS AFTER GINA

The core of the conflict relates to the breadth of HIPAA's access right. This makes it necessary to offer a brief introduction to the mechanics of the access right. The Privacy Rule was first promulgated in December 2000<sup>394</sup> and, after minor revisions in 2002,<sup>395</sup> took effect on a phased schedule in 2003-2004. The Privacy Rule has always

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387. *See id.* at 43-44.

388. *See supra* Part IV.A.

389. *See* Thernstrom, *supra* note 383, at 42-43, 47.

390. *See id.* at 44.

391. *Id.*

392. *See infra* Part VII.

393. *See infra* notes 510-14 and accompanying text.

394. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164).

395. Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182 (Aug. 14, 2002) (codified at 45 C.F.R. pts. 160, 164).

included an individual access right.<sup>396</sup> The basic mechanics of this access right have not changed over the years and are summarized below. GINA led to Privacy Rule amendments in 2013<sup>397</sup> and 2014.<sup>398</sup> The summary below highlights differences between the original access right and the post-GINA access right in effect since 2014.

### *A. Application and Enforcement*

HIPAA's individual access right is a legally enforceable civil right arising under 45 C.F.R. § 164.524.<sup>399</sup> With limited exceptions, HIPAA-covered entities must provide access in response to an individual's request within thirty days with one 30-day extension permissible if the covered entity provides a written explanation.<sup>400</sup> Failure to provide access can lead to administrative enforcement action and civil penalties.<sup>401</sup> Entities that are not HIPAA-covered are not required to provide access.<sup>402</sup>

### *B. Exceptions Allowing Denial of Individual Access*

#### *1. Exceptions That Have Not Changed Over Time*

The Privacy Rule provides very narrow grounds for a covered entity to deny HIPAA access.<sup>403</sup> HHS intends for covered entities to

396. 45 C.F.R. § 164.524 (2018).

397. See Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; 78 Fed. Reg. 5566 (Jan. 25, 2013) (to be codified at 45 C.F.R. pts. 160, 164) (amending the Privacy Rule to protect genetic information as defined by GINA).

398. See CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. 7290 (Feb. 6, 2014) (to be codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164).

399. See 45 C.F.R. § 164.524.

400. See *id.* § 164.524(b)(2) (providing for access within thirty days, with up to one thirty-day extension possible if the covered entity provides a written explanation).

401. See, e.g., *Sebelius v. Uplift Med., P.C.*, No. RWT 11cv2168, 2012 WL 8251345, at \*1 (D. Md. Aug. 30, 2012) (enforcing civil fines of \$4.3 million for denial of timely HIPAA access by forty-one patients, or approximately \$100,000 per denied patient).

402. See CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7294.

403. See 45 C.F.R. § 164.524(a)(2)-(3) (describing nonreviewable and reviewable grounds for denial of access).

invoke these access exceptions “rarely, if at all.”<sup>404</sup> They include, for example, exceptions for data held by correctional facilities and data that would divulge confidential information about third parties.<sup>405</sup> There are reviewable grounds for a covered entity to deny access to data that would endanger the “life or physical safety” of the requesting person or another party,<sup>406</sup> but HHS construes this access exception very narrowly (for example, suicide risk qualifies, but mere emotional distress or psychosocial harm do not).<sup>407</sup>

There is also a limited research exception to HIPAA access.<sup>408</sup> Some research facilities, including many of those affiliated with large academic medical centers, are subject to the HIPAA Privacy Rule.<sup>409</sup> Their data files are subject to HIPAA’s access right.<sup>410</sup> HIPAA’s access right has always—ever since the Privacy Rule was finalized in December 2000<sup>411</sup>—allowed access to both research and clinical data as long as the data are stored at a HIPAA-covered facility. Precisely for this reason, the Privacy Rule has always had an access exception allowing research sites to suspend research participants’ access rights temporarily during a clinical trial.<sup>412</sup> Otherwise, research participants could access their data and “un-blind”

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404. See Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,981 (proposed Nov 3, 1999).

405. See *id.* at 59,938, 59,982-83.

406. 45 C.F.R. § 164.524(a)(3)(i).

407. See CLIA Program an HIPAA Privacy Rule, Patients’ Access to Test Reports, 79 Fed. Reg. at 7296; see also *Conference: Return of Genetic Results in the All of Us Research Program*, NAT’L INST. HEALTH (Mar. 7, 2017), <https://videocast.nih.gov/summary.asp?Live=21887&bhcp=1> [<https://perma.cc/P6AC-JTEV>] (statement by Deven McGraw, J.D., MPH, Deputy Director of Health Information Privacy, U.S. Dep’t of Health & Human Servs., Office for Civil Rights) (discussing the narrowness of this access exception).

408. 45 C.F.R. § 164.524(a)(2)(iii).

409. See Evans et al., *supra* note 352, at 801 (explaining situations in which research laboratories may become HIPAA-covered entities).

410. See *id.*

411. See Standards for Privacy of Individually Identifiable Health Information; Final Rule, 65 Fed. Reg. 82,462 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164) (promulgating the HIPAA Privacy Rule and including the access right at 45 C.F.R. § 164.524).

412. See 45 C.F.R. § 164.524(a)(2)(iii); see also OCR, 2016 ACCESS GUIDANCE, *supra* note 308 (summarizing this exception as allowing access to be delayed if the requested information is “in a designated record set that is part of a research study that includes treatment (e.g., clinical trial) and is still in progress, provided the individual agreed to the temporary suspension of access when consenting to participate in the research. The individual’s right of access is reinstated upon completion of the research”).

the trial.<sup>413</sup> This exception allows research data to be withheld *temporarily* and only if the individual agreed to the denial of access when consenting to the research.<sup>414</sup> Access must be reinstated upon completion of the research,<sup>415</sup> so data from completed studies can never qualify for this exception.

## 2. Changes in 2014 that Altered Exceptions for Laboratory-Held Data

The original Privacy Rule did not require HIPAA access to data held by CLIA-regulated and CLIA-exempt laboratories<sup>416</sup> located in states where direct individual access to laboratory data would violate state law.<sup>417</sup> HHS interpreted this exception as also encompassing data held by research laboratories that operate under CLIA's research exception.<sup>418</sup> The 2014 Privacy Rule revisions eliminated these exceptions, and HIPAA-covered clinical and research laboratories are now subject to HIPAA's access right.<sup>419</sup>

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413. *HHS Recommendations*, *supra* note 195, § II.C.2.

414. 45 C.F.R. § 164.524(a)(2)(iii).

415. *Id.*

416. CLIA-regulated and exempt laboratories are those that comply with the CLIA regulation, either by obtaining a CLIA certificate or by complying with the licensing requirements of a state (New York or Washington) where HHS has determined the state law requirements are equivalent to CLIA. *See* 42 C.F.R. § 493.2; *see also List of Exempt States Under the Clinical Laboratory Improvement Amendment*, *supra* note 151.

417. These exceptions to laboratory data access were in 45 C.F.R. § 164.524(a)(1)(iii) of the pre-2014 Privacy Rule. *See* CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. 7290, 7291 (Feb. 6, 2014) (to be codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164) (explaining, in the preamble to the 2014 final rule granting laboratory data access, that the right of access under the original Privacy Rule did not apply to "[p]rotected health information maintained by a covered entity that is—(1) subject to CLIA to the extent the provision of access to the individual would be prohibited by law; or (2) exempt from CLIA. These exceptions, found at § 164.524(a)(1)(iii)(A) and (B) of the [original] Privacy Rule, cover test reports and other protected health information only at CLIA and CLIA-exempt laboratories"). HHS emphasized that for purposes of this access exception, it interpreted "exempt" laboratories as including research laboratories operating under CLIA's research exception. *See* Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,485 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164).

418. *See supra* note 417; *see also* 42 C.F.R. § 493.3(b)(2).

419. *See* CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7290.

### *C. Scope of Information Access After GINA*

#### *1. Basic Access Provisions that Have Not Changed Over Time*

Individuals have a right of access to their “designated record set” (DRS),<sup>420</sup> which HHS modeled on the “system of records” to which individuals have access under the Privacy Act of 1974.<sup>421</sup> The Privacy Rule defines the DRS as:

A group of records maintained by or for a covered entity that is:  
(i) The medical records and billing records about individuals maintained by or for a covered health care provider; (ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.<sup>422</sup>

The term “record” refers to “any item, collection, or grouping of information that includes protected health information [PHI] and is maintained, collected, used, or disseminated by or for a covered entity.”<sup>423</sup>

There is no requirement for covered entities to provide interpretive assistance to help people understand the significance of their data.<sup>424</sup> Thus, the HIPAA access right is a data-only right: what the covered entity has on file is what you get. HIPAA’s access right does not, however, include psychotherapy notes or data compiled in anticipation of civil, criminal, or administrative legal proceedings.<sup>425</sup>

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420. See 45 C.F.R. § 164.501 (defining the DRS); see also *id.* § 160.103 (defining “health information” as used in the definition of the DRS).

421. See Standards for Privacy of Individually Identifiable Health Information, 64 Fed. Reg. 59,918, 59,980-81 (proposed Nov. 3, 1999).

422. 45 C.F.R. § 164.501.

423. *Id.*

424. See CLIA Program and HIPAA Privacy Rule; Patients’ Access to Test Reports, 79 Fed. Reg. at 7293 (stating, in the preamble to the final rule granting laboratory data access, “[f]inally, we clarify that this final rule does not require that laboratories interpret test results for patients. Patients merely have the right to inspect and receive a copy of their completed test reports and other individually identifiable health information maintained in a designated record set by a HIPAA-covered laboratory”).

425. 45 C.F.R. § 164.524(a)(1)(i)-(ii).

The accessible DRS only includes data that is “maintained” by or for the HIPAA-covered entity.<sup>426</sup> Data cease to be part of an individual’s DRS if the covered entity discards or destroys the data.<sup>427</sup> The HIPAA Privacy Rule does not itself impose any record-retention requirement.<sup>428</sup> Moreover, the DRS only includes data that can be clearly identified as relating to the individual.<sup>429</sup> This is implicit in the definitions that “records” include PHI, and PHI is “individually identifiable” information.<sup>430</sup> Data stored in de-identified form are no longer part of a person’s DRS.<sup>431</sup>

## *2. Changes in 2013 that Expanded the Range of Genomic Data Subject to HIPAA Access*

Under the original Privacy Rule, genomic information was PHI only to the extent it was *health* information.<sup>432</sup> If clinically significant test results had been reported into medical records held by a person’s healthcare providers, those results were PHI and were accessible via HIPAA access requests to the healthcare provider.<sup>433</sup>

GINA required “genetic information,” broadly defined, to be placed under the Privacy Rule.<sup>434</sup> In 2013,<sup>435</sup> HHS complied with this directive by changing the Privacy Rule’s definition of PHI to include “genetic information” as defined by GINA.<sup>436</sup> This amendment vastly expanded the amount of genetic information that was considered

426. *Id.* § 164.524(a)(1).

427. *See id.*

428. *See generally* 45 C.F.R. pts. 160, 164.

429. *See* 45 C.F.R. § 164.501 (defining the term “record” as used in the definition of the DRS).

430. *See id.*; *see also id.* § 160.103 (defining “health information” and “protected health information”).

431. *See id.* § 160.103.

432. *See supra* Part II.

433. *See supra* notes 349-50 and accompanying text.

434. *See supra* Part II.

435. *See* Modification to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5566, 5568 (Jan. 25, 2013) (to be codified at 45 C.F.R. pts. 160, 164) (amending the Privacy Rule to protect genetic information as defined by GINA).

436. 45 C.F.R. § 160.103 (defining the DRS); *see also supra* note 130 (describing GINA-related amendments affecting the health information included in the DRS); notes 169-71 and accompanying text (describing the breadth of genetic information now included).



PHI and hence part of an individual's DRS. Post-GINA, a person's DRS includes virtually any genetic testing data a HIPAA-covered entity has on file, regardless of whether the data are clinically significant or have analytic validity, clinical validity, or clinical utility, and regardless of whether the laboratory has reported it to a healthcare provider.<sup>437</sup>

## VII. THE CONSUMER SAFETY REGULATORY EMPIRE STRIKES BACK: SAFETY AND TRANSPARENCY IN CONFLICT

### *A. Concerns About Individual Access to Research Data*

Regulations and bioethical standards historically have been mutually reinforcing given their shared goal of protecting individuals. The formalization of genomic civil rights regulations after GINA exposed a rift between the two. The rift concerns how safety and civil rights should be prioritized if the two come into conflict.

#### *1. FDA Expresses Concern*

Three days before HIPAA's right of access to laboratory data "went live" on October 6, 2014, FDA published two draft guidances proposing to expand FDA's oversight of laboratory-developed tests—a category that includes many tests used in genomic research.<sup>438</sup> One of the drafts suggested that research laboratories would need to obtain an Investigational Device Exemption (IDE) from FDA if experimental "test results are returned to patients without confirmation by a medically accepted diagnostic product or procedure."<sup>439</sup> To be clear, FDA long has had the power to require

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437. See *supra* note 436.

438. Framework for Regulatory Oversight of Laboratory Developed Tests; Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories; Availability, 79 Fed. Reg. 59,776 (Oct. 3, 2014); Food & Drug Administration Notification and Medical Device Reporting for Laboratory Developed Tests; Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories; Availability, 79 Fed. Reg. 59,779 (Oct. 3, 2014).

439. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., FRAMEWORK FOR REGULATORY OVERSIGHT OF LABORATORY DEVELOPED TESTS: DRAFT GUIDANCE 36-37 (2014), <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm416685.pdf> [<https://perma.cc/B28U-TNCJ>].

an IDE when investigational devices (those that have not been cleared or approved by FDA)<sup>440</sup> are used in studies that pose “significant risk” for the research subjects.<sup>441</sup> For example, FDA can require an IDE if research uses an experimental test as the basis for making decisions that affect research participants’ safety.<sup>442</sup> An example would be using experimental test results to assign participants to receive one or another cancer drug during a clinical trial “without confirmation of the diagnosis by another, medically established diagnostic product or procedure.”<sup>443</sup>

It thus was not surprising that FDA’s 2014 draft guidance stated that FDA can sometimes require IDEs when experimental genomic tests are used in research.<sup>444</sup> The surprise lay in its suggestion that merely allowing research subjects to exercise their HIPAA access rights might be a “significant risk” activity that triggers the need for an IDE.<sup>445</sup> This was all the more surprising because HIPAA access is a “data-only” right that merely allows access to data (such as uninterpreted variant data) that a laboratory holds in its files; HIPAA does not require laboratories to provide any interpretive assistance or make any statements about the clinical significance of the data.<sup>446</sup> In the years leading up to the 2014 draft guidance, FDA officials had signaled that the agency would not view “data-only” direct-to-consumer testing services—those that provide variant data without making interpretive statements—to be medical devices that FDA can regulate.<sup>447</sup>

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440. See 21 C.F.R. § 812.3(g) (1991).

441. Medical Devices; Procedures for Investigational Device Exemptions, 45 Fed. Reg. 3732, 3738 (Jan. 18, 1980). See generally Barbara J. Evans, *The Limits of FDA’s Authority to Regulate Clinical Research Involving High-Throughput Genome Sequencing*, 70 FOOD & DRUG L.J. 259, 264-70 (2015) (discussing FDA’s authority to require IDEs in academic research where the use of an investigational device poses significant risk to research participants).

442. See Evans, *supra* note 441, at 264.

443. 21 C.F.R. § 812.2(c)(3)(iv) (2018).

444. See FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 439, at 36.

445. See *id.* at 36-37.

446. See CLIA Program and HIPAA Privacy Rule; Patients’ Access to Test Reports; Final Rule, 79 Fed. Reg. 7290, 7293 (Feb. 6, 2014) (codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164); see also *supra* Part VI.C.

447. Dan Vorhaus, *DTC Testing and the FDA: Is There an End in Sight to the Regulatory Uncertainty?*, PRIVACY L. REP. (June 16, 2011), <https://theprivacyreport.com/2011/06/16/dtc-genetic-testing-and-the-fda-is-there-an-end-in-sight-to-the-regulatory-uncertainty/> [<https://perma.cc/Q6CM-UBX3>].

The 2014 draft guidance did not clearly state that HIPAA access would trigger the need for an IDE, yet it raised the possibility.<sup>448</sup> FDA later elected not to finalize the draft guidance, to the relief of research laboratories.<sup>449</sup> HIPAA sets a thirty-day deadline, extendable once to sixty days, for laboratories to provide HIPAA access when an individual requests it.<sup>450</sup> Timely access is mandatory, with only limited exceptions.<sup>451</sup> Obtaining an IDE can take many months.<sup>452</sup> Complying with both demands would have been impossible.

## 2. CMS Complicates HIPAA Access

CMS joined OCR in promulgating the February 2014 final rule on laboratory data access,<sup>453</sup> implying that CMS saw no conflict between the HIPAA and CLIA regulations at that time. Shortly after the new access right took effect, however, CMS published a portable data format (PDF) file<sup>454</sup> on its main CLIA web page.<sup>455</sup> This PDF file suggests that research laboratories operating under CLIA's research exception<sup>456</sup> will violate the CLIA regulations if they comply

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448. See generally FOOD & DRUG ADMIN., DEP'T OF HEALTH & HUMAN SERVS., *supra* note 439, at 36-37.

449. FOOD & DRUG ADMIN., DEP'T OF HEALTH & HUMAN SERVS., DISCUSSION PAPER ON LABORATORY DEVELOPED TESTS (LDTs) (2017), <https://www.fda.gov/downloads/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/laboratorydevelopedtests/ucm536965.pdf> [<https://perma.cc/HN5A-W4G9>] (noting that FDA recently announced it would not be issuing final guidance on laboratory developed tests to allow further discussion).

450. 45 C.F.R. § 164.524(b)(2) (2018).

451. See 45 C.F.R. § 164.524(a)(2)-(3) (2018) (describing nonreviewable and reviewable grounds for denial of access).

452. See Evans, *supra* note 441, at 260.

453. See CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports; Final Rule, 79 Fed. Reg. 7290, 7290 (Feb. 6, 2014) (to be codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164).

454. CTRS. FOR MEDICARE & MEDICAID SERVS., RESEARCH TESTING AND CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) REGULATIONS (2014), <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/Research-Testing-and-CLIA.pdf> [<https://perma.cc/76YH-E4HT>].

455. *Clinical Laboratory Improvement Amendments (CLIA)*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=CLIA/> [<https://perma.cc/8QTB-SZZV>] (publishing the PDF file in the "Downloads" section).

456. 42 C.F.R. § 493.3(b)(2).

with HIPAA's access right.<sup>457</sup> The PDF file does not disclose its authorship, leaving it vague whether it is an official statement by CMS or merely an analysis by an unnamed CMS staff member.<sup>458</sup> It was never published in the Federal Register, as the Administrative Procedure Act (APA)<sup>459</sup> requires when federal agencies issue an interpretative rule or general policy statement (together, "guidance document").<sup>460</sup> Nevertheless, its prominent display on CMS's main CLIA web page conveys the impression that CMS endorses it. It has created a perceived conflict of regulations that has had the practical effect of blocking individuals' HIPAA access rights at some research laboratories.<sup>461</sup>

The position expressed in CMS's PDF file contradicts the plain text of the CLIA statute and the CLIA regulations.<sup>462</sup> The scope of

457. See CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 454.

458. See *id.*

459. Administrative Procedure Act, Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified as amended in scattered sections of 5 U.S.C.).

460. See 5 U.S.C. §553(b)(3)(A) (providing an exception to the APA's notice-and-comment requirement when agencies issue "interpretative [*sic*, that is, interpretive] rules, general statements of policy, or rules of agency organization, procedure, or practice," which scholars refer to collectively as non-legislative rules. This exception applies unless another statute, such as the agency's enabling statute, provides otherwise.). *But see* 5 U.S.C. § 552(a)(1)(D) (requiring interpretative rules to be published in the Federal Register); Sean Croston, *The Petition is Mightier than the Sword: Rediscovering an Old Weapon in the Battles Over Regulation Through Guidance*, 63 ADMIN. L. REV. 381, 382 (2011) (defining guidance documents as "those official 'statement[s] of general applicability and future effect, other than [regulations]' that set forth 'a policy on a statutory, regulatory, or technical issue or on interpretation of a statutory or regulatory issue'" (alterations in original) (quoting Office of Management and Budget, Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3434 (Jan 25, 2007), which drew on the Administrative Procedure Act's definition of a "rule" at 5 U.S.C. 551(4) in developing this definition)); Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents*, 90 TEX. L. REV. 331, 334 n.14 (2011) (citing Michael Asimow, *Guidance Documents in the States: Toward a Safe Harbor*, 54 ADMIN. L. REV. 631, 632 (2002) for using "guidance documents" to refer collectively to policy statements and interpret[at]ive rules).

461. Steven J. Keating, personal communication (Jan. 5, 2018) (on file with author) (noting, with respect to the access barriers, "[T]he CLIA/HIPAA issue you describe is the exact barrier that prevented me from accessing my own tumor genome that was done in a research study at my own university a couple years ago").

462. See generally Evans & Wolf, *supra* note 325 (providing a detailed analysis of the statutory provisions summarized here); see also Attachment C: Return of Individual Results and Special Consideration of Issues Arising from Amendments of HIPAA and CLIA, U.S. DEPT HEALTH & HUM. SERVS. (Sept. 28, 2015), <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2015-september-28-attachment-c/index.html> [<https://perma.cc/5856-3E9S>] (finding this position to be "at odds with the plain language" of the CLIA regulation).

CLIA's applicability is mind-numbing subject matter but merits a brief discussion because people's civil rights depend on it.

The current CLIA statute copied its jurisdictional provision from earlier legislation, the Clinical Laboratory Improvement Act of 1967.<sup>463</sup> The CLIA framework has always been directed at clinical laboratories that perform tests to support patient care in clinical healthcare settings, rather than at research laboratories that perform tests to advance scientific discovery.<sup>464</sup> The statute implements this intent through its jurisdictional provision, which states that CLIA only applies to laboratories that perform tests for the purpose of "providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."<sup>465</sup> Two points stand out about this provision: first, it is intent-based and, second, it is an artful exercise in federalism.<sup>466</sup>

On this first point, CLIA does not supply a special definition for the word "for," so the word takes its ordinary meaning.<sup>467</sup> The primary meaning of "for" is as "a function word to indicate purpose" and "to indicate an intended goal."<sup>468</sup> To fall under CLIA, a laboratory must do two things: it must perform an act ("providing information") and possess *scienter*: namely, the laboratory must act with intent for the information to be used in clinical health care ("diagnosis, prevention, or treatment of any disease or impairment of, or

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463. Clinical Laboratories Improvement Act of 1967, Pub. L. No. 90-174, 81 Stat. 536.

464. See 113 CONG. REC. 26006 (1967) (statement of Rep. Harley O. Staggers, Chairman, H. Comm. on Interstate Foreign Commerce, on the occasion when the House bill that became the 1967 Clinical Laboratory & Improvement Act was reported out of Committee) (noting that "it should be pointed out that the bill does not cover laboratories engaged in research where examination of specimens is directed toward that end rather to the treatment of patients").

465. 42 U.S.C. § 263a(a) (2012); see also 81 Stat. at 536 (showing the language of the 1967 version of 42 U.S.C. § 263a(a), which was the same as the current jurisdictional provision, except that it used the term "health of man" instead of the more modern "health of human beings").

466. See *infra* this Part.

467. ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 69 (2012) (describing the "Ordinary-Meaning Canon," which provides that "[w]ords are to be understood in their ordinary, everyday meanings—unless the context indicates they bear a technical sense").

468. See *For*, MERRIAM-WEBSTER DICTIONARY, <https://www.merriam-webster.com/dictionary/for> [<https://perma.cc/N5UE-C32W>] (stating, as the primary definition of the word "for": "a—used as a function word to indicate purpose" and "b—used as a function word to indicate an intended goal").

the assessment of the health of, human beings”).<sup>469</sup> CLIA’s intent-based jurisdictional scheme closely resembles the approach Congress took in FDA’s jurisdictional provisions, which ask whether a manufacturer intends its product for clinical use, when deciding whether the product is an FDA-regulated “drug” or “device.”<sup>470</sup>

On the second point, states have long been concerned about federal intrusions on their authority to regulate the practice of medicine.<sup>471</sup> State medical practice acts, regulations, and common law define the scope of medical practice and when it begins and ends.<sup>472</sup> Honoring longstanding principles of federalism, CLIA does not define the terms “diagnosis,” “prevention,” “treatment,” and “assessment of health.”<sup>473</sup> Instead, CLIA leaves it for the States to decide the meaning of these terms and, hence, the scope of CLIA’s applicability within their jurisdictions.<sup>474</sup>

The CLIA regulations draw their jurisdictional language directly from the CLIA statute.<sup>475</sup> This was a deliberate choice by CMS’s

469. 42 U.S.C. § 263a(a).

470. See 21 U.S.C. § 321(g)(1) (defining “drug[s]” that FDA has jurisdiction to regulate); *id.* § 321(h) (Supp. IV 2017) (defining FDA-regulated devices, including diagnostic devices).

471. See, e.g., Joel E. Hoffman, *Administrative Procedures of the Food and Drug Administration*, in 2 FUNDAMENTALS OF LAW AND REGULATION: AN IN-DEPTH LOOK AT THERAPEUTIC PRODUCTS 159, 165-66 (David G. Adams et al. eds., 1997) (discussing the intense debate about federal power to regulate medical practice that preceded passage of the Food, Drug, and Cosmetic Act in the 1930s).

472. 46 AM. JUR. 2D *Proof of Facts* 373 §§ 3, 5, 6, 9, Thompson Reuters (database updated Feb. 2019) (discussing sources of state law that define the scope of medical practice and clinical care); Patrick D. Blake, Note, *Redefining Physicians’ Duties: An Argument for Eliminating the Physician-Patient Relationship Requirement in Actions for Medical Malpractice*, 40 GA. L. REV. 573 (2006) (same).

473. Cf. Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903 (codified as amended at 42 U.S.C. § 263a) (which lacks definitions for these terms).

474. See Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and Clinical Laboratory Improvement Act Program Fee Collection, 58 Fed. Reg. 5215, 5218-19 (Jan. 19, 1993) (reaffirming, in the preamble to 1993 revisions to the CLIA regulations, that the Health Care Financing Administration [the former name of today’s CMS] did not intend to regulate laboratories that report results for purposes unrelated to the “patient care context which helps define the scope of the CLIA statute and these regulations”); see also 46 AM. JUR. 2D *Proof of Facts* 373, *supra* note 472, §§ 3, 5, 6, 9; Blake, *supra* note 472.

475. See 42 C.F.R. § 493.1 (2018) (applying the CLIA regulations to “all laboratories as defined under ‘laboratory’ in § 493.2 of this part”); *id.* § 493.2 (defining “laboratory” using the same language the CLIA statute uses: as a facility that conducts tests for the purpose of “providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings”); see also 42 U.S.C. § 263a(a)

predecessor, the Health Care Financing Administration (HCFA), as it updated the regulations after passage of the 1988 CLIA statute.<sup>476</sup> During that rulemaking, research laboratories expressed divergent concerns, with some wanting reassurance that they would not be CLIA-regulated while others wanted to have CLIA-regulated status.<sup>477</sup> In its proposed rule, HCFA tried to interpret the statute's definition of a "laboratory" so as to clarify which research laboratories would fall under CLIA.<sup>478</sup> The final rule, however, rejected this approach in favor of simply "parroting" the statute's definition of a regulated "laboratory."<sup>479</sup> HCFA stated that the statute "clearly defines the type of facility subject to regulation and is specific with respect to its applicability."<sup>480</sup> In the post-*Chevron*<sup>481</sup> world, HCFA felt Congress had clearly spoken to the issue, leaving no room for the regulations to add anything.<sup>482</sup>

HCFA did clarify one important point by inserting a research exception in the CLIA regulations.<sup>483</sup> Recall that CLIA's basic rule is that a laboratory falls under the CLIA regulations by "*providing information* for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."<sup>484</sup> The research exception interprets and narrows the

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(2012) (using this same language).

476. See Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 57 Fed. Reg. 7002, 7015 (Feb. 28, 1992) (to be codified at 42 C.F.R. Parts 405, 410, 416, 417, 418, 440, 482, 483, 484, 485, 488, 491, 493, and 494).

477. See *id.* (discussing the laboratories' various concerns).

478. See Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), 55 Fed. Reg. 20896, 20917 (proposed May 21, 1990) (proposing a definition of "laboratory" at 42 C.F.R. § 493.2 that added to the statutory language at 42 U.S.C. § 263a(a)).

479. See *Gonzales v. Oregon*, 546 U.S. 243 (2006) (recognizing an exception to *Auer* deference when an agency is interpreting a regulation that simply parrots, or incorporates, statutory language). See generally Hanah Metchis Volokh, *The Anti-Parroting Canon*, 6 N.Y.U. J.L. & LIBERTY 290 (2011) (discussing the exception recognized in *Gonzales v. Oregon*).

480. Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 57 Fed. Reg. at 7014.

481. *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

482. See *id.* at 842-83 ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.").

483. 42 C.F.R. § 493.3(b)(2) (2018).

484. 42 U.S.C. § 263a(a) (2012) (emphasis added); 42 C.F.R. §§ 493.1, 493.2 (emphasis added).

phrase “providing information”<sup>485</sup> to highlight one particular type of information that it is potentially problematic for research laboratories to provide: patient-specific test results. The research exception states that a research laboratory *escapes* CLIA jurisdiction if it “*do[es] not report patient specific results* for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients.”<sup>486</sup> This stresses that reporting “patient-specific results” is the act that may cause a research laboratory to fall under CLIA, but only if the laboratory does so with the required *scienter*.<sup>487</sup> Providing patient-specific results for nonclinical uses is permitted and will not cause a research laboratory to fall under CLIA. Providing other types of research information—such as sharing aggregate, deidentified research results for an entire group of participants—also is permitted, by this view.

The crucial point here is that the research exception parrots the statute’s *scienter* requirement verbatim.<sup>488</sup> This is why there is no conflict between HIPAA access and CLIA’s research exception: When responding to an individual’s request for HIPAA access, a research laboratory is supplying information with the goal of complying with federal privacy law.<sup>489</sup> This privacy law serves various enumerated civil-rights and economic regulatory policy objectives discussed earlier, rather than the clinical purposes that trigger CLIA regulation.<sup>490</sup> It is hard to make out how the mere act of providing HIPAA access could subject a research laboratory to CLIA regulation.

CMS’s 2014 PDF file advances an alternative view. It suggests that a research laboratory falls under the CLIA regulations if it reports patient-specific results for *any* reason.<sup>491</sup> It states that CMS will *presume* a research laboratory to be subject to CLIA if it reports

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485. 42 U.S.C. § 263a(a); 42 C.F.R. § 493.2.

486. 42 C.F.R. § 493.3(b)(2).

487. *Id.*

488. *See id.*; *see also* 42 U.S.C. § 263a(a) (stating the same *scienter* requirement).

489. 45 C.F.R. § 164.524.

490. *See supra* Part IV.

491. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 454 (“In accordance with [the research exception at 42 C.F.R. § 493.3(b)(2)], only those facilities performing research testing on human specimens that *do not report patient-specific results* may qualify to be excepted from CLIA certification.”).



patient-specific results and “those results will or could be used” for clinical purposes.<sup>492</sup> By this view, the laboratory’s intended use for the data is irrelevant; what matters is the potential for data to be misused by other parties after the laboratory reports it. A research laboratory will be CLIA-regulated if it reports patient-specific data that *could be* misused for clinical care by other parties such as physicians, genetic counselors, or the individual.

This view strays too far from the text of CLIA regulations to be lawfully implemented through a guidance document.<sup>493</sup> The 2014 PDF file does not merely interpret, but amends, the CLIA research exception.<sup>494</sup> Agencies can amend their regulations only after notice and public comment, and they must publish the amended regulation in the Federal Register at least thirty days before it takes effect.<sup>495</sup> CMS did not heed these APA requirements. Moreover, the policy CMS announced in its 2014 PDF file seemingly cannot be legitimated via rulemaking because it is inconsistent with the jurisdictional scheme of the CLIA statute itself, which only Congress can amend.<sup>496</sup> Nevertheless, the PDF file has had the practical binding effect of depriving many research participants of their HIPAA access rights.<sup>497</sup>

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492. *Id.* (“In most cases, research testing where patient-specific results are reported from the laboratory, and those results will be or could be used ‘for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings’ are presumed to be subject to CLIA absent evidence to the contrary.”).

493. See 42 C.F.R. § 493.2 (detailing the CLIA regulation’s basic jurisdictional rule).

494. See *supra* this Part.

495. 5 U.S.C. § 553(b)-(c) (2012).

496. See *generally* Evans & Wolf, *supra* note 325 (describing, in more detail, the ways that CMS’s policy statement is inconsistent with the CLIA statute as well as other federal statutes).

497. See *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021 (D.C. Cir. 2000) (invalidating a guidance document the Environmental Protection Agency had informally posted to its website and noting that nonbinding guidance documents “as a practical matter, have a binding effect” if the agency “acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule” and “if it leads private parties ... to believe” that the agency will apply the policy expressed in the document); see also Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use them to Bind the Public?*, 41 DUKE L.J. 1311, 1323, 1327-28 (1992) (noting that nonlegislative rules—interpretive rules, policy statements, and guidance documents—that ostensibly are not legally binding may have practical binding effect, such that notice and comment procedures should be followed).

### 3. OCR Flees Controversy

In a 2016 guidance document, OCR carefully sidestepped confrontation with CMS.<sup>498</sup> The guidance described HIPAA's access right accurately, but it placed key parts of the discussion under a heading that created a false impression that HIPAA's right of access to genomic data may only apply at clinical laboratories, as opposed to research laboratories.<sup>499</sup> As already discussed, HIPAA's access right never has—and still does not—draw any distinction between research and clinical laboratories as long as they are HIPAA-covered facilities.<sup>500</sup> Precisely *because* the access right applies to research data, HIPAA provides an exception that allows a temporary delay in access to research data during clinical trials.<sup>501</sup> Elsewhere in the 2016 Access Guidance, OCR correctly described this narrow research exception,<sup>502</sup> and, in 2017 public statements, an OCR official reiterated that this is the only access exception that specifically applies to research data.<sup>503</sup>

OCR's artfully ambiguous guidance avoided a confrontation with CMS, but it perpetuated widespread confusion. A large class of individuals—people whose genomes were sequenced in HIPAA-covered research labs—has endured ongoing deprivation of a federally protected civil right: their right of access under the HIPAA Privacy Rule.<sup>504</sup>

Civil rights enjoy a special status in U.S. federal law, exemplified by Section 242 of Title 18 of the U.S. Code, which makes it a crime for a public official acting under color of law to willfully deprive people of rights protected by the Constitution or laws of the United States.<sup>505</sup> The Department of Justice explains that “under color of

498. See OCR, 2016 ACCESS GUIDANCE, *supra* note 308.

499. See *id.* (positioning discussion under the heading: “Does an individual have a right under HIPAA to access from a clinical laboratory the genomic information the laboratory has generated about the individual?”).

500. See *supra* Part VI.B.

501. See 45 C.F.R. § 164.524(a)(2)(iii) (2018).

502. See OCR, 2016 ACCESS GUIDANCE, *supra* note 308 (explaining the HIPAA access exception at 45 C.F.R. § 164.524(a)(2)(iii)).

503. See *Conference: Return of Genetic Results in the All of Us Research Program*, *supra* note 407 (statement by Deven McGraw).

504. 45 C.F.R. § 164.524.

505. See 18 U.S.C. § 242 (2012) (“Whoever, under color of any law, statute, ordinance,

law” includes actions public officials take within their lawful authority as well as “acts done beyond the bounds of that official’s lawful authority, if the acts are done while the official is purporting to or pretending to act in the performance of his/her official duties.”<sup>506</sup> It is not necessary to show that the act was “motivated by animus toward the race, color, religion, sex, handicap, familial status or national origin of the victim.”<sup>507</sup>

The HIPAA access right is a law of the United States that enables various genomic civil rights, including some—like the right of assembly and right to petition the government—that are protected by the Constitution.<sup>508</sup> Other regulators—including safety regulators—cannot use powers they have (or feign powers they do not have) to interfere with it. Access to one’s own genetic information held at HIPAA-covered laboratories is, after GINA, a federally protected civil right.<sup>509</sup>

Nothing in this discussion is meant to suggest that federal safety regulators have violated Section 242, at least not yet. It is a criminal statute best known as a tool for prosecuting racist sheriffs in the Jim Crow South.<sup>510</sup> FDA appreciated that constitutionally sensitive issues were at stake and deferred action on the 2014 draft guidance that would have interfered with HIPAA access.<sup>511</sup> CMS, in publishing its 2014 PDF file, did take action under the color of law,<sup>512</sup> and this action has had the practical effect of depriving people of a civil right. However, section 242, because it is a criminal statute, has a

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regulation, or custom, willfully subjects any person ... to the deprivation of any rights, privileges, or immunities secured or protected by the Constitution or laws of the United States ... shall be fined under this title or imprisoned not more than one year, or both; and if bodily injury results from the acts committed in violation of this section ... shall be fined under this title or imprisoned not more than ten years, or both.”)

506. *Deprivation of Rights Under Color of Law*, U.S. DEP’T JUST. (Aug. 6, 2015), <https://www.justice.gov/crt/deprivation-rights-under-color-law> [<https://perma.cc/Q76U-R2UD>].

507. *Id.*

508. See U.S. CONST. amend. I (protecting “the right of the people peaceably to assemble, and to petition the Government for a redress of grievances”); see also *supra* notes 226-29 and accompanying text.

509. See 45 C.F.R. § 164.524.

510. See, e.g., *Screws v. United States*, 325 U.S. 91, 93 (1945).

511. FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 449 (announcing that FDA did not intend to finalize its draft LDT guidances because public comments revealed more complexity and stakeholder resistance than FDA initially anticipated).

512. See *Deprivation of Rights Under Color of Law*, *supra* note 506.

*scienter* requirement.<sup>513</sup> It requires a willful deprivation.<sup>514</sup> Safety regulators that have acted to block HIPAA access appear to have mistaken it for an ill-advised consumer health and safety regulation that needed to be blocked. Being mistaken is not equivalent to being willful. HIPAA's access right is indeed a bad safety regulation because it is not a safety regulation at all. It is a civil rights regulation.

#### 4. *The National Academies Weigh In*

As the impasse dragged into its fourth year, three federal agencies enlisted the prestigious National Academies of Science, Engineering, and Medicine (the "Academies") to prepare a report on the appropriate sharing of data generated during research with research participants (the "Report").<sup>515</sup> The Report's three sponsors were FDA, CMS, and the NIH which is a major source of funding for genomic research; OCR, which administers HIPAA's access right, was not a sponsor.<sup>516</sup> The Academies are highly influential private bodies that have advised the federal government on science and medical policy issues since 1863.<sup>517</sup> Many view them as "the nation's pre-eminent source of high-quality, objective advice on science, engineering, and health matters."<sup>518</sup> "[R]eports of the Academies are viewed as being valuable and credible because of the institution's reputation for providing independent, objective, and nonpartisan advice with high standards of scientific and technical quality."<sup>519</sup>

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513. 18 U.S.C. § 242 (2012).

514. *Id.*

515. COMM. ON THE RETURN OF INDIVIDUAL-SPECIFIC RESEARCH RESULTS, NAT'L ACADS. OF SCIS., ENG'G, & MED., RETURNING INDIVIDUAL RESEARCH RESULTS TO PARTICIPANTS: GUIDANCE FOR A NEW RESEARCH PARADIGM (Jeffrey R. Botkin, Michelle Mancher, Emily R. Busta & Autumn S. Downey eds., 2018) [hereinafter REPORT], [http://nationalacademies.org/hmd/reports/2018/returning-individual-research-results-to-participants.aspx?\\_ga=2.125510026.1285413390.1534711400-1676621809.1532099289](http://nationalacademies.org/hmd/reports/2018/returning-individual-research-results-to-participants.aspx?_ga=2.125510026.1285413390.1534711400-1676621809.1532099289) [<https://perma.cc/MCL5-HMQV>].

516. *Id.* at 2.

517. *Who Are We*, NAT'L ACADS. SCI. ENGINEERING & MED., <http://www.nationalacademies.org/about/whoweare/index.html> [<https://perma.cc/YZX8-8RB6>].

518. *What We Do*, NAT'L ACADS. SCI. ENGINEERING & MED., <http://www.nationalacademies.org/about/whatwedo/index.html> [<https://perma.cc/Z977-AE46>].

519. *Policies and Procedures*, NAT'L ACADS. SCI. ENGINEERING & MED., [http://www.nationalacademies.org/nasem/na\\_064188.html](http://www.nationalacademies.org/nasem/na_064188.html) [<https://perma.cc/EG2B-8L28>].

This Report is a rare deviation from the Academies' usually high standards for quality and rigor.<sup>520</sup> The Report's Statement of Task (SOT)—the set of instructions that the Academies and sponsors agree upon prior to a study<sup>521</sup>—recites the flawed position CMS advanced in its PDF file as if it were a widely accepted truth: “Currently, any research laboratory that returns individual-specific research results is regulated by CLIA.”<sup>522</sup> The Report notes that CMS's position is controversial, but adopts it anyway.<sup>523</sup> The SOT required this: it ordered that the study must “not provide any legal interpretation or analysis regarding the scope of applicability of CLIA.”<sup>524</sup> In other words, do not look at the CLIA statute or ask whether CMS's PDF file correctly states the law.<sup>525</sup> The Report notes that the “sponsors indicated to the committee that it would be appropriate to include in its description of the current regulatory environment for the return of individual research results the CMS's current interpretation of the scope and applicability of CLIA.”<sup>526</sup> This was an instruction for the committee to take CMS's side in an ongoing legal dispute. It is heartbreaking to see our nation's trusted Academies agree to these terms.

The Report opens with a statement that HIPAA's access right is in conflict with the CLIA regulations and repeats this allegation throughout the Report.<sup>527</sup> This posits a regulatory conflict that does

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520. See Evans & Wolf, *supra* note 325 (examining the root causes of this deviation).

521. NAT'L ACADS. OF SCIS., ENG'G, & MED., WORKING WITH THE NATIONAL ACADEMIES: A GUIDE FOR PROSPECTIVE STUDY SPONSORS 2, [http://www.nationalacademies.org/site\\_assets/groups/nasite/documents/webpage/na\\_069619.pdf](http://www.nationalacademies.org/site_assets/groups/nasite/documents/webpage/na_069619.pdf) [<https://perma.cc/2TXC-2GXP>].

522. See REPORT, *supra* note 515, at 5 (quoting the statement of task).

523. *Id.* at 9 (noting that legal scholars question this interpretation).

524. *Id.* at 7 box S-2 (quoting the statement of task).

525. *Id.* at 46 (noting that “the committee was advised that making any comments, analysis, or conclusions regarding the appropriateness of that [CMS] interpretation would be beyond what was intended in the Statement of Task”).

526. *Id.* at 9.

527. *Id.* at 28 (stating, “[A]s currently written and implemented, the laws and regulations governing access to laboratory test results, both clinical and research, are not harmonized”); *id.* at xxvii (stating that “regulatory conflicts create dilemmas for laboratories, investigators, and institutions” and noting the prohibition on return of results from laboratories that are not CLIA-certified and that HIPAA may require return of results regardless of whether they were generated in a CLIA-certified laboratory); *id.* at 250 tbl.6-2 (stating that a non-CLIA-certified laboratory has a “[l]egal obligation[ ]” to make “[m]andatory disclosure under HIPAA (but the act of disclosure then requires laboratory to become CLIA-certified)” —in other words, the required act of providing access to data under HIPAA will trigger CLIA jurisdiction for

not actually seem to exist.<sup>528</sup> The Report then offers recommendations to resolve the alleged conflict. Most notably, Recommendation 12A calls on OCR (which was not a study sponsor and had not requested the Academies' advice) to redefine the Privacy Rule's individually accessible DRS "to include only individual research results generated in a CLIA-certified laboratory or under the externally accountable quality management system for research laboratories (see Recommendation 2)."<sup>529</sup> The problem with this recommendation is that it is unlawful: It calls on OCR to violate GINA's privacy provisions and portions of the Public Health Service Act and the Social Security Act that GINA introduced.<sup>530</sup>

The Report implicitly recommends repeal of GINA's privacy provisions: it would be unlawful for OCR to implement the regulatory changes suggested in Recommendation 12A *unless* Congress repeals GINA's genetic privacy provisions, which passed by a vote of 95-0 in the Senate<sup>531</sup> and 414-1 in the House.<sup>532</sup> In 2017, the latest year for which figures are available, the Academies received 78 percent of their funding doing studies for federal agencies,<sup>533</sup> and the Report in question was 100 percent federally funded.<sup>534</sup> It is distressing to see the public's funds spent on a study that seeks to strip Americans of genetic privacy protections that Congress, by decisive margins, enacted as part of GINA. A congressional investigation into what went wrong here would not be out of order.

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laboratories that would not otherwise be subject to the CLIA regulation). *But see id.* at 315 tbl.C-4 (including, in a similar statement by the Committee's legal consultant, an important proviso that this statement was true "according to CMS"—a proviso that the Committee deleted in its own statement on page 250).

528. *See supra* Part II.

529. REPORT, *supra* note 515, at 267.

530. *See supra* Part II; *see also* Evans & Wolf, *supra* 325 (itemizing current statutes that Recommendation 12A would violate).

531. 154 CONG. REC. 6830, 6841 (2008).

532. *Id.* at 7499, 7519-20.

533. NAT'L ACADS. OF SCIS., ENG'G, & MED., 2017 REPORT TO CONGRESS 59, [http://www.nationalacademies.org/annualreport/Report\\_to\\_Congress\\_2017.pdf](http://www.nationalacademies.org/annualreport/Report_to_Congress_2017.pdf) [<https://perma.cc/5VHN-AQ7V>].

534. *See* REPORT, *supra* note 515, at 2 (listing three federal agencies as study sponsors).

*B. The Ethical Imperative for Research Data Access*

Lost in the recent debate is the notion that individual data access is essential to the legitimacy and vitality of the biomedical research enterprise. This notion has deep roots extending back to the 1977 PPSC report and to the 1997 recommendations for Congress that HHS prepared pursuant to the HIPAA statute.<sup>535</sup> The ethical principles they identified grow ever more important in the current age when biomedical discovery depends on research uses of people's sensitive health and genetic information. This Section aims to revive these ethical principles, now often forgotten.

The PPSC and HHS ethical analyses can be summarized as follows: If our society recognizes an ethical requirement for people to consent to secondary uses of their data, then an individual access right is necessary to ensure valid, informed consents.<sup>536</sup> On the other hand, if our society lets people's data be used in research without their express consent,<sup>537</sup> people will need an individual access right in order to protect their civil rights.<sup>538</sup> Either way, ethical principles weigh in favor of granting individuals a right of access to research data held at HIPAA-covered facilities.

In its 1997 recommendations to Congress, HHS anticipated that many research facilities would focus strictly on research and not be involved in the provision of health care.<sup>539</sup> In current terminology, many research institutions would not be HIPAA-covered entities.<sup>540</sup> Data generated at such facilities would not be subject to the access right.<sup>541</sup> HHS recognized, however, that some research involves the provision of clinical health care and takes place at academic medical centers subject to the access right.<sup>542</sup> HHS stated its belief that "a right to see one's own record, properly managed, need not impair

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535. See generally PRIVACY PROT. STUDY COMM'N, *supra* note 224, ch. 15; *HHS Recommendations*, *supra* note 195, § II.A.

536. See *infra* notes 544-49 and accompanying text.

537. See Kulynych & Greely, *supra* note 13, at 95 (explaining that genomic data are widely used in research without individual consent).

538. See *infra* note 552 and accompanying text.

539. See *HHS Recommendations*, *supra* note 195, § II.A.

540. See 45 C.F.R. § 160.103 (2018) (defining "covered entity").

541. See 45 C.F.R. § 164.524; see also *HHS Recommendations*, *supra* note 195, § II.C.2.

542. See *HHS Recommendations*, *supra* note 195, § II.C.2.

research.<sup>543</sup> HHS recognized just one exception: situations where individual access would “un-blind” a clinical trial.<sup>544</sup> Apart from that narrow research exception, HHS felt HIPAA-covered facilities should provide individual access to research data on the same basis as clinical data.<sup>545</sup>

The underlying ethical concern was that, without an access right, people could not grant valid consents for their data to be used in the growing field of informational research: “[the] “decision whether to disclose a record may depend on what the record says, and so access to the record is integral to making an informed choice to disclose [information].”<sup>546</sup> An individual access right, in HHS’s view, enabled secondary uses of research-quality data by making valid consents possible.<sup>547</sup> This concern is rarely voiced today, and some research bioethicists recommend restricting individual access to research data.<sup>548</sup> This perhaps reflects a world where individual consent is so frequently waived that obtaining valid consent seems a quaint historical concern.<sup>549</sup>

The PPSC, writing in 1977, foresaw just such a dystopian world. In discussing individual access to data collected for research,<sup>550</sup> PPSC felt that individual access to research data may not be warranted if the information is not used to make decisions about the individual *and* if the information “cannot be ... disclosed in individually identifiable form for any other purpose.”<sup>551</sup> PPSC stressed, however, that if research records are not “totally protected against the possibility that individually identifiable information in them will be disclosed for any other purpose,” individual access is “highly relevant.”<sup>552</sup>

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543. *Id.*

544. *See id.* (highlighting the need to prevent clinical trial subjects from discovering the identity of the medication they are taking until the trial is completed); *supra* notes 409-15 (discussing this exception).

545. *See HHS Recommendations*, *supra* note 195, § II.C.2.

546. *Id.*

547. *See id.*

548. *See supra* note 122 (providing examples of scholarly works recommending various restrictions on individual access).

549. *See* Kulynych & Greely, *supra* note 13, at 95 (noting the prevalence of unconsented uses of genomic data).

550. PRIVACY PROT. STUDY COMM’N, *supra* note 224, ch. 15.

551. *Id.* at 573.

552. *Id.* at 599.



The PPSC thus articulated the concern that, forty years later, drove Congress to enact sections 102 and 105 of GINA: data that lack clinical significance may nevertheless have civil rights significance, subjecting people to a risk of unjust discrimination and other adverse social consequences if inappropriately disclosed.<sup>553</sup> Individual access to research-quality data empowers people to protect their civil rights in situations where researchers and research funding agencies, in their quest to share and use data for secondary purposes and to assemble large-scale research data commons,<sup>554</sup> pursue data sharing practices that place individuals' privacy at risk.

PPSC split third-party access and individual access Solomonically. PPSC concluded that unconsented research use of people's data is sometimes ethically justified, but it maintained that individual access is the civil rights quid pro quo for policies that allow such research without informed consent.<sup>555</sup> Those policies endanger people's civil rights in order to advance socially beneficial research and public health uses of their data. If protecting people's civil rights through rigorous consent requirements would chill scientific discovery, then at least empower people to try to protect their civil rights as well as they can by granting them access to their own data. They have a right to know what may be shared without their consent.

The PPSC's 1977 recommendations also played a role in early development of the Common Rule.<sup>556</sup> The National Research Service Award Act of 1974 established a National Commission for the Study of Ethical Problems in Medicine and Biomedicine to guide development of the Common Rule.<sup>557</sup> The National Commission's

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553. See *supra* note 176.

554. See Kulynych & Greely, *supra* note 13, at 108; see also Katherine J. Strandburg et al., *Knowledge Commons and the Road to Medical Commons*, in *GOVERNING MEDICAL KNOWLEDGE COMMONS* 1, 5 (Katherine J. Strandburg et al. eds., 2017) (discussing data commons for use in biomedical research and public health studies); Patricia A. Deverka et al., *Creating a Data Resource: What Will It Take to Build a Medical Information Commons?*, 9 *GENOME MED.* 84, 84 (2017) (discussing the same).

555. See *supra* notes 550-52 and accompanying text.

556. See 45 C.F.R. pt. 46, subpt. A. (2018).

557. See National Research Act, Pub. L. No. 93-348, §§ 201-02, 88 Stat 342, 348-50 (1974) (enacting 42 U.S.C. § 2891-1, the precursor of today's § 300v-1, creating the National Commission and describing its role in developing substantive standards of human subject

recommendations, published in 1978,<sup>558</sup> incorporated the PPSC's views on research that uses existing data and biospecimens.<sup>559</sup> The Commission embraced the PPSC's advice that unconsented third-party use of people's data and specimens is sometimes ethically justified,<sup>560</sup> but it ignored PPSC's proviso that unconsented secondary use, if allowed, gives rise to an ethical duty to grant people access to their data.<sup>561</sup>

After reviewing the Commission's recommendations, Congress enacted the National Research Act of 1978,<sup>562</sup> which authorized the Secretary of HHS to promulgate the Common Rule,<sup>563</sup> subject to a constraint that HHS should either follow the Commission's recommendations or else explain why the Secretary was rejecting them.<sup>564</sup> The Common Rule traditionally has allowed unconsented access to people's data and biospecimens for use in research without granting them an individual access right.<sup>565</sup> By the PPSC's reckoning, this is unethical.<sup>566</sup> The Common Rule amendments that took effect in January 2019 have partly addressed this lapse by deferring to the HIPAA Privacy Rule to regulate many uses of data and biospecimens to which the Common Rule previously applied.<sup>567</sup> The Privacy Rule faithfully implements the PPSC's principle that if researchers can obtain your data without your consent, then you should have access, too.

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protection).

558. *See* Institutional Review Boards: Report and Recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 43 Fed. Reg. 56,174 (proposed Nov. 30, 1978).

559. *See id.* at 56,181.

560. *See id.*

561. *See id.*

562. *See* Community Mental Health Centers Extension Act of 1978, Pub. L. No. 95-622, 92 Stat 3412 (creating a new commission to replace the expiring National Commission, with the new commission having received Congressional instructions to maintain continuity).

563. *See* 42 U.S.C. § 300v-1(b) (2012).

564. *Id.* § 300v-1(b)(2).

565. *See* 45 C.F.R. § 46.116(d) (2016) (allowing, as part of the traditional Common Rule, an IRB to waive individual consent to the use of people's data in research).

566. *See supra* this Part.

567. *See* Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7261-62 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46 and in various other regulations of implementing agencies) (adopting a new regulation at § 46.104(d)(4)(iii) that excludes research and public health studies that are HIPAA-regulated from the Common Rule's jurisdiction); *supra* note 98 and accompanying text.

## VIII. RECONCILING SAFETY AND TRANSPARENCY

*A. Statutory Basis of the Individual Access Right*

Lost in the recent debate is the fact that the 2013 and 2014 rules that expanded the Privacy Rule's access right were implementing a congressional civil rights mandate given in GINA.<sup>568</sup> This fact is indeed difficult to spot in the preamble to the 2014 final rule that created HIPAA's right of access to laboratory test results. The 2014 amendments went beyond what GINA required and provided access to nongenetic as well as genetic laboratory test results.<sup>569</sup> GINA, of course, only addressed genetic information.

The 2014 HIPAA amendments, in fact, rest on three sources of statutory authority. First, the Administrative Simplification provisions of the 1996 HIPAA statute arguably already empowered OCR to require individual access to PHI stored at HIPAA-covered laboratories and to include genetic information within HIPAA's definition of PHI.<sup>570</sup> Second, any uncertainty about that fact was resolved in 2008 by GINA's mandate for OCR to include genetic information within HIPAA's definition of PHI and to place it under the Privacy Rule's protections.<sup>571</sup> Third, the American Recovery and Reinvestment Act of 2009 (ARRA)<sup>572</sup> included the Health Information Technology for Economic and Clinical Health (HITECH) Act.<sup>573</sup> HITECH established a federal advisory committee on health information technology policy, which recommended expanding

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568. Genetic Information Nondiscrimination Act § 105(a), 42 U.S.C. § 1320d-9(a) (2012).

569. See CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports; Final Rule, 79 Fed. Reg. 7290 (Feb. 6, 2014) (to be codified at 42 C.F.R. 493 and 45 C.F.R. 164).

570. See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 264(c), 110 Stat. 1936, 2033-34 (calling for Congress to implement federal health data privacy legislation by August 21, 1999 and providing that, if Congress failed to do so, the U.S. Department of Health and Human Services would have authority to promulgate the HIPAA Privacy Rule).

571. Genetic Information Nondiscrimination Act § 105(a); see *supra* note 130 (discussing GINA's mandate to treat genetic information as "health information" for purposes of the HIPAA regulations).

572. See American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115.

573. See *id.* div. A., tit. XIII; *id.* div. B, tit. IV (codified at 42 U.S.C. §§ 17931-17940).

individuals' access to their own laboratory-held data, including non-genetic as well as genetic test results.<sup>574</sup>

The 2014 preamble discussed the HITECH and HIPAA statutes at some length, but it did not mention GINA.<sup>575</sup> The reason for this omission was that GINA's major directive—to place genetic information under the Privacy Rule's protections—had already been implemented in a separate rulemaking the prior year.<sup>576</sup> The 2014 amendments simply expanded HIPAA's access right to include laboratory-held PHI, which already included genetic information following those 2013 amendments.<sup>577</sup> The Obama Administration's HHS department had shepherded HIPAA's expanded access right through a contentious rulemaking process extending over three years and two presidential terms<sup>578</sup> and justifiably viewed it as an important civil rights accomplishment.<sup>579</sup> It was perhaps only human for the preamble to highlight its link to the HITECH Act, enacted shortly after Mr. Obama took office in 2009, while downplaying the role of the Bush-era GINA statute.

Insofar as the HIPAA access right includes genetic information, OCR acted under three sources of statutory authority: its general authority to regulate under HIPAA, amplified by a congressional mandate to regulate under GINA, confirmed by recommendations

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574. See CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. 7290 (Feb. 6, 2014) (to be codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164) (discussing recommendations of the Health Information Technology Policy Committee).

575. *Id.* at 7290-91.

576. See Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications of the HIPAA Rules, 78 Fed. Reg. 5566, 5568 (Jan. 25, 2013) (to be codified at 45 C.F.R. pts. 160, 164) (amending the Privacy Rule to protect genetic information as defined by GINA).

577. See CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7290.

578. See CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 76 Fed. Reg. 56,712 (Sept. 14, 2011) (to be codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164) (proposing the laboratory access right); CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7290 (finalizing this right).

579. Press Release, U.S. Dep't of Health & Human Servs., HHS Strengthens Patients' Right to Access Lab Test Reports (Feb. 3, 2014), <http://wayback.archive-it.org/3926/20170128005213/https://www.hhs.gov/about/news/2014/02/03/hhs-strengthens-patients-right-to-access-lab-test-reports.html> [<https://perma.cc/AJ83-2Q59>] (announcing the expanded access right and labeling it a "cornerstone of the Privacy Rule").

developed under HITECH.<sup>580</sup> The individual's civil right of access to genetic information has one of the most unimpeachable statutory pedigrees of any U.S. federal regulation: Congress thrice authorized it. Safety regulators wishing to block this right would need to address their concerns to Congress.

### *B. Safety Solutions That Preserve Civil Rights*

The way forward lies in crafting policies that preserve people's civil right of access while making access as safe and as ethical as it can be. The following ideas are offered simply as examples to stimulate further discussion and debate.

#### *1. The Limits of Prospective CLIA Compliance as a Solution*

CMS has suggested that research laboratories must comply with the CLIA regulation, if they provide HIPAA access.<sup>581</sup> Subjecting research laboratories to CLIA regulation would add costs and regulatory compliance burdens without necessarily improving substantive data reliability. As already discussed, CLIA does not address clinical validity or utility.<sup>582</sup> CLIA also may fail to ensure analytic validity at laboratories that conduct novel genomic tests for which proficiency testing materials do not exist or at laboratories whose use of a research test is too brief to be captured by CLIA's biennial survey/inspection process.<sup>583</sup> Requiring CLIA certification may address a legal technicality, but it does not ensure that data from research laboratories meet bioethicists' concept of clinical-quality data.

There is a deeper problem with prospective compliance. If a laboratory previously operated under CLIA's research exception, it may hold stores of past research data. These past stores of data can never be brought into compliance with the CLIA regulations, even if the laboratory follows CLIA requirements prospectively. The laboratory seemingly faces costly and burdensome OCR enforcement actions if

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580. *See supra* notes 570-74 and accompanying text.

581. *CTRS. FOR MEDICARE & MEDICAID SERVS.*, *supra* note 454.

582. *See supra* note 160 and accompanying text.

583. *See supra* Part III.

it fails to honor individual's HIPAA access rights with respect to its old data, or a CMS enforcement action if it does.<sup>584</sup> Individuals need access to old as well as new data to protect their civil rights. Any workable solution therefore must support access to past as well as future research data.

### *2. Data Destruction Policies*

Stored data only raise civil rights concerns for as long as they remain in storage. For this reason, a person's HIPAA-accessible DRS only includes information that is "maintained" by or for the HIPAA-covered entity.<sup>585</sup> Data cease to be part of an individual's DRS if the covered entity discards or destroys the data.<sup>586</sup> If safety regulators and bioethicists determine that individual access to research data poses serious risks to research participants, one ethical solution would be to require research laboratories to destroy data after research has been completed. This solution runs counter to the desire to maintain data for socially beneficial secondary uses, but it must be mentioned as a possible pathway to protect research participants' civil rights while simultaneously protecting their safety.

### *3. Moving Genomic Research to Non-HIPAA Research Facilities and Implementing Specially Tailored Privacy Policies*

If HIPAA access poses unacceptable risks to research participants, another possible solution is to protect their civil rights by implementing strong privacy protections that prevent their data from being used without their permission.

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584. See *Health Information Privacy: How OCR Enforces the HIPAA Privacy & Security Rules*, U.S. DEP'T HEALTH & HUM. SERVS. (June 7, 2017), <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/examples/how-ocr-enforces-the-hipaa-privacy-and-security-rules/index.html> [<https://perma.cc/M7L3-KHHC>] (discussing OCR's enforcement of the HIPAA Privacy Rule); see also *Health Information Privacy: All Case Examples*, U.S. DEP'T HEALTH & HUM. SERVS. (June 7, 2017), <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/examples/all-cases/index.html> [<https://perma.cc/43JV-7QBT>] (same).

585. See 45 C.F.R. § 164.524(a)(1) (2014).

586. See 45 C.F.R. § 160.103 (2018).

HIPAA's access right only applies at HIPAA-covered facilities.<sup>587</sup> Many genomic research laboratories have HIPAA-covered status as a result of being affiliated with, or being a business associate of, an academic medical center that provides health care.<sup>588</sup> There are various legal and organizational options for structuring research activities to avoid becoming HIPAA-covered. If HIPAA's access right poses unacceptable safety risks to research participants, one option would be to restructure activities so that genomic research is only carried out at non-HIPAA laboratories.

If research data were placed outside HIPAA's privacy protections, an alternative privacy framework seemingly would need to be created to address privacy risks of genomic research. The HIPAA Privacy Rule is merely a set of general privacy protections designed for use in contexts other than genomic research. Its privacy protections are inherently weak<sup>589</sup> and widely criticized.<sup>590</sup> It should not be difficult to develop specially tailored privacy policies that better address the concerns people feel about genomic research. These policies might include, for example, policies addressing the difficulties of deidentifying genomic data and managing reidentification risks; placing meaningful restrictions on downstream uses and re-disclosure; requiring robust individual authorization for secondary uses and more restrictive conditions on the granting of waivers of individual authorization; and providing more transparency about downstream use and storage of data than HIPAA's weak accounting framework provides. These specially tailored policies could be implemented by moving genomic research to non-HIPAA laboratories and then requiring the laboratories to comply with the policies as a condition of research funding or publication in high-impact journals.

In designing such policies, the original ethical analyses of the PPSC and HHS have continued relevance.<sup>591</sup> According to the PPSC, a right of individual access would be ethically unnecessary if records were "totally protected against the possibility that individually identifiable information in them will be disclosed for any other

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587. 45 C.F.R. §§ 160.102, 160.103.

588. See Evans et al., *supra* note 352, at 799.

589. See *supra* Part IV.B-C.

590. See Ohm, *supra* note 191, at 1740.

591. See *supra* Part VII.B.

purpose.”<sup>592</sup> However, HHS cautioned that people can grant valid consents for secondary uses of their records only if they know what the records contain.<sup>593</sup> Herein lies the rub: any privacy policy that eliminates the ethical need for individual access seemingly needs to be even more stringent than the HIPAA Privacy Rule is. Such a policy therefore may make secondary research uses of data and the creation of research data commons even harder than they currently are, although it might be possible to create a highly secure “sharing space” within which genomic researchers could share data under an agreed set of highly rigorous data security standards.

#### *4. Issue HIPAA Guidance to Ensure Accurate Identification of Data in the DRS*

CLIA regulations are sometimes seen as protecting against mix-ups in which one person’s data or biospecimens are mistaken for another’s. One concern about allowing HIPAA access to data from non-CLIA research laboratories is that people may obtain copies of data that are not even their own. As already noted, CLIA’s sample and record identification requirements are modest, and many research laboratories already implement procedures that are equally if not more stringent.<sup>594</sup> Forcing research laboratories to comply with CLIA may add little value, in terms of avoiding mix-ups. A better way to address this concern may be through HIPAA’s own access procedures.

By definition, HIPAA’s DRS—the dataset an individual is entitled to access—only includes data if the data are “about” the individual.<sup>595</sup> Data erroneously attributed to an individual are not rightly part of the DRS to which the individual has a HIPAA access right.<sup>596</sup> It is well within OCR’s discretion to set standards to ensure the integrity of each person’s DRS. OCR could, for example, publish a guidance stating that a research laboratory’s data should only be regarded as traceable to the individual, and therefore part of the

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592. PRIVACY PROT. STUDY COMM’N, *supra* note 224, at 599.

593. *HHS Recommendations*, *supra* note 195, § II.C.2.

594. *See supra* Part III.

595. 45 C.F.R. § 164.501 (2018).

596. *See id.*



individual's accessible DRS, if the laboratory used the individual's name and one other unique identifier for purposes of sample and record identification—in other words, procedures equivalent to what CLIA requires.<sup>597</sup>

Requiring CLIA-equivalent sample and record-tracking procedures is not the only, or necessarily the best, policy solution that OCR could adopt. Suppose, for example, a research laboratory used name only, without recording a second unique identifier, when it generated and stored a person's genomic data in the past. Should these data be excluded from the person's DRS, denying the person's important civil right of access to the data? With genomic data, the variant data themselves uniquely identify the individual; nobody else has that same set of variants.<sup>598</sup> Years later, when the person requests HIPAA access, it would be a simple matter to retest a small sample of the person's variants—for example, the thirteen CODIS markers, which the FBI uses to identify suspected criminals with a high degree of confidence<sup>599</sup>—to ensure that the data stored under the person's name are, in fact, the person's own data. Such a procedure would resolve any lingering concerns about the potential for mix-ups at research laboratories that failed to follow CLIA-equivalent sampling and record-tracking procedures in the past, while preserving people's civil right of access to their data.

A final point is that people's civil rights can be affected when data are wrongly identified to them, and HIPAA access is valued as a mechanism to help people detect and correct instances where misidentification has occurred.<sup>600</sup> In most situations, people do not actually need to obtain a copy of data that have been wrongly stored in their files; they simply need to have the wrongly attributed data removed from their files. An OCR guidance addressing accurate identification of data to be included in individuals' DRS should provide that any data found to be erroneously attributed to the individual should be promptly removed or destroyed.

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597. See Chen et al., *supra* note 165 (describing sample identification for molecular testing laboratories under CLIA).

598. See Annas et al., *supra* note 11, at 360.

599. See *What Is CODIS?*, *supra* note 126.

600. See *supra* Part IV.B.

*5. Warnings, Disclosures, and Other Measures to Mitigate the Risks of Access*

Blocking access is an extreme way to address the safety concerns that access raises. Safety regulators have a duty under federal law to craft more nuanced solutions that address safety concerns without blocking civil rights.

An example may help put things in perspective. Suppose, hypothetically, that there is strong evidence that an FDA-approved drug causes an unusually high rate of serious injuries to members of a specific racial group. FDA's enabling statute authorizes the agency to impose "elements to assure safe use" (restrictions on use, sale, and distribution) to address serious drug safety problems.<sup>601</sup> One way to address the safety concern would be to impose restrictions that block members of the affected racial group from obtaining the drug. Yet doing so would violate their civil rights. Even if FDA had strong evidence that every single member of the group would be injured by the drug, it is ultimately for patients and their physicians to decide whether the potential benefits outweigh the risks. FDA has other tools at its disposal to address safety risks without violating people's civil rights: the FDA can require a warning in the drug's labeling;<sup>602</sup> it can require Medication Guides at the point of sale to inform consumers about the risk;<sup>603</sup> it can send "Dear Doctor" letters warning physicians;<sup>604</sup> it can use the power of publicity to alert the public to the problem;<sup>605</sup> it can order postmarketing studies

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601. 21 U.S.C. § 355-1(f)(3) (2012).

602. *See, e.g.*, 21 C.F.R. § 201.57(c)(1) (2018) (allowing FDA to require boxed warnings in drug labeling for serious risks, particularly those that may result in death or serious injury). *See generally* 21 U.S.C. § 355(o)(4) (authorizing FDA to require manufacturers of approved drugs and biologics to make safety-related labeling changes based on new safety information that becomes available after approval of the drug or biological product).

603. *See* 21 C.F.R. § 208.1 (explaining that FDA can require patient labeling for prescription drugs that raise serious and significant public health concerns).

604. *See id.* § 200.5 (providing for manufacturers, distributors, and FDA to mail letters to physicians and healthcare providers, in specific formats, to notify them of important warnings, important prescribing information, and important corrections of past information about the drug).

605. *See* 21 U.S.C. § 375(b) ("The Secretary may also cause to be disseminated information regarding food, drugs, devices, tobacco products, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer."); *see also* Shannon E. Johnson, *Publicity and the FDA, An Update* (1997) (manuscript at 1),

or clinical trials to better clarify the risk.<sup>606</sup> Title 18, section 242 of the U.S. Code requires safety regulators to pursue civil-rights-preserving options such as these instead of broadly denying the rights of an entire class of consumers.

The same is true of HIPAA access. Regulators have many tools at their disposal to address safety concerns without blocking the right. They can require research laboratories to disclose that data provided under HIPAA's access right may be unreliable or even misattributed to the individual. They can require stern warnings that the data are being provided only for civil rights purposes and must not be used for making medical decisions. They can send "Dear Doctor" letters advising clinicians that patients may approach them with low-quality HIPAA access data and instructing clinicians to resolve any doubts about the source or quality of genetic information in favor of retesting. They can engage state medical practice boards in developing disciplinary sanctions for physicians who act on genetic findings without confirming the source of those findings. It is entirely foreseeable that people, despite all warnings, may seek interpretation of variants included in their HIPAA access files. Safety regulators can develop publicly available quality scores for genomic interpretation services to help steer people to the more reliable ones. They can initiate public education campaigns to help the public understand the limitations of research-quality data. But they cannot, consistent with federal civil rights law, block people's access right.

#### *6. Responsibilities of the Medical Profession and Medical Practice Regulators*

Subclinical-quality test results cannot lead to inappropriate medical procedures unless healthcare providers cooperate in providing such care. In a world where individuals have access to subclinical-quality information from various sources, healthcare providers

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<https://dash.harvard.edu/bitstream/handle/1/8846783/sjohnson.pdf?sequence=1> [<https://perma.cc/TF9Q-63Q3>] (noting that "[a] single Food and Drug Administration (FDA) press release announcing the dangers of a product can instantaneously alter the consumption patterns of millions of consumers").

606. See 21 U.S.C. § 355(o)(3) (2012).

occupy an uncomfortable position as gatekeepers, responsible for denying imprudent follow-up care yet fearing potential liability for their failure to provide such care.<sup>607</sup> At the heart of this dilemma is the absence of a well-defined standard of appropriate follow-up care in the situation where a worried, but asymptomatic, patient arrives at a physician's office with genetic test results but no other clinical indication or history suggestive of disease.

In many instances, such patients may not meet criteria for insurance reimbursement of confirmatory testing or follow-up evaluation, so uncertain data may be the only data available.<sup>608</sup> Consumer safety regulators like FDA and CMS, cannot, by themselves, ensure that genetic information is "safe" because safety is, in large part, a medical practice issue. There is a need for medical practice regulators and state legislators to engage with the problem of establishing an appropriate standard of care in this situation. For example, when is it appropriate for a physician to decline to assist a patient in interpreting data of dubious provenance or quality? Under what circumstances does a patient's refusal (or financial inability) to pursue follow-up testing and evaluation absolve a physician of liability? What are the limits of a physician's—and the healthcare system's—responsibility to respond to requests for interpretive services when the underlying data were not reported for clinical use? Are there more efficient institutional solutions for responding to the natural curiosity individuals feel upon receiving access to their data?

### 7. *Covering the Costs of HIPAA Access*

It is unfair to portray safety regulators as the sole force opposing HIPAA access. It is costly and troublesome to set up an administrative apparatus to receive and track individuals' requests for access,

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607. See Morgan, *supra* note 254, at 544 (discussing the dilemmas medical geneticists face when confronted with patients who seek counseling based on experimental or uncertain genomic test results, and the potential liabilities on either side of acting or not taking action).

608. See Deverka & Dreyfus, *supra* note 142 (discussing the barriers to insurance reimbursement of genomic testing); Morgan, *supra* note 254, at 544 ("Health insurance coverage for medical interventions in asymptomatic individuals based on mutations detected by experimental genomic screening is deniable unless the insurer has a written, specific policy assuring such coverage.").

locate their data, and deliver the data within HIPAA's tight thirty-day time frame.<sup>609</sup> Even commercial data holders complain of the associated financial burdens.<sup>610</sup> Many research laboratories may have welcomed the apparent conflict between safety and civil rights regulations, which has provided a pretext not to provide HIPAA access.

HHS estimated that laboratories nationwide would collectively incur costs of up to \$3.2-63 million to provide HIPAA access during the first year of implementation with these figures trending downward over time, but still \$1-60 million during the fifth year.<sup>611</sup> It is plausible that genomic research laboratories may bear a disproportionate share of these costs: they hold a large share of the genomic data now in existence,<sup>612</sup> and genomic data tend to be viewed as interesting and perhaps worth the effort of filing access requests.

Research laboratories often are funded by grants lasting just several years. Grants do not include a budget line item for staffing a HIPAA access office—not even while the grant is active and certainly not after it concludes. These costs would come out of a grant's fixed allowance for facilities and administrative costs,<sup>613</sup> which institutions may prefer to use for other things, such as building new laboratories. Research laboratories and the grant sponsors that fund them may regard HIPAA's access right as an unfunded federal civil rights mandate that dilutes limited research budgets. Congress, by enacting GINA, created genomic civil rights, and Congress may need to revisit the question of how to fund the costs of making individual data access work.

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609. See 45 C.F.R. § 164.524(b)(2) (2018).

610. See, e.g., Evan Sweeney, *Ciox Health Sues HHS to Stop 'Irrational' HIPAA Enforcement*, FIERCEHEALTHCARE (Jan. 10, 2018), <https://www.fiercehealthcare.com/regulatory/ciox-health-hhs-eric-hargan-hipaa-medical-records-request-ocr-lawsuit> [<https://perma.cc/NY4U-37Y6>] (describing a suit over the allegedly inadequate cost-based fees data holders can charge when responding to patient access requests).

611. See CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. 7290, 7312-13 (Feb. 6, 2014) (to be codified at 42 C.F.R. pt. 493 and 45 C.F.R. pt. 164).

612. See *supra* Part III.

613. See 7.3 *Direct Costs and Facilities and Administrative Costs*, NAT'L INST. HEALTH (Oct. 1, 2017), [https://grants.nih.gov/grants/policy/nihgps/html5/section\\_7/7.3\\_direct\\_costs\\_and\\_facilities\\_and\\_administrative\\_costs.htm](https://grants.nih.gov/grants/policy/nihgps/html5/section_7/7.3_direct_costs_and_facilities_and_administrative_costs.htm) [<https://perma.cc/7CKT-PK9L>] (describing the allowance for facilities and administrative costs in NIH grants).

## CONCLUSION: GINA'S OPEN FUTURE

As GINA enters its second decade, its civil rights protections are more important than they were ten years ago: people's genomic data are widely used in research, often without their consent; bio-informatics algorithms grow more efficient at reidentifying de-identified data; and progress of genetic science is expanding the range of privacy-invasive inferences that can be drawn when data are wrongly shared or misappropriated.

The right of autonomous individuals to inspect and receive copies of stored data about themselves has deep roots in U.S. federal law and rests on firm ethical principles set out in two studies commissioned by the U.S. Congress. Congress reaffirmed these principles in the GINA statute, which requires people's genomic information to receive the full protection of the HIPAA Privacy Rule, including its individual access provision.

Recent resistance to HIPAA's access right appears to be based on well-intentioned confusion about the nature of the access right. It is the product of a congressional civil rights mandate given in GINA and, as such, it deserves compliance and respect. If individuals' access to their own genetic data raises valid concerns about costs or safety, then these concerns unquestionably need to be addressed. But they must be addressed in ways that preserve people's civil rights, always bearing in mind that civil rights have never been free, or free of risk.