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A Virtuous Circle: How Health Solidarity Could Prompt Recalibration of Privacy and Improve Data and Research

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A VIRTUOUS CIRCLE: HOW HEALTH SOLIDARITY COULD PROMPT RECALIBRATION OF PRIVACY AND IMPROVE DATA AND RESEARCH

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I. Introduction

The U.S. health system has the health privacy system it deserves. It is fragmented, based on regulatory technicalities rather than principle, and is frequently exploited by rent-seekers. Suppose, however, the U.S. health system evolved or was changed into a system designed not around individualism (or individual choice) but solidarity.[1] Would that change enable a recalibrated health privacy system? What could it look like, and

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1. Health solidarity argues that ill health is a social cost and therefore should be borne by all through (typically) a universal system of care. Solidarity (or health equity) often is viewed as oppositional to the American value of individualism *See generally* William M. Sage, *Solidarity: Unfashionable, but Still American*, *in* HASTINGS CTR., CONNECTING AMERICAN VALUES WITH HEALTH REFORM 10 (Mary Crowley ed., 2009); Lindsay F. Wiley, *From Patient Rights to Health Justice*, 37 CARDOZO L. REV. 833 (2016).

would that somewhat relaxed health privacy system itself improve the health system, thereby completing a virtuous circle?

At the outset, we emphasize that this Article is not a thinly veiled attempt at reducing or removing health privacy protections. Health data, because of their psychological and emotional implications, particular sensitivity, and potential for enabling stigma and discrimination, deserve exceptional protection. Rather, we posit a thought experiment, examining how health care and health privacy could evolve together, benefiting both.

The core proposition that we advance is that there is (or should be) a hydraulic relationship between healthcare and health privacy, that is as healthcare access increases, the need for health privacy will decrease (and vice versa). First, if health care continues to robustly prohibit health discrimination and continues to grow closer to universal access, the need for health data protection should decrease. This decrease would result not because privacy declines as a value but because exposures of health information would be less consequential. Second, it is broadly accepted that the United States imprudently spends a considerably larger percentage of its "health dollars" on clinical health rather than public health. The outsized role of social determinants, zip-code health, and institutionalized health inequities have been accentuated during the COVID-19 pandemic. Public health recognizes solidarity (social and health interdependence) as a fundamental tenet. As the recovery from COVID-19 begins and we "build back better,"[2] public health (and hence, solidarity) likely will be strengthened. Third, the movements towards universal access and more vibrant public health are likely to be premised on a shift away from health individualism to solidarity. As this shift slowly develops, it is likely to engender more sharing of personal information in order to improve the overall health of the population.

In summary, the hydraulic relationship we posit is that if health care continues to robustly prohibit health discrimination and continues to grow closer to universal access, the need for health data protection should decrease. We further suggest that this could be part of unlocking the puzzle of clinical and public health being slowed by individualism holding sway over solidarity; if the consequences of data exposure are reduced, this should encourage further sharing of data and overall system improvement.

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2. WHITE HOUSE, BUILD BACK BETTER (2021), https://www.whitehouse.gov/build-back-better/ (detailing President Biden's three-part plan to rebuild the American economy following the COVID-19 pandemic).

II. Relating Health Privacy to Health Care

Data laws impacting healthcare lack theoretical integration into the broader space of U.S. healthcare law and policy. They may be taught in health law classes but are often treated as outliers ("class, we may not reach the end of the syllabus and be able to discuss HIPAA[3]"). While data laws were given a seat with older, relationship-based health law such as tort duties, they are not seen as a crucial part of the modern healthcare regulatory system and are viewed only from a distance when healthcare history and policy are discussed. However, in this Article, we argue that our healthcare data laws have a closer relationship to the healthcare law mothership than is often portrayed (and that is not necessarily a compliment).

Both healthcare and healthcare data protection are essentially accidental systems, in large part because policymakers committed "original sins" from which the two systems have never recovered.[4]

Our healthcare system is a public-private hybrid whose Frankensteinian properties are exacerbated every day that passes without us pushing the "pause" button and tackling foundational questions. As Abbe Gluck puts it, "Congress should be debating . . . whether health care falls into the category of goods that individuals should either acquire on their own or go without. Instead, all of our modern political health debates are about changes on the margins."[5]

U.S. healthcare data laws suffer from a similar lack of intellectual focus. Policymakers, from the President, to Congress, to the Supreme Court, punt on the core issue of our privacy rights, and mouth platitudes about how important privacy is, while skirmishing over minor issues[6] such as whether your cable company must ask before it sells your browsing history.[7]

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3. HIPAA refers to the Privacy and Security Rules, 45 C.F.R. Part 160 and Part 164, Subparts A, C and E made pursuant to the 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.)

4. Nicolas P. Terry, *Regulatory Disruption and Arbitrage in Health-Care Data Protection*, 17 YALE J. HEALTH POL'Y, L. & ETHICS 143, 149 (2017) [hereinafter Terry, *Regulatory Disruption*]; *see also* Nicolas P. Terry, *Structural Determinism Amplifying the Opioid Crisis: It's the Healthcare, Stupid!*, 11 NE. U. L. REV. 315, 330 (2019).

5. Abbe Gluck, *America Needs to Decide: Is Health Care Something We Owe Our Citizens?*, VOX (Mar. 18, 2017, 9:36 AM EDT), http://www.vox.com/the-big-idea/2017/3/6/14826974/health-care-aca-philosophy-republican-obamacare (emphasis omitted).

6. *See* Terry, *Regulatory Disruption*, *supra* note 4, at 168.

7. *See* Sarah Krouse & Patience Haggin, *Internet Providers Look to Cash in on Your Web Habits*, WALL ST. J. (June 27, 2019, 5:30 AM ET), https://www.wsj.com/articles/

A. Privatized Health Care and Underregulated Health Privacy

In the absence of fundamental or foundational principles to build on, our data laws lack paths to develop ahead or in conjunction with growing threats. Notwithstanding, some government actors have stepped up to the plate. The Department of Health and Human Services Office of Civil Rights (HHS-OCR) has been increasingly effective in enforcing the HIPAA Security and Privacy rules.[8] The Federal Trade Commission (FTC) has trained its sights on healthcare,[9] and as Daniel Solove and Woodrow Hartzog concluded, the "FTC's privacy jurisprudence is functionally equivalent to a body of common law" and the "FTC's privacy jurisprudence is quite thick."[10] Admirable, yes, but such common-law case-by-case analogues tend to be quite inefficient.

Worse, given the lack of political consensus regarding increased data protection outside of conventional healthcare, our data protection becomes more dependent on private actors and soft regulation—for example, app stores policing mobile medical apps, or famously weak industry codes of conduct.[11] Even those private actors are at war among themselves as the recent spat between Facebook and Apple over the latter's increased transparency rules resulted in public rebukes from the former.[12]

Mothership healthcare policymakers also are enamored of the private sector. Lacking a big reset button, they rely on market approximating policies trotted out as though the late Kenneth Arrow never spent time on this planet.[13] Rather than adopting a public option to private programs, they

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facebook-knows-a-lot-about-you-so-does-your-internet-provider-11561627803 (discussing privacy concerns about how companies use consumer data and why the FTC asked internet-service providers to explain their data-privacy policies).

8. *Cf.* Terry, *Regulatory Disruption*, *supra* note 4, at 203.

9. *See, e.g.*, MARKUS H. MEISER ET AL., FED. TRADE COMM'N, OVERVIEW OF FTC ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS 1 (2019).

10. Daniel J. Solove & Woodrow Hartzog, *The FTC and the New Common Law of Privacy*, 114 COLUM. L. REV. 583, 586 (2014).

11. *See* Casey Ross & Erin Brodwin, *Hospitals Turn to Big Tech Companies to Store and Analyze Their Data — Leaving Patients in the Dark on Privacy Protections*, STAT (Mar. 12, 2020), https://www.statnews.com/2020/03/12/hospitals-big-tech-store-analyze-data-privacy/.

12. *See, e.g.*, Dipayan Ghosh, *Nice Try, Facebook. iOS Changes Aren't Bad for Small Businesses*, WIRED (Dec. 24, 2020, 9:00 AM), https://www.wired.com/story/sorry-facebook-ios-changes-not-bad-for-small-businesses/ (discussing how Facebook criticized Apple's iOS 14, which gave users the choice to ban data tracking and established a more protective data-privacy policy, for allegedly being too unfair to small businesses).

13. *See* Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*,

spend their days adding private options to public programs.[14] As if Elizabethan poor laws-inspired drug-testing and work requirements are not enough, they want our Medicaid populations to open health accounts and, like Medicare recipients, "enjoy" the benefits of privately ordered managed care.[15]

Although dwindling in their frequency, there are still claims that the United States has "the best health care delivery system in the world."[16] However, that proposition is exploded by basic comparisons with other healthcare systems:[17] first, on outright quality metrics, and second, even more seriously when judged on cost-effectiveness based on expended percentages of GDP.[18] The flawed response to the pandemic and the resulting exorbitant death rate in the United States have served as stark reality checks that private health care entities lack incentives "to invest in healthcare solidarity to achieve herd-based improvements to the health of all."[19] Similarly, it has been fashionable to claim that U.S. data laws were groundbreaking and ahead of other countries. If that was ever true, it was

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53(5) THE AM. ECONOMIC REV. 53, 941–73 (1963), http://www.jstor.org/stable/1812044. *See generally* Steven Durlauf, *Kenneth Arrow and the Golden Age of Economic Theory*, VOXEU (Apr. 8, 2017), https://voxeu.org/article/ideas-kenneth-arrow.

14. *See, e.g.*, Mark Miller, *When Medicare Choices Get 'Pretty Crazy,' Many Seniors Avert Their Eyes*, N.Y. TIMES (Nov. 13, 2020), https://www.nytimes.com/2020/11/13/business/medicare-advantage-retirement.html (discussing Medicare and how it has undergone greater privatization since the 1990s, notably with Medicare Part D for prescription drug coverage).

15. *See generally* Elizabeth Hinton et al., *10 Things to Know About Medicaid Managed Care*, KAISER FAM. FOUND. (Oct. 29, 2020), https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-managed-care/ (discussing state Medicaid programs). For a more in-depth critique of Medicaid programs, Medicaid expansion under the Affordable Care Act, and state work requirements for Medicaid programs, see Nicolas P. Terry, *Medicaid and Opioids: From Promising Present to Perilous Future*, 92 TEMP. L. REV. 865, 867–78 (2020) [hereinafter Terry, *Medicaid and Opioids*].

16. *See, e.g.*, *"Face the Nation" Transcripts, July 1, 2012: Speaker Boehner, Senators Schumer and Coburn, Governors Walker and O'Malley*, CBS NEWS (July 1, 2012, 2:55 PM), https://www.cbsnews.com/news/face-the-nation-transcripts-july-1-2012-speaker-boehner-senators-schumer-and-coburn-governors-walker-and-omalley/.

17. *See, e.g.*, Roosa Tikkanen & Melinda K. Abrams, *U.S. Health Care from a Global Perspective, 2019: Higher Spending, Worse Outcomes?*, COMMONWEALTH FUND (Jan. 30, 2020), https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/us-health-care-global-perspective-2019.

18. *Id.*

19. Nicolas Terry, *COVID-19 and Healthcare Lessons Already Learned*, 7 J.L. & BIOSCIENCES, May 2020, at 10 [hereinafter Terry, *Covid-19 Lessons*].

revealed as a myth when Warren and Brandeis's foundational "The Right to Privacy"[20] wound up and down an intentional torts cul-de-sac.[21]

Privatization also leads to the corruption of privacy as bad actors use it to create proprietary data silos, either to monetize the data directly or, in the case of healthcare providers, to protect other networks from competing for their patients.[22] Policymakers have responded by disfavoring such "information blocking" and favoring patient data liquidity.[23] However, there is still too much friction in the system. This friction is proving a major impediment to increasing care coordination that depends on longitudinal rather than episodic models of care.[24] Equally, broader incorporation of socio-demographic data necessary to combat social determinants must see health care privacy embracing public health models (that lean towards solidarity) and require broad data access and sharing.

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20. Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193 (1890). This 1890 article was influenced, in part, by technological advances within the second half of the nineteenth century, such as the camera. Brandeis and Warren identified four types of harms that were based on the "right to be let alone" and recognized that generally one's private matters are to be protected from publication. *See, e.g.*, Bruce E. Boyden, *Regulating at the End of Privacy*, 2013 U. CHI. LEGAL F. 173, 226.

21. *See* Terry, *Regulatory Disruption*, *supra* note 4, at 148 ("Today, the article's 'Right to Privacy' title plays better than its substance and, perversely, that title now exists merely as a slogan inaccurately preserving the myth of strong U.S. data protection.").

22. Privacy advocates have expressed concerns about private actors profiting off of and selling individuals' health data, more commonly known as "data mining." *See, e.g.*, Kirsten Ostherr, *Telehealth Overpromises During the Covid-19 Pandemic*, STAT (Mar. 19, 2020), https://www.statnews.com/2020/03/19/telehealth-overpromises-during-the-covid-19-pandemic/ (expressing concerns about big tech companies storing individuals' health data). Moreover, privacy concerns about data mining have become a bigger issue in recent years. *See, e.g.*, Melanie Evans, *Hospitals Give Tech Giants Access to Detailed Medical Records*, WALL ST. J. (Jan. 20, 2020, 5:30 AM ET), https://www.wsj.com/articles/hospitals-give-tech-giants-access-to-detailed-medical-records-11579516200.

23. *See* 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016) (codified as amended at 42 U.S.C. § 201 and other scattered sections of the U.S.C.); *see also* Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 70064 (Nov. 4, 2020) (to be codified at 45 C.F.R. pts. 170, 171).

24. *See, e.g.*, *Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement*, U.S. DEP'T HEALTH & HUM. SERVS. (Dec. 10, 2020), https://www.hhs.gov/sites/default/files/hhs-ocr-hipaa-nprm.pdf (strengthening HIPAA patient access and improving information sharing for care coordination and case management).

B. Original Sins and Fragmentation

These accidental and incoherent systems were both the product of "original sins."[25] Elisabeth Rosenthal argues that "[t]he very idea of health insurance is in some ways the original sin that catalyzed the evolution of today's medical-industrial complex."[26] An even more likely candidate for the original transgression was the insertion of the employer into the provision of access to healthcare. Post-World War II, government price controls and favorable Internal Revenue Service (IRS) rulings saw participation in employer-provided plans rise sevenfold between 1940 and 1953, to eventually cover over sixty percent of the population.[27] What should have happened thereafter was a transition to a national health insurance model. What actually happened was a two-tier system of healthcare access based on employment status. From 1965 to 2010, politically charged government interventions followed, providing insurance to increasingly narrow slices of the population based on the federal poverty level, disability, age, and so on.[28]

The orthogonal data protection sin was the Privacy Act of 1974,[29] passed in the aftermath of Watergate. A 1973 Department of Health, Education, and Welfare advisory commission had recommended a comprehensive privacy law.[30] Instead, Congress enacted privacy legislation to control only the data collecting practices of the federal government.[31]

Those original sins begat fragmentation. The United States barely has a healthcare "system," instead surviving on a stew featuring a little Bismarck,

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25. Terry, *Regulatory Disruption*, *supra* note 4, at 149. Likewise, Frank Pasquale calls the "original sin" of American privacy law the failure to embrace a comprehensive rather than piecemeal approach to data protection. *See id.* (citing *Episode 7: Mark Rothstein, Big Data & Health Research, Apple ResearchKit, White House Consumer Privacy Bill*, WK. HEALTH L. (Apr. 8, 2015), http://twihl.podbean.com/e/7-mark-rothstein-big-data-health-research-apple-reserachkit-white-house-consumer-privacy-bill/ [https://perma.cc/LQ48-W2RL]).

26. ELISABETH ROSENTHAL, AN AMERICAN SICKNESS: HOW HEALTHCARE BECAME BIG BUSINESS AND HOW YOU CAN TAKE IT BACK 14 (2017).

27. Alex Blumberg & Adam Davidson, *Accidents of History Created U.S. Health System*, NPR (Oct. 22, 2009, 3:28 PM ET), http://www.npr.org/templates/story/story.php?storyId=114045132.

28. *See* Abbe R. Gluck & Nicole Huberfeld, *What Is Federalism in Healthcare for?*, 70 STAN. L. REV. 1689, 1708–19 (2018).

29. Privacy Act of 1974, Pub. L. No. 93-579, 88 Stat. 1896 (codified as amended at 5 U.S.C. § 552a).

30. *See generally* U.S. DEP'T HEALTH, EDUC. & WELFARE, DHEW PUB. NO. (OS) 73–94, RECORDS, COMPUTERS, AND THE RIGHTS OF CITIZENS (1973).

31. *See* 5 U.S.C. § 552a.

a dash of Beveridge, some Canada, and still too much sub-Saharan Africa.[32] Indeed, the most difficult task is cataloging the different types of fragmentation; they include, for example, resource allocation (e.g., public health versus clinical care, downstream to patients rather than upstream to pre-patients), funding streams, insurance markets, lack of coordination in patient care, and so on.[33]

U.S. data protection also exhibits chronic fragmentation.[34] A comprehensive data protection law is multifaceted across both horizontal and vertical dimensions. Horizontally, it should apply to all sectors of the economy. Vertically, it should feature Fair Information Practice Principles (FIPPs)[35]—like protective standards throughout the data lifecycle: creation through destruction. Upstream protections should include data minimization and context or purpose limitations on data collection. Downstream, where data is processed and disclosed, the law should require (at the least) quality, security, integrity, and confidentiality limitations. And, of course, data subjects should be given access, correction, use, and erasure rights, while data custodians should owe duties of accountability and breach notification.[36]

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32. *See generally* INTERNATIONAL PROFILES OF HEALTH CARE SYSTEMS (Roosa Tikkanen et al. eds., 2020).

33. *See* Terry, *COVID-19 Lessons*, *supra* note 19, at 10–11 (discussing the United States' fragmented health care system and how it has impacted the response to the COVID-19 pandemic).

34. *See, e.g.*, Gramm-Leach-Bliley Act, Pub. L. No. 106-102, 113 Stat. 1338 (1999) (codified as amended at 15 U.S.C. §§ 6801–6809) (imposing data protection requirements on financial institutions); Consumer Credit Protection Act, Pub. L. No. 90-321, 82 Stat. 146 (1968) (codified as amended at 15 U.S.C. §§ 1681–1681x) (governing the collection and use of information and its effects on consumers' creditworthiness); Consumer Financial Protection Act of 2010, Pub. L. No. 111-203, § 1031, 124 Stat. 1955, 2005 (codified as amended at 12 U.S.C. §§ 5491–5603) (providing authority to take action to prevent a "covered person" from "committing or engaging in an unfair, deceptive, or abusive act or practice").

35. The Federal Trade Commission (FTC) developed these core privacy principles or FIPPS that include the following: "(1) Notice/Awareness; (2) Choice/Consent; (3) Access/Participation; (4) Integrity/Security; and (5) Enforcement/Redress." Terry, *Regulatory Disruption*, *supra* note 4, at 148 (citing FED. TRADE COMM'N, PRIVACY ONLINE: A REPORT TO CONGRESS 7 (1998)).

36. Compare, for instance, the European Union's General Data Protection Regulation (GDPR) which recognizes health data privacy as a fundamental right. 2016 O.J. (L 119) 32. Instead of governing data privacy based on how and where the information was received, the GDPR favors strong personal data uniform protections. *See id.* There is a presumption against data collection, and data can only be collected if one of six exceptions applies. 2016 O.J. (L 119) 36; *see also* Lothar Determann, *Healthy Data Protection*, 26 MICH. TECH. L.

In contrast to such an ideal, U.S. data laws lack both horizontal and vertical comprehensive characteristics. On the horizontal axis, our data laws are split by domain or sector, so healthcare has a different data law compared to, say, financial services.[37] On the vertical axis, our data laws almost exclusively favor downstream models, protecting some dissemination but seldom inhibiting collection.[38]

Of course, HIPAA is illustrative of both limitations; vertically, it applies only to healthcare, and horizontally, it provides only downstream protections (confidentiality, security, and breach notification).[39] However, HIPAA is at the root of more serious fragmentation because of its relatively narrow application. Rather than applying to healthcare data generally, it applies to an increasingly narrow group of data custodians, primarily "covered entities."[40] If there was truth in advertising, the "HIPAA privacy rule" would have been called "the doctor-hospital-health insurer" confidentiality rule.[41]

REV. 229, 237 (2020) (discussing the European Union privacy-protection framework). Another more comprehensive privacy model making waves is the California Consumer Privacy Act (CCPA). CAL. CIV. CODE §§ 1798.100–1798.199.100 (2021). The CCPA defines personal data more expansively than the European Union's GDPR does. *Compare id.* § 1798.140(v)(1) (defining personal data as "information that identifies, relates to, describes, is reasonably capable of being associated with, or could reasonably be linked, directly or indirectly, with a particular consumer or household"), *with* 2016 O.J. (L 119) 33 (defining personal data as "any information relating to an identified or identifiable natural person"). Although controversial, the CCPA has sparked a debate at the state level. Some states, such as Nevada, Maine, Virginia, and Colorado have passed their own data privacy laws in the wake of the CCPA. *See e.g.,* Kayvan Alikhani, *California's CCPA Triggers a Tsunami of State-Level Data Privacy Laws*, FORBES (Feb. 20, 2020, 7:45 AM EST), https://www.forbes.com/sites/forbestechcouncil/2020/02/20/californias-ccpa-triggers-a-tsunami-of-state-level-data-privacy-laws/?sh=63cafde76cad.

37. *See* Terry, *Regulatory Disruption*, *supra* note 4, at 150 ("[S]ectoral models inevitably encourage differential levels of protection, and that more often promotes a race to the bottom rather than to the top. Worse, high levels of protection can be characterized as outliers and targeted for 'reform.'").

38. Nicolas P. Terry, *Assessing the Thin Regulation of Consumer-Facing Health Technologies*, 48 J.L. MED. & ETHICS 94, 95 (2020).

39. *See* Terry, *Regulatory Disruption*, *supra* note 4, at 155.

40. *See* 45 C.F.R. §§ 160.102–160.103 (2020).

41. For a more in-depth discussion, see Terry, *Regulatory Disruption*, *supra* note 4, at 162. While the HITECH Act of 2009 expanded HIPAA's reach to business associates, the protection provided to health data remains relatively narrow. *See* HITECH Act, Pub. L. No. 111-5, § 13401, 123 Stat. 226, 260 (2009) (codified as amended in scattered sections of 42 U.S.C.).

Self-evidently, data held by data custodians other than covered entities or by the data subject lack HIPAA protection. This omission results in problems as we seek to protect data held in or by mobile devices,[42] fitness bands, big data brokers, the Internet of Things—and the list keeps growing.[43] Unfortunately, healthcare data protection exhibits far deeper fragmentation than is caused by HIPAA's narrow verticality. Even within HIPAA things get complicated. For example, process notes taken by psychotherapists are viewed as personal notes and the Privacy Rule therefore likely exempts most from the rule's patient access and healthcare provider disclosure provisions.[44] Meanwhile, there has been an increase in use of personal data (that previously would not have been considered health data) by some HIPAA covered entities, who now rely on "health plan prediction models" based on consumer data such as "income, marital status, and the number of cars owned, to predict emergency room usage and urgent care needs."[45]

Outside of HIPAA, there is even more health care data protection fragmentation. For example, Title II of the Genetic Information Nondiscrimination Act of 2008 (GINA) applies an upstream (collection) data protection rule to certain genetic information.[46] Regulations promulgated under the Americans with Disabilities Act of 1990 (ADA) police some employer wellness plans.[47] And (at least until recently)[48] the Substance Abuse Confidentiality Regulations (often referred to by their citation, "42 C.F.R. Part 2") promulgated under the Drug Abuse Office and

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42. *See Resources for Mobile Health Apps Developers*, U.S. DEP'T HEALTH & HUM. SERVS. (Sept. 30, 2020), https://www.hhs.gov/hipaa/for-professionals/special-topics/health-apps/index.html.

43. *See* Terry, *Regulatory Disruption*, *supra* note 4, at 194; *see also* Mark A. Rothstein et al., *Unregulated Health Research Using Mobile Devices: Ethical Considerations and Policy Recommendations*, 48 J.L. MED. & ETHICS 196, 196 (2020).

44. 45 C.F.R. § 164.501 (2020); *see also Summary of the HIPAA Privacy Rule*, U.S. DEP'T HEALTH & HUM. SERVS. (July 26, 2013), https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

45. Kirk J. Nahra, *Healthcare in the National Privacy Law Debate*, AM. BAR ASS'N (Dec. 5, 2019), https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2019-2020/december-2019/healthcare-debate/ (citing Natasha Singer, *When a Health Plan Knows How You Shop*, N.Y. TIMES (June 28, 2014), https://www.nytimes.com/2014/06/29/technology/when-a-health-plan-knows-how-you-shop.html [https://perma.cc/HCP6-HGD8]) .

46. *See* 29 U.S.C. § 1182(d)(1).

47. *See, e.g.*, 29 C.F.R. § 1630.14 (2020).

48. *See infra* notes 129–31 and accompanying text.

Treatment Act of 1972[49] applied, in addition to HIPAA, to federally assisted programs that maintain alcohol and substance use patient records.

C. Uneasy Federalism

Our healthcare system and data protection rules share another trait, what could be described as uneasy federalism, as neither our federal or state governments fully agree as to either policy or implementation. The healthcare federalism built on top of our federal system of government has resulted in a dizzying array of actors, sources of finance, and reimbursement models that have created different rules governing access, benefits, out-of-pocket expenses, and so on for different segments of the population.[50] Both holdings in *National Federation of Independent Business v. Sebelius*[51] reflected how far the United States is from a national healthcare system; the Court deemed the Commerce Clause unable to sustain the individual mandate, while states' rights prevailed and upset Medicaid expansion.[52] Once again, where Americans lived was likely to determine their access to healthcare.[53]

Beyond constitutional restraints, the primary cause of this uneasy federalism is that the federal government has little or no interest—or apparent ability—to design or implement a health care system.[54] Its competence begins and ends with financing the endeavors of others which, in some cases, it also regulates. Those "others" are the states and frequently rent-seeking private actors, including health insurers and large health care providers. Medicare may be a national program but, while nationally financed, it primarily depends on implementation by the private sector and state regulators.[55] Similarly, the majority of Medicaid funding comes from

49. Pub. L. No. 92-255, 86 Stat. 65 (codified as amended in 42 U.S.C. § 290ee-3).

50. *See* Terry, *Covid-19 Lessons*, *supra* note 19, at 3.

51. 567 U.S. 519 (2012).

52. *Id.* at 588.

53. Terry, *Covid-19 Lessons*, *supra* note 19, at 4; *see also* Rachel Garfield et al., *The Coverage Gap: Uninsured Poor Adults in States That Do Not Expand Medicaid*, KAISER FAM. FOUND. (Jan. 21, 2021), https://www.kff.org/medicaid/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicaid/.

54. *See generally* Nicolas Terry, *From Health Policy to Stigma and Back Again: The Feedback Loop Perpetuating the Opioids Crisis*, 2019 UTAH L. REV. 785, 788 (discussing the lack of a "coherent national health policy" to combat the opioid crisis in the United States).

55. *See* Laura Snyder & Robin Rudowitz, *Medicaid Financing: How Does It Work and What Are the Implications?*, KAISER FAM. FOUND. (May 20, 2015), https://www.kff.org/medicaid/issue-brief/medicaid-financing-how-does-it-work-and-what-are-the-implications/.

the federal government, particularly in the case of Medicaid expansion's enhanced match.[56] Though some federal regulatory guardrails exist, it is the states who, by contract with the federal government, design and implement their plans (again, primarily using private actors).[57] Further, it is clear that one national political party subscribes to the policy of reducing those who benefit from Medicaid either by implementing work requirements or forcing states to reduce access by moving the financing model to one of block grants.[58] As for claims from the right that the Affordable Care Act (ACA) was a federal government takeover of health care,[59] the most that should be conceded is that it was a dramatic expansion of federal health insurance regulation. Tragically, COVID-19 illustrated that the federal government's disinterest in implementing a national clinical care strategy extended to public health. From managing shortages of Personal Protective Equipment (PPE) and ventilators, to testing, and failing to implement a workable plan for the vaccine roll-out, the federal government acted as though the Tenth Amendment was simply a policy directive to avoid meaningful cooperation.[60] For example, the federal government was unable to replicate the early successes of vaccine development with a workable plan for states to accomplish actual vaccinations.[61]

Data protection fares no better. Doctrinally, the HIPAA Privacy Rule is an example of cooperative federalism.[62] While it preempts, it also permits federal law to defer to some state laws—in particular, those that offer more stringent[63] protection for patient data.[64] So, for example, one state's privacy

56. *See, e.g.*, Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 2001(a)(3)(B)(y), 124 Stat. 119, 272 (codified as amended in 42 U.S.C. ch. 157).

57. *See* Snyder & Rudowitz, *supra* note 55.

58. *See, e.g.*, Terry, *Medicaid and Opioids*, *supra* note 15, at 882–83 (discussing how fiscal conservatives have attempted to use a block-grant framework for Medicaid).

59. *See* Bill Keller, *Five Obamacare Myths*, N.Y. TIMES (July 15, 2012), https://www.nytimes.com/2012/07/16/opinion/keller-five-obamacare-myths.html.

60. *See generally* PUB. L. HEALTH WATCH, ASSESSING LEGAL RESPONSES TO COVID-19 (Scott Burris et al. eds., 2020).

61. *See, e.g.*, Dan Diamond, *The Crash Landing of 'Operation Warp Speed'*, POLITICO (Jan. 17, 2021, 7:00 AM EST), https://www.politico.com/news/2021/01/17/crash-landing-of-operation-warp-speed-459892.

62. Under a cooperative federalism framework, there is an overlapping of responsibilities between the federal and state governments. *See* Mary Hallock Morris, *Cooperative Federalism*, CTR. FOR STUDY FEDERALISM, https://encyclopedia.federalism.org/index.php/Cooperative_Federalism (last visited May 28, 2021).

63. *See* 45 C.F.R. § 160.202(1)–(6) (2020).

64. See id. § 160.203. This generally occurs with three types of state laws: (1) laws that grant individuals more privacy protections or rights to their health information; (2) laws

law may require that a psychologist obtain a patient's consent to disclose medical records over and above HIPAA requirements.[65] Cooperative federalism thus enables states to be innovative and to provide greater privacy protections for persons with medical or psychological conditions associated with social or economic impact.[66] But, because state privacy law was developed haphazardly, and is subject to continual developments in related areas (such as reporting requirements, licensure, and certification), the partial preemptive framework of cooperative federalism is confusing, burdensome, and costly for many stakeholders.[67]

III. Healthcare and Healthcare Privacy Hydraulics

Both healthcare and healthcare data protection are flawed. Indeed, to an extent, they deserve each other. Both have also been the subject of voluminous but unrelated reform proposals. Suppose, however, that we use a different lens through which healthcare and healthcare data protection are seen, one in which they exist in more of a hydraulic relationship. Specifically, we should consider whether, as healthcare protections increase, healthcare data protection should become less stringent or vice versa. The culmination of the former process would be the re-engineering of the U.S. healthcare system as one rotating around solidarity rather than individualism. If that process was ever completed, it could justifiably lead to a recalibration of health data protection—a new model that concentrates less on protecting individual slivers of personal data and more on enabling responsible flows of health data. Subsequently, as the health data protection system increasingly is re-purposed to improve the health system, it would complete a virtuous circle.

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creating reporting requirements, such as those for disease, injury, child abuse, or public health surveillance; (3) laws that require health plans to report or provide access to information for financial audits, program monitoring, or licensure or certification. *See id.* § 160.203(b)–(d). In addition, the HHS Secretary can grant a state's request for non-preemption for certain reasons, including where the Secretary finds the state law serves a compelling need related to public health, safety, and welfare. *See id.* § 160.203(a)(1)–(2).

65. *See* Jennifer Daw Holloway, *What Takes Precedence: HIPAA or State Law?*, AM. PSYCHOL. ASS'N (Jan. 3, 2003), https://www.apa.org/monitor/jan03/hipaa.

66. *See* Grace Ko, *Partial Preemption Under the Health Insurance Portability and Accountability Act*, 79 S. CAL. L. REV. 497, 522 (2006).

67. *Id.* at 507–08; *see also* Jennifer Guthrie, *Time Is Running Out–The Burdens and Challenges of HIPAA Compliance: A Look at Preemption Analysis, the "Minimum Necessary" Standard, and the Notice of Privacy Practices*, 12 ANNALS HEALTH L. 143, 157 (2003).

There are several logical ancillaries to this thought experiment, and some are speculative or for some other reason difficult to establish. For example:

Is there evidence that healthcare data protection has inhibited clinical or public health data collection and analysis; in other words, does solidarity-based public health pay a privacy "tax" for its data?

Equally, how could we validate or measure an increase in the level of clinical and public health research to justify the removal of the privacy tax?

Would increased solidarity in clinical and public health create a societal or policy environment whereby data subjects would be in favor of the recalibration of healthcare data protection?

Is there a political route for the United States to establish clinical care solidarity, meaning a scenario whereby not only would all persons have access to healthcare (universalism) but also all cohorts would have access to the same healthcare system without today's segmentation based on reimbursement, etc.?

Could sufficient trust in solidarity health be built using legal tools such as antidiscrimination rules which render bad actors' misuse of data less consequential such that lower levels of data protection would be palatable?

If this thought experiment were to evolve into policy, then we would need to grapple with each of these questions and more. As explained above, however, we are far from the goals of this thought experiment. The U.S. healthcare system and health privacy systems operate in separate domains that have been subject to numerous, unsuccessful reform efforts, resulting in both systems remaining fragmented, overly complex, and underperforming. But all is not lost. Hiding in plain sight are several examples of successful shifts or recalibrations toward solidarity principles. These examples justify the hydraulic hypothesis and may help shine a light on the path forward.

A. ACA, GINA, and Pre-Existing Conditions

The relationship between the ACA's prohibitions of health discrimination and GINA[68] provides not an example of an actual hydraulic relationship, but more of a "what could have been" scenario.

GINA utilizes two types of data protection to safeguard against discrimination based on genetic test results. First, GINA prohibits downstream point of use discrimination by health insurers (Title I)[69] and

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

69. *Id.* §§ 101–106.

employers (Title II).[70] Second, GINA prohibits the requiring or (in many cases) acquiring of genetic information.[71] The latter is an example of upstream (collection-centric) protection.[72] As Bradley Areheart and Jessica Roberts note, by using an upstream model that prohibits the collection of genetic data, GINA has acted "more as a protection against invasions of privacy than as a protection against discrimination,"[73] although in practice it did both.

In contrast, the ACA works to improve clinical care and promote public health by prohibiting health insurance discrimination based on health status, essentially by outlawing medical underwriting.[74] The ACA has now survived its third existential encounter with the Supreme Court[75] and increasingly seems immune to serious challenges in either judicial or political spheres. However, in the future, if the ACA was invalidated or repealed, the revocation of the prohibition on medical underwriting would be only one of the many tragedies for public health. While some limited genetic data regarding genetic susceptibility may still be protected under GINA, any evidence of "manifest disease" could subject individuals to adverse employment actions, denial of coverage, or increased coverage rates.[76]

Leaving aside that existential threat, the ACA has removed the ability for individual market insurers to deny coverage to or overcharge[77] the 54,000,000 non-elderly Americans with pre-existing conditions who would find themselves uninsurable in the individual marketplace if they were laid off and lost health benefits.[78]

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70. *Id.* §§ 201–213.

71. *See, e.g.*, *id.* § 101(b)(d)(1) (prohibiting, in general, health insurers from requiring, requesting, or purchasing genetic information for purposes of underwriting); *id.* § 202(b) (prohibiting, in general, employers from requiring, requesting, or purchasing genetic information about an employee).

72. *See* Terry, *Regulatory Disruption*, *supra* note 4, at 172.

73. Bradley A. Areheart & Jessica L. Roberts, *GINA, Big Data, and the Future of Employee Privacy*, 128 YALE L.J. 710, 714 (2019).

74. *See* 42 U.S.C. §§ 300gg-1 to -7.

75. *See* California v. Texas, 141 S. Ct. 2104 (2021).

76. *See* Reed Abelson & Abby Goodnough, *If the Supreme Court Ends Obamacare, Here's What It Would Mean*, N.Y. TIMES (Mar. 22, 2021), https://www.nytimes.com/article/supreme-court-obamacare-case.html.

77. *Id.*

78. *See* Gary Claxton et al., *Pre-Existing Condition Prevalence for Individuals and Families*, KAISER FAM. FOUND. (Oct. 4, 2019), https://kff.org/health-reform/issue-brief/pre-existing-condition-prevalance-for-individuals-and-families/; Karen Pollitz, *Pre-Existing Conditions: What Are They and How Many People Have Them?*, KAISER FAM. FOUND. (Oct.

Suppose, however, the ACA and its prohibitions on health discrimination had existed *prior* to the Human Genome Project. Would (in *very* general terms) Title II of GINA still have been necessary? Simply stated, if the benefits to insurers from having access to genetic data on which to base their medical underwriting had not existed, would their incentives to acquire such data have evaporated along with the necessity for genetic privacy? There are other reasons why genetic data should be protected and, no doubt, rent seekers such as big data brokers would have continued to collect data to sell to customers other than health insurers. Notwithstanding, the hydraulic point is theoretically valid; if health law and policy reduces the likelihood of discriminatory or other worrying uses of health data, then less health data protection may be possible. Equally, if discrimination is re-enabled as it was during the Trump Administration's recent assault of the ACA's section 1557 nondiscrimination protections,[79] arguably additional data protection would be necessary.

B. Public Health, HIPAA, and Waivers

The HIPAA Privacy Rule describes a relatively cozy relationship between healthcare entities holding protected health information (PHI) and federal, state, and tribal public health authorities (PHAs).[80] Covered entities may disclose such information to those authorities[81] subject to the minimum necessary standard.[82] A 2020 HHS-OCR guidance further detailed how Health Information Exchanges (HIEs), typically acting as business associates,[83] may be used as conduits in such data transfers.[84]

1, 2020), https://www.kff.org/policy-watch/pre-existing-conditions-what-are-they-and-how-many-people-have-them/.

79. *See generally* Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37160 (June 19, 2020) (to be codified at 42 C.F.R. pts. 438, 440, 460 and 45 C.F.R. pts. 86, 92, 147, 155, 156) (significantly narrowing the scope of section 1557 by limiting nondiscrimination protections to individuals participating in health programs or activities receiving HHS funding, programs or activities administered by HHS under Title I of the ACA, and health insurance marketplaces and insurance plans participating in such marketplaces); *see also* Walker v. Azar, 480 F. Supp. 3d 417, 429–30 (E.D.N.Y. 2020) (striking down some of the Trump Administration's rules removing antidiscrimination provisions made by the Obama Administration pursuant to section 1557 of the ACA).

80. *See generally* 45 C.F.R. §§ 160.101–160.316 (2020); *id.* §§ 164.102–164.106; *id.* §§ 164.500–164.534.

81. *See id.* § 164.512.

82. *See id.* § 164.514(d)(3).

83. *See* 45 C.F.R. § 160.103; *see also id.* §§ 164.502(e), 164.504(e), 164.532(d)–(e).

The hydraulic nature of this relationship is illustrated by how the relationship between public health and privacy is adjusted during emergencies. In 2004, Congress provided the Secretary of Health and Human Services (HHS) the authority to waive certain health regulatory requirements during times of national emergency.[85] HHS, in turn, has issued waivers during several emergencies, such as Hurricanes Katrina, Harvey, Erma and Maria, and the 2017 California wildfires.[86] Indeed, the recent HIPAA notice of proposed rulemaking (NPRM) proposes a "good faith belief" about an individual's best interests in disclosing information involving emergency scenarios, including substance use and the pandemic.[87]

Not surprisingly, therefore, in March 2020, and based on the current rules, HHS-OCR issued a limited waiver of HIPAA sanctions and penalties during the COVID-19 national emergency.[88] This had the effect of waiving sanctions and penalties for failure to comply with the following HIPAA requirements: (1) to obtain a patient's agreement to speak with family members or friends involved in the patient's care; (2) to honor a request to opt-out of the facilities; (3) to distribute a notice of privacy practices; (4) to request privacy restrictions; and (5) to request confidential communications.[89] This waiver, however, is limited to hospitals that have instituted a disaster protocol for up to seventy-two hours so that hospitals may focus on providing patient care during crises instead of being inundated with privacy-related paperwork.[90]

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84. U.S. DEP'T OF HEALTH & HUM. SERVS., HIPAA, HEALTH INFORMATION EXCHANGES, AND DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR PUBLIC HEALTH PURPOSES 1–3 (Dec. 18, 2020).

85. Project BioShield Act of 2004, Pub. L. No. 108-276, § 9, 118 Stat. 835, 863–64 (codified as amended in scattered sections of 42 U.S.C.).

86. *Emergency Situations: Preparedness, Planning and Response*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/index.html (last visited May 29, 2021).

87. *See Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement*, *supra* note 24 (detailing NPRM's efforts to strengthen HIPAA patient access and improve information sharing for care coordination and case management).

88. *Waiver or Modification of Requirements Under Section 1135 of the Social Security Act*, PUB. HEALTH EMERGENCY (Mar. 13, 2020), https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.

89. *Id.*

90. *See* U.S. DEP'T OF HEALTH & HUM. SERVS., COVID-19 & HIPAA BULLETIN: LIMITED WAIVER OF HIPAA SANCTIONS AND PENALTIES DURING A NATIONWIDE PUBLIC HEALTH EMERGENCY 1 (Mar. 2020); *see also Proposed Modifications to the HIPAA Privacy*

In the weeks and months that followed, HHS-OCR issued additional FAQs, guidance, and notifications of enforcement discretion to prioritize information sharing (subject to the minimally necessary standard).[91] Those provisions permitted providers to disclose PHI of those infected with or exposed to COVID-19 to first responders and PHAs;[92] allowed the use of certain, less secure communications platforms for telehealth;[93] permitted the unauthorized use and disclosure of PHI by business associates for public health activities;[94] allowed the participation of covered entities (such as pharmacy chains) in community-based-testing sites (such as drive-through testing stations);[95] and permitted contacting former patients with regard to

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Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, *supra* note 24 (discussing paperwork burdens).

91. *See HIPAA and COVID-19*, U.S. DEP'T HEALTH & HUM. SERVS.: HEALTH INFO. PRIVACY (Apr. 2, 2021), https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html; *see also* Stacey Tovino, Professor of Law, Univ. of Okla. Coll. of Law, Address at the Richard J. Childress Memorial Lecture, Tradeoffs: Technology, Privacy, and the Law (Oct. 2, 2020), https://www.slu.edu/law/law-journal/programs/childress-lecture.php (discussing prioritization and subordination of privacy rights).

92. *OCR Issues Guidance to Help Ensure First Responders and Others Receive Protected Health Information About Individuals Exposed to COVID-19*, U.S. DEP'T HEALTH & HUM. SERVS. (Mar. 24, 2020), https://www.hhs.gov/about/news/2020/03/24/ocr-issues-guidance-to-help-ensure-first-responders-and-others-receive-protected-health-information-about-individuals-exposed-to-covid-19.html.

93. *OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency*, U.S. DEP'T HEALTH & HUM. SERVS. (Mar. 17, 2020), https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html; U.S. DEP'T OF HEALTH & HUM. SERVS., FAQS ON TELEHEALTH AND HIPAA DURING THE COVID-19 NATIONWIDE PUBLIC HEALTH EMERGENCY 4–5 (Mar. 2020) (clarifying that health care providers may use popular apps, such as FaceTime or Skype, for telehealth appointments and patient communication while prohibiting the use of public facing communication apps such as Facebook Live, Twitch, and TikTok).

94. *OCR Announces Notification of Enforcement Discretion to Allow Uses and Disclosures of Protected Health Information by Business Associates for Public Health and Health Oversight Activities During the COVID-19 Nationwide Public Health Emergency*, U.S. DEP'T HEALTH & HUM. SERVS. (Apr. 2, 2020), https://www.hhs.gov/about/news/2020/04/02/ocr-announces-notification-of-enforcement-discretion.html.

95. *OCR Announces Notification of Enforcement Discretion for Community-Based Testing Sites During the COVID-19 Nationwide Public Health Emergency*, U.S. DEP'T HEALTH & HUM. SERVS. (Apr. 9, 2020), https://www.hhs.gov/about/news/2020/04/09/ocr-announces-notification-enforcement-discretion-community-based-testing-sites-during-covid-19.html.

plasma donations.[96] In January 2021, HHS-OCR announced enforcement discretion for violations of the HIPAA Rules in connection with the good-faith use of online or web-based scheduling applications for COVID-19 vaccinations.[97]

HHS-OCR fine-tuned these re-calibrations to emphasize that there are some instances where the right to information sharing should be subordinated to individual privacy, particularly when it came to media access to patients' PHI, which can invoke stigma and discrimination, and even subject patients to scams from bad actors.[98]

Overall, however, this area provides a clear example of the hydraulic relationship between public health and data protection (privacy and security). As public health needs increased during the pandemic, HHS-OCR (minimally) recalibrated HIPAA rules in a slight shift away from health individualism privacy and toward public health solidarity to improve the overall health of the population.

C. Clinical Trials, The Common Rule-HIPAA Construct, and IRB Waivers

The public health consequences and economic concerns associated with the pandemic have ignited a need for medical research to create safe and effective treatments and vaccines. This imperative has illustrated the (often false) dichotomy between safety (which tends to emphasize regulation) and speedy access (which values innovation and individual choice) in moving treatments and vaccines from bench to bedside. For instance, since the beginning of the pandemic, the Food and Drug Administration (FDA) has been under intense pressure to approve[99]—or at the very least make

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96. *OCR Issues Guidance on How Health Care Providers Can Contact Former COVID-19 Patients About Blood and Plasma Donation Opportunities*, U.S. DEP'T HEALTH & HUM. SERVS. (June 12, 2020), https://www.hhs.gov/about/news/2020/06/12/guidance-on-hipaa-and-contacting-former-covid-19-patients-about-blood-and-plasma-donation.html.

97. U.S. DEP'T OF HEALTH & HUM. SERVS., ENFORCEMENT DISCRETION REGARDING ONLINE OR WEB-BASED SCHEDULING APPLICATIONS FOR THE SCHEDULING OF INDIVIDUAL APPOINTMENTS FOR COVID-19 VACCINATION DURING THE COVID-19 NATIONWIDE PUBLIC HEALTH EMERGENCY (Jan. 2021).

98. *OCR Issues Guidance on Covered Health Care Providers and Restrictions on Media Access to Protected Health Information About Individuals in Their Facilities*, U.S. DEP'T HEALTH & HUM. SERVS. (May 5, 2020), https://www.hhs.gov/about/news/2020/05/05/ocr-issues-guidance-covered-health-care-poviders-restrictions-media-access-protected-health-information-individuals-facilities.html (clarifying restrictions on disclosures to the media); *see also* Tovino, *supra* note 91.

99. Contrary to public opinion, the FDA has one of the fastest drug approval processes in the world, with drugs in the United States largely getting approval before they reach that

available[100]—investigational products for the prevention and treatment of COVID-19, including the botched attempt with hydroxychloroquine.[101] To what extent do hydraulic relationships operate in the arena of drug development and approval?

Obviously, giving access to investigational products, usually pursuant to an Emergency Use Authorization (EUA)[102] is an example of a hydraulic

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stage in either Europe or Canada. *See* Benjamin N. Rome & Jerry Avorn, *Drug Evaluation During the Covid-19 Pandemic*, 382 NEW ENG. J. MED. 2282, 2283 (2020).

100. Over the last few decades, the FDA has increased the amount of expedited approval pathways, reformed its expanded access pathway, and allowed submission of real-world evidence and earlier surrogate endpoints to satisfy safety and efficacy standards. *See id.* at 2283–84. Within the context of the pandemic, the FDA further implemented a special emergency acceleration pathway for SARS-COV-2: Coronavirus Treatment Acceleration Program (CTAP). *See Coronavirus Treatment Acceleration Program (CTAP)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/coronavirus-Sars-Cov-2-drugs/coronavirus-treatment-acceleration-program-ctap (last visited May 29, 2021).

101. For example, political controversy ensued after the FDA granted (based on what some argued was inappropriate political pressure) then later revoked an Emergency Use Authorization (EUA) that allowed for chloroquine phosphate and hydroxychloroquine sulfate to be used to treat certain hospitalized patients. *See* Rome & Avorn, *supra* note 99, at 2283; *see also Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine*, U.S. FOOD & DRUG ADMIN. (June 15, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and. Data now shows that chloroquine and hydroxychloroquine are neither safe nor effective and can present fatal side effects, primarily affecting the heart muscle, causing changes in electrical activity or causing inflammation. *See FDA Cautions Against Use of Hydroxychloroquine or Chloroquine for COVID-19 Outside of the Hospital Setting or a Clinical Trial Due to Risk of Heart Rhythm Problems*, U.S. FOOD & DRUG ADMIN. (July 1, 2020), https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or. Indeed, a tragic consequence occurred after a couple in Arizona attempted to self-medicate with chloroquine phosphate, a related chemical compound that is used to treat fish for parasites, resulting in the death of the man. Kimberly Hickok, *Husband and Wife Poison Themselves Trying to Self-Medicate With Chloroquine*, LIVE SCI. (Mar. 24, 2020), https://www.livescience.com/coronavirus-chloroquine-self-medication-kills-man.html.

102. Following the September 11 terrorist attacks and the subsequent anthrax attacks, Congress provided the FDA the ability to issue an EUA whereby investigational medical products can be made available to patients in certain public health emergencies before the rigorous premarket approval process is completed. *See* Project BioShield Act of 2004, Pub. L. No. 108-276, § 4, 118 Stat. 835, 853–59 (codified as amended in scattered sections of 42 U.S.C.); *see also Emergency Use Authorization*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (last visited May 29, 2021).

relationship, albeit one between public health and drug safety.[103] But EUAs (and the entire FDA pre-market approval process for investigational products) also depend upon obtaining comprehensive and accurate health data from human subjects in the clinical trial process.[104] To an extent, therefore, the drug approval apparatus—and in particular the institutions that balance data protection, research protocols, and drug approval—operate as a hydraulic process.

As is well known, the many historic abuses conducted in the name of medical research (including, but certainly not limited to, atrocities from the Nazi medical experiments[105] and the horrific Tuskegee Syphilis study[106]) resulted in stronger research standards for human experimentation. In the United States, the various research standards culminated in the "Common Rule,"[107] which, in part, requires that Investigational Review Boards (IRBs) protect, to the extent possible, human subjects from risks associated with medical research.[108] IRBs review research proposals to make sure they

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103. The FDA will only issue an EUA where it is "reasonable to believe" that a treatment "may be effective" and the known benefits outweigh the risks. *See* U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION OF MEDICAL PRODUCTS AND RELATED AUTHORITIES 7–8 (Jan. 2017), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.

104. Outside the scope of this section are the additional complexities that exist when considering data protection for data about or affecting health that is not subject to HIPAA (but may be subject to other federal or state laws) because such data is held in or by mobile devices, fitness bands, big data brokers, the Internet of Things, etc. *See* Terry, *Regulatory Disruption*, *supra* note 4, at 179; Rothstein et al., *supra* note 43, at 196.

105. Allan Gaw, *Beyond Consent: The Potential for Atrocity*, 99 J. ROYAL SOC'Y MED. 175, 175 (2006).

106. *Id.*

107. The Common Rule is the name used for HHS's Policy for the Protection of Human Subjects. The term "Common Rule" was derived from the fact that fifteen different federal departments and agencies adopted nearly identical regulations to govern the protection of human subjects. *Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEP'T HEALTH & HUM. SERVS. (Mar. 18, 2016), https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html.

108. These horrific abuses did result in some stronger research standards, including the National Research Award Act of 1974, Pub. L. No. 93-348, 88 Stat. 342, and the Belmont Report in 1979 that provided greater clarification on equitable policies for medical research, *The Belmont Report*, U.S. DEP'T HEALTH & HUM. SERVS. (Apr. 18, 1979), https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf. While the Belmont Report served as inspiration for the Common Rule, none of these legal tools engendered trust in medical research, particularly for people of color and vulnerable populations. Much still needs to be done—from making sure that clinical trials are sufficiently diverse to

protect participants' welfare and rights, and that the research conducted is ethical.[109] While privacy and confidentiality are considered, they were not initially the central focus of the Common Rule. HIPAA was designed to fill in the gaps with additional privacy protections associated with the use and disclosure of the research participants' PHI.[110] Thus, the Privacy Rule[111] allows covered entities to use PHI internally for research (regardless of funding or whether FDA regulates the research) or to disclose to outside researchers where certain circumstances or conditions are met.[112]

Under the Privacy Rule, researchers generally must obtain a patient's authorization for the use and disclosure of PHI for research purposes. However, the Privacy Rule provides flexibility for an IRB to waive or alter the authorization requirement in some situations, thereby enabling a covered entity to use or disclose PHI for research without a patient authorization.[113] In order to waive or alter the authorization requirement, an

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verifying a just and equitable allocation of resources, such as vaccines and medications, for populations hit hardest by the pandemic.

109. *See Institutional Review Boards Frequently Asked Questions*, U.S. FOOD & DRUG ADMIN. (Apr. 18, 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions.

110. *See* U.S. GEN. ACCT. OFF., MEDICAL RECORD PRIVACY: ACCESS NEEDED FOR HEALTH RESEARCH, BUT OVERSIGHT OF PRIVACY PROTECTIONS IS LIMITED 13, 16 (Feb. 1999) (acknowledging that the Common Rule did not sufficiently address the issues of confidentiality and privacy in research settings).

111. *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, § 261, 110 Stat. 1936, 2021–31 (codified as amended in scattered sections of 29 and 42 U.S.C.). The Privacy Rule has subsequently been amended pursuant to the Genetic Information Nondiscrimination Act of 2008, Pub. L. 110-233, § 105, 122 Stat. 881, 903–05 (codified as amended in scattered sections of 42 U.S.C.), and the HITECH Act, Pub. L. 111-5, §§ 13401–13411, 123 Stat. 226, 260–76 (2009) (codified as amended in scattered sections of 42 U.S.C.). For most covered entities, compliance with the Privacy regulations was required as of April 14, 2003. *Enforcement Highlights*, U.S. DEP'T HEATH & HUM. SERVS. (Apr. 30, 2014), https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/data/enforcement-highlights/2014-april/index.html.

112. *See* 45 C.F.R. § 164.512 (2020) (detailing situations where PHI may be used or disclosed without permission of individuals). Note that section 164.512(b)(iii)(A) enables disclosure without authorization for adverse event reporting for clinical trial drug sponsors or others under the jurisdiction of the FDA.

113. *See id.* § 164.512(i). Waivers or alteration may also be done by a Privacy Board. However, even where the authorization requirement is altered or waived, the IRB has an express responsibility to protect research participants from risks under 45 C.F.R. part 46 (HHS's Regulations for the Protection of Human Subjects) and 21 C.F.R parts 50 and 56 (FDA regulations on the Protection of Human Subjects). In addition, other federal and state laws and regulations may impose other restrictions on the use of PHI that may not be waived or altered by an IRB or Privacy Board.

IRB (or Privacy Board) must determine that the disclosure could not be conducted without access to and use of the PHI or that the disclosure involves no more than a minimal risk.[114] So, for example, an IRB may completely waive the authorization requirement where obtaining authorization is either impracticable or impossible, such as in the case where multiple research participants' contact information is unknown.[115] Likewise, an IRB can also partially waive the authorization requirement in a situation where a researcher needs to obtain PHI to contact and recruit potential research subjects.[116] An IRB may also alter the authorization requirement by eliminating a required element, such as the requirement to describe the purpose of the requested use or disclosure.[117]

In addition to the dynamic calibration that comes from placing IRBs at the center of privacy-safety-research relationships, some more conventional hydraulics can also be identified. For example, the FDA issued a guidance in March 2020 permitting researchers to follow patients through the use of less secure telehealth platforms, as opposed to onsite testing.[118] These virtual platforms ensured that clinical trials could continue at a robust clip during the pandemic and continue to generate useful data.[119]

The relationship between the Common Rule and the Privacy Rule acknowledges that, although safeguards need to be provided to protect the privacy and confidentiality of PHI, when it comes to medical research, "[health data] is most useful when shared."[120] The Common Rule-Privacy

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114. *See id.* § 164.512(i)(2). Minimal risk requires, at least, the presence of an adequate plan (1) to protect PHI identifiers from improper use and disclosure; (2) to destroy those identifiers at the earliest opportunity, unless otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except required, authorized, or otherwise permitted. *Id.* § 164.512(i)(2)(ii)(A)(1)–(3).

115. *Institutional Review Boards and the HIPAA Privacy Rule*, U.S. DEP'T HEALTH & HUM. SERVS.: NAT'L INSTS. HEALTH (July 8, 2004), https://privacyruleandresearch.nih.gov/irbandprivacyrule.asp.

116. *Id.*

117. *See Clinical Research and the HIPAA Privacy Rule*, U.S. DEP'T HEALTH & HUM. SERVS.: NAT'L INSTS. HEALTH (June 22, 2004), https://privacyruleandresearch.nih.gov/clin_research.asp.

118. *See* FOOD & DRUG ADMIN. ET AL., U.S. DEP'T OF HEALTH & HUM. SERVS., CONDUCT OF CLINICAL TRIALS OF MEDICAL PRODUCTS DURING COVID-19 PUBLIC HEALTH EMERGENCY: GUIDANCE FOR INDUSTRY, INVESTIGATORS, AND INSTITUTIONAL REVIEW BOARDS 14–15 (Mar. 2020).

119. *See id.*

120. Douglas Peddicord et al., *A Proposal to Protect Privacy of Health Information While Accelerating Comparative Effectiveness Research*, 29 HEALTH AFFS. 2082, 2082–83 (2010).

Rule construct thus is a recalibration, with health research given preferential treatment vis-à-vis privacy. And, by design, IRBs may fine-tune this calibration in favor of research goals.

D. Substance Use Confidentiality and the CARES Act

As already noted with regard to the ACA and its prohibition of medical underwriting, privacy rules and antidiscrimination rules are capable of a powerful hydraulic relationship, suggesting that increasing the latter could justify reducing the former. This relationship is powerfully (if somewhat controversially) illustrated by the Coronavirus Aid, Relief, and Economic Security (CARES) Act's[121] reform of The Confidentiality of Alcohol and Drug Abuse Patient Records regulations (commonly known as Part 2).[122]

In addition to HIPAA Privacy, Part 2 provides a layer of confidentiality to the identity and records of Substance Abuse Disorder (SUD) patients. It applies to federally assisted programs that diagnose, treat, or refer SUD patients.[123] However, that can include personnel or a unit within a general medical facility. Part 2 requires a detailed consent in writing from the patient for any sharing of records.[124] The reason for the sharing and the identity of the recipient must be identified with specificity. In most cases redisclosure is prohibited, and the rules also impose limitations on how the recipient of the information can use and disclose the information.[125]

Dating from the 1970s, Part 2 was enacted before any modern federal or state health data protections[126] and is part of the history of segregated treatment of those with mental health or substance use needs. Part 2 survived the passage of HIPAA and remains as an additional level of protection for substance use records. However, as substance use treatment became more mainstream and providers relied more on electronic health records (EHRs), Part 2 increasingly became controversial. Specifically, the

121. Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, 134 Stat. 281 (2020). *See generally* Nicolas Terry, Melissa Goldstein & Kirk Nahra, *COVID-19: Substance Use Disorder, Privacy, and the CARES Act*, HEALTH AFFS. BLOG (June 8, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200605.571907/full/.

122. 42 C.F.R. §§ 2.1–2.4 (2020); *id.* §§ 2.11–2.23; *id.* §§ 2.31–2.35; *id.* §§ 2.51–2.53; *id.* §§ 2.61–2.67.

123. *Id.* §§ 2.12(a)(1)(ii), (b).

124. *See id.* § 2.13.

125. *See Substance Abuse Confidentiality Regulations*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (Mar. 30, 2021), https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs.

126. Dennis McCarty et al., *The Perceived Impact of 42 CFR Part 2 on Coordination and Integration of Care: A Qualitative Analysis*, 68 PSYCHIATRIC SERVS. 245, 245 (2017).

dual regimes caused headaches for providers' workflows while a frequent inability to add SUD records to an EHR hampered emergency department assessment, coordinated care, HIE data sharing, and SUD research based on EHR data.[127] Countering these arguments have been very real concerns about the sensitivity of SUD records and the history of discrimination against SUD patients.[128]

In recent years, the Substance Abuse and Mental Health Services Administration (SAMHSA) has updated Part 2 but resisted efforts to integrate it more fully with HIPAA, in large part because of limitations in the enabling statute.[129] In 2019, HHS published a draft framework for a more fundamental reworking of Part 2.[130] In July 2020, in what will probably be the final revision of the "old" Part 2, the rule was revised to "facilitate better coordination of care in response to the opioid epidemic while maintaining its confidentiality protections against unauthorized disclosure and use."[131]

By then, the future of Part 2 had already been written by the major changes introduced in March 2020 by CARES. Fundamental changes to Part 2's enabling legislation will lead to fundamental changes to Part 2's use and disclosure rules because they are aligned with the HIPAA standards. Indeed, after an initial, less rigorous consent to use and disclosure rules, the HIPAA rules will govern. HIPAA's breach notification rule has also been extended to substance use records.[132]

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127. *See id.* at 247–48 (discussing a group of state healthcare providers' concerns about operating under both HIPAA and Part 2).

128. *See, e.g.*, Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 6052, 6053 (Jan. 18, 2017) (to be codified at 42 C.F.R. pt. 2) ("The disclosure of records of individuals with substance use disorders has the potential to lead to a host of negative consequences, including: Loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution, and incarceration.").

129. *See, e.g.*, *id.* at 6060–61; *see also* Confidentiality of Substance Use Disorder Patient Records, 83 Fed. Reg. 239, 240 (Jan. 3, 2018) (to be codified at 42 C.F.R. pt. 2).

130. *HHS 42 CFR Part 2 Proposed Rule Fact Sheet*, U.S. DEP'T HEALTH & HUM. SERVS. (Aug. 22, 2019), https://www.hhs.gov/about/news/2019/08/22/hhs-42-cfr-part-2-proposed-rule-fact-sheet.html.

131. *Fact Sheet: SAMHSA 42 CFR Part 2 Revised Rule*, U.S. DEP'T HEALTH & HUM. SERVS. (July 13, 2020), https://www.hhs.gov/about/news/2020/07/13/fact-sheet-samhsa-42-cfr-part-2-revised-rule.html; *see* Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 42986–87 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2).

132. Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, § 3221(h), 134 Stat. 281, 378 (2020).

The ADA recognizes substance use as a qualifying disability.[133] However, its qualification regarding unlawful use[134] has been at least one reason why Part 2's more fervent supporters have viewed it as an inadequate antidiscrimination provision. In contrast, the CARES Act includes robust antidiscrimination provisions in an apparent attempt to balance out the privacy changes.[135] These provisions prohibit discrimination "on the basis of information received . . . pursuant to an inadvertent or intentional disclosure of records, or information contained in [substance use] records."[136] The discrimination is prohibited in several domains, including healthcare, employment, housing, the courts, and social services.[137]

Needless to say, there are several variables in play here. The changes to Part 2 will require as yet unwritten regulations, while the true worth of the antidiscrimination provisions likely will depend on investigation and enforcement. Only when those pictures become clearer will we know whether the new relationship between substance use data protection and healthcare discrimination has been successfully recalibrated.

IV. Conclusion

This thought experiment had modest goals. We wanted to critically examine the existing relationship between the U.S. healthcare system and our health privacy system and reimagine how these systems may function if they were designed around principles of solidarity, rather than health individualism. As stated earlier, this is not an attempt to eliminate healthcare data protections. Health data are sensitive in nature and deserve exceptional protection because of their potential for enabling stigma and discrimination. Privacy protections have an intrinsic value in our existing healthcare system because they promote trust, which leads to information sharing and better health outcomes. But, like taxes, enhanced privacy protections are burdensome, costly, and can hinder medical innovation. We provided some examples of where laws, regulations, and practices were successfully calibrated to shed light on how a careful shift toward solidarity principles can create a hydraulic relationship between healthcare and health

133. 42 U.S.C. § 12114(b).

134. An individual that is "currently engaging in the illegal use of drugs" is not a qualified individual with a disability under the ADA. *Id.* § 12114(a).

135. *See* Coronavirus Aid, Relief, and Economic Security (CARES) Act § 3221(g).

136. *Id.* § 3221(g)(i)(1).

137. *Id.*

privacy, which would encourage information sharing in a way that benefits both clinical and public health.

First, if our healthcare system evolves toward universal access and continues prohibiting health discrimination, such with the ACA's protection of preexisting conditions, GINA, and the CARES Act's robust antidiscrimination protections regarding substance abuse information, then the need for health data protection may decrease because exposure would become less consequential.

Second, the pandemic has magnified many ugly truths about our healthcare system, including how emphasis on clinical health over public health has resulted in the outsized role of social determinants, zip-code health, and institutionalized health inequities. Much work needs to be done. However, strengthening avenues for information sharing that prioritize communication and information sharing (particularly as it relates to public health), such as regulations and guidance by HHS, OCR, and even the FDA during the pandemic is a good start. Likewise, changes to Part 2's use and disclosure rules (although awaiting enabling legislation) to better coordinate care, and the flexibility given to IRB (or a Privacy Board) to waive authorization in certain circumstances are minimal, yet successful recalibrations, the underlying premise of which could be replicated in other areas of healthcare.

And finally, when we have an opportunity to look back at the pandemic's unnecessary death toll and begin the difficult task of rebuilding better, perhaps we can adopt a unified approach—one which considers our healthcare system in tandem with our health privacy system, and envisions how, if recalibrated in a manner that favors solidarity principles, each system could complement and improve each other, thereby completing a virtuous circle.