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NOTE

Revisiting Incentive-Based Contracts

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Abstract:

Incentive-based pay is rational, intuitive, and popular. Agency theory tells us that a principal seeking to align its incentives with an agent's should be able to simply pay the agent to achieve the principal's desired results. Indeed, this strategy has long been used across diverse industries—from executive compensation to education, professional sports to public service—but with mixed results. Now a new convert to incentive compensation has appeared on the scene: the United States' behemoth health-care industry. In many ways, the incentive mismatch story is the same. Insurance companies and employers are concerned about constraining the cost of care, and patients are concerned about quality of care. Physicians lack an adequate financial incentive to pay attention to either. Health care's recent move away from the traditional fee-for-service compensation model to incentive pay is perhaps unsurprising.

But there is a problem: mixed preliminary evidence and potential mal-effects on vulnerable third-party patients. This Article employs a new lens—the legal and behavioral literature on optimal contract specificity—to suggest why incentive pay is problematic and why the health-care experience will be no different than other industries. The use of incentive pay is a change in contract-drafting strategy, a decision to write a more detailed, control-based contract rather than one that relies on discretion. The contracts literature suggests that this strategy will only work well where simple compliance is the goal rather than creativity or innovation. The health industry will not succeed in implementing incentive pay better than other industries have. What it needs is to recognize the limits of incentive pay and implement it sparingly. The new Trump Administration may be particularly primed to heed this call.

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INTRODUCTION

Incentive-based compensation has its roots in classic economic theory: rational, selfish actors who are motivated to maximize their own wealth will do their best work if they will get a financial reward for doing so. Material incentives are generally believed to be powerful motivators. The Aztecs rewarded successful warriors with land and better food.[1] Roman warriors were rewarded in the same ways.[2] The use of financial incentives in particular is now pervasive across very different industries, from executive compensation to professional sports and education.[3] Common sense and economic principles both suggest that connecting pay to quality metrics will yield better results.

Incentive pay is a concept that almost everyone seems to be able to get behind. Indeed, incentive regimes are a part of the new ideological hybrid—libertarian paternalism—that encourages behavior by making it attractive without regulating it.[4] The liberal Obama Administration has firmly embraced the idea, arguing that rewarding excellence with pay improves quality.[5] And conservatives generally support incentive pay because it is essentially a private, market-based solution.[6] It remains to be seen if the new Trump Administration will stay the course or not, but there is reason to believe it may not.[7]

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1. *See* MONICA DOMINGUEZ TORRES, MILITARY ETHOS AND VISUAL CULTURE IN POST-CONQUEST MEXICO 23 (2013).

2. *See* James Lloyd, *Roman Army*, ANCIENT HISTORY ENCYCLOPEDIA (Apr. 30, 2013), http://www.ancient.eu/Roman_Army [https://perma.cc/VD26-XJVP].

3. See *infra* Part III.A. for further discussion of other industries' use of incentive pay.

4. *See* Richard Thaler & Cass Sunstein, *Libertarian Paternalism*, 93 AM. ECON. REV. 175 (2003) (coining the term libertarian paternalism); *see also* Eric Felten, *Age of Incentives: Paying Big Bucks for Puny Results*, WALL ST. J. (Jun. 18, 2010), http://www.wsj.com/articles/SB10001424052748704009804575308710787390320 [https://perma.cc/N587-SRYZ] (discussing proliferation of incentive pay as a form of libertarian paternalism).

5. In his March 2009 education speech, Obama argued, "Too many supporters of my party have resisted the idea of rewarding excellence in teaching with extra pay, even though we know it can make a difference in the classroom." Press Release, White House, Remarks of the President to the United States Hispanic Chamber of Commerce (Mar. 10, 2009), https://obamawhitehouse.archives.gov/the-press-office/remarks-president-united-states-hispanic-chamber-commerce [https://perma.cc/C7PL-JLLJ].

6. Exec. Order No. 13,410, 71 Fed. Reg. 51089 (Aug. 22, 2006) ("Each agency shall develop and identify, for beneficiaries, enrollees, and providers, approaches that encourage . . . high-quality and efficient health care."); Juleanna Glover, *A Budget Win in a Conservative Approach to Social Programs?*, WALL ST. J.: WASHINGTON WIRE (Dec. 30, 2014) http://blogs.wsj.com/washwire/2014/12/30/a-budget-win-in-a-conservative-approach-to-social-programs [https://perma.cc/RW48-5VT8] (discussing conservative approaches for social program reimbursements that utilize pay-for-performance schemes).

7. The Trump Administration's new Secretary of Health and Human Services has publicly criticized the shift to value-based care. *See, e.g.*, Bruce Japsen, *As Trump's HHS Secretary, Tom Price Could Slow Shift To Value-Based Care*, FORBES (Nov. 29, 2016, 7:02 AM),

It may be right to revisit the move to incentive pay. The history of incentive pay across industries has been mixed.[8] Scholars and policymakers have identified a host of observed and potential mal-effects, from cherry picking easy cases or cheating on the metrics, to excessively focusing on the metrics to the detriment of overall quality of performance.[9] The effectiveness of financial incentives in motivating top performance is very much an unanswered question.

But it is a question that the literature on incomplete contracts can illuminate. The issue of how to structure reimbursement agreements is really one of how to draft contracts to maximize party performance. Economists, social scientists, and contracts scholars have contributed to an immense literature addressing the effects of contract drafting strategies on agents' cognition, compliance, and motivation to perform.

This literature—theoretical, experimental, and empirical—is complicated, and at times, seemingly conflicting. Financial incentives can motivate,[10] but can also crowd out intrinsic motivation.[11] Contract specificity can inform goals and facilitate improved performance, while reducing the likelihood that parties will use contractual gaps to justify unethical behavior.[12] But specificity can also cause agents to focus too narrowly and ignore hard cases, decreasing overall performance, among a host of other identified effects.[13]

The literature suggests that the detailed, control-based contracting approach is a better fit for easily measurable, compliance-oriented tasks not requiring creativity or innovation than it is for more difficult-to-define tasks that require motivating the agent's best performance. Experience with incentive-based contracting across industries seems to bear out these predictions.

The health-care industry provides a new lens through which to study this longstanding problem. There is an overtreatment problem in health care that has

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http://www.forbes.com/sites/brucejapsen/2016/11/29/as-trumps-hhs-secretary-tom-price-could-slow-shift-to-value-based-care/#3b6187b0f96f [https://perma.cc/U9RQ-3XRS].

8. *See infra* Part II.B.

9. *See, e.g.*, Andrew M. Ryan & Rachel M. Werner, *Doubts About Pay-for-Performance in Health Care*, HARV. BUS. REV. (Oct. 9, 2013), https://hbr.org/2013/10/doubts-about-pay-for-performance-in-health-care [https://perma.cc/J57E-W6GH]; *infra* Section II(A)(iii).

10. *See, e.g.*, Bengt Holmstrom & Paul Milgrom, *Multitask Principal-Agent Analyses: Incentive Contracts, Asset Ownership, and Job Design*, 7 J.L. ECON. & ORG. 24, 25 (1991) (finding that incentive pay motivates hard work and directs allocation of attention among duties).

11. *See* Edward Deci, *Effects of Externally Mediated Rewards on Intrinsic Motivation*, 18 J. PERSONALITY & SOC. PSYCH. 105 (1971) (finding that college students will stop playing puzzles for free after being paid to solve them); Wendy Netter Epstein, *Facilitating Incomplete Contracts*, 65 CASE W. RES. L. REV. 297 (2014) (summarizing the literature on crowd out effects); *see generally* DANIEL PINK, DRIVE: THE SURPRISING TRUTH ABOUT WHAT MOTIVATES US (2009) (arguing that intrinsic motivation, rather than external rewards or punishments, is the biggest driver of high performance in the workplace).

12. *See infra* Part II.

13. *Id.*

variously been called an epidemic,[14] one of our nation's most critical issues,[15] and a catastrophic force that increases the cost of health care.[16] A recent study of Medicare claims data found that in a single year, a whopping forty-two percent of Medicare beneficiaries had received care known to provide minimal clinical benefit.[17] According to the Institute of Medicine (IOM), overtreatment—too many tests and too many procedures that do not improve health—is costing the United States at least $210 billion per year.[18]

Many believe that the traditional system of reimbursement in U.S. health care encourages this overtreatment problem and therefore is highly problematic.[19] Medicare, and most other payers in the United States, have historically paid physicians on a fee-for-service basis. This means that physicians bill out for, and receive compensation for, each service provided (such as office visits, tests, or procedures). To maximize compensation, doctors must increase the volume of care they provide or bill for more expensive services. Assuming physicians behave as both rational and selfish economic actors, they are incentivized to deliver high-volume, high-cost care. They lack financial incentive to stem systemic costs or deliver high-quality care.[20] Their incentives are mismatched

14. *See* Atul Gawande, *Overkill: An Avalanche of Unnecessary Medical Care is Harming Patients Physically and Financially. What Can We Do About It?*, NEW YORKER (May 11, 2015), http://www.newyorker.com/magazine/2015/05/11/overkill-atul-gawande [https://perma.cc/6CRA-QQAE] (discussing a "global epidemic of overtesting, overdiagnosis, and overtreatment" caused by "[d]octors [who] get paid for doing more, not less"); *see also* Tara Parker-Pope, *Overtreatment is Taking a Harmful Toll*, N.Y. TIMES: WELL (Aug. 27, 2012), http://well.blogs.nytimes.com/2012/08/27/overtreatment-is-taking-a-harmful-toll [https://perma.cc/2PZT-R59M].

15. Parker-Pope, *supra* note 14 (discussing how overtreatment "is costing the nation's health care system at least $210 billion a year, according to the Institute of Medicine, and taking a human toll in pain, emotional suffering, severe complications and even death").

16. Ezekiel J. Emanual & Victor R. Fuchs, *The Perfect Storm of Over-Utilization*, 299 JAMA 2789 (2008) (discussing the "financial incentive for physicians to order and perform more expensive procedures" as one factor in ballooning health-care costs).

17. Aaron L. Schwartz et al., *Measuring Low-Value Care in Medicare*, 174 JAMA 1067 (2014).

18. INST. OF MED., BEST CARE AT LOWER COST: THE PATH TO CONTINUOUSLY LEARNING HEALTH CARE IN AMERICA 3–10 (Mark Smith, Robert Saunders, Leigh Stuckhardt & J. Michael McGinnis eds., 2013); *see also* Annie Lowrey, *Study of U.S. Health Care System Finds Both Waste and Opportunity to Improve*, N.Y. TIMES (Sept. 11, 2012), http://www.nytimes.com/2012/09/12/health/policy/waste-and-promise-seen-in-us-health-care-system.html [https://perma.cc/KX54-YFW8].

19. *See generally* Adam Candeub, *Contract, Warranty, and the Patient Protection and Affordable Care Act*, 46 WAKE FOREST L. REV. 45, 51–53 n.27 (2011) (summarizing the literature on the connection—or lack thereof—between expenditures and outcomes in health care); Harold Miller, *From Volume to Value: Better Ways to Pay for Health Care*, 28 HEALTH AFF. 1418 (2009); Rita Redberg & Judith Walsh, *Pay Now, Benefits May Follow – The Case of Cardiac Computed Tomographic Angiography*, 359 NEW ENG. J. MED. 2309 (2008) (arguing fee-for-service inflates health costs); Lynn A. Stout, *Killing Conscience: The Unintended Behavioral Consequences of "Pay for Performance"*, 39 J. CORP. L. 525, 536 (2014) (summarizing the literature).

20. *See generally* sources cited *supra* note 19. There are, of course, altruistic reasons providers might care about delivering high-quality care. But there is now little doubt that financial incentives

with those of payers preferring low-cost care and patients preferring high-quality care—similar to the incentive mismatches that motivate the use of incentive pay in other industries.

It is perhaps unsurprising that under the fee-for-service payment system, too much care is being delivered in the United States that does not improve health outcomes.[21] This problem manifests in a health care system that is the most expensive in the world, yet which suffers from lower overall quality than all other industrialized nations.[22]

The general consensus in the industry is that physician financial incentives must be addressed as a part of addressing overall cost and quality concerns.[23] In recent years, the industry has gotten behind the incentive-based compensation solution.[24] If the problem is that doctors' incentives are out of step with those of payers and patients, then align their incentives; pay physicians for delivering cost-effective, quality care, not for simply delivering more care.

Just as in other industries, the health-care commitment to incentive compensation evidences a commitment to a more detailed contracting approach. In a fee-for-service system, the contracts between physicians and payers are, relatively speaking, unspecific and make only limited use of control elements, such as reporting requirements and financial incentives tied to performance. Although payers do generally only cover care that is deemed "medically necessary,"[25] and do exercise a good deal of control over the list of compensable

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can influence the behavior of a significant percentage of physicians.

21. *See, e.g.*, Gawande, *supra* note 14; Emanuel & Fuchs, *supra* note 16, at 2790 (discussing the fee-for-service incentive for overutilization).

22. *See, e.g.*, Karen Davis et al., *Mirror, Mirror on the Wall, 2014 Update: How the Performance of the U.S. Health Care System Compares Internationally*, COMMONWEALTH FUND 8, http://www.commonwealthfund.org/~/media/files/publications/fund-report/2014/jun/1755_davis_mirror_mirror_2014.pdf [https://perma.cc/DUV2-78NF] (noting that the United States ranks last in overall quality relative to 10 other industrialized nations); Emanuel & Fuchs, *supra* note 21, at 2789 ("The United States spends substantially more per person on health care than any other country, and yet US health outcomes are the same as or worse than those in other cou[n]tries."). Note, however, that it is not necessarily clear that substandard care is the cause of worse health outcomes. For a brief explanation of the potential importance of social spending to health outcomes, see, for example, David Squires & Chloe Anderson, *U.S. Health Care from a Global Perspective: Spending, Use of Services, Prices, and Health in 13 Countries*, COMMONWEALTH FUND (2015), http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2015/oct/1819_squires_us_hlt_care_global_perspective_oecd_intl_brief_v3.pdf [https://perma.cc/DU58-PMDM].

23. It is worth noting, however, that despite this consensus, implementation of incentive pay is slow to occur.

24. Incentive-based compensation and variants of it go by many names in the literature. *See infra* note 30; *see also* Arnold Epstein, *Paying for Performance in the United States and Abroad*, 355 NEW ENG. J. MED. 406, 406 (2006) ("Policymakers now almost universally agree that the amplification and extension of the use of financial incentives will promote a higher quality of care.").

25. *See, e.g.*, *What Part B Covers*, MEDICARE.GOV, https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html [https://perma.cc/UWD4-S3PS] [hereinafter *What*

procedures, a fee-for-service approach gives physicians significant discretion in how they approach care. Importantly, it commits to payment regardless of outcome.

Incentive-based compensation, on the other hand, requires much more detailed contract drafting. The payer provides, *ex ante*, a list of metrics the physician is required to meet. The payer also defines the financial implications of meeting, exceeding, or falling short of those metrics. If fee-for-service contracts tend to be vague in task definition and tend to make limited use of control elements, incentive pay is a move to the other end of the contract-drafting spectrum: detailed task specification and extensive use of contractual control mechanisms such as reporting, monitoring, and financial incentives.

The health-care industry has been focused on how to improve this new payment model—for instance, how to determine the proper amount of the financial incentive and how to choose the correct quality metrics. This Article suggests that focus is misplaced. The key question the health-care industry should be focused on solving is not how to improve this new payment model, although that work may be useful, but rather on where and where not to use the model. The legal, economic, and behavioral literature teaches that an across-the-board approach such as the one currently being hailed in the industry will not be effective. The industry must determine, and then implement, a more nuanced approach that draws the line between tasks where incentive-pay mechanisms will be helpful and those where they will be ineffective at best or harmful at worst. Changing focus in this way is much more likely to yield successful results, even if it requires recognizing that incentive-based compensation cannot solve all of the health industry's problems.

This Article moves the debate forward by starting to sketch some ways the industry might attempt to draw that line. For instance, the health-care industry has massive amounts of data in its possession to help differentiate between the two categories: where incentive pay should be used, and where it should not. It could make better use of that data to target the application of incentive pay. And the health profession has already started to draw some lines that might be helpful to the incentive-pay context: for example, the line between the sort of work that advanced practice providers, such as physicians' assistants, are statutorily permitted to do versus the kind of work only doctors are permitted to do. The line between care where process and outcomes are closely tied and where they are not is also worth considering.

This Article proceeds in four parts. Part I starts by describing the incentive-misalignment problem and how incentive pay is intended to work as a theoretical matter. It then explains how incentive-based compensation is being applied in the health-care context to address the physician-payer-patient incentive-

Part B Covers] ("Medicare covers services . . . and supplies . . . considered medically necessary to treat a disease or condition."); *see also* Annotation, What Services, Equipment, or Supplies are "Medically Necessary" for Purposes of Coverage under Medical Insurance, 75 A.L.R.4th 763.

misalignment problem and the Affordable Care Act's strong adoption of systemic delivery model reform along these lines.

Because this switch in models is akin to a switch in contract-drafting strategies, Part II surveys the scholarly literature discussing the effect of contract-drafting strategies on agent performance. While there is much still to learn, this literature yields some lessons and suggests some predictions about where a more complete contract that relies on incentive-based compensation is likely to be successful and where it is less likely to be so. It discusses the importance of differentiating between contracts designed to prompt mere compliance and those designed to motivate the strongest possible agent performance.[26]

Part III then explores the evidence on the effectiveness of incentive-pay regimes, first in the executive compensation, education, and sports industries, and then the preliminary evidence in health care specifically. It suggests that the experience across industries is accurately predicted by the scholarly literature surveyed in Part II.

Finally, Part IV starts the discussion of how payers may refine this new contracting approach in health care to yield more desirable results. The Article argues that the goals of improved quality and reduced cost cannot be accomplished with a one-size-fits-all incentive-pay solution. Some areas of medicine are compliance oriented and can be routinized or automated. Some areas cannot. This Article appreciates the distinction and uses it to define a middle path for incentive pay. Differentiating between areas of medicine that require compliance and those that require creativity and innovation is a difficult, but not impossible, task.

I. THE INCENTIVE-MISALIGNMENT PROBLEM AND THE PREVAILING INCENTIVE-PAY SOLUTION

A. The Incentive Pay Theory

Incentive-based compensation has its roots in agency theory.[27] An agency relationship is formed when a principal hires an agent to perform a task on the principal's behalf. The agent and the principal have varying personal interests. The agent's self-interest may cause her to engage in behavior that benefits the

26. Oliver Hart and John Moore famously differentiate between perfunctory and consummate performance. For example, if a contract specifies the number of jokes a comedienne must tell, a perfunctory performance will do strictly that—comply with those requirements. A comedienne delivering consummate performance, however, will go for the big laughs, even though the contract does not specify how funny her jokes must be. *See* Oliver Hart & John Moore, *Contracts as Reference Points*, 123 Q.J. ECON 1, 6 (2008).

27. Wendy Netter Epstein, *Public-Private Contracting and the Reciprocity Norm*, 64 AM. U. L. REV. 1, 16–17 (2014) (describing agency theory and incentive alignment); Hamid Mehran, *Executive Compensation Structure, Ownership, and Firm Performance*, 38 J. FIN. ECON. 162, 165–67 (1995) (discussing the application of agency theory in modern executive compensation models).

agent but harms the principal. Problems arise, in particular, when the agent has better information about her performance than the principal—information asymmetry—and when the principal (or the market) cannot easily monitor the agent.

In the classic depiction, aligning the incentives of the principal and agent can mitigate agency problems. For instance, the interests of shareholders and the corporation's CEO may diverge in that shareholders want the CEO to increase company profitability and stock price, but the CEO may be motivated to make choices that will benefit the CEO personally—say empire building by acquiring companies to increase the CEO's power—that are not necessarily in the best interests of the corporation.[28] To align incentives, shareholders may tie a CEO's bonus to stock price or profitability or give the CEO equity in the company.

The theory is appealing: tie compensation to the results you want. An economically rational, self-interested agent will be motivated by the prospect of increasing compensation and will act accordingly.[29]

Within those general parameters, the idea of aligning incentives through compensation takes many forms and goes by many names in the literature, including pay-for-performance, merit (or performance) pay, differentiated pay, performance measures, incentive or value-based compensation, to name some.[30] But the idea is always to specify, *ex ante*, the desired outcomes and the financial reward (or punishment) for attaining the desired goals,[31] and to ensure that the desired outcomes are readily observable, or that goal attainment can otherwise be assessed by monitoring or reporting.[32] A rational agent seeking to maximize

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28. *See, e.g.*, LUCIAN BEBCHUK & JESSE FRIED, PAY WITHOUT PERFORMANCE 16 (2004); Andrew C. W. Lund & Gregg D. Polsky, *The Diminishing Returns of Incentive Pay in Executive Compensation Contracts*, 87 NOTRE DAME L. REV. 677, 736 (2011); Troy A. Paredes, *Too Much Pay, Too Much Deference: Behavioral Corporate Finance, CEOs, and Corporate Governance*, 32 FLA. ST. U. L. REV. 673, 685 (2005); Randall S. Thomas, *Explaining the International CEO Pay Gap: Board Capture or Market Driven?*, 57 VAND. L. REV. 1171, 1244 (2004).

29. Wendy Netter Epstein, *Contract Theory and the Failures of Public-Private Contracting*, 34 CARDOZO L. REV. 2211, 2233–34 (2013); Sarah Bonner & Geoffrey Sprinkle, *The Effects of Monetary Incentives on Effort and Task Performance: Theories, Evidence, and a Framework for Research*, 27 ACCT. ORGS. SOC'Y 303, 308 (2002).

30. *Pay for Performance in Health Care: Methods and Approaches*, RTI INT'L 2 (Jerry Cromwell et al. eds., 2011), https://www.rti.org/sites/default/files/resources/bk-0002-1103-mitchell.pdf [https://perma.cc/MER5-UXNF] (discussing performance measures and value-based pay); *id.* at 33 (defining pay-for-performance); *id.* at 88 (discussing merit pay). CMS defines pay-for-performance as the "use of payment methods and other incentives to encourage quality improvement and patient-focused high value care." Letter from Dennis G. Smith, Director, Ctr. for Medicaid & State Operations, U.S. Dep't of Health & Human Servs., to State Health Officials (Apr. 6, 2006), http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO040606.pdf [https://perma.cc/YH2E-RPQW].

31. *See* Stout, *supra* note 19, at 531–32 ("Ex ante agreement to an objective performance goal is essential . . . .").

32. KIERON WALSH, PUBLIC SERVICES AND MARKET MECHANISMS: COMPETITION, CONTRACTING AND THE NEW PUBLIC MANAGEMENT 37 (1995) (describing how principals invoke reporting procedures to assess goals that motivate desired agent performance).

compensation, in theory, will then make every effort to achieve the defined goals.

B. Misaligned Incentives in Health Care

As in other industries, the U.S. health-care industry has problems with misaligned incentives. Health care's traditional fee-for-service compensation model is, in part, to blame. Fee for service means that providers bill and receive payment for each service (e.g., an office visit or procedure) they perform. Compensation can influence the behavior of a significant percentage of providers.[33] A rational provider seeking to increase reimbursement under the current fee-for-service system may choose to bill for more expensive, higher-margin procedures.[34] Alternatively, a provider may choose to bill for a higher volume of procedures from treating more patients or from ordering that more be done for existing patients.[35]

The fee-for-service compensation system creates an incentive mismatch between payers and providers, and to an extent, patients, as well.[36] Payers would prefer for providers to deliver lower cost care.[37] Patients prefer higher-quality care. Providers are incentivized, in a strict economic sense, to provide higher-cost care that is not necessarily linked to higher-quality care. This creates a principal-agent problem. Providers as agents have a certain degree of power to make decisions that impact payers as principals. The problem is created when the physician-agent is motivated to act in ways that further his or her own financial self interest, rather than those of the payer-principal.

Providers cannot engage in strictly self-interested, profit-maximizing behaviors alone. Patients must consent to tests and procedures.[38] Payers must also

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33. *See* J. Tufano et al., *Effects of Compensation Models on Physician Behaviors*, 7 AM. J. MANAGED CARE 363 (2001) (finding that compensation method is perceived to influence physician productivity); *see also* David Hemenway et al., *Physicians' Responses to Financial Incentives. Evidence from a For-Profit Ambulatory Care Center*, 322 NEW ENG. J. MED. 1059, 1059-1063 (1990); Alan Hillman, Mark Pauly & Joseph Kerstein, *How Do Financial Incentives Affect Physicians' Clinical Decisions and the Financial Performance of Health Maintenance Organizations?*, 321 NEW ENG. J. MED. 86, 88–91 (1989) (concluding that financial incentives influence physician behavior).

34. *See* David Hyman & Charles Silver, *You Get What You Pay for: Result-Based Compensation for Health Care*, 58 WASH. & LEE L. REV. 1427, 1442 (2001) (noting that FFS compensation "encourages providers to be exhaustive in work-ups and treatments," and to upcode and deliver unnecessary services).

35. *See* Candeub, *supra* note 19, at 45–47.

36. *See* Åke Blomqvist, *The Doctor as Double Agent: Information Asymmetry, Health Insurance, and Medical Care*, 10 J. HEALTH ECON. 411, 412 (1991); Hyman & Silver, *supra* note 34, at 1442–43; *see generally* Stanley S. Wallack & Christopher P. Tompkins, *Realigning Incentives in Fee-For-Service Medicare*, 22 HEALTH AFF. 59 (2001) (discussing the incentive mismatch in fee-for-service Medicare).

37. *See* Sheila Leatherman et al., *The Business Case for Quality: Case Studies and an Analysis*, 22 HEALTH AFF. 17 (2003).

38. *See* Paul Appelbaum, *Assessment to Patients' Competence to Consent to Treatment*, 357 NEW ENG. J. MED. 1834 (2007) ("Physicians are required by law and medical ethics to obtain the

agree to pay. And physicians are limited by the fraud and abuse and tort laws in what they can do to pursue heightened personal compensation.[39]

But providers have a lot of power. Most patients lack effective means to evaluate a provider's advice on what testing or procedures are necessary.[40] And most patients do not sufficiently care about incurring the cost of additional procedures because they do not experience the true cost.[41] Most patients pay only small (relatively speaking) copays or a low percentage of the total cost of the procedure.[42] Some patients may make decisions based on cost. For others, cost may not be a highly salient part of the decision calculus.[43] As such, providers are positioned to greatly influence treatment decisions simply by their advice to patients.[44]

As to payers, most only cover "medically necessary" procedures.[45] And payers negotiate (or sometimes flat out set) rates of reimbursement, which can affect provider incentive structures. But there is no central rationing of care in the U.S. system.[46] Even payers can only do so much to impact provider incentives.

The bottom line is that fee-for-service systems incentivize providers to suggest more care—and more expensive care—which drive up health costs in ways that do not necessarily improve quality. Many believe that this incentive

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informed consent of their patients before initiating treatment.").

39. This explanation admittedly focuses only on the purely economic drivers of physician actions. In reality, physicians may act altruistically or their behavior may be influenced by professional and social norms more generally.

40. *See, e.g.*, Hyman & Silver, *supra* note 34, at 1445 ("Individual patients frequently have difficulty assessing quality of care."); Matthew P. Manary et al., *The Patient Experience and Health Outcomes*, 368 NEW ENG. J. MED. 201 (2013); Wendy Netter Epstein, *Nudging Patient Decision-Making*, WASH. L. REV. (forthcoming 2017).

41. *See* Peter Zweifel & Willard G. Manning, *Moral Hazard and Consumer Incentives in Health Care*, *in* 1 HANDBOOK OF HEALTH ECONOMICS 409, 451–54 (Anthony J. Culyer & Joseph P. Newhouse eds., 2000); Elisabeth Rosenthal, *Paying Till it Hurts – A Case Study in High Costs*, N.Y. TIMES (Jun. 1, 2013), http://www.nytimes.com/2013/06/02/health/colonoscopies-explain-why-us-leads-the-world-in-health-expenditures.html [https://perma.cc/69DR-3MSA]. With the consumer-based, health-care movement urging more patient out-of-pocket expenditures, however, this may be changing. *See also* Wendy Netter Epstein, *Price Transparency and Incomplete Contracts in Health Care* (forthcoming).

42. The payer foots the bill for the rest. Rosenthal, *supra* note 41 ("Patients with insurance pay a tiny fraction of the bill, providing scant disincentive for spending."). A typical PPO plan costs the consumer twenty percent coinsurance.

43. Rosenthal, *supra* note 41.

44. Epstein, *supra* note 40; *see also* Candeub, *supra* note 19 at 47 n.9 ("The physician-induced-demand hypothesis posits that physicians take advantage of patients' ignorance by recommending treatment that they may not need, thus 'inducing' demand for medical services.") (citing Rune J. Sørensen & Jostein Grytten, *Competition and Supplier-Induced Demand in a Health Care System with Fixed Fees*, 8 HEALTH ECON. 497, 497 (1999)).

45. *See What Part B Covers*, *supra* note 25; Linda A. Bergthold, *Medical Necessity: Do We Need It?*, 14 HEALTH AFF. 180, 188 (1995).

46. *See* Peter Singer, *Why We Must Ration Health Care*, N.Y. TIMES (Jul. 15, 2009), http://www.nytimes.com/2009/07/19/magazine/19healthcare-t.html [https://perma.cc/ZF7F-47YY] (comparing the United States' lack of rationing with central rationing in Great Britain).

structure has at least in part created the overtreatment problem we face in the United States.[47] In fact, unnecessary tests and procedures not only increase cost,[48] but may also harm patients.[49]

Policymakers and lawmakers have, in recent years, turned their focus to addressing this incentive mismatch. Health-care costs in the United States are unbearably high, while key indicators of quality are disappointingly low when compared to peer nations.[50] Although most health economists agree that a combination of factors is to blame, the incentive mismatch encourages overtreatment, which drives up costs and does not necessarily improve quality.[51]

Many view this problem as low-hanging fruit that can be solved by aligning the incentives of providers[52] with those of payers and patients.[53] The next subpart discusses the incentive-compensation model in health care.

C. The Health Industry's Incentive-Pay Solution

Linking payment with desired results has been touted by members of Congress as the panacea for health care that can save the United States $700 billion a year, while simultaneously improving quality.[54] The following explains

47. *See, e.g.*, Gawande, *supra* note 14; Peter R. Orszag, *Health Costs Are the Real Deficit Threat*, WALL ST. J. (May 15, 2009, 12:01 AM), http://www.wsj.com/articles/SB124234365947221489 [https://perma.cc/EAX2-UBPD].

48. Aaron L. Schwartz et al., *Measuring Low-Value Care in Medicare*, 174 JAMA INTERNAL MED. 1067 (July 2014).

49. Gawande, *supra* note 14.

50. 155 CONG. REC. S11132-05 (daily ed. Nov. 5, 2009) (statement of Sen. Hagan) ("[T]he United States spends $2.3 trillion each year on health care – the most per capita of all industrialized nations. Yet we still have higher infant mortality and lower life expectancy than many of the other industrialized nations."). Some have argued that health-care costs more in the U.S. because we are a wealthier country and are buying better quality, but data should disabuse us of that notion. *See* Candeub, *supra* note 19 at 51 (2011) ("There is little to no data linking total health care expenditures with positive health care outcomes.").

51. *See, e.g.*, *The High Costs of Health Care*, N.Y. TIMES (Nov. 25, 2007), http://www.nytimes.com/2007/11/25/opinion/25sun1.html [https://perma.cc/D48J-T2VY] (detailing various causes of the high cost-low quality health-care problem); Julie Appleby, *Seven Factors Driving Up Your Health Care Costs*, KAISER HEALTH NEWS (Oct. 24, 2012), http://khn.org/news/health-care-costs [https://perma.cc/749T-C2AN] (describing the roles providers and consumers have in driving up health-care costs).

52. The term "provider" has many definitions in the literature and in the statutes. Here, I define it as a person who delivers health-care services. For the most part, this will mean physicians, but particularly as I start to flesh out solutions in Part IV, I use the term more broadly to cover advanced practice practitioners, as well. *See* Part IV(B), *infra*. I do not mean "provider" to include hospitals and other such entities.

53. *See, e.g.*, *Report of The National Commission on Physician Payment Reform*, NAT'L COMMISSION ON PHYSICIAN PAYMENT REFORM 15 (2013), http://physicianpaymentcommission.org/wp-content/uploads/2013/03/physician_payment_report.pdf [https://perma.cc/9LB8-329V] [hereinafter *Physician Payment Reform*] (finding provider compensation as a main driver of health-care costs and recommending a blended payment system to reduce costs).

54. 155 CONG. REC. S11132 (daily ed. Nov. 5, 2009) (statement of Sen. Hagan).

how incentive-based compensation is expected to work.

In the health context specifically, the typical pay-for-performance program provides a bonus to health-care providers (or hospitals or other medical entities)[55] if they meet or exceed agreed-upon metrics, although some are structured to penalize providers that fail to meet defined metrics.[56] Programs may also reward improvement in metrics over time.[57]

Quality and performance measures differ by program, but generally fall into four categories: process, outcome, patient experience, or structure. Process metrics require providers to follow a predefined process to satisfy the metric, such as giving aspirin to heart-attack victims within a certain amount of time after the patient arrives in the emergency room. Outcome measures focus on results. Morbidity and mortality data are the classic examples. More recently, there has been a focus on defining more-specific outcome measures, such as reductions in hemoglobin A1c in diabetic patients.[58] Patient experience measures the patients' perception of the care they receive and is usually collected by compiling the results of patient surveys. Finally, structure considers the inputs into health-care provision, from the facilities and equipment used in treatment, to the adoption of health information technology. Incentive pay in the health-care setting may be predicated on any one category of metrics or, more commonly, a combination of several.

The Institute of Medicine's (IOM) 2001 study on the quality of health care in the United States is generally credited for prompting the incentive-pay movement, both for government and private payers. The report defined the problem: "Health care harms patients too frequently and routinely fails to deliver its potential benefits. Indeed, between the health care that we now have and the health care that we could have lies not just a gap, but a chasm."[59] It then suggested that one way to narrow that chasm was to "align[] payment policies with quality improvement."[60] Health maintenance organizations (HMOs), which

55. This Article focuses on financial incentives for providers, although the industry move to value-based compensation captures a much larger set of players that future work should address.

56. Julia James, *Health Policy Brief: Pay-for-Performance*, HEALTH AFF. (Oct. 11, 2012), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_78.pdf [https://perma.cc/EAB6-HFH4].

57. *Id.*

58. *Id.* Hemoglobin A1c is "a common blood test used to diagnose type 1 and type 2 diabetes and then to gauge how well [an individual is] managing [his] diabetes. . . . The A1C test results reflects [the] average blood sugar level. . . . The higher [the] A1C level, the poorer [the] blood sugar control and the higher [the] risk of diabetes complications." *A1C Test Overview*, MAYO CLINIC (Jan. 7, 2016), http://www.mayoclinic.org/tests-procedures/a1c-test/home/ovc-20167930 [https://perma.cc/BLB5-7P2G].

59. *Crossing the Quality Chasm: A New Health System for the 21st Century*, INST. OF MED. 1 (Mar. 2001), https://iom.nationalacademies.org/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf [https://perma.cc/AKA8-9LVQ].

60. *Id.* at 6.

were suffering under the appearance that they cut cost at the sacrifice of quality, particularly heeded the call.

1. Early Experiments in Paying for Quality in Health Care

a. Health Maintenance Organizations

HMOs initially came about as an alternative to the traditional fee-for-service system, primarily designed to contain skyrocketing health-care costs.[61] HMOs typically offered flat-fee payment (capitation).[62] Salary holdbacks designed to ensure that physicians reduced costs were also common.[63] If fee for service encouraged providers to bill for more volume, HMOs encouraged providers to offer the least service possible in order to maximize provider profits.

By most accounts, capitation successfully incentivized providers to reduce costs to payers relative to the fee-for-service model.[64] The problem is that insufficient attention was paid to quality.[65] Market wide, this made HMOs fall out of favor with patients who came to associate them with rationing care.[66]

Following the IOM report, many HMOs, some of which had already been experimenting with pay for performance, quickly jumped on board the incentive-pay movement.[67] At the state level, California HMOs were early adopters.[68] In early 2000, the Integrated Healthcare Association was formed to establish a statewide set of key measures on which health plans could base incentive

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61. *See, e.g.*, Arnold J. Rosoff, *The Federal HMO Assistance Act: Helping Hand or Hurdle?*, 13 AM. BUS. L.J., 137, 137–39; *see also* Jennifer Evans & Jaclyn Schiff, *A Timeline of Kennedy's Health Care Achievements and Disappointments*, KAISER HEALTH NEWS (Sept. 17, 2010), http://khn.org/news/kennedy-health-care-timeline [https://perma.cc/3RNE-9RZP].

62. *Capitation Models*, HEALTH CARE INCENTIVES IMPROVEMENT INST., http://www.hci3.org/thought-leadership/why-incentives-matter/capitation/capitation-models [https://perma.cc/3YXY-23WP].

63. HMOs held back a percentage of physician salary. At the end of the year, if treatment costs were within target ranges, the HMO would pay out the physician the hold back amount, but if costs exceeded targets, the HMO would retain the holdback amount. *See, e.g.*, Barry R. Furrow, *Managed Care Organizations and Patient Injury: Rethinking Liability*, 31 GA. L. REV. 419 (1997).

64. *See, e.g.*, Harold Miller, *From Volume to Value: Better Ways to Pay for Health Care*, 28 HEALTH AFF. 1418 (2009), http://content.healthaffairs.org/content/28/5/1418.full.pdf [https://perma.cc/SH8U-GL9W].

65. *Id.* There was some early experimentation with accounting for quality in pay. For instance, in 1987, U.S. Healthcare introduced quality-based compensation for primary care physicians and created the Quality Care Compensation System (QCCS). Nicholas Hanchak et al., *U.S. Healthcare's Quality-Based Compensation Model*, 17 HEALTH CARE FINANCING REV. 143 (1996).

66. Richard Friedenberg, *Health Care Rationing: Every Physician's Dilemma*, 217 RADIOLOGY 626 (2000).

67. *See* Meredith B. Rosenthal et al., *Pay for Performance in Commercial HMOs*, 355 NEW ENG. J. MED. 1895 (2006).

68. Integrated Healthcare Association, *Advancing Quality Through Collaboration: The California Pay for Performance Program*, 3 IND. HEALTH L. REV. 455, 457–59 (2006).

payments.[69] Since then, California health plans have done just that. Blue Cross Blue Shield of Massachusetts is doing something similar with their Alternative Quality Contract (AQC).[70] HMO-level use of incentive pay has also been spurred by a couple of programs with larger scope, such as the Leapfrog Group,[71] and Bridges to Excellence.[72]

In 2005, a nationwide study of commercial HMOs found that more than half were using incentive-pay programs in their contracts with providers.[73] The most common metrics used were process-oriented metrics (e.g., use of mammography, asthma medication, etc.). Measures of patient satisfaction were also popular.

HMOs were a logical site of first experimentation because they required beneficiaries to select a primary-care physician, who could then be responsible for the overall quality (and quantity) of care the patient received.[74] HMOs were also more motivated than other delivery models to respond to criticisms about quality.[75]

b. Early Government Experiments

The IOM report also prompted the government to experiment with incentive pay. In the Medicare context, the Medicare Physician Group Practice (PGP) Demonstration was the primary pilot program. It began in April 2005, and was designed to be a hybrid between fee-for-service and capitation models in the sense that physician groups were initially paid on a fee-for-service basis, but were eligible for bonuses equal to the percentage of savings in Medicare expenditures that the physician groups generated for their patients.[76] CMS

69. *Id.* at 455–56 (2006).

70. James, *supra* note 56. Other examples of private initiatives include Humana's Provider Quality Rewards program, United Healthcare's program in Illinois, Blue Cross Blue Shield of Minnesota's provider contracts, and HealthPartners programs in the upper Midwest. Adria Schmedthorst, *Commercial Payers and Value-Based Reimbursement*, GO PRACTICE BLOG (Mar. 30, 2016), http://gopractice.kareo.com/article/commercial-payers-and-value-based-reimbursement [https://perma.cc/7BHV-M3GX].

71. The Leapfrog Group is a nationwide group of health-care purchasers (employers) that encourages public reporting of health-care quality and outcomes and rewarding doctors and hospitals for improving quality and cost metrics. In 2005, it initiated a hospital-focused program that tied improvement in five clinical areas to financial incentives. Robert S. Galvin et al., *Has the Leapfrog Group Had an Impact on the Health Care Market*, 24 HEALTH AFF. 228, 229–30 (2005).

72. Bridges to Excellence is a multi-state, multi-employer organization that operates reward programs created to encourage improvements in the quality of care. *Bridges to Excellence*, HEALTH CARE INCENTIVES IMPROVEMENT INSTITUTE, http://www.hci3.org/programs-efforts/bridges-to-excellence [https://perma.cc/NZ7E-NFKZ].

73. Rosenthal et al., *supra* note 67 at 1895.

74. *Id.* at 1901 ("Several characteristics of HMOs were associated with the use of pay for performance, including . . . role of the PCP . . . .").

75. Neelam K. Sekhri, *Managed Care: The US Experience*, 78 WHO BULLETIN 830, 830, 838–39 (2000) (noting managed health care faced much backlash in response to limited provider compensation, rationed care, and subpar quality of care).

76. *Physician Group Practice Transition Demonstration*, CTRS. MEDICARE & MEDICAID SERVS.

calculated savings by comparison with the expenditures of a local "control" group not participating in the demonstration project. In addition, physician groups were eligible to retain a higher percentage of savings if they demonstrated strong performance on certain quality metrics. The pilot ran from 2005 through 2010, with the addition of a transition demonstration that ran from January 2011 through December 2012.[77] By 2010, the participating physician groups reached "benchmark performance on at least 30 of the 32" quality metrics.[78] Further, the physician groups "received performance payments totaling $29.4 million as their share of the $36.2 million of [the] savings generated."[79]

This early government experimentation fueled the desire to implement incentive compensation in a more global and systematic manner.

2. The Affordable Care Act's Commitment to Incentive-Based Compensation

Despite the contentious political debates that surrounded and continue to surround the Affordable Care Act (ACA), there was strong bipartisan support for a key category of reform reflected in the bill: restructuring the Medicare delivery system by tying financial incentives to performance.[80] The Institute of Medicine has estimated that the United States could save $750 billion a year by changing

(Oct. 20, 2016), https://innovation.cms.gov/initiatives/physician-group-practice-transition [https://perma.cc/T5K3-24F8]; Wallack & Tompkins, *supra* note 36. This pilot was an early experiment in what later became the Medicare Shared Savings Program. *Shared Savings Program*, CTRS MEDICARE & MEDICAID SERVS. (Sept. 15, 2016), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html [https://perma.cc/GJF7-NB7Y].

77. At the state level, Medicaid also did some early experimentation with incentive-based provider payments. A study published in 2007 by the Commonwealth Fund surveyed state Medicaid programs and found that over half of all states were using programs that relied on incentive-based compensation in at least some respect. *See* Kathryn Kuhmerker & Thomas Hartman, *Pay-for-Performance in State Medicaid Programs: A Survey of State Medicaid Directors and Programs*, COMMONWEALTH FUND (2007), http://www.commonwealthfund.org/~/media/files/publications/fund-report/2007/apr/pay-for-performance-in-state-medicaid-programs—a-survey-of-state-medicaid-directors-and-programs/1018_kuhmerker_payforperformance_state_medicaid_progs_v2.pdf [https://perma.cc/JTK7-TEU8]. The final results of the Medicare Physician Group Practice Demonstration can be found at *Evaluation of the Medicare Physician Group Practice Demonstration Final Report*, CTRS. MEDICARE & MEDICAID (Sept. 2012), https://innovation.cms.gov/Files/Reports/PGPFinalreport.pdf [https://perma.cc/4TU3-FY7M] [hereinafter *Physician Group Practice*].

78. *Medicare Physician Group Practice Demonstration: Physician Groups Continue to Improve Quality and Generate Savings Under Medicare Physician Pay-for-Performance Demonstration*, CTRS MEDICARE & MEDICAID 5 (July 2011), https://innovation.cms.gov/Files/fact-sheet/PGP-Fact-Sheet.pdf [https://perma.cc/T36K-3HZ2] [hereinafter *PGP Demonstration*]; *see also Physician Group Practice*, *supra* note 77, at 141 ("Given these findings, we believe the observed differences (i.e., larger improvements by the PGPs) were beyond random chance, and that the Demonstration had a positive effects on the quality of care delivered by the participating PGPs.").

79. *PGP Demonstration*, *supra* note 78 at 5.

80. Candeub, *supra* note 19 at 54.

the provider compensation approach.[81] By some measures, the ACA includes forty five different provisions aimed at reforming health-care delivery to either improve the quality and/or the efficiency of health care in some way.[82] Common amongst all of these new ACA initiatives, however, is the measurement of quality by attainment of process or outcome goals and cost savings, and the provision of a financial reward based on those metrics. What differs is the target, mechanism of administration, size of the incentive, and measures used to determine payments.[83] The three largest initiatives are: (1) the establishment of a Shared Savings Program to benefit Accountable Care Organizations; (2) the new incentive-based compensation model for physicians (and hospitals); and (3) a pilot program to test bundled payments, among other initiatives.[84]

a. Accountable Care Organizations

Of all the provisions aimed at reforming the delivery model by aligning incentives, Accountable Care Organizations (ACOs) have received the most attention. Section 3022 of the ACA requires the Secretary to establish a Medicare Shared Savings Program under which eligible doctors, hospitals, and other

81. *See Synopsis and Overview,* INST. OF MED., *The Healthcare Imperative: Lowering Costs and Improving Outcomes* 2 (Pierre L. Yong et al. eds., 2011); *see also* 159 CONG. REC. S16057 (daily ed. Jul. 13, 2013) (statement of Sen. Whitehouse) ("The President's Council of Economic Advisers has estimated that we could save approximately $700 billion . . . The Institute of Medicine took a look at the same question. They put the savings number at $750 billion."); Candeub, *supra* note 19 at 46–47 ("The belief that health care provision is wracked with inefficiency motivated . . . The Patient Protection and Affordable Care Act . . . and The Health Care and Education Reconciliation Act . . . with the White House acknowledging the elimination of this $700 billion waste as a chief goal.").

82. *See, e.g., Pay for Performance*, U.S. HEALTH POLICY GATEWAY (Dana Beezely-Smith ed., 2015), http://ushealthpolicygateway.com/payer-trade-groups/qualitysatisfaction/quality-improvement/general-approaches/pay-for-performance [ttps://perma.cc/CF6M-H7TC]. This does not include, for instance, the recent enactment of the Medicare Access and CHIP Reauthorization Act of 2015 and its expansion of value-based payment systems for providers. *See* Pub. L. No. 114-10, 129 Stat. 87 (codified in scattered sections of 42 U.S.C.). For a comprehensive summary of MACRA, see JIM HAHN & KIRSTIN B. BLOM, CONG. RESEARCH SERV., R43962, THE MEDICARE ACCESS AND CHIP REAUTHORIZATION ACT OF 2015 (2015).

83. *See, e.g.*, Ateev Mehrotra et al., *Using the Lessons of Behavioral Economics to Design More Effective Pay-for-Performance Programs*, 16 AM. J. MANAGED CARE 497 (2010); Brian M. Stecher et al., *Toward a Culture of Consequences: Performance-Based Accountability Systems for Public Services*, RAND CORP. (2010), http://www.rand.org/content/dam/rand/pubs/monographs/2010/RAND_MG1019.pdf [https://perma.cc/7YVP-LWAP].

84. These are three of the major provisions, but overall, the ACA, by some counts, reflects these goals in 45 different provisions. *Major Affordable Care Act Delivery and Payment Reforms*, AM. PUB. HEALTH ASS'N (Oct. 2013), https://www.apha.org/~/media/files/pdf/topics/aca/delivery_reforms_table_apha_oct2013.ashx [https://perma.cc/QQ33-HTJA]; *see also* Candeub, *supra* note 19 at 51 (2011). These mechanisms span many actors in the health-care system. In the text, the main focus is on the incentives at the provider level, although because some of the programs are collaboration based, it is not possible to entirely isolate the providers from other players.

providers receive financial bonuses relating to the cost savings they achieve for Medicare, assuming certain predefined quality metrics are also met.[85] To participate in the Shared Savings Program, eligible entities must create or participate in an ACO.[86] An ACO is a network of care providers committed to improving quality and reducing cost through coordination of efforts. Rather than individual specialists treating one patient without collaboration (thus duplicating tests and procedures, and lacking a cohesive view of the entire patient), ACOs deliver integrated care enabled by shared medical records and other coordination. In theory, ACOs avoid duplication of services and prevent medical errors. By giving providers who have at least some control over cost and quality of care a bonus for cost and quality metrics improvement (and in some cases a penalty for failing to meet goals), the ACO model aligns provider incentives with governmental priorities.[87]

Both cost savings and quality metrics play a part in determining ACO compensation. First, CMS sets a benchmark of average Medicare expenditures, taking into account a projected growth rate in expenses. CMS also sets a list of quality metrics and associated benchmarks.[88] The thirty-three measures span four quality domains: (1) Patient/Caregiver Experience; (2) Care Coordination/Patient Safety; (3) Preventive Health; and (4) At-Risk Population.[89] Seven measures are assessed from survey data, three are calculated via claims, one is calculated from Medicare and Medicaid Electronic Health Record (EHR) Incentive Program data, and twenty two are collected by reporting mechanisms.[90]

ACOs receive points on a sliding scale based on level of performance relative to the benchmarks. For instance, ACOs must report on certain preventive health measures administered to patients, such as immunizations for influenza and mammography screenings. ACOs must also report outcome measures for patients with various illnesses. For example, for patients with diabetes, ACOs must document control of Hemoglobin A1c, and for patients with hypertension, ACOs must report on patient blood pressure. ACOs that do well on these measures can earn a Physician Quality Reporting System (PQRS) incentive.

The quality metrics differentiate ACOs from HMOs and, in theory, prevent

85. Patient Protection and Affordable Care Act (PPACA) § 3022, 42 U.S.C. § 1395jjj (2012); *see* infra note 89 for further information on the quality metrics.

86. *See* 42 C.F.R. § 425 (2016).

87. *Finalized Changes to the Medicare Shared Savings Program Regulations*, CTRS. MEDICARE & MEDICAID SERVS. (June 4, 2015), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-06-04.html [https://perma.cc/9E63-K9SH] [hereinafter *CMS Medicare Shared Savings Fact Sheet*].

88. *Id.*

89. *Quality Measures and Performance Standards*, CTRS. MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Quality_Measures_Standards.html [https://perma.cc/48DE-S7CD].

90. *Id.*

ACOs from saving money by rationing necessary care.[91] Ultimately, CMS compares actual expenditures at term end to the benchmark, and then factors in performance on the quality metrics to assess shared savings (or potential shared losses).

According to CMS, ACOs serve nearly nine million Americans with Medicare, and Medicare is continuing to aggressively expand the program.[92] In January 2015, the Department of Health and Human Services (HHS) publicly announced a goal of tying fifty percent of payments to alternative payment models, such as ACOs, by the end of 2018.[93]

b. Incentive-Based Compensation for Physicians

The ACA also changes the method of physician payment through the Physician Value-Based Payment Modifier.[94] The program applies to traditional fee-for-service Medicare reimbursement where physicians are currently paid according to a fee schedule. The modifier adjusts fees paid to physicians using data reported on quality and resource use. In other words, physician payments are modified to reflect the *value* of care they provide.[95] It is intended to work in the same manner as traditional incentive pay: the government pays physicians more

91. Whether this distinction will ultimately play out as intended, however, is a matter of continuing debate. Consider, for instance, recent findings of implicit rationing in centralized health systems such as the Veterans Health Administration and the National Health Service. *See, e.g.*, Nancy M. Schlichting et al., *Commission on Care: Final Report*, COMMISSION ON CARE (Jun. 30, 2016), https://commissiononcare.sites.usa.gov/files/2016/07/Commission-on-Care_Final-Report_063016_FOR-WEB.pdf [https://perma.cc/VT8U-728V]; Richard Vize, *Rationing Care is a Fact of Life for the NHS*, GUARDIAN (Apr. 24, 2015), https://www.theguardian.com/healthcare-network/2015/apr/24/rationing-care-fact-of-life-nhs [https://perma.cc/LG5B-BBAH].

92. *See* S. Lawrence Kocot & Ross White, *Medicare ACOs: Incremental Progress, But Performance Varies*, HEALTH AFF.: BLOG (Sept. 21, 2016), http://healthaffairs.org/blog/2016/09/21/medicare-acos-incremental-progress-but-performance-varies [https://perma.cc/N4VR-W94Z] ("[N]early 9 million Medicare beneficiaries [are] attributed to the Medicare ACO programs . . . ."). This number has steadily increased from 7.8 million in 2015, *see* David Muhlestein, *Growth and Dispersion of Accountable Care Organizations in 2015*, HEALTH AFF.: BLOG (Mar. 31, 2015), http://healthaffairs.org/blog/2015/03/31/growth-and-dispersion-of-accountable-care-organizations-in-2015-2 [https://perma.cc/2TDK-NQQS], and 5.6 million in 2014, *see* Press Release, Ctrs. for Medicaid and Medicare Servs., Medicare ACOs Continue to Succeed in Improving Care, Lowering Cost Growth (Nov. 11, 2015), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-11-10.html [https://perma.cc/9N3A-EYHL].

93. Press Release, U.S. Dept. of Health & Human Servs., Better, Smarter, Healthier: In Historic Announcement, HHS Sets Clear Goals and Timeline for Shifting Medicare Reimbursements from Volume to Value (Jan. 26, 2015), http://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html [https://perma.cc/6JVT-GSAA]. It is unclear whether the Trump Administration will still seek to satisfy this goal.

94. 42 U.S.C. § 1395w-4 (2012).

95. *Medicare FFS Physician Feedback Program/Value-Based Payment Modifier*, CTRS. MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html [https://perma.cc/7PHX-YJJC].

if physicians do what the government wants them to do.[96]

The program started by focusing on measures of clinical processes and results of patient-satisfaction surveys, but over time has come to rely more heavily on outcome measures, such as mortality rates, rather than measures of process compliance.[97]

This new adjustment was first applied in 2015 to group practices with one hundred or more eligible professionals, using quality reporting data from 2013. The program will be scaled up to apply to all physicians by 2018.[98] The program is budget neutral for the government; therefore, some physicians will see their pay increase while others will see it decrease.[99]

c. Bundled Payments

Finally, Section 3023 of the ACA establishes a five-year program to test bundled payments.[100] Bundled payments mean that rather than paying per procedure or per test, reimbursement will be based on the expected costs for an entire episode of care (e.g., a single illness or course of treatment).[101] The payment arrangement includes both cost and quality components to assess value provided for the episode of care. The idea is, if a predefined sum of money will be awarded for patient care and total reimbursement cannot be increased by ordering more tests or procedures, providers will think hard about whether that extra test is likely to yield valuable information before ordering it and will coordinate their efforts to avoid costly and unnecessary duplication.

A number of models are currently being piloted.[102] Recently, Secretary of

96. Section 3001 of the ACA establishes the Hospital (In-Patient) Value-Based Purchasing Program, which works based on a similar mechanism. *See* 42 U.S.C. § 1395ww(o)(1)(A) (2012).

97. *See id.* (explaining that CMS adjusts payments to hospitals based on how well a hospital performs based on four domains, and how much the hospital improves on those domains).

98. Initially the program was intended to apply to physicians by 2017, *see Value-Based Payment Modifier and the Physician Feedback Program*, CTRS. MEDICARE & MEDICAID SERVS. (Nov. 1, 2011), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2011-Fact-sheets-items/2011-11-01-6.html [https://perma.cc/23PV-SVEE], but now it will apply to physicians by 2018, *see Value-Based Payment Modifier*, CTRS. MEDICARE & MEDICAID SERVS., https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeedbackprogram/valuebasedpaymentmodifier.html [https://perma.cc/4L2R-CQE6].

99. *See Summary of 2015 Physician Value-based Payment Modifier Policies*, CTRS. MEDICARE & MEDICAID SERVS. (2015), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/CY2015ValueModifierPolicies.pdf [https://perma.cc/B3L7-NMYY].

100. 42 U.S.C. § 1395cc-4 (2012).

101. *Bundled Payments for Care Improvement Initiative*, CTRS. MEDICARE & MEDICAID SERVS. (Sept. 30, 2013), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2013-Fact-sheets-items/2013-01-31.html [https://perma.cc/SC5E-45BJ].

102. *See, e.g.*, National Pilot Program on Payment Bundling, 42 U.S.C. § 1395cc-4 (2012); *Bundled Payments for Care Improvement Initiative (BPCI) Fact Sheet*, CTRS. MEDICARE & MEDICAID SERVS. (Aug. 13, 2015), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-

Health and Human Services Sylvia M. Burwell announced a pilot of bundled payments for hip- and knee-replacement procedures. The Secretary stated:

> By focusing on episodes of care, rather than a piecemeal system, hospitals and physicians have an incentive to work together to deliver more effective and efficient care. This model will incentivize providing patients with the right care the first time and finding better ways to help them recover successfully.[103]

The financial incentive in this model flows directly to the hospital and not the physician, although physician behavior is intended to be targeted as well.[104]

The next Part discusses why these new approaches really indicate a shift in contract drafting strategy and surveys the relevant literature.

II. THE EFFECTS OF CONTRACT DRAFTING STRATEGIES ON PARTY PERFORMANCE

For decades, scholars across disciplines have studied the effects of contracting strategies on party performance. Because the shift from fee-for-service to incentive compensation is a shift in contract-drafting strategy, this literature yields important, yet understudied, lessons for the health industry.

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sheets/2015-Fact-sheets-items/2015-08-13-2.html [https://perma.cc/99Q8-2XCZ]; Comprehensive Care for Joint Replacement (CJR) Program, 42 C.F.R. § 510.1; *Oncology Care Model*, CTRS. MEDICARE & MEDICAID SERVS. (Jan. 6, 2017), https://innovation.cms.gov/initiatives/oncology-care [https://perma.cc/B7N3-NFKN].

103. Press Release, U.S. Dept. of Health & Human Servs., CMS Proposes Major Initiative for Hip and Knee Replacements (July 9, 2015), http://www.hhs.gov/about/news/2015/07/09/cms-proposes-major-initiative-for-hip-and-knee-replacements.html [https://perma.cc/DRV4-3YW9]; *see also* Press Release, Ctrs. for Medicaid & Medicare Servs., Medicare's Delivery System Reform Initiatives Achieve Significant Savings and Quality Improvements – Off to a Strong Start (Jan. 30, 2014), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2014-Press-releases-items/2014-01-30.html [https://perma.cc/TR9J-N5FJ]. For a review of the four models of bundled payments under the Bundled Payments for Care Initiative, see *Bundled Payments for Care Improvement Initiative (BPCI)*, CTRS. MEDICARE & MEDICAID SERVS., https://innovation.cms.gov/initiatives/bundled-payments [https://perma.cc/QZ72-FLL8] [hereinafter *BCPI*].

104. With increasing numbers of physicians being employed by hospitals, the question is whether hospitals are passing incentives down to physicians. A thorough review of that question is outside the scope of this paper, but there is at least some evidence that the trend is for hospitals to structure physician employment contracts to have both a salary portion and an incentive-based portion, such that ultimately both the hospital itself and the individual physicians have financial incentives to provide higher-quality medical care. *See, e.g.*, Gerard F. Anderson et al., *Medicare Payment Reform: Aligning Incentives for Better Care*, COMMONWEALTH FUND (June 2015), http://www.commonwealthfund.org/publications/issue-briefs/2015/jun/medicare-payment-reform-aligning-incentives [https://perma.cc/2QAL-4BFP].

A. History and Background on the Incomplete-Contracts Literature

Historically, contracts were thought to exist on a spectrum ranging from less complete to more complete. At one end of the spectrum was a perfectly complete contingent contract specifying the rights and duties of all parties in every possible state of the world.[105] At the other end of the spectrum was a rather vague agreement that might be so indefinite as not to be enforceable by a court.[106]

The literature on contract-drafting strategy initially focused on the choice to draft a relatively more-complete or a relatively less-complete contract.[107] But scholarly attention eventually turned to the question of the impact of contract form on party performance. In other words, once the choice to draft a rather-more-complete or a rather-less-complete contract has been made, does that choice affect the success of the deal?

Law and economics scholars posited that less-complete contracts would be more likely to result in litigation because failure to give adequate guidance to the parties about their duties and obligations would be more likely to lead to the breakdown of a deal.[108] A less-complete contract would tend to yield opportunistic behavior. On the other hand, more-complete contracts were thought to be less likely to result in litigation because the parties were clear in their contractual obligations.[109]

In recent decades, there have been two major shifts in this conversation. The first shift grew out of work in the behavioral sciences. The law and economics account of incomplete contracts assumed parties acted both rationally and selfishly. But experiments started to show that individual behavior often deviated from these predictions.[110] In a quest to understand these behavioral anomalies, a much broader literature that built upon the law and economics model, but that also considered the impact of these new findings, began to emerge.

In particular, this work acknowledges that drafting choices can affect both an

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105. An entirely complete contract is merely a theoretical construct. No contract could ever be entirely complete. *See, e.g.*, Robert E. Scott, *A Theory of Self-Enforcing Indefinite Agreements*, 103 COLUM. L. REV. 1641, 1641 (2003).

106. *See id.* at 1643–644 (describing how courts dismiss claims of breach due to a contract's indefiniteness).

107. *See* Oliver Williamson, *Assessing Contract*, 1 J.L. ECON. & ORG. 177, 197 (1985) (analyzing possible solutions for limiting litigation in the face of incomplete contracts); *see also* Ronald Dye, *Costly Contract Contingencies*, 26 INT'L ECON. REV. 233 (1985) (discussing the conflict between costs and benefits regarding completeness in contracts).

108. *See, e.g.*, Richard A. Posner, *The Law and Economics of Contract Interpretation*, 83 TEX. L. REV. 1581 (2005) (discussing the potential costs of litigation arising from an incomplete contract).

109. *Id.*

110. *See, e.g.*, Daniel Kahneman & Amos Tversky, *Prospect Theory: An Analysis of Decision Under Risk*, 47 ECONOMETRICA 263 (1979); Amos Tversky & Daniel Kahneman, *The Framing of Decisions and the Psychology of Choice*, 211 SCIENCE 453 (1981); Richard Thaler, *Toward a Positive Theory of Consumer Choice*, 1 J. ECON. BEHAV. & ORG. 39 (1980).

agent's compliance and the agent's motivation.[111] Compliance describes the desire for an agent to execute the precise task that the principal has defined. Compliance requires that the agent understand the task the principal is asking the agent to undertake (cognition), and has the ability to do the work.[112] Motivation, on the other hand, describes how much effort the agent puts into the task. A talented agent may not need to try very hard to achieve compliance. But in many circumstances, the principal might want to get more than mere compliance from the agent. The principal might want to get the best possible performance that goes above and beyond the minimum requirements of the contract.

The second shift reflected the realization that contracts are not as one dimensional as the spectrum from less complete to more complete had suggested. Rather, there are many dimensions in which a contract may be "complete" or "incomplete," and those different dimensions may have differing impacts on party performance.[113]

For instance, a contract may define the agent's required tasks and performance goals in either a more-specific way or a more-vague way.[114] A more "complete" contract may include regular reporting or monitoring requirements. Or a less "complete" contract may require no reporting and no monitoring at all.[115] A third dimension of contract completeness concerns the use of financial incentives. Financial incentives often go hand-in-hand with task specification and

111. Many scholars have differentiated between compliance and motivational or performance effects in this area, but a forthcoming article by Constantine Boussalis and colleagues does a particularly good job surveying the literature using this framework. *See* Constantine Boussalis et al., *An Experimental Analysis of the Effect of Specificity on Compliance and Performance*, REG & GOVERNANCE (forthcoming 2017) (manuscript at 1, 3), https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID2708193_code2338814.pdf?abstractid=2539190 [https://perma.cc/AH8C-55P3]; *see also* Epstein, *supra* note 11, at 309; Erik A. Mooi & Mrinal Ghosh, *Contract Specificity and its Performance Implications*, 74 J. MARKETING 105, 106 (2010) (noting specification leads agents to focus on particular tasks); Gerard H. Seijts & Gary P. Latham, *The Effect of Distal Learning, Outcome, and Proximal Goals on a Moderately Complex Task*, 22 J. ORGANIZATIONAL BEHAV. 291, 302, 304 (2001) (finding specific, challenging goals make agents desire to perform better and exert higher levels of effort).

112. Ray Worthy Campbell, *The End of Law Schools: Legal Education in the Era of Legal Service Businesses*, 85 MISS. L.J. 1, 50 (2016) ("[C]ompliance requires an understanding of the legal requirements imposed on corporations . . . .").

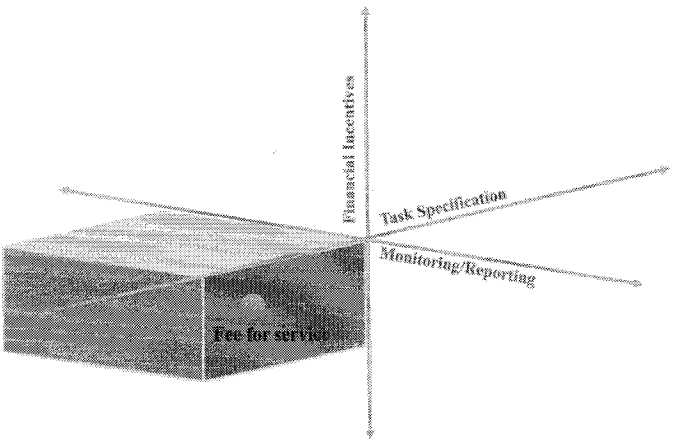
113. *See, e.g.*, George S. Geis, *An Empirical Examination of Business Outsourcing Transactions*, 96 VA. L. REV. 241, 256 (2010) ("It is important, therefore, to go beyond any aggregate measure of complexity and to look more carefully at specific terms, structures, and features in a micro-analytical manner.").

114. *See* Robert E. Scott & George G. Triantis, *Anticipating Litigation in Contract Design*, 115 YALE L.J. 814, 818 (2006) (discussing the value of using vague terms for contract conditions); Posner, *supra* note 108, at 1582-83 (examining the costs and benefits of using specific terms in contracts).

115. The decision to include monitoring or reporting requirements might actually impact party performance differently. Reporting requirements, for instance, may convey more trust of the agent than monitoring if the reporting is self reporting and the monitoring is third-party monitoring. However, I treat them as having similar effect here because the purpose is essentially the same.

monitoring—for instance, a contract may specify goals, require reporting on the goals, and award funds for the achievement of the goals. But contracts could also include provisions for awarding discretionary bonuses not necessarily tied to specific tasks.[116]

In the health-care sector, the move from fee for service to pay for performance is a move along the contract-completeness spectrum. The fee-for-service approach, relatively speaking, did not specify tasks in detail, did not make significant use of monitoring or reporting, and did not utilize financial incentives.[117] Payers did little to define desired goals or outcomes or even processes in which providers should engage. And in general, assuming the services provided fell within reimbursable categories, payers promised to pay for the services rendered.[118]



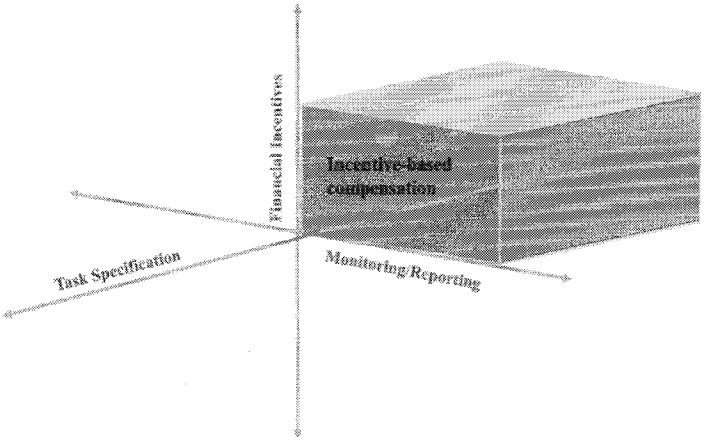
Incentive-based compensation is, in many ways, the opposite, requiring

116. These are not the only three aspects of contract completeness worth separately considering. Empiricists have suggested many other ways to classify contract drafting strategies. *See, e.g.*, George S. Geis, *An Empirical Examination of Business Outsourcing Transactions*, 96 VA. L. REV. 241, 256 (2010). But these three aspects of contract completeness are the most salient for present purposes.

117. For instance, a sample fee-for-service contract between a provider and CMS is a single-page agreement. It states simply that the provider agrees to request "direct Part B payment from the Medicare program" and that the payment will be the "full charge for the service covered under Part B" other than the applicable deductible and coinsurance. *See, e.g.*, *Medicare Participating Physician or Supplier Agreemen*, CTRS. FOR MEDICAID AND MEDICARE SERVS. (Apr. 2010), https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms460.pdf [https://perma.cc/KK5H-TLG6].

118. Medicare does set the reimbursable rates for procedures and only covers what it considers "medically necessary." And there are other preconditions to reimbursement, including state laws that dictate what services a particular type of practitioner is licensed to provide and both national and local coverage decisions made as to whether a particular item or service is covered under Medicare's rules. *See Learning What Medicare Covers and How Much You Pay*, CTRS. FOR MEDICAID AND MEDICARE SERVS. (Dec. 2016), https://www.medicare.gov/pubs/pdf/11472-Learn-What-Medicare-Covers.pdf [https://perma.cc/B95A-P83P].

much more detailed contract drafting.[119] The payer must provide detailed criteria to which a physician must adhere and must define the financial implications of meeting, exceeding, or falling short of those metrics. If fee-for-service contracts tend to be less specific in task definition and not make use of reporting and financial incentives (i.e., payers agree to pay regardless of performance), incentive-based compensation is a move toward the other end of the contract-drafting spectrum: higher on task specificity and a greater use of contractual control mechanisms, such as monitoring and financial incentives.



One of the main insights of this Article is to suggest the literature that studies the effect of contract-drafting strategy on party performance should inform this new strategy in the health-care industry.[120]

B. The Literature on Compliance and Motivation

Contract-drafting choices can influence party performance in ways that are more complicated than the early literature—more complete is better and less complete is bad—suggested.

In an ideal world, contracts would prompt both agent compliance and agent motivation. The question is: Can a shift from a less complete to a more complete contract prompt both, or is there a competing effect between the two? The next subpart considers what effects specifying tasks, using monitoring and reporting mechanisms, and employing financial incentives have on both compliance and motivation. There is a lot of nuance in the literature, but one major takeaway is that the more complex the task and the more the principal wants to prompt agent

119. *See* Stout, *supra* note 19, at 536 (2014).

120. For a significant portion of the population, what the contract actually says matters to performance. *See, e.g.*, Ernst Fehr et al., *Reciprocity as a Contract Enforcement Device: Experimental Evidence*, 65 ECONOMETRICA 833, 833 (1997); Eileen Chou et al., *The Devil Is in the Details: Less Specific Contracts Promote Feelings of Autonomy, Intrinsic Motivation and Work Persistence* 5 (unpublished manuscript) (on file with author).

creativity, innovation, and top effort level, the less well the incentive compensation model will fit.

1. Task Specification

Many studies have shown that task specification aids cognition, particularly in the obvious way that people better understand what they are supposed to do when the task is spelled out in some detail. Consider the task of putting together the Ultimate Collector's Millennium Falcon (Star Wars) LEGO® Set, which has over 10,000 pieces.[121] While a user may understand the overall goal of the project without the detailed instructions, to build a LEGO® Millennium Falcon, the detailed instructions certainly help the average user understand how best to get from point A (a box full of 10,000 individual Legos) to point B (the completed Millennium Falcon).[122]

In the contract context specifically, studies have demonstrated that drafting more-detailed clauses that clearly specify responsibilities reduces the likelihood of agent misunderstanding.[123] And, in general, there a line of research in both the goal-setting literature, specifically, and the behavioral literature, more broadly, that seems to suggest clear instructions are superior to less-specific ones for the purpose of directing an agent's understanding of a project and ensuring compliance with dictates.

Complexity, however, is an important variable. Research has also shown that specification of very complex tasks actually creates a perception of vagueness and leads to under-compliance.[124]

Other studies also document less-positive effects of specificity on cognition and compliance. For instance, task specificity can cause agents to focus on the specified details to the detriment of other, less-highly-specified elements of the

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121. LEGO, http://shop.lego.com/en-US/Millennium-Falcon-75105 [https://perma.cc/9F4S-DCYD].

122. This assumes that there is a well-tested path to success. If the goal were to prompt users to find the best way to build the Millennium Falcon with the provided pieces, detailed instructions may negatively impact creativity. *See, e.g.*, Christina E. Shalley et al., *The Effects of Personal and Contextual Characteristics on Creativity: Where Should We Go from Here?*, 30 J. MGMT. 933 (2004) (synthesizing studies on prompting creativity).

123. *See, e.g.*, Mooi & Ghosh, *supra* note 111 at 108 (Mar. 2010) (arguing greater specificity in procurement contracts for IT hardware/software decreases the likelihood for misunderstanding between the parties); Kenneth H. Wathne & Jan B. Heide, *Opportunism in Interfirm Relationships: Forms, Outcomes, and Solutions*, 64 J. MARKETING 36, 39 (2000) (noting, in general, lack of contractual specificity enables a party to evade contractual obligations).

124. *See* Jérôme Barthélemy & Bertrand V. Quélin, *Complexity of Outsourcing Contracts and Ex Post Transaction Costs: An Empirical Investigation*, 43 J. MGMT. STUDIES 1775, 1790 (2006) (noting the high complexity of outsourcing contracts makes performance specification, verification, and monitoring difficult); Ehud Guttel & Alon Harel. *Uncertainty Revisited: Legal Prediction and Legal Postdiction*, 107 MICH. L. REV. 467, 486 (2008) ("Different levels of specificity [of legal norms], even when producing the same level of uncertainty, can inhibit or encourage behavior.").

task. In other words, task specification directs attention away from understanding the ultimate goal of the work.[125]

Studies of the checklist approach demonstrate this point. Checklists are used to ensure compliance with a specified set of tasks, and have proven effective at improving performance.[126] This is particularly true in situations such as an airplane cockpit where pilots have to remember many details under pressure. However, checklists have also been shown to impede cognition and decrease project-level compliance because they make tasks automatic.[127] Checklists discourage thinking, which in some situations can be a detriment to performance.

In sum, task specification enables cognition and prompts compliance where the task is relatively straightforward and the agent has the ability to execute the task without the need to do much learning. Specification is less likely to prompt compliance for complex tasks that require understanding of the overall task rather than piecemeal tasks, or tasks that require individual thinking and creativity.

Whether or not task specification is good for agent motivation is an area of much study and some dispute in the literature.[128] Some studies have found that specific, challenging goals make agents desire to perform better and exert higher levels of effort.[129] In other words, task specification can make agents rise to the

125. *See* Boussalis et al., *supra* note 111, at 6 (noting that setting goals based on the volume of task units completed may decrease creativity); *see also* Gideon Parchomovsky & Alex Stein, *Catalogs*, 115 COLUM. L. REV. 165 (2015) (discussing the use of vague standards coupled with specific examples, a so-called "catalog approach").

126. *See, e.g.*, Robert Gibbons & Rebecca Henderson, *What Do Managers Do? Exploring Persistent Performance Differences Among Seemingly Similar Enterprises*, *in* HANDBOOK OF ORGANIZATIONAL ECONOMICS 680–731 (R. Gibbons and J. Roberts eds., 2013).

127. Bridgette M. Hales & Peter J. Pronovost, *The Checklist: A Tool for Error Management and Performance Improvement*, 21 J. CRITICAL CARE 231, 234 (2006) ("Checklist 'fatigue,' whereby the overwhelming number of available or required checklists becomes a hindrance rather than an aid, is becoming a more common theme in areas that have been heavily targeted with this type of intervention. If overused . . . checklists can act to impede the quality and speed of service delivery. Checklist users may also become dependent on these tools in their practice, which can interfere both with their professional judgment and the objectivity of their decision-making process.").

128. Some scholars suggest less task specification increases agent motivation. *See, e.g.*, Gibbons & Henderson, *supra* note 126; *see also* George G. Triantis, *The Efficiency of Vague Contract Terms: A Response to the Schwartz-Scott Theory of U.C.C. Article 2*, 62 LA. L. REV. 1065, 1072 (2002) (noting that conditioning reward on specified tasks distorts efforts to those tasks and away from ones the agent might otherwise have undertaken). Meanwhile, other scholars argue task specification increases agent motivation. *See* Emily C. Haisley & Roberto A. Weber, *Self-Serving Interpretations of Ambiguity in Other-Regarding Behavior*, 68 GAMES & ECON. BEHAV. 614–25 (2010); Seijts & Latham, *supra* note 111.

129. Gary P. Latham & Edwin A. Locke, *Goal Setting – A Motivational Technique that Works*, 8 ORGANIZATIONAL DYNAMICS 68, 75 (1979) ("Specific, challenging goals lead to better performance than do easy or vague goals . . . ."). *But see* Eileen Chou et al., The Control-Motivation Dilemma: Contract Specificity Undermines Intrinsic Motivation, Persistence, and Creativity 3–4 (2014) (unpublished manuscript) (on file with author) (demonstrating through experiment that less-specific contracts prompt intrinsic motivation in the employment context).

occasion.[130]

Specification may also be beneficial for motivating agent performance because task specification could reduce the likelihood that agents would use ambiguity to justify questionable behavior that does not benefit the principal.[131] For instance, several studies have shown that agents are more likely to act dishonestly or immorally in the face of contractual ambiguity than in the face of specificity.[132]

But this is an area where there seems to be conflict in the literature because many studies have also shown that task specificity can signal mistrust and can crowd out an agent's intrinsic desire to perform well.[133] In the contract setting, for these reasons, more-specific contracts can lead to poorer agent performance than less-specific ones.[134]

Task specification has also been shown to decrease motivation particularly where the task is complex and learning is still ongoing.[135] There is therefore now much support for the idea that task specification decreases effort level because it crowds out intrinsic motivation.[136]

130. *See* Seijts & Latham, *supra* note 111.

131. *See* Haisley & Weber, *supra* note 128.

132. *See* Yuval Feldman & Doron Teichman, *Are All Contractual Obligations Created Equal?*, 100 GEO. L.J. 5, 12 (2011) (discussing a study where participants playing the role of painters who must choose between using a generic paint of inferior quality or a better quality paint were more likely to choose the lower quality paint if they were told that the lower quality paint may or may not "be deemed a breach of a contractual obligation to use 'reasonable' materials"); *see also* Yuval Feldman & Alon Harel, *Social Norms, Self-Interest and Ambiguity of Legal Norms: An Experimental Analysis of the Rule vs. Standard Dilemma*, 4 REV. L. & ECON. 81 (2008) (discussing a study documenting relationship between self-interest and legal ambiguity); Nina Mazar & Dan Ariely, *Dishonesty in Everyday Life and Its Policy Implications*, 25 J. PUB. POL'Y & MARKETING 117, 121–22 (2006) (analyzing the role of self-deception in dishonest behavior).

133. In a famous study testing the motivational effects of implicit versus explicit contracts, Fehr and Gächter found that principals who chose the explicit contract lost on average nine tokens per contract, compared to a profit of 26 tokens per implicit contract and that the difference was attributable to effort levels. Ernst Fehr & Simon Gächter, *Fairness and Retaliation: The Economics of Reciprocity*, 14 J. ECON. PERSP. 159, 170 (2000); *see also* Ernst Fehr et al., *supra* note 120, at 833.

134. Chou et al., *supra* note 120 at 5; *see also* Laura Poppo & Todd Zenger, *Do Formal Contracts and Relational Governance Function as Substitutes or Complements?*, 23 STRATEGIC MGMT. J. 707, 711–12 (2000) (discussing the importance of lack of specificity to increase in trust); Armin Falk & Michael Kosfeld, *The Hidden Costs of Control*, 96 AM. ECON. REV. 1611, 1612–13 (2006) ("[A]gents are averse to being controlled, and consequently lower their performance if the principal implements a more complete contract.").

135. *See* Lisa D. Ordóñez et al., *Goals Gone Wild: The Side Effects of Over-Prescribing Goal Setting*, (Harvard Bus. Sch., Working Paper No. 09-083), http://www.hbs.edu/faculty/Publication%20Files/09-083.pdf [https://perma.cc/7DYR-WQR5]; Nicholas Argyres et al., *Complementarity and Evolution of Contractual Provisions: An Empirical Study of IT Services Contracts*, 18 ORG. SCI. 3 (2007).

136. *See* sources cited *supra* notes 120, 122, 124, 134.

2. Monitoring/Reporting Mechanisms

In addition to specifying tasks, many contracts also require that an agent report on certain metrics or subject themselves to external monitoring of performance.[137] The primary purpose of reporting requirements and monitoring rights is to prevent opportunistic behavior and ensure compliance. But there is some controversy about how well it works, and what effect such terms have on motivation.

First, requiring reporting or monitoring forces agents to focus on contractual requirements.[138] This is particularly true if reporting is likely to be linked to either a positive or negative consequence.[139] Agents react to and are likely to comply in the case of measurable metrics.[140] This result is not surprising. Agents are more likely to do what is asked of them if they know the principal will be watching.[141]

Yet as with task specification, reporting requirements also focus an agent's attention on certain aspects of performance that are designated important because reporting is required or because it is being monitored. This leaves less cognitive attention to be focused on other aspects of the contract where reporting and monitoring are not pertinent.[142]

A related negative implication of reporting and monitoring requirements is that it can prompt gaming behavior. Agents who know they will be evaluated based on reported metrics tend to act dishonestly to maximize those metrics that will in turn better their individual position (financially or otherwise).[143]

But perhaps one of the biggest concerns about monitoring is its implications for motivation.[144] Monitoring and reporting mechanisms should, in theory, cause

137. *See, e.g.*, Lisa Bernstein, *Beyond Relational Contracts: Social Capital and Network Governance in Procurement Contracts*, 7 J. LEGAL ANALYSIS 561, 581–96 (discussing use of Supplier Scorecards to report compliance with relatively objective performance metrics).

138. *See* Boussalis et al., *supra* note 111, at 7 ("[P]eople's intrinsic motivation to perform well is crowded out by the relationship between performance, measurement, and payment. Therefore, specificity combined with monitoring that focuses only on given measurable components (the letter of the law) seems to produce a straightforward effect of crowding out intrinsic motivation and decreasing overall performance.").

139. *See* Edward P. Lazear, *The Power of Incentives*, 90 AM. ECON. REV. 410–14 (2000) (arguing that when compensation is tied too closely to performance, employees are likely to focus on the specific tasks tied to compensation, potentially declining to pursue other beneficial options).

140. *Id.*

141. Boussalis et al., *supra* note 111, at 7 (noting that agents focus more attention on measurable metrics).

142. Boussalis et al., *supra* note 111, at 7 ("According to these theories, over time, the accuracy of measurement decreases as people concentrate their effort strictly on the measured components of an activity, resulting in a decline in the overall quality of their performance.").

143. *See, e.g.*, Gunter G. Shulze & Bjorn Frank, *Deterrence Versus Intrinsic Motivation: Experimental Evidence of the Determinants of Corruptibility*, 4 ECON. GOVERNANCE 143 (2003).

144. David Dickinson & Marie-Claire Villeval, *Does Monitoring Decrease Work Effort? The Complementarity Between Agency and Crowding-Out Theories*, 63 GAMES &

agents to exert high levels of effort. In the absence of monitoring or reporting, the concern is that agents will not exert effort because they lack an effective way to find out how they performed.

Some studies confirm the theory in practice.[145] For instance, a 2008 study found that monitoring results in agents increasing their level of effort.[146] However, the same study reports that when monitoring exceeds a certain threshold, motivation begins to be crowded out and agents actually exert less effort.[147]

Just as specification can signal distrust and crowd out intrinsic motivation, it seems so can monitoring. Or at least that monitoring can negatively impact the relationship between principal and agent. That is what a 2013 review of the literature determined.[148] Essentially, an agent is more motivated by having discretion in a task, reading discretion to mean that the principal is conveying an element of trust. An agent reacts less well to the suggestion that the principal must be watching to ensure good performance. There is similar evidence about the function of financial incentives, which is discussed below.

3. Financial Incentives

Financial incentives are specifically designed to direct focus and improve effort level. In the law and economics account, individuals will focus their attention on tasks that are directly tied to compensation and will exert high levels of effort if that effort will be financially rewarded.[149] The efficacy of financial incentives is hotly debated in the literature. Some studies suggest that they work to prompt compliance.[150] This tends to be most frequently the case for tasks that

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ECON. BEHAV. 56, 57 (2008) (noting that monitoring has the potential to decrease agent motivation).

145. *See, e.g.*, Armen A. Alchian & Harold Demsetz, *Production, Information Costs, and Economic Organization*, 62 AM. ECON. REV. 777 (1972) (developing theory); Eugene F. Fama & Michael C. Jensen, *Separation of Ownership and Control*, 26 J. LAW & ECON 301 (1983) (developing theory).

146. Dickinson & Villeval, *supra* note 144.

147. *Id.*

148. Margit Osterloh & Bruno Frey, *Motivation Governance*, *in* HANDBOOK OF ECONOMIC ORGANIZATION: INTEGRATING ECONOMIC AND ORGANIZATION THEORY 26–40 (Anna Grandori ed., 2013).

149. *See* Boussalis et al., *supra* note 111, at 4 ("According to the rational choice prediction, the agent focuses most of his work on the tasks for which he can be given an incentive").

150. *See, e.g.*, Geoffrey B. Sprinkle, *The Effect of Incentive Contracts on Learning and Performance*, 75 ACCT. REV. 299, 299 (2000); *see also* Antonio Guiffrida & David J. Torgerson, *Should We Pay the Patient? Review of Financial Incentives to Enhance Patient Compliance*, 315 BRITISH MED. J. 703, 706 (Sept. 20, 1997) (noting "the use of some form of financial inducement increases compliance" with patient treatment plans); Joseph E. Murphy, *Using Incentives in Your Compliance and Ethics Program*, SOC'Y CORP. COMPLIANCE & ETHICS 15 (Nov. 2011) ("Incentives can work as effective tools for a business that wishes to promote compliance by employing concrete actions." (quoting *Corporate Compliance Programs*, CANADA BUREAU COMPETITION 21 (Sept. 27, 2010), http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/cb-bulletin-corp-

are fairly mechanical and require little cognitive effort,[151] for instance, replacing windshields.[152]

However, studies also find that compliance may be temporary.[153] And there is the same concern as with reporting requirements that incentives can prompt cheating or untoward manipulation.[154]

There is also a large body of literature suggesting that agents are actually less compliant and exert less effort when subject to incentives. A number of famous experiments suggest the reason for this is that incentives crowd out intrinsic motivation.[155] For instance, college students will spontaneously work on challenging puzzles, but lose interest once they are paid a fee to solve them.[156] Fewer people will donate blood once an incentive payment is added.[157] A randomized controlled trial at an Israeli day care found that where fines were

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compliance-e.pdf/$FILE/cb-bulletin-corp-compliance-e.pdf [https://perma.cc/D7BV-PDAD])); Lois Synder & Richard L. Neubauer, *Pay-for-Performance Principles That Promote Patient-Centered Care: An Ethics Manifesto*, 147 ANNALS INTERNAL MED. 792, 793 (2007) ("Pay-for-performance and other programs that create strong incentives for high-quality care set up a potential conflict between this duty [to care for patients] and the competing interest of trying to comply with a performance measure-whether the measure is a priority for that patient or not.").

151. Dan Ariely et al., *Large Stakes and Big Mistakes* (Fed. Res. Bank of Boston, Working Paper No. 05-11, 2005) (demonstrating pay-for-performance works for mechanical tasks, but if cognitive skills are required, it leads to poorer performance); *see* DANIEL H. PINK, DRIVE: THE SURPRISING TRUTH ABOUT WHAT MOTIVATES US 103 (2009).

152. *See* Matthew Wynia, *The Risks of Rewards in Health Care: How Pay-for-Performance Could Threaten, or Bolster, Medical Professionalism*, 24 J. GEN. INTERNAL MED. 884, 885 (2009).

153. *See* Pat Redmond et al., *Can Incentives for Healthy Behavior Improve Health and Hold Down Medicaid Costs?*, CTR. ON BUDGET & POL'Y PRIORITIES (June 2007), http://www.cbpp.org/archiveSite/6-1-07health.pdf [https://perma.cc/NQ44-FNZK]; Drake Baer, *Why Incentives Don't Actually Motivate People to do Better Work*, BUS. INSIDER (Apr. 1, 2014), http://www.businessinsider.com/why-incentives-dont-actually-make-people-do-better-work-2014-3 [https://perma.cc/ST36-FRFA]; Alfie Kohn, *Why Incentive Plans Cannot Work*, HARV. BUS. REV., Sept.-Oct. 1993, https://hbr.org/1993/09/why-incentive-plans-cannot-work [https://perma.cc/2F7J-GRFX]; Dyann M. Matson et al., *The Impact of Incentives and Competitions on Participation and Quit Rates in Worksite Smoking Cessation Programs*, 7 AM. J. HEALTH PROMOTION 270, 270–80 (1993).

154. Adam Grant & Jitendra Singh, *The Problem with Financial Incentives – and What to Do About It*, KNOWLEDGE @ WHARTON (Mar. 30, 2011), http://knowledge.wharton.upenn.edu/article/the-problem-with-financial-incentives-and-what-to-do-about-it [https://perma.cc/CZ4M-EJJ2] ("Incentives can enhance performance, but they don't guarantee that employees will earn them by following the most moral or ethical paths. . . . [W]hen people are rewarded for goal achievement, they are more likely to engage in unethical behavior, such as cheating.").

155. *See* Epstein, *supra* note 11, at 308-09 (explaining autonomy tends to boost motivation more than control, which signals distrust); *see also* Chou et al., *supra* note 120 at 5; Edward L. Deci et al., *Facilitating Internalization: The Self-Determination Theory Perspective*, 62 J. PERSONALITY 119, 122 (1994); Wendy S. Grolnick & Richard M. Ryan, *Parent Styles Associated with Children's Self-Regulation and Competence in School*, 81 J. EDUC. PSYCHOL. 143, 144 (1989); Richard M. Ryan & Edward L. Deci, *Self-Determination Theory and the Facilitation of Intrinsic Motivation, Social Development, and Well-Being*, 55 AM. PSYCHOLOGIST 68, 70 (2000).

156. Edward Deci, *supra* note 11, at 114–15.

157. *See* Lorenz Goette et al., *Prosocial Motivation and Blood Donations: A Survey of the Empirical Literature*, 37 TRANSFUSION MED. & HEMOTHERAPY 149 (2010).

imposed for tardy retrieval of children, parents responded by increasing rates of late pick up (the opposite of the intended effect).[158] The explanation was that absent a fine, parents felt a moral duty to retrieve their children on time. Once a fine was implemented, it turned into a market transaction: as long as parents were willing to pay the fee, it was acceptable to pick up their children late.

Context seems to matter. Intrinsic motivation is likely to be strongest in situations with a strong moral framing (such as donating blood) or ones that are cognitively challenging. In those situations, financial incentives seem to have the potential to be most harmful in crowding out that intrinsic motivation.[159] When intrinsic motivation is not strong, incentives are more likely to work as economic theory predicts. This may also explain why incentives work well for more repetitive or rote tasks, which are not the type of work people tend to be intrinsically motivated to do in the first place.

But even this distinction is not entirely straightforward. For instance, in one study comparing flat-wage compensation contracts to incentive contracts in an experiment that required both exerting effort and learning over time—which should be intrinsically motivating—the subjects receiving incentive pay exerted higher levels of effort and learned more over the course of the experiment.[160] The author theorized that "the incentive-based contract . . . motivate[d] participants to implement the first-best strategy . . . and to use feedback to maximize the total expected performance."[161]

C. Lessons About Highly Detailed Contracts That Use Reporting Mechanisms and Financial Incentives

Contract drafters use various techniques in an attempt to prompt compliance and motivation. While it would be ideal for a strategy to positively impact both, what the evidence suggests is that the relationship between these strategies is complex and, at times, competing.

For instance, there is solid evidence suggesting that task specification works best for delivering cognitive clarity and directing the agent's focus to particular tasks.[162] Task specification tends to work better to prompt compliance with easily defined tasks than it does to motivate agents to innovate or come up with creative

158. *See* Uri Gneezy & Aldo Rustichini, *A Fine is a Price*, 29 J. LEGAL STUD. 1 (2000).

159. *See* Edward Deci et al., *A Meta-Analytic Review of Experiments Examining the Effects of Extrinsic Rewards on Intrinsic Motivation*, 125 PSYCHOL. BULL. 627, 650-52 (1999); *see also* Bohnet et al., at 131–51 (finding incentive contracts decrease cooperation); Bruno S. Frey & Reto Jegen, *Motivation Crowding Theory: A Survey of Empirical Evidence*, 15 J. ECON. SURVS. 589, 589–612 (2001) (suggesting that monetary incentives are not as effective as reciprocity arrangements for providing motivation).

160. *See* Sprinkle, *supra* note 150, at 310, 319–20.

161. *See id.* at 302.

162. *See, e.g.*, Edwin A. Locke & Gary P. Latham, *New Directions in Goal-Setting Theory*, 15 CURRENT DIRECTIONS PSYCHOL. SCI. 265 (2006); Mark A. Mone & Christine E. Shalley, *Effects Specificity on Change in Strategy and Performance Over Time*, 8 HUM. PERFORMANCE 243 (1995).

solutions to complex problems.[163] It comes with a risk of overly focusing on the specified metrics to the detriment of commitment to the success of the overall project, so specification seems to be best used in areas where this type of focus is less of a concern.[164] These areas likely overlap with the simple versus complicated divide. There is little risk of hyperfocus when the task is relatively straightforward in the first place.[165] There is more risk when the task is complicated and the principal needs the agent to comply with all aspects of the project, not just those that are highly specified.[166]

Reporting and monitoring also tend to be the best fit for easier, compliance-based tasks.[167] The risk with monitoring is that agents will view it as a signal of distrust and will exert lower effort in response.[168] But if monitoring is used to ensure compliance—e.g., with a checklist—where there is little expectation of creativity, it can be useful and can be effective to deter opportunistic behavior.[169]

Financial incentives also seem to work best for compliance-oriented tasks rather than complex tasks that require creativity and consummate performance.[170] But even as to simple tasks, the effect is not straightforward. Whether or not strong intrinsic or morality-based motivation exists in the first place seems to be an important determinant.

This nuance might help to explain why results of incentive-pay schemes in health care and in other industries have been so mixed. Incentive-based compensation is a contract-drafting strategy that employs task specification, reporting and monitoring, and the use of financial incentives. That approach is likely to be effective only in a relatively small subset of contexts. The next Part illustrates this point.

III. INCENTIVE BASED COMPENSATION: THE EVIDENCE SO FAR

Although incentive-based compensation is, relatively speaking, new to health care, it has long been employed in other industries, such as executive compensation, professional sports, and education. These three industries provide an interesting comparison to health care because despite some salient differences,

163. *See, e.g.*, Shalley et al., *supra* note 122.

164. *See* Mone & Shalley, *supra* note 162; Samuel Bowles, *Policies Designed for Self-Interested Citizens May Undermine 'The Moral Sentiments': Evidence from Economic Experiments*, 320 SCIENCE 1605 (2008); Holstrom & Milgrom, *supra* note 10.

165. Holstrom & Milgrom, *supra* note 10.

166. *Id.*

167. *Id.*; *see also* MICHAEL DORFF, INDISPENSABLE AND OTHER MYTHS: WHY THE CEO PAY EXPERIMENT FAILED AND HOW TO FIX IT (2014) (discussing difficulties in motivating CEO-level employees with incentive pay).

168. *See, e.g.*, Falk & Kosfeld, *supra* note 134.

169. *See* Dominique Demougin & Claude Fluet, *Monitoring Versus Incentives*, 45 EUROPEAN ECON. REV. 1741 (2001).

170. This is one of the main arguments in Daniel Pink's book *Drive: The Surprising Truth About What Motivates Us* (2009).

in all three contexts, an agency problem motivates the use of performance incentives. A principal is concerned that a utility-maximizing agent will not act in the principal's best interests and that the agent has better information than the principal about the effort that the agent exerts. As such, the principal designs a compensation structure—implemented by contract—intended to provide the agent with incentives to act in the principal's best interests. In all three contexts, performance incentives are used in somewhat analogous ways to how they are used in health care. Additionally, all three contexts have seen some success with incentive compensation and have noted some areas for concern.

This Part argues that the experience with incentive pay in other industries is accurately predicted by the theoretical literature explained in Part II, where the most important takeaway was that the "complete" contracting mechanisms (task specification, monitoring, and financial incentives) are a better fit for easily measurable, compliance-oriented tasks than for tasks requiring the exercise of discretion and an agent's top performance.

A. Experience with Incentive Pay in Other Industries

1. Executive Compensation

The most studied use of incentive pay is in executive compensation. Before the advent of the modern corporation, businesses were owner run. The dairy farmer who sold his milk was also the one who cared for and milked the cows. The owner had all the incentive he needed to act in ways that would maximize the profitability of the enterprise. There was a direct link between owner performance and owner profit. But as businesses began to transition from owner run to manager run, agency problems and moral hazard arose.[171] To solve the agency problem, different techniques were developed to align managerial incentives with those of the businesses they were entrusted to run. The earliest ones were the imposition of fiduciary duties,[172] which were in many ways insufficient.[173] Next came a market-based solution: linking executive compensation to some measure of corporate profit or stock price.[174] Proponents

171. *See* ADOLPH BERLE, JR. & GARDINER MEANS, THE MODERN CORPORATION AND PRIVATE PROPERTY (1932).

172. Lawrence E. Mitchell, *The Death of Fiduciary Duty in Close Corporations*, 138 U. PA. L. REV. 1675, 1675 (1990) ("[T]he law of corporations historically has attempted to provide a principled and coherent set of regulations to ensure those who hold power are accountable to those who are dependent upon its fair exercise.").

173. David A. Hoffman, *Self-Handicapping and Managers' Duty of Care*, 42 WAKE FOREST L. REV. 803, 805 (2007) (noting corporate managers rarely face monetary damages for violations of fiduciary duties due to the business judgment rule, exculpation, and indemnification).

174. *See* Linda J. Barris, *The Overcompensation Problem: A Collective Approach to Controlling Executive Pay*, 68 IND. L.J. 59, 61 (1992); Sharon Hannes, *Compensating for Executive Compensation: The Case for Gatekeeper Incentive Pay*, 98 CAL. L. REV. 385, 437 (2010); Michael Jensen & Kevin J. Murphy, *CEO Incentives—It's Not How Much You Pay, But How*, HARV. BUS.

of incentive pay for executives argue that:

> a well-designed compensation scheme can make up for the fact that directors cannot monitor or evaluate many of their top executives' decisions. Such a well-designed scheme can substantially reduce agency costs, improve performance, and increase shareholder value.[175]

In the 1980s and 1990s—particularly after Michael Jensen and Kevin Murphy's influential article on the topic[176]—executive compensation packages that included some element of performance pay proliferated.[177] Performance pay runs the gamut from short-term, formula-driven incentives (for example a CEO might receive a bonus tied to incremental profitability of the company) to long-term incentives that may look at performance over a three to five year period. And according to at least one survey by Stanford School of Business, "CEOs and directors believe that 75 percent of a CEO's compensation" in large U.S. companies is tied in some way to performance.[178]

With notable exceptions, quantitative and qualitative empirical work suggests that performance pay for executives is an effective motivator.[179] Studies

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REV., May-June 1990, at 138 (calling for executive incentive-based compensation).

175. BEBCHUK & FRIED, *supra* note 28, at 19 (stating the theoretical argument, but then explaining why it does not work that way in practice).

176. Jensen & Murphy, *supra* note 174.

177. This was especially true for publicly traded companies without a controlling stockholder. But performance pay has also now been introduced at lower hierarchy levels. *See* Steven Kaplan & Josh Rauh, *Wall Street and Main Street: What Contributes to the Rise in the Highest Incomes?*, REV. FIN. STUD. (2007); Xavier Gabaix & Augustin Landier, *Why Has CEO Pay Increased So Much?*, 123 Q. J. ECON. 49 (2008).

178. *CEOs and Directors on Pay: 2016 Survey on CEO Compensation*, STAN. GRADUATE SCH. BUS. 2 (2016), https://www.gsb.stanford.edu/sites/gsb/files/publication-pdf/cgri-survey-2016-ceo-compensation_0.pdf [https://perma.cc/RJ2T-8Z4Z].

179. Jensen & Murphy, *supra* note 174; Edward B. Rock, *Adapting to the New Shareholder-Centric Reality*, 161 U. PA. L. REV. 1907, 1914 (2013) ("[F]ixed pay may lead managers to seek quiet lives, while performance pay can motivate managers."); Susan J. Stabile, *Motivating Executives: Does Performance-Based Compensation Positively Affect Managerial Performance?*, 2 U. PA. J. LAB. & EMP. L. 227, 229 (1999) ("Contingent compensation motivates executives and/or rewards them."); Randall S. Thomas, *Should Directors Reduce Executive Pay?*, 54 HASTINGS L.J. 437, 448 (2003) ("[I]ncentive pay can motivate workers to put forth their best efforts."); Michael C. Jensen & Kevin J. Murphy, *Remuneration: Where We've Been, How We Got to Here, What are the Problems, and How to Fix Them* (Euro. Corp. Governance Inst., Working Paper No. 44/2004, 2004), at 19 (July 12, 2004), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=561305 [https://perma.cc/5J93-3LD9] ("A well-designed remuneration package for executives . . . will accomplish three things: attract the right executives at the lowest cost; retain the right executives at the lowest cost . . . ; and motivate executives to take actions that create long-run shareholder value and avoid actions that destroy value."). *But see* Stout, *supra* note 19, at 536–37 (2014) ("[T]he ideology of incentives is being embraced . . . despite the fact that there is little or no empirical evidence to demonstrate it actually works"); James F. Reda, David M. Schmidt & Kimberly A. Glass, *Study of 2013 Short- and Long-Term Incentive Design Criterion Among Top 200 S&P 500 Companies*, ARTHUR J. GALLAGHER & CO. (2014), https://www.ajg.com/media/1420659/study-of-

have found that, particularly over short periods of time, incentive pay for executives can be correlated with an increase in corporate stock price.[180] Scholars theorize that incentive compensation works particularly well to motivate executives in an industry where profit motivation is typically strong.[181] Also, incentive-based compensation is easy to implement in executive pay because metrics such as profit and stock price are, relatively speaking, easy to measure and verify, at least compared with other options.[182]

But the downsides of incentive pay for executives are also now well documented.[183] Incentive pay causes executives to focus on the metrics to which compensation is tied, causing short-shrift to be given to other aspects of the business.[184] Indeed, executives have been shown to manipulate the performance criteria in their favor, or game the system to maximize rewards.[185] Incentive pay has also been shown to substitute motivation based on financial reward for the intrinsic motivation, or professional commitment to success, that had previously existed.[186]

2013-short-and-long-term-incentive-design-criterion-among-top-200.pdf [https://perma.cc/KZ7B-FULG] (finding that where companies used total shareholder return as the incentive metric, stocks underperformed compared to companies using other benchmarks such as earnings-per-share based on generally accepted accounting principles).

180. *See* Carola Frydman & Dirk Jenter, *CEO Compensation*, Rock Ctr. for Corp. Governance Stanford Univ., Working Paper No. 77, 20–22 (2010), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1582232 [https://perma.cc/NS9S-34P4] (discussing multiple studies demonstrating a link between incentive pay and firm performance). *But see Share and Share Unalike*, ECONOMIST (Aug. 7, 1999), http://www.economist.com/node/230106 [https://perma.cc/KZ5C-6MDY] ("[T]here is surprising little direct evidence that higher pay-performance sensitivities lead to higher stock performance." (quoting Kevin Murphy, EXECUTIVE COMPENSATION, *in* A HANDBOOK OF LABOUR ECONOMICS (Orley Ashenfelter & David Card eds., 1998))); Michael J. Cooper et al., *Performance for Pay? The Relationship Between CEO Incentive Compensation and Future Stock Price Performance* 26 (Working Paper, Nov. 2016), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1572085 [https://perma.cc/9G3F-PAMV] (finding a negative relation between CEO incentive compensation and firm stock price).

181. *See* Jensen & Meckling, *Theory of the Firm: Managerial Behavior, Agency Costs, and Ownership Structure*, 3 J. FIN. ECON. 305, 308–11 (Oct. 1976) (discussing confounding variables).

182. *Id.*

183. BEBCHUK & FRIED, *supra* note 28, at 19 (2004) (explaining that because executives tend to be risk-averse, performance based compensation is worth less to them).

184. Kristopher Yingling, Comment, *Pay Ratio Disclosure: Another Failed Attempt to Curtail Executive Compensation*, 18 U. PA. J. BUS. L. 203, 212–13 (2015) ("Incentive-based compensation . . . induced excessive short-term risks through its asymmetrical rewards. Because companies used certain metrics, like stock price, to determine CEO's performance, they greatly incentivized CEOs to expand those metrics to increase their own compensation.").

185. Bruno Frey & Margit Osterloh, *Yes, Managers Should Be Paid Like Bureaucrats*, 14 J. MGMT. INQUIRY 96, 97 (2005) (summarizing studies finding a connection between executive incentive-based pay and fraudulent activity).

186. Kohn, *supra* note 154, at 62 ("Few will be shocked by the news that extrinsic motivators are a poor substitute for genuine interest in one's job. What is far more surprising is that rewards, like punishment, may actually undermine the intrinsic motivation that results in optimal performance."); LUKAS HENGARTNER, EXPLAINING EXECUTIVE PAY: THE ROLES OF MANAGERIAL POWER AND COMPLEXITY 41 (2007).

Worse, incentive pay can induce excessive risk taking and even fraudulent behavior.[187] It is said to have contributed to some of the worst economic crises of the past thirty years, from the savings and loan crisis of the 1980s to the 2008 credit crisis spurred by subprime loans.[188] This is in part because of the risk-taking behavior executives engaged in to maximize personal compensation under incentive-pay schemes.[189]

2. Professional Sports

As in executive compensation, professional sports teams frequently employ methods of incentive-based compensation in contracts with their players to mitigate an agency problem.[190] Teams want to ensure that their players exert the highest possible effort levels. Players may not be motivated to exert *top* effort for any number of reasons. For instance, they may fear injury or less longevity in the sport if they do exert top effort, or perhaps they can earn their large salaries without the need to exert top effort.[191] Information asymmetry is also a problem in that players know the effort they are exerting, but management, to an extent, does not.[192]

The agency problem in this context is somewhat less severe, however, than in other contexts. For one, while a player best knows his own level of effort, effort level is to some extent publicly observable.[193] Intrinsic motivation to perform well in professional sports and social norms to perform well and win games may also be somewhat stronger in the sports context than in other contexts.[194] Still, sports teams use a number of different types of incentive pay to induce optimal level of effort, generally falling into two categories: team incentives and individual incentives.[195]

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187. *See* Stout, *supra* note 19, at 534 (noting that incentive pay has been statistically linked with "earning manipulations, accounting frauds, and excessive risk-taking.").

188. *See id.*

189. *See* William W. Bratton, *Enron and the Dark Side of Shareholder Value*, 76 TUL. L. REV. 1275, 1327–28 (2003); Charles M. Yablon, *Bonus Questions-Executive Compensation in the Era of Pay for Performance*, 75 NOTRE DAME L. REV. 271, 273 (1999).

190. Daniel Faber, *The Evolution of Techniques for Negotiation of Sports Employment Contracts in the Era of the Agent*, 10 U. MIAMI ENT. & SPORTS L. REV. 165, 189–190 (1993) (describing performance bonuses in famous athletes' contracts).

191. *See* Bernd Frick, *Performance, Salaries, and Contract Length: Empirical Evidence from German Soccer*, 6 INT'L J. SPORT FIN. 87 (2011) (describing the common view that players can vary performance before and after signing a new contract); *see also* Dean Tripp et al., *Fear of Reinjury, Negative Affect, and Catastrophizing Predicting Return to Sport in Recreational Athletes With Anterior Cruciate Ligament Injuries at 1 Year Postsurgery*, 52 REHABILITATION PSYCHOLOGY 74 (2007) (examining the effect the fear of re-injury has on an athlete's future performance).

192. Kevin J. Stiroh, *Playing for Keeps: Pay and Performance in the NBA*, 45 ECON. INQUIRY 145, 148 (2007).

193. Frick, *supra* note 191, at 90.

194. *Id.*

195. Mike Mondello & Joel Maxcy, *The Impact of Salary Dispersion and Performance Bonuses*

Team incentives provide bonuses for team-level achievements: winning games or winning intermediate or ultimate-level championships.[196] They might also reward achievements such as total points scored, team rankings in different statistical categories, or the like.[197]

Individual incentives are also prevalent. Professional sports contracts, however, limit the type of measures that can form part of players' payment structure. Depending on the sport, there may be more emphasis on process measures rather than outcome measures. For example, contracts in Major League Baseball generally emphasize process (e.g., number of innings pitched) as opposed to outcome (e.g., number of home runs hit).[198] But in football, statistical accomplishments (e.g., touchdown passes scored, yards rushed, etc.) can form the basis of the incentive pay.[199] Other measures include physical-conditioning metrics (e.g., amount of weight lifted), playing time, and rankings compared to other players.[200] The use of financial incentives in American professional sports leagues is extensive.[201] For instance, in the National Football League, sixty-five to seventy-five percent of players receive payments based on individual accomplishments.[202]

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in NFL Organizations, 47 MGMT. DECISION 110, 115 (2009).

196. *Id.*

197. *Id.*; *see also National Football League Collective Bargaining Agreement*, NAT'L FOOTBALL LEAGUE & NAT'L FOOTBALL LEAGUE PLAYERS ASS'N, Art. 7 § 6 (Aug. 4, 2011), https://nflpaweb.blob.core.windows.net/media/Default/PDFs/General/2011_Final_CBA_Searchable_Bookmarked.pdf [https://perma.cc/7K52-CZ52] [hereinafter *NFL Collective Bargaining*].

198. *See* Faber, *supra* note 190, at 189 ("The professional sports industry needed a flexible means of structuring contracts to pay athletes salaries that closely track performance. Sports law responded with incentive bonuses. . . . [P]itcher Bob Walk with the Pittsburg Pirates received] bonuses for innings pitched and pitching appearances.").

199. *Id.* at 189–90 ("Running back Mike Rozier's 1990 contract with the Atlanta Falcons was structured [to provide Rozier] $30,000 for rushing for 200 yards, $30,000 for rushing for 400 yards, and $40,000 for reaching 600 yards. Rozier gained 675 yards, thus earning $100,000 in bonuses.").

200. Mondello & Maxcy, *supra* note 195, at 115; *see also NFL Collective Bargaining*, *supra* note 197, at Art. 7 § 6 (noting allowable performance incentives).

201. *See* Martin J. Greenberg, *The Second Annual Sports Dollars & Sense Conference: A Symposium on Sports Industry Contracts and Negotiations: Drafting of Player Contracts and Clauses*, 4 MARQ. SPORTS L.J. 51, 57 (1993) (discussing incentive clauses in professional sports contracts); Jeffery A. Smith, *It's Your Move –No It's Not! The Application of Patent Law to Sports Moves*, 70 U. COLO. L. REV. 1051, 1085–86 (1999) (discussing incentive clauses in professional sports contracts such as being selected to the Pro Bowl and reaching predetermined levels of performance); Frederick Tung, *Bankruptcy Symposium: The Future Claims Representative in Mass Tort Bankruptcy: A Preliminary Inquiry*, 3 CHAP. L. REV. 43, 66 (2000) ("Player contracts in professional sports . . . routinely contain bonus contingencies for exceptional performance based on objective measures."); Melissa Steedle Bogad, Note, *Maybe Jerry Maguire Should Have Stuck With Law School: How the Sports Agent Responsibility And Trust Act Implements Lawyer-like Rules for Sports Agents*, 27 CARDOZO L. REV. 1889, 1903 (2006) (explaining Congressman Tom Osbourne urged Congress to adopt legislation regulating agents, in part, due to the huge financial incentives for athletes and agents in professional sports).

202. Mondello & Maxcy, *supra* note 195, at 115 ("In the NFL, incentive bonuses now account for about 25 per cent of player compensation.").

Financial incentives are thought to work well in the sports context for a number of reasons.[203] First, athletic performance (if not effort level per se) can be objectively measured.[204] In professional sports, performance criteria are set by the league and are measured in a transparent and objective manner.[205]

Second, although cooperation and team play are often necessary to success, many professional sports emphasize personal abilities.[206] In this sense, financial incentives are well-suited to encourage individual effort.

Third, financial incentives in sports can be tied to short-term performance.[207] As such, there is a closer temporal tie between effort and reward.

Some of the best evidence of the effects of incentive pay in sports come from the tournament context. There, results have shown a correlation between financial incentives and player performance.[208] Indeed, the magnitude and differential between awards has received a lot of attention. In NASCAR racing, it seems that increasing the prize differential going to top finishers has the potential to increase overall driver performance.[209]

But the literature also documents some important challenges in the use of performance pay in sports. For one, in team sports like football and basketball, the statistics on which performance pay are based are only partially indicative of the effort level of an individual player.[210] The appearance of individual performance also reflects the performance of teammates and of the opponent.[211]

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203. Frick, *supra* note 191, at 90 (explaining how the objective data of professional sports makes it easy to attach incentives to reach particular milestones).

204. Yehuda Baruch et al., *Performance-Related Pay in Chinese Professional Sports*, 15 INT. J. OF HUM. RESOURCE MGMT. 245 (2004).

205. *Id.*; *see* Frick, *supra* note 191, at 90.

206. Sherwin Rosen & Allen Sanderson, *Labour Markets in Professional Sports*, ECON. J., F47, F52 (2001) (discussing the financial incentives for individual athletes to seek a competitive advantage even in team sports).

207. *Id.*

208. Brian E. Becker & Mark A. Huselid, *The Incentive Effects of Tournament Compensation Systems*, 37 ADMIN. SCI. Q. 336, 342 (1992).

209. *Id.*

210. STANLEY COHEN, THE MAN IN THE CROWD: A FAN'S NOTES ON FOUR GENERATIONS OF NEW YORK BASEBALL 208 (2012) ("Individual records in other [sports besides baseball] require a measure of cooperation. Passing efficiency depends largely on the quality of the team's receivers, the protection afforded the quarterback, even the running game. . . . But when a batter steps into the batter's box he is all alone."); Roderick I. Swaab et al., *The Too-Much-Talent Effect: Team Interdependence Determines When More Talent is Too Much or Not Enough*, 25 PSYCHOL. SCI. 1581, 1582 (June 2014) (explaining basketball and football require a higher degree of task interdependence, meaning "team members [must] cooperate and work interactively to complete tasks," than baseball, which as a sport, has relatively low levels of interdependence, meaning "each individual's talent contributes additively to the team's outcome, and thus less coordination among team members is required").

211. Mondello & Maxcy, *supra* note 195, at 115 (explaining performance bonuses are divided into team incentives, including winning games, total points scored, yards accumulated, and sacks registered, and individual incentives, including statistical accomplishments such as touchdowns scored, physical conditioning benchmarks, and rankings compared to other position players).

For instance, the number of yards a quarterback passes is dependent in large part on the quality of the receivers he passes to and the quality of the defenders.[212] Thus, while metrics are objective and observable, they are not perfect.

Second, the use of financial incentives can promote risk-taking behavior and even cheating. The illegal use of steroids was a major problem in the 1990s and 2000s in Major League Baseball.[213] While it is hard to quantify the extent to which financial incentives encouraged steroid use rather than norms such as professional acclaim and fame, theorists have examined how financial incentives can bring out such behavior.[214] Incentive effects have been shown to promote risky behavior in other contexts, as well. For instance, larger prizes and a larger prize differential between top finishers and lower finishers have been shown to encourage more risk-taking in professional car racing.[215]

In short, pay does motivate performance, and it is thought to work well because of ease of measurement. But the effect is complicated by other reasons to perform well, both intrinsic (i.e., drive to succeed, reputation) and extrinsic (i.e., potential for endorsements).

3. Education

Just as shareholders and professional sports teams experience difficulties in motivating their management and players respectively, schools face similar challenges in motivating teacher performance. In education, the use of performance pay is both prevalent and controversial.[216] The most common example is the award of bonuses to teachers based on their students' performance on standardized tests.[217] President George W. Bush's *No Child Left Behind* and

212. STANLEY COHEN, THE MAN IN THE CROWD: A FAN'S NOTES ON FOUR GENERATIONS OF NEW YORK BASEBALL 208 (2012) ("Passing efficiency depends largely on the quality of the team's receivers, the protection afforded the quarterback, even the running game.").

213. *See The Steroids Era*, ESPN (Dec. 5, 2012), http://espn.go.com/mlb/topics/_/page/the-steroids-era [https://perma.cc/P8EX-J4Y3].

214. *See, e.g.*, Tiffany D. Lipscomb, Note, *Can Congress Squeeze the "Juice" Out of Professional Sports? The Constitutionality of Congressional Intervention into Professional Sports' Steroid Controversy*, 69 OHIO ST. L.J. 303, 317 (2008) ("'Juiced' players typically perform better, generating more revenue for owners, which in turn generates higher salaries for players."); Lisa Pike Masteralexis, *Drug Testing Provisions: An Examination of Disparities in Rules and Collective Bargaining Agreement Provisions*, 40 NEW ENG. L. REV. 775, 777 (2006) ("[P]layers are playing in an ultra-competitive environment where many, many players are striving for a limited number . . . [of positions]. Anything that will take a player over that hurdle . . . will be enticing, especially when one sees other players reaping substantial financial benefits, being rewarded by media, fans, and management."); Edward Rippey, *Contractual Freedom over Substance-Related Issues in Major League Baseball*, 1 SPORTS LAW. J. 143, 159 (1994).

215. Becker & Huselid, *supra* note 208, at 344.

216. Donald Gratz, *Special Topic: The Problem with Performance Pay*, 67 EDUC. LEADERSHIP 76, 76 (2009) ("Education performance pay stretches back hundreds of years. In the mid-1800s, British schools and teachers were paid on the basis of the results of student examinations, for reasons much like today's.").

217. Sanctions are also employed, but usually sanctions function to penalize low-performing

President Barack Obama's *Race to the Top*, both placed high stakes on standardized test scores.[218] Both linked student test scores to teacher evaluations and pay.[219]

The theory in the education context is that offering bonuses based on student achievement will incentivize teachers to ensure that their students perform better.[220] This example is somewhat different from the prior two because the incentive is not tied to individual performance directly, but to the performance of third parties that the teacher is expected to influence. In this way, education might be the closest analogy to health care, where patients are the relevant third party. Some studies have shown that there is a positive correlation between providing teachers with performance-based incentives and higher student achievement (expressed through higher test scores).[221] Teachers exert higher effort levels when incentivized by pay tied to student test scores.[222] And this effect seems to apply whether bonuses are awarded for positive performance or sanctions are threatened for negative performance.[223]

But other studies find the opposite. One large scale study that offered incentives tied to students' test scores, graduation, and attendance rates that provided up to $3,000 per teacher at high-needs New York City schools, found that "incentives . . . did not increase student achievement in any meaningful way. If anything, student achievement declined."[224] In addition, a study in Tennessee that found that students of teachers offered up to $15,000 in bonuses tied to

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schools with removal of funds, not individual teachers. *See generally* Hanley Chiang, *How Accountability Pressure on Failing Schools Affects Student Achievement*, 93 J. PUB. ECON. 1045 (2009) (discussing the long term impact of penalties for poor performance on student test scores).

218. No Child Left Behind Act (NCLBA) of 2001 § 1001, 20 U.S.C. § 6301 (2012); Joseph P. Viteritti, *The Federal Role in School Reform: Obama's "Race to the Top"*, 87 NOTRE DAME L. REV. 2087, 2121 (2012) (outlining Race to the Top).

219. *See* Viteritti, *supra* note 218 at 2108, 2110–11 (discussing teacher pay and evaluations based on student success); *see also* Valerie Strauss, *How and Why Convicted Atlanta Teachers Cheated on Standardized Tests*, WASH. POST (Apr. 1, 2015), https://www.washingtonpost.com/news/answer-sheet/wp/2015/04/01/how-and-why-convicted-atlanta-teachers-cheated-on-standardized-tests [https://perma.cc/FYS7-FD9B].

220. *See, e.g.*, David N. Figlio & Lawrence W. Kenny, *Individual Teacher Incentives and Student Performance*, 91 J. PUB. ECON. 901 (2007).

221. *See, e.g.*, David N. Figlio & Lawrence W. Kenny, *supra* note 221, at 903 ("We find a positive association between the use of individual teacher incentives and student achievement."); Victor Lavy, *Performance Pay and Teacher's Effort, Productivity, and Grading Efforts*, 99 AM. ECON. REV. 1979 (2009). http://www.aeaweb.org/articles.php?doi=10.1257/aer.99.5.1979 [https://perma.cc/752Q-FS2R].

222. *See, e.g.*, David N. Figlio & Lawrence W. Kenny, *supra* note 221 (concluding that one explanation for findings was that providing teachers with monetary incentives based on student test scores increases teacher effort).

223. *See, e.g.*, Chiang, *supra* note 217, at 1056 (noting that schools threatened with sanctions led to an increase in math scores). Teachers seem most able to affect test scores when they concentrate on basic skills that are relatively easy to teach, but more studies on this issue are necessary. *Id.*

224. Fryer, *supra* note 220, at 377.

student improvement did not perform significantly better than their peers taught by teachers with standard compensation.[225]

Although evidence is not conclusive, for those who report efficacy of performance pay, it is thought to work well because standardized tests provide an objective measure of student performance.[226] But as in the other contexts, the measure is imperfect. Teachers may help students to improve test scores by improving familiarity with the format of the test. And students may acquire short-term knowledge sufficient to improve test scores that does not equate with retained knowledge and long-term learning. If the goal of education is the latter, improving the former is of limited value.[227] Studies have shown that "teaching to the test," rather than teaching to educate, is a pervasive problem.[228]

There are some additional well-documented challenges to utilizing performance pay to motivate teachers and some confounding variables to consider. First, when pay is linked to student test scores, teachers narrow their curriculum to focus on tested material at the sacrifice of other worthy areas.[229] In general, teachers invest more effort in tasks that receive the most weight in the performance measurement system.[230]

Second, teachers have been documented to be less willing to work with high needs students when subject to performance pay.[231] Teachers tend to focus on

225. Matthew G. Springer et al., *Teacher Pay for Performance: Experimental Evidence from the Project on Incentives in Teaching*, NAT'L CTR. ON PERFORMANCE INCENTIVES (2010), https://my.vanderbilt.edu/performanceincentives/files/2012/09/Full-Report-Teacher-Pay-for-Performance-Experimental-Evidence-from-the-Project-on-Incentives-in-Teaching-20104.pdf [https://perma.cc/GZW8-GY5D].

226. Steven Friedland, *A Critical Inquiry into the Traditional Uses of Law School Evaluation*, 23 PACE L. REV. 147, 156 (2002) ("[S]tandardized tests . . . provide an objective, reliable measure of the relevant skills being tested."); *2013 State Teacher Policy Yearbook: National Summary*, NAT'L COUNCIL ON TEACHER QUALITY 10 (Jan. 2014), http://www.nctq.org/dmsView/2013_State_Teacher_Policy_Yearbook_National_Summary_NCTQ_Report.pdf [https://perma.cc/GK3T-BWVZ] (noting many states have tied student performance to teacher evaluation).

227. *See* Eva L. Baker et al., *Problems with the Use of Student Test Scores to Evaluate Teachers*, ECON. POL'Y INST. 7 (Aug. 28, 2010), http://www.epi.org/files/page/-/pdf/bp278.pdf [https://perma.cc/3PA8-HZ23] ("[Standardized tests] are narrow measures of what students know and can do, relying largely on multiple-choice items that do not evaluate students' communication skills, depth of knowledge and understanding, or critical thinking and performance abilities.").

228. *See id.* at 16–17; Brian A. Jacob & Steven D. Levitt, *Catching Cheating Teachers: The Results of an Unusual Experiment in Implementing Theory*, 2003 BROOKINGS-WHARTON PAPERS URB. AFF. 185 (describing the pervasive issue of "teaching to the test"); Craig D. Jerald, *'Teach to the Test'? Just Say No*, CTR. FOR COMPREHENSIVE SCH. REFORM & IMPROVEMENT 1–2 (2006), http://files.eric.ed.gov/fulltext/ED494086.pdf [https://perma.cc/D89Q-EQN6] (describing the pervasiveness of "teaching to the test" and summarizing studies demonstrating poor generalization when the curriculum focuses on preparation for standardized tests).

229. Jacob & Levitt, *supra* note 228, at 16 ("[A]n emphasis on test results for individual teachers exacerbates the well-documented incentives for teachers to focus on narrow test-taking skills, repetitive drill, and other undesirable instructional practices.").

230. *Id.*

231. Charles Clotfelter et al., *Do School Accountability Systems Make It More Difficult for Low-*

students whose test scores can be improved with the least effort.

Third, when performance pay is utilized, studies have shown that teachers are less likely to collaborate.[232] Also, "some argue that teacher incentives can decrease a teacher's intrinsic motivation or lead to harmful competition between teachers in what some believe to be a collaborative environment."[233]

Finally, just as incentive pay in executive compensation encouraged creative accounting to maximize individual compensation, and in sports may have encouraged players to illegally use steroids, financial incentives in education seem to also encourage cheating on the metrics. A recent, well-publicized example in Atlanta illustrates the point. In 2009, after the media started to question how Atlanta public school students had substantially improved test scores, the state investigated.[234] It uncovered a wide range of cheating behavior by both teachers and administrators, who changed student answers and misreported test scores.[235] There are other documented examples of teachers and administrators doctoring test scores to obtain personal bonuses,[236] but it is unknown to what extent such practices are employed nationwide.[237]

4. Experience in Other Industries Confirms Many Predictions of the Contracts Literature

The experience in these three industries is illuminating for a number of reasons. First, it seems to bear out many of the predictions of the literature. While financial incentives do seem to motivate, at least according to some studies, they tend to do so best where easy-to-measure goals are closely associated with the

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Performing Schools to Attract and Retain High-Quality Teachers?, 23 J. POL'Y ANALYSIS & MGMT. 251 (2004) (describing a study on the effects of North Carolina's accountability system on low-performing schools that found that low-performing schools perform even worse because quality teachers are more reluctant to teach there); Jacob & Levitt, *supra* note 228, at 16 ("Within a school, teachers will have incentives to avoid working with such students likely to pull down their teacher effectiveness scores.").

232. *See* Baker et al., *supra* note 227, at 8.

233. Fryer, *supra* note 220, at 374 (citation omitted).

234. Strauss, *supra* note 219.

235. Nearly 180 employees were accused of wrongdoing in an effort to collect bonuses, or in some cases, to keep threatened jobs. In April 2015, eleven teachers and administrators were convicted of racketeering charges stemming from the scandal and sentenced to up to 20 years in prison. Alan Blinder, *Atlanta Educators Convicted in School Cheating Scandal*, N.Y. TIMES (Apr. 1, 2015), http://www.nytimes.com/2015/04/02/us/verdict-reached-in-atlanta-school-testing-trial.html [https://perma.cc/H5Z4-Y7GG].

236. *See, e.g.*, Winnie Hu & Noah Remnick, *City Invalidates Test Scores of Third Graders at Harlem School*, N.Y. TIMES (July 26, 2015), http://www.nytimes.com/2015/07/27/nyregion/city-invalidates-test-scores-of-third-graders-at-harlem-school.html [https://perma.cc/A6N9-DNHF] (explaining that the results of third-grader standardized tests were invalidated after allegations of testing improprieties by school's principal).

237. Also worth considering is the complaint that these bonuses give administrators too much discretionary authority, are not transparent enough, and are based on very crude measures.

performance the principal wishes to prompt from the agent.[238] But there is an overarching difficulty in disentangling the effect of the financial motivation from other sources of motivation—both intrinsic and extrinsic.[239] This is especially tricky in the context of professional motivation, which is also an issue in the health-care context. And there are other overarching concerns. Financial incentives seem to cause focus on the metric to which compensation is tied, and in particular, promote paying attention to metrics that are easier to move, while ignoring the harder cases.[240] Performance pay can also encourage risk-taking behavior and even cheating.

Second, it confirms that performance pay works better in some contexts than others. Key attributes of successful performance pay systems appear to be: (1) easy to define and measure tasks; (2) low ability or need to cheat on the metrics; and (3) a low likelihood of crowding out already strong intrinsic motivation, either because intrinsic motivation is weak to begin with or intrinsic motivation is not particularly necessary to successful execution of the task.

B. Early Results of Incentive Pay in Health Care

Although the use of performance pay in executive compensation, sports, and education has a longer history, a preliminary set of data is developing in the health industry.[241] Many of these early stage studies have significant limitations.[242] And it is worth noting that physician incentive pay is not yet particularly widely implemented. But as with other industries, the early results in health care are mixed or inconclusive.[243] The meta-studies and systematic

238. *See supra* Part II.C.

239. *See supra* Part II.B.3.

240. *See id.*

241. *See* Stephen Campbell et al., *Quality of Primary Care in England with the Introduction of Pay for Performance*, 357 NEW ENG. J. MED. 181 (2007); Frank Eijkenaar et al., *Effects of Pay for Performance in Health Care: A Systematic Review of Systematic Reviews*, 110 HEALTH POL'Y 115 (2013); Ellen T. Kurtzman et al., *Performance-Based Payment Incentives Increase Burden And Blame For Hospital Nurses*, 30 HEALTH AFF. 211 (2011).

242. For instance, many of the studies lack the necessary rigor because they are not randomized or controlled or have very small sample sizes. Also, many are based simply on physician and beneficiary surveys but do not use any other quality metrics. Many studies focus either on the cost question or the quality question, but not both. And there are few long-term studies, in part because pay-for-performance in health care is relatively new and also frequently changing in format. Finally, the providers that become subject to incentive pay may reflect selection bias. This is particularly true in the experiments that study the Pioneer ACOs, where government criteria to participate in the program was rigorous. *See CMS Medicare Shared Savings Fact Sheet*, *supra* note 87 (describing the Pioneer ACO Model).

243. *Compare* David J. Nyweide et al., *Association of Pioneer Accountable Care Organizations vs Traditional Medicare Fee for Service With Spending, Utilization, and Patient Experience*, 313 JAMA 2152 (2015) (finding that pay for performance decreased costs and maintained quality for most ACOs), *and* Sule Calikoglu et al., *Hospital Pay-For-Performance Programs In Maryland Produced Strong Results, Including Reduced Hospital-Acquired Conditions*, 31 HEALTH AFF. 2649 (2012) (finding that Maryland's Quality Reimbursement Program reduced the prevalence of

analyses summarize that:

- Studies are mixed and inconclusive on whether the use of pay for performance (P4P) improves the quality of care in primary care.[244]
- The effects of P4P on quality of care and outcomes remains uncertain as uncontrolled studies suggest P4P improves quality of care, while higher-quality studies suggest otherwise.[245]
- There is a growing trend of rewarding PCPs with financial incentives for reaching quality benchmarks; however, there is insufficient data to determine whether the incentives actually improve quality.[246]

The next subparts consider the evidence to date in more detail.

1. Financial Incentive Effects on Quality Metrics

The majority of empirical work studying provider incentive-based compensation has focused on the question of quality improvement. One meta-study reports that out of nine studies on the use of financial incentives to provider groups, only two found statistically significant improvement in quality metrics.[247] In five of the studies, there was a small improvement in the measure of quality that was not statistically significant.[248] In two studies, there was no effect compared with the control group.[249] In general, the analyses suggest that those with the lowest baseline measures of quality were the easiest to move with

hospital-acquired conditions), *with* Ruth McDonald & Martin Roland, *Pay for Performance in Primary Care in England and California: Comparison of Unintended Consequences*, 7 ANNALS FAM. MED. 121 (2009) (analyzing the unintended consequences of paying physicians according to performance, such as destruction of the patient-physician relationship and physician autonomy).

244. Eijkenaar et al., *supra* note 241, at 119 ("[A]ll authors . . . essentially reached the same conclusion: results are mixed and inconclusive and there is insufficient evidence to support the use of P4P to improve the quality of preventative and chronic care in primary care.").

245. Sherilyn Houle et al., *Does Performance-Based Remuneration for Individual Health Care Practitioners Affect Patient Care? A Systematic Review*, 157 ANNALS INTERNAL MED. 889, 889 (2012) ("Uncontrolled studies (15 before-after studies, 2 cohort comparisons) suggested that P4P improves quality of care, but higher-quality studies with contemporaneous controls failed to confirm these findings. . . . The effect of P4P targeting individual practitioners on quality of care and outcomes remains largely uncertain.").

246. Anthony Scott et al., *The Effect of Financial Incentives on the Quality of Health Care Provided by Primary Care Physicians*, COCHRANE DATABASE OF SYSTEMATIC REVS., at 2 (2011) ("The use of financial incentives to reward PCPs for improving the quality of primary healthcare services is growing. However, there is insufficient evidence to support or not support the use of financial incentives to improve the quality of primary health care. Implementation should proceed with caution . . . .").

247. Laura A. Peterson et al., *Does Pay-for-Performance Improve the Quality of Health Care?*, 145 ANNALS INTERNAL MED. 265, 267 (2006).

248. Peterson et al., *supra* note 247, at 267.

249. Peterson et al., *supra* note 247, at 268.

financial incentives.[250] And process-of-care measures were more sensitive to incentive effects than outcome measures.[251]

Other systematic analyses tend to find that some quality metrics are correlated with the financial incentive, while others do not.[252] For instance, one study found a positive correlation between the incentive and quality of care for diabetes and asthma, but not for heart disease.[253] Another study also found significant variation in metrics, finding better results for immunizations than cancer screenings.[254]

But in general, studies have found that process measures are easier to move than patient outcomes.[255] This has generally been seen as problematic in the industry because its ultimate goal is to improve outcomes rather than just processes.

A study done at Fairview Health Services is also instructive. Fairview is a Pioneer ACO that operates forty-four primary-care clinics in Minnesota.[256] In April 2011, Fairview implemented a compensation model that tied primary care physician compensation to clinic-level performance on quality metrics.[257]

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250. *Id.* at 268–69.

251. *Id.* at 269.

252. *See, e.g.*, R. Adams Dudley et al., *Strategies to Support Quality-Based Purchasing: A Review of the Evidence*, 10 TECHNICAL REVIEW, at *i*, *v* (July, 2004) (finding a correlation with incentive for only seven out of eleven metrics); Robert Town et al., *Economic Incentives and Physicians' Delivery of Preventive Care – A Systematic Review*, 28 AM. J. PREVENTIVE MED. 234, 234 (2005) (finding only one out of eight outcomes significantly improved with financial incentive).

253. *See* Jon B. Christianson et al., *Lessons from Evaluations of Purchaser Pay-for-Performance Programs: A Review of the Evidence*, 65 MED. CARE RES. & REV., 5S, 19S (2008).

254. Susan A. Sabatino et al., *Interventions to Increase Recommendation and Delivery of Screening for Breast, Cervical, and Colorectal Cancers by Healthcare Providers Systematic Reviews of Provider Assessment and Feedback and Provider Incentives*, 35 AM. J. PREVENTIVE MED. S67 (2008); *see also* Sandra Tanenbaum, *Pay for Performance in Medicare: Evidentiary Irony and the Politics of Value*, 34 J. HEALTH POL. POL'Y & L. 717, 723–24 (2009) (discussing a study that found a significant improvement on diabetes measurements as a result of pay-for-performance).

255. *See* Gerd Flodgren et al., *An Overview of Reviews Evaluating the Effectiveness of Financial Incentives in Changing Healthcare Professional Behaviours and Patient Outcomes*, COCHRANE DATABASE OF SYSTEMATIC REVS. (2011). But some noted that positive findings particularly for process measures may be based on increased documentation rather than changed practices. *See, e.g.*, Campbell et al., *supra* note 241, at 187–88 (discussing the common criticism "of pay-for-performance programs that their main effect is to promote better recording of care rather than better care").

256. Pioneer ACOs were those selected by CMS after a rigorous proposal process because they are experienced entities ready to share losses in exchange for the opportunity to recoup a higher percentage of savings achieved. *See CMS Medicare Shared Savings Fact Sheet*, *supra* note 87 (describing the Pioneer ACO Model).

257. Prior to 2011, Fairview utilized a traditional fee-for-service model with the possibility of a small annual quality bonus. *See* Jessica Greene et al., *Large Performance Incentives Had The Greatest Impact On Providers Whose Quality Metrics Were Lowest At Baseline*, 34 HEALTH AFF. 673, 673 (2015).

Specifically, forty percent of physician compensation was based on performance on five quality metrics: diabetes care (12%), vascular care (12%), cancer screening (6%), depression care (6%), and asthma care (4%).[258] For example, if a clinic performed at the state median for diabetes care, then twelve percent of the physician's salary would be at median market salary. But if the clinic performed above that median, physicians would receive above market salary for that twelve percent of their compensation (based on a sliding scale). And if the clinic performed below the state median for that metric, the physician would receive below market salary for that twelve percent. If performance on a metric was particularly poor (below twenty percent of the state median), a physician could receive no compensation at all for that portion of their salary.

Fairview's data was studied to determine whether the incentive model correlated with greater improvement on quality metrics than for comparable groups of physicians not using incentive-based compensation.[259] The study "found that Fairview's improvement . . . was not greater than the improvement in other comparable Minnesota medical groups."[260] But providers who were the poorest performers at the start of the study improved the most relative to other groups.[261] And performance pay seemed to narrow the variation in quality among the participating clinics. Overall, though, the study concluded that "[t]he large quality incentive fell short of its overall quality-improvement aim."[262] Many other studies similarly have found no difference in quality-improvement rates between the participating group and the control group.[263]

On the other hand, some studies have found success in using financial incentives to improve quality metrics, particularly in the Medicare context.[264] The Medicare Physician Group Practice Demonstration is one example. Researchers there found an improvement in quality associated with paying financial

258. Compensation under a pay-for-performance system "can range from small bonuses for performance on a few quality indicators to as much as one-quarter of a provider's income for performance on over 100 metrics." *Id.* Fairview is an interesting example because forty-percent incentive pay is quite high relative to most other pay-for-performance schemes. *Id* at 674.

259. The study methodology compared improvement on performance metrics (determined by comparing data from pre-incentive compensation to data post-incentive compensation) by Fairview clinics to the same data for comparable medical groups not on an incentive-based pay plan. *Id.* at 673.

260. *Id.*

261. *Id.*

262. *Id.*

263. Andrew Ryan & Jan Blustein, *The Effect of the MassHealth Hospital Pay-for-Performance Program on Quality*, 46 HEALTH SERVS. RES. 712 (2011) (finding the Massachusetts Medicaid hospital pay-for-performance program did not improve quality of care); Rachel Werner et al., *The Effect of Pay-for-Performance in Hospitals: Lessons for Quality Improvement*, 30 HEALTH AFF. 690, 694–95 (2011) (finding no difference in mortality rates between hospitals using the Medicare Premier Hospital Quality Incentive program and nonparticipating hospitals).

264. *See* Karan Ho et al., *Can Incentives to Improve Quality Reduce Disparities?*, 45 HEALTH SERVS. RES. 1 (2010); James, *supra* note 56; Werner et al., *supra* note 263.

bonuses.[265] Although the data is not focused solely on physician-level incentives, some of the more recent data from the early years of the Pioneer ACOs is optimistic, at least in the aggregate. Pioneer ACO data from CMS suggests modest improvements in quality over the three years in the program. Between year two and year three, ACOs improved by 3.6 percent on average across the thirty-three quality measures on which ACOs must report.[266] Also, in five out of seven measures, patient experience scores improved.[267]

In short, though, more data, and more study is needed in this area to report any conclusive results. Particularly as to physician pay, many programs are still in their infancy. As these programs scale up, more data will be available to analyze.

2. Link to Cost Reduction

A number of studies also assess the extent to which pay for performance can be linked to cost savings. The most salient inquiry is whether cost savings can be achieved while quality metrics are simultaneously maintained or improved. The purpose of incentive-pay models is not to achieve cost savings at the sacrifice of quality. Arguably that was the problem with HMOs.

Again, results are mixed. Some are positive. For instance, one study found evidence of cost-effectiveness for twelve measures included in the quality and outcomes framework.[268] Another study of the Yale New Haven Health System found the implementation of quality indicators reduced hospital costs per patient.[269] Others actually found that where quality improves as intended, cost increases rather than decreases.[270]

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265. Carrie Colla et al., *Spending Differences Associated With the Medicare Physician Group Practice Demonstration*, 308 JAMA 1015 (2012). Although note that for Medicare's Premier Hospital Quality Incentive Demonstration, it seemed for the first two years that process of care quality indicators improved more rapidly for the incentive hospitals than control hospitals, but differences between the two groups were not detectable by five years out, and patient outcomes did not improve. Werner et al., *supra* note 263.

266. *See Pioneer ACO Model: Performance Year 3*, CTRS. MEDICARE & MEDICAID SERVS., https://innovation.cms.gov/Files/x/pioneeraco-fncl-py3.pdf [https://perma.cc/HPW3-FR8W]; *Pioneer ACO Model: Performance Year 3*, CTRS. MEDICARE & MEDICAID SERVS., https://innovation.cms.gov/Files/x/pioneeraco-fncl-py2.pdf [https://perma.cc/BW2T-ZXNF].

267. Sources cited *supra* note 266.

268. Anne Mason et al., *The GMS Quality and Outcomes Framework: Are the QOF Indicators a Cost-Effective Use of NHS Resources?*, *in* QUALITY AND OUTCOMES FRAMEWORK: JOINT EXECUTIVE SUMMARY REPORTS TO THE DEPARTMENT OF HEALTH (2008).

269. Agency for Healthcare Research and Quality, *AHRQ Quality Indicators Case Study: Yale New Haven Health System*, U.S. DEP'T OF HEALTH & HUMAN SERVS. AGENCY FOR HEALTHCARE RESEARCH AND QUALITY 3 (Nov. 2015), http://www.qualityindicators.ahrq.gov/Downloads/Resources/Case_Studies/AHRQ_QI_YNHHS_Case_Study.pdf [https://perma.cc/4W6T-279T].

270. Martin Emmert et al., *Economic Evaluation of Pay-for-Performance in Health Care: A Systematic Review*, 13 EUR. J. HEALTH ECON. 755, 762 (2012) ("A majority of studies showed that improved quality of care can be achieved with higher costs.").

The meta and systemic analyses summarize that incentive-based compensation "can potentially be (cost-)effective, but the evidence is not convincing; many studies failed to find an effect and there are still few studies that convincingly disentangled the [incentive] effect from the effect of other improvement initiatives."[271]

Again, the Medicare data is perhaps the most promising. In the Medicare Physician Group Practice Demonstration, with the improvement in quality described in the prior subpart, researchers also found a modest reduction in the growth of spending for most Medicare beneficiaries.[272]

3. Unintended Consequences

Several studies have also investigated whether incentive pay yields unintended consequences. In other words, some providers might succeed in improving quality and decreasing cost, but might do so in ways that have undesirable effects in other areas.

First, policymakers have been concerned that physician financial incentives will result in adverse selection, where physicians cherry pick the easier cases while harder cases receive less attention. Some researchers have noted this possibility, but empirical evidence remains sparse.[273] One study of performance incentives for providers of substance abuse treatment found that the numbers of severely ill patients in the control group increased while those in the treatment group (for which financial incentives were awarded) decreased.[274]

Second, some studies have assessed whether incentive pay tied to certain procedures or categories of care has negative spillover effects on unincentivized procedures. But results are conflicting or inconclusive. One study compared trends between incentivized and unincentivized metrics and found no difference between the two.[275] Other studies found that quality deteriorated somewhat for non-incentivized measures.[276] Interestingly, one study found that "unincentivized measures improved when they were part of a condition for which there were

271. Eijkenaar et al., *supra* note 241, at 115.

272. Colla et al., *supra* note 265.

273. Eijkenaar et al., *supra* note 241, at 124.

274. *Id.*

275. *See, e.g.*, Andrew Ryan, *Effects of the Premier Hospital Quality Incentive Demonstration on Medicare Patient Mortality and Cost*, 44 HEALTH SERVS. RES. 821, 837–38 (2009) ("[M]ortality rates for PHQID participants follow similar trends to noneligible hospitals immediately before and after the PHQID began for the nonincentivized conditions (stroke and gastrointestinal hemorrhage.").

276. Tim Doran et al., *Effect of Financial Incentives on Incentivized and Non-Incentivized Clinical Activities: Longitudinal Analysis of Data from the UK Quality and Outcomes Framework*, 342 BMJ d3590 (2011), http://www.bmj.com/content/bmj/342/bmj.d3590.full.pdf [https://perma.cc/4UL2-KRS6] (finding small detrimental effects for that performance on non-incentivized aspects of care).

incentives for other measures."[277] Spillover effects may exist. If they do, it is unclear if they tend to be positive or negative in nature.

Third, there has been concern over gaming the system or cheating on the metrics. There is some evidence to suggest that manipulating data to increase compensation is occurring, but nothing conclusive has been shown.[278]

The fourth unintended consequence concerns whether the use of financial incentives affects the intrinsic motivation of providers or provider professionalism. Here, there is some evidence that the use of incentive-pay results in a loss of professional autonomy, which has negative effects on motivation and professionalism.[279] On the flip side, there is evidence that incentives work less well to motivate changes in behavior when they run up against entrenched professional norms.[280]

Relatedly, some studies have noted that the use of incentive pay has adversely affected the physician-patient relationship.[281] For instance, physicians have reported resentment toward non-compliant patients who negatively impact their compensation.[282] In one study, physicians also reported pressure to convince patients to agree to certain treatments or to bypass the informed-consent process.[283]

In general, it is hard to draw concrete lessons from this very preliminary and mixed data. But it at least suggests that the predictions of the incomplete contracts literature may bear out in the health industry, as they seem to do in the executive compensation, education, and professional sports examples, and that there may be additional challenges unique to the health-care context. As such, the incomplete-contracts literature is a valuable tool for helping the industry to capitalize on the positive effects of this contracting strategy, while minimizing the negative effects. Doing so requires a much closer focus on the contexts in

277. Eijkenaar et al., *supra* note 241, at 124.

278. *See* Edward Norton, *Incentive Regulation of Nursing Homes*, 11 J. HEALTH ECON. 105, 123–127 (1992) (explaining how nursing homes under an incentive programs could "game to receive bonus payments"); *see also* Peterson et al., *supra* note 247, at 267 (finding that U.S. nursing homes were admitting "extremely disabled" patients who later recovered over a short period of time); Pieter van Herck et al., *Systematic review: Effects, Design Choices, and Context of Pay-for-Performance in Health Care*, 10 BMC HEALTH SERVS. RES. 247 (2010) (noting limited evidence of gaming).

279. McDonald & Roland, *supra* note 243, at 124 (2009).

280. Jillian Chown, Situated Professionalism: When Do Financial Incentives Influence Professional Behavior? (Oct. 23, 2015) (unpublished manuscript), http://faculty.chicagobooth.edu/workshops/orgs-markets/past/pdf/Chown.pdf [https://perma.cc/E5EL-DPFK].

281. *See, e.g.*, Christina et al., *supra* note 253; Ruth George et al., *Value-Based Purchasing and the Doctor-Patient Relationship*, 28 J. MED. PRAC. MGMT. 341 (2013).

282. McDonald & Roland, *supra* note 243.

283. *Id.* Note that it is this concern—about the effect of incentive pay on the doctor-patient relationship—that has caused Tom Price, U.S. Secretary of Health and Human Services, who is also a physician, to come out publicly against the use of incentive pay in health care. Japsen, *supra* note 7.

which incentive pay is likely to succeed compared to those in which it is unlikely to do so. The next Part takes up that question and starts the conversation on how the health industry might implement incentive pay in a much narrower set of circumstances—ones where it is more likely to have the desired effects.

IV. A NEW FOCUS: TARGETING INCENTIVE PAY TO COMPLIANCE-ORIENTED TASKS IN HEALTH CARE

While the industry is firmly behind incentive-based pay for doctors, it is not novel to suggest that incentive pay is potentially problematic. Those who raise concerns about it, however, tend to fall into one of two camps: they either think (1) we have not yet gotten incentive pay right;[284] or (2) incentive pay is fundamentally flawed and cannot be fixed.[285] This Article stakes out a new middle position. Because the contracts literature suggests that context is so important, the primary focus for the health-care industry should be on determining where to implement incentive pay and where not to.

At present, little is being done to focus implementation. Whereas incentive pay began in the context of HMOs using process measures for primary-care physicians, it is now being used across delivery models for all types of physicians, and across a broad spectrum of quality measures. Indeed, the movement has been to expand implementation of incentive pay from process measures to outcome measures, which may be the exact wrong approach.

Incentive pay seems to be a better fit for compliance-oriented tasks that are not cognitively complex. When tasks are complex or require innovation or creativity, concerns about hyperfocus, cheating, and the counter-motivational effects of financial incentives become salient. As Michael Dorff explained, "[P]erformance pay works great for mechanical tasks like soldering a circuit but works poorly for tasks that are deeply analytic or creative."[286] Giving someone financial incentives is not going to make them magically better at a difficult task or more innovative or creative. In fact, it can negatively impact their intrinsic motivation to succeed in such contexts.[287]

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284. These scholars generally argue that pay for performance can be improved by identifying better quality metrics or changing the magnitude or delivery model of the incentives. *See, e.g.*, Michael F. Cannon, *Pay-for-Performance: Is Medicare a Good Candidate?*, 7 YALE J. HEALTH POL'Y, L. & ETHICS 1, 5 (2007); Werner et al., *supra* note 263, at 691.

285. *See, e.g.*, Stout, *supra* note 19, at 536 (2014) (suggesting moving to nonfinancial or *ex post* rewards instead).

286. James Surowiecki, *Why C.E.O. Pay Reform Failed*, NEW YORKER (Apr. 20, 2015), http://www.newyorker.com/magazine/2015/04/20/why-c-e-o-pay-reform-failed [https://perma.cc/568W-BGEY] (quoting Michael Dorff).

287. Marianne Promberger & Theresa M. Marteau, *When Do Financial Incentives Reduce Intrinsic Motivation? Comparing Behaviors Studied in Psychological and Economic Literatures*, 32 HEALTH PSYCHOL. 950, 950-53 (2013); Tomas Chamorro-Premuzic, *Does Money Really Affect Motivation? A Review of the Research*, HARV. BUS. REV. (Apr. 10, 2013), https://hbr.org/2013/04/does-money-really-affect-motiv [https://perma.cc/PP7Q-GDFY].

This Part starts the conversation, suggesting some ways the health-care industry might draw the line between contexts to implement incentive pay and contexts not to.

A. Big Data and Evidence-Based Medicine

The Big Data movement has created a lot of buzz across industries in recent years. Big Data refers to the ability to analyze large datasets to find correlations and make predictions about behavior.[288] Big Data is now commonly used to better understand customer behaviors and preferences to better target consumer marketing. For instance, Wal-Mart uses Big Data to more accurately predict which products will sell.[289] Insurance companies also use Big Data, for instance to better detect fraudulent claims.[290] And the government uses Big Data to get ahead of security threats.[291]

The health-care industry was somewhat late to join the Big Data movement, but the revolution is now fully underway.[292] There are four major pools of data

288. Nicolas P. Terry, *Big Data Proxies and Health Privacy Exceptionalism*, 24 HEALTH MATRIX 65, 77 (2014) (explaining that Big Data refers to collection and storage of large data sets, but also data mining and predictive analytics to process data, make predictions or discover correlations, and drive decisions).

289. *See* Bernard Marr, *Big Data, Walmart and The Future of Retail*, LINKEDIN: PULSE (Feb. 19, 2015), https://www.linkedin.com/pulse/big-data-walmart-future-retail-bernard-marr [https://perma.cc/7H4R-BN4Z]; *see generally* Bernard Marr, *Big Data: A Game Changer in The Retail Sector*, FORBES (Nov. 10, 2015), http://www.forbes.com/sites/bernardmarr/2015/11/10/big-data-a-game-changer-in-the-retail-sector [https://perma.cc/JCU8-LLH9] (discussing the use of Big Data in retail).

290. *See* Mark Isbitts, *Preventing Health Care Fraud with Big Data and Analytics*, LEXISNEXIS: INSIGHTS, http://www.lexisnexis.com/risk/insights/health-care-fraud-layered-approach.aspx [https://perma.cc/C6SU-KY29] (last accessed Jan. 7, 2017); *see also* Andrea Eichhorn, *Leverage Big Data to Fight Claims Fraud*, IBM SOFTWARE (June 2013), http://www-935.ibm.com/services/multimedia/Exploiter_le_Big_Data_pour_lutter_contre_la_fraude_aux_sinistres_Juin_2013.pdf [https://perma.cc/DWK8-6ZBT].

291. *See* John Podesta et al., *Big Data: Seizing Opportunities, Preserving Values*, EXECUTIVE OFFICE PRESIDENT 27 (May 1, 2014), https://www.obamawhitehouse.gov/sites/default/files/docs/big_data_privacy_report_may_1_2014.pdf [https://perma.cc/D5UU-WT34]; Bernhard Warner, *What the Intelligence Community is Doing With Big Data*, BLOOMBERG (Feb. 5, 2013), http://www.bloomberg.com/news/articles/2013-02-05/what-the-intelligence-community-is-doing-with-big-data [https://perma.cc/P6HX-PXQB]; Press Release, MeriTalk, MeriTalk Study Shows 81 Percent of Federal Government Agencies Using Big Data Analytics to Cut Cybersecurity Breaches (Aug. 29, 2016), https://meritalk-q1msnaybldf.netdna-ssl.com/wp-content/uploads/2016/08/49503-MeriTalk_Cloudera_Disruptive_Press_Release_FINAL_082916.pdf [https://perma.cc/6PPE-Y4TB].

292. For instance, Kaiser Permanente has implemented HealthConnect, a system designed to ensure data exchange across facilities to reduce cost and improve quality. *Connectivity*, KAISER PERMANENTE, https://share.kaiserpermanente.org/total-health/connectivity [https://perma.cc/6XLS-VHWL]; Neil Versel, *Big Data Helps Kaiser Close Healthcare Gaps*, INFORMATIONWEEK: HEALTHCARE (Mar. 7, 2013, 11:51 AM), http://www.informationweek.com/healthcare/electronic-health-records/big-data-helps-kaiser-close-healthcare-gaps/d/d-id/1108977 [https://perma.cc/F68Y-2AKU]. Blue Shield of California, in partnership with NantHealth, is similarly developing an integrated technology system. Press Release, Blue Cross Calif., NantHealth and Blue Shield of

available in health care: activity (claims) and cost data, clinical data, pharmaceutical R&D data, and patient behavior and sentiment data.[293] These data are already being used to fast track and improve medical research by finding important correlations without the need to enroll patients in new clinical studies and by vastly improving sample sizes.[294] They are also being used to personalize medicine to make better diagnostic predictions and treatment suggestions.[295] And they are being used to predict epidemics and improve public health.[296]

Some have said that Big Data will be important to the success of incentive pay because stakeholders will need to use it to improve outcomes and obtain the financial reward.[297] But Big Data has the potential to do something else—to help determine *where* financial incentives should even be employed in the first place.

Big Data can help the industry understand where incentives work and where they do not in a number of different ways. First, it can improve the available information that now mostly comes from discrete studies. With claims data, outcome data, and information about where financial incentives were used, Big Data can yield very useful insight on where financial incentives seem to work and where they do not.

Big Data can also improve current attempts at evidence-based medicine.[298] The goal of evidence-based medicine is to identify situations where a treatment is highly correlated with a positive outcome. If such scenarios can be identified, and all that is required is compliance, or implementation of a clear directive, those are situations where incentive pay is likely to be particularly effective. Many

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California Form Proactive Healthcare Collaborative to Coordinate and Personalize Care (Oct. 2, 2012), https://www.blueshieldca.com/bsca/about-blue-shield/media-center/nant-100212.sp [https://perma.cc/Z64W-6MW7].

293. *See* Kate Crawford & Jason Schultz, *Big Data and Due Process: Toward A Framework to Redress Predictive Privacy Harms*, 55 B.C. L. REV. 93, 128 (2014); Basel Kayyali et al., The Big-Data Revolution in US Health Care: Accelerating Value and Innovation, MCKINSEY & COMPANY (Apr. 2013), http://www.mckinsey.com/insights/health_systems_and_services/the_big-data_revolution_in_us_health_care [https://perma.cc/2UME-PN6V].

294. *See, e.g.*, CAPRICORN, http://capricorncdrn.org/?page_id=88 [https://perma.cc/JU5K-99QD]; Ho Ting Wong et al., *Big Data as a New Approach in Emergency Medicine Research*, 4 J. ACUTE DISEASE 178 (2015); Jennifer Frankovich et al., *Evidence-Based Medicine in the EMR Era*, 365 NEW ENG. J. MED. 1758 (2011); Jake Luo et al., *Big Data Application in Biomedical Research and Health Care: A Literature Review*, 8 BIOMED INFORM INSIGHTS 1 (2016).

295. *See* Maryam Panahiazar, *Empowering Personalized Medicine with Big Data and Semantic Web Technology: Promises, Challenges, and Use Cases*, 2014 PROC. IEEE INT'L CONF. BIG DATA 790 (Oct. 2014).

296. Bernard Marr, *How Big Data is Changing Healthcare*, FORBES (Apr. 21, 2015), http://www.forbes.com/sites/bernardmarr/2015/04/21/how-big-data-is-changing-healthcare [https://perma.cc/VBD7-F4Q7].

297. In this new environment, health-care stakeholders have greater incentives to compile and exchange information. *See, e.g.*, Sean Gleeson et al., *Evaluating a Pay-for-Performance Program for Medicaid Children in an Accountable Care Organization*, 170 JAMA PEDIATRICS 259 (2016) (studying data to test whether financial incentives improved physician performance in ACO serving Medicaid children).

298. *See* Kayyali et al., *supra* note 294.

physicians have opposed the idea of evidence-based medicine—and the idea that physicians should rely on efficacy data in making decisions about care—on the basis that professional judgment is important and that medicine is part science, and also part art.[299] It is undoubtedly true that not all of medicine can be reduced to a study of the data. But the data can help to differentiate between aspects of medicine where individual judgment is important, and aspects where compliance with established practices is desired.[300]

The proliferation of electronic health record (EHR) systems is one form of Big Data that can have a profound effect on evidence-based medicine. EHRs can "report timely data that could facilitate surveillance of infectious diseases, disease outbreaks, and chronic illnesses."[301] EHRs can then be analyzed to identify medical procedures that are most effective at treating illnesses. Standardizing EHR systems is particularly important to these goals.

But there are some challenges to this approach. For one, much of the necessary information is siloed, with some in the hands of payers and some held by providers and hospitals. Stakeholders would need to find effective ways to share data. But some of that is already occurring, and the ACA's push toward collaborative care should help.

There are also privacy and confidentiality concerns. And it is possible that the analysis will ultimately tell us that there are not many areas of practice where tasks can be routinized. But nonetheless, there is reason to believe that Big Data may hold some answers here.

B. Physicians vs. Other Health Providers

Another possibility to consider is the distinction that industry has already drawn between the work that physicians do and the work that advanced practice clinicians do.[302] Advanced practice providers are medical providers who are not

299. *See* Joshua J. Goldman & Tiffany L. Shih, *The Limitations of Evidence-Based Medicine—Applying Population-Based Recommendations to Individual Patients*, 13 AMA J. ETHICS 26, 26 (2011); Hasnain-Wynia Romana, *Is Evidence-Based Medicine Patient-Centered and is Patient-Centered Care Evidence-Based?*, 41 HEALTH SERVS. RES. 1, 4 (2006).

300. Evidence from early attempts at pay-for-performance suggests that changes to process often did not beget better outcomes. *See* Werner et al., *supra* note 263, at 691.The hope is that Big Data can more effectively determine the right processes that *will* beget better outcomes. Much of health care cannot be reduced to tried and true processes (think about difficult patients with multiple comorbidities) but also much of it can.

301. Sharona Hoffman & Andy Podgurski, *Big Bad Data: Law, Public Health, and Biomedical Databases*, 41 J.L. MED. & ETHICS 56, 56 (2013).

302. Advanced practice providers are sometimes referred to as mid-level practitioners. *See, e.g.*, 21 C.F.R. § 1300.01 ("Mid-level practitioner means an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by

physicians but who are licensed to diagnose and treat patients, sometimes under the supervision of a physician.[303] Advanced practice providers include physician assistants (PAs) and nurse practitioners (NPs), among other categories.

A PA, according to the American Academy of Physician Assistants, is a "nationally certified and state-licensed medical professional" who practices "on healthcare teams with physicians and other providers."[304] PAs perform a range of activities, usually (but not always) in the realm of primary care. Most commonly, they take medical histories and perform physical examinations, order and interpret lab tests, diagnose and treat common illnesses, and prescribe medication to treat those illnesses.[305] The number of PAs in practice in the United States is proliferating.[306] Studies suggest they provide quality care in the areas in which they practice that is comparable to the care provided by physicians.[307]

An NP is a registered nurse who has additional training in physical diagnosis, psycho-social assessment, and health management in primary care.[308] Most NPs can order tests, diagnose common acute and chronic conditions, and prescribe medication.[309] Increasingly, NPs are practicing independently, rather than under the supervision of physicians.[310]

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the State in which they practice."). However, many in the profession have objected to the descriptor "mid-level" to apply to a group of professionals with advanced degrees. *See, e.g.*, Catherine S. Bishop, *Advanced Practitioners Are Not Mid-Level Providers*, 3 J. ADVANCED PRAC. ONCOLOGY 287 (2012); Michael D. Pappas, *Stop Calling Nurse Practitioners Mid-Level Providers*, KEVINMD (Jul. 14, 2014), http://www.kevinmd.com/blog/2014/07/stop-calling-nurse-practitioners-mid-level-providers.html [https://perma.cc/Y893-7AKX]. As such, this Article will employ the term advanced practice providers or practitioners.

303. *See, e.g.*, Ruth McCorkle, *Transition to a New Cancer Care Delivery System: Opportunity for Empowerment of the Role of the Advanced Practice Provider*, 3 J. ADVANCED PRAC. ONCOLOGY 34 (2012) (defining advanced practice provides to include nurse practitioners and physician assistants).

304. *See What is a PA?*, AM. ACAD. PAS, https://www.aapa.org/What-is-a-PA [https://perma.cc/F8UV-MMU6].

305. *Id.*

306. *See Occupational Outlook Handbook: Physician Assistants*, BUREAU LAB. STAT. (Dec. 17, 2015), http://www.bls.gov/ooh/healthcare/physician-assistants.htm [https://perma.cc/EHS6-QLTP]; *2015 Statistical Profile of Certified Physicians Assistants*, NAT'L COMMISSION ON CERTIFICATION PHYSICIANS ASSISTANTS (Mar. 2016), https://www.nccpa.net/Uploads/docs/2015StatisticalProfileofCertifiedPhysicianAssistants.pd [https://perma.cc/R6S4-ZYM2] (stating that the PA profession grew 35.9% between 2010 and 2015).

307. *See* Amitesth Agarwal et al., *Process and Outcome Measures among COPD Patients with a Hospitalization Cared for by an Advance Practice Provider or Primary Care Physician*, PLOS ONE (Feb. 24, 2016), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0148522 [https://perma.cc/HWH6-SPEW]; Mary O. Mundinger et al., *High Quality of Care: Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: A Randomized Trial*, 283 JAMA 59 (2000).

308. *See What is an NP?*, AM. ASS'N NURSE PRACTITIONERS, https://www.aanp.org/all-about-nps/what-is-an-np [https://perma.cc/3WNX-QWD3].

309. *Id.*

310. *See* John K. Inglehart, *Meeting the Demand for Primary Care: Nurse Practitioners Answer the Call*, NIHCM FOUND. (Oct. 2014), http://www.aacn.nche.edu/downloads/aacn-future-task-

There is some controversy about how to define the scope of medical practice—tasks that can only be done by physicians and not other health providers—given the proliferation of these advanced practice practitioners. While there are some differences at the state level,[311] the general idea is that these practitioners are permitted to do much of the more-routine and less-complex work that used to be solely within the purview of physicians.[312] According to the American Health Lawyers Association, "[t]he general consensus is that these practitioners provide patient care services requiring less acuity and which are more routine, thereby freeing up physicians to focus their attention upon cases with greater complexity."[313]

Therefore, one possibility is to apply incentive pay to the work of PAs and NPs, but not to physicians. If incentive pay is a better match for compliance-oriented tasks that do not require innovation, this might be one way to draw the line.

A counter argument, though, is that not all work that PAs and NPs do is routine or compliance based, particularly to the extent that they have to employ their judgment to make diagnoses. Advanced practice providers, too, will encounter complex cases in their practice that will require creativity and high levels of effort. It is not clear, for instance, that an office visit requiring an advanced practice provider to diagnose an illness is more rote and less creative than a surgery a physician has performed 10,000 times. Additionally, these advanced practice practitioners may have high levels of intrinsic motivation that incentive pay could crowd out. In short, it is not clear that applying incentive pay to advanced practice practitioners instead of physicians would have the desired effect, but there is reason to at least test this method, particularly because a high

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force/Inglehart-PC-Article.pdf [https://perma.cc/3UGV-CWHC]; Amanda Van Vleet & Julia Paradise, *Tapping Nurse Practitioners to Meet Rising Demand for Primary Care*, KAISER FAM. FOUND. (Jan. 20, 2015), http://kff.org/medicaid/issue-brief/tapping-nurse-practitioners-to-meet-rising-demand-for-primary-care [https://perma.cc/P2DC-X43T].

311. *See, e.g.*, Physician Assistant Practice Act of 1987, 225 ILL. COMP. STAT. § 95/4 (2013) (defining the scope of practice for PAs practicing in Illinois); South Carolina Physician Assistants Practice Act, S.C. CODE ANN. § 40-47-935 (2016) (defining the scope of practice for PAs practicing in South Carolina); Physician Assistant Scope of Practice, IND. CODE § 25-27.5-5-1 to -6 (2016) (defining scope of practice for PAs practicing in Indiana).

312. *See, e.g.*, 225 ILL. COMP. STAT. § 95/4 (2013) (defining the scope of practice for PAs practicing in Illinois); *PA Scope of Practice*, AM. ACAD. PAS (Jan. 2017), https://www.aapa.org/WorkArea/DownloadAsset.aspx?id=583 [https://perma.cc/FN4L-R5H4]; *State Practice Environment*, AM. ASS'N NURSE PRACTITIONERS https://www.aanp.org/legislation-regulation/state-legislation/state-practice-environment [https://perma.cc/R2R6-ZG58].

313. Almeta E. Cooper & Paul W. Kim, *Mid-level Practitioners in the Hospital Setting: Physician Assistants and Advanced Practice Nurses*, AM. HEALTH LAW. ASS'N (AHLA-Papers P02070218, Feb. 7, 2002); *see also* Jessica Wolf, *Eliminating Scope of Practice Barriers for Illinois Physician Assistants*, 23 ANNALS HEALTH L.: ADVANCE DIRECTIVE 16, 17–18 (2013) ("PAs play an integral role in the delivery of health care by managing common diagnoses, providing routine treatments, and allowing physicians to focus on more complex patient care that requires their full expertise.").

percentage of the work they do is more likely to be compliance-based than in other areas of medicine.

C. Preventive Care vs. Responsive Treatment

One final idea is to utilize incentive pay for preventive care, but not responsive care. Preventive care is care that can help people avoid illness and improve general health.[314] It includes care such as diagnostic testing, well visits, or vaccinations.[315] Preventive care is, for the most part, routine, and does not require innovation or creativity. Therefore, it might be a good fit for incentive-based compensation.

Many in the industry believe that improving preventive care will not only improve actual health, but will also reduce health costs and improve quality of care.[316] The idea is similar to why parties should specify contracts *ex ante*—to prevent additional costs *ex post*. It is cheaper to vaccinate people than to treat them if they become very ill from a preventable illness.[317] And it is cheaper to screen for cancer and catch it early than not to engage in screening.[318] Yet, too little preventive care is being done.[319]

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314. On the other hand, responsive care refers to treating a problem or disease once it manifests.

315. *See Preventive Care*, U.S. DEP'T HEALTH & HUM. SERVS. (Jul. 27, 2015), http://www.hhs.gov/healthcare/about-the-law/preventive-care/index.html [https://perma.cc/MJV3-C2WJ].

316. *See Building Healthier Communities by Investing in Prevention*, U.S. DEP'T HEALTH & HUM. SERVS. (Feb. 9, 2011), http://www.hhs.gov/healthcare/facts-and-features/fact-sheets/building-healthier-communities-by-investing-in-prevention/index.html [https://perma.cc/CYE7-G9T5]. *But see* Katherine Baicker et al., *The Oregon Experiment—Effects of Medicaid on Clinical Outcomes*, 368 NEW ENG. J. MED. 1713 (2013) (describing a study where access to preventive services through Medicaid coverage was found to improve mental health, although not physical outcomes). *But see* Joshua T. Cohen et al., *Does Preventive Care Save Money? Health Economics and the Presidential Candidates*, 358 NEW ENG. J. MED. 661 (2008) (critiquing the assumption that preventive care will reduce costs).

317. This proposition is not without controversy. *Compare* Fangjun Zhou et al., *Economic Evaluation of the Routine Childhood Immunization Program in the United States, 2009*, 133 PEDIATRICS 577 (2014) (finding that routine childhood immunizations result in net savings of $13.5 billion in direct costs and $68.8 billion in total societal costs), *with* David Brown, *In the Balance: Some Candidates Disagree, but Studies Show It's Often Cheaper to Let People Get Sick*, WASH. POST (Apr. 8, 2008), http://www.washingtonpost.com/wp-dyn/content/article/2008/04/04/AR2008040403803.html [https://perma.cc/85MG-3MT3] (discussing evidence that preventive care, including vaccines, may not actually save money long-term).

318. *See The Economics of Cancer Prevention and Control*, UNION INT'L CANCER PREVENTION & CONTROL (2014), http://www.iccp-portal.org/sites/default/files/resources/WCLS2014_economics_of_cancer_FINAL-2.pdf [https://perma.cc/2CFH-PGCW] (describing the economic benefits of prevention). *But see* William Black et al., *Cost-Effectiveness of CT Screening in the National Lung Screening Trial*, 371 NEW ENG. J. MED. 1793 (2014) (finding that screening actually costs an additional $81,000 per quality adjusted life year gained.).

319. *See* Kimberly S.H. Yarnall et al., *Primary Care: Is There Enough Time for Prevention?*, 93 AM. J. PUB. HEALTH 635 (2003) (finding that time constraints limit primary care physicians' ability to provide preventive care).

Part of the problem is that under fee for service, even with recent bumps in rates, preventive care tends to yield low rates of reimbursement for providers.[320] Providers need an incentive to encourage patients to obtain preventive care. Incentive-based compensation could provide that incentive. Indeed, part of the motivation of the new incentive-based schemes under the ACA was to address this problem—to give providers a reason to have their eyes on the long-term health of their patients.

Some attempts at tying payment incentives to increasing rates of preventive care services have generated positive results.[321] But also, many of the early experiments in pay for performance tended to focus on preventive care, and there is no evidence to date that those experiments were more effective than the broader implementation currently being undertaken.[322] As such, more study and experimentation with this targeted implementation needs to be done.

CONCLUSION

The health-care industry has rallied behind a far-reaching implementation of incentive pay, one that applies across delivery models, to generalist and specialty physicians, and to a wide range of procedures and diagnoses. The contracts literature suggests that this is too blunt of an approach. Task specification and control-based contracting that utilizes monitoring and financial incentives tends to work best for ensuring compliance. But it works less well for motivating consummate performance because it can signal distrust and crowd out social and professional norms that would otherwise have operated to improve performance. Task specification coupled with control mechanisms can also lead to gamesmanship and cheating on the metrics to secure increased compensation. The health-care industry should be focusing on where to implement incentive pay to capture its benefits for compliance and standardization, but minimize its negative impact on innovation and the operation of positive norms. The new Trump Administration has an opportunity to study this issue further and to claw back some of the misguided attempts to implement incentive pay where it is likely to have mal-effects. These are lessons to be extrapolated to other industries, as well.

320. *Physician Payment Report*, *supra* note 53, at 15; Adam Atherly & Karoline Mortensen, *Medicaid Primary Care Physician Fees and the Use of Preventive Services Among Medicaid Employees*, 49 HEATLH SERVS. RES. 1306 (2014).

321. *See* Janusz Kaczorowski, *Views of Family Physicians Before and After Participation in a Reminder and Recall Project (P-PROMPT)*, 57 CAN. FAM. PHYSICIAN 690 (2011).

322. *See, e.g.*, Alan L. Hillman, *Physician Financial Incentives and Feedback: Failure to Increase Cancer Screening in Medicaid Managed Care*, 88 AM. J. PUB. HEALTH 1699 (1998); Meredith B. Rosenthal, *How Will Paying for Performance Affect Patient Care?*, 8 AMA J. ETHICS 162 (2006).

Paying Research Participants: Regulatory Uncertainty, Conceptual Confusion, and a Path Forward

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Abstract:

The practice of offering payment to individuals in exchange for their participation in clinical research is widespread and longstanding. Nevertheless, such payment remains the source of substantial debate, in particular about whether or the extent to which offers of payment coerce and/or unduly induce individuals to participate. Yet, the various laws, regulations, and ethical guidelines that govern the conduct of human subjects research offer relatively little in the way of specific guidance regarding what makes a payment offer ethically acceptable—or not. Moreover, there is a lack of definitional agreement regarding what the terms coercion and undue inducement mean in the human subjects research context. It is, therefore, unsurprising that investigators and Institutional Review Boards (IRBs) experience confusion about how to evaluate offers of payment, and lean toward conservative approaches. These trends are exemplified by our pilot data regarding the ways in which some IRB members

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and investigators (mis)understand the concepts of coercion and undue inducement, as well as the ways in which certain research institutions oversee offers of payment at a local level.

This article systematically examines the legal and ethical dimensions of offering payment to research participants. It argues that many concerns about offers of payment to research participants can be attributed to the misguided view that such offers ought to be treated differently than offers of payment in other contexts, a form of "research exceptionalism." We show that rejection of research exceptionalism with respect to payment helps settle open debates about both how best to define coercion and undue influence, and how to understand the relation between these concepts and offers of payment. We argue for adoption of our preferred definitions, ideally by regulatory authorities, and against the conventional conservatism toward payment of research participants. Instead, we draw attention to the rarely asked, even radical, question: are research participants paid *enough*? We conclude by arguing that we ought to change the default to favor, rather than encourage suspicion of, offers of payment to research participants.

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INTRODUCTION

In the early days of 2016, news broke that six men had been hospitalized—one of whom was pronounced brain-dead—after a "serious accident" in the course of a drug trial conducted in France.[1] The men were all participants in a Phase I, or first-in-human, trial of BIA 10-2474,[2] a novel compound designed to treat "anxiety and motor disorders associated with Parkinson's disease, and chronic pain in people with cancer and other conditions."[3] Each participant had been paid €1,900 (about $2,060), "including travel expenses; in return, they agreed to stay at [the testing] facility in Rennes [France] for 2 weeks, swallow a drug on 10 consecutive days, undergo extensive medical tests, and provide at least 40 blood samples."[4] The amount of payment was widely reported in the wake of the tragedy, with the implication that the offer of payment, or the amount of payment, signaled that the trial itself was ethically questionable.

Clearly, something went terribly wrong in France.[5] Yet, if we focus on what was known at the time the offer of payment was made, rather than allowing retrospective judgments and suspicions about pecuniary incentives to cloud our ethical evaluations, was it acceptable to offer the research participants €1,900? And if it was not, why not?

Offers of payment made to research participants[6] have been described as "one of the more contentious ethical problems" facing institutional review boards (IRBs).[7] The U.S. federal regulations and the leading international codes of research ethics require that consent to participation in research be obtained in a

1. Sewell Chan, *6 Hospitalized, One of Them Brain-Dead, After Drug Trial in France*, N.Y. TIMES (Jan. 15, 2016), http://www.nytimes.com/2016/01/16/world/europe/french-drug-trial-hospitalization.html [https://perma.cc/H4LQ-BU73].

2. John Brosky & Cormac Sheridan, *Six Hospitalized in Bial Clinical Trial in France*, BIOWORLD, http://www.bioworld.com/content/six-hospitalized-bial-clinical-trial-france [https://perma.cc/NM6D-KC2C].

3. Declan Butler & Ewen Callaway, *Scientists in the Dark After French Clinical Trial Proves Fatal*, 529 NATURE 263, 263 (2016).

4. Martin Enserink, *More Details Emerge on Fateful French Drug Trial*, SCIENCE (Jan. 16, 2016), http://www.sciencemag.org/news/2016/01/more-details-emerge-fateful-french-drug-trial [https://perma.cc/6HFB-TTNL].

5. Declan Butler & Ewen Callaway, *Researchers Question Design of Fatal French Clinical Trial*, NATURE: NEWS (Jan. 22, 2016), http://www.nature.com/news/researchers-question-design-of-fatal-french-clinical-trial-1.19221 [https://perma.cc/J5JG-6JLJ].

6. We prefer and will use the term "research participant" rather than "research subject." While "subject" is the more traditional of the two terms, over the past several decades, there has been a shift to using "participant" because many see it as more respectful. There continues, however, to be debate. *See* Ali Hall, *What's in a Name? Research "Participant" Versus Research "Subject"*, PRIM&R (Jan. 6, 2014), http://primr.blogspot.com/2014/01/whats-in-name-research-participant.html [https://perma.cc/7KA7-865W].

7. Bruce G. Gordon, Joseph Brown, Christopher Kratochvil & Ernest D. Prentice, *Paying Research Subjects*, *in* INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION 154 (Robery J. Amdur and Elizabeth A. Banker eds., 2002).

manner that minimizes the possibility of coercion and undue influence (a term used interchangeably with undue inducement). Offers of payment made to research participants have been linked to both concepts, and yet the various laws, regulations, and ethical guidelines that govern the conduct of human subjects research offer relatively little in the way of specific guidance about what factors or features render offers of payment ethically acceptable, or not—or even how to define coercion and undue inducement. Therefore, IRBs—the administrative bodies "established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which [the IRB is] affiliated"[8]—and investigators are left largely without a compass to determine whether any particular offer of payment is appropriate.

Given the lack of clear regulatory guidance, one would fully expect the space inhabited by IRBs and investigators to be characterized by confusion and a general trend toward conservative approaches to offers of payment—better to be safe than sorry in the midst of uncertainty. To the extent that IRBs and investigators are identifying legitimate ethical concerns about payment, such conservatism is appropriately protective of research participants. On the other hand, if ethical concerns about payment are overestimated (or simply wrong), the limits that follow from a conservative approach are not only unnecessary to protect research participants, but could actually be ethically inappropriate to the extent that they prevent research participants from receiving offers of payment that would fairly compensate them for the risks and burdens of their participation. Unnecessarily conservative approaches to payment might also hinder trial recruitment,[9] thereby delaying scientific and medical progress and/or unethically exposing research participants to risks and burdens that cannot be justified by their scientific value if studies fail to complete.[10] Moreover, such conservative approaches might result in an unfair distribution of the burdens and/or benefits[11] of research participation over the broader population, by failing to attract a more diverse group of participants. All of this is to say that there are potential practical and ethical costs to the confusion experienced by IRBs and investigators, and the "better safe than sorry" approach is not necessarily safer at

8. U.S. DEP'T HEALTH & HUMAN SERVS., INSTITUTIONAL REVIEW BOARD GUIDEBOOK ch. 1 (1993).

9. *See generally* Jeffrey L. Probstfield & Robert L. Frye, *Strategies for Recruitment and Retention of Participants in Clinical Trials*, 306 JAMA 1798 (2011); Darlene R. Kitterman, Steven K. Cheng, David M. Dilts & Eric S. Orwoll, *The Prevalence and Economic Impact of Low-Enrolling Clinical Studies at an Academic Medical Center*, 86 ACAD. MED. 1360 (2011).

10. Scott D. Halpern, Jason H.T. Karlawish & Jesse A. Berlin, *The Continuing Unethical Conduct of Underpowered Clinical Trials*, 288 JAMA 358, 358 (2002).

11. Joseph M. Unger et al., *Patient Income Level and Cancer Clinical Trial Participation: A Prospective Survey Study*, 2 JAMA ONCOLOGY 137, 137 (2016) ("[L]imiting income disparities is important for ensuring rapid enrollment and fair access to trials.").

all.

This article systematically examines the legal and ethical dimensions of offering payment to research participants. It argues that many concerns about offers of payment in this context are attributable to misguided "research exceptionalism"—simply put, the idea that research is meaningfully different from other contexts in which individuals assume risk. As we show, the rejection of research exceptionalism with respect to payment helps settle open debates within the research ethics community about both how best to define coercion and undue inducement and how to understand their relation to offers of payment. Recognition that research exceptionalism is problematic, coupled with the adoption of our preferred definitions of coercion and undue inducement, should help resolve the confusion exhibited by IRBs and investigators with regard to offers of payment for research participation. Moreover, it should allow IRBs and investigators—two groups that have traditionally focused on whether offers of payment are too high—to focus on the more ethically salient question: are research participants being paid *enough*? We think the answer to that question is often "No."

The article proceeds as follows: Part I provides background on why payment is sometimes considered ethically problematic, and reviews the existing literature on offers of payment made to research participants. Such offers are a pervasive feature of research involving both "healthy volunteers" and "patient volunteers," individuals who have the disease or condition under study. Moreover, offers of payment span the spectrum of studies from those that pose minimal risk to participants to those that are far riskier and more burdensome. The relative frequency with which payment is offered means that investigators who design payment schedules and the IRBs that review those payment schedules routinely confront questions about the ethical acceptability of payment.

Part II surveys regulations and guidelines on the ethics of biomedical research at two levels: national and international. First, we briefly describe the U.S. federal regulations and relevant guidance documents governing human subjects research from both the Office of Human Research Protections (OHRP) within the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA). Next, we examine international guidelines, which are highly influential and may be formally (or even legally) applicable, depending on where research is conducted. Treatment of payment within these regulations and guidelines is highly uneven: some fail altogether to address offers of payment, while others address the purpose, amount, mechanism, and timing of offers of payment, albeit in a fairly high-level way. As a result, IRBs and investigators bear significant responsibility both for determining what the terms coercion and undue influence mean in the context of offers of payment and for correctly identifying and addressing those ethical concerns when they see them. While we concede that discretion will always be needed to determine whether

coercion and undue inducement are present in particular circumstances, the lack of clear definitions and guidance can lead to unnecessary confusion and conservative approaches.

In Part III, we consider a potential explanation for the debate surrounding offers of payment to research participants: research exceptionalism. Research exceptionalism is the view that biomedical research is meaningfully different from other contexts in which individuals assume risk. Although many individuals implicitly endorse the idea that research is different, we suggest that nine common justifications for research exceptionalism ultimately fail, at least when it comes to offers of payment. Though we favor robust regulatory protections for participants in human subjects research, we maintain that common arguments for research exceptionalism do not identify characteristics of research that can justify regulating offers to payment to research participants more heavily than offers of payment made in other areas.

Part IV explores the considerable academic discussion related to coercion and undue inducement in the context of research ethics generally and in relation to payment specifically. No clear consensus has materialized regarding what these concepts mean, but we review the dominant themes and arguments that have emerged. We argue for our preferred definitions of coercion and undue inducement and show that some definitions necessarily fail with the rejection of research exceptionalism.

To demonstrate how the regulatory underdevelopment and conceptual confusion play out in practice, Part V reviews selected institutional policies related to payment of research participants. Such policies, typically promulgated by IRBs in conjunction with administrators, guide both investigators' design of and IRBs' deliberations regarding offers of payment to research participants. The want of substantive direction from either regulatory authorities or international bodies has unsurprisingly resulted in correspondingly wide variation in institutional policy.

In Part V, we also present the results of two small pilot surveys we conducted with a sample of IRB members, administrators, investigators, and study coordinators. Our aim was to examine how individuals who are actively engaged in human subjects research and protection think about offers of payment generally, and about the concepts of coercion and undue inducement specifically. While these are preliminary findings, and we call for more research, our data contribute to the growing empirical literature showing that confusion exists among IRB members regarding how to define the terms coercion and undue inducement.[12] Our pilot survey is the first to examine how investigators define

12. Emily A. Largent et al., *Money, Coercion, and Undue Inducement: A Survey of Attitudes About Payments to Research Participants*, 34 IRB: ETHICS & HUM. RES. 1 (2012); Robert Klitzman, *How IRBs View and Make Decisions About Coercion and Undue Influence*, 39 J. MED. ETHICS 224 (2013).

those terms; it is unsurprising but valuable to see that investigators are confused in much the same way that IRB members are. Moreover, both groups subscribe to definitions that are consistent with research exceptionalism, and inconsistent with our preferred approaches.

Finally, Part VI builds on our analysis, definitions, and findings to make recommendations for policy and practice. We recognize that it may be impossible for IRBs and investigators to reach consensus amongst themselves on what the terms coercion and undue inducement mean, given the relative ambiguity of U.S. federal regulations and international guidelines and the persistent lack of agreement among bioethicists about the features of ethically acceptable offers of payment. In the short-term, it is desirable that IRB members and investigators stop assuming that labels—that is, calling an offer "coercive" or "unduly influential"—alone do sufficient explanatory work when deciding whether a payment is ethically acceptable. In the long-term, we believe that official regulatory guidance and educational efforts by enforcement agencies are needed to clarify these concepts.

Helping the research community speak with greater precision about their concerns regarding offers of payment by adoption of common definitions will enable a more concrete separation of ethically acceptable and unacceptable payment structures, which may have the effect of improving trial recruitment and promoting fair compensation of research participants, with new attention paid to the problem of underpayment.

I. BACKGROUND: OFFERS OF PAYMENT IN BIOMEDICAL RESEARCH

Human subjects research is research in which human beings ("as opposed to animals, atoms, or asteroids"[13]) are the subjects of study. A "human subject" is defined by the regulations governing most federally-funded human subjects research as "a living individual about whom an investigator . . . conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."[14]

Clinical research is that "subset of human subjects research which focuses

13. David Wendler, *The Ethics of Clinical Research*, STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed., 2012), http://plato.stanford.edu/archives/fall2012/entries/clinical-research/ [https://perma.cc/W7ME-A2H2].

14. 45 C.F.R. § 46.102(f) (2015). The amended regulations, finalized in January 2017 and effective in 2018 (assuming no change before then), define a human subject as "a living individual about whom an investigator . . . conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private, information or identifiable biospecimens." Federal Policy for the Protection of Human Subjects, 82 FED. REG. 7149, 7260 (Jan. 19, 2017). *See also* 21 C.F.R. § 50.3(6) (2017) ("*Human subject* means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.").

on improving human health and well-being."[15] Clinical research is "designed to test an hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge. . . . Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective."[16]

Central to the distinction between research and care is "the idea that the purpose of clinical research is fundamentally different from that of clinical medicine: whereas medical care focuses on providing optimal care to individual patients, clinical research is primarily concerned with producing generalizable knowledge for the benefit of future patients," even when individual research participants may fortuitously accrue benefits themselves.[17] Other characteristics of research include the use of distinctive methodologies—such as randomization, placebo controls, and blinding—that "sacrifice personalization of care" in favor of scientific validity and the inclusion of some "procedures that hold no prospect of medical benefit for the research participant, but which are justified in light of their scientific value."[18] Research also presents a distinctive relationship between the research participant and the investigator, which is best understood in opposition to the relationship between a patient and her doctor. Franklin Miller and Howard Brody explain:

> [W]hen physicians of integrity practice medicine, physicians' and patients' interests converge. The patient desires to regain or maintain health to relieve suffering; the physician is dedicated to providing the medical help that the patient needs. In clinical research, by contrast, the interests of investigators and patient volunteers are likely to diverge, even when the investigator acts with complete integrity.[19]

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15. Wendler, *supra* note 13. Social behavioral research studies individuals' responses to internal and external stimuli. While social-behavioral research is not the focus of this paper, payment is often used in that research as well. Many of the concerns raised herein would also be relevant in that context. *See also* 21 C.F.R. § 50.3(c) ("*Clinical investigation* means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.").

16. NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979) [hereinafter THE BELMONT REPORT].

17. Emily A. Largent, Steven Joffe & Franklin G. Miller, *Can Research and Care Be Ethically Integrated?*, 41 HASTINGS CENTER REP. 37, 37 (2011).

18. *Id.* at 37–38.

19. Franklin G. Miller & Howard Brody, *A Critique of Clinical Equipoise: Therapeutic Misconception in the Ethics of Clinical Trials*, 33 HASTINGS CENTER REP. 19, 21 (2003).

Again, this is because the purpose of research is to advance science and medicine, not necessarily to benefit individual participants. Given these key differences between research and care, it is unsurprising that the two activities are governed by distinctive normative commitments.[20]

The phrase "offer of payment" is an umbrella term used to capture all instances in which money—either cash or cash equivalent—is provided to research participants. Although controversy persists surrounding offers of payment to research participants, the practice is widespread and growing.[21]

A. Why Might Offers of Payment Be Ethically Concerning?

The practice of offering payment to individuals in exchange for their participation in certain types of clinical studies is generally recognized as an important—and often essential—tool to reach enrollment targets.[22] Despite the longstanding nature of the practice, whether payment is a "necessary evil" or legitimate compensation for services rendered is the source of substantial debate. A minority of commentators contends that altruism should be an individual's sole motivation for research participation, such that payment beyond reimbursement of a participant's out-of-pocket costs is ethically inappropriate.[23] The majority of academic literature on this topic, however, has focused on establishing those circumstances under which offers of payment may be ethically acceptable, addressing concerns related to the amount, mechanism, timing, and context of

20. Emily A. Largent, Steven Joffe & Franklin G. Miller, *A Prescription for Ethical Learning*, 43 HASTINGS CENTER REP. S28, S28 (2013).

21. *See, e.g.*, Neal Dickert & Christine Grady, *What's the Price of a Research Subject? Approaches to Payment for Research Participation*, 341 NEW ENG. J. MED. 198, 198 (1999); *see also* Christine Grady et al., *An Analysis of U.S. Practices of Paying Research Participants*, 26 CONTEMP. CLINICAL TRIALS 365, 366 (2005); Christine Grady, *Money for Research Participation: Does It Jeopardize Informed Consent?*, 1 AM. J. BIOETHICS 40, 40 (2001).

22. Leah E. Hutt, *Paying Research Subjects: Historical Considerations*, 12 HEALTH L. REV. 16, 16 (2003). Offers of payment to research participants are often defended on the pragmatic grounds that they facilitate timely recruitment of the right numbers and types of participants. *See, e.g.*, Laura B. Dunn & Nora E. Gordon, *Improving Informed Consent and Enhancing Recruitment for Research by Understanding Economic Behavior*, 293 JAMA 609 (2005). While there is a need for more empirical research to show how increasing incentives affects recruitment for clinical trials specifically, there is evidence from survey research that larger offers of payment improve recruitment. *See, e.g.*, Nancy L. Keating et al., *Randomized Trial of $20 Versus $50 Incentives to Increase Physician Survey Responses*, 46 MEDICAL CARE 878 (2008); Connie M. Ulrich et al., *Does It Pay to Pay? A Randomized Trial of Prepaid Financial Incentives and Lottery Incentives in Surveys of Nonphysician Healthcare Professionals*, 54 NURSING RES. 178 (2005); Scott D. Halpern et al., *Randomized Trial of $5 Versus $10 Monetary Incentives, Envelope Size, and Candy to Increase Physician Response Rates to Mailed Questionnaires*, 40 MED. CARE 834 (2002); David A. Asch et al., *Conducting Physician Mail Surveys on a Limited Budget: A Randomized Trial Comparing $2 Bill versus $5 Bill Incentives*, 36 MED. CARE 95 (1998).

23. *E.g.*, Tod Chambers, *Participation as Commodity, Participation as Gift*, 1 AM. J. BIOETHICS 48 (2001).

payment.[24]

As mentioned above, and as will be discussed at greater length in Part II, the U.S. federal regulations, as well as the leading international codes of research ethics, explicitly stipulate that consent to participation in research should be obtained in a manner that minimizes the possibility of both coercion and undue inducement.[25] Informed consent, central to ethical clinical research, serves to "ensure not only that individuals control whether or not they enroll in clinical research," but also that "they participate only when doing so is consistent with their values and interests."[26] In order to provide adequate informed consent, prospective research participants must be: (1) *informed* of the purpose, methods, risks, benefits, and alternatives to research participation; (2) *comprehend* this information and understand its particular relevance to them; and (3) make a *voluntary* decision to participate.[27]

Unfortunately, there is no broad consensus in the research ethics literature as to what constitutes coercion or undue inducement—a matter we delve into at length in Parts II and IV. Therefore, we will not define the terms here, instead reserving that discussion for later. There is, however, general consensus that coercion and undue inducement render consent invalid, though the mechanism by which they do so remains open to debate. Many understand both coercion and undue inducement to compromise voluntariness,[28] whereas others argue that coercion compromises voluntariness while undue inducement chiefly compromises comprehension.[29]

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24. *See generally* Carl Elliott & Roberto Abadie, *Exploiting a Research Underclass in Phase 1 Clinical Trials*, 358 NEW ENG. J. MED. 2316 (2008); Ezekiel J. Emanuel, *Undue Inducement: Nonsense on Stilts?*, 5 AM. J. BIOETHICS 9 (2006); Ruth W. Grant & Jeremy Sugarman, *Ethics in Human Subjects Research: Do Incentives Matter?*, 29 J. MED. & PHIL. 717 (2004); Trudo Lemmens & Carl Elliott, *Guinea Pigs on the Payroll: The Ethics of Paying Research Subjects*, 7 ACCOUNTABILITY IN RES. 3 (1999). In addition to broad concerns about offers of payment to research participants, unique ethical concerns also arise with respect to particular sub-populations of participants, for example, drug users. *See, e.g.*, Craig L. Fry et al., *The Ethics of Paying Drug Users Who Participate in Research: A Review and Practical Recommendations*, 1 J. EMPIRICAL RES. ON HUM. RES. ETHICS 21 (2006).

25. *E.g.*, 45 C.F.R. § 46 (2015); *see also* COUNCIL FOR INT'L ORGS. OF MED. SCIS. (CIOMS), INTERNATIONAL ETHICAL GUIDELINES FOR HEALTH-RELATED RESEARCH INVOLVING HUMANS 44 (2016), http://www.cioms.ch/ethical-guidelines-2016 [https://perma.cc/AKC2-TXXC] (stating that the informed consent process requires "ensuring that the person has adequately understood the material facts and has decided or refused to participate without having been subjected to coercion, undue influence, or deception.").

26. Ezekiel J. Emanuel et al., *What Makes Clinical Research Ethical?*, 283 JAMA 2701, 2706 (2000).

27. *See generally* JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 249 (2001).

28. *E.g.*, David Casarett et al., *Paying Hypertension Research Subjects: Fair Compensation or Undue Inducement?*, 17 J. GEN. INTERN. MED. 651, 651 (2002) ("Undue inducements decrease voluntariness, an essential component of valid consent.").

29. *E.g.*, Emily Largent et al., *Misconceptions About Coercion and Undue Influence:*

The potential effect of offers of payment on research participants has been described as either coercive, unduly influential, or both, and therefore potentially problematic in terms of satisfying the ethical (and legal) requirement for valid informed consent. Simply put, many think that the offer of money can hold an overwhelming allure for research participants, the result of which is to render invalid their consent to research participation. To pick but one example, a writer discussing the adverse events in the BIA 10-2474 trial described at the outset of this article stated that "[w]ith many in poverty, there is an inherent coercion in this type of trial" and concluded that it is "imperative . . . that we . . . minimize the coercion of financial incentives" in clinical research.[30]

Because people have highly disparate views on the necessary and sufficient conditions for coercion and undue inducement, there is great heterogeneity regarding when offers of payment are thought to be acceptable. To fully appreciate the controversy engendered by offers of payment, it is necessary to consider them at a more granular level. Various characteristics of both the payment itself and the study for which payment is being offered are thought to have normative importance when determining the ethical acceptability of an offer of payment. That is what we turn to next.

B. Which Research Participants Receive Offers of Payment?

From an investigator's perspective, research participants are selected through the development of inclusion and exclusion criteria, as well as through recruitment strategies.[31] Inclusion and exclusion criteria are standards prospectively set forth in a study protocol that are used to determine whether an individual is or is not eligible to participate in a particular study.[32] For example, inclusion and exclusion criteria may account for age, pregnancy-status, comorbidities, or an individual's treatment history.

Although inclusion and exclusion vary widely by study, a basic and fundamental distinction can be drawn between research participants who are healthy volunteers—individuals with no known health problems—and those who are patient volunteers—individuals at risk for or with the condition under study.

Reflections on the Views of IRB Members, 27 BIOETHICS 500, 507 (2013) (arguing that coercion compromises voluntariness, whereas undue influence compromises comprehension of risks).

30. Judy Stone, *Bial's Clinical Trial in France Ends in Disaster. What Went Wrong?*, FORBES (Jan. 16, 2016), http://www.forbes.com/sites/judystone/2016/01/16/bials-french-clinicial-trial-ends-in-disaster-what-went-wrong/#6a59c2f49b2c [https://perma.cc/A72X-YYCF].

31. Emanuel et al., *supra* note 26, at 2704 (discussing the ethical importance of fair subject selection).

32. Whereas inclusion criteria are characteristics that individuals must have in order to participate, exclusion criteria are characteristics the possession of which disqualifies an individual. *See generally* Harriette G.C. Van Spall et al., *Eligibility Criteria of Randomized Controlled Trials Published in High-Impact General Medicine Journals: A Systematic Sampling Review*, 297 JAMA 1233, 1233 (2007).

Presently, demand for research participants often outstrips the number of individuals willing to take part.[33]

From a potential research participant's perspective, diverse factors may prompt agreement to participate in clinical research.[34] For instance, healthy volunteers may be motivated by a wish to help others, to move science forward, or to receive financial compensation.[35] Patient volunteers may be motivated by these factors as well, but they may also wish to receive innovative therapies only available in the research context in hopes that they will receive direct medical benefit. A direct benefit to research participants is a benefit that arises from receiving the intervention being studied, as opposed to other types of so-called collateral benefits that may be associated with trial participation, such as access to specialists and more attentive care.[36]

There is a common perception "that money is offered only to healthy subjects in research, and rarely to patient-subjects with the disease or condition under study."[37] Relatedly, commentators sometimes assume (or argue) that while it is legitimate to offer payment to healthy volunteers for their participation in research, one should not offer to pay patient volunteers, at least when they stand to accrue other benefits from research participation.[38] Others, however, have persuasively argued that there is no inherent reason to treat healthy volunteers and patient volunteers differently with respect to payment.[39] Data suggest that, in practice, researchers do in fact nearly always offer payment to healthy research participants, and also increasingly offer payment to patients who participate in clinical research, even when the study holds the prospect of direct medical benefit.[40]

C. Why Are Offers of Payment Made to Research Participants?

Investigators may be motivated to offer payment to research participants for a number of reasons, and the perceived ethical acceptability of these reasons

33. Dinora Dominguez et al., *Commonly Performed Procedures in Clinical Research: A Benchmark for Payment*, 33 CONTEMP. CLINICAL TRIALS 860, 860 (2012).

34. *See, e.g.*, Leanne Stunkel & Christine Grady, *More Than Money: A Review of the Literature Examining Healthy Volunteer Motivations*, 32 CONTEMP. CLINICAL TRIALS 342 (2011).

35. *E.g.*, Luis Almeida et al., *Why Healthy Subjects Volunteer for Phase I Studies and How They Perceive Their Participation?*, 63 EUR. J. PHARMACOLOGY 1085 (2007) (finding financial reward was the most important motivation).

36. Nancy M.P. King, *Defining and Describing Benefit Appropriately in Clinical Trials*, 28 J.L. MED. & ETHICS 332 (2000).

37. Grady et al., *supra* note 21, at 366.

38. *E.g.*, Trudo Lemmens & Carl Elliott, *Justice for the Professional Guinea Pig*, 1 AM. J. BIOETHICS 51, 52 (2001). *But see* Dickert & Grady, supra note 21, at 198.

39. Dickert & Grady, *supra* note 21, at 198.

40. *See* Christine Grady, *Payment of Clinical Research Subjects*, 115 J. CLINICAL INVESTIGATION 1681, 1681 (2005); Grady et al., *supra* note 21, at 372.

varies greatly.[41] Figure 1 shows possible reasons for offering payment that have been identified by IRBs and regulators, arrayed from least to most controversial.[42] It is important to appreciate that it is not just the dollar value of payment that is subject to ethical critique, but also the function that the payment is understood to serve by the investigator and the IRB.[43]

First, money might be offered to *reimburse* participants for research-related expenses, for example, travel to the study site. Such offers may enable individuals who could not otherwise afford to participate or who would not be willing to make a financial sacrifice to participate to do so.[44] The practice of offering money as reimbursement is uncontroversial and widely accepted.[45]

Additionally, money may *compensate* individuals for time and effort expended or inconvenience experienced in the course of participating in research, beyond true out-of-pocket costs. Payment may be used as a recruitment *incentive*, too, particularly if the amount offered is high enough to overcome lack of interest, or—for certain subgroups within the population—lack of awareness or distrust.[46] Money also can serve as a *token of appreciation*; in contrast to an incentive, which is offered prospectively, and in contrast to compensation, which aims to match the value of what has been given, a token of appreciation is generally small and offered only after the decision to participate has already been made.[47] While offers of compensation and tokens of appreciation are generally not controversial, because they aim to make a participant whole, are quite minimal or are offered in a way that would not influence decisions to participate, use of money as an incentive garners mixed reactions.[48]

Finally, money could be viewed as a *benefit* to research participants in assessing whether the risks of participation are reasonable in comparison to the benefits.[49] This approach, however, is extremely controversial since it could

41. *Id.*

42. This figure was developed, in part, using the empirical data presented in Largent, Grady, Miller & Wertheimer, *supra* note 12.

43. *See, e.g.*, Office of Human Research Prots., *When Does Compensating Subjects Undermine Informed Consent or Parental Permission?*, U.S. DEP'T HEALTH & HUM. SERVS., http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent [https://perma.cc/CUT4-BXXU] ("Information submitted to IRBs should indicate and justify proposed levels and purposes of remuneration, which also should be clearly stated in the accompanying consent forms.").

44. Emanuel et al., *supra* note 26, at 2701.

45. Largent et al., *supra* note 12, at 5.

46. Grady, *supra* note 40, at 1682.

47. Grant & Sugarman, *supra* note 24, at 735 n.3 (2004) ("[I]n the research context, providing a benefit after the decision to participate has been made is a gift or a token of appreciation, not an incentive properly speaking because the benefit does not serve as a motivator.").

48. Largent et al., *supra* note 12, at 5.

49. Alan Wertheimer, *Is Payment a Benefit?*, 27 BIOETHICS 105, 105 (2013).

allow even very risky research to proceed so long as the "price" was right.[50] Indeed, IRBs are warned not to consider remuneration as a way of offsetting risks when it comes to approving research.[51] Nonetheless, this does not preclude consideration of risks when setting appropriate remuneration amounts, and there are no restrictions on how prospective research participants might view or perceive the offer of payment when deciding whether or not to participate.[52]

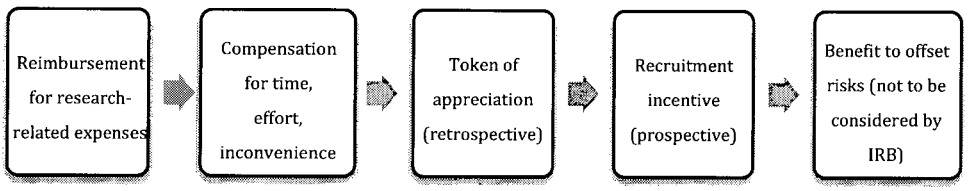

Figure 1. Reasons for Offering Payment to Research Participants, arrayed from least to most controversial.

D. How Much Payment is Offered to Research Participants?

Published journal articles rarely mention whether payment was offered to research participants, and almost never mention the amount.[53] Additionally, most research studies do not specify a dollar value for any given procedure in either the protocol or consent document.[54] Yet, some efforts have been made to quantify what research participants are paid. In 2012, ethicists at the National Institutes of Health (NIH) Clinical Center reviewed four years of data to estimate payment amounts for common research procedures.[55] They estimated $20 for a blood sample, $10 for a urine sample, and $30 for a 1-hour questionnaire.[56] This is generally consistent with data from a national survey conducted by Elizabeth Ripley and colleagues,[57] as well as with suggested monetary compensation for

50. *Id.* at 111 (discussing the "jacking-up" argument).

51. Office of Human Research Prots., *supra* note 43; *see also* Holly Fernandez Lynch, *Human Research Subjects as Human Research Workers*, 14 YALE J. HEALTH POL'Y L. & ETHICS 122, 156–157 (2014) ("Although technically silent on the matter of whether payment to subjects may be based on risk, the [U.S. federal] regulations' direction to avoid undue inducement is often taken to mean that risk-based payment is impermissible.").

52. Office of Human Research Prots., *supra* note 43 ("remuneration to subjects may include compensation for risks associated with their participation in research and that compensation may be an acceptable motive for agreeing to participate in research.").

53. Brandon Brown et al., *Transparency of Participant Incentives in HIV Research*, 3 LANCET e456 (2016); Robert Klitzman et al., *The Reporting of Monetary Compensation in Research Articles*, 2 J. EMPIRICAL RES. ON HUM. RES. ETHICS 61, 64 (2007).

54. Christine Grady, *Payment of Clinical Research Subjects*, 115 J. CLINICAL INVESTIGATION 1681, 1681 (2005); Grady et al., *supra* note 21, at 369.

55. Dinora Dominguez et al., *Commonly Performed Procedures in Clinical Research: A Benchmark for Payment*, 33 CONTEMP. CLINICAL TRIALS 860, 867 (2012).

56. *Id.*

57. Elizabeth Ripley et al., *Why Do We Pay? A National Survey of Investigators and IRB*

routine research procedures outlined by the Boston-based Partners Healthcare Human Research Protection Program.[58] Others have found that the procedure-related dollar value for MRIs can range from $25 to $120 (mean $58) and that variation can occur even within the same institution.[59]

While these are valuable benchmarks, they hardly exhaust the spectrum of offers of payment—particularly as studies vary with respect to complexity, number of procedures, length, et cetera.[60] One study of consent documents for thirteen HIV cure studies found a range from "no payment to nearly $2,000," though neither the median nor mean payment was identified.[61] In 2005, a review of IRB-approved protocols and consent forms from 467 studies offering payment to research subjects approved by eleven IRBs across the United States found that the total amount of compensation offered for a complete study varied from $5 to $2,000.[62] The authors found that nearly two-thirds of studies offered less than $250, and the median total across all studies was $155.[63] Studies with some prospect of direct medical benefit, studies having at least one invasive procedure, and studies with a greater number of clinic visits were associated with higher dollar amounts offered.[64]

It is not possible to offer a straightforward explanation for the observed variation in offers of payment. The methods by which investigators determine how much payment to offer have proven difficult to discern, as there is no clear-cut correlation between the amount offered and explicit factors, such as procedures or visits.[65] This has led some to speculate that these decisions are simply "guesstimates."[66] That is, investigators pick a lump sum that feels appropriate to them and/or that is likely to pass muster with their IRB. Variation, then, may be the result, among other factors, of vague guidance regarding the appropriateness of payment or different understandings of how to value research participation or of the functions that payment serves. More concretely, variation

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Chairpersons, 5 J. EMPIRICAL RES. ON HUM. RES. ETHICS 43, 54 (2010).

58. Partners Human Research Comm., *Remuneration for Research Subjects*, PARTNERS HEALTHCARE, http://navigator.partners.org/ClinicalResearch/Remuneration_for_Research_Subjects.pdf [https://perma.cc/2DEU-KBAJ].

59. Grady et al., *supra* note 21, at 369.

60. Our work focused on offers of payment to adults, but for data on offers of payment to adolescents *see* Dina L.G. Borzekowski et al., *At What Price? The Current State of Subject Payment in Adolescent Research*, 33 J. ADOLESCENT HEALTH 378 (2003).

61. Gail E. Henderson, *The Ethics of HIV "Cure" Research: What Can We Learn from Consent Forms?*, 31 AIDS RES. & HUM. RETROVIRUSES 56, 60 (2015).

62. Grady et al., *supra* note 21, at 370.

63. *Id.*

64. *Id.*; *see also The Ethics of Compensation for Healthy Trial Participants*, QUORUM REVIEW IRB (Sept. 10, 2015), http://www.quorumreview.com/ethics-compensation-healthy-trial-participants [https://perma.cc/7KKM-PDJQ].

65. Grady et al., *supra* note 21, at 373.

66. *Id.*

can be explained by the constraints established by study budgets and desires to avoid certain paperwork, tax reporting, or other requirements that are triggered when payments exceed a certain threshold.[67]

Considered together, these figures suggest that the offer of payment made to participants in the French experiment discussed at the beginning of this paper is on the higher end of the spectrum, but certainly not off the charts.[68]

II. REGULATIONS AND GUIDELINES RELATED TO PAYMENT OF RESEARCH PARTICIPANTS

With this background in mind, we now turn to regulations and guidelines governing human subjects research to describe what they say about coercion and undue inducement generally and what, if anything, they say about offers of payment specifically. In short, the answer is not much. The want of meaningful guidance at both the U.S. and international levels may help to explain the heterogeneity of offers of payment described in the preceding section, as well as the conservative approaches to payment we see both anecdotally[69] and in many institutional policies, as described in Part V. In what follows, we outline the various definitions of coercion and undue inducement offered in these regulations and guidelines, but we refrain from normative evaluation until Part IV because the shortcomings of these definitions are most evident when facilitated by the discussion of research exceptionalism provided in Part III.

A. American Regulations and Guidelines

Federal laws governing human subjects research demonstrate "a societal commitment to the advancement of scientific knowledge provided that the advances occur in accord with ethically sound principles and practices."[70] Although federal regulations and guidelines call attention to some of the ethical issues that payment raises, they offer little substantive guidance regarding how ethically to offer payments to research participants.[71]

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67. For example, we know from talking with investigators that some institutions require that payments in excess of, e.g., $50 be paid by check. In order to satisfy participants' preference for cash and to avoid the administrative burden and delays of having checks issued, offers of payment will be kept at or below $50, even if a higher level of payment could be justified.

68. The individuals who experienced severe adverse reactions in the 2006 TeGenero trial were paid approximately $3,500 to participate. Meredith Wadman, *London's Disastrous Drug Trial Has Serious Side Effects for Research*, 440 NATURE 388, 388 (2006).

69. *See, e.g.*, Eleanor Singer & Robert Bossarte, *Incentives for Survey Participation: When Are They Coercive?*, 31 AM. J. PREV. MED. 411, 413 (2006) (relating how IRBs are "increasingly saying" that $40 to $100 incentives for survey response have been deemed "coercive").

70. Jonathan Moreno et al., *Updating Protections for Human Subjects Involved in Research*, 280 JAMA 1951, 1951 (1998).

71. Dickert & Grady, *supra* note 39, at 198.

1. The Belmont Report

The BELMONT REPORT,[72] promulgated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, is one of the foundational documents of bioethics, setting forth ethical principles and guidelines to govern the conduct of human subjects research. The report itself is not legally binding, but we begin with it here because its principles underlie the current U.S. federal regulations.[73]

The BELMONT REPORT explains that "[r]espect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied."[74] As described above, informed consent is understood to ensure that individuals control whether they participate in research and that they participate only when participation is consistent with their values, preferences, and interests. The *Belmont Report* states that:

> [a]n agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. **Coercion** occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. **Undue influence**, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influence if the subject is especially vulnerable.[75]

The authors of the BELMONT REPORT clearly understood coercion and undue inducement as distinct concepts, but it is implied that both affect the voluntariness of consent. It is worth noting that the authors resisted drawing a bright line between that which is a mere inducement (i.e., ethically acceptable)

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72. THE BELMONT REPORT, *supra* note 16. Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("National Commission") in 1974 amidst "public outrage and congressional uncertainty over the Tuskegee syphilis experiments and other questionable uses of humans in research." Tom L. Beauchamp, *The Belmont Report*, *in* THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 149 (Ezekiel J. Emanuel et al. eds., 2008).

73. David A. Hyman, *Institutional Review Boards: Is this the Least Worse We Can Do?*, 101 NW. U. L. REV. 749, 750 n.3 (2007) ("Although there were classified regulations governing human experimentation issued by the Atomic Energy Commission and Department of Energy in the 1940s and 1950s, and the National Institutes of Health issued regulations on research involving human subjects in 1966, most scholars date the beginning of comprehensive feral regulation of human subjects research to 1974, when the regulation that ultimately gave rise to the Common Rule was issued.").

74. THE BELMONT REPORT, *supra* note 16.

75. *Id.* (emphasis added).

and that which is *undue* (i.e., ethically unacceptable), instead emphasizing the contextual nature of undue inducements. The BELMONT REPORT does not directly address payment.

2. The Common Rule

The Federal Policy for the Protection of Human Subjects is codified in the separate, but identical, regulations of eighteen Federal departments and agencies, and accordingly referred to as the "Common Rule."[76] The Common Rule is "a uniform regulatory floor for human subjects research . . . which generally requires informed consent, independent ethical review, and the minimization of avoidable risks."[77] Common Rule standards apply to all research funded by these eighteen departments and agencies, regardless of where that research occurs. The FDA has not adopted the Common Rule, but applies essentially the same standards to all clinical investigations of products regulated by FDA involving human subjects, regardless of funding source.[78]

The Common Rule requires IRBs to ensure that investigators will secure research participants' informed consent.[79] It states that "[a]n investigator shall seek [informed] consent only under circumstances that provide the prospective subject . . . sufficient opportunity to consider whether or not to participate and that minimize the possibility of **coercion** or **undue influence**."[80] The Common Rule does not define either term, nor does it directly address offers of payment. However, to the extent such offers trigger concerns about either coercion or undue influence, they fall within the IRB's regulatory purview to address and responsibility to resolve.

The fact that the Common Rule (and its FDA equivalent) cover almost all clinical research conducted in the U.S., and a broad swath of research conducted abroad,[81] underscores the important role of IRBs in reviewing offers of payment to research participants and the importance of understanding the many open questions IRB members—and investigators—face when assessing the acceptability of said offers.

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76. *Moral Science: Protecting Participants in Human Subjects Research*, PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES (PCSBI) 2 (2011), http://bioethics.gov/sites/default/files/Moral%20Science%20June%202012.pdf [https://perma.cc/SLX9-K4TN]. All participating departments and agencies include language identical to that of the HHS codification at 45 C.F.R. § 46, subpart A in their chapters of the Code of Federal Regulations. We will, therefore, refer to the HHS regulations.

77. *Id.*

78. 21 C.F.R. §§ 50, 56 (2015).

79. 45 C.F.R. § 46.116 (2015).

80. 45 C.F.R. § 46.116 (2015) (emphasis added).

81. PCSBI, *supra* note 76, at 39–40.

3. OHRP Frequently Asked Questions About Human Research

Created in 2000,[82] OHRP is the office within HHS that "provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research"[83] funded or conducted by the Department. OHRP's website addresses a number of Frequently Asked Questions (FAQs) about human subjects research, including questions regarding offers of payment. Because the FAQs "provide guidance that represents OHRP's current thinking on these topics",[84] they offer helpful insight, though they "should [merely] be viewed as recommendations, unless specific regulatory requirements are cited."[85]

On the one hand, OHRP acknowledges that "[p]aying research subjects in exchange for their participation is a common and, in general, acceptable practice."[86] On the other, it cautions that despite, or perhaps because of, the "lack of clear-cut standards on the boundaries of inappropriate and appropriate forms of influence, investigators and IRBs *must be vigilant* about minimizing the possibility of **coercion** and **undue influence**."[87] Although more research is needed, one might infer that a call to be "vigilant" from an important oversight body—one with a variety of enforcement mechanisms available to it, including institution-wide suspension of research—coupled with limited substantive guidance on how best to offer payment to research participants could lead to extreme caution and support expansive understandings of coercion and undue inducement. A review of OHRP enforcement letters in complaint-initiated investigations uncovered only a handful of instances in which the agency found "unethical inducement through large offers of money,"[88] but the mere threat of regulatory action in this space is often enough to shape behavior.[89] This is

82. Before OHRP was formed, the Office for Protection from Research Risks (OPRR) was housed at the NIH. OPRR was dissolved in 2000 and responsibility was transferred to the office of the Secretary of Health and Human Services.

83. Office of Human Research Prots., *About OHRP*, U.S. DEP'T HEALTH & HUM. SERVS. http://www.hhs.gov/ohrp/about [https://perma.cc/4BQU-TZ3Q]; *see also* Scott Burris & Jen Welsh, *Regulatory Paradox: A Review of Enforcement Letters Issued by the Office for Human Research Protection*, 101 NW. U. L. REV. 643, 647 (2007).

84. Office of Human Research Prots., *Frequently Asked Questions about Human Research*, U.S. DEP'T HEALTH & HUM. SERVS., http://www.hhs.gov/ohrp/policy/faq [https://perma.cc/Q45Y-DYPW].

85. *Id.*

86. Office of Human Research Protections, supra note 43.

87. *Id.* (emphasis added).

88. Burris & Welsh, *supra* note 83, at 664.

89. Consider, for example, that FDA inspection activity has a deterrent effect on industry non-compliance, though only a small portion of clinical trial sites are inspected. Mary K. Olson, *Agency Rulemaking, Political Influence, Regulation, and Industry Compliance*, 15 J.L. ECON. & ORG. 573, 599 (1999). Office of the Inspector General, *Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials*, U.S. DEP'T HEALTH & HUM. SERVS. (June 2010),

supported by our pilot data, described below, as well as anecdotal experience with IRB administrative staff and members.

4. Definitions

In one FAQ, the following question is posed: "What does it mean to minimize the possibility of coercion or undue influence?"[90] In response, OHRP provides the following definitions of coercion and undue inducement that largely—though incompletely—align with those found in the *Belmont Report*, as well as examples:

> **Coercion** occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research.[91]
>
> **Undue influence**, by contrast, often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing possible subjects. If, however, she offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.[92]

With respect to undue inducement, the FAQ observes that "it is often difficult for IRBs to draw a bright line delimiting undue influence" because it is highly contextual.[93]

5. Substantive Recommendations Regarding Payment

OHRP acknowledges that "difficult questions must be addressed by the

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http://oig.hhs.gov/oei/reports/oei-01-08-00510.pdf [https://perma.cc/T6PJ-UCD7] (FDA inspected only 1.9% of domestic clinical trial sites).

90. Office of Human Research Prots., *What Does It Mean to Minimize the Possibility of Coercion or Undue Influence?*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/Informed-Consent/index.html [https://perma.cc/TJ8P-HXQU].

91. Elsewhere within the FAQs, "overt coercion" is defined as "e.g., threatening loss of services or access to programs to which the potential subjects are otherwise entitled." Office of Human Research Prots., *Can Non-Financial Enrollment Incentives Constitute Undue Influence?*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/Informed-Consent/index.html [https://perma.cc/TJ8P-HXQU] (emphasis added).

92. Office of Human Research Prots., *supra* note 90.

93. *Id.*

IRB."[94] The FAQ "When does compensating subjects undermine informed consent or parental permission?" advises the following:

> • "Remuneration for participation in research should be just and fair. However, the specifics of each protocol will influence how those determinations are made. Both researchers and IRBs need to be familiar with the study population and the context of the research in order to make reasonable judgments about how compensation might affect participation."[95]
> • "IRBs should be cautious that payments are not so high that they create an '**undue influence**' or offer **undue inducement** that could compromise a prospective subject's examination and evaluation of the risks or affect the voluntariness of his or her choices."[96]
> • "IRBs and investigators should ensure that the consent process includes a detailed account of the terms of payment, including a description of the conditions under which a subject would receive partial or no payment (e.g., what will happen if he or she withdraws part way through the research or the investigator removes a subject from the study for medical or noncompliance reasons)."[97]
> • "[I]n studies of considerable duration or that involve multiple interactions or interventions, OHRP recommends that payment be prorated for the time of participation in the study rather than delayed until study completion, because the latter could **unduly influence** a subject's decision to exercise his or her right to withdraw at any time."[98]

It noteworthy that this FAQ links offers of payment *only* to undue inducement and not to coercion, suggesting that offers of payment cannot be coercive. We take precisely this position below, although it is one that is disputed in the research ethics community. The FAQ does not, however, explicitly say that offers of payment cannot be coercive, which would be an even clearer — and we suggest more desirable — statement on the matter. Additionally, the FAQ suggests that undue inducement affects the voluntariness element of consent.

6. FDA Information Sheet

FDA also offers an Information Sheet on Payment to Research Subjects,[99]

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94. *Id.*
95. Office of Human Research Prots., *supra* note 43.
96. *Id.* (emphasis added).
97. *Id.*
98. *Id.* (emphasis added).
99. *Payment to Research Subjects—Information Sheet*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm [https://perma.cc/JG27-

which like the OHRP FAQs is a non-binding guidance document, but also the most extensive guidance IRBs have when seeking to implement and adhere to FDA regulations. The Information Sheet acknowledges that "[i]t is not uncommon for subjects to be paid for their participation in research, especially in the early phases of investigational drug, biologic or device development."[100]

Among other things, the Information Sheet advises IRBs to "review both the amount of payment and the proposed method and timing of disbursement to assure that neither are **coercive** or present **undue influence**."[101] Specific guidelines for evaluating offers of payment include:

> • "All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document."[102]
>
> • "Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a **coercive** practice, payment to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn."[103]
>
> • "While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not **coercive**."[104]
>
> • "The IRB should determine that the amount paid as a bonus for completion is reasonable and not so large as to **unduly induce** subjects to stay in the study when they would otherwise have withdrawn."[105]

Unlike the OHRP FAQ, the FDA guidance clearly links offers of payment to *both* coercion and undue inducement. As noted above and discussed further below, we disagree with this approach. Therefore, it is useful to note that OHRP and FDA could be seen as coming out on different sides of this debate.

B. International Guidelines

While the Common Rule and its FDA equivalent cover most clinical

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100. *Id.*
101. *Id.* (emphasis added).
102. *Id.*
103. *Id.* (emphasis added).
104. *Id.* (emphasis added).
105. *Id.* (emphasis added).

research conducted in the United States,[106] investigators' and IRBs' deliberations regarding what constitutes an acceptable offer of payment may also be influenced by a number of prominent ethical guidelines relating to the conduct of biomedical research. Some countries have adopted these as regulatory requirements, while in other places, they are merely advisory. Investigators may voluntarily import them into protocols or be mandated to do so under certain conditions.

Many of these international guidelines were written in the aftermath of ethics scandals or in response to the perceived shortcomings of prior documents.[107] As a result, there is a tendency to emphasize some ethical requirements while overlooking others.[108] This context may help explain why the guidelines provide little specific guidance regarding offers of payment.

1. Nuremberg Code

The Nuremberg Code was formulated by American judges "sitting in judgment of Nazi doctors accused of conducting murderous and torturous human experiments in the concentration camps." [109] Although the Code says nothing about payment specifically, it does address coercion. The first principle is: "The voluntary consent of the human subject is absolutely essential." The Code goes on to specify that "[t]his means that the person involved should . . . be able to exercise free power of choice, without the intervention of any element of . . . **coercion**; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision."[110] Coercion is not defined, however.

2. Declaration of Helsinki

The World Medical Association's Declaration of Helsinki is "a statement of ethical principles for medical research involving human subjects . . . addressed primarily to physicians."[111] Like other guidelines and regulations discussed in this article, the Declaration places an emphasis on the importance of voluntary consent to participation in research. Additionally, the 2013 revision of Declaration states that "[t]he protocol should include information regarding . . . incentives for subjects" and be submitted for consideration and approval to an

106. PCSBI, *supra* note 76, at 31, 39–40.

107. Emanuel et al., *supra* note 26, at 2701.

108. *Id.* at 2701–02 (offering examples of selective emphases and oversights).

109. Evelyne Shuster, *Fifty Years Later: The Significance of the Nuremberg Code*, 337 NEW ENG. J. MED. 1436, 1436 (1997).

110. 10 TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS 181–182 (1949), https://www.loc.gov/rr/frd/Military_Law/pdf/NT_war-criminals_Vol-X.pdf [https://perma.cc/4GDC-Z7P4] (emphasis added).

111. WORLD MED. ASS'N (WMA), DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (2013).

IRB.[112] The Declaration does not define coercion or undue inducement, nor does it raise these concerns in relation to offers of payment.[113]

3. Good Clinical Practice Guidelines

The International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines are "an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects."[114] They provide "a unified standard for the European Union, Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in those jurisdictions."[115]

According to the ICH GCP E6 guidelines, the IRB should "review both the amount and method of payment to subjects to assure that neither presents problems of **coercion** or **undue influence** on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject."[116] Additionally, the IRB "should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified."[117] Unlike the OHRP FAQs but like the FDA information sheet on payment, the GCP guidelines suggest that payments can be both coercive and unduly influential. Neither term is defined.

4. CIOMS International Ethical Guidelines for Biomedical Research

Compared with the preceding guidelines, the recently revised 2016 International Ethical Guidelines for Health-related Research Involving Humans, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), offer a more definitive answer to questions about offers of payment to research participants.[118] Guideline 13 (Reimbursement and compensation for research participants) states:

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112. *Id.*

113. *Id.* (stating only that the research ethics committee must be free of "any other undue influence").

114. *Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance,* U.S. DEP'T HEALTH & HUMAN SERVS. (April 1996), http://www.fda.gov/downloads/Drugs/. . . /Guidances/ucm073122.pdf [https://perma.cc/2B9A-9VTY].

115. *ICH Guidance Documents,* U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219488.htm [https://perma.cc/2TYA-WR96].

116. *Guidance for Industry E6, supra* note 114, at 11 (emphasis added).

117. *Id.*

118. CIOMS, *supra* note 25, at 45 (emphasis added).

> Research participants should be reasonably reimbursed for costs directly incurred during the research, such as travel costs, and compensated reasonably for their inconvenience and time spent. Compensation can be monetary or non-monetary. The latter might include free health services unrelated to the research, medical insurance, educational materials, or other benefits.
>
> Compensation must not be so large as to induce potential participants to consent to participate in the research against their better judgment ("**undue inducement**"). A local research ethics committee must approve reimbursement and compensation for research participants.[119]

Helpfully distinguishing between reimbursement and other types of payment, the Commentary on Guideline 13 explains further that participants should not have to pay to participate in research in the form of bearing direct expenses like transportation costs themselves, and calls for participants to be reasonably reimbursed for such expenses. In addition, "participants must be appropriately compensated for the time spent and other inconveniences resulting from study participation" – although explicitly not for risk that participants agree to undertake – and payment amounts "should be calculated using the minimum hourly wage" in the trial location. The commentary goes on to clarify that the "obligation to reasonably reimburse and compensate" participants arises even when participants otherwise stand to benefit from their participation.[120]

Recognizing the relevance of a study's risk level, the commentary notes that "[e]specially when the research poses low risks, providing compensation should not raise concerns about undue inducement." This is notable among all the guidance discussed so far, as it is the only statement of a reason *not* to worry about payment in some contexts. However, the commentary does state that "as the risks of research procedures having no potential individual benefit for participants increase, so does the concern that compensation may constitute an **undue inducement**. Monetary or in-kind compensation for research participants must not be so large as to persuade them to volunteer against their better judgment or deeply held beliefs ('**undue inducement**')."[121]

The commentary acknowledges the contextual nature of undue inducement in the sense that individuals may view compensation differently depending on their personal situation. Thus, the responsibilities laid on research ethics committees are substantial:

> Research ethics committees must evaluate monetary and other forms of compensation in light of the traditions and socio-economic context of

119. *Id.*
120. *Id.*
121. *Id.*

> the particular culture and population in order to determine whether the average participant expected to enrol [sic] in the study is likely to participate in the research against his or her better judgment because of the compensation offered. The appropriateness of compensation is likely better judged by local research ethics committees than by international ones. Consultation with the local community may help to ascertain this even in the case of research conducted in the researcher's own community.[122]

In total, CIOMS offers the most explicit guidance regarding offers of payment to research participants – providing additional guidance regarding persons who are incapable of giving informed consent themselves, the timing of payment in relationship to early withdrawal, and the need for empirical study of financial incentives themselves. Nonetheless, it still leaves a considerable amount of discretion to the IRB to determine what constitutes an acceptable offer of payment. Emphasis is placed on the possibility that offers of payment will be unduly influential, rather than coercive.

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In this section, we have reviewed payment-related guidance at both the U.S. and international levels. This is important because discussions of payment-related regulations are often focused on the Common Rule, and it serves as a useful reference to assemble these documents together.

As we have indicated throughout, these documents may or may not be legally applicable depending on where research is conducted, but they are nevertheless highly influential. They consistently emphasize the importance of research participants' informed consent and point out that coercion and undue influence can vitiate consent. Yet, treatment of payment within these regulations and guidelines is highly uneven and at times contradictory. For example, whereas one might reasonably infer that OHRP does not worry about offers of payment being coercive, FDA clearly links payment to coercion, as does the ICH GCP E6 guideline.

As a result, IRB members and investigators bear significant responsibility both for determining what the terms coercion and undue influence mean, how (if at all) they apply to offers of payment, and for correctly identifying and addressing those ethical concerns when they arise.

III. AN ARGUMENT AGAINST RESEARCH EXCEPTIONALISM WITH REGARD TO PAYMENT

As Part II established, regulations and guidelines regarding offers of payment to research participants generally establish as the default that such offers are to be subjected to scrutiny because they may be unduly influential, coercive,

122. *Id.*

or both, and so might undermine the validity of research participants' informed consent. Given this default, it is perhaps unsurprising that in the context of human subjects research, offers of payment are often viewed with a high index of suspicion, despite being quite common. We attribute much of the concern about offers of payment to research participants to the problem of research exceptionalism.

Many people have been taught—or intuitively believe—that research is meaningfully different than other areas of life in which we accept burdens, discomforts, and risks. They are, therefore, much more concerned about threats to the validity of consent posed by payment in the research context than they are in other contexts, such as employment.[123] As a result, research in general, and offers of payment made to research participants in particular, are more stringently regulated and scrutinized than many other activities that involve both payment and the imposition of seemingly similar—or even greater—levels of risk.[124] While people often worry that offers of payment made to research participants may be too high, we do not hear comparable concerns voiced about payment to individuals engaged in risky work, such as police offers, firefighters, pilots, and even commercial truck drivers.[125] Indeed, many would argue that these individuals are not paid enough. Why the discrepancy?

Of course, the fact of this divergent thinking is not in and of itself proof that the current level of oversight and scrutiny applied to clinical research payments is, as a normative matter, too great. Instead, one might argue that (1) offers of payment made *elsewhere* are insufficiently scrutinized, and that we should not level-down in the research context, or (2) there are sound ethical reasons why offers of payment made to research participants, in particular, should be treated differently.[126] Position (2) is consistent with a view of justified research exceptionalism.

Here, we will identify nine arguments made in favor of research exceptionalism, some with more force and frequency than others, and show that they all ultimately fail to justify the more stringent regulation of offers of payment made to research participants. There may, we concede, be reasons to think that research is meaningfully different from other contexts and that some enhanced protections are appropriate for research participants in general. However, in our view, these reasons do not relate to payment.

123. Largent et al., *supra* note 12.

124. James Wilson & David Hunter, *Research Exceptionalism*, 10 AM. J. BIOETHICS 45, 45 (2010) (offering a "qualified defense" of research exceptionalism).

125. It may be that people in these jobs deserve higher payments for a variety of reasons—such as shift-work and specialized training or skill—but risk is among them.

126. *Cf.* Wilson & Hunter, *supra* note 124, at 45.

A. History of Ethical Abuses

Probably the foremost reason given in favor of special regulation of human subjects research is the history of egregious ethical abuses.[127] Many of the ethical guidelines and regulations governing human subjects research have grown out of particular scandals.[128] The scandal-and-reform dynamic has led to a progressive ratcheting up of research participant protections.[129]

We don't dispute the seamy history. Yet, we agree with James Wilson and David Hunter that

> [t]hese cases do provide prima facie evidence that unregulated research can be abused. However, they fall short of demonstrating the case for research exceptionalism. . . . First, they do not show that these risks are specific to research: Abuses can and have occurred in many other areas of human existence. Second, they do not show that regulation will prevent these abuses. To justify research exceptionalism, we need to demonstrate that there are risks that are *either specific to research or are more likely in research.*[130]

Additionally, and most importantly for our purposes, these foundational and transformational abuses have nothing directly to do with offers of payment. Instead, they were related to concerns with outright torture (e.g., Nazi experimentation[131]), deception (e.g., the Tuskegee syphilis studies[132]), researcher conflicts of interest (e.g., the Jesse Gelsinger gene therapy case[133]), and the like.

Even in high-profile cases where the offer of payment was subsequently subject to scrutiny, ethical fault laid with the way the trials were conducted,

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127. *See generally* Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966) (detailing examples of unethical and questionably ethical studies).

128. Emanuel et al., *supra* note 26, at 2701.

129. Other ethics regulations also follow this scandal-reform dynamic. *See, e.g.*, G. CALVIN MACKENZIE & MICHAEL HAFKEN, SCANDAL PROOF: DO ETHICS LAWS MAKE GOVERNMENT ETHICAL? 55–86 (2002) (discussing cumulative efforts to regulate the ethical behavior of executive branch officials).

130. Wilson & Hunter, *supra* note 124, at 49 (emphasis added).

131. George J. Annas & Michael A. Grodin, *The Nuremberg Code*, *in* THE OXFORD TEXTBOOK OF RESEARCH ETHICS 136–37, (Ezekiel J. Emanuelet al. eds., 2008) ("The victims who did not die in the course of such experiments surely wished that they had.").

132. *See generally* JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT (1992).

133. Gelsinger, who was 18 years old, participated in a gene therapy trial at the University of Pennsylvania. He experienced a severe immune reaction to the vector (i.e., the gene's delivery vehicle) and became the first person to die because of participation in gene-therapy research. The major questions after his death involved informed consent and conflict of interest disclosure. Sheryl Gay Stolberg, *The Biotech Death of Jesse Gelsinger*, N.Y. TIMES MAG. (Nov. 28, 1999), http://www.nytimes.com/1999/11/28/magazine/the-biotech-death-of-jesse-gelsinger.html [https://perma.cc/SWJ2-H2LQ].

rather than with the offer of payment itself (e.g., the TeGenero TGN1412 trial[134]). Critically, the tragic outcomes attributable to ethical violations in these cases would have been no more acceptable if payment had *not* been offered to research participants.[135] The mere fact that money was offered to research participants should not, therefore, bias our evaluation of whether the research was conducted ethically. Scandal does not make payment in the research context exceptional.

B. Risk of Harm to Research Participants

Another common argument given in support of research exceptionalism is that research exposes participants to the risk of harm. Research-related risks can be analyzed as a function of two distinct components: (1) the likelihood that harm will occur, and (2) should it occur, the magnitude of the harm.[136]

Admittedly, participation in research can be associated with significant risks: individuals have been seriously injured and even died as a result of their participation.[137] Yet, "research participation . . . is not usually as risky as the general public perceives it to be."[138] Additionally, many quotidian activities expose individuals to at least some risk of harm. The pervasive nature of risk is acknowledged in the Common Rule, which defines minimal risk research in terms of risks "ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."[139] Even granting that *some* research studies are riskier than the risks we ordinarily assume in daily life, "[i]t is not clear that research *per se* is specifically risky."[140] Therefore, the risk of harm does not itself justify research exceptionalism.

The argument from risk of harm also clearly fails when applied more narrowly to offers of payment to research participants. As explained in detail in our other scholarship, we think that participation in research is most appropriately analogized to labor; relevant comparators include police work and military service, jobs that are important to the community but also offer personal

134. *See generally* Ezekiel J. Emanuel & Franklin G. Miller, *Money and Distorted Ethical Judgments about Research: Ethical Assessment of the TeGenero TGN1412 Trial*, 7 AM. J. BIOETHICS 76 (2007); Wadman, *supra* note 68.

135. Emanuel & Miller, *supra* note 134, at 78.

136. Annette Rid et al., *Evaluating the Risks of Clinical Research*, 304 JAMA 1472, 1473 (2010).

137. *See, e.g.*, Julian Savulescu, *Harm, Ethics Committees and the Gene Therapy Death*, 27 J. MED. ETHICS 148 (2001) (discussing the death of Jesse Gelsinger); Robert Steinbrook, *Protecting Research Subjects—The Crisis at Johns Hopkins*, 346 NEW ENG. J. MED. 716 (2002) (discussing the death of 24-year-old Ellen Roche in an asthma study).

138. Lynch, *supra* note 51, at 133; *see generally* Chris J.D. Zarafonetis et al., *Clinically Significant Adverse Effects in a Phase 1 Testing Program*, 24 CLINICAL PHARMACOLOGY & THERAPEUTICS 127 (1978).

139. 45 C.F.R. § 46.102(i) (2015).

140. Wilson & Hunter, *supra* note 124, at 49.

benefit.[141] There is little normative debate about whether it is acceptable to offer payment, or higher payment, to people who accept risky jobs. To the contrary, outside the research context, the main concern seems to be that people will be unfairly compensated—that is, exploited—if they are paid too *little*. For example, "[t]he life-and-death nature of the job [policing] is used to push for extremely generous . . . pay packages."[142]

> [I]n theory, the market should dictate (and some laws do) that risky work be better compensated, a phenomenon called the compensating wage differential. Further, even when risky jobs are held by those with few other options for less risky work that is comparably compensated, the law does not require that their payment be restricted on that basis.[143]

Thus, the fact that research participation exposes people to risk of harm cannot stand alone as an argument against offering payment—even generous payment—research participants.

C. Uncertainty of Risk in Research

The next possibility we consider is that it is not the risk of harm per se but some characteristic of that risk that justifies research exceptionalism. For example, it might be that the risk in research is uniquely amorphous. Research is, after all, intended to answer open questions regarding interventions about which knowledge is limited; therefore, "[u]ncertainty is a fundamental characteristic of research."[144] At the outset, it may be impossible to know with certainty the scope of potential or likely harms—as well as the potential benefits—faced by research participants.[145]

Yet, there is less uncertainty about research risks than it may appear, particularly as investigational products proceed through their development. Before a study of a new FDA-regulated product can proceed to human trials, for example, FDA must be convinced that there is adequate data from laboratory and animal testing to support the claim that the drug is safe enough to give to research participants;[146] IRB approval will be required as well, as a further check

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141. *See* Lynch, *supra* note 51, at 141.

142. David Feige, *The Myth of the Hero Cop*, SLATE (MAY 25, 2015), http://www.slate.com/articles/news_and_politics/politics/2015/05/the_myth_of_the_hero_cop_police_unions_have_spread_a_dangerous_message_about.html [https://perma.cc/ZD2B-YZGA].

143. Lynch, *supra* note 51, at 157 (internal citations omitted).

144. Wilson & Hunter, *supra* note 124, at 51.

145. *Id.*

146. *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm [https://perma.cc/WCP7-U6W9]; *see also IND Application Procedures: Clinical Hold*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm362971.htm

on whether the risks are appropriately minimized and reasonable. Moreover, as clinical research progresses through the different phases, there will be a substantial accretion of data; therefore, uncertainty should dissipate over time.

While granting that there is some degree of uncertainty in clinical research, it is necessary to point out that there is uncertainty about risks in many contexts—consider, for example, exposure to environmental pollutants, or even approved drug products. When risk is uncertain, regulation can be an appropriate response, but the key observation to our present analysis is that it is not clear why research should be regulated *more* stringently than other areas similarly characterized by uncertainty.

Looking to offers of payment specifically, even if uncertainty about research risks was somehow unique, it is unclear why that uncertainty would be a reason to pay research participants *less*. Above, we discussed the compensating wage differential for risky work, and here, we would reiterate that it may be appropriate to pay research participants *more* when risks are uncertain, precisely as compensation for that uncertainty. The argument from uncertainty of risks does not necessarily or even obviously lead to the conclusion that offers of payment to research participants should be constrained, and so further justificatory work is needed to defend research exceptionalism with respect to payment.

D. Risk Assumed for the Benefit of Others

A fourth possible argument in favor of research exceptionalism is that the purpose of research is to generate socially valuable knowledge. As discussed above, research-related risks and burdens are justified not in light of the potential to benefit the individual research participant but in light of their potential to benefit future patients. In research, unlike in other activities, the argument goes, there is tension between the individual good and the public good because risk is assumed for the benefit of others, and so additional scrutiny is needed.

This apparent distinction also proves illusory, however. First, at least some individuals may, in fact, benefit from participation in research, for example from a successful experimental intervention or from free medical care that is delivered in the course of the study.[147] Even when individuals are motivated to participate in clinical research solely by altruism, they may benefit by contributing to research when they share the ends for which the research is undertaken.[148]

[https://perma.cc/GF4A-LBJM].

147. Nancy M.P. King, *Defining and Describing Benefit Appropriately in Clinical Trials*, 28 J.L. MED. & ETHICS 332, 333 (2000). While payments made to research participants are, technically, a collateral benefit, they are treated separately in research ethics and policy. *Id.*

148. *Cf.* Lynn A. Jansen, *The Problem with Optimism in Clinical Trials*, 28 IRB: ETHICS & HUM. RES. 13, 18 (2006).

Second, assumption of risk in other areas of life cannot accurately be characterized as entirely self-interested; it is often also for the benefit of society. Again, consider police officers. While it is clearly in their personal interests to work in order to collect a paycheck, their jobs only exist because *others* experience a clear benefit and, therefore, create demand for such jobs. Additionally, consider the job of commercial fishing – a risky occupation that exists to satisfy consumer demand for fish; the social benefit is mere satisfaction of consumers' taste for fish.

If society is willing to pay people to engage in risky but socially beneficial activities – even when the benefits are arguably frivolous, as in the fishing example – "then consistency seems to require that they also be allowed to receive payments for participating in socially beneficial research involving serious risk."[149] Thus, the argument that risk is assumed for the benefit of others in clinical research also fails to support the exceptional scrutiny given to research payments.

E. The Optional Nature of Medical Progress

A fifth possible argument—a variant of that just considered—is that medical progress is optional, whereas other risky but socially beneficial endeavors are not. Hans Jonas has, for instance, admonished us "not [to] forget that progress [in the conquest of disease] is an optional goal."[150]

Relatedly, and arguing specifically against payment of research participants, Paul McNeil concedes that some dangerous work, such as fire fighting, is necessary, but he denies that "experiments are . . . necessary to society in the way in which some dangerous work may be."[151] He argues that the risks of research cannot be justified in the same way as the risks of necessary work. McNeil's distinction, fails, however. As we have explained elsewhere:

> If dangerous work such as fire fighting is necessary . . . why is dangerous work such as research participation — which may also save lives and meet basic human needs — any less so? There seems to be no reason to distinguish between different types of potentially preventable deaths when people have voluntarily put themselves at risk in the

149. Terrence F. Ackerman, *An Ethical Framework for the Practice of Paying Research Subjects*, 11 IRB: ETHICS & HUM. RES. 1, 1 (1989).

150. Hans Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, DAEDALUS 219, 245 (1969). Jonas goes on to say, "Let us also remember that a slower progress in the conquest of disease would not threaten society, grievous as it is to those who have to deplore that their particular be not yet conquered, but that society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having." *Id.*

151. Paul McNeill, *Paying People to Participate in Research: Why Not?*, 11 BIOETHICS 390, 392 (1997).

service of a greater good.[152]

On our view, medical progress is not optional. Some kinds of research are morally obligatory to conduct, assuming they can be conducted ethically. One might respond that a fire fighter who rushes into a burning building to save someone offers an *immediate* benefit, whereas participation in research saves lives over a much longer time-scale. Admittedly, that will often be the case. Yet, as a matter of intergenerational equity, it is unclear why we should favor lives currently in existence (or presently in jeopardy) over lives not yet in existence (or not presently in jeopardy). Our moral impulse to save identifiable lives should not blind us to the imperative to save statistical lives when possible.[153]

Yet, even if we were to assume *arguendo* that medical progress is optional, one must allow that some risky jobs that yield social benefits but are indisputably optional, like commercial fishing, exist without controversy. If we allow payment for those jobs—and we do—then the optional nature of social benefit, if true, could not justify research exceptionalism with respect to payment.

F. Difficulty Securing Research Participants' Informed Consent

Another argument for research exceptionalism stems from the now substantial evidence that many who participate in research suffer from the therapeutic misconception—that is, they confuse the goals of clinical research (social benefit) with the goals of clinical care (individual benefit)—and, at least some individuals may be unaware that they are participating in research at all.[154] More generally, some people may assume the risks of research participation despite a failure to fully comprehend them. Some commentators use this fact to argue that "we should not allow people to make significant life choices without fully understanding the potential consequences for their lives."[155]

Yet, as Wilson and Hunter astutely point out, "[W]hile research protocols may be difficult to understand, they are no more difficult and often considerably

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152. Lynch, *supra* note 51, at 157.

153. In our personal morality, we believe that we do have greater obligations to identified individuals than to individuals unknown to us. Personal morality cannot, however, be neatly transposed on the public sphere. *Cf.* Emily A. Largent & Steven D. Pearson, *Which Orphans Will Find a Home? The Rule of Rescue in Resource Allocation for Rare Diseases*, 42 HASTINGS CENTER REP. 27, 30 (2012).

154. *See, e.g.*, Paul S. Appelbaum et al., *Therapeutic Misconception in Clinical Research: Frequency and Risk Factors*, 26 IRB: ETHICS & HUM. RES. 1, 4–5 (2004) ("A total of 61.8% (n=139) of participants were judged to have a TM."); Charles W. Lidz et al., *Therapeutic Misconception and the Appreciation of Risks in Clinical Trials*, 58 SOC. SCI. & MED. 1689, 1693 (2004) ("23.9% (n = 37) of subjects reported *no risks or disadvantages* of any sort from participating in these trials."); Steven Joffe et al., *Quality of Informed Consent in Cancer Clinical Trials: A Cross-Sectional Survey*, 358 LANCET 1772, 1774 (2001) ("A quarter of respondents did not agree that the main purpose of clinical trials is to benefit future patients. Many did not realise that the treatment being research was not proven to be the best for their cancer.").

155. Wilson & Hunter, *supra* note 124, at 50.

less difficult to understand than many official documents such as the fine print on mortgage documentation."[156] Of course, the risks are not clearly analogous (e.g., physical v. financial), but as the housing crisis made clear, signing a mortgage without full comprehension can have devastating repercussions. Moreover, the conduct of research—like mortgages—is heavily regulated, and there are calls to make informational documents easier to understand in both contexts.[157] Nevertheless, the fact that it is difficult to secure truly informed consent from research participants does not, on its own, justify research exceptionalism. True understanding is a challenge in many contexts.

In fact, difficulty in securing research participants' genuinely informed consent may be a stronger argument *in favor of* payment than against it. Offers of payment may help research participants distinguish clinical research from clinical care, since offering payment to research participants "might send the message that they were participating in these trials for the sake of science and should be compensated for it, which would not occur if they were . . . expected to benefit from it."[158] Certainly, our doctors do not pay us in the course of clinical care; instead, we pay them. Accordingly, any offer of payment might help flag for research participants the distinct risks and burdens of research, presumably with higher payments offering even stronger signals. This is an empirical claim that deserves further examination.

G. Commodification

One potential justification for research exceptionalism with respect to payment, in particular, is that offering to pay people who participate is wrongful commodification. It has been said, for example, that "[p]ayment to patients to serve as research subjects is an ethically unacceptable commodification of research practice."[159] Individuals concerned with commodification feel that it is improper to offer money for certain goods or services, even if the validity of the consent is not in doubt. This may be a threshold concern as to whether payment

156. *Id.*

157. The Consumer Financial Protection Bureau's (CFPB) Know Before You Owe mortgage disclosure rule is "designed to help consumers . . . avoid costly surprises at the closing table." *Know Before You Owe – Mortgages*, CONSUMER FIN. PROTECTION BUREAU, http://www.consumerfinance.gov/know-before-you-owe/ [https://perma.cc/AH2J-97KG]. Similarly, the NPRM aims to address concerns that "[i]nformed-consent documents grow ever longer and consistently exceed the eighth-grade reading level, with wide variation in participants' comprehension." Ezekiel J. Emanuel, *Reform of Clinical Research Regulations, Finally*, 373 NEW ENG. J. MED. 2296, 2297 (2015).

158. William Glannon, *Phase I Oncology Trials: Why the Therapeutic Misconception Will Not Go Away*, 32 J. MED. ETHICS 252, 254 (2008) ("[T]his option at best would ameliorate but not resolve the problem of misperception about research."); *see also* Dickert & Grady, *supra* note 39, at 198.

159. Ruth Macklin, The Paradoxical Case of Payment as Benefit to Research Subjects, 11 IRB: ETHICS & HUM. RES. 1, 3 (1989).

can be offered at all—and not just the amount of payment.

Commodification concerns do animate certain laws and policies outside the research context. For example, a central provision of the National Organ Transplant Act (NOTA), § 301(a), bans the buying and selling of human organs.[160] The legislative history of NOTA clearly shows that Congress felt that buying and selling of organs was contrary to society's moral values.[161] One might question—as many have—whether prohibitions against organ sales are appropriate on these grounds.[162] Yet, even if one accepts that commodification concerns are relevant in some contexts, *services* offered by research participants are not the same as selling the constituent *parts* of one's body. As we have suggested throughout this section, participation in research is most appropriately analogized to essential (albeit unskilled) labor.[163] In the context of unskilled labor—and skilled labor as well—we generally permit people to sell their bodily services,[164] even when sale of those services exposes them to risk of bodily harm. It should be "no more worrisome to commodify a person's labor as a research subject than to commodify a person's labor in other contexts, which happens all the time."[165]

H. Crowding Out Altruism

As mentioned above, a minority of commentators believes that altruism should be the *sole* motivation for research participation.[166] For them, this may be a threshold concern as to whether payment can be offered *at all* for research participation. Most commentators, however, have focused on the conditions under which offers of payment can be ethical, suggesting that research participation does not have to be exclusively or even primarily altruistically motivated.

Yet, even some who accept a role for offers of payment continue to emphasize the importance of preserving altruistic motivation. Lynn Jansen observes, "Those who seek to justify clinical research often point to the possibility that participants . . . have altruistic motives for participating."[167] The

160. 42 U.S.C. § 274e(a) (2012).

161. Emily A. Largent, *NOTA: Not A Good Act for Tissues to Follow*, 19 QUINNIPIAC HEALTH L.J. 179 (2016) (analyzing prohibitions against the sale of human organs and tissues).

162. *See id.*

163. Lynch, *supra* note 51, at 137.

164. Obvious exceptions would be surrogacy and sex work. While it is beyond the scope of the present article to defend this proposition, we are of the opinion that it should generally be permissible to sell the bodily services of surrogacy and sex. *See, e.g.*, Martha C. Nussbaum, *"Whether from Reason or Prejudice": Taking Money for Bodily Services*, 27 J. LEGAL STUDIES 693 (1998).

165. Lynch, *supra* note 51, at 159.

166. Tod Chambers, *Participation as Commodity, Participation as Gift*, 1 AM. J. BIOETHICS 48, 48 (2001).

167. Lynn A. Jansen, *The Ethics of Altruism in Clinical Research,* 39 HASTINGS CENTER REP.

argument goes that if research participants have genuinely altruistic motives, "then it is easier to justify imposing costs and sacrifices on them in the course of a trial" than if they do not.[168] That is, altruism plays an ethically significant role in justifying the imposition of risk on research participants. Another argument for research exceptionalism regarding payment, then, is that offers of payment must be closely scrutinized to avoid the perverse consequence of diluting prospective participants' intrinsic motivation to enroll in research.[169]

In practice, and as mentioned above, research participants—even those who are paid—report experiencing a variety of motivations, including altruism.[170] This is comparable to studies of police officers that have found individuals enter policing for both altruistic and practical reasons; they value the opportunity to help others but also the attractive job benefits.[171] These findings are both unsurprising and untroubling; if individuals are capable of satisfying a role's requirements, why should their motivations matter? Moreover, given that a variety of motivations can simultaneously coexist within a single individual, there is no clear argument for why altruistic motivation should be valued more highly than financial motivation in research, or than it is (or should be) in other contexts.

Two possible practical implications of crowding out altruistic motivations among research participants in favor of financial motivations are more troubling, and could potentially justify greater scrutiny of offers of payment in the research context than elsewhere. If offering payment dilutes altruistic motivation, this might (1) reduce the overall pool of prospective research participants, i.e., some altruists may not participate at all if payment is offered because they find the offer repugnant, and/or (2) selectively appeal to individuals who are somehow less desirable as research participants due to their motivation by payment.[172] While a number of experimental studies have examined the effects of financial incentives on altruistic motivations in other contexts, particularly blood donation, and generally found results consistent with the crowing out hypothesis,[173] data is needed about research participation in particular. We grant that these concerns may be valid in some research contexts; however, they cannot justify restrictive

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26, 26 (2009).

168. *Id.* at 30.

169. *Cf.* RICHARD M. TITMUSS, THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY (1971).

170. *See generally* Leanne Stunkel & Christine Grady, *More Than Money: A Review of the Literature Examining Healthy Volunteer Motivations*, 32 CONTEMP. CLINICAL TRIALS 342 (2011).

171. Anthony J. Raganella & Michael D. White, *Race, Gender, and Motivation for Becoming a Police Officer: Implications for Building a Representative Police Department*, 21 J. CRIM. JUST. 501, 509 (2004).

172. *Cf.* Simone A. Glynn et al., *Attitudes Toward Blood Donation Incentives in the United States: Implications for Donor Recruitment*, 43 TRANSFUSION 7 (2003).

173. Nicola Lacetera & Mario Macis, *Do All Material Incentives for Pro-Social Activities Backfire? The Response to Cash and Non-Cash Incentives for Blood Donations*, 31 J. ECON. PSYCHOL. 738, 738 (2010).

approaches to payment in *all* instances. Rather, a more tailored approach is appropriate, focused on those situations in which payment might have damaging instrumental effects, and also considering whether those effects might be avoided through mechanisms other than limiting payment.

I. Importance of Public Trust

The final argument we consider in favor of research exceptionalism has nothing to do with protecting research participants themselves, but rather with protecting the research enterprise of which they are a part. Public trust is "essential to secure funding and institutional support for research and to recruit human subjects."[174] Therefore, the argument goes, research exceptionalism is justified if it promotes and preserves the public trust. Wertheimer observed,

> Whereas society accepts with a relative yawn the fact that people incur job related injuries or deaths as coal miners, fishermen, and off-shore oil service workers, society seems to react with great intensity to research related injuries and deaths, as evidenced by the public concern with the Jesse Gelsinger case.[175]

As our replies to prior arguments suggest, we believe the public is mistaken to react more intensely to harms attributable to research participation than to harms attributable to traditional work. Yet, even if that more intense response is mistaken, "the public trust argument maintains that public beliefs are a fact that must be accommodated."[176]

In response, we first note that there is little evidence that "members of the public are both generally aware of the existence of [IRBs] and find the notion reassuring."[177] In other words, they may simply be unaware of the ways in which they are protected from research risks, such that these protections cannot possibly contribute to trust building. More specifically, it is only speculative that research exceptionalism with respect to payment specifically promotes public trust. To the contrary, rigorously restricting offers of payment to research participants—indeed, "protecting" them from offers of payment—could erode public trust by suggesting that research is more dangerous than it really is, and that participation is something to be avoided. If individuals nonetheless choose to participate, restricting payment could also cause research participants to feel they have been treated unfairly as a result of inadequate compensation.

Beyond these considerations, we believe it would be a mistake to

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174. David B. Resnik, *Public Trust as a Policy Goal for Research with Human Subjects*, 10 AM. J. BIOETHICS 15, 16 (2010); *see also* Emily A. Largent, *What's Trust Got to Do with It? Trust and the Importance of the Research-Care Distinction*, 15 AM. J. BIOETHICS 22 (2015).

175. Wertheimer, *supra* note 49, at 116.

176. *Id.*

177. Wilson & Hunter, *supra* note 124, at 51.

accommodate erroneous beliefs that research is dramatically different from other potentially risky/uncertain endeavors, and instead favor attempts at education that build the right kinds of trust. Therefore, public trust—while doubtlessly important to the research enterprise—is not an acceptable argument for research exceptionalism, particularly with regard to payment.

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We have considered nine arguments sometimes made in favor of research exceptionalism with respect to payment—that is, in favor of the view that offers of payment to research participants need to be regulated more stringently than offers of payment made to individuals in other contexts where they also assume risks for the benefit of others. For the reasons outlined above, we maintain that each of these arguments fails. Significantly, we do not claim that these arguments have failed to identify characteristics of research that might merit regulatory attention; indeed, we favor robust regulatory protections for human subjects research, including IRB review. Rather, we claim that these nine arguments fail to identify factors that justify regulating offers of payment to research participants more heavily than offers of payment made in other areas.

IV. FROM CONFUSION TO CLARITY: DEFINING COERCION AND UNDUE INDUCEMENT

As we have discussed in the preceding sections, despite a general consensus that coercion and undue inducement are to be avoided, there is a lack of clear regulatory guidance about what constitutes an acceptable offer of payment and disagreement about when offers of payment to research participants violate ethical norms. In this section, we will look at the considerable debate within the research ethics community about how best to define coercion and undue inducement. For both terms, we will highlight areas of consensus, briefly review the range of definitions offered within the literature, and offer our preferred definitions.

A. Coercion

As discussed above, there is a general ethical requirement that prospective participants give their voluntary consent to participate in research.[178] The main worry about coercion is that it affects the voluntariness of consent, and the most prominent definitions from the bioethics literature relate to voluntariness. Here, we will consider three commonly used definitions and also address a divisive question: can offers ever be coercive?

178. Of course, there may be exceptions, such as in emergency research. *See, e.g.*, Emily A. Largent et al., *Is Emergency Research without Informed Consent Justified? The Consent Substitute Model*, 170 ARCHIVES INTERNAL MED. 668 (2010).

1. Threatening to Make One Worse Off

Recall that the influential BELMONT REPORT states that coercion "occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance."[179] It is perhaps unsurprising, then, that broad consensus exists that coercion includes the use of a threat of harm to compel another to do something against his or her will.[180] Christine Grady, for example, has stated, "By definition, coercion is understood to involve a threat of physical, psychological, or social harm in order to compel an individual to do something, such as participate in research."[181] Given the consistent references to harm, it is generally understood that the person coercing is threatening to make the person coerced *worse off* than he would be at his status quo baseline.

2. Threatening to Violate Rights

Alan Wertheimer[182] and Franklin Miller offer a view of coercion that is similar—but not identical—to that of the BELMONT REPORT.[183] On their rights-violating view of coercion:

> A coerces B to do X in a way that invalidates B's consent only if (1) A proposes or threatens to violate B's rights or not fulfill an obligation to B if B chooses not do X and (2) B has no reasonable alternative but to accept A's proposal. Both conditions are necessary.[184]

Wertheimer and Miller state that "the main point is that A's proposal is coercive only if A's 'declared unilateral plan'—[that is,] what A proposes to do if B does not do X—would violate B's rights."[185] A classic example would be when a mugger pulls a knife on someone and says: "Your money or your life." The mugger is threatening to kill his victim, which would violate the victim's right

179. THE BELMONT REPORT, *supra* note 16.

180. *E.g.*, RUTH FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 235–73 (1986); Steven D. Pearson et al., *Medicare's Requirement for Research Participation as a Condition of Coverage: Is it Ethical?*, 296 JAMA 988, 989 (2006) ("Coercion occurs when a threat of some harm compels a person to act in a manner that he or she would not otherwise choose. An example is that of a kidnapper demanding ransom. The kidnapped victim's family may be coerced into giving up money to avoid the threatened harm to their loved one.") (internal citations omitted).

181. Christine Grady, *Payment of Clinical Research Subjects*, 115 J. CLINICAL INVESTIGATION 1681, 1683 (2005).

182. Wertheimer's book COERCION (1987) "sets the current standard and starting point for continued scholarship" regarding coercion. Scott Anderson, *Coercion*, THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed., 2015), http://plato.stanford.edu/archives/sum2015/entries/coercion [https://perma.cc/W8VK-UZLJ].

183. Largent, Grady, Miller & Wertheimer, *supra* note 12, at 505.

184. Alan Wertheimer & Franklin G. Miller, *Payment for Research Participation: A Coercive Offer?*, 34 J. MED. ETHICS 389, 390 (2008).

185. *Id.*

not to be wantonly harmed by others, if the victim does not acquiesce to surrender his property. Thus, the victim is coerced to hand over his wallet.

Wertheimer and Miller concede that "[t]here is often little difference between the worse-off and the rights-violating accounts."[186] After all, both views of coercion will reach the same conclusion in the case of the mugger—what the mugger has done is coercive.

> However, when the two differ, the rights-violating approach is more accurate, because it allows us to handle (1) cases in which A has a right to make B worse off than B's status quo, and also (2) cases in which A has an obligation to render B better off than B's status quo.[187]
>
> To illustrate (1), a prosecutor does not coerce defendants into pleading guilty to a crime in exchange for a relatively lenient sentence when he proposes to take them to trial if they do not plead guilty, even though both options—pleading guilty and going to trial—are worse than B's status quo. Why? Because the prosecutor's declared unilateral plan to take the defendants to trial does not violate their rights relative to *that* option, the prosecutor is actually making an offer of leniency rather than a threat of severity. . . . The defendants' guilty pleas are voluntary.
>
> To illustrate (2), if a physician (A) has an obligation to provide a patient (B) with medical services free of charge, say, because A is employed by the national health service, then A actually does coerce B into paying a fee if A proposes not to provide such services unless B pays. And this is so even though A does not propose to make B worse off than at present if B declines.[188]

We emphasize that in the example for (2), Wertheimer and Miller say A does not propose to make B worse off than B is *at present*. In other words, B is presently untreated and would continue to be untreated if B refuses to capitulate to A's demand, so B's status quo is unchanged and B is, at least in a sense, not made any worse off. However, A has an obligation to help B achieve something superior to the status quo at present, which is why we find coercion under the rights-violating view when we may not under the worse-off view. Note that there may be disputes about how to identify the appropriate status quo, however, because under an alternative approach, one might suggest that A is indeed threatening to make B worse off by failing to achieve the status quo to which B is entitled, which is to be treated by A.

Resolving this question about which status quo baseline is the proper one to

186. *Id.*
187. *Id.*
188. *Id.*

focus on under the rights-violating view can be the source of reasonable debate. However, it is unnecessary to resolve the matter here because we argue momentarily that offers of payment cannot be coercive. Thus, in the payment context, it is unnecessary to strictly distinguish between the worse-off and rights-violation definitions of coercion, since neither will be present.

That said, we favor the rights-violating account because of its broader explanatory power. In other words, simply asking if the threat would cause harm inappropriately identifies coercion in scenarios in which harm is justifiable (e.g., when an investigator threatens to remove a subject from a potentially beneficial clinical trial for failure to comply with the study procedures), and might fail to identify coercion when harm is arguably not present, but there is an obligation to make one better off. Importantly, neither the worse-off view nor the rights-violating view of coercion falls prey to research exceptionalism, since they both reflect common views of coercion applied outside of the context of research as well.

3. No Reasonable Alternative

The notion of coercion as existing only when threats of adverse consequences (harm or rights violation) override the exercise of genuinely free choice has been characterized as "cramped" by some commentators.[189] Thus, another proposed definition of coercion is that an individual is coerced when she has *no reasonable alternative* but to accept another's proposal.[190]

In contrast to the two prior definitions, this definition does not require a threat at all. Proponents of this view classify having no reasonable alternative as a sufficient condition of coercion, not merely a necessary one.[191] Importantly, due to its expansive scope, this approach might result in a substantial portion of research being deemed coercive, since research participation may be a patient volunteer's best available alternative for therapeutic improvement or a healthy volunteer's best available alternative to make a comparable amount of money in a given period of time. Both types of participants may feel that they have no reasonable alternative, even though individuals always have the option not to participate in research as a regulatory matter.

Importantly, if one rejects research exceptionalism, the no-reasonable-alternative view is clearly wrong. Consider these familiar examples from outside the research context: first, a woman is diagnosed with breast cancer, and her oncologist tells her that she is unlikely to survive more than a year without surgery. We would not say that the oncologist has coerced the woman by offering

189. Lars Noah, *Coerced Participation in Clinical Trials: Conscripting Human Research Subjects*, 62 ADMIN. L. REV. 329, 350 (2010).

190. Joan McGregor, *"Undue Inducement" as Coercive Offers*, 5 AM. J. BIOETHICS 24, 25 (2005) (emphasis added).

191. Wertheimer & Miller, *supra* note 184, at 391.

surgery, and it would be nonsensical to claim that the woman cannot give valid consent to the surgical intervention because she has "no choice" but to have it. Second, turning to an instance in which payment changes hands, it is unlikely anyone would say an individual had been coerced to take an unpleasant, risky (but perfectly legal) job if that was his best or even only option to earn sufficient funds to cover his bills. In common parlance, we may suggest that both of these individuals were "forced" in some way to make an unpleasant decision, but we would not maintain that there had been any ethical violation. If we do not think that morally problematic coercion occurs in these circumstances, it would be unjustifiable research exceptionalism to argue that it occurs when research participants believe—in the absence of any threat—that they have no reasonable alternative but to participate in research due to an offer of payment.

4. Coercive Offers?

A notable fissure in the literature relates to whether *genuine* offers, rather than threats, can ever be coercive.[192] One of the most visible advocates of the view that offers can be coercive is Ruth Macklin.[193] In a 1989 article, she noted that the "reason for holding that it is ethically inappropriate to pay patients to be research subjects is that [offers of payment are] likely to be coercive."[194] Joan McGregor more explicitly links the concept of coercive offers to the no-reasonable-alternative view just discussed. She suggests that coercive offers are "*offers* because they propose to make the person 'better off' relative to his or her baseline . . . but they are *coercive* since, because of the recipient's lack of options, the proposal is likely to present the only eligible choice."[195] Others have accepted that offers may be coercive on the condition that the offerer is responsible for the offeree's bad circumstances.[196]

Many, however, have reached a contrary conclusion and assert that genuine offers (as opposed to veiled threats) cannot be coercive.[197] While threats reduce

192. Obviously, a threat may be veiled such that it appears to be an offer (e.g., "I will refrain from shooting you if you give me your money."). This would not be a genuine offer.

193. Ruth Macklin, *'Due' and 'Undue' Inducements: On Paying Money to Research Subjects*, 3 IRB: ETHICS & HUM. RES. 1 (1981). Macklin demurred from saying more about this, writing, "Space does not permit a discussion here of the distinction between undue inducement and coercive offers." *Id.* at 3 n.7.

194. Ruth Macklin, *The Paradoxical Case of Payment as Benefit to Research Subjects*, 11 IRB: ETHICS & HUM. RES. 1, 3 (1989).

195. McGregor, *supra* note 190 (arguing that *"undue inducements* might be referred to as 'coercive offers'"); *see also* Joan McGregor, *Bargaining Advantages and Coercion in the Market*, 14 PHIL. RES. ARCHIVES 23 (1988); Joan L. McGregor, *Free Markets, Bargaining Power, and the Rules of Exchange*, 5 PUB. AFF. QUARTERLY 353 (1991).

196. Martin Wilkinson & Andrew Moore, *Inducement in Research*, 11 BIOETHICS 373, 378 (1997).

197. Wertheimer & Miller, *supra* note 184, at 390; *see also* FADEN & BEAUCHAMP, supra note 180, at 235–73; Alan Wertheimer & Franklin G. Miller, *There are (STILL) No Coercive Offers*, 40 J. MED. ETHICS 592 (2014).

the choices available to an individual, genuine offers expand the individual's choice set and, therefore, by definition, do not coerce.[198] Wertheimer and Miller are emphatic that the "claim that the offer of financial payments can actually constitute a coercive offer in a manner that undermines informed consent is both false and incoherent, because *genuine offers cannot coerce*."[199] If one thinks that coercion requires a threat (whether of harm or of rights violations), as we do, offers of payment to research participants cannot be coercive.

For emphasis, our view is that *coercion is not a valid or relevant concern when evaluating offers of payment*, although that is not to say that subjects may not be coerced to participate in other ways. This conclusion does not definitively resolve the question of whether offers of payment in the research context are ethically permissible, however, since they may, in some circumstances, cause undue inducement.

B. Undue Inducement

Although there is also a lack of consensus about how to define undue inducement, there are several points of general agreement. First, if an inducement is undue, it could "prompt subjects to lie, deceive, or conceal information that, if known, would disqualify them as participants in a research project."[200] This not only threatens to harm research participants—for example, by exposing them to risks that the exclusion criteria were designed to shield them from—but also jeopardizes the scientific integrity of the research.

A second area of agreement is that determining the existence of an undue inducement is highly contextual. For example, Emanuel, Wendler, and Grady state, "[L]ocal traditions and economic conditions will influence when financial payments may constitute undue inducements."[201] Wertheimer and Miller suggest that an individual's situation determines whether there is undue inducement; they emphasize that the "distinction between an unproblematic . . . inducement and an undue inducement is not a feature of the inducement itself. It is a function of the relation between the inducement and the subject's response to it."[202] Ruth Grant and Jeremy Sugarman have written that "*[u]nder certain conditions*, incentives are implicated in problems of manipulation in the form of undue influence."[203]

198. Wertheimer & Miller, *supra* note 184, at 390.

199. *Id.* at 389.

200. Macklin, *supra* note 194, at 2; *see also* U.S. DEP'T HEALTH & HUM. SERVS., INSTITUTIONAL REVIEW BOARD GUIDEBOOK ch. 3 (1993) (warning that undue inducements "may prompt subjects to lie or conceal information that, if known, would disqualify them from enrolling—or continuing—as participants in a research project"). *But see* Ezekiel J. Emanuel, *Ending Concerns About Undue Inducement*, 32 J.L. MED. & ETHICS 100, 103–104 (2004) (stating that it is unclear whether lying is a general problem).

201. Emanuel, Wendler & Grady, *supra* note 26, at 2708.

202. Wertheimer & Miller, *supra* note 184, at 391.

203. Grant & Sugarman, *supra* note 24, at 732 (emphasis added). For Grant and Sugarman,

Finally, Ruth Macklin explored the question of how large a payment constitutes undue inducement and found it "impossible to arrive at a single, objective criterion serving to mark off due from undue monetary inducements to participate in research."[204]

Taking these areas of consensus as our starting point, we will consider three commonly used definitions of undue inducement and also review the empirical evidence regarding the actual existence of undue inducement in research.

1. Excessive Reward

According to the BELMONT REPORT, "undue influence. . . occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance."[205] On this view, the defining feature of an undue inducement is an offer so disproportionate to what the person is asked to do that it alone appears as evidence of nefarious intent. Of course, what constitutes a disproportionate offer may be subjective.

2. Excessive Reward Producing Bad Judgment Entailing Risk of Harm

Ezekiel Emanuel offers a four-part definition of undue inducements, of which a reward's excessiveness is only one feature:

> First, they entail an offer of a welcomed good, a positive incentive. The induced person is getting something he or she deems desirable. Second, the incentive, by some metric, appears excessive or irresistible. While there is no physical force or external psychological pressure, there is considerable internal attraction because of the quantity or type of the incentive. Third, the incentive does not just make the person do something they are not otherwise induced to do. The incentive must produce bad judgments. Finally, the bad judgments must in turn engender ethically, legally, or prudentially undesirable activities. The activities are undesirable because they contravene the person's interests and thereby harm them. While bad judgment is necessary, alone it is insufficient to constitute undue inducement. Undue inducement requires the action entail a substantial risk of serious harm . . . That is, there must be a risk of a serious adverse effect for the person. Absent potentially

incentives become problematic when conjoined with "the following factors, singly or in combination with one another. Where the subject is in a dependency relationship with the researcher, where the risks are particularly high, where the research is degrading, where the participant will only consent if the incentive is relatively large because the participant's aversion to the study is strong, and where the aversion is a principled one—when these conditions are present, the use of incentives is highly questionable." *Id.*

204. Macklin, *supra* note 194, at 2.

205. THE BELMONT REPORT, *supra* note 16.

> serious adverse consequences of the bad judgment there is no undue inducement.[206]

Emanuel stresses that all four elements are necessary for an undue inducement to exist.[207] The first condition, that the thing offered be a positive incentive, immediately distinguishes undue inducement from our preferred view of coercion, which requires a threat. The second condition requires—like the excessive-reward view—that the incentive is relatively large in light of what is being asked. Condition three distinguishes *undue* inducements from *mere* inducements, which is a critical distinction since mere inducements are not morally problematic (e.g., paying employees a salary so they show up to work, which they would not be inclined to do for free). By contrast, an undue inducement is a genuine offer that "distorts people's reasoning abilities to such a degree that they undertake something that exposes them to unreasonable risks, the kind of risks they would not do were they more sober and reasoning clearly, or to forsake deeply held value."[208] The fourth condition requires that engaging in the activity be unreasonably against a person's interests. The irresistible nature of the inducement coupled with the cognitive distortion results in acceptance of unreasonable risks.

Unlike the excessive-reward view, which speaks solely to the size and nature of the offer, the Emanuel account of undue inducement has the advantage of speaking to how the offer affects the target (i.e., the potential research participant). Emanuel writes that "[i]nducements prompt ethical concern when they distort people's judgment, encouraging them to engage in activities that contravene their interests because they are harmful."[209] Thus, his account is superior to the excessive-reward view because it clearly articulates the widely held concern that an undue inducement creates a cognitive distortion that impacts the validity of consent to enroll.[210] It also provides additional criteria that more comprehensively articulate what is wrong about undue inducement.

On our view, as on Emanuel's, if an offer of payment, even an extremely large one, simply motivates people to enroll in research when they otherwise would not—and does not distort their perception of the risks or lead them to lie—then it is a *mere* inducement and not an *undue* one.

> Given that inducement is a common element of human life, it seems difficult to see what would be uniquely worrisome about inducement in

206. Emanuel, *supra* note 200, at 101.

207. Emanuel, *supra* note 24, at 9.

208. *Id.*

209. Emanuel, *supra* note 200, at 100.

210. *See, e.g.*, U.S. DEP'T HEALTH & HUM. SERVS., INSTITUTIONAL REVIEW BOARD GUIDEBOOK ch. 3 (1993) (warning that offers that are "too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment" about the risks of participation in research). Wertheimer & Miller, *supra* note 184, at 391.

> research. Working life often involves inducements and in particular sometimes involves inducements for engaging in risky working behavior (so-called "danger money") . . . If we are to complain about inducement in research, it seems apt to consider it elsewhere as well.[211]

Thus, without research exceptionalism, it is difficult to show that anything is wrong with the use of offers of payment merely to induce participation in research. In contrast, it is consistent with views of offers of payment outside of research to be concerned when amounts are so high as to cause people to behave irrationally in ways that could result in unreasonable harm.

What are the practical implications of this definition? According to Emanuel, "[u]ndue inducement cannot occur in otherwise ethical clinical research because there is no possibility of excessive risks, of assuming risks a reasonable person would not assume."[212] This is because IRB approval is conditioned on a determination that a study has a favorable risk-benefit ratio, completely independent of any offer of payment, and a person could reasonably decide to participate.[213] IRBs "are required to determine that any risks of serious harm are *offset or outweighed* by either the prospect of individual benefit or by the value of the knowledge that the trial is designed to generate."[214] Even when the social value of a proposed study is very high, IRBs must ensure that risks to individual participants have been minimized. Thus, according to Emanuel, once a protocol has been approved by an IRB, it is essentially by definition a reasonable proposal to put before potential participants.

Nonetheless, because an IRB is approving a protocol for a *general* population, and not evaluating the circumstances of *individual* participants, we suggest that it remains possible that in some cases, an individual's particular circumstances might make his or her participation in an approved study unreasonable, i.e., the result of bad judgment. In other words, it is possible that participation is against the individual interest of any particular research participant.[215] One might, for example, think of a devout Jehovah's Witness who is considering participating in an IRB-approved study that requires receiving a blood transfusion because it is high paying.[216] For this reason, we do not ascribe to Emanuel's view that undue inducements *cannot* occur in otherwise ethical

211. Wilson & Hunter, *supra* note 124, at 50.

212. Emanuel, *supra* note 24, at 11.

213. *Id.*

214. Alex John London, *Undue Inducements and Reasonable Risks: Will the Dismal Science Lead to Dismal Research Ethics*, 5 AM. J. BIOETHICS 29, 30 (2005).

215. Participants might also be motivated to lie in order to participate in research, thereby skirting IRB protections.

216. *Why Don't Jehovah's Witnesses Accept Blood Transfusions?*, JEHOVAH'S WITNESSES, https://www.jw.org/en/jehovahs-witnesses/faq/jehovahs-witnesses-why-no-blood-transfusions [https://perma.cc/E7GU-HWKJ].

research.[217]

However, we do think they are relatively *unlikely* to occur. This is because situations in which an individual's interests may be so unique as to fall completely outside of the risks and benefits evaluated by the IRB are likely to be rare. A default position of encouraging highly restrictive approaches to offers of payment in research—intended to forestall undue inducements—is, therefore, inappropriate if IRB review functions as intended, i.e., as a bulwark against unethical research.

3. Coercive Offers

Professor Joan McGregor flatly rejects Emanuel's four-part definition of undue inducement as "wrong."[218] She counters, "Only the first condition from his list, that a good is offered in exchange for something, is necessary for undue inducement. The other conditions are too vague to be useful or are clearly not necessary conditions."[219]

McGregor instead favors defining undue inducements as "coercive offers."[220] Notably, this seemingly eliminates undue inducement as a distinct concept and places McGregor back in the discussion of coercion above. From McGregor's perspective, the prohibition against undue inducements is intended to guard against taking advantage of vulnerable populations, including impoverished persons with few, if any, alternatives.[221] Note the similarity of this position to the view of coercion as simply having no reasonable alternative. For reasons discussed above, we find this definition untenable.

4. Empirical Evidence of Undue Inducement

Once undue inducement is defined to include distortion of a person's rational risk assessment as a necessary condition, we have an empirical question: does such distortion actually occur in practice? Importantly, available empirical research suggests that it may not. To the contrary, some studies indicate that offers of payment draw prospective research participants' attention to risks (rather than causing risks to be ignored), while other studies have found no association between offers of payment and perceived research risk.

Cynthia Cryder and colleagues found that while higher offers of payment increased willingness to participate, these offers also increased perceived risk and

217. Emily A. Largent & Holly Fernandez Lynch, *Paying Research Participants: The Outsized Influence of "Undue Influence"*, 39 IRB: ETHICS & HUM. RES. ___ (forthcoming 2017).

218. McGregor, *supra* note 190 (suggesting that Emanuel's account fails to capture our intuitions about Joel Feinberg's "lecherous millionaire" example, in which a millionaire offers to pay for a sick boy's medical care if his impoverished mother will be the millionaire's mistress).

219. *Id.* at 24.

220. *Id.*

221. *Id.*

the time spent reviewing information about research-related risks.[222] Jacquelyn Slomka and colleagues conducted in-depth interviews with individuals taking part in three HIV prevention studies.[223] While the interviewees saw money as a necessary incentive to attract research participants, at least some expressed a belief that large financial incentives might raise concerns about risks.[224] Scott Halpern and colleagues found that, although higher payment motivates research participation, there was no evidence that higher payments altered patient's perceptions of the risks of research participation, that is, their comprehension.[225] John Bentley and P.G. Thacker determined that higher levels of payment increase willingness to participate, but, perhaps counter intuitively, there was no association between monetary payment and perceived risk.[226] Finally, Eleanor Singer and Mick Couper conducted an online vignette-based survey and concluded that while larger incentives induced greater overall participation, "respondents do not appear to exchange higher incentives for greater risks."[227] Although more data are needed, these studies do not indicate that higher payment necessarily or even frequently leads to cognitive distortion regarding the risks of research participation.

That said, however, empirical evidence does suggest that higher payments may prompt research participants to lie, deceive, or otherwise conceal information from investigators.[228] Some individuals interviewed by Slomka and colleagues "believed that if a large amount of money was offered, individuals would be more likely to provide false information to investigators and 'say anything' to obtain the money."[229] Bentley and Thacker's study "showed that

222. Cynthia E. Cryder et al., *Informative Inducement: Study Payment as a Signal of Risk*, 70 SOC. SCI. & MED. 455 (2010).

223. Jacquelyn Slomka et al., *Perceptions of Financial Payment for Research Participation among African-American Drug Users in HIV Studies*, 22 J. GEN. INTERNAL MED. 1403 (2007).

224. *Id.* at 1405 ("In response to questions about monetary influences on risk assessment, some respondents said they would participate in a study if the price was right in spite of the risks, whereas others said they would decline certain risky studies no matter what amount of money was offered.").

225. Scott D. Halpern et al., *Empirical Assessment of Whether Moderate Payments are Undue or Unjust Inducements for Participation in Clinical Trials*, 164 ARCHIVES INTERNAL MED. 801, 803 (2004).

226. John P. Bentley & Paul G. Thacker, *The Influence of Risk and Monetary Payment on the Research Participation Decision Making Process*, 30 J. MED. ETHICS. 293, 296–297 (2004).

227. Eleanor Singer & Mick P. Couper, *Do Incentives Exert Undue Influence on Survey Participation? Experimental Evidence*, 3 J. EMPIRICAL RES. ON HUM. RES. ETHICS 49, 53 (2008).

228. Investigators who responded to our pilot survey, described in Part V, raised this as a concern. For example, one respondent explained: "Recruiting through Craigslist or other online methods seems to draw a lot of people who are unduly influenced by the compensation, to the point that they will lie about their medical history." Another stated, "'Professional subjects' are very problematic for us. They lie during the screening process in order to get into the study, they have poor compliance, and their data messes up our findings. For this reason, we compensate as little as possible, to decrease the number of these subjects that we enroll."

229. Slomka et al., *supra* note 223, at 1406.

higher levels of monetary payment may influence subjects' behaviors regarding concealing information about restricted activities."[230] They expressed concern that "[I]f such activities were actually engaged in, the results of the hypothetical studies may have been distorted."[231] In our view, this act of deception may indicate a distorted understanding of risks or an unreasonable willingness to assume risks of participation, for example, by circumventing exclusion criteria or lying about adverse events that could lead to disqualification. Thus, some concern about undue inducement in practice remains.[232]

Nonetheless, we note that "[w]orkers may lie about their qualifications too, in ways that put both themselves and their employers' output in jeopardy, and they may be enticed to do so by money."[233] Without research exceptionalism, the fact that highly-compensated research participants might be more likely to lie than unpaid or less-compensated research participants cannot justify a limit on compensation to research participants but not for other jobs. The immediate response to deceit by research participants should not be to reduce payment. Regulatory oversight bodies, sponsors, and investigators "could implement national subject registries to track participants [to avoid duplicative enrollment for financial gain], . . . utilize more extensive screening before enrollment [to better check against inclusion/exclusion criteria], and increase use of physical testing rather than relying on qualitative subject feedback whenever possible."[234] In some instances, it may be necessary to limit payment to avoid the problems entailed by deceitful research participants, but these cannot justify blanket limits on offers of payment in all clinical research.[235]

C. The Relationship Between Coercion and Undue Inducement

On one view, coercion and undue inducement are not distinct concepts, but rather fall on a sliding scale, with one being a more extreme version of the other. This view purports that the "quantity of payment is directly correlated with the 'pressure' on the decision-maker, and the threshold of pressure necessary to constitute undue influence is less than the threshold of pressure necessary to constitute coercion."[236] The sliding scale view is intuitively appealing and may be implied by some of the leading regulatory and ethical guidelines, like the U.S. Common Rule, which mention coercion and undue inducement together and do not draw a clear conceptual distinction between them.[237]

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230. Bentley & Thacker, *supra* note 226, at 297.
231. *Id.*
232. Largent & Lynch, *supra* note 217.
233. Lynch, *supra* note 51, at 162.
234. *Id.* (internal citations omitted).
235. Largent & Lynch, *supra* note 217.
236. Largent et al., *supra* note 29, at 506.
237. *Id.*

Nevertheless, we join others in forcefully arguing for distinguishing undue inducement and coercion as distinct concepts. Emanuel, for instance, contends that "[u]ndue inducement is the diametric opposite of coercion. While both make a person do what may be unethical, illegal, or imprudent, the former dangles a good, a positive offer to induce bad judgment that leads to harm, while the latter entails an overwhelming threat. . . . Coercion requires a threat of what the person considers a worse consequence, while undue inducement offers a positive good."[238] Additionally, whereas undue inducement may compromise the validity of consent by creating a cognitive distortion and impairing comprehension, coercion compromises the voluntariness of consent by the threat of harm.[239]

Additional support for the argument that these are distinct concepts may be found in the legal rules, or canons, of statutory interpretation. It is a "cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word will be superfluous, void, nugatory, or insignificant."[240] In the case of the Common Rule, quoted above, this would favor understanding coercion and undue inducement as distinct concepts, rather than one as an extreme form of the other. Moreover, as discussed above, both the Belmont Report and OHRP's FAQs distinguish conceptually coercion from undue influence.

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In this section, we have illustrated the lack of definitional consensus within the bioethics community pertaining to coercion and undue inducement. The conceptual definitions are highly variable, and as a result, different individuals reviewing an offer of payment may reach different conclusions in practice about whether that offer is coercive or unduly influential, and in turn, whether it is ethically permissible or impermissible. Moreover, it is easy to see that, depending on how two individuals define the respective terms, they could talk past one another. They may be using the same term to refer to different ethical concerns; different terms to refer to the same concern; or different terms to refer to different concerns.

Clearly, it is desirable for the human subjects research community to come to consensus on what these terms mean. We have argued that once one rejects research exceptionalism, certain definitions come to the fore, as depicted in Figure 2. Yet, even if one continues to defend research exceptionalism with regard to payment, it is possible to endorse our preferred definitions on the

238. Emanuel, *supra* note 200, at 101 ("The 'your money or your life' threat of coercion is clearly different from the $1 million offer of undue inducement.").

239. Largent et al., *supra* note 29, at 506; *see also* Wilkinson & Moore, *supra* note 196, at 378 ("Coercion is paradigmatically a case of the denial of autonomy, since it consists in the deliberate imposition of one person's will on another. However, coercion usually takes the form of threats, which restrict people's options. Inducements are offers, not threats, and they expand people's options.").

240. 82 C.J.S. *Statutes* § 433.

grounds of their superior explanatory power and consistency with the canon of non-surplusage.

Coercion

- A threat to violate rights or not fulfill an obligation + no reasonable alternative
  - Affects voluntariness
  - Not implicated by genuine offers
  - Possible in research but not caused by offers of payment

Undue Inducement

- Offer of positive, excessive incentive + bad judgment leading to undesirable activities (against one's self-defined interests)
  - May affect comprehension of risks
  - Limited empirical evidence of undue inducement in practice
  - Unlikely in IRB-approved research

Figure 2. Best Definitions of Coercion and Undue Inducement

V. CASE STUDY: CONFUSION IN PRACTICE

As the preceding sections have highlighted, it is reasonable to expect that the lack of substantive guidance regarding offers of payment from key regulatory agencies and other influential bodies in research ethics, the misguided tendency toward research exceptionalism, and the want of clarity about how to define coercion and undue influence will result in conceptual confusion among IRBs and investigators, as well as a general trend toward conservative approaches to payment. In this section, we present preliminary research that illustrates precisely such confusion and an emphasis on protecting subjects from payments that are deemed to be "too high." The purpose of this case study is to show that the challenges identified herein are not just theoretical, but can have concrete effects in practice.

A. Institutional Guidelines

IRBs—and the institutions with which they are affiliated—have wide discretion when it comes to overseeing offers of payment made to research participants. As a result, one finds predictably wide variation in institutional policies. As part of this project, we reviewed payment-related policies for all of the IRBs affiliated with Harvard Catalyst. Harvard Catalyst, Harvard's Clinical and Translational Science Center, is part of the National Clinical and Translational Science Award (CTSA) consortium[241] and "works with Harvard

241. Sixty medical research institutions are members of the CTSA Consortium, which is funded

schools and the academic healthcare centers (hospitals) to build and grow an environment where discoveries are rapidly and efficiently translated to improve human health."[242]

In 2015, we reviewed official copies of policies and guidelines regarding payment of research participants for each of the Harvard Catalyst-affiliated institutions.[243] Although we do not suggest that these institutions provide a representative sample of research institutions across the country, they do range from world-renowned academic medical centers to local community hospitals. Because the goal is simply to demonstrate variety, rather than to praise or criticize any institution's policy, we refrain in this discussion from attributing particular policies to particular institutions.[244]

Several of the Harvard Catalyst-affiliated institutions share umbrella IRBs (and therefore were covered by a single policy). In all, six institutions had no policy governing offers of payment to research participants, whereas 13 IRBs (covering the remainder of the participating institutions) did have a payment-specific policy or policies.[245] Of those with policies, there is a great deal of heterogeneity: whereas some largely parrot the regulations, others go into much more extensive detail. In Appendix 1, we have compiled information about each of these policies on a range of parameters.

When an institution has a policy regarding offers of payment to research participants, that policy can reasonably be expected to establish the default for how payment is viewed by both IRB members and investigators. Two policies were particularly striking in their contrast. The first of these stated: "It is sometimes desirable to provide payments to subjects and their families for their participation in research projects."[246] By contrast, the second stated:

> It is not necessary, required, or desirable that all subjects involved in clinical research receive monetary compensation for their participation. Some subjects derive medical benefit as a result of their participation; some subjects volunteer out of sheer altruism . . . or for other personal reasons.[247]

The former sets a default that is much more favorable to offers of payment

by the National Center for Advancing Translational Sciences (NCATS), a part of the National Institutes of Health (NIH). *National CTSA Consortium*, HARV. CATALYST, http://catalyst.harvard.edu/about/consortium.html [https://perma.cc/CA5T-83TH].

242. *About Harvard Catalyst*, HARV. CATALYST, http://catalyst.harvard.edu/about [https://perma.cc/J6WF-W5YQ].

243. There are thirty-one participating institutions. *Id.*

244. Policies are on file with the authors.

245. This is consistent with the findings presented in Neal Dickert et al., *Paying Research Subjects: An Analysis of Current Policies*, 136 ANNALS INTERNAL MED. 368, 369 (2002).

246. *See infra* app. at pp. 132–34 (Institution A).

247. *See infra* app. at pp. 132–34 (Institution B).

than the latter, and also seems to be more in line with approaches to payment that might be expected outside of the research context, whereas the latter appears to be influenced by research exceptionalism.

In reviewing these policies, we observed several trends relevant to our present discussion. First, and most notably, the vast majority of policies do not include definitions of either coercion or undue inducement, despite (or perhaps because of) the fact that these terms are not clearly defined in the U.S. federal regulations, nor are there broadly accepted definitions in the research ethics literature. There were two notable exceptions. The first defines coercion, roughly correctly, as "undue pressure."[248] The second, however, suggests coercion means "unduly inducing individuals to participate because compensation would be difficult to refuse."[249] Not only is this definition of coercion clearly incorrect on our preferred definitions, it mistakenly conflates coercion with undue influence, suggesting the terms are interchangeable when they are correctly understood as distinct.

Second, the policies reviewed also reflected the widespread—albeit mistaken on our view—belief that offers of payment can be coercive. One policy states, for instance: "Payment should not be coercive."[250] Another explains, "When subjects are being paid, the [IRB] will review both the amount of payment and the proposed method and timing of disbursement to assure that neither is coercive."[251] A third states, "The IRB reviews remuneration plans to assess whether the amount, schedule and type of any proposed compensation . . . could be considered coercive."[252] As we have stressed above, genuine offers of payment are never coercive because they do not threaten to violate an individual's rights but instead expand an individual's options.

Third, the policies generally allowed advertisements to indicate that payment would be offered, as long as undue emphasis was not placed on the offer of payment.[253] A typical policy stated, "[A]dvertisements *may* state that Human Subjects will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type."[254] None of the polices we reviewed expressly forbade inclusion of payment nor did they require that offers of payment be explicitly mentioned in the advertising materials. While the policies do not explicitly link limits on advertising to either coercion or undue inducement, presumably such limits are motivated by a fear that research

248. *Id.*

249. *See infra* app. at pp. 135–136 (Institution F). Undue influence was never defined by this policy.

250. *See infra* app. at pp. 139–141 (Institution L).

251. *See infra* app. at pp. 139–141 (Institution K).

252. *See infra* app. at pp. 135–136 (Institution F).

253. *See generally* Megan S. Wright & Christopher T. Robertson, *Heterogeneity in IRB Policies with Regard to Disclosures About Payment for Participation in Recruitment Materials*, 42 J.L. MED. & ETHICS 375, 375–376 (2014).

254. *See infra* app. at pp. 132–134 (Institution C) (emphasis added).

participants could be inappropriately influenced to participate in research by an emphasis on payment in advertising materials. Given our view on the broad acceptability of offers of payment made to research participants, we believe policies that allow inclusion of reasonable information about payment at the investigators' discretion are not only appropriate but ideal.

Of course, we understand the difficulty of drafting these policies in the absence of clear regulatory guidance and the presence of robust academic debate. The confusion they reflect is reasonable given the confused circumstances from which they emerge. Ideally, however, institutions would bridge the gap between policy and practice, defining crucial terms and providing substantive guidance on ethically acceptable offers of payment that could guide investigators and IRB members as they design and evaluate offers of payment made to research participants. There is, as we have shown, an unfortunate divergence between the ideal and reality. While this divergence is neither unexpected nor blameworthy, the lack of clear institutional guidance, layered upon a lack of clear regulatory guidance, likely reinforces a tendency toward conservative approaches to payment among IRB members and investigators.

B. Individual Survey Data

In addition to a review of institutional policies, we conducted pilot surveys of individuals at Harvard Catalyst-affiliated research institutions in order to develop preliminary data about attitudes of both IRB members and investigators regarding payment generally, and about their beliefs regarding coercion and undue inducement in particular. This is the first survey to assess how investigators, as opposed to IRB members alone, define these terms.

We included investigators in our sample because they are responsible for designing—and oftentimes justifying—the offer of payment that is submitted to the IRB for review. While factors extrinsic to ethical concerns about coercion and undue influence, most notably the study budget, will influence how much payment an investigator offers, their understanding of coercion and undue influence may be relevant, as well as their expectations regarding likely IRB response. Furthermore, it is useful to know how much daylight there is between the perspectives of IRB members and investigators on these issues to determine how best to address conservative approaches to payment moving forward.

1. Methods

Two online surveys were conducted. The first (hereafter, the "IRB Survey") was sent to IRB members and administrators and was distributed via the Harvard Catalyst Regulatory Committee, which "is comprised of institutional officials, compliance officers, and directors of human research protections from Harvard

Catalyst-participating institutions."[255] The second survey (hereafter, the "Investigator Survey") was sent to investigators and study coordinators and distributed via the Harvard Catalyst Clinical Research Center (HCCRC) email list.[256]

Two draft survey instruments, one for IRB members and one for investigators, were developed using an iterative process that began with a comprehensive review of the literature on coercion and undue inducement and offers of payment to research participants and included several rounds of revision based on input from IRB members, administrators, and experts on the ethics of human subjects research. Because much of our work was exploratory in nature, we used a combination of open- and close-ended questions. The draft surveys were pretested with IRB members, administrators, and investigators who were asked to comment on the content and design of the survey. Feedback was incorporated to refine and clarify survey items. The Investigator Survey was finalized after we had the results from the IRB Survey, and several additional changes were made to further enhance clarity.[257]

Potential participants received an email embedded with an HTML link to the confidential, self-administered survey instrument, which was administered in Qualtrics, a web-based survey tool. Two subsequent reminder emails were sent. Responses received by June 1, 2015 were included in our analysis. This project was approved by the Committee on the Use of Human Subjects, the IRB for Harvard University's Cambridge campus. No compensation was provided to participants.

Because this study was designed as an exploratory analysis, we summarized data using frequency distributions and descriptive statistics. We evaluated associations between responses using simple frequencies and evaluated the interrelationships between survey response items using cross-tabulations without adjustment for multiple comparisons. Statistical significance by chi-square test was defined as $p < 0.05$.

2. Results and Analysis

Of the 694 emailed invitations to participate in the IRB survey, 116 surveys were completed, for a response rate of 16.7%.[258] Of the 1,596 emailed invitations

255. *Regulatory Foundations, Ethics, and Law Program*, HARV. CATALYST, https://catalyst.harvard.edu/programs/regulatory/howwework.html [https://perma.cc/YL4H-XM3T].

256. *Harvard Catalyst Clinical Research Center (HCCRC)*, HARV. CATALYST, https://catalyst.harvard.edu/programs/hccrc [https://perma.cc/DA6U-M4G4].

257. Survey instruments on file with the author.

258. Some of the IRBs made the members' emails publicly available or shared them upon request; in other cases, the IRB chair agreed to forward our emails. As we did not send all of the email invitations directly, we are unsure how many emails were returned as undeliverable and how many emails were forwarded without notifying us of that fact. Therefore, the adjusted response rate may differ.

to participate in the investigator survey, 115 surveys were completed, for a response rate of 7.2%.[259]

Respondents who provided demographic information were predominately non-Hispanic white (90%) and female (62%), with a mean age of 54 (±13) for IRB members and administrators and a median age of 41–50 for investigators.[260] The majority of respondents (76%) held a masters, doctorate, or professional degree. Those with experience serving on an IRB had an average of 8 (±6) years of experience, and all but 7% said that their IRB reviewed biomedical research. Investigators reported submitting an average of 14 (±20) protocols to their current IRB. All respondents held a role or roles related to human subjects research (see Table 1).

259. As we did not send any of these email invitations directly, we are unsure how many emails were returned as undeliverable. Therefore, the adjusted response rate may be higher.

260. The CUHS asked us to change how we asked questions about age between the two studies, which is why the results are reported differently.

Table 1.
Respondents' Current Roles Related to Human Subjects Research

*Role**	*Frequency*	*Percent*
Researcher	85	36.8%
IRB Member	91	39.4%
Study Coordinator	54	23.4%
Research Nurse	6	2.6%
Clinician, Non-Researcher	14	6.1%
Professor	39	16.9%
Ethicist	8	3.5%
Sponsor	3	1.3%
Regulator	4	1.7%
Subject Recruiter	11	4.8%
Evaluate Grants	14	6.1%
Write Policy	16	6.9%
Member of Human Research Protection Program	14	6.1%
Other Study Staff	10	4.3%
Other	16	6.9%

*Respondents could choose more than one role

Beyond these demographics, however, we will generally present the results for investigators and IRB members together because there were few instances in which the differences in their answers reached statistical significance; where the difference was statistically significant, we have included a footnote indicating that to be the case. This is an interesting finding in itself because it shows that IRB members and investigators think about coercion and undue influence in similar ways.

Respondents were asked to select which of a given series of definitions properly defined coercion, and were permitted to select more than one option; we did not indicate which definition reflected our preferred view. See Table 2. Nearly all respondents agreed that a research participant is coerced if threatened with harm or loss of benefits to which he is otherwise entitled if he doesn't

participate in research (87.0%),[261] a definition consistent with the rights-violating view of coercion we endorse. The vast majority also agreed that a research participant is coerced if he participates as the result of intimidation, or some other form of pressure or force (90.0%), consistent with the worse-off view. While we favor the rights-violating view, for reasons discussed above, there is often little difference between the two views in practice. These results are encouraging in the sense that they indicate that most respondents include the correct (by our analysis) definitions of coercion in their understanding of the term.

Less encouraging, however, is that respondents might also be including incorrect definitions. A majority agreed that a research participant is coerced if the offer of payment causes him to feel he has no reasonable alternative but to participate in research (71.0%), if the offer of payment distorts his ability to perceive accurately the risks and benefits of research (63.6%),[262] or if the offer of payment makes him participate in research he would not otherwise participate in (51.1%). From our perspective, that a majority of respondents would endorse these definitions demonstrates a widespread and fundamental misunderstanding of what coercion is. With respect to the first option, although some ethicists defend the no-reasonable-alternative view of coercion, we indicated above why this approach is inconsistent with understandings of what counts as coercive outside of the research context, and why it must be rejected as an instance of inappropriate research exceptionalism. The second option, that offers of payment may distort comprehension of risks and benefits is the correct definition for undue inducement, not for coercion. This illustrates how the two terms are often conflated. Finally, the third option is consistent not with coercion but with an ethically unproblematic *mere* inducement. More than two-thirds (68.6%) of respondents agreed with the following statement, which we view to be false: "Offers of payment can be coercive."

Next, respondents were given the same series of definitions and asked which defined undue influence. See Table 2. Three-quarters (74.5%) of respondents agreed that a research participant is unduly influenced if the offer of payment distorts his ability to perceive accurately the risks and benefits of research, which means that a full quarter of respondents failed to identify what we view to be the correct definition of undue inducement. It is perhaps most worrisome that more than half of the respondents (58.9%) agreed that research participants are unduly influenced if the offer of payment makes them participate in research they would not otherwise participate in. Again, this seems more accurately to describe a mere

261. Investigators were significantly more likely than IRB members ($p < 0.05$) to say that a research participant was coerced if threatened with harm or loss of benefits to which he is otherwise entitled (92.2% vs. 81.7%). Thus, investigators were more likely to get it right in our view.

262. Investigators were significantly more likely than IRB members ($p < 0.05$) to say that a research participant was coerced if an offer of payment distorts the research participant's ability to perceive accurately the risks and benefits of research, which is part of our definition of undue inducement (75.9% vs. 51.3%).

inducement (i.e., something that one would not otherwise have done), not one that is *undue per se*, and is an expansive view potentially at odds with the pervasive use of offers of payment as an incentive for participation in research.

In these numbers, we again see evidence that IRB members and investigators often conflate undue influence and coercion. The majority agreed that research participants are unduly influenced if they participate as the result of intimidation, or some other form of pressure or force (60.6%)[263] or if they are threatened with harm or loss of benefits to which they are otherwise entitled if they do not participate in research (55.8%),[264] both of which are definitions applicable instead to coercion.

Table 2.
Definitions of Coercion and Undue Inducement

% of respondents who agreed that if . . .	Then . . . *it is coercion*	Then . . . *it is undue inducement*
The research participant is threatened with harm or loss of benefits to which he is otherwise entitled if he doesn't participate in research	87.0%	55.8%
The research participant participates as the result of intimidation, or some other form of pressure or force	90.0%	60.6%
The offer of payment makes the research participant participate in research he would not otherwise participate in	51.1%	58.9%
The offer of payment distorts the research participant's ability to perceive accurately the risks and benefits of research	63.6%	74.5%
The offer of payment causes the research participant to feel he	71.0%	69.3%

263. Investigators were significantly more likely than IRB members ($p < 0.05$) to say that a research participant was unduly induced if she participates as the result of intimidation, or some other form of pressure or force (69.8% vs. 51.3%), which is instead one of our definitions of coercion.

264. Investigators were significantly more likely than IRB members ($p < 0.05$) to say that a research participant was unduly induced if threatened with harm or loss of benefits to which they are otherwise entitled (64.7% vs. 47.0%), which is instead one of our definitions of coercion.

has no reasonable alternative but to participate in research

Undue inducement and coercion are often said to be conflated,[265] a claim consistent with our findings. Our data suggest that people use these terms somewhat interchangeably. Some individuals chose the same definitions for both coercion and undue inducement. Moreover, a majority of respondents (65.2%) agreed with the statement that "coercion is an extreme form of undue influence," consistent with the "sliding scale view" and demonstrating a failure to appreciate that coercion and undue inducement are distinct concepts.[266]

Finally, two-thirds (67.4%) of respondents agreed with the statement "offering to pay subjects is different from offering to pay people in other contexts." This finding is consistent with widespread research exceptionalism, which may, in addition to confusion about how to define the key terms, encourage conservative approaches to payment.

3. Limitations

This was an exploratory study without a nationally representative sample and with a low response rate, which imposes limits on the conclusions we can draw. While the respondents are professionally diverse and have considerable experience in human subjects research, they may have views that differ from others involved in the research enterprise, especially given that our results were generated exclusively from Harvard Catalyst-affiliated research institutions. Yet, as mentioned above, Harvard Catalyst encompasses institutions ranging from academic medical centers to community hospitals to schools of medicine and public health.

Another limitation to this exploratory data is that we asked about concepts only in the abstract, rather than including case studies. Thus, it is possible that even if IRB members and investigators adopt overly expansive definitions of coercion and undue inducement when asked about these terms in the abstract, these definitions have little impact on their decisions to approve or not approve offers of payment in specific instances. Yet, the federal Common Rule requires investigators to seek informed "consent only under circumstances. . .that minimize the possibility for coercion or undue influence,"[267] and OHRP cautions investigators and IRBs to "be vigilant about minimizing the possibility of

265. *E.g.*, Ezekiel J. Emanuel et al., *Undue Inducement in Clinical Research in Developing Countries,* 366 LANCET 336, 337 (2005) (describing how it is not unusual for undue inducement to be "conflated with coercion, exploitation, injustice, deception, misunderstanding, and other ethical transgressions as if they were equivalent or interchangeable").

266. Largent, Grady, Miller & Wertheimer, *supra* note 29, at 506.

267. 45 C.F.R. § 46.116 (2015).

coercion or undue influence."[268] Therefore, although more research is needed, we hypothesize that these confused views *do* influence how IRBs interpret offers of payment as well as how investigators structure offers of payment.

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In response to our pilot survey, some IRB members and investigators readily admitted to their confusion,[269] and many others showed themselves to have a faulty conceptual understanding of coercion and undue inducement on our preferred definitions. Some respondents identified the best definitions while also endorsing incorrect views, suggesting that their understanding of these concepts is overly expansive. In some instances, respondents identified a legitimate ethical concern but called it by the wrong name. In other instances, they expressed concern about something that is not a legitimate ethical concern at all, but called it by an ethically charged name.

As a result, we fear that IRBs sometimes incorrectly reject offers of payment that really ought to be ethically acceptable, thereby eliminating a potentially important tool in clinical trial recruitment. The flip-side of this is that investigators share many of the misconceptions that IRB members have—not only do investigators have the same dearth of guidance on what these terms mean, they may also be reliant on the IRB to guide them in how to understand and apply these terms. As a result, they may not submit protocols with offers of payment that they expect will be met unfavorably by the IRB, or may fail to advocate for offers of payment once the IRB has questioned them, even when those payments really ought to be viewed as ethically acceptable.

While preliminary, our results suggest that guidance and educational efforts targeted at both IRB members *and* investigators are needed to clarify coercion and undue inducement and to address research exceptionalism if we are to advance the goals of research ethics to promote socially valuable research while providing appropriate protections for research participants.

VI. IMPLICATIONS FOR POLICY AND PRACTICE: THE PATH FORWARD

Given the potential for confusion and conservative approaches to payment demonstrated above, it is clear that something must be done. Here, we will consider several possible solutions to the problems we have identified.

A. If Not Accuracy, Precision

In the field of science, accuracy tells us how close a measurement is to the true value. Precision, by contrast, refers to the closeness of two or more

268. Office of Human Research Prots., *supra* note 90.

269. For instance, a handful (5%) of respondents to the IRB survey explicitly stated that they were not certain how to define undue influence in answer to a free response question.

measurements to each other.[270] Unfortunately, our data suggests that currently when IRB members and investigators define and use the terms coercion and undue inducement, they are often neither accurate nor precise. While we have argued above for the definitions that we think are best, we also recognize that reasonable disagreement is possible. In the face of disagreement among ethicists about what each of these concepts mean, it seems unrealistic—at least in the absence of a definitive statement from OHRP or FDA, which we discuss below—to ask that IRB members and investigators universally accept one meaning as factually correct. This may be particularly difficult, given an ingrained culture of payment conservatism. Therefore, accuracy might be too much to hope for, but precision is not.

How might we achieve precision? As a first step, we propose relying much less on these labels to do the heavy lifting. It appears from our data and some strands of the bioethics literature that the terms coercion and undue inducement may be used as "catchalls" when something about research (e.g., an offer of payment) seems somehow not right. Because most everyone agrees that coercion and undue inducement in the context of human subjects research are wrong, use of these terms can be a conversation killer and result in not approving a protocol or an aspect of a protocol. Yet, to the extent that people understand these terms expansively or understand them in wildly different ways, people may well be talking past one another when these terms are used. Therefore, leveling the charge that an offer of payment is coercive or unduly influential should be the beginning, rather than the end, of the conversation. Individuals interested in protecting research participants should explain *precisely why* they think that a particular payment is problematic rather than assuming that the label alone does sufficient explanatory work, or that the label itself will carry the same meaning for the listener as it does for the speaker.

So, for example, instead of saying that a proposed offer of payment would create undue inducement, it would be vastly preferable to say that a proposed offer of payment appears so high that it might prevent prospective research participants from adequately evaluating the risks and burdens of enrolling in the associated trial, while also offering specific evidence for why that worry is present in this particular case. Employing that level of specificity will limit the extent to which individuals talk past each other and allow the conversation to be focused on the ethical concern at hand. To continue with the example, once the concern is expressed as money impinging on the evaluation of risks, it is possible to have a substantive discussion about whether the offer of payment is so high that it predictably creates a cognitive distortion, whether the research is otherwise ethical such that a reasonable person could agree to participate, or whether

270. Imagine you have a box that you know weighs exactly 10 pounds. You take it home and weigh it five times on your bathroom scale. Each time, the scale says that the box weighs 7.5 pounds. Your scale is precise because it said that the box weighed 7.5 pounds each time, but your scale is not accurate because 7.5 pounds is not close to the known value of 10 pounds.

additional safeguards are needed for the informed consent process. Such questions would, for example, have been useful to assess prospectively the offer of payment made to research participants in France.

B. Changing the Default Rules to Favor Payment

As described above, we think that research exceptionalism is generally wrongheaded when it comes to offers of payment, and that offers of payment do not need to be subjected to greater scrutiny in the research context than elsewhere. If so, that is a strong argument in favor of changing the default to generally accept even high offers of payment to research participants unless there is compelling evidence that they are harmful. Even if one continues to accept some form of research exceptionalism, if coercion and undue inducement are not actually happening in practice when payment is offered to participants, then we are making mountains out of molehills when we set the default in favor of low (or no payment).

We have argued that coercion is incorrectly associated with genuine offers of payment. While undue inducement is a more credible concern when offers of payment are extended to research participants, we caution that there is little evidence that undue inducement is occurring in practice. As described above, empirical research has failed to substantiate the claim that offers of payment lead to irrational choices by research participants. In fact, some scholars have found that offers of payment heighten subjects' attention to the risks and burdens of research participation. We suggest that many regulators, IRBs, investigators, and other stakeholders in human subjects research are, therefore, inappropriately concerned about offers of payment being too high in most cases. Offers of payment, even extremely high ones, should not generally be cause for ethical concern.

From our perspective, the larger concern is that subjects may be *inadequately* compensated for their contribution to socially beneficial research, which may slow recruitment, hinder retention, or exploit research participants who are not paid enough. According to Wertheimer, to exploit someone is to take *unfair* advantage of him or her.[271] Exploitation occurs when, due to an asymmetry of bargaining power, one party to a transaction insufficiently benefits or assumes an unfair share of the burden relative to other parties to the transaction. The possibility of exploitation suggests that a default in favor of payment is preferable to a default against payment.

At a minimum, individuals "should not have to pay for making a contribution to the social good of research."[272] This entails providing reimbursement for any research-related expenses they incur and adequate compensation for their time and effort, as well as risks they willingly incur as a

271. ALAN WERTHEIMER, EXPLOITATION 22–23 (1996).

272. CIOMS, *supra* note 25, at 65.

result of their participation in research. Such offers of payment demonstrate respect for research participants, and treat them in accordance to what would be expected outside the research context. In some studies, acceptable offers of payment may be *de minimus* (e.g., a study that consists of a one-time blood draw), but in other studies, the minimum acceptable payment may be substantially higher.

Additionally, offers of payment can unproblematically be used to incentivize research participation. We think it is fundamentally wrong to argue, as some have, that "the need for large incentives can be a rough indicator that there may be an ethical concern that requires attention."[273] People may simply wish to avoid the discomforts or burdens of research participation, and just as incentives are acceptable in other areas of life to override such reluctance, they are acceptable in the context of human subjects research—particularly if one accepts, as we do, the role of a well-functioning IRB in determining that the risks of a study are reasonable in relation to the benefits, either to the individual or to society.

We do note that some people worry "that poverty or otherwise compromised circumstances may force people to take an inducement that people in a better situation shun."[274] This concern is often raised when research is conducted in developing countries, but its application is not geographically limited. Yet, "tempting offers in desperate situations that have clear good results are not undue inducements"[275] because accepting such an offer can be a reasoned judgment that does not necessarily contradict one's interests. It is an unfortunate consequence of research exceptionalism to frame these offers as undue inducements, and it would be unacceptably paternalistic to protect competent research participants from their fully voluntary and rational undertakings. Moreover, it is backward to think that protecting them requires paying *less* in light of their poverty; ideally, the response should be to pay them more.

To demonstrate this point, consider that a person who is facing poverty might be willing to work as a day laborer, which may be risky and burdensome, whereas a more affluent person would not be willing to do so. Of course, this does not mean day laborers should be paid less. If we think paid day labor is acceptable, then it is an instance of research exceptionalism to suggest that paid research participation is unacceptable simply because more affluent individuals may not find participation a compelling offer, given other options they have available. The factors that lead some people to participate in research in order to earn a living or supplement their income might be circumstances we would all think of as unjust, and would prefer not to have occurred, but those circumstances are not reasons to limit the options of competent adults given the realities—and other protections for research participants—that exist.

273. Grant & Sugarman, *supra* note 24, at 734.

274. Emanuel et al., *supra* note 265, at 338.

275. *Id.*

Additionally, although we do not think offers of payment are a panacea for recruitment problems, greater incentives may have the dual benefit of improving enrollment and drawing a more diverse pool of research participants. This could ensure that socially valuable research is completed and that the burdens and benefits of research participation are spread more broadly, more fairly over the population. While more empirical research is needed to determine the effect of offers of payment on participation,[276] lack of completion due to low enrollment is known to be a problem. A 2015 study of 787 cancer trials, for example, found that 18% closed with low accrual or were accruing at less than 50% of target three years or more after initiation.[277] A review of terminated trials in clinicaltrials.gov found that insufficient rate of accrual was a leading reason for trial termination.[278] Additionally, and contrary to the logic that only the poor participate in trials, researchers have "found that patients with annual household incomes below $50,000 were 27% less likely to participate in [cancer] clinical trials."[279] These researchers speculated that "incentives or reimbursements may be appropriate" to promote fair access to cancer trials, but warned, mistakenly, that such payments "should not be coercive to patients."[280]

In medicine, a false positive is an error where a result is improperly reported as positive when it actually is not. A false negative is an error where a result is improperly reported as negative when it actually is not.[281] This is contrasted with a true result: a true positive or a true negative. The judgments of an IRB can be fallible just as medical tests can be fallible. We might equate disapproval of an offer of payment that is actually ethically acceptable with a false negative. Although our survey data do not allow us to determine conclusively how frequently this occurs, the attitudes reflected in the survey suggest that under the current scheme, there may be many false negatives.

Some false positives or false negatives may be unavoidable. One consequence of changing the default to generally accept offers of payment is that some offers of payment that are ethically concerning might get through—yet, we expect that this is only a slight possibility. We have argued that coercion and undue inducement are unlikely to occur in otherwise ethical clinical research.

276. *See, e.g.*, Claudine G. Jennings et al., *Does Offering an Incentive Payment Improve Recruitment to Clinical Trials and Increase the Proportion of Socially Deprived Elderly Participants?*, 16 TRIALS 1 (2015) (finding a £100 incentive payment led to "small but significant improvements" in the number of patients who consent to be screened for a clinical trial).

277. Caroline S. Bennette et al., *Predicting Low Accrual in the National Cancer Institute's Cooperative Group Clinical Trials*, 108 J. NAT'L CANCER INST. 1 (2016).

278. Rebecca J. Williams et al., *Terminated Trials in the ClinicalTrials.gov Results Database: Evaluation of Availability of Primary Outcome Data and Reasons for Termination*, 10 PLOS ONE 1 (2015).

279. Unger et al., *supra* note 11, at 137–138.

280. *Id.* at 138.

281. For example, if a pregnancy test says you are pregnant when you actually are not, that is a false positive.

Given that the harms from overpayment are generally overstated, and the harms from underpayment are understated or even ignored, we advocate changing the default rules so that offers of payment will be deemed acceptable unless someone can articulate a clear (i.e., precise) and persuasive—as opposed to speculative—reason why it is not.

C. Policy Guidance and Rulemaking

Policy guidance and educational efforts are sorely needed to clarify the concepts of coercion and undue inducement as applied to payment in the research setting. Unfortunately, it is unlikely that the U.S. regulations will be amended to address this issue in the near future, but there are other avenues to improvement.

In November 2009, representatives from HHS and other departments convened to draft the first substantive reforms to the Common Rule since it was published in 1991; these representatives had the dual aims of enhancing research participant protections and increasing the efficiency of the research oversight process.[282] Their meetings led to the release of an Advanced Notice of Proposed Rulemaking (ANPRM) entitled "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators" in July 2011.[283] The ANPRM did not substantively address payment, coercion, or undue inducement.

In September 2015, the long awaited NPRM[284] was published in the Federal Register.[285] Coming in at 131 Federal Register pages, the NPRM proposed a number of significant changes to the Common Rule, as well as numerous minor ones.[286] Again, however, payment was not substantively addressed.

Most recently, in January 2017, on the last day of President Obama's administration, the final rule was published in the Federal Register, completing a long and drawn out regulatory process, the outcome of which remains unclear in light of its timing and the present political climate. Given the intense difficulty of getting to this point, it is extremely unlikely that new rulemaking will be forthcoming any time soon. The final rule modifies populations that are deemed

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282. Emanuel, *supra* note 157, at 2297.

283. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512 (proposed July 26, 2011) (to be codified at 21 C.F.R. §§ 50, 56 & 45 C.F.R. §§ 46, 160, 164), https://www.gpo.gov/fdsys/pkg/FR-2011-07-26/pdf/2011-18792.pdf [https://perma.cc/9755-ACPT].

284. Leslie Meltzer Henry, *Revising the Common Rule: Prospects and Challenges*, 41 J.L. MED. & ETHICS 386, 387 (2013) (describing "pessimism" that progress toward issuing a NPRM was "stalled, at least for the foreseeable future, if not permanently").

285. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933 (proposed Sept. 8, 2015), https://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf [https://perma.cc/T3CM-ZE4C].

286. Office of Human Research Prots., *NPRM 2015–Summary*, U.S. DEP'T HEALTH & HUM. SERVS., http://www.hhs.gov/ohrp/humansubjects/regulations/nprm2015summary.html [https://perma.cc/GC38-4WFY].

likely to be vulnerable to coercion and undue influence, dropping reference to pregnant women and those with physical disabilities – but it does nothing to clarify the definition of the terms or their precise role in evaluating offers of payment.[287]

Unfortunately, this was likely a lost opportunity. If past experience is any guide, the research community will be working with the rule finalized in 2017 for some time (assuming it survives the political process and change in administrations), meaning that additional formal rulemaking specifically regarding payment is unlikely in the foreseeable future.

Therefore, we propose that OHRP update its FAQs and that the FDA update its Information Sheet on payment to research participants, at least as a first step. While this guidance would not be binding, as the embodiment of the agencies' current thinking, it would likely be persuasive for many IRBs and investigators and could help to address the present payment-conservative IRB culture. Indeed, Jerry Menikoff, Director of OHRP, suggested at a recent public meeting that OHRP is not particularly worried about payment resulting in undue inducement, which he believes—as we do—to be rare.[288] This perspective indicates that clarifying OHRP guidance on this topic would potentially be feasible, with the salutary effect of rendering IRBs less worried about enforcement actions should they approve higher payments.

Any such guidance should provide clear definitions of coercion and undue inducement, as well as of exploitation—a concern that is not currently addressed at all, but that we think is ethically salient, and increasingly so as more research is conducted in developing countries. We would strongly advocate for our preferred definitions. At a minimum, this guidance should clarify—by stating explicitly rather than leaving it for the reader to infer—that genuine offers of payment are never coercive and reflect the empirical evidence suggesting that undue inducement is rare. It should also emphasize the importance of offering reimbursement for research-related expenses and compensation for time, effort, and inconvenience. Ideally, the guidance would also state that use of offers of payment to incentivize research participation are generally acceptable and that payment can be used to address exploitation, or an unfair distribution of research benefits and burdens.

Additionally, we encourage efforts to reform international research guidelines pertaining to payment. The recently revised 2016 CIOMS guidelines, discussed above, are particularly welcome in this respect.[289] While these

287. Federal Policy for the Protection of Human Subjects, 82 FED. REG. 7149, 7203–04 (Jan. 19, 2017)

288. *Secretary's Advisory Committee on Human Research Protections – May 2016 (Day 1)*, NAT'L INSTS. HEALTH, (May 18, 2016), https://videocast.nih.gov/summary.asp?Live=19186&bhcp=1 [https://perma.cc/9G4V-ATHA].

289. *See* Emily A. Largent, *Recently Proposed Changes to Legal and Ethical Guidelines Governing Human Subjects Research*, 3 J.L. & BIOSCIENCES 10 (2016).

documents are of variable legal effect, they can be very influential in how people think about the ethics of human subjects research.

CONCLUSION

The practice of offering payment to individuals in exchange for their participation in clinical research is widespread and longstanding. Nevertheless, offers of payment to research participants remain the source of substantial debate. Two ethical charges routinely arise in relation to these offers—that they are coercive or unduly influential. Because there is general agreement that coercion and undue inducement are wrong in human subjects research, such a charge can shut down conversation among IRB members and investigators, and result in rejection of an offer of payment, or failure to make an offer in the first place.

As we have recounted, the various laws, regulations, and ethical guidelines that govern the conduct of human subjects research offer relatively little in the way of specific guidance about what factors or features characterize ethically acceptable offers of payment. Additionally, there is a lack of agreement regarding what exactly the terms coercion and undue inducement mean in the human subjects research context. It is, therefore, unsurprising that the space inhabited by IRB members and investigators is characterized by confusion and conservatism. The results of our pilot survey suggest that IRB members and investigators are worried about things that they probably do not need to be worried about. That may lead to overprotection, and possibly distraction from things they should actually be worried about—particularly the possibility that offers of payment are too low. Ultimately, resolving misplaced concerns about offers of payment being too high will offer investigators a more powerful recruitment tool and, hopefully, speed the pace of innovation and discovery.

Appendix 1. Comparing Policies of Harvard Catalyst-Affiliated Research Institutions on Offers of Payment to Research Participants

	Institution A
Policy Regarding Payment Discussion of Coercion, Undue Influence, or Exploitation - direct or indirect	Yes "Remuneration may not be sizeable enough to induce subjects to participate, regardless of how minimal the risk."
Definitions of Key Terms	
Recognized Uses of Payment	Reimbursement Compensation Tokens of appreciation Incentives
Factors Influencing the Acceptability of Payment	"The [IRB] will consider the protocol, including the time commitment and the proposed procedures, when determining if the planned amount is appropriate. . . . The [IRB] recognizes that varying amounts and methods of remuneration may be appropriate depending on the particular circumstances of a protocol."
Amounts	"There are no established policies as to the amount . . . of payments that may be offered." "The [IRB] does *not* have a set list of recommended remuneration amounts for specific tests or length of visits, nor does it require that one method (gift cards, cash, etc.) must be used."
Prorating	"Investigators may not require that a subject complete the research in order to receive compensation. If a subject withdraws from a study, he or she must be offered payment for the completed portion of the study."
Completion Bonuses	"'Completion bonuses' or additional payments above and beyond reimbursements . . . are generally discouraged in pediatric research however the [IRB] will consider whether an incentive unduly influences a child and/or family to participate when reviewing and approving this type of payment."
Informed Consent	Should include when participant will receive remuneration, what will be provided, and "other appropriate details"
Advertising	"If participants will receive compensation/reimbursements, it can be noted (e.g. reimbursement for parking and/or your time will be provided). However, do not overly stress the compensation. In general, the [IRB] does not allow dollar values to be specified."
General Attitudes Toward Payment	"It is sometimes desirable to provide payments to subjects and their families for their participation in research projects."

	Institution B
Policy Regarding Payment	Yes
Discussion of Coercion, Undue Influence, or Exploitation - direct or indirect	"The goal of IRB oversight of research subject compensation is to ensure that stipends paid to research subjects provide fair compensation without undue pressure (coercion) to participate. Excessive monetary compensation may cause subjects to undertake risks or discomforts that they otherwise would not assume. This unfairly targets subjects of lower socioeconomic groups and places more of the 'risk burden' of medical research on these groups. In the case of healthy volunteer studies, the IRB is often in the position of suggesting decreased compensation over that suggested by investigators, in an effort to decrease the element of financial coercion."
Definitions of Key Terms	"undue pressure (coercion)"
Recognized Uses of Payment	Reimbursement Compensation
Factors Influencing the Acceptability of Payment	
Amounts	"[A] list of approximate monetary compensations for a variety of frequently performed clinical activities is listed below. This list is meant to guide investigators, and is based upon active protocols currently approved by the [IRB]. Although not every procedure is listed, these amounts may guide investigators by allowing comparison of new procedures in terms of time and discomfort."
Prorating	"It is a general policy that compensation for participation in research projects is pro-rated according to the amount of time devoted to the project."
Completion Bonuses	"In many protocols where completion of all visits or procedures is paramount, there is some element of 'incentive' provided by withholding some compensation until the end of the study, or providing a 'bonus' for completion of all segments of the study. Such procedures should be explained and rationalized in detail in the research protocol, and clearly outlined in the informed consent documents."
Informed Consent	Should include information on completion bonuses.
Advertising	"All advertisements should be tastefully composed and not inappropriately emphasize monetary remuneration." "Specify the amount of monetary compensation (if you wish)." "Don't: Feature monetary compensation as a lead in before the description of study purpose and procedures; bold, italicize, underline or enlarge fonts on type describing monetary compensation."
General Attitudes Toward Payment	"It is not necessary, required, or desirable that all subjects involved in clinical research receive monetary compensation for their participation."

Institution C
Yes
"The [IRB] shall determine that Human Subjects are not subject to coercion or undue influence to participate in the Research. Factors such as, but not limited to, . . . payment for participation, and unfair inducements should be taken into consideration." "The [IRB] is required to review payments to subjects to determine that: (1) The amount of payment and the proposed method and timing of disbursement is neither coercive [n]or presents undue influence. . . . (3) Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn."
"The [IRB] is required to review payments to subjects to determine that . . . [c]redit for payment accrued as the study progresses is not contingent upon the subject completing the entire study."
"The [IRB] is required to review payments to subjects to determine that . . . [a]ny amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn."
"Investigator should seek consent under circumstances that minimize coercion or undue influence"
"Advertisements may state that Human Subjects will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type."

	Institution D
Policy Regarding Payment	Yes
Discussion of Coercion, Undue Influence, or Exploitation - direct or indirect	"The . . . IRB must determine that the following requirements are satisfied before it approves research: . . . There are appropriate additional safeguards included in the study to protect the rights and welfare of participants who are likely to be vulnerable to coercion or undue influence."
Definitions of Key Terms	
Recognized Uses of Payment	
Factors Influencing the Acceptability of Payment	
Amounts	
Prorating	
Completion Bonuses	
Informed Consent	
Advertising	"Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount of be paid, by such means as larger or bold type and compensation information should be added towards the bottom of the advertisement."
General Attitudes Toward Payment	

Institution E	Institution F
Yes	Yes
"The IRB shall review both the amount of payment and the proposed method and timing of disbursement to determine that neither are coercive nor present undue influence."	"The IRB reviews remuneration plans to assess whether the amount, schedule and type of any proposed compensation is fair for the participant, and to assess whether the payments could be considered coercive (i.e., by unduly inducing individuals to participate because compensation would difficult to refuse."
	Remuneration
"Payment to research subjects for participation in studies is considered compensation for time and inconvenience rather than a benefit to subjects."	Compensation
	"In general, remuneration . . . should be comparable to other projects involving similar time, effort, and inconvenience."
"Payment(s) shall be made to the subject as the study progresses and shall not be contingent upon the subject completing the entire study. If, for example, payment is made for each appointment attended, the payment must be made after each appointment."	"In general, remuneration . . . [s]hould be pro-rated based on the number of procedures and study visits and should not be conditioned on completing the entire study, although a bonus for completing the study may be acceptable."
	"Any amount paid as a bonus for completion must be reasonable and not so large as to unduly induce participants to stay in the study who otherwise would have withdrawn."
"[A] timetable for the payments themselves must be . . . presented to every subject as part of the Informed Consent process." "The Informed Consent Form must clearly establish how the subject is to be paid, i.e. cash, check, etc. A subject must sign a receipt for any cash payment, and this procedure must also be described as part of the Informed Consent process."	"In general, remuneration . . . [s]pecifics (including the amount per visit and payment schedule) should be documented in the consent form under the 'Compensation' section--but not under the 'Benefits section.'"
"Advertising materials shall not include the following: . . . an emphasis on the payment or the amount to be paid, by such means as larger or bold type. The IRB has authority to approve whether compensation shall be included in the advertisement."	"Recruitment materials should not emphasize remuneration for participation (e.g., larger or bold type)."
	"Remuneration . . . ordinarily offered as a form of appreciation for the individual's time and effort in the research project."

	Institution G
Policy Regarding Payment	Yes
Discussion of Coercion, Undue Influence, or Exploitation - direct or indirect	"The [IRB] is required to review payments to subjects to determine that: . . . The amount of payment and the proposed method and timing of disbursement is neither coercive or presents undue influence." See also 'Completion Bonuses'
Definitions of Key Terms	
Recognized Uses of Payment	
Factors Influencing the Acceptability of Payment	
Amounts	
Prorating	"The [IRB] is required to review payments to subjects to determine that: . . . Credit for payment accrued as the study progresses is not contingent upon the subject completing the entire study."
Completion Bonuses	"The [IRB] is required to review payments to subjects to determine that: . . . Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn."
Informed Consent	
Advertising	
General Attitudes Toward Payment	

Institution H	Institution I
Yes	Yes
"Under Federal regulations, the [IRB] must review and approve methods used to recruit subjects to ensure that the methods are not coercive."	"PIs are responsible to: . . . Ensure the informed consent process is free from coercion or undue influence." "NOTE: Payment cannot be held until the end of the study as that is potentially coercive."
	Reimbursement Compensation
	"Indicate how much subjects will receive for each portion of the study completed and the payment form (e.g., cash, check, gift card). Specify the payment schedule, including a prorated plan should a subject withdraw or be withdrawn from a study prior to his/her completion."
	"The IRB, when appropriate, will . . . consider whether the following additional elements of informed consent are required and whether they are adequately included in the [informed consent document]: . . . An explanation of the payment plan or a statement that subjects will not be paid for participation."
"Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type."	

	Institution J
Policy Regarding Payment	Yes
Discussion of Coercion, Undue Influence, or Exploitation - direct or indirect	In the consent process section, "Describe any steps that will be taken to minimize the possibility of coercion or undue influence."
Definitions of Key Terms	
Recognized Uses of Payment	Reimbursement Compensation
Factors Influencing the Acceptability of Payment	
Amounts	
Prorating	
Completion Bonuses	
Informed Consent	"Both the informed consent discussion and the written informed consent form and any other written information to be provided to participants should include explanations of the following . . . The anticipated prorated payment, if any, to the participant for participating in the trial." "Include the following information . . . Money or other forms of compensation or reimbursement, e.g., gift certificate, meal voucher, parking voucher, and travel expenses. Include the method and timing of the compensation. . . . Include how the amount of compensation is calculated if the participant does not complete the entire study for any reason." "If participants will not be paid or will not receive other forms of compensation for participation, please state so."
Advertising	
General Attitudes Toward Payment	

Institution K

Yes

"When subjects are being paid, the [IRB] will review both the amount of payment and the proposed method and timing of disbursement to assure that neither is coercive."
"The [IRB] must review both the amount of payment and the proposed method of disbursement to ensure that neither entails problems of coercion or undue influence."
"The [IRB] pays particular attention to remuneration and other inducements that might encourage people with limited resources to participate in research projects in which they might not otherwise participate. Compensation should not be the sole grounds for participation in a research project, and should not cause participants to assume risks that they would not ordinarily find acceptable. The [IRB] considers persons with limited resources to be vulnerable to the extent that inducements to participate in research may result in their acting against their own best interests. Where the population from which subjects will be recruited primarily consists of people with limited resources, . . . [t]he investigator will be asked to justify the compensation being offered. If the [IRB] finds it to be coercive, then the [IRB] will ask the investigator to provide alternative compensation so as not to impede the subjects' decision about whether they should participate in the research project."

Reimbursement
Incentive

"In general payments should be proportional to the degree of risk, inconvenience, or discomfort associated with participation."

"The consent form must describe the terms of payment and the conditions under which subjects would receive partial payment or no payment (e.g., if they withdraw from the study before their participation is completed)."

"The [IRB] will review advertisements to ensure that they do not . . . unduly emphasize the amount subjects receive in compensation."

"Payment to research subjects may be an incentive for participation or a way to reimburse a subject for travel and other expenses incurred due to participation. However, payment for participation is not considered a research benefit. Regardless of the form of remuneration, investigators must take care to avoid coercion of subjects. In general payments should be proportional to the degree of risk, inconvenience, or discomfort associated with participation."

	Institution L
Policy Regarding Payment	Yes
Discussion of Coercion, Undue Influence, or Exploitation - direct or indirect	"Subjects may receive reasonable payment for the time and trouble associated with participating in a study. Payment should not be coercive."
Definitions of Key Terms	
Recognized Uses of Payment	
Factors Influencing the Acceptability of Payment	
Amounts	"All subjects should be paid the same."
Prorating	"If a subject withdraws before the conclusion of the experiment, payment must be pro-rated."
Completion Bonuses	"Incentive or bonus payments may . . . be appropriate under certain circumstances to encourage completion of experiments. Such payments may not be given for assuming increased risk."
Informed Consent	"The informed consent document should mention the possibility of tax withholding, when appropriate." "If some groups are either not paid or paid differently from other groups, the differences in payment must be explained in the informed consent form."
Advertising	
General Attitudes Toward Payment	

Institution M

Yes

"Subjects must give consent without coercion or undue influence and the prospective subject or legally authorized representative must be provided with sufficient opportunity whether or not to participate in the research."

"If completion of research is not a condition of compensation, you must describe how compensation will be prorated and calculated for subjects who withdraw early."

"All information concerning payment to subjects, including the amount, type (cash, check, or in kind) and schedule of payments, must be included in the consent form."

Regulatory Disruption and Arbitrage in Health-Care Data Protection*

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Abstract:

This article explains how the structure of U.S. health-care data protection (specifically its sectoral and downstream properties) has led to a chronically uneven policy environment for different types of health-care data. It examines claims for health-care data protection exceptionalism and competing demands such as data liquidity. In conclusion, the article takes the position that health-care-data exceptionalism remains a valid imperative and that even current concerns about data liquidity can be accommodated in an exceptional protective model. However, re-calibrating our protection of health-care data residing outside of the traditional health-care domain is challenging, currently even politically impossible. Notwithstanding, a hybrid model is envisioned with downstream HIPAA model remaining the dominant force within the health-care domain, but being supplemented by targeted upstream and point-of-use protections applying to health-care data in disrupted spaces.

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"Your previous provider refused to share your electronic medical records, but not to worry—I was able to obtain all of your information online."[1]

INTRODUCTION

In 1994, two years before passage of the statute that authorized the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security rules, the Institute of Medicine (IOM) took the position that "legislation should clearly establish that the confidentiality of person-identifiable data is an attribute afforded to the data elements themselves, regardless of who holds the data."[2] That exhortation was ignored, allowing a regulatory vector between the protection of health-care data held inside and outside of the conventional health care space. Policymakers' persistent, systemic failure to safeguard health-care data outside the HIPAA domain is now exemplified by the minimal, sub-HIPAA data protection afforded health-care data either held by data brokers ("companies that collect consumers' personal information and resell or share that information with others"[3]) or created by mobile apps.

The result of this policy misstep is an emerging narrative of regulatory disruption and arbitrage. Simply put, disruption and arbitrage can occur when disruptive businesses in a lightly regulated domain create products previously associated with incumbents of a highly regulated domain.

This is not just another story of emerging technologies exposing the lamentable state of data protection in the United States. It is also an account of the likely depreciation of a health-care-specific policy position that was hard won and as yet has not been convincingly refuted. This policy is health-care privacy exceptionalism. As described below, the fundamental flaw in U.S. data protection was the rejection of generalized or universal protection in favor of a domain-specific model. Virtually alone among those domains, health care carved out a reasonably effective data protection position, referred to as health-care privacy exceptionalism, courtesy of the HIPAA Privacy and Security Rules[4] and their

1. Kaamran Hafeez, *Daily Cartoon*, THE NEW YORKER (Sept. 11, 2015), http://www.newyorker.com/cartoons/daily-cartoon/daily-cartoon-friday-september-11th-healthcare-doctor-visit [https://perma.cc/K3N6-6BW4].

2. INSTITUTE OF MEDICINE, HEALTH DATA IN THE INFORMATION AGE: USE, DISCLOSURE, AND PRIVACY 191 (Molla S. Donaldson & Kathleen N. Lohr eds., 1994) [hereinafter HEALTH DATA IN THE INFORMATION AGE].

3. *Data Brokers: A Call for Transparency and Accountability*, FED. TRADE COMMISSION i (2014), https://www.ftc.gov/system/files/documents/reports/data-brokers-call-transparency-accountability-report-federal-trade-commission-may-2014/140527databrokerreport.pdf [https://perma.cc/M9M5-A6P8] [hereinafter *Data Brokers*].

4. *HIPAA Administrative Simplification, Regulation Text, 45 C.F.R. pts. 160, 162, and 164*

state law analogues.[5] Exceptionalism also has a downside. Conversations about mainstream data protection have tended to ignore, even isolate health care, viewing the domain as *sui generis* and adequately protected by HIPAA.

The key to understanding current disruption and arbitrage in the health-care data sector is an appreciation of the U.S. data protection approach and, obviously, its particular application to health care. While the sectoral nature of U.S. health-care data protections is generally understood, other properties, such as the distinction between upstream and downstream data protection models, may not be so well-known. The intersections of multiple data protection models help explain the current declining state of health-care data protection. Equally, understanding multiple models is helpful in refuting over-simplified binaries (for example, privacy versus data liquidity) and provides insight into potential data protection reforms.

The analysis that follows suggests two examples of regulatory disruption and arbitrage in in health-care data. The first example considers health-care data collected, analyzed, and sold by big data brokers. Some of those data are created within the highly regulated space of health-care practice but legally "exported" (for example, they may have been de-identified). Other big data are created outside the highly regulated health-care domain but are medically inflected, and, once combined with other data points, operate as data proxies for protected HIPAA data. In both scenarios, data triangulation may defeat any de-identification. In the second example, users increasingly generate wellness, fitness, and sickness data on mobile health platforms or by mobile health apps. Again, the picture is complicated (hence the disruption). Some data are created in a highly regulated space but then exported to a mobile device; other data are processed in the opposite direction.

This article takes the position that health-care-data exceptionalism remains a valid imperative and that even current concerns about data liquidity can be accommodated in an exceptional protective model. However, re-calibrating our protection of health-care data residing outside of the traditional health-care domain is challenging. This article envisions a hybrid model, with downstream HIPAA model remaining the dominant force within the health-care domain, supplemented by upstream and point-of-use protections applying to health-care data in disrupted spaces.

(Unofficial Version, as amended through March 26, 2013), U.S. DEP'T HEALTH & HUM. SERVS., http://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/combined/hipaa-simplification-201303.pdf [https://perma.cc/P9R8-QH7A].

5. *See generally* Joy L. Pritts, *Altered States: State Health Privacy Laws and the Impact of the Federal Health Privacy Rule*, 2 YALE J. HEALTH POL'Y L. & ETHICS 327, 332–40 (2002).

I. BACKGROUND: KEY CHARACTERISTICS OF U.S. DATA PROTECTION

The dysfunctional nature of U.S. data protection is ironic given its often-heralded roots. Samuel Warren and Louis Brandeis's famous Harvard article[6] has achieved mythic fame for birthing its eponymous "Right to Privacy." However, looking back at their article today, it is striking to see the relatively narrow driver that led those famous lawyers to propose the recognition of the "right to be let alone."[7] Primarily, they seemed concerned about some members of the press (perhaps, in today's terms, the paparazzi) and what the authors viewed as an inappropriate appetite for gossip and triviality.[8] Indeed, Jill Lepore has described the article, "a manifesto against the publicity of modernity."[9] 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. Those seeking the source of the contemporary data protection debate are more likely to find it, albeit accompanied by dystopian contexts, in Alan Westin's 1967 book *Privacy and Freedom*[10] or his 1972 preview of today's data broker issues, *Databanks in a Free Society*.[11]

With no little irony given the health-care context of this paper, it was the U.S. Department of Health, Education, and Welfare (HEW), a precursor to the Department of Health & Human Services (HHS), which first considered a comprehensive privacy law applying across all domains and regulating both public and private entities.[12] The HEW report discussed both government and non-governmental information practices[13] and outlined one of the first iterations of Fair Information Practice Principles (FIPPs).[14] FIPPs are a distillation of the best information practices common to developed democracies and, as noted by the Federal Trade Commission (FTC), include some core privacy principles: (1) Notice/Awareness; (2) Choice/Consent; (3) Access/Participation; (4) Integrity/Security; and (5) Enforcement/Redress."[15]

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6. Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193 (1890).

7. *Id.* at 195.

8. *Id.* at 196.

9. Jill Lepore, *The Prism: Privacy in an Age of Publicity*, NEW YORKER (June 24, 2013), http://www.newyorker.com/reporting/2013/06/24/130624fa_fact_lepore [https://perma.cc/5AN6-EAH5].

10. ALAN F. WESTIN, PRIVACY AND FREEDOM (1967).

11. ALAN F. WESTIN, MICHAEL A. BAKER, DATABANKS IN A FREE SOCIETY: COMPUTERS, RECORD-KEEPING, AND PRIVACY (1972).

12. SECRETARY'S ADVISORY COMM., U.S. DEP'T. HEALTH, EDUC. & WELFARE, DHEW PUB. NO. (OS) 73–94, RECORDS, COMPUTERS, AND THE RIGHTS OF CITIZENS (1973), http://www.justice.gov/opcl/docs/rec-com-rights.pdf [https://perma.cc/ZU4D-DGC9].

13. *Id.* at 33–46.

14. *Id.* at xx-xxi, xxiii.

15. *Privacy Online: A Report to Congress*, FED. TRADE COMMISSION, 7 (1998),

Unfortunately, the misstep that followed was that the HEW report only recommended, and Congress only enacted, privacy legislation to control the data collecting practices of the federal government. Many of the issues discussed in this article can be traced back to this Pyrrhic victory, the Privacy Act of 1974.[16] What Frank Pasquale has termed U.S. privacy law's "original sin" was the failure to embrace a comprehensive rather than piecemeal approach to data protection.[17]

A. Sectoral Data Protection

Thereafter, as acknowledged by the 2012 White House report, "most Federal data privacy statutes appl[ied] only to specific sectors, such as healthcare, education, communications, and financial services or, in the case of online data collection, to children."[18] The original sin is not just about preferring sectoral to more comprehensive regulation. The patchwork of resulting protections "results from the sectoral approach having been created backwards. Rather than coming up with an overall picture and then breaking it up into smaller pieces that mesh together, Congress has been sporadically creating individual pieces of ad hoc legislation."[19] Thus, the "sectoral approach is emblematic of the lack of a perceptible, cohesive commercial data privacy policy, which creates complexity and costs for businesses and confuses consumers."[20]

The sectoral approach has played out over multiple industries. As is well known, the Gramm–Leach–Bliley Act (GLBA) governs consumer privacy in the financial sector.[21] GLBA, like HIPAA, is sectoral, applying to narrowly defined data custodians, specifically groups of financial entities. Just as HIPAA does not apply to all custodians of health-care data, so GLBA does not apply to all who

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https://www.ftc.gov/sites/default/files/documents/reports/privacy-online-report-congress/priv-23a.pdf [https://perma.cc/UXR2-VQLC]. The FIPPs are principles or properties of privacy codes that were initially developed by the FTC but are now featured in codes across the world.

16. 5 U.S.C. § 552a (2012).

17. *Episode 7: Mark Rothstein, Big Data & Health Research, Apple ResearchKit, White House Consumer Privacy Bill*, WEEK HEALTH L. (Apr. 8, 2015), http://twihl.podbean.com/e/7-mark-rothstein-big-data-health-research-apple-researchkit-white-house-consumer-privacy-bill/ [https://perma.cc/LQ48-W2RL].

18. *Consumer Data Privacy in a Networked World: A Framework for Protecting Privacy and Promoting Innovation in the Global Digital Economy*, WHITE HOUSE, 6 (Feb. 2012), https://www.whitehouse.gov/sites/default/files/privacy-final.pdf [https://perma.cc/4YS7-FWWH] [hereinafter *Framework for Protecting Privacy*].

19. *Commercial Data Privacy and Innovation in the Internet Economy: Dynamic Policy Framework*, U.S. DEP'T COM. 60 (Dec. 2010), http://www.ntia.doc.gov/report/2010/commercial-data-privacy-and-innovation-internet-economy-dynamic-policy-framework [https://perma.cc/PG6Z-V6HM] (summarizing commenters).

20. *Id.* at 59.

21. Gramm-Leach-Bliley Act, Pub. L. No. 106-102, § 501, 113 Stat. 1338, 1436–37 (1999). *See generally* Edward J. Janger & Paul M. Schwartz, *The Gramm-Leach-Bliley Act, Information Privacy, and the Limits of Default Rules*, 86 MINN. L. REV. 1219, 1219–20 (2002).

hold consumer financial data.[22] And like HIPAA, GLBA is a downstream data-protection model that erects a duty of confidentiality[23] and requires notice to consumers of an institution's privacy policies and practices.[24] The Fair Credit Reporting Act (FCRA) applies to consumer reporting agencies regarding important if narrow requirements relating to quality, transparency, and access.[25] Other examples cover still narrower sectors such as video rental records.[26] Even now, with the sectoral approach to data protection understood as causing severe regulatory gaps, calls for narrowly focused "fixes" continue, whether to protect student records from big data brokers[27] or to prevent automobiles from "spying" on their drivers.[28]

A sectoral approach to data protection has other flaws. For example, sectoral 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."

This sectoral limitation of substantive law spills over into rulemaking and enforcement. Inter-agency cooperation has never been a core strength of the federal government, and turf wars likely exacerbate regulatory gaps. It is one thing not to have a comprehensive privacy model. It is another not to have a unified data-protection agency. For example, the European Union has had a (relatively) uniform law since 1995.[29] The new General Data Protection Regulation (GDPR)[30] has attracted interest because of its erasure[31] and breach

22. *See* 15 U.S.C. § 6805(a) (2012). Notwithstanding, the FTC does have some broad residual powers. *See* Privacy of Consumer Financial Information; Final Rule, 65 Fed. Reg. 33,646 (May 24, 2000) (codified at 16 C.F.R. pt. 313).

23. 15 U.S.C § 6802(a)(1) (2012) (requiring non-disclosure of "nonpublic personal information" to "nonaffiliated third parties").

24. *See* 15 U.S.C. §§ 6803(a), (c) (2012).

25. 15 U.S.C. §§ 1681–1681x (2012).

26. Pub. L. No. 100–618, 102 Stat. 3195. *See generally* Mollett v. Netflix, Inc., 795 F.3d 1062 (9th Cir. 2015). For more examples of narrow, sectoral legislation *see* Daniel J. Solove, *Privacy and Power: Computer Databases and Metaphors for Information Privacy*, 53 STAN. L. REV. 1393, 1440–44 (2001).

27. *See, e.g.*, Press Release, Sen. Ed Markey, Sens. Markey & Hatch Reintroduce Bipartisan Legislation to Protect Student Privacy (May 13, 2015), http://www.markey.senate.gov/news/press-releases/sens-markey-and-hatch-reintroduce-bipartisan-legislation-to-protect-student-privacy [https://perma.cc/AD5Y-7JP9].

28. Press Release, Sen. Ed Markey, Sens. Markey, Blumenthal Introduce Legislation to Protect Drivers from Auto Security, Privacy Risks with Standards & "Cyber Dashboard" Rating System (July 21, 2015), http://www.markey.senate.gov/news/press-releases/sens-markey-blumenthal-introduce-legislation-to-protect-drivers-from-auto-security-privacy-risks-with-standards-and-cyber-dashboard-rating-system [https://perma.cc/2ZMZ-BMWA].

29. Directive 95/46/EC, of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with regard to the Processing of Personal Data and on the Free Movement of such Data, 1995 O.J. (L 281/31), http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:31995L0046 [https://perma.cc/S49Z-VL4V].

30. Commission Regulation 2016/679 of the European Parliament and of the Council of 27

notification[32] provisions. However, arguably one of its most significant achievements is to make enforcement and interpretation more consistent across the EU by designating a primary, "one-stop shop" regulator[33] and promoting additional coordination through the European Data Protection Board.[34]

Of course, the observation that U.S. data protection is flawed because of its sectoral nature is only part of the story. The sectors (including health care) are narrowly defined. After conventional health and, arguably[35] financial services, the drop off in protections is sharp. In large part, this is because the United States has favored relatively-low-protection models, most of which are downstream.

B. Upstream vs. Downstream Protection Models

The upstream-downstream typology described here may appear somewhat complex. However, its origins can be traced to a much simpler relationship—that between privacy and confidentiality. According to Tom Beauchamp and James Childress:

> [A]n infringement of a person's right to confidentiality occurs only if the person or institution to whom the information was disclosed in confidence fails to protect the information or deliberately discloses it to someone without first-party consent. By contrast, a person who, without authorization, enters a hospital record room or computer database violates rights of privacy but does not violate rights of confidentiality. Only the person or institution that obtains information in a confidential relationship can be charged with violating rights of confidentiality.[36]

This description captures a clear process chronology. First, "privacy"

April 2016 on the Protection of Natural Persons with regard to the Processing of Personal Data and on the Free Movement of such Data, and Repealing Directive 95/46/EC, 2016 O.J. (L 119) 1 (General Data Protection Regulation), http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG&toc=OJ:L:2016:119:TOC [https://perma.cc/R5NP-FR2Z].

31. *Id.* art. 17.

32. *Id.* arts. 33–34.

33. *Id.* arts. 56–65.

34. *Id.* arts. 68–76.

35. *Cf.* Kathleen A. Hardee, *The Gramm-Leach-Bliley Act: Five Years After Implementation, Does The Emperor Wear Clothes?*, 39 CREIGHTON L. REV. 915 (2006).

36. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 316–17 (7th ed. 2013); *see also* Humphers v. First Interstate Bank of Oregon, 696 P.2d 527 (Or. 1985) ("Although claims of a breach of privacy and of wrongful disclosure of confidential information may seem very similar in a case like the present, which involves the disclosure of an intimate personal secret, the two claims depend on different premises and cover different ground . . . [T]he most important distinction is that only one who holds information in confidence can be charged with a breach of confidence. If an act qualifies as a tortious invasion of privacy, it theoretically could be committed by anyone.")

protects against the unauthorized collection of health-care data. Subsequently, once the collection has been authorized, the recipient subsequently owes a duty of "confidentiality" not to disclose the data. That is, privacy (different flavors of which either prohibit or place limitations or conditions on the collection of data) protects data upstream of confidentiality.

Thus, the lifecycle of data can be mapped to a timeline-based typology. That typology may be expanded beyond "privacy" and "confidentiality" to include other data-protective models including core FIPPS, such as transparency, individual participation (including consent, access, correction, and redress), purpose specification, data minimization, use limitation, data quality and integrity, security, accountability, and auditing.[37] In broad terms, models that are applicable before or during collection are labeled "upstream," while those applied post-collection are labeled "downstream."

To privacy (upstream) and confidentiality (downstream) I now add some other basic data protection models (which may or may not be deployed by ethical, legal, or technological systems) such as anonymization, de-identification,[38] breach notification, inalienability, point-of-use regulation, or security.

Anonymizing data prior to any collection or using something like an inalienability or market inalienability[39] rule to reduce the use case/value of the data will tend to reduce the likelihood that the data are collected.

Upstream Models	
Model	**Detail**
Anonymization	Mandates removal of certain identifiers *before* data can be collected
Inalienability	Prohibits transfer of certain data, thus reducing their value and disincentivizing collection
Privacy	Prohibits or places limitations or conditions on the collection of data

37. *National Strategy for Trusted Identities in Cyberspace: Enhancing Online Choice, Efficiency, Security, and Privacy*, WHITE HOUSE 45 (April 2011), https://www.whitehouse.gov/sites/default/files/rss_viewer/NSTICstrategy_041511.pdf [https://perma.cc/7JH3-MX7P].

38. While anonymization removes all associations between data and data subject, de-identification removes only select associations, leaving open the possibility, however slight, of re-identification. *See generally* Simson L. Garfinkel, *De-Identification of Personal Information*, U.S. DEP'T COM. NAT. INST. STANDARDS TECH., 2 (October 2015), http://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf [https://perma.cc/Q898-QD5K].

39. *See generally* Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849 (1987).

In contrast, point-of-use regulation (such as the prohibition of discriminatory uses), security, and breach notification are downstream, post-collection protective models.

Downstream Models	
Model	**Detail**
Point-of-Use Regulation	Prohibits the use of legally collected data for certain (typically discriminatory) purposes
Security	Requires perimeter, encryption, or behavioral controls to impede unauthorized data access
Confidentiality	Prohibits data disclosure by data custodian or limits disclosure to certain persons or for certain purposes
Breach Notification	Obligates data custodian to disclose data compromise to data subject and/or regulator

This basic upstream-downstream relational structure may now be expanded to include other protective sub-models and also cross-walked to FIPPS.

Characteristic	Data Protection Model	Sub-Models/FIPPS
Upstream	Anonymization	
	Inalienability	
		Market Inalienability
	Privacy (Broad Control of Collection)	
		Control/Consent
		Purpose Specification
		Data Minimization/Proportionality
		Transparency
Downstream	Right of Erasure	
		De-linking

Point of Use Regulation	
	Non-discrimination
	Purpose limitation
Security	
	Accounting/Audit
	Quality & Integrity
Confidentiality (Broad Control of Disclosure)	
	Use Limitation
	Quality & Integrity
	Anonymization
	De-identification
	Pseudonymization
	Suppression
	Perturbation
	Prohibitions on Reidentification
	Transparency
	Access/Accuracy/Correction
	Accounting/Audit
Breach Notification	

This more complex representation also reflects that some protections (for example, transparency or, where they overlap, anonymization and de-identification) can occur at multiple times in the lifecycle of the data. Note also that some sub-models are complimentary. For example, the upstream privacy (collection) sub-model that prohibits collection of data other than for a disclosed purpose would likely be complemented by a downstream prohibition on disclosure other than for the stated purpose.

I suggest several interrelated takeaways from this typology. First, and most obviously, policymakers (or, for that matter, data custodians) can and *should*

choose from a broad array of data protection models. Having a comprehensive toolbox should help regulators finely calibrate their approach to particular data risks and help them be prepared to deal with evolving or currently unknown data risks.

Second, a broad understanding of the various data protection models *and* their relative approaches to protecting data should make it less likely that policymakers and data custodians will resort to generalized statements about protecting data. For example, those who use "privacy" rhetoric should have their feet held to the fire about the specifics of their calls for more or less data protection.

Third, the complexity of this typology is worthwhile if it helps push back against the tendency to reduce policy discussions to binaries or other over-simplifications. Even a creaking common law found room for both privacy and confidentiality models, while today policymakers and regulators can choose from an array of upstream and downstream data protection models. For example, it has been common for mainstream data protection proposals to exclude data or data custodians subject to HIPAA.[40] However, once it is appreciated that HIPAA is a downstream confidentiality model, it makes sense to *include* health care in discussions about the adoption of future *upstream* protective models.

Finally, this typology locates health-care data protection within the mainstream of data protection. Mainstream data protection should embrace health-care data protection as one of its own and learn from its experiences. The resolutely downstream, highly detailed, prescriptive HIPAA privacy rule is unique and the law and policy literature surrounding it is robust. This is a two-way street. As argued below, health-care data protection needs to move beyond its HIPAA-centricity and see what additional models could be used to protect health-care data generated or used both inside and outside of traditional health-care environments. Non-health-care domains, conversely, should learn from health care's twenty years of experience with HIPAA.

II. REGULATORY TURBULENCE, DISRUPTION & ARBITRAGE

Regulatory turbulence, disruption, and arbitrage presuppose the juxtaposition of at least two regulatory domains. In the simplest case, one domain would be regulated, the other unregulated. Turbulence and disruption exist on a continuum. Regulatory turbulence may be only transient or, in the scheme of things, relatively benign. Regulatory disruption has more permanent and serious

40. *See, e.g.*, *Protecting Consumer Privacy in an Era of Rapid Change: Recommendations for Businesses and Policymakers*, FED. TRADE COMMISSION, i-v (Mar. 2012), https://www.ftc.gov/sites/default/files/documents/reports/federal-trade-commission-report-protecting-consumer-privacy-era-rapid-change-recommendations/120326privacyreport.pdf [https://perma.cc/VJ9Q-KQU4] [hereinafter *Protecting Consumer Privacy*]; *Framework for Protecting Privacy*, *supra* note 18, at 38.

implications. Regulatory arbitrage occurs when a business purposefully exploits disruption, making business choices on the basis of the difference between the two regulatory domains.

A slightly different way to think about these phenomena is to posit horizontal and vertical products. Turbulence and disruption occur when horizontal business products (for example, cloud services or smartphone platforms) are dropped into vertical markets without regard to potentially unique regulatory issues. On the other hand, arbitrage tends to occur when a business is aware of a vertical market's unique regulation and builds a surrogate or proxy business in a less regulated vertical market.

A. Turbulence and Disruption

Regulatory turbulence, disruption and potentially arbitrage will most likely occur following some type of business disruption. True to Clayton Christensen's classic disruption theory,[41] such a business disruption frequently occurs because a disruptive technological innovation has empowered an entrant attacker to challenge mainstream industry incumbents.[42] Disruptive technologies may initially underperform (or undershoot) incumbents' sustaining technologies. However, disruptive technologies "are typically cheaper, simpler, smaller, and, frequently, more convenient to use."[43] Business disruption can also include "[n]ew-market disruptive innovations," which "occur when characteristics of existing products limit the number of potential consumers or force consumption to take place in inconvenient, centralized settings."[44]

Regulatory turbulence and disruption tend to develop in parallel with or soon after business disruption. Take ride-hailing services typified by Uber[45] or Lyft.[46] They generally obey the business disruption model. Incumbent taxi services, although featuring (apparently) professionally-trained drivers, access at major locations, and liveried cabs, rely on sustaining technologies such as telephone bookings or in-person ride-hailing, and cash or often poorly implemented credit card payments. Disruptive ride-hailing services leverage spare capacity in private owners' vehicles, ubiquitous mobile communication, expanded locations, and payment services to deliver nimbler, more convenient services. The core "assets"

41. *See, e.g.*, CLAYTON M. CHRISTENSEN, THE INNOVATOR'S DILEMMA: WHEN NEW TECHNOLOGIES CAUSE GREAT FIRMS TO FAIL (1997).

42. *See generally* Nicolas P. Terry, *Information Technology's Failure to Disrupt Health Care*, 13 NEV. L.J. 722 (2013).

43. CHRISTENSEN, *supra* note 41, at xv.

44. CLAYTON M. CHRISTENSEN ET AL., SEEING WHAT'S NEXT: USING THE THEORIES OF INNOVATION TO PREDICT INDUSTRY CHANGE xvii (2004).

45. UBER TECHNOLOGIES, INC., https://www.uber.com [https://perma.cc/7R88-X93Q].

46. LYFT, INC., https://www.lyft.com [https://perma.cc/7AY4-T2VL].

of ride-hailing or housing (such as Airbnb[47]) businesses are traditionally-underused resources that modern technologies can easily make available to a "sharing economy." In addition, their business models clearly embrace regulatory disruption.

Ride-hailing services initially caused regulatory turbulence, based on uncertainty as to whether they were subject to existing regulatory models. Indeed, this appeared to be a deliberate part of their disruptive strategy. Uber, in particular, challenged local regulations or argued they were ambiguous. Their CEO noting in 2013: "It's a regulatory disruption . . . We don't talk about that a lot in tech. But you can disrupt from all sorts of directions."[48] These businesses, whether sharing unused automobile or housing resources, at the root are adopting business models that seek to reduce costs relative to incumbent competitors by avoiding or marginalizing self-regulatory organizations (such as guilds[49]), governmental rationing (such as medallions[50]), or regulatory models (such as licensure[51] or employment laws[52]).

Initial regulatory turbulence buys time during which the innovator can press for accommodating regulatory compromises (that themselves further continued

47. AIRBNB, INC., https://www.airbnb.com [https://perma.cc/5XQ8-LEV9].

48. *Uber CEO Talks Regulatory Disruption, Maintaining Startup Culture*, MIT SLOAN MGMT. (Nov. 6, 2013), http://mitsloan.mit.edu/newsroom/articles/uber-ceo-talks-regulatory-disruption-maintaining-startup-culture [https://perma.cc/NG3C-XWC7].

49. *See generally* Justin Fox, *The Problem with Guilds, from Silversmiths to Taxi Drivers*, HARV. BUS. REV. (Dec. 4, 2014), https://hbr.org/2014/12/the-problem-with-guilds-from-silversmiths-to-taxi-drivers [https://perma.cc/G5YR-45H5]; *see also*, Erik Engquist, *Judge Rules on Taxi Industry Lawsuit: Compete with Uber or Die*, CRAIN'S N.Y. BUS. (Sept. 9, 2015), http://www.crainsnewyork.com/article/20150909/BLOGS04/150909863/judge-rules-on-taxi-industry-lawsuit-compete-with-uber-or-die [https://perma.cc/E7D4-T2NE].

50. Aamer Madhani, *Once a Sure Bet, Taxi Medallions Becoming Unsellable*, USA TODAY (May 18, 2015), http://www.usatoday.com/story/news/2015/05/17/taxi-medallion-values-decline-uber-rideshare/27314735 [https://perma.cc/VD9D-NJ65].

51. *See, e.g.*, Colleen Wright, *Uber Says Proposed Freeze on Licenses in New York City Would Limit Competition*, N.Y. TIMES (June 30, 2015), http://www.nytimes.com/2015/07/01/nyregion/uber-says-proposed-freeze-on-licenses-would-limit-competition.html [https://perma.cc/R2MN-JU39]; *see also* Sebastian Anthony, *London Mayor Says Uber Is Systematically Breaking the Law*, ARS TECHNICA (Oct. 5, 2015), http://arstechnica.com/cars/2015/10/boris-johnson-says-uber-is-systematically-breaking-the-law-in-london [https://perma.cc/7SGM-R4XN]; Leon Daniels, *Transport for London: Uber and London's Private Hire Trade Need New Regulations*, CITY A.M., LTD. (Oct. 20, 2015), http://www.cityam.com/226929/transport-for-london-uber-and-londons-private-hire-trade-need-new-regulations [https://perma.cc/7AR2-8DCW]. Leah Thorsen, *Defying Regulators, Uber Launches Service, Files Lawsuit*, STLTODAY.COM (Sept. 19, 2015), http://www.stltoday.com/business/local/uber-sues-st-louis-taxicab-commission-launches-service-without-approval/article_42b7f122-b8a6-536f-ba68-6acef3503075.html [https://perma.cc/DC7W-UAQY].

52. *See, e.g.*, Sean Buckley, *California Unemployment Office Says Uber Driver was an Employee*, ENGADGET (Sept. 11, 2015), http://www.engadget.com/2015/09/11/california-unemployment-office-says-uber-driver-was-an-employee [https://perma.cc/UX3X-453C].

disruption) or create or exploit regulatory gaps (enabling regulatory arbitrage).[53] All the while, the disruptive services and their technologies mature, cease undershooting the incumbents, and gain popularity and market share that regulators will fear to reverse.[54] Former White House aide Ron Klain describes the phenomenon as follows:

> [W]hat these Internet 3.0 companies are disrupting is not really technology, but regulatory regimes. What makes AirBnb exceptional is not any technological breakthrough, but how it is challenging local hospitality regulation, condo board rules, and all the other limitations on who can charge what and when for short-term housing usage. Crowdfunding sites likewise use technology that has been around for years: what they are disrupting is the vast array of federal and state regulations that govern who can invest in what, and under what terms. The same is true of so many other emerging Internet companies: their impact is far more in disrupting governmental and quasi-governmental rules than it is in technological breakthroughs.[55]

While policy and political allegiances slowly determine a regulatory re-calibration, incumbents and attackers operate in an uneven, even incoherent regulatory system that applies different rules to what should be competing services.

In the health-care space, some service providers claim or are hailed as having Uber-like characteristics. For example, *American Well* promises 24x7 doctor consultations,[56] while *Heal*[57] and *pager*[58] promise timely house calls by a physician. However, these are far less disruptive than they appear at first sight. They generally are respectful of regulatory systems and while leveraging mobile technologies do not attack incumbents' features, such as third party

53. *Cf.* Amar Toor, *Uber Drivers Stage Protest over French Response to Taxi Strike*, VERGE (Feb. 3, 2016), http://www.theverge.com/2016/2/3/10903662/uber-protest-paris-taxi-strike-vtc [https://perma.cc/N448-SYDD].

54. Of course, there are exceptions. *See* Mark Scott, *Uber's No-Holds-Barred Expansion Strategy Fizzles in Germany*, N.Y. TIMES (Jan. 3, 2016), http://www.nytimes.com/2016/01/04/technology/ubers-no-holds-barred-expansion-strategy-fizzles-in-germany.html [https://perma.cc/Q4GT-3S58].

55. Ron Klain, *Airbnb's Biggest Disruption: America's Laws*, FORTUNE (Sept. 10, 2014), http://fortune.com/2014/09/10/airbnbs-biggest-disruption-americas-laws [https://perma.cc/MJY3-U2PX].

56. AMERICAN WELL, https://www.americanwell.com/how-it-works [https://perma.cc/5B5Q-JZXT].

57. *What is Heal?*, HEAL, https://help.getheal.com/hc/en-us/articles/204181405-What-is-Heal [https://perma.cc/248B-3WKQ]; *see generally* Kavita Daswani, *Feeling Sick? How About a House Call from a Doctor? A New App, Heal, Makes it Happen*, L.A. TIMES (Nov. 7, 2015), http://www.latimes.com/health/la-he-heal-at-home-20151107-story.html [https://perma.cc/MC8X-QF99].

58. PAGER, https://pager.com [https://perma.cc/L4WK-WQJG].

reimbursement. So far, they have opted for more of a concierge model that has limited scalability.

Indeed, business disruption has generally failed in the health-care space. The most conspicuous failure has been Google's failed challenge to the data hegemony of incumbent health-care entities by offering low-cost personal health records (PHRs).[59] The low level of business disruption probably explains the relatively low level of regulatory turbulence or disruption in the domain, at least until recently.

There are several reasons why technology companies have found health care difficult to disrupt. The dominant reason is health care's primary financing model. "Third-party reimbursement systems sap motivation for innovation—particularly disruptive innovation—out of the system."[60] However, there are additional, deep-seated causes. Thus, the "meaningful use" debacle suggests that while market failure was one explanation for the slow adoption of Electronic Health Records (EHRs), underperforming products may have been as salient.[61] Further, information technologies may not be a good fit for current, unreformed health care. Information technology maps best to processes, not health care's flawed episodic nature. Additionally, information technologies thrive on liquid data, which health care still struggles to promote.[62] It is also possible that technology companies, perhaps fooled by the presence of vertical integration and positive outliers (such as the VA or Kaiser Permanente), underestimated the challenge of changing culturally constipated, heterogeneous providers.

Notwithstanding the absence of direct business disruption, two phenomena, big data collection and mobile health, are proving to be indirectly disruptive—with the potential to move into a more direct mode. Indeed, the argument can be made that mobile health is an example of Uber-like regulatory disruption or "uberfication," a disruptive, tech-heavy approach that promotes "uber-convenience" through always-on mobile services that instantly match patient demand with health-care supply. Both mobile health and big data analytics have developed primarily outside of (and sometimes in parallel to) traditional health-care spaces. As their overlaps increase, however, they are also providing technologically-mediated alternatives to traditional health-care interactions, services, and data. In this regard, they offer the potential for business disruption. As discussed below, they are already disrupting regulatory models and exhibiting some arbitrage.[63]

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59. *See infra* text accompanying note 117.

60. CHRISTENSEN, *supra* note 44, at 197.

61. Nicolas P. Terry, *Pit Crews With Computers: Can Health Information Technology Fix Fragmented Care?*, 14 HOUS. J. HEALTH L. & POL'Y 129, 168–75 (2014).

62. *Id.*

63. *See infra* text accompanying note 196, 212.

B. Arbitrage

In Victor Fleischer's words, regulatory arbitrage "exploits the gap between the economic substance of a transaction and its legal or regulatory treatment . . ."[64] However, Fleischer was primarily interested in "regulatory gamesmanship" and modeling the tradeoff between regulatory and transaction costs. The examination of regulatory arbitrage in this article more closely resembles leveraging differences in regulatory substance between different jurisdictions. A well-known example is the "double-Irish," when a taxpayer shifts income out of a high-tax jurisdiction into a tax haven.[65] Examples in the health-care domain would include Israeli gays, prohibited by domestic law from using surrogacy, employing third world surrogates instead,[66] a UK resident avoiding a health-care shortage (wait-list) by having the procedure performed elsewhere in the European Union and subsequently requiring the UK to reimburse them,[67] and providers attracting patients to jurisdictions where CRISPR-Cas gene editing is available.[68]

Of course, the issue discussed herein is not transnational, but rather domestic arbitrage that exploits variances between U.S. regulatory silos. An evolving example of domestic regulatory disruption or arbitrage in our health-care domain is the growing "off-label use" of FDA approved drugs. Two "disruptions" enabled the regulatory arbitrage. First, business disruption created massive (and highly profitable) markets for unapproved uses. Second, the legal disruption (or "First Amendment opportunism"[69]) caused by the rapid development of (commercial) speech jurisprudence.[70]

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64. Victor Fleischer, *Regulatory Arbitrage*, 89 TEX. L. REV. 227, 229 (2010).

65. *See, e.g.*, *Death of the Double Irish*, ECONOMIST (Oct. 18, 2014), http://www.economist.com/news/finance-and-economics/21625876-irish-government-plans-alter-one-its-more-controversial-tax [https://perma.cc/NTS3-JEPT]; *see generally* Annelise Riles, *Managing Regulatory Arbitrage: A Conflict of Laws Approach*, 47 CORNELL INT'L L.J. 63 (2014).

66. Ruth English, *Among Nepal's Earthquake Survivors: Israeli Gays and Their Surrogate Babies*, WASH. POST (Apr. 30, 2015), https://www.washingtonpost.com/world/how-an-earthquake-highlighted-the-plight-of-israeli-gays-and-their-surrogate-babies/2015/04/29/419d60e8-ecf0-11e4-8050-839e9234b303_story.html [https://perma.cc/39M7-P964].

67. *See* C-372/04, Watts v. Bedford Primary Care Trust, 2006 E.C.J. I-04325; *see generally* Nicolas P. Terry, *Under-Regulated Healthcare Phenomena in a Flat World: Medical Tourism and Outsourcing*, 29 W. NEW ENG. L. REV. 421–72 (2007).

68. *See, e.g.*, R. Alta Charo, *On the Road (to a Cure?)—Stem-Cell Tourism and Lessons for Gene Editing*, 374 NEW ENG. J. MED. 901 (2016).

69. FREDERICK SCHAUER ET AL., ETERNALLY VIGILANT: FREE SPEECH IN THE MODERN ERA 175–76 (Lee C. Bollinger & Geoffrey R. Stone eds., 2001).

70. *See, e.g.*, Sorrell v. IMS Health Inc., 131 S.Ct. 2653 (2011). *See generally* Jennifer M. Keighley, *Can You Handle the Truth? Compelled Commercial Speech and the First Amendment*, 15 U. PA. J. CONST. L. 539 (2012); Robert Post, *Transparent and Efficient Markets: Compelled Commercial Speech and Coerced Commercial Association in United Foods, Zauderer, and Abood*, 40 VAL. U. L. REV. 555 (2006). *See also* Aaron S. Kesselheim, *Off-Label Drug Use and Promotion: Balancing Public Health Goals and Commercial Speech*, 37 AM. J.L. & MED. 225 (2011).

In *U.S. v. Caronia*, the Second Circuit overturned the conviction of a drug representative for promoting an off-label use of a central nervous system depressant. Applying strict scrutiny, the court held the government could not prosecute manufacturers or representatives for speech promoting the lawful, off-label use of an approved drug.[71] Dissenting, Judge Livingston recognized the regulatory disruption caused by her colleagues. "[T]he majority calls into question the very foundations of our century-old system of drug regulation."[72] The court described the regulatory gap exploited by the drug company as follows: "[t]o obtain FDA approval, drug manufacturers are required to demonstrate, through clinical trials, the safety and efficacy of a new drug for each intended use or indication" but that "[o]nce FDA-approved, prescription drugs can be prescribed by doctors for both FDA-approved and -unapproved uses; the FDA generally does not regulate how physicians use approved drugs."[73] By marketing its regulated drug to unregulated (in this context) physicians, the drug company created regulatory disruption. Subsequently, in *Amarin Pharma, Inc. v. FDA*, a district court rejected FDA's narrow reading of *Caronia* and enjoined the agency from threatening a misbranding action in another off-label use case because it chilled protected speech.[74] One of the FDA's goals in pursuing such actions is to "encourage use of the FDA's drug review and approval process" and "deter manufacturers from evading the FDA's review process for additional uses of approved drugs."[75] By leveraging the differential regulatory models applied to drug manufacturers and doctors, the industry is avoiding that very process.

C. Implications of Regulatory Disruption and Arbitrage

As discussed above, using ride-hailing and accommodation-sharing services as examples, regulatory turbulence tends to create uncertainty, which increases information costs among market participants, policymakers, and regulators. This may be followed by far more serious regulatory disruption where incumbents and attackers face uneven policy environments. These *de facto* differential regulatory environments may be a product of non-enforcement by regulators. For example, regulators may exercise discretion for fear of, say, frustrating innovation or the political cost of "interfering" with a popular new service. Equally, in an attempt

71. 703 F.3d 149, 169 (2nd Cir. 2012).

72. *Id.*

73. *Id.* at 153 (citations omitted).

74. 119 F. Supp. 3d 196 (S.D.N.Y. 2015). Subsequently Amarin and FDA settled the case. Order of Settlement, Amarin Pharma, Inc. v. FDA, 119 F. Supp. 3d 196 (S.D.N.Y. 2015) (No. 1:15-CV-03588). *See also* Kathleen M Sanzo, Lisa D. Dykstra & Jacqueline R. Berman, *FDA and Amarin Reach Settlement on First Amendment and Off-Label Statements*, NAT'L L. REV. (Mar. 10, 2016), http://www.natlawreview.com/article/fda-and-amarin-reach-settlement-first-amendment-and-label-statements [https://perma.cc/7GYE-LDTR].

75. *Amarin*, 119 F. Supp. 3d at 205.

to deal temporarily with disruption during a time of policy recalibration, agencies might issue sub-regulatory "guidances." Seeking to be supportive of both incumbents and innovators can be unclear, so the regulatory guidances create ambiguity and therefore increase disruption. In the data space, regulatory disruption does not stop with similar data being subject to differential regulation. Additionally, data subjects may experience regulatory "churn" during their lifecycle, as data repeatedly enter or exit regulated and lightly regulated spaces (or even exist in both spaces simultaneously), further adding to the information costs in identifying a current regulatory state.

III. EXCEPTIONALISM AND THE HEALTH-CARE DATA PROTECTION MODEL

HIPAA has been one of the most consistently criticized regulatory constructs in the health-care sector.[76] Yet, its levels of data protection and enforcement likely would provoke envy from data subjects in other domains. HIPAA provides relatively robust protections against unauthorized uses of health information by a relatively narrow set of traditional health-care provider data custodians. Its inherent limitations are because of its narrow domain inclusions (some traditional health-care providers and insurers, *not* all custodians of health-care data) and because it uses downstream data protection modes (that is, it does almost nothing to regulate the *collection* of health data). An accurately labeled HIPAA privacy rule would be something like "the doctor/hospital/insurer" confidentiality rule. The other HIPAA rules—security and breach notification—have the same limitations; U.S. health-care data protection is not only sectoral, but also almost completely downstream.

A. Sectoral Model

As noted by the White House report on big data, "[i]n the United States during the 1970s and 80s, narrowly-tailored sectoral privacy laws began to supplement the tort-based body of common law. These sector-specific laws create privacy safeguards that apply only to specific types of entities and data."[77] When HIPAA was originally drafted, there was every reason to believe that the domain-limited model was intended, in large part, to separate health-care data

76. *See, e.g.*, Nicolas P. Terry & Leslie P. Francis, *Ensuring the Privacy and Confidentiality of Electronic Health Records*, 2007 U. ILL. L. REV. 681 (2007); Nicolas P. Terry, *What's Wrong with Health Privacy?*, 5 J. HEALTH & BIOMEDICAL L. 1 (2009). More recently, *see* Charles Ornstein & Annie Waldman, *Few Consequences for Health Privacy Law's Repeat Offenders*, PROPUBLICA (Dec. 29, 2015), https://www.propublica.org/article/few-consequences-for-health-privacy-law-repeat-offenders [https://perma.cc/LD6S-FJNA]; Mark Rothstein, *The End of the HIPAA Privacy Rule?*, 44 J.L. MED. & ETHICS 352 (2016).

77. *Big Data: Seizing Opportunities, Preserving Values*, WHITE HOUSE 18 (May 2014), https://www.whitehouse.gov/sites/default/files/docs/big_data_privacy_report_may_1_2014.pdf [https://perma.cc/QTU9-6FB3] [hereinafter *Big Data: Seizing Opportunities*].

from financial services data.[78]

There could have been no misapprehension that all health-care data custodians would be covered by the rule given the limitations of the enabling legislation.[79] The likely proof is that the coverage of outsiders such as law firms and marketing companies had to be "patched" with mandatory contracts between insider-covered entities and their outsider "business associate."[80] It was not until 2009 when additional statutory authority provided by the Health Information Technology for Economic and Clinical Health (HITECH) Act[81] allowed for their direct regulation.[82] Similarly, it was apparent early on that neither life insurers, nor most employers[83] (except to the extent that they were also health plan administrators[84]) were covered. Those exceptions aside, HIPAA appeared to blanket health care, at least as we knew it in 1999. This was achieved using sector-specific language: "(1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction. . ."[85]

Ignoring the technical verbiage, HIPAA regulated health insurers and traditional health-care providers such as doctors, hospitals and pharmacists.[86] A couple of other limitations to the definition of protected data minimally reduced the ranks of regulated providers. For example, the requirement of transmittal of "any health information in electronic form"[87] may have excluded some technologically limited, often rural providers.

Other exclusions are more implicit. For example, only "individually identifiable health information"[88] is protected, and "[h]ealth information that does not identify an individual . . . is not individually identifiable health information."[89] As a result, de-identified data are not subject to HIPAA regulation. De-identification may be achieved by the use of the expert (aka

78. *See infra* text accompanying note 133 *et seq.*

79. The legislation primarily was concerned with imposing e-commerce models on those engaged in traditional health-care transactions. Hence, the regulatory authority was limited to providers, insurers and clearinghouses. *See* HIPAA Act of 1996, Pub. L. No. 104-191, § 262, 110 Stat. 1936, 2021–31 (codified in scattered sections of 42 U.S.C.).

80. 45 C.F.R. §§ 160.103, 164.502(e), .504(e), .532(d)(e) (2016).

81. Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, Pub. L. No. 111-5, § 13401, 123 Stat. 115, 260.

82. *See* 45 C.F.R. § 160.102(b) (2016).

83. 45 C.F.R. § 160.102 (2015) (protected health information).

84. 45 C.F.R. § 164.504(f) (2016).

85. 45 C.F.R. § 160.102 (2016).

86. For a broad critique of the limitations of HIPAA's reach, *see* Terry & Francis, *supra* note 76, at 713–17.

87. 45 C.F.R. § 160.103 (2016) (covered entity).

88. 45 C.F.R. § 164.103 (2016).

89. 45 C.F.R. § 164.514 (2016).

statistical) method[90] or the removal of certain identifying elements so as to trigger a safe harbor.[91] Furthermore, an Institutional Review Board (IRB) can, in limited circumstances, act as a surrogate for individuals and waive consent/authorization for the use of identifiable data for research purposes.[92] Taken together, these provisions suggest that most, but not all,[93] researchers fall outside of HIPAA regulation, their use of data instead being subject to the Common Rule.[94]

As a result, HIPAA's own "original sin" is easy to identify. The data protection model is structured around a group of identified health-care data custodians rather than around health-care data. Although HITECH expanded direct applicability and enforcement to business associates in 2009, it granted no additional expansion of the Privacy or Security Rules to deal with health-care data existing outside of the HIPAA-zone. There was one exception: the nature of which illustrated rather than solved the HIPAA deficit. HITECH provided for a breach notification rule applicable to the providers of PHRs by some non-HIPAA-regulated entities. However, it did not extend the HIPAA rule[95] to them; instead, it provided for distinct FTC rule-making for this limited group of non-HIPAA entities.[96] This approach therefore highlights two of the problems associated with sectoral models: fragmentation of data protection by custodian type and sector/sub-sector-specific regulators.

B. Downstream Protection Favored

Contemporary health-care data protection is resolutely and almost exclusively downstream. The HIPAA Privacy Rule employs a downstream data protection model ("confidentiality") that seeks to contain the collected data within the health-care system by prohibiting its migration to non-health-care parties.[97] Its complementary Security Rule imposes physical and technological constraints on patient data storage designed to impede those outside of the health-care system from acquiring such data without consent.

The only upstream protection in HIPAA, patient consent at initiation of the provider-patient relationship was, as discussed below,[98] removed even before the

90. 45 C.F.R. § 164.514(b)(1) (2016).

91. 45 C.F.R. § 164.514(b)(2) (2016).

92. 45 C.F.R. § 164.512 (2016).

93. *Cf.* 45 C.F.R. § 164.514(e) (2016) (limited data set recipients).

94. *See generally Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEP'T HEALTH & HUM. SERVS., http://www.hhs.gov/ohrp/humansubjects/commonrule [https://perma.cc/273L-SGT2].

95. HITECH Act § 13402, 42 U.S.C. § 17932 (2012) (Omnibus Rule).

96. HITECH Act § 13407, 42 U.S.C. § 17939 (2012) (Health Breach Notification Rule).

97. *See, e.g.*, 45 C.F.R. § 164.502 (2016).

98. *See infra* text accompanying note 138.

Privacy Rule came into effect. In modern law, HIPAA aside,[99] only one health-care data-protection law, the Genetic Information Nondiscrimination Act of 2008 (GINA),[100] has exhibited any upstream modeling.[101]

Historically, some upstream, collection-centric data protection models, such as the intentional tort of intrusion into seclusion, have seen limited application in the health-care domain. However, these have experienced only limited build-out. Thus, the seclusion tort seems most comfortable when applied to obviously intentional outlying factual situations such as unconsented-to photography by physicians.[102] Routinely, now, courts seem to prefer the downstream breach of confidence tort as the dominant common law model of health-care data protection.[103]

Even aside from aligning with the prevalent model of U.S. data protection, it is not hard to explain why health-care data protection opted for a downstream path. Historically, the culture of medicine has seemed to favor collecting *everything*. Such a model was largely uncomplicated given the available technologies and diagnostic practice. It was also largely uncontroversial in the context of a traditional, two-party physician-patient relationship; the patient exercised his or her autonomy rights and disclosed all data to the physician in return for more effective treatment and a promise of confidentiality. It is hard to imagine that upstream FIPPS such as context or data minimization would have been explored in this simple health-care data exchange scenario. Rather, any conflicts that arose would tend to be dealt with in the framework of restrictions on data disclosure and the reach of exceptions from it.

It should have been relatively obvious that this model would not scale well to industrial health care. It is not particularly surprising that the eventual federal model would persist with downstream protections—it was after all based on state common law and statutes that also were primarily downstream. Even the latest addition to the health-care data protection regime, the quintessentially downstream breach notification rule introduced in 2009, was likely inspired by

99. This is something of an exaggeration as HIPAA and GINA are tied together in some places, such as by the provisions of the HITECH Act.

100. Pub. L. No. 110–233, 122 Stat. 881 (2008).

101. *See infra* text accompanying note 148 *et seq.* One reviewer made the interesting observation that medical data used in research may be subject to some upstream regulation under the Common Rule, 45 C.F.R. pt. 46. This seems correct in at least two situations. First, some research involving vulnerable populations (such as children or prisoners) is prohibited or regulated so strictly that it may be impractical. Second, unlike clinical data, the Common Rule does require consent prior to the collection or use of data and therefore does operate upstream.

102. *See, e.g.*, McCormick v. England, 494 S.E.2d 431, 435 (S.C. Ct. App. 1997); Burger v. Blair Med. Assocs., 964 A.2d 374, 379 (Pa. 2009); *see also* Susan Candiotti & Alan Duke, *Source: Joan Rivers' Doctor Took Selfie, Began Biopsy Before Her Cardiac Arrest*, CNN (Nov. 11, 2014), http://www.cnn.com/2014/09/16/showbiz/joan-rivers-clinic [https://perma.cc/G5CX-NCCD].

103. *See, e.g.*, Biddle v. Warren Gen. Hosp., 715 N.E.2d 518, 523 (Ohio 1999); Humphers v. First Interstate Bank of Oregon, 696 P.2d 527 (Or. 1985).

state models given the absence of any federal example. The shift from individual to institutional care also highlights a cultural peculiarity with regard to data "ownership" or its control. While the pre-industrial model was an informal sharing of responsibilities between physician and patient, joint ownership did not survive the transition. Today, it is providers who own and control patient data. Indeed, this is the premise behind HIPAA privacy and security. This is not only different from the more individual human rights-based protections recognized in non-US data protection frameworks, but also a major hurdle as reformers seek to engage patients in their health care, including their data.[104]

Additionally, health-care data protection has appeared increasingly blind to the impact of information technology. Looking through the health-care industry lens this should not be too surprising. Almost every contemporary technological challenge thrown at the health-care industry—Y2K,[105] the HIPAA transactional mandate,[106] HIT adoption,[107] Meaningful Use,[108] and ICD-10[109]—have been met with objection and prevarication.[110]

While it seems a truism that the common law has marched "with medicine but in the rear and limping a little,"[111] the lag of regulation in the face of information technology has been even more marked. If the HIPAA architects thought they had a fairly good grasp on the health-care domain in the 1990s, thereafter the vector between regulation and technology has increased considerably. In hindsight, perhaps the greatest flaw in HIPAA is that it takes a pre-IT (maybe even pre-industrialized medicine) approach to data use; it is either permitted or prohibited. That binary may have been appropriate for the limited records of the Marcus Welby, M.D.-era.[112] At the time the HIPAA rules were first promulgated, EHRs were barely visible and HHS was chasing e-commerce

104. See *infra*, discussion of "Blue Button," text accompanying note 175 *et seq.*

105. *See generally* Lily Rothman, *Remember Y2K? Here's How We Prepped for the Non-Disaster*, TIME (Dec. 31, 2014), http://time.com/3645828/y2k-look-back [https://perma.cc/R6ZZ-Z7SK].

106. *Transactions Overview*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Transactions/TransactionsOverview.html [https://perma.cc/EAG5-QCS9].

107. *See generally* Nicolas P. Terry, *Information Technology's Failure to Disrupt Healthcare*, 13 NEV. L.J. 722 (2013).

108. *See generally* Nicolas P. Terry, *Meaningful Adoption: What We Know or Think We Know About the Financing, Effectiveness, Quality, and Safety of Electronic Medical Records*, 34 J. LEGAL MED. 7 (2013).

109. *Data and Systems*, MEDICAID.GOV, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/data-and-systems/icd-coding/icd.html [https://perma.cc/Y6ZK-E34C].

110. *See generally* Robert Wachter, *Meaningful Use: Born 2009 – Died 2014?*, HEALTHCARE IT NEWS (Nov. 13, 2014), http://www.healthcareitnews.com/blog/meaningful-use-born-2009-died-2014 [https://perma.cc/V8G9-CQS8].

111. *Mount Isa Mines v Pusey* (1970) 125 CLR 383, 395 (Austl.) (Windeyer J).

112. *See Marcus Welby, M.D.*, WIKIPEDIA, https://en.wikipedia.org/wiki/Marcus_Welby,_M.D. [https://perma.cc/6D3Q-DW2Z] (last modified Sept. 20, 2016).

models that were already well-established a decade before in other domains. The cycle then seemed to repeat. By 2009, the country was in the middle of a federal initiative to bring EHRs to all hospitals and the same legislation authorized an expensive subsidy program to catch-up.[113] Yet, most of the data protection provisions in HITECH were designed to correct or tweak ten-year-old flaws in HIPAA.[114]

The most "outside-the–box" provision in the HITECH Act was the discrete breach notification rule for non-HIPAA PHRs. This was the first acknowledgment that HIPAA-like data were being created or processed by data custodians who were not subject to HIPAA. For a brief period in the late 2000s, PHRs seemed poised to gain some traction as an alternative to the slowing Bush administration ten-year EHR initiative.[115] Of the PHRs that were launched in this period, *Google Health* was by far the most potentially disruptive. Indeed, it was a clear example of incipient regulatory arbitrage because Google intended to avoid HIPAA by dealing directly with patients (data subjects) rather than covered entities (regulated data custodians).[116] Shortly after Google *Health* launched, HITECH introduced the Meaningful Use program based around proprietary EHR formats. Google, its technical model built around open web standards, shuttered *Google Health*.[117] By the time most of the HITECH provisions found a regulatory form in the 2013 *Omnibus Rule*, the ball had moved again, with concerns being raised about big data and mobile health data. More recently, questions about health-care data protection also have been raised about the Internet of Things, described by the FTC, as "an interconnected environment where all manner of objects have a digital presence and the ability to communicate with other objects and people."[118]

The sector-based approach to data protection has led to today's chronically uneven policy environment, causing, as discussed below, regulatory disruption and enabling arbitrage in the health-care domain. It is policymakers' over-

113. HITECH Act of 2009, Pub. L. No. 111-5, Title XIII, 123 Stat. 115, 226-79 (codified as amended in scattered sections of 42 U.S.C. (2012)).

114. The exception was section 13405(d) prohibiting certain sales of EHR data. *See also* 45 C.F.R. § 164.502(a)(5)(ii) (2016).

115. *Transforming Health Care: The President's Health Information Technology Plan*, WHITE HOUSE: PRESIDENT GEORGE W. BUSH (Jan. 20, 2004), http://georgewbush-whitehouse.archives.gov/infocus/technology/economic_policy200404/chap3.html [https://perma.cc/FHV6-DJYW].

116. Terry, *supra* note 107, at 745–46.

117. Aaron Brown & Bill Weihl, *An Update on Google Health and Google PowerMeter*, GOOGLE BLOG (June 24, 2011), http://googleblog.blogspot.com/2011/06/update-on-google-health-and-google.html [https://perma.cc/G3Z3-CVQK]. *See generally* Nicolas P. Terry, *Personal Health Records: Directing More Costs and Risks to Consumers?*, 1 DREXEL L. REV. 216 (2009).

118. *Internet of Things, Privacy & Security in a Connected World*, FED. TRADE COMMISSION 1 (Jan. 2015), https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-staff-report-november-2013-workshop-entitled-internet-things-privacy/150127iotrpt.pdf [https://perma.cc/R94L-AP6C].

commitment to downstream rules that makes reform problematic, however. Arguably, tweaked downstream rules cannot deal with the challenges to health-care data protection; upstream models must also be deployed.

C. Understanding Exceptional Health-Care Data Protection

To an extent, health-care data privacy exceptionalism has enjoyed more legal recognition than health-care exceptionalism, although that may now be changing. The exceptional treatment of health care was dealt a blow in *National Federation of Independent Businesses v. Sebelius* when a Supreme Court majority rejected any special treatment under the Commerce or Necessary & Proper Clauses.[119] Yet, three years later in *King v. Burwell*, an exceptionalism argument found favor with the majority. There Chief Justice Roberts justified the adoption of a *Chevron* zero approach to interpretation of the Affordable Care Act[120] on the fact that the Act's insurance provisions raised issues of "deep 'economic and political significance.'"[121] The opinion later held: "Congress passed the Affordable Care Act to improve health insurance markets, not to destroy them. If at all possible, we must interpret the Act in a way that is consistent with the former, and avoids the latter."[122] Certainly, exceptionalism would explain Justice Scalia's scathing comment in the dissent, "[w]e should start calling this law SCOTUScare."[123]

Health-care data protection exceptionalism has had a far more consistent history, and HIPAA still stands tall when compared to protections given to personal data in other sectors. This exceptional protection is of great importance. Outside of health care, there is no history or expectation of strong data protection in the U.S. Of course, there are other protected sectors, but the level of data protection is relatively low or prefers data-custodian-favoring choice architectures such as opt-out. Outside of health care, the mantras of "get over it,"[124] self-regulation, and market solutions have gained more traction. The health data protection model has a far stronger baseline that resists the arguments of privacy defeatists.

The story of exceptional health-care data protection has one additional implication: the relative isolation of health-care data protection from general data protection. Health-care lawyers may not be to blame here. After all, HIPAA's

119. 132 S. Ct. 2566 (2012). *See generally* Abigail R. Moncrieff, *Understanding the Failure of Healthcare Exceptionalism in the Supreme Court's Obamacare Decision*, 142 CHEST 559, 559–60 (2012).

120. *See generally* Cass R. Sunstein, *Chevron Step Zero*, 92 VA. L. REV. 187 (2006).

121. 135 S. Ct. 2480, 2489 (2015).

122. *Id.* at 2496.

123. *Id.* at 2507.

124. Polly Sprenger, *Sun on Privacy: 'Get Over It'*, WIRED (Jan. 26, 1999), http://archive.wired.com/politics/law/news/1999/01/17538 [https://perma.cc/L4DD-JXHH].

"more stringent than" cooperative preemption model accepts that HIPAA provides a privacy and security floor permitting federal law's deferral to some state laws.[125] Further, health privacy policymakers have recognized that HIPAA's downstream models normatively are not the end of the line, recognizing that health-care entities also should conduct themselves by reference to FIPPS.[126] If anything, the difficulty is that health-care data protection issues have been shunned by those outside the field. HIPAA seems to be viewed as *sui generis* and health-care data protection as "solved." For example, two reports issued in 2012 by the White House and the FTC excluded health-care data from their data protection proposals.[127] However, this situation may be turning around. For instance, in its 2014 *Data Brokers* report, the FTC included the health domain in its study, even making a specific legislative recommendation to acquire the express consent of data subjects before adding health-care data.[128] Looking forward, general data protection should learn from health care's experience in dealing with downstream protective models. Similarly, policymakers revisiting health-care data protection need to accept that many of its issues cannot be handled by older models such as HIPAA or common law confidentiality.

1. History of Exceptionalism

Neither historically nor in modern law has the action for breach of confidence been unique to health-care relationships. Notwithstanding this fact, actions involving physicians are disproportionately represented in the confidence jurisprudence and the physician-patient fiduciary relationship seems to have been a powerful rationale upon which the various doctrinal bases have rested. Consider, for example, some of the very earliest breach of confidence cases that based the action (too early to call it a tort) on positive duties imposed by medical licensure statutes.[129] Later cases would

> [R]ely on various sources of public policy favoring the confidentiality of communications between a physician and a patient, including state licensing or testimonial privilege statutes, or the Principles of Medical Ethics of the American Medical Association (1957), Section 9, or the Oath of Hippocrates. Some note that while public policy considerations

125. 45 C.F.R. § 160.203(b) (2016).

126. Letter from Paul Tang, Vice Chair, HIT Policy Comm., to Dr. David Blumenthal, Nat'l Coordinator, Health Info. Tech. at 2–3 (Sept. 1, 2010), http://www.healthit.gov/sites/faca/files/hitpc_transmittal_p_s_tt_9_1_10_0.pdf [https://perma.cc/22ZW-UXNM].

127. *Framework for Protecting Privacy*, *supra* note 18, at 38; *Protecting Consumer Privacy*, *supra* note 40, at i-v.

128. *Data Brokers*, *supra* note 3 at 52.

129. *See, e.g.*, Simonsen v. Swenson, 177 N.W. 831, 832 (Neb. 1920); *see also* Smith v. Driscoll, 162 P. 572 (Wash. 1917).

> are a sound enough basis to support liability, a more appropriate basis can be found in the nature of the physician-patient relationship itself, either because of its fiduciary character or because it is customarily understood to carry an obligation of secrecy and confidence.[130]

Today, breach of confidence is recognized as a tort of general applicability.[131] However, just as its genesis depended on health-care-specific doctrines, so its primary usage remains in the health-care domain. Indeed, the tort can lay claim to being the first exceptional protection of health-care data.

In 1999, representing physician organizations, Dr. Richard Harding testified before the House of Representatives and argued, "[i]t is critically important to recognize the difference between medical records privacy and financial privacy" because "damages from breaches of medical records privacy are of a different nature."[132] This he ascribed to the extremely sensitive nature of the information contained therein, "heart disease, terminal illness, domestic violence, and other women's health issues, psychiatric treatment, alcoholism and drug abuse, sexually transmitted diseases and even adultery" that, if disclosed "can jeopardize our careers, our friendships, and even our marriages."[133]

The well-respected Institute of Medicine has long endorsed exceptionalism:

> For the most part, privacy law in [the United States] has been formulated under the assumption that holders of information about people may generally do with it what they please, constrained only by corporate ethics and the good taste of business, societal acceptance (or outrage), occasional attention by the government, pressures of consumer activist groups, and the consequences of legal actions brought by individuals or consumer groups. This historical view may prove inappropriate or even dangerous in regard to health data.[134]

Of course, the ultimate proof of exceptionalism is almost two decades of HIPAA itself and the simple fact that the largest industry in the United States is subject to the country's most comprehensive, if flawed, data protection regulation and enforcement. Although disliked by powerful health-care interests,[135] HIPAA has not faced any significant challenges. When President George W. Bush came into office, the HIPAA Privacy rule had only just been issued by Donna Shalala,

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130. Biddle v. Warren Gen. Hosp., 715 N.E.2d 518, 523 (Ohio 1999).

131. *Id.*

132. Financial Services Act of 1999, H.R. 10, 106th Cong. § 351 (1999) (addressing the confidentiality of health and medical information).

133. *Id.*

134. HEALTH DATA IN THE INFORMATION AGE, *supra* note 2, at 191.

135. *See, e.g.*, Robert Pear, *New Privacy Rules Are Challenged*, N.Y. TIMES (Dec. 21, 2000), http://www.nytimes.com/2000/12/21/us/new-privacy-rules-are-challenged.html [https://perma.cc/F85D-YQPH].

President Clinton's HHS Secretary.[136] Incoming Secretary Tommy Thompson promised a thorough rethinking of the rule.[137] Yet only minor tweaks were made,[138] and the secretary soon announced, "President Bush wants strong patient privacy protections put in place now. Therefore, we will immediately begin the process of implementing the patient privacy rule that will give patients greater access to their own medical records and more control over how their personal information is used."[139] In 2009, the bipartisan HITECH Act strengthened HIPAA privacy, broadened its scope to directly regulate "Business Associates," and included authority to issue a health-care data breach notice (recall that Congress has not been able to pass one of general applicability).

2. Health Subdomain Exceptionalism

Obviously, general health-care data are exceptionally protected. However, a few of its subdomains exhibit additional levels of exceptionalism.[140] One of these is actually provided for in the HIPAA Privacy Rule. Process notes taken by psychotherapists are personal notes and "typically are not required or useful for treatment, payment, or health care operations purposes, other than by the mental health professional who created the notes."[141] As a result, the Privacy Rule therefore applies exceptional restrictions on patient access and health-care provider disclosure.[142]

Moving outside of HIPAA, several subdomains exhibit enhanced

136. Beth Wilson, *Clinton Issues Health Privacy Rules*, AMARILLO GLOBE-NEWS (Dec. 21, 2000), http://amarillo.com/stories/2000/12/21/usn_clintonissues.shtml#.VfBV47SRq-I [https://perma.cc/25GU-D98A].

137. *HHS Moves to Implement and Modify HIPAA Privacy Rules*, AUNTMINNIE.COM (Apr. 12, 2001), http://www.auntminnie.com/index.aspx?sec=ser&sub=def&pag=dis&ItemID=50551 [https://perma.cc/8JQY-RCTX].

138. For example, replacing the original requirement of consent, *see* 45 C.F.R. § 164.506(a), with a privacy notice, *see id.* § 164.506(b)(1) (2016).

139. Press Release, U.S. Dep't Health & Hum. Servs., Statement by Tommy G. Thompson, Secretary Department of Health and Human Services (Apr. 12, 2001), http://archive.hhs.gov/news/press/2001pres/20010412.html [https://perma.cc/G34Y-E3MS].

140. The list of examples that follow is not closed. For example, Stacey Tovino has floated neuroimaging exceptionalism. Stacey A. Tovino, *Functional Neuroimaging Information: A Case for Neuro Exceptionalism?*, 34 FLA. ST. U. L. REV. 415, 485 (2007). Further, Mark Rothstein has discussed the possibility for epigenetic exceptionalism. Mark A. Rothstein, *Epigenetic Exceptionalism*, 41 J.L. MED. & ETHICS 733, 735; *see also* Nicolas P. Terry, *Developments in Genetic and Epigenetic Data Protection in Behavioral and Mental Health Spaces*, 33 BEHAV. SCI. & L. 653 (2015). Finally, some states have safe harbor rules that protect physicians who are diverted to physician health programs in the case of mental health or substance use disorders. *See generally* J. Wesley Boyd & John R. Knight, *Ethical and Managerial Considerations Regarding State Physician Health Programs*, 6 J. ADDICT. MED. 243 (2012).

141. *HIPAA Privacy Rule and Sharing Information Related to Mental Health*, U.S. DEP'T HEALTH & HUM. SERVS., http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/mhguidance.html [https://perma.cc/U8CU-QW4M].

142. 45 C.F.R. § 164.501 (2016).

exceptionalism. HIV-AIDS is treated exceptionally compared to other STDs.[143] Generally-applicable federal law, such as the Rehabilitation Act[144] and the Americans with Disabilities Act, apply to claims of discrimination.[145] And, of course, HIPAA applies a data protection baseline.[146] However, state laws tend to provide additional, exceptional data protection such as anonymous testing and heightened controls on disclosure.[147]

GINA utilizes two models of data protection. First, GINA prohibits downstream point of use discrimination by employers (Title I) and health insurers (Title II). However, GINA also prohibits the requiring or (in many cases) acquiring of genetic information. This is an upstream collection model of protection and has resulted in large settlements with the EEOC in cases dealing with unlawful requests for family medical histories[148] and a landmark $2.2 million jury verdict in the recent "devious defecator" case.[149]

Less well-known are the Substance Abuse Confidentiality Regulations (often referred to by their citation, "45 C.F.R. Part 2") promulgated by HHS's Substance Abuse and Mental Health Services Administration (SAMSHA).[150] These regulations subject federally-assisted programs that maintain alcohol and drug abuse patient records to downstream disclosure restrictions that are considerably more stringent than those found in HIPAA. There is also a complex web of overlapping state mental health and substance abuse laws that further complicate the picture.[151] Recently, 45 C.F.R. Part 2 has attracted considerable attention because of Congressional concerns over the information–sharing costs

143. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 120990 (West 2017); MICH. COMP. LAWS ANN. § 333.5133 (West 2011). *Cf.* MONT. CODE ANN. § 50-16-1014 (West 2016).

144. Rehabilitation Act of 1990 § 504, 42 U.S.C. § 12101 (2012).

145. *See* Bragdon v. Abbott, 524 U.S. 624 (1998).

146. *See Health Information Privacy Enforcement Examples Involving HIV/AIDS*, U.S. DEP'T HEALTH & HUM. SERVS., http://www.hhs.gov/ocr/civilrights/activities/examples/AIDS/hiphiv/aidscases.html [https://perma.cc/3RFM-YBBF].

147. *See, e.g.*, N.Y. PUB. HEALTH LAW ch. 45, art. 27-F (McKinney 2016); *see generally* Roger Doughty, Comment, *The Confidentiality of HIV-Related Information: Responding to the Resurgence of Aggressive Public Health Interventions in the Aids Epidemic*, 82 CAL. L. REV. 111 (1994).

148. *See, e.g.*, Press Release, U.S. Equal Employment Opportunity Comm'n, Founders Pavilion Will Pay $370,000 to Settle EEOC Genetic Information Discrimination Lawsuit (Jan. 13, 2014), http://www.eeoc.gov/eeoc/newsroom/release/1-13-14.cfm [https://perma.cc/K9EX-QXAM].

149. *Georgia Workers Win $2.2 Mln in 'Devious Defecator' Case*, REUTERS (June 23, 2015), http://www.reuters.com/article/verdict-dna-defecator-idUSL1N0Z916520150623 [https://perma.cc/7ZAY-Y8V4].

150. Promulgated under the Drug Abuse Prevention, Treatment, and Rehabilitation Act § 408, 42 U.S.C. § 290ee-3 (2012).

151. *See generally* RTI INTERNATIONAL, BEHAVIORAL HEALTH DATA EXCHANGE CONSORTIUM: ONC STATE HEALTH POLICY CONSORTIUM PROJECT FINAL REPORT (June 2014), https://www.healthit.gov/sites/default/files/bhdeconsortiumfinalreport_06182014_508_compliant.pdf [https://perma.cc/ZHA2-NKSF].

it imposes.[152] For example, in a letter to a Congressional committee supportive of the 21st Century Cures Act the Patient Safety Movement urged, "[a]t a minimum, this problem should be addressed by streamlining the consent process for the sharing of medical records in integrated care settings."[153] Reform of Part 2 has also been targeted in Congressman Tim Murphy's Helping Families in Mental Health Crisis Act of 2016,[154] creating concern among some privacy advocates.[155] In January 2017, SAMSHA published a rule that allows a broad "to whom" consent that it believes will increase the sharing of substance use records through EHRs and Health Information Exchanges. The rule also permits health-care data custodians to share substance abuse data with researchers.[156]

IV. TURBULENCE, DISRUPTION, AND ARBITRAGE IN PRACTICE

A. Professional Health-Care Domain vs. Consumer Domain

In the words of a recent report by the HIT Policy Committee (HITPC), a federal advisory committee established by the HITECH Act,[157] "[m]uch of the health-related information generated today is not regulated by [HIPAA,]"[158] and "[t]he exact same health-related information is regulated differently based on the entity processing the information."[159] As already discussed, the prerequisite for regulatory turbulence, disruption, and potentially arbitrage is the existence of differential regulatory models. For the purposes of the present analysis, two

152. *See generally* Michelle Andrews, *Debate Arises Over HHS Plans For Privacy Rules On Addiction Treatment*, KAISER HEALTH NEWS (Mar. 22, 2016), http://khn.org/news/debate-arises-over-hhs-plans-for-privacy-rules-on-addiction-treatment [https://perma.cc/XD7T-CYG6].

153. Letter from Jim Bialick, President, Patient Safety Movement Foundation, to Fred Upton, Chairman, Energy & Commerce Committee, and Frank Pallone, Ranking Member, Energy & Commerce Committee (Aug. 19, 2015), http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Letters/hr6/PSMF.pdf [https://perma.cc/J55G-5N5V].

154. Helping Families in Mental Health Crisis Act of 2016, H.R. 2646, 114th Cong. (as passed by House, Jul. 6, 2015).

155. *See, e.g.*, Kimberly Leonard, *Would Mental Health Laws Threaten Privacy and Patients' Rights?*, U.S. NEWS & WORLD REPORT (Aug. 12, 2015), http://www.usnews.com/news/articles/2015/08/12/patients-rights-privacy-concerns-highlighted-in-mental-health-laws [https://perma.cc/9DEB-9C6E]; Peter Sullivan, *Dems Introduce Alternative to GOP's Mental Health Bill*, THE HILL (Feb. 2, 2016), http://thehill.com/policy/healthcare/267868-dems-introduce-alternative-to-gop-led-mental-health-bill [https://perma.cc/SW23-NKT6].

156. Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 6052 (Jan. 18, 2017) (to be codified at 42 C.F.R. pt. 2).

157. HITECH Act § 3002, 42 U.S.C. 300jj-12 (2012).

158. *Health Big Data Recommendations*, HEALTH IT POL'Y COMMITTEE PRIVACY & SECURITY WORKGROUP, 4 (Aug. 2015), http://www.healthit.gov/facas/sites/faca/files/HITPC_Draft_PSWG_Big_Data_Transmittal_2015-08-11.pdf [https://perma.cc/8NL4-V9BT] [hereinafter *Health Big data Recommendations*].

159. *Id.* at 11.

regulatory domains are posited: first, a *professional* health-care domain and second, a *consumer* health-care domain.

The professional domain is heavily populated with regulatory models. For example, it is home to state regulation of health-care providers, custom-based quality and safety, medical malpractice doctrine, the federal regulation of prescription drugs and medical devices, state and federal regulation of professional data curators (HIPAA data custodians), unique "fraud and abuse" transactional regulations, specialized antitrust scrutiny, and institutional review board/Common Rule scrutiny of human subjects research. Befitting the country's most regulated industry, there are considerably more examples that could be cited.

In contrast, the *consumer* health-care domain is larger, yet both less regulated and considerably more indeterminate. For example, OTC pharmaceuticals are only lightly regulated by FDA,[160] a few issues regarding consumer platforms may attract some FCC scrutiny, common law products liability or the Consumer Product and Safety Act may apply to a narrow range of safety issues, and mobile apps and wearables are either unregulated or currently benefiting from FDA discretion. Meanwhile, some parts of the domain, crowdsourcing research models, for example, are barely regulated. Others, such as data-curation by data subjects, seem very hard to regulate.

Parallel, and potentially exacerbating, regulatory disruptions can occur at the process level when different regulatory agencies operate in different domains. For example, HHS's Office for Civil Rights (HHS-OCR) regulates professional domain data protection but FTC regulates consumer space. Similarly, FDA regulates medical devices but the Consumer Product Safety Commission or the FCC might deal with the consumer domain. A further complication may be overlapping state and federal laws (e.g., state products liability law overlapping with FDA or state law or health-care data protection legislation overlapping with HIPAA privacy or security).

Differentiated regulatory domains can tolerate *some* turbulence. Further, not all turbulence develops into disruption. Consider the following episodes of turbulence between professional and consumer domain. First, Google Glass: Google introduced (initially only to "Glass Explorers") this augmented reality wearable in 2013. It was designed and sold as a consumer product.[161] Increasingly, doctors joined the ranks of the "explorers" and soon Glass appeared

160. *See Drug Applications for Over-the-Counter (OTC) Drugs*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm [https://perma.cc/V33W-4JHU].

161. Vidya Viswanathan, *Is There a Place for Google Glass in Hospitals?*, ATLANTIC (July 21 2014), www.theatlantic.com/health/archive/2014/07/is-there-a-place-for-google-glass-in-hospitals/374153/ [https://perma.cc/BF27-85YZ].

in hospitals, used during surgeries, for EHR access and training.[162] The problem was that while Glass satisfied the minimal regulatory standards of the consumer domain, it caused regulatory problems in the professional domain. For example, it was not HIPAA-compliant, in some implementations it came close to FDA regulated device territory, and its "stealth" camera tempted marginal collection of health and personal data.[163] Before Glass could become an example of full-on regulatory disruption, Google announced it would cease selling the device.[164]

23andMe, a consumer-facing DNA test kit and analytic service, was launched in 2007.[165] The product's marketing stated that the kits provided health reports on multiple diseases and conditions, written with enough specificity to prompt FDA inquiry. 23andMe featured genotyping, not sequencing (although those technologies are beginning to merge). Notwithstanding that distinction, here was an example of professional DNA testing migrating into the consumer health domain.[166] Apparently, FDA spent four years trying to work with 23andMe before sending the archetypal warning letter informing the company it was selling an unapproved medical device contrary to the Food, Drug and Cosmetic Act.[167] As George Annas and Sherman Elias later noted, "[c]linicians will be central to helping consumer–patients use genomic information to make health decisions."[168] As a result they argued, "[a]ny regulatory regime must recognize this reality by doing more than simply adding the tagline on most consumer ads for prescription drugs: 'Ask your physician.'"[169] When *23andMe* finally had to confront the FDA's concerns, it decided to stop marketing the kit

162. Vala Afshar, *How Google Glass Will Transform Healthcare*, HUFFINGTON POST (Oct. 17, 2014), http://www.huffingtonpost.com/vala-afshar/how-google-glass-will-tra_b_6003100.html [https://perma.cc/FLE6-EX5V]; Helen Gregg, *5 Hospitals Using, Piloting Google Glass*, BECKER'S HEALTHCARE (Mar. 18, 2014), http://www.beckershospitalreview.com/healthcare-information-technology/5-hospitals-using-piloting-google-glass.html [https://perma.cc/R8T3-8RD8].

163. *See generally* Nicolas P. Terry, Chad S. Priest & Paul P. Szotek, *Google Glass and Health Care: Initial Legal and Ethical Questions*, 8 J. HEALTH & LIFE SCI. L. 93 (2015).

164. Jim Edwards, *Google Ends Sales of Google Glass*, BUSINESS INSIDER (Jan. 16, 2015), http://www.businessinsider.com/google-ends-sales-of-google-glass-2015-1 [https://perma.cc/V8ZM-7C6F].

165. Lisa Baertlein, *Google-Backed 23andMe Offers $999 DNA Test*, USA TODAY (Nov. 20, 2007), http://usatoday30.usatoday.com/tech/webguide/internetlife/2007-11-20-23andme-launch_N.htm [https://perma.cc/K4SC-A7XY].

166. *See, e.g.*, Robert J. Elshire et al., *A Robust, Simple Genotyping-by-Sequencing (GBS) Approach for High Diversity Species*, 6 PLOS ONE e19379 (2011).

167. Letter from Alberto Gutierrez, Director, Office of In vitro Diagnostics and Radiological Health, to Ann Wojcicki, CEO, 23andMe, Inc. (Nov. 22, 2013), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm [https://perma.cc/SE8F-5C8U]; *see generally* Matthew Herper, *23andStupid: Is 23andMe Self-Destructing?*, FORBES (Nov. 25, 2013), http://www.forbes.com/sites/matthewherper/2013/11/25/23andstupid-is-23andme-self-destructing/ [https://perma.cc/WM3Q-WDQK].

168. George J. Annas & Sherman Elias, *23andMe and the FDA*, 370 NEW ENG. J. MED. 985, 987 (2014).

169. *Id.*

as a diagnostic tool and changed its reports to generic information rather than anything approaching diagnostics.[170] Subsequently, FDA approved the company's marketing of more narrowly focused tests for Bloom syndrome[171] and autosomal recessive disorders.[172] Furthermore, the FDA designation of the tests as over-the-counter[173] led to the obviation of some state law limitations on the services, making them available across the country.[174]

23andMe was a private initiative at first avoiding and subsequently seeking regulatory approval. In contrast, the "Blue Button"[175] is a federal government initiative permitting Medicare beneficiaries[176] and VA patients[177] to transfer their health records. Users may download the data in text, PDF, or Blue Button formats. The Office of the National Coordinator (ONC) and the Centers for Medicare & Medicaid Services (CMS) are targeting similar models as a way of increasing patient engagement and data liquidity in Stages 2 and 3 of Meaningful Use.[178]

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170. Brian Fung, *Bowing Again to the FDA, 23andMe Stops Issuing Health-related Genetic Reports*, WASH. POST (Dec. 6, 2013), https://www.washingtonpost.com/news/the-switch/wp/2013/12/06/bowing-again-to-the-fda-23andme-stops-issuing-health-related-genetic-reports [https://perma.cc/UT4M-ZLC7].

171. Press Release, U.S. Food & Drug Admin., FDA Permits Marketing of First Direct-to-Consumer Genetic Carrier Test for Bloom Syndrome (Feb. 19, 2015), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM435003 [https://perma.cc/XAV7-8FSA].

172. Andrew Pollack, *23andMe Will Resume Giving Users Health Data*, N.Y. TIMES (Oct. 21, 2015), http://www.nytimes.com/2015/10/21/business/23andme-will-resume-giving-users-health-data.html [https://perma.cc/JP2T-26CU]. FDA continues to investigate other direct-consumer genetic tests. *See, e.g.*, Letter from James L. Woods, Deputy Director Patient Safety and Product Quality, Office of In Vitro Diagnostics and Radiological Health, to Rajasingam S. Jeyendran, DNA-Cardiocheck, Inc. (Nov. 2, 2015), http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM471784.pdf [https://perma.cc/Q4NP-84JK].

173. Letter from Courtney H. Lias, Director, Division of Chemistry and Toxicology Devices, Office of In Vitro Diagnostics and Radiological Health, to Kathy Hibbs, Chief Legal and Regulatory Officer, 23andMe, Inc. (Oct. 1, 2015), http://www.accessdata.fda.gov/cdrh_docs/pdf14/den140044.pdf [https://perma.cc/A86T-7JWU].

174. Press Release, 23andMe, 23andMe Genetic Service Now Fully Accessible to Customers in New York and Maryland (Dec. 4, 2015), http://mediacenter.23andme.com/?p=2084 [https://perma.cc/RMG4-FERN].

175. *About Blue Button*, HEALTHIT.GOV, http://www.healthit.gov/patients-families/blue-button/about-blue-button [https://perma.cc/G8C5-626J].

176. *Download Claims with Medicare's Blue Button*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.medicare.gov/manage-your-health/blue-button/medicare-blue-button.html [https://perma.cc/44LQ-SKGV].

177. *The My HealtheVet Community*, U.S. DEP'T VETERANS AFF., https://www.myhealth.va.gov/mhv-portal-web/mhv-community [https://perma.cc/G2GZ-7L7L].

178. Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2, 77 Fed. Reg. 53,968, 53,973 (Sept. 4, 2012) (to be codified at 42 C.F.R. pts. 412, 413, and 495). For more detail see *Eligible Professional, Meaningful Use Core Measures, Measure 7 of 17, Stage*, CTRS. FOR MEDICARE & MEDICAID SERVS. 2 (Aug. 2014), https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Stage2_EPCore_7_PatientElectronicAccess.pdf [https://perma.cc/E5XM-MRHR].

What do we learn from these three examples of regulatory turbulence? Both Google Glass and *23andMe* were temporary phenomena. The former was a consumer domain product that caused some turbulence in the professional space but which was withdrawn from the market before disruption could occur (or HIPAA indeterminacy or FDA device regulation issues were resolved). The latter was the inverse; a professional domain technology sold into consumer space. *23andMe* likely was subject to professional domain medical device regulation. It caused turbulence at a process level because its developer seemingly was oblivious to or unmindful of FDA regulations. As a result, for several years there was accidental disruption until regulator-regulatee information costs equalized. Once *23andMe* was forced to confront the FDA's concerns, it decided to stop marketing the kit as diagnostic.

Only the last of these three examples exhibits a transition from turbulence to disruption. The entirely well meaning, patient-autonomy-respecting Blue Button program has a seriously disruptive effect. It takes HIPAA-protected data and, with a single click from the data subject, moves it into an almost completely unprotected domain. This is a model now being repeated by Stage 3 of Meaningful Use, which adds the option of an application programming interface (API) linkage between a provider's EHR and a patient's app.[179] It could be argued that there is simply no data protection issue when the data subject holds the data. However, the data likely implicates persons other than the data subject (such as the subject's family members) and so any data compromise is neither benign nor intrinsically limited. Further, there is disruption in fact and substantial potential for confusion when the "same" data are subject to both professional domain regulation (professional curation) and consumer domain-regulation-lite (personal curation). Clicking the Blue Button strips data protection from clinical data. Major questions arise as to how to adequately warn the data subject at the point of conversion and whether policymakers can appropriately remodel data subjects' expectations and responsibilities.

B. Example One: Big Data

Observations as to either the sectoral limitations of U.S. data protection or the rise of commercial data brokers are hardly novel. A decade ago, Dan Solove and Chris Hoofnagle noted, "[a]lthough most industrialized nations have comprehensive data protection laws, the United States has maintained a sectoral approach where certain industries are covered and others are not. In particular, emerging companies known as 'commercial data brokers' have frequently

179. Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62,762 (Oct. 16, 2015); 42 C.F.R. § 495.24 (2016).

slipped through the cracks of U.S. privacy law."[180] Solove and Hoofnagle did not use the terms disruption or arbitrage but probably had something similar in mind when stating, "[m]any companies brokering in data have found ways to avoid being regulated by [FCRA]."[181] More recently, Kate Crawford and Jason Schultz observed, "[n]ot only does Big Data's use have the potential to circumvent existing antidiscrimination regulations, but it may also lead to privacy breaches in health care . . ."[182]

As reported by FTC:

> [D]ata brokers. . . purchase information about individuals from wide-ranging commercial sources. For example, the data brokers obtain detailed, transaction-specific data about purchases from retailers and catalog companies. Such information can include the types of purchases (e.g., high-end shoes, natural food, toothpaste, items related to disabilities or orthopedic conditions), the dollar amount of the purchase, the date of the purchase, and the type of payment used.[183]

In most cases, data brokers will not find dealing directly with HIPAA covered entities (or their business associates) to be a good source of clinical data. Generally, HIPAA entities would be unable to supply clinical data without data subject (patient) authorization,[184] a heightened form of consent. Or, if HIPAA entities agree to the broker's request for a "limited data set," the disclosure would be restricted to "research" only processing and subject to a re-identification-limiting data use agreement.[185]

Denied access to most of the health-care "deep web,"[186] data brokers therefore construct clinical data "proxies" from other data pools. These pools, like the public records and other databases they mine, exist outside of HIPAA-protected space. They do not completely ignore data that has been subject to HIPAA protection. For example, they may acquire de-identified data; HIPAA data that have been de-identified are no longer subject to HIPAA.[187] They may also acquire HIPAA data that have been legally shared with public health authorities,[188] who subsequently made anonymized or de-identified data sets

180. Daniel J. Solove & Chris Jay Hoofnagle, *A Model Regime of Privacy Protection*, 2006 U. ILL. L. REV. 357, 357 (2006).

181. *Id.* at 359.

182. Kate Crawford & Jason Schultz, *Big Data and Due Process: Toward A Framework to Redress Predictive Privacy Harms*, 55 B.C. L. REV. 93, 99 (2014).

183. *Data Brokers*, *supra* note 3, at 13.

184. 45 C.F.R. § 164.508 (2016).

185. 45 C.F.R. § 164.514 (2016).

186. *See generally* Jose Pagliery, *The Deep Web You Don't Know About*, CNN (Mar. 10, 2014), http://money.cnn.com/2014/03/10/technology/deep-web/index.html [https://perma.cc/DJP9-4YG9].

187. *See supra* text accompanying note 90 *et seq.*

188. 45 C.F.R. § 164.512(b) (2016).

available.[189]

As discussed elsewhere,[190] these data are supplemented by medical-inflected data, what McKinsey refers to as "[p]atient behavior and sentiment data that describe patient activities and preferences, both inside and outside the healthcare context."[191] These data are culled from social media interactions, retail stores, web trackers, online transactions, mobile phone location trackers, fitness wearables, and so on. Data brokers subsequently leverage their sophisticated algorithms and the breadth of their triangulation databases to re-identify the data.[192]

Increasingly, our everyday interactions will trigger unrealized or unconsented collection of data about us from Internet of Things devices, including our location and physical, even medical, condition. As pointed out by Elizabeth Pike, another likely data pool is the "non-consensual collection and use of genetic material."[193] Pike identifies regulatory disruption because "[i]n many ways, commercial endeavors are less heavily regulated than federally funded research endeavors outside the Common Rule's reach. And commercial entities are unlikely to be "covered entities" subject to HIPAA's Privacy Rule."[194]

These disparate, essentially unregulated data pools make possible the following claim by one major data broker:

> We have one of the largest and most comprehensive collections of healthcare information in the world, spanning sales, prescription and promotional data, medical claims, electronic medical records and social media. Our scaled and growing data set, containing over 10 petabytes of unique data, includes over 85% of the world's prescriptions by sales revenue and approximately 400 million comprehensive, longitudinal, anonymous patient records. We standardize, organize, structure and integrate this data by applying our sophisticated analytics and leveraging our global technology infrastructure to help our clients run their organizations more efficiently and make better decisions to improve their operational and financial performance.[195]

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189. *See, e.g.*, Sean Hooley & Latanya Sweeney, *Survey Of Publicly Available State Health Databases*, HARV. U. 3 (2013), http://dataprivacylab.org/projects/50states/1075-1.pdf [https://perma.cc/P8KE-2NDK].

190. *See* Nicolas P. Terry, *Big Data Proxies and Health Privacy Exceptionalism*, 24 HEALTH MATRIX 65, 84–87 (2014).

191. Peter Groves et al., *The 'Big Data' Revolution in Healthcare*, MCKINSEY & CO. 3 (Jan. 2013), http://www.pharmatalents.es/assets/files/Big_Data_Revolution.pdf [https://perma.cc/RG3E-2JQ5].

192. *See generally* Terry, *supra* note 140.

193. Elizabeth R. Pike, *Securing Sequences: Ensuring Adequate Protections for Genetic Samples in the Age of Big Data*, 37 CARDOZO L. REV. 1977, 1980 (2015).

194. *Id.* at 2007 (references omitted).

195. *Registration Statement under the Securities Act of 1933 (Form S-1)*, IMS HEALTH

The regulatory disruption is clear and arbitrage highly likely. Data brokers, generally shut out of protected health-care data, are able to create proxies for those data in a lightly regulated HIPAA-free zone. Crawford and Schultz go further, noting that the "predictive privacy harms" caused by big data are such that traditional upstream and downstream data protection models ("collection, processing and disclosure") can be circumvented.[196]

Medically inflected data collected from, say, social media, apps, and retail stores can quickly result in highly targeted advertising. The predictive analytics at the root of big data "learns from experience (data) to predict the future behavior of individuals in order to drive better decisions."[197] *Smith v. Facebook, Inc.*,[198] a recently filed class action against the social media company and various health-care providers offers insight into how such systems work. According to the complaint, the web sites of various health-care providers include "referrer" headers and third-party tracking "cookies" that allow Facebook to link search requests (e.g., stomach cancer diagnosis) to its own users. These search requests, coupled with other data such as "like" activity, allegedly enabled Facebook to create health-related profiles of its users against which it could sell health-related advertising specifically targeted at them. Indeed, the world's largest social media platform collects ninety-eight personal data points about their users for the purpose of targeting advertising.[199] These include all manner of personal and financial information, including parental status and whether pregnant.[200]

Increasingly, health scoring and other data segmentation carries the threat of discrimination. At first sight, wellness firms that mine data about employees and then "nudge" them into healthier pursuits seem relatively benign. However, there are considerable risks of these data being exposed to employers or their aggregate nature being undermined by small populations, enabling identification.[201]

Health data acquired by data brokers can also be looped back into the health-care space for discriminatory purposes. As is well known, the ACA prohibits pre-

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HOLDINGS, INC. (Jan. 2, 2014), http://www.sec.gov/Archives/edgar/data/1595262/000119312514000659/d628679ds1.htm [https://perma.cc/G385-EFVF].

196. Crawford & Schultz, *supra* note 182, at 106.

197. ERIC SIEGEL, PREDICTIVE ANALYTICS: THE POWER TO PREDICT WHO WILL CLICK, BUY, LIE, OR DIE 11 (2013).

198. Complaint, Smith v. Facebook, Inc., 2016 WL 1042966 (N.D.Cal.) (5:16-cv-01282) (filed Mar. 15, 2016).

199. Caitlin Dewey, *98 Personal Data Points That Facebook Uses to Target Ads to You*, WASH. POST, (Aug. 19, 2016), https://www.washingtonpost.com/news/the-intersect/wp/2016/08/19/98-personal-data-points-that-facebook-uses-to-target-ads-to-you/ [https://perma.cc/75Y9-APB5].

200. *Id.*

201. *See* Rachel Emma Silverman, *Bosses Tap Outside Firms to Predict Which Workers Might Get Sick*, WALL ST. J. (Feb. 17, 2016), http://www.wsj.com/articles/bosses-harness-big-data-to-predict-which-workers-might-get-sick-1455664940 [https://perma.cc/WFM3-RPFF]; Valentina Zarya, *Employers Are Quietly Using Big Data to Track Employee Pregnancies*, FORTUNE (Feb. 17, 2016), http://fortune.com/2016/02/17/castlight-pregnancy-data [https://perma.cc/W88H-CV3N].

existing condition exclusions, discriminatory premium rates, and generally requires guaranteed issue.[202] Guaranteed issue and related regulations generally do not apply to life insurers who are customers for big data proxies. Even more troubling are reports of health insurers who use data-mined prescription drug data to continue their discrimination against high cost patients.[203] For example, big data analytics permit insurers to predict the health conditions of those in their risk pools. They could then move drugs associated with patients with expensive chronic conditions to high cost-sharing tiers in the hope of discouraging those patients from applying for coverage.[204] As a result, unregulated big data has the potential to frustrate some of the mainstay policies of our health-care system.

C. Example Two: Mobile Health Data

The defining characteristic of mobile health is that it is patient-facing. Unlike most examples of digital health, patients or pre-patients interact directly with mobile health hardware and software, frequently without the direct involvement of conventional health-care providers. Most of these relationships form and interactions occur in a consumer rather than a professional space. As a result, serious turbulence, even regulatory disruption, can occur. In some ways, emerging mobile health-care services mirror the Uber-Lyft model. Like those car services, mobile health steps around bureaucracy-laden incumbents that have been slow to adopt information technologies, reform their guilds, modernize their financing, or offer coherent alternatives to inconvenient centralized locations.

Consequently, mobile health, a combination of mobile health apps, wearable devices, and the rapidly iterating Internet of Health Things, suggest some health-care business disruption. Specifically, mobile health promises personalized care, improved convenience, and lower cost.

Of course, the HIPAA privacy and security rules apply to traditional health-care providers such as doctors and hospitals. Therefore, if a hospital or health insurer (or a business associate) builds a patient portal app to provide access to EHR or claims information, HIPAA likely applies. However, the vast majority of health apps are not curated, sold or implemented by HIPAA "covered entities"; they are built by technology companies and sold through app stores. As a result,

202. Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 1201, 124 Stat. 119, 154–61 (2010).

203. *See, e.g.*, Jordan Robertson, *The Pitfalls of Health-Care Companies' Addiction to Big Data*, BNA BLOOMBERG HEALTH IT L. & INDUSTRY REP. (Sept. 23, 2015), http://news.bna.com/hiln/HILNWB/split_display.adp?fedfid=76390826&vname=hitrbulallissues&jd=a0h3f2f8b0&split=0 [https://perma.cc/DQL6-2YB4].

204. Douglas B. Jacobs & Benjamin D. Sommers, *Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace*, 372 NEW ENG. J. MED. 399 (2015); *see also* Julie Appleby, *Got Insurance? You Still May Pay a Steep Price for Prescriptions*, KAISER HEALTH NEWS (Oct. 13, 2014), http://khn.org/news/got-insurance-you-still-may-pay-a-steep-price-for-prescriptions [https://perma.cc/YVX4-V73M].

much of the fitness and health data collected by mobile apps and wearables have very thin legal protection. ONC recognized this problem in a 2016 report to Congress concluding "Wearable fitness trackers, health social media, and mobile health apps are premised on the idea of consumer engagement. However, our laws and regulations have not kept pace with these new technologies."[205]

This also seems to be the case with mobile platform health data aggregators and APIs, such as those offered by Apple with its "Health" app, HealthKit SDK,[206] and "CareKit" framework.[207] Platform developers appear to take the position that their apps do not access any HIPAA-protected data but merely act as traffic cops working at the direction of the data subject. Take as an example a patient who uses a tracker to collect health data and who wants to share that with his or her health-care provider's patient portal app. The sharing is facilitated through the mobile platform health app. If that app is only opening and closing doors at the instructions of the patient then, the argument is made, the platform app is not "touching" any HIPAA data.[208]

Tens of thousands of mobile health apps are now collecting vast quantities of health-care data. However, the majority of these apps are operating in the HIPAA-free zone with little or no regulation as to how they should share data with third parties or what the security is expected of any off-device data storage. Of course, some app/wearable developers (no doubt with an eye on the growing market for "wellness" products being promoted or required by insurers and employers) are beginning to advertise HIPAA-compliance.[209]

The mobile health app space is a perfect breeding ground for regulatory disruption and arbitrage. The professional domain is highly regulated by HIPAA

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205. *Examining Oversight of the Privacy & Security of Health Data Collected by Entities Not Regulated by HIPAA*, U.S. DEP'T HEALTH & HUM. SERVS. 32 (June 2016), https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf [https://perma.cc/4JV7-8DDT] [hereinafter *Health Data Collected by Entities Not Regulated by HIPAA*].

206. *Develop Health and Fitness Apps that Work Together*, APPLE, INC., https://developer.apple.com/healthkit [https://perma.cc/7L9A-QG27].

207. Press Release, Apple, Inc., Apple Advances Health Apps with CareKit: New Software Framework Helps Developers Empower People to Take a More Active Role in their Health (Mar. 21, 2016), http://www.apple.com/pr/library/2016/03/21Apple-Advances-Health-Apps-with-CareKit.html [https://perma.cc/26SQ-NLT5].

208. *See* Mark Sullivan, *While Apple HealthKit Works out Bugs, Cleveland Clinic Uses Microsoft's HealthVault Platform to Reach Remote Patients*, VENTUREBEAT (Sept. 23, 2014), http://venturebeat.com/2014/09/23/while-apple-healthkit-works-out-bugs-cleveland-clinic-uses-microsofts-healthvault-platform-to-reach-remote-patients [https://perma.cc/KMM3-AHJU].

209. *See* Press Release, Fitbit, Inc., Fitbit Extends Corporate Wellness Offering with HIPAA Compliant Capabilities (Sept. 16, 2015), http://www.businesswire.com/news/home/20150916005371/en/#.VgAIX7SRq-I [https://perma.cc/B6FN-2EFA] ("Our compliance with HIPAA safeguards formalizes this commitment, and, more importantly, it creates opportunities for more effective relationships with corporate wellness customers." (quoting James Park, CEO and Co-Founder, Fitbit).

but the consumer domain is either unregulated or less regulated (limited to *ab initio* app store[210] or *ex post facto* FTC[211] regulation). Disruption and arbitrage in this mobile space are ongoing, as can be seen from the dysfunctional state of medical device regulation.[212] Indeed, the current regulatory status of these devices is sufficiently complicated that HHS-OCR, FTC, and FDA have felt compelled to publish an interactive tool in attempt to guide app developers through the regulatory confusion.[213]

Privacy and security issues are mounting.[214] Many medical apps have unsatisfactory data privacy policies,[215] and one recent study found "that on average 87.7% of Android devices are exposed to at least one of [eleven] known critical vulnerabilities. . ."[216] More pointedly, Huckvale and colleagues recently examined the privacy and security risks of mobile health apps that had been accredited (for clinical safety) by the English National Health Service (NHS) Health Apps Library. Overall, the study found a low level of encryption of user data at rest (on the device) or in motion and a lack of transparency in privacy policies.[217] In a 2016 report funded by the Office of the Privacy Commissioner of Canada, Hilts and colleagues documented how fitness trackers (Apple's Watch aside) emitted persistent unique identifiers that could enable tracking of users and that several also had other basic security flaws, including a failure to encrypt data in motion.[218]

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210. *App Store Review Guidelines*, APPLE, INC., https://developer.apple.com/app-store/review/guidelines [https://perma.cc/CDB8-Q2F4].

211. *See, e.g.*, LabMD, Inc., FTC No. 102-3099 (2016), https://www.ftc.gov/enforcement/cases-proceedings/102-3099/labmd-inc-matter [https://perma.cc/BR4S-Z6AM].

212. *See generally* Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173 (2014).

213. *Mobile Health Apps Interactive Tool*, FED. TRADE COMMISSION, https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool [https://perma.cc/QV96-C7EH].

214. *See generally* Nicolas Terry, Hall Render Professor of Law & Executive Director, Hall Center for Law and Health, Indiana University Robert H. McKinney School of Law, Opening Remarks for House Energy and Commerce Subcommittee Hearing on Health Care Apps (July 13, 2016), http://docs.house.gov/meetings/IF/IF17/20160713/105197/HHRG-114-IF17-Wstate-TerryN-20160713.pdf [https://perma.cc/HVF2-K29J]; *Disrupter Series: Health Care Apps: Hearing Before the Subcomm. on Commerce, Mfg., & Trade of the H. Comm. on Energy & Commerce*, 114th Cong. (Jul. 13, 2016), https://energycommerce.house.gov/hearings-and-votes/hearings/disrupter-series-health-care-apps [https://perma.cc/3T2A-XNRU].

215. Sarah R. Blenner, Melanie Köllmer, Adam J. Rouse, Nadia Daneshvar, Curry Williams & Lori B. Andrews, *Privacy Policies of Android Diabetes Apps and Sharing of Health Information*, 315 JAMA 1051 (2016).

216. Daniel R. Thomas et al., *Security Metrics for the Android Ecosystem*, U. CAMBRIDGE (Oct. 12, 2015), https://www.cl.cam.ac.uk/~drt24/papers/spsm-scoring.pdf [https://perma.cc/TG3N-LJBW].

217. Kit Huckvale et al., *Unaddressed Privacy Risks in Accredited Health and Wellness Apps: A Cross-Sectional Systematic Assessment*, 13 B.M.C. MED. 1 (2015).

218. Andrew Hilts et al., EVERY STEP YOU FAKE: A COMPARATIVE ANALYSIS OF FITNESS TRACKER PRIVACY AND SECURITY, OPEN EFFECT, (Feb. 2016), https://openeffect.ca/reports

Finally, the patient-facing, patient-data curating aspects of mobile health apps and their wearable fellow-travelers raise another, much more fundamental issue (and one not necessarily unique to health-care data). Data protection models and their implementation have been built around institutional curation of people's data and carve-outs for other institutions interested in that data. Personal or self-curation enabled by personal technologies presents an asymmetric question, whether institutions can access that data under conditions set by data subjects.[219] That question was at the root of the 2016 stand-off between Apple and the FBI over access to data encrypted on an iPhone.[220] If technology continues to outstrip regulation, an open question is whether pre-patients and patients will combat regulatory disruption by moving their data to the secure enclaves[221] they control and thereafter decide themselves if, how, and when to share data with institutions whose services they wish to engage. At one level this technological and conceptual shift will protect health-care data and reduce regulatory arbitrage. At another, however, it will cripple appropriate data sharing between patients and providers or researchers and sadly signal policymakers' inability to address the level of data protection desired by consumers.

V. DATA PROTECTION VERSUS DATA LIQUIDITY

Calls for increased data liquidity to further fuel the information society are hardly new. In the health-care domain, they frequently translate into public goods arguments. Further, in the traditional health-care space, there are some critically important policy initiatives that often are cast as at odds with existing HIPAA protections, let alone any increased upstream data protection. Currently, these include clinical interoperability and medical research.

A. Clinical Interoperability

Interoperability began with a plan announced by President Bush in 2004 "to ensure that most Americans have electronic health records within the next 10 years."[222] Moving from paper to electronic records merely substitutes electronic

/Every_Step_You_Fake.pdf [https://perma.cc/AUQ4-D74U].

219. *See generally* Adrian Groper, *Apple and the 3 Kinds of Privacy Policies*, HEALTH CARE BLOG (Feb 22, 2016), http://thehealthcareblog.com/blog/2016/02/22/apple-and-the-3-kinds-of-privacy-policies [https://perma.cc/ZVJ5-27G8].

220. *See generally* Brian Barrett, *The Apple-FBI Battle Is Over, But The New Crypto Wars Have Just Begun*, WIRED (March 30, 2016), http://www.wired.com/2016/03/apple-fbi-battle-crypto-wars-just-begun/ [https://perma.cc/2F8A-RN8B]; Kim Zetter, *Apple's FBI Battle Is Complicated. Here's What's Really Going On*, WIRED (Feb. 18, 2016), http://www.wired.com/2016/02/apples-fbi-battle-is-complicated-heres-whats-really-going-on/ [https://perma.cc/CYF9-L2LB].

221. *See generally iOS Security: iOS 9.0 or Later*, APPLE, INC. (Sept. 2015), https://www.apple.com/business/docs/iOS_Security_Guide.pdf [https://perma.cc/9VVE-DZ2U].

222. *Transforming Health Care: The President's Health Information Technology Plan*, WHITE HOUSE: PRESIDENT GEORGE W. BUSH (Jan. 20, 2004), http://georgewbush-

solos for their file room predecessors. Thus, that 10-year plan rotated around the implementation of *interoperable* records. However, by 2009 "information systems in more than 90% of U.S. hospitals [did] not even meet the requirement for a basic electronic-records system."[223] Not surprisingly, therefore, the federal government's Meaningful Use subsidy program,[224] introduced by the HITECH Act, made interoperability a major goal,[225] albeit one that has proven particularly difficult to execute.[226]

The search for the magic bullet that will make clinical data more liquid within professional health-care space has implicated HIPAA privacy rules. Specifically, there are concerns that rigorous downstream data protection models impede data sharing. For example, a 2015 ONC report found that "privacy and security laws are cited in circumstances in which they do not in fact impose restrictions" such as when "providers . . . cite the HIPAA Privacy Rule as a reason for denying the exchange of electronic protected health information for treatment purposes, when the Rule specifically permits such disclosures."[227]

In its interoperability roadmap, ONC has laid out a ten-year plan for converting U.S. health care into a truly interoperable learning[228] health-care system.[229] Throughout, the report stresses that data protection will not suffer: "It is essential to maintain public trust that health information is safe and secure. To better establish and maintain that trust, stakeholders will strive to ensure that appropriate, strong and effective safeguards for electronic health information are in place as interoperability increases across the industry."[230]

Interestingly, the report also calls on stakeholders to "support greater

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whitehouse.archives.gov/infocus/technology/economic_policy200404/chap3.html [https://perma.cc/2U68-DXS9].

223. Ashish K. Jha et al., *Use of Electronic Health Records in U.S. Hospitals*, 360 NEW ENG. J. MED. 1628, 1634 (2009).

224. *Electronic Health Records (EHR) Incentive Programs*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html [https://perma.cc/VVK8-82GJ].

225. *See* Deth Sao et al., *Interoperable Electronic Health Care Record: A Case for Adoption of a National Standard to Stem the Ongoing Health Care Crisis*, 34 J. LEGAL MED. 55 (2013).

226. *See* Terry, *supra* note 61, at 164–68.

227. Office of the Nat'l Coordinator for Health Info. Tech., *Report on Health Information Blocking*, U.S. DEP'T HEALTH & HUM. SERVS. 16 (Apr. 2015), https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf [https://perma.cc/3JNE-HUPT] [hereinafter *Report on Health Information Blocking*].

228. *See generally The Learning Healthcare System: Workshop Summary*, INST. MED. (LeighAnne Olsen et al. eds. 2007) https://www.nap.edu/catalog/11903/the-learning-healthcare-system-workshop-summary-iom-roundtable-on-evidence [https://perma.cc/5JVB-SCYL].

229. Office of the Nat'l Coordinator for Health Info. Tech., *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap*, U.S. DEP'T HEALTH & HUM. SERVS. (Oct. 2015), https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf [https://perma.cc/34M4-6AA2].

230. *Id.* at xiv.

transparency for individuals regarding the business practices of entities that use their data, particularly those that are not covered by the HIPAA Privacy and Security Rules, while considering the preferences of individuals."[231] This statement reads as a somewhat dejected admission that a dysfunctional regulatory system increasingly is hopeful of leveraging corporate stakeholder empathy to influence those they do business with to respect health-care data protection.

Due to the pressure to increase data interoperability and exchange, policymakers will continue to embrace calls to reduce some of the exceptional protections granted health-care data. The most likely initial casualty is the additional exceptional protections currently granted behavioral health records.[232] Although SAMSHA delivered on its promise to deliver an updated draft regulation within the next eighteen months,[233] its Congressional critics remain unimpressed.[234]

In the next few years, the increasingly difficult task for policymakers will be to distinguish between: first, the "noise" of overstating HIPAA barriers, second, attempts to use the goal of enhanced interoperability as a straw man designed to increase commercial expropriation of clinical data and third, genuine, nuanced policy collisions that require resolution (including data protection deprecation).

B. Medical and Population Health Research

Claims on clinical and medically inflected and health-determining data for research purposes are also increasing. Much of the research is taking place within clinical spaces. Of particular relevance to issues of data regulation, health-care providers claim that the growing field of outcomes research is covered by HIPAA's permitted use exception for "health care operations"[235] Other research involves big data analytics (examples include the President's *Precision Medicine Initiative*[236] and the NIH's Big Data to Knowledge program[237]) and typically uses de-identified clinical data or an identified "limited data set" subject to a data use

231. *Id.*

232. *See supra* text accompanying note 150 *et seq.*

233. *See supra* text accompanying note 150.

234. "This regulations [sic] continues the redundant multiple-step process that makes it a huge burden for patients, providers, and health care professionals that could make it difficult for a provider to get relevant information quickly and it is a barrier to integrated care." David Pittman, *Senate HELP Alters Its Health IT Draft*, POLITICO (Feb. 8, 2016), http://www.politico.com/tipsheets/morning-ehealth/2016/02/senate-help-alters-its-health-it-draft-212591 [https://perma.cc/8J9V-TYL5] (quoting email from office of Rep. Murphy).

235. 45 C.F.R. § 164.506 (2016).

236. *The Precision Medicine Initiative*, WHITE HOUSE, https://www.whitehouse.gov/precision-medicine [https://perma.cc/BE9M-RVM7].

237. *About BD2K*, NAT'L INST. HEALTH, https://datascience.nih.gov/bd2k/about [https://perma.cc/M8EW-6W8K].

agreement.[238] As noted by Barbara Evans, "[a] major challenge in twenty-first century privacy law and research ethics will be to come to terms with the inherently collective nature of knowledge generation in a world where large-scale informational research is set to play a more prominent role."[239] Jane Bambauer goes further, arguing that, because HIPAA "attempt[s] to anticipate and account for every public policy override, and set an otherwise inflexible rule of nondisclosure[,]" its "privacy provisions have had perverse effects on access to critical research data, quality of care, and overall public health."[240]

That tension between data protection and responsible research will only increase. Furthermore, technology continually chisels away at the professional-consumer health-care space divide. For example, the IOM has recommended that some social and economic determinants of health should be recorded in EHRs,[241] adding social media to clinical data shows promise,[242] and, increasingly, clinical research is occurring outside of recognized professional spaces using crowdsourcing or mobile apps such as those built around Apple's ResearchKit.[243]

C. Refuting the Binary

Arguments about the negative impact of data protection on clinical interoperability, medical research, or positive disruption suffer from one consistent shortcoming. They tend to posit unsupportable, simplistic binaries, painting "privacy" as oppositional to innovation or progress. There are several flaws underpinning this "all or nothing" position.

First, data protection rules that impact research or other data sharing, while occasionally deliberately obstructive, often are misinterpreted or used perversely to create barriers. In 2010 the President's Council of Advisors on Science and Technology noted how "The complex mandates of both HIPAA and state laws and regulations leads organizations to equate protection to sequestration, with little or no provision for either access based on roles . . . or for legitimate secondary uses of data . . . although HIPAA itself actually does allow disclosures in many such cases."[244] In the intervening years HHS-OCR, which is charged

238. 45 C.F.R. § 164.514 (2016).

239. Barbara J. Evans, *Much Ado About Data Ownership*, 25 HARV. J.L. & TECH. 69, 76 (2011).

240. Jane Bambauer, *Is Data Speech?*, 66 STAN. L. REV. 57, 114 (2014).

241. Nancy E. Adler & William W. Stead, *Patients in Context — EHR Capture of Social and Behavioral Determinants of Health*, 372 NEW ENG. J. MED. 698 (2015).

242. *See, e.g.*, Kevin A. Padrez et al., *Linking Social Media and Medical Record Data: A Study of Adults Presenting to an Academic, Urban Emergency Dep't*, 25 BMJ QUALITY & SAFETY 414 (2016).

243. *See, e.g.*, Press Release, Apple, Inc., Apple Announces New ResearchKit Studies for Autism, Epilepsy & Melanoma (Oct. 15, 2015), http://www.apple.com/pr/library/2015/10/15Apple-Announces-New-ResearchKit-Studies-for-Autism-Epilepsy-Melanoma.html [https://perma.cc/6KG8-LBXF].

244. President's Council of Advisors on Sci. & Tech., *Report to the President Realizing the*

with HIPAA enforcement, has repeatedly issued guidance reminding stakeholders that HIPAA allows sharing of PHI between provider and patient[245] and between providers.[246] Equally, Congress[247] and ONC[248] have been critical of any attempts providers have made to use HIPAA as a barrier for intentional non-sharing, usually referred to as "information blocking." Ironically, medically-inflected data (the health-care data collected and processed outside of HIPAA protection) is likely more liquid than data held by traditional health-care providers. However, as technologies improve and both providers and patients become better educated about data sharing *within* a protected environment, that should change.

Second, data protection is contextual and the level of protection should be calibrated against particular data types, intended uses, and the commercial ambitions of data custodians. With regard to the last, and as noted by the FTC:

> Organizations have used big data to predict life expectancy, genetic predisposition to disease, likelihood of hospital readmission, and likelihood of adherence to a treatment plan in order to tailor medical treatment to an individual's characteristics. This, in turn, has helped health-care providers avoid one-size-fits-all treatments and lower overall health-care costs by reducing readmissions. Ultimately, data sets with richer and more complete data should allow medical practitioners more effectively to perform "precision medicine," an approach for disease treatment and prevention that considers individual variability in genes, environment, and lifestyle.[249]

In contrast, the commercial use of sensitive personal-health-care or medically-inflected data exported from or created outside of the health-care space impacts quite different policy questions. When data are being used by providers for, say, clinical outcomes research, restrictive rules are less called for so long as

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Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward, EXECUTIVE OFFICE PRESIDENT 47 (Dec. 2010), https://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf [https://perma.cc/TCG3-TQQ7].

245. *See, e.g.*, *Individuals' Right under HIPAA to Access Their Health Information 45 CFR § 164.524*, U.S. DEP'T HEALTH & HUM. SERVS., http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html [https://perma.cc/KY6C-JMDU].

246. *Does the HIPAA Privacy Rule Permit a Doctor, Laboratory, or Other Health Care Provider to Share Patient Health Information for Treatment Purposes by Fax, E-mail, or Over the Phone?*, U.S. DEP'T HEALTH & HUM. SERVS., http://www.hhs.gov/hipaa/for-professionals/faq/482/does-hipaa-permit-a-doctor-to-share-patient-information-for-treatment-over-the-phone/index.html [https://perma.cc/WTM9-75A2].

247. *See, e.g.*, 21st Century Cures Act, Pub. L. No. 114-255, § 4004, 130 Stat. 1033, 1176–80 (2016) (to be codified at 42 U.S.C. § 300jj-52).

248. *See, e.g.*, *Report on Health Information Blocking*, *supra* note 227, at 11–14.

249. *Big Data: A Tool for Inclusion or Exclusion? Understanding the Issues*, FED. TRADE COMMISSION 7 (Jan. 2016), https://www.ftc.gov/system/files/documents/reports/big-data-tool-inclusion-or-exclusion-understanding-issues/160106big-data-rpt.pdf [https://perma.cc/WR4N-9AMB] [hereinafter *Big Data Report*] (references omitted).

the data are used for the stated purpose and kept within the clinical domain.

Third, "privacy" is not a single concept but rather is descriptive of a broad array of upstream and downstream protective models. Take a recent opinion piece by David Agus, which at first sight seemed to be adopting the anti-HIPAA rhetoric of medical research trumping privacy when he argued: "Patients understandably don't want their acquaintances and employers to know all their private health information. But we cannot let these fears suppress the powerful insights medical data can offer us."[250] Yet, elsewhere in the piece, he argued for increased data encryption and other security, careful protection against health-care data-driven discrimination and generally seemed to be arguing for the sharing of de-identified information.

The trick is that we can have both research and data protection. Similarly, data market disruption or mobile health disruption can drive progress in health care without exposing patient's data to exploitation. Neither need endanger properly calibrated health-care data protection.

VI. REGULATORY RESPONSES TO DISRUPTION AND ARBITRAGE

In the face of regulatory disruption and arbitrage, it should be no surprise that additional data protection is required to safeguard health-care information that resides outside of traditional, highly regulated spaces. Policymakers must address considerations of timing and approach together with the question of whether they need to add additional protections to continue the tradition of exceptionalism. First, however, it is worth considering whether to deal with the issue by attacking disruption, rather than by better regulating the disrupted state.

A. Is Disruption Worth the Trouble?

Is it possible to put a positive spin on disruption? Returning once again to the analogy of mobile health and ride-hailing apps, there seems little doubt that the traditional taxi industry presents with serious anti-competitive properties: a guild mentality, non-market limitations on the number of market participants via medallions, and agency capture to name just a few.[251] Is there an argument to be made that regulatory disruption does what policymakers often fail to do; to take a clean-sheet look at the regulation of innovative businesses rather than simply

250. David B. Agus, *Give Up Your Data to Cure Disease*, N.Y. TIMES (Feb. 6, 2016), http://www.nytimes.com/2016/02/07/opinion/sunday/give-up-your-data-to-cure-disease.html [https://perma.cc/KZ9M-YW4J]

251. *See generally* Rohin Dhar, *The Tyranny of the Taxi Medallions*, PRICECONOMICS (Apr. 10, 2013), http://blog.priceonomics.com/post/47636506327/the-tyranny-of-the-taxi-medallions [https://perma.cc/39FZ-UR9E]; Jason Snead, *Taxicab Medallion Systems: Time for a Change*, HERITAGE FOUND. (Dec. 10, 2015), http://www.heritage.org/research/reports/2015/12/taxicab-medallion-systems-time-for-a-change [https://perma.cc/8XJM-XHE3].

apply or add to the sedimentary layers of outdated laws?

Of course, health care makes the taxi industry look like a candidate for a Nobel Prize in economics. Indeed, there is nothing novel about the observation that health care fails to obey most market norms.[252] Equally, it is well known that at various times physicians, hospital administrators,[253] and insurers[254] have held market-controlling positions. Examples are legion and regulators, such as the FTC, do rail against some of the worst market abuses. For example, in *North Carolina State Bd. of Dental Examiners v. F.T.C.*, Justice Kennedy denied application of state antitrust immunity when government "abandon[s] markets to the unsupervised control of active market participants, whether trade associations or hybrid agencies."[255]

For every attempt to limit, say, guild power, there are defeats elsewhere, however. For instance, the Federal Trade Commission and the Antitrust Division of the U.S. Department have been sharply critical of health care's "medallion" systems such as state requirements for Certificates of Need (CON): "CON laws raise considerable competitive concerns and generally do not appear to have achieved their intended benefits for health care consumers. For these reasons, the Agencies historically have suggested that states consider repeal or retrenchment of their CON laws."[256] Yet, most courts seem unimpressed by legal challenges to these relics of 1970s centralized planning.[257]

Are, therefore, big data and mobile health disruptions positives? After all, entrenched stakeholders (incumbents) seem to have little interest in positively reforming data protection regimes. This is not always because of a genuine commitment to patient privacy. Rather, health-care stakeholders frequently view patient data as proprietary and will use the excuse of privacy to keep such valuable assets close. "Disruption as laboratory" is also a tempting model because of the current tension between data protection and data liquidity. In the words of Cisco executive Shanti Gidwani, "Disruptive is a good thing. . . It moves us to be transformational and innovative."[258]

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252. Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963).

253. *See, e.g.*, PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE (1982).

254. *See, e.g.*, CHRISTY FORD CHAPIN, ENSURING AMERICA'S HEALTH, THE PUBLIC CREATION OF THE CORPORATE HEALTH CARE SYSTEM (2015).

255. 135 S. Ct. 1101, 1117 (2015).

256. Fed. Trade Comm'n & U.S. Dep't of Justice, Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250, at 17 (Jan. 11, 2016), https://www.ftc.gov/policy/policy-actions/advocacy-filings/2016/01/joint-statement-federal-trade-commission-antitrust [https://perma.cc/22HR-R92Z].

257. *See, e.g.*, Colon Health Centers of Am., LLC v. Hazel, 813 F.3d 145 (4th Cir. 2016).

258. Jeremy Hainsworth, *Disruptive Techs Can Help Health-Care*, BNA NEWS (Feb. 17, 2016), http://www.bna.com/disruptive-techs-help-n57982067427 [https://perma.cc/W7QU-PU2T].

B. A Different Type of Laboratory, the States

With federal law allowing disruption and arbitrage and the absence of any clear legislative or regulatory paths, might state law fulfill its traditional laboratory role by implementing some stopgap measures? Clearly, states *do* operate in this space, although they may not conceptualize their actions as data protection. Take, for example, the impact of past criminal records on employment decisions. Federal law, represented by EEOC Guidance, takes the position that the overrepresentation of persons of color in "contact with the criminal justice system" could impact some discriminatory hiring or other employment decisions.[259] In contrast, several states have taken a far more direct approach, enacting "second chance" laws that permit convicted persons to withhold information about expunged crimes.[260]

In the health-care data protection space, few states have moved far from the HIPAA norm. Even California's Confidentiality of Medical Information Act,[261] long held out as the model for regulation that goes beyond HIPAA, does little to deal with the disruption and arbitrage discussed here. At first sight, the statute's inclusion of "[a]ny business that offers software or hardware to consumers shall be deemed to be a provider of health care"[262] suggests the obvious. However, additional verbiage and a cross-reference suggest that in reality regulatory coverage is only extended to some PHRs.

Texas goes further, more successfully increasing the scope of health-care data protection (albeit still concentrating on downstream models). For example, the Texas statute uses a far broader definition of "covered entity" than HIPAA to include a "business associate, health care payer, governmental unit, information or computer management entity, school, health researcher, health care facility, clinic, health care provider, or person who maintains an Internet site[.]"[263] The statute also prohibits unconsented to reidentification[264] and the sale of PHI.[265]

The "laboratory of the states" argument is always attractive during a time of Congressional logjam. Stakeholders are paying careful attention to forthcoming state privacy legislation, although for now there is little in the way of health-care data protection. For example, the Tenth Amendment Center and the ACLU

259. *See Consideration of Arrest and Conviction Records in Employment Decisions Under Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP. OPPORTUNITY COMMISSION, https://www.eeoc.gov/laws/guidance/upload/arrest_conviction.pdf [https://perma.cc/3B6E-8HEU].

260. *See, e.g.*, Greg Glod, *"Second Chance" Legislation is Smart Criminal Justice Reform*, RIGHT ON CRIME (Apr. 10, 2015), http://rightoncrime.com/2015/04/second-chance-legislation-is-smart-criminal-justice-reform [https://perma.cc/W5ZG-G6HE].

261. CAL. CIV. CODE D. 1, Pt. 2.6 (West 2016).

262. CAL. CIV. CODE § 56.06(b) (West 2016).

263. TEX. HEALTH & SAFETY CODE ANN. § 181.001(a)(2) (West 2015).

264. TEX. HEALTH & SAFETY CODE ANN. § 181.151 (West 2015).

265. TEX. HEALTH & SAFETY CODE ANN. § 181.153 (West 2015).

recently participated in the coordinated announcement of various state data protection measures, primarily aimed at reducing surveillance.[266]

C. What Style of Regulation is Appropriate for Disruptive Technologies?

Nathan Cortez has offered a thoughtful critique of the conventional wisdom as to how agencies should regulate disruptive businesses.[267] His starting point is Tim Wu's context-based defense of "agency threats," sub-regulatory signals that include "statements of best practices, interpretative guides, private warning letters, and press releases" [268] directed at industries facing uncertainty or disruption.[269]

Threats are not intended as a permanent solution, but rather as part of a longer process. If successful and widely respected, it is possible that a threat may create an industry norm, removing the need for rulemaking at all. Alternatively, a threat regime may be a pilot, as it were, for eventual lawmaking. The law created by rulemaking or adjudication will then benefit from the facts developed under the threat regime.[270]

Cortez's opposing argument is that "agencies need not be so deliberate and tentative with regulating innovations—even disruptive ones."[271] Rather "[t]he public interest demands that agencies maintain their fortitude in the face of regulatory disruption. And, somewhat counterintuitively, new technologies can benefit from decisive, well-timed regulation."[272] Cortez argues, "[t]he trick is to craft enduring policy under high uncertainty[,]" suggesting the use of "sunsets" and "deadlines."[273]

An early sign of regulatory disruption in the mobile health space came with regard to patient safety when, in 2013, the FDA essentially ceded its regulatory territory with a sub-regulatory Guidance as to which mobile apps it would choose to regulate under Section 201(h) of the Federal Food, Drug, and Cosmetic Act.[274]

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266. Mike Maharrey, *16 States Simultaneously Announce Efforts to Protect Privacy, #TakeCTRL*, TENTH AMEND. CTR. (Jan. 20, 2016), http://tenthamendmentcenter.com/2016/01/20/16-states-simultaneously-announce-efforts-to-protect-privacy/ [https://perma.cc/SNZ6-J5MX]; *see generally* Andy Greenberg, *5 Things Congress Should Learn From New State Privacy Bills*, WIRED (Jan, 21, 2016), http://www.wired.com/2016/01/five-things-new-state-privacy-bills-could-teach-congress/ [https://perma.cc/G7CE-NX7J]; Hamza Shaban, *To Strengthen Consumer Privacy, the ACLU Looks to the States*, BUZZFEED NEWS (Jan. 20, 2016), http://www.buzzfeed.com/hamzashaban/aclu-takes-consumer-privacy-battle-to-the-states#.luoj0nXMY [https://perma.cc/78AH-A22W].

267. Nathan Cortez, *Regulating Disruptive Innovation*, 29 BERKELEY TECH. L.J. 175 (2014).

268. Tim Wu, *Agency Threats*, 60 DUKE L.J. 1841, 1841 (2011).

269. *Id.* at 1848.

270. *Id.* at 1851.

271. Cortez, *supra* note 267, at 227.

272. *Id.* at 179–80.

273. *Id.* at 217.

274. *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*, U.S. FOOD & DRUG ADMIN., (Feb. 2015),

Under this Guidance, FDA elected to exercise regulatory discretion over common health related apps such as trackers.

Rather than solve problems, the guidance seems to have had the opposite effect, arguably supporting Cortez's arguments. For example, Apple omitted health-monitoring features such as blood pressure and stress level when it launched Apple Watch in 2015. It is widely believed that this decision was made, at least in part, because of regulatory concerns.[275] Subsequently, Apple CEO Tim Cook stated:

> We don't want to put the watch through the Food and Drug Administration (FDA) process. I wouldn't mind putting something adjacent to the watch through it, but not the watch, because it would hold us back from innovating too much, the cycles are too long. But you can begin to envision other things that might be adjacent to it -- maybe an app, maybe something else.[276]

In fact, FDA practice suggests a very light regulatory hand, featuring not only sub-regulatory guidance, but also under-enforcement. For example, so far the agency has only reined in one mobile app developer.[277]

Not surprisingly, developers are selling apps that apparently perform medical device functions, yet are "saved" from regulation by "small print" characterizations. For example, take the app "Instant Blood Pressure." Its developer includes the following in its FAQ:

> Instant blood pressure is not a medical device. It is for recreational use only. It is not a replacement for a medical grade blood pressure monitor. It is not intended for use in and should not be used for the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease.[278]

As a matter of law, this statement is not determinative, as the manufacturer's

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http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf [https://perma.cc/4FVZ-F6D7] (the Guidance is primarily the same as that originally issued in September 2013).

275. Daisuke Wakabayashi, *What Exactly Is an Apple Watch For?*, WALL ST. J. (Feb. 16, 2015), http://www.wsj.com/articles/challenge-of-apple-watch-defining-its-purpose-1424133615?mod=e2fb [https://perma.cc/3GQL-EMBK].

276. Allister Heath, *Apple's Tim Cook Declares the End of the PC and Hints at New Medical Product*, TELEGRAPH (Nov. 10, 2015), http://www.telegraph.co.uk/technology/apple/11984806/Apples-Tim-Cook-declares-the-end-of-the-PC-and-hints-at-new-medical-product.html [https://perma.cc/DJ4Y-6Q4U].

277. Letter from Food & Drug Admin. to Myshkin Ingawale, Biosense Technologies Private Limited, http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm353513.htm [https://perma.cc/C9FQ-7N6S].

278. *Support FAQs*, INSTANT BLOOD PRESSURE, http://www.instantbloodpressure.com/support/ [https://perma.cc/CWA2-T97Z].

intent is objectively determined.[279] However, statements like this—and there are many similar statements included within other apps—at least temporarily allow for arbitrage as the app is characterized as consumer, rather than professional, in nature.

Regarding health-care data protection, HHS simply lacks regulatory authority over most of the mobile health activity. Very few mobile app developers or service providers will be covered entities or their business associates. Likely, even a guidance would be viewed as overreaching.[280] The furthest HHS-OCR has gone on its own has been to post a lightly-trafficked Q&A page for health app developers[281] and, as mentioned above, worked with the FTC and the FDA on a web-based interactive tool for app developers.[282] Under pressure from Congress, HHS (with a little help from the FTC) has made clear their relative powerless in the emerging mobile health space.

Health information is increasingly collected, shared, or used by new types of organizations beyond the traditional health care organizations currently covered by HIPAA, such as peer health communities, online health management tools, and websites used to generate information for research, any of which might be accessed on computers or smart phones and other mobile devices. If they are not determined to be health plans, health care clearinghouses, or health care providers conducting certain electronic transactions, and they are not acting on behalf of, or providing a service to, a HIPAA covered entity, they are not subject to the HIPAA standards for covered entities and business associates.[283]

Specifically, HHS's analysis pointed to five classes of data protection responsibilities in which non-covered entities faced lower data protection duties than HIPAA covered entities: access rights, third-party data use, security standards, required privacy notices, and disclosure limitations.[284]

The FDA has gingerly entered the data protection space with a series of sub-regulatory guidances on device security.[285] In a recent draft guidance, FDA

279. 21 C.F.R. § 801.4 (2016).

280. Consider the stakeholder concerns about ONC overstepping its authority in the 2016 NPRM on EHR certification. *See* Rajiv Leventhal, *ONC's New Leader Defends Agency's Role in EHR Oversight*, HEALTHCARE INFORMATICS (Sept. 20, 2016), http://www.healthcare-informatics.com/article/ehr/onc-s-new-leader-defends-agency-s-role-ehr-oversight [https://perma.cc/D2Q4-S4Y2].

281. *Health App Developers: Questions About HIPAA?*, U.S. DEP'T HEALTH & HUMAN SERVS., http://hipaaqsportal.hhs.gov/a/home [https://perma.cc/7UKQ-VHQQ].

282. *Mobile Health Apps Interactive Tool*, FED. TRADE COMMISSION, https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool [https://perma.cc/D9HK-E73S].

283. *Health Data Collected by Entities Not Regulated by HIPAA*, *supra* note 205, at 4.

284. *Id.* at 20–30.

285. *Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, U.S. FOOD & DRUG ADMIN., (May 2005), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/

"emphasize[d] that manufacturers should monitor, identify and address cybersecurity vulnerabilities and exploits as part of their postmarket management of medical devices."[286] Presumably, however, even this guidance would not apply to mobile medical apps that are currently excluded from device regulation under the 2015 Guidance.[287]

In 2013, the FTC published a lower-level, sub-regulatory "guide," *Marketing Your Mobile App: Get It Right from the Start*, that urged transparency, truthfulness, consent, and data minimization:

> Under the law, you still have to take reasonable steps to keep sensitive data secure. One way to make that task easier: If you don't have a specific need for the information, don't collect it in the first place. The wisest policy is to:
>
> 1. collect only the data you need;
> 2. secure the data you keep by taking reasonable precautions against well-known security risks;
> 3. limit access to a need-to-know basis; and
> 4. safely dispose of data you no longer need.[288]

Notwithstanding its lowly status, the agency has undoubtedly heightened the agency threat status of this "guide" through their subsequent agency enforcement activities with regard to security[289] and privacy.[290] Indeed, the FTC's track record in security cases warranted the publication of yet another guide in 2015, *Start*

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ucm089593.pdf [https://perma.cc/8XW7-65J9]; *Guidance to Industry: Cybersecurity for Networked Medical Devices Containing Off-the-Shelf* (OTS) Software, U.S. FOOD & DRUG ADMIN., (Jan. 2005), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf [https://perma.cc/N278-M3QK].

286. *Draft Guidance for Industry and Food and Drug Administration Staff: Postmarket Management of Cybersecurity in Medical Devices*, U.S. FOOD & DRUG ADMIN. 4 (Jan. 2016), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482022.pdf [https://perma.cc/J382-SBP7].

287. *See supra* text accompanying note 274.

288. *Marketing Your Mobile App: Get It Right from the Start*, FED. TRADE COMMISSION 5 (Apr. 2013), https://www.ftc.gov/system/files/documents/plain-language/pdf-0140_marketing-your-mobile-app.pdf [https://perma.cc/WEM8-24WY].

289. *See, e.g.*, Fed. Trade Comm'n v. Wyndham Worldwide Corp., No. 14-3514 (3rd Cir. filed Aug. 24, 2015), http://www2.ca3.uscourts.gov/opinarch/143514p.pdf [https://perma.cc/A89H-VN29]; *see also* Press Release, Fed. Trade Comm'n, Fandango, Credit Karma Settle FTC Charges That They Deceived Consumers by Failing to Securely Transmit Sensitive Personal Information (Mar. 28, 2014), https://www.ftc.gov/news-events/press-releases/2014/03/fandango-credit-karma-settle-ftc-charges-they-deceived-consumers [https://perma.cc/5RL2-XFKX].

290. *See, e.g.*, Nomi Technologies, Inc., FTC No. 132-3251 (2015), https://www.ftc.gov/enforcement/cases-proceedings/132-3251/nomi-technologies-inc-matter [https://perma.cc/F8YW-EGQX].

with Security, A Guide for Business that is subtitled *Lessons Learned from FTC Cases*.[291]

In 2016 The FTC began hosting a "Mobile Health Apps Interactive Tool" jointly produced with HHS, ONC, and FDA designed to "give [mobile app developers] a snapshot of a few important laws and regulations from three federal agencies."[292] The FTC also has continued in its somewhat lonely role of curbing the worst excesses of big data. Recently it followed up on its 2014 *Data Brokers* report[293] with another report, *Big Data: A Tool for Inclusion or Exclusion?*[294] While the former was investigatory, the latter is a clear agency "threat," as the agency notes its specific (e.g., FCRA) and general (§5(a)) powers to police big data.

D. The Level of Regulation: The Case for Continued Exceptionalism

There seem to be few arguments that health-care data are not sensitive and deserving of protection. The real question in today's environment, is whether health privacy advocates should throw in their lot with those arguing for heightened protection across all domains. This section asks whether continuing calls for health data protection exceptionalism have any particular salience. Several claims seem to have merit.

First, from earliest times the physician-patient-data relationship has involved special data obligations. A patient holds health information (either literally or as data that can be released during diagnosis). The patient's rights over this data are protected by both ethical and legal principles; an autonomy model requiring consent to data sharing.[295] Thus, in both the legal and ethical senses, the patient (instrumentally) exercises this right of privacy when the patient gives a physician access to these data. In exchange for that consent the physician agrees to hold the data in confidence, an obligation sourced in ethical frameworks, the confidence tort, and ethical-legal hybrids such as the duty owed by fiduciaries.[296] In the

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291. *Start with Security: A Guide for Business*, FED. TRADE COMMISSION (June 2015), https://www.ftc.gov/system/files/documents/plain-language/pdf0205-startwithsecurity.pdf [https://perma.cc/V3MG-V97W].

292. *Mobile Health Apps Interactive Tool*, FED. TRADE COMMISSION, https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool [https://perma.cc/S26G-T68P].

293. *Data Brokers*, *supra* note 3.

294. *Big Data Report*, *supra* note 249.

295. "The primary justification seems closer to respect for autonomy. . . . We owe respect in the sense of deference to persons' autonomous wishes not to be observed, touched, intruded on, and the like. The right to authorize or decline access is basic." BEAUCHAMP & CHILDRESS, *supra* note 36, at 313–14.

296. *See generally* Nicolas P. Terry, *What's Wrong with Health Privacy?*, 5 J. HEALTH & BIOMEDICAL L. 1, 1–32 (2009); *see also* SANDRA PETRONIO, BOUNDARIES OF PRIVACY: DIALECTICS OF DISCLOSURE 28 (2002) (describing operation of "communication privacy management" such that "when a person confides, the recipient is held responsible for the information and a set of expectations is communicated by the discloser.").

words of Bill Gardner:

> [H]ealth services data are the residue of the touches of living persons against the health care system. As such, they reflect the experience of those patients, even if such effects are often obscure to the analyst. The data are lit from within by the experience of patients, even if only faintly. Medical data are the relics of human suffering, recovery, and death. We wouldn't be looking at them if there wasn't a signal there.[297]

In the health-care domain, therefore, there is a deep, culturally significant, and relationship-based demand for the strongest level of data protection. As noted by the HITPC in 2010, "[t[he relationship between the patient and his or her healthcare provider is the foundation for trust in health information exchange, particularly with respect to protecting the confidentiality of personal health information."[298]

Second, patients have been conditioned to disclose all data to their health-care providers on the basis of this very promise; that such data will be protected like no other. This somewhat reductionist argument should not be dismissed lightly. Patients have grown up with a system that has seemed impervious to even basic data sharing. Almost every visit to a provider involves filling out a new intake form or, at least, updating insurance and other personal information. As had been argued, "[p]atients should not be surprised about or harmed by collections, uses, or disclosures of their information."[299] For the past 15 years almost every health-care encounter will have been marked by the production of a HIPAA privacy notice,[300] the right to inspect and obtain copies,[301] and receive an accounting of disclosures.[302] Think of the surprise, the dashed expectations if a patient was to find that his or her data no longer was exceptionally protected because of an informational accident as to where they were created (e.g., on a smartphone) or who was their curator (a data broker).

Third, health-care data deserves exceptional protection in the face of exceptional threats. Health-care data is a hot commodity on the dark web.[303] It is

297. Bill Gardner, *Ethics and Data: What's at Stake*, INCIDENTAL ECONOMIST (Sept. 25, 2015), http://theincidentaleconomist.com/wordpress/ethics-and-data-whats-at-stake [https://perma.cc/N68V-ZJU4].

298. Letter from Paul Tang, *supra* note 126.

299. *Id.*

300. 45 C.F.R. § 164.520 (2016).

301. 45 C.F.R. § 164.524 (2016).

302. 45 C.F.R. § 164.528 (2016).

303. *See generally* Damon Beres, *What You Should Know About the 'Dark Web,' An Anonymous Haven for Hackers*, HUFFINGTON POST (Aug. 19, 2015), http://www.huffingtonpost.com/entry/what-is-the-dark-web_55d48c50e4b0ab468d9f17d7 [https://perma.cc/6XZH-W8UC]; *see also* Andrea Peterson, *Why Hackers Are Going After Health-care Providers*, WASH. POST. (Mar. 28, 2016), https://www.washingtonpost.com/news/the-switch/wp/2016/03/28/why-hackers-are-going-after-health-care-providers [https://perma.cc/C2B5-R8YC].

the fastest growing target for cyber-attacks,[304] accounting for 21% of data breaches globally.[305] Data brokers see a strong market for health-based ratings products. App stores are populated by tens of thousands of health and wellness apps, often of dubious provenance. Even respectable outcomes and human subject researchers covet clinical data at a time when the choice architecture for patient consent has not been agreed upon.

Fourth, health-care data seems particularly susceptible to discriminatory and other harmful uses. As noted in the 2015 HITPC report, under U.S. law some "discriminatory uses of health information are either not prohibited or are expressly permitted (for example, use of health information in life and disability insurance decisions)."[306] The report also acknowledged, "a lack of consensus on which uses are 'harmful,' particularly with respect to health big data analytics, as well as an inability to predict which future uses could be harmful and which beneficial, creating challenges to enacting policies to prohibit or place additional constraints on such uses."[307] The real issue is that the use of health-care data outside of the clinical setting with the potential for real or perceived harms will devastate the trust that accompanied the initial patient sharing of data with the provider. Without trust, patients will share less, and both their clinical care and the responsible research that could be performed using those data will suffer.[308]

Finally, while as citizens we may generally view the market as the best available solution to our problems and support the liquidity of data to foster innovation, we continue to stake out some limits. Policymakers have spent untold energy in trying to reverse health care's chronic market failure[309] and make it work more like other "normal" products and services. But in the words of David Blumenthal, "[p]eople feel differently" about health care "than they do about the myriad other things that get bought and sold, without controversy, in normal markets."[310] And, as result "[g]overnment is involved in health care because

304. *See, e.g.*, Lucas Mearian, *Cyberattacks Will Compromise 1-in-3 Healthcare Records Next Year*, COMPUTERWORLD (Dec 8, 2015), http://www.computerworld.com/article/3013013/healthcare-it/cyberattacks-will-compromise-1-in-3-healthcare-records-next-year.html [https://perma.cc/6YP7-PS5Z]; Shannon Pettypiece, *Rising Cyber Attacks Costing Health System $6 Billion Annually*, BLOOMBERG (May 7, 2015), http://www.bloomberg.com/news/articles/2015-05-07/rising-cyber-attacks-costing-health-system-6-billion-annually [https://perma.cc/XV5L-4JZW].

305. *2015 First Half Review*, BREACH LEVEL INDEX 10 (Sept. 2015), http://www.breachlevelindex.com/pdf/Breach-Level-Index-Report-H12015.pdf [https://perma.cc/D73Q-3LVY].

306. *Health Big Data Recommendations*, *supra* note 158, at 12.

307. *Id.* at 12–13.

308. "Failing to pay attention to these issues undermines trust in health big data analytics, which could create obstacles to leveraging health big data to achieve gains in health and well-being." *Id.* at 13.

309. ARROW, *supra* note 252, at 941–73.

310. David Blumenthal, *What's the Big Deal About Drug Prices?*, COMMONWEALTH FUND BLOG (Oct. 9, 2015), http://www.commonwealthfund.org/publications/blog/2015/oct/whats-the-big-deal-about-drug-prices [https://perma.cc/LQ5E-NW6W].

Americans deeply desire the health care protections government provides."[311] In short, data protection regarding our health care *is* important enough to us to warrant exceptional protection.

VII. MOVING BEYOND HIPAA, EXPLORING THE POTENTIAL OF MULTIPLE DATA PROTECTION MODELS

Privacy policymakers and champions for regulation have pushed back against data brokers, accusing them of expropriation[312] and encouraging data determinism.[313] In many cases, the same accusations can be made against those collecting data with mobile apps (particularly those selling the data to big data brokers). In *The Black Box Society*, Frank Pasquale described how those data-gathering and analytic tools might impact health-care data subjects:

> [A] "body score" may someday be even more important than your credit score. Mobile medical apps and social networks offer powerful opportunities to find support, form communities, and address health issues. But they also offer unprecedented surveillance of health data, largely ungoverned by traditional health privacy laws (which focus on doctors, hospitals, and insurers). Furthermore, they open the door to frightening and manipulative uses of that data by ranking intermediaries— data scorers and brokers— and the businesses, employers, and government agencies they inform.[314]

In its 2014 report on data brokers' practices, the FTC noted how health information or medically-inflected data was used to create "potentially sensitive categories [that] highlight certain health-related topics or conditions, such as "Expectant Parent," "Diabetes Interest," and "Cholesterol Focus."[315] In *Here's Looking at You*, the California HealthCare Foundation noted:

> Consumer scores are now ubiquitous across peoples' activities: financial and credit, energy use, law enforcement, environmental, social clout, tax returns, environmental "green-ness," and health. In 2014, there were at least a dozen health scores available in the marketplace, including the

311. *Id.*

312. Julie Brill, Comm'r, Fed. Trade Comm'n, Keynote Address at the 23rd Computers, Freedom, and Privacy Conference: Reclaim Your Name 11–12 (June 26, 2013), http://www.ftc.gov/speeches/brill/130626computersfreedom.pdf [https://perma.cc/Y4KU-FUN4].

313. Edith Ramirez, Chairwoman, Fed. Trade Comm'n, Keynote Address at the Tech. Pol'y Inst. Aspen Forum: The Privacy Challenges of Big Data: A View from the Lifeguard's Chair 7 (Aug. 19, 2013), http://ftc.gov/speeches/ramirez/130819bigdataaspen.pdf [https://perma.cc/XS6V-BAVT].

314. FRANK PASQUALE, THE BLACK BOX SOCIETY: THE SECRET ALGORITHMS THAT CONTROL MONEY AND INFORMATION 26 (2015) (references omitted).

315. *Data Brokers*, *supra* note 3, at 47.

> Affordable Care Act (ACA) Individual Health Risk Score, FICO Medication Adherence Score, several frailty scores, personal health scores (e.g., WebMD, One Health Score), and medical complexity scores (e.g., Aristotle for scoring of surgery for congenital health conditions). Consumers are largely unaware of the existence and use of these scores and the algorithms that create them.[316]

Notwithstanding its flaws, HIPAA was a reasonable approach to health-care data protection in the last decade of the twentieth century. At the time, both "privacy" and security threats primarily arose from inside the health-care system. Data protection required an update from the haphazard nature of state confidentiality-based protections as the industry swapped PCs for paper, while hospital IT needed a solid nudge to lock some doors and reduce the number of stolen laptops and thumb drives. As such, combining a solid, if exclusively downstream, national HIPAA floor and compliance-based policing made some sense.

Fast-forward to 2009, and policymakers seemed unable to look to the future. The HITECH Act was designed to improve the HIPAA system just enough to absorb the unprecedented growth of EHRs, which the same legislation was about to subsidize.[317] The only attempt to think outside the hospital-based technology box was the introduction of a breach notification rule for PHRs. Yet, the implications of big data mining and data aggregation were already being discussed and the iPhone's introduction in 2007,[318] followed a year later by its app store,[319] suggested the birth of a mobile revolution.

The closing argument of this article is that today the traditional, exceptional, justifiably high protection of health-care data is seriously threatened by the disruption and arbitrage displayed in big data and mobile spaces. Waiting in the wings are other threats from emerging, more autonomous technologies such as the Internet of Things, self-driving vehicles, and robots.[320]

Because of the threats to health-care data protection, legislation providing for data minimization and context-based limitations is urgently required.

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316. *Here's Looking at You: How Personal Health Information Is Being Tracked and Used*, CAL. HEALTH CARE FOUND., 8 (July 2014), http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/PDF%20H/PDF%20HeresLookingPersonalHealthInfo.pdf [https://perma.cc/L9TG-Y3XJ].

317. *See generally* Terry, *supra* note 108.

318. Press Release, Apple, Inc., Apple Reinvents the Phone with iPhone (Jan. 9, 2007), https://www.apple.com/pr/library/2007/01/09Apple-Reinvents-the-Phone-with-iPhone.html [https://perma.cc/73ZX-8BA5].

319. Michael Arrington, *iPhone App Store Has Launched (Updated)*, TECHCRUNCH (July 10, 2008), http://techcrunch.com/2008/07/10/app-store-launches-upgrade-itunes-now [https://perma.cc/FS55-W2RS].

320. *See, e.g.*, Drew Simshaw et al., *Regulating Healthcare Robots: Maximizing Opportunities While Minimizing Risks*, 22 RICH. J.L. & TECH. 3 (2016); Nicolas Terry, *Will the Internet of Things Disrupt Healthcare?*, 19 VAND. J. ENT. & TECH. L. ___ (forthcoming 2017).

Consider, for example, some features of the European General Data Protection Regulation[321] that maintain or even strengthen existing data protections that have existed under the EU Data Directive.[322] In this scenario, processing of "data concerning health" is prohibited unless it falls within quite limited exceptions including diagnosis and some research.[323] Further, the "purpose limitation" endures such that "Personal data shall be . . . collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes."[324] Along with data minimization, the purpose limitation puts major constraints on big data collection and analytics.[325] The regulation also restricts the use of "automated processing, including profiling."[326]

The most appropriate solution would be for Congress to enact a new, hopefully FIPPS-rich, federal privacy code and/or give rule-making power to the FTC or some new data protection agency (perhaps a model based on Senator Elizabeth Warren's Consumer Financial Protection Bureau). Any code or regulations could apply equally to all data types. Or, as seems more likely, they could also single out certain sensitive data types such as health data for additional protection. Whichever route Congress were to adopt, they must apply the correct approach to any future "sectoral" model of protection. First, agree on the general protective principles, and only then build out conceptually consistent protections.

Framed in large part, although not exclusively, by the explosion of big data services, various branches of the federal government published privacy reports and proposals between 2012 and 2015. All favored increased regulation, including of data brokers, yet failed to agree on much else.[327] Thereafter, and with implications for mobile health, the FTC recommended broad,

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321. *Supra*, discussion on page 252.

322. *See, e.g.*, Directive 95/46/EC, of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with regard to the Processing of Personal Data and on the Free Movement of such Data, 1995 O.J. (L 281/42), § 6 http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:31995L0046.

323. Commission Regulation 2016/679, art. 9, 2016 O.J. (L 119) 1, 38.

324. *Id.* art. 5.

325. *See generally* Opinion of the Working Party on the Protection of Individuals with regard to the Processing of Personal Data, Article 29 WP, Opinion 03/2013 on Purpose Limitation, 00569/13/EN, WP 203 (April 2, 2013) at 45–47, Example 9, http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2013/wp203_en.pdf [https://perma.cc/XDA6-VRL3].

326. Commission Regulation 2016/679, art. 22, 2016 O.J. (L 119) 1, 46.

327. *Framework for Protecting Privacy*, *supra* note 18; *Protecting Consumer Privacy*, *supra* note 40; *Big Data: Seizing Opportunities*, *supra* note 77; President's Council of Advisors on Sci. & Tech., *Big Data and Privacy: A Technological Perspective*, EXECUTIVE OFFICE PRESIDENT, (May 2014), http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_big_data_and_privacy_-_may_2014.pdf [https://perma.cc/QN7C-CMXP]; *Administration Discussion Draft: Consumer Privacy Bill of Rights Act of 2015*, WHITE HOUSE (2015), https://www.whitehouse.gov/sites/default/files/omb/legislative/letters/cpbr-act-of-2015-discussion-draft.pdf [https://perma.cc/57XV-3HYB].

technologically-neutral privacy legislation backed up with self-regulatory programs for the Internet of Things.[328]

There is no indication that these recommendations have any traction or that Congress would even consider such sweeping legislation. However, there is the potential—particularly in the wake of, say, some massive big data breach or scandal-quality privacy violation—that Congress might consider highly targeted legislation providing for explicit consent to health data being shared with data brokers. In its data brokers report, the FTC urged: "Congress should . . . consider imposing important protections for sensitive information, such as certain health information, by requiring that consumer-facing sources obtain consumers' affirmative express consent before collecting and sharing such information with data brokers."[329] Such baseline legislation likely would satisfy Cortez's "enduring policy" goal while other, more comprehensive proposals are explored through guidance and codes of conduct.

Another approach would be to extend HIPAA applicability to all custodians or processors of health-care data. Consider an analogous, superficially attractive, yet ultimately naïve, approach to health-care reform: Medicare for All, achieved by removing the age eligibility from federal coverage and, creating a single payer, universal care health-care system.[330] Yet, whether judged through political, constitutional, or organizational lenses, it isn't that simple. As Harold Pollack notes, "Medicare for All cannot offer itself as the replacement of our depressing health politics. It would have to arise as another product of that very same process, passing through the very same legislative choke points, constrained by the very same path dependencies that bedevil the ACA."[331]

Similarly, the answer to whether HIPAA should be broadened with a single stroke of the pen also must be "no." Such an extension of HIPAA is not rejected on normative grounds. Health-care data residing outside traditional health-care space should receive no less protection than that inside it. Indeed, a good argument can be made that the former deserves *more* legal protection because health-care insiders are additionally constrained or policed by professional standards and ethics thus reducing data subjects' privacy risks. HIPAA's approach to data protection is exclusively mapped to and calibrated for the traditional health-care domain. The existential threats to health-care data protection are from outside of the professional domain and they are not threats that can be countered only with downstream data protection models. HIPAA was

328. FED. TRADE COMMISSION, *supra* note 118, at 48–49.

329. *Data Brokers*, *supra* note 3, at 52.

330. Nancy Altman, *How and Why Medicare for All Is a Realistic Goal*, HUFFINGTON POST BLOG (Jan. 24, 2016), http://www.huffingtonpost.com/nancy-altman/how-and-why-medicare-for_b_9063970.html [https://perma.cc/JD42-C8SA].

331. Harold Pollack, *Medicare for All—If It Were Politically Possible—Would Necessarily Replicate the Defects of Our Current System*, 40 J. HEALTH POL., POL'Y & L. 921, 926 (2015).

specifically designed to map (whether successfully or not) to professional health-care workflows and issues. Any fundamental broadening of its scope would be highly problematic. Most importantly, the data protection problems highlighted by big data and mobile health suggest that upstream regulatory models are required, not the types of downstream protections (HIPAA privacy, security and breach notification) offered by HIPAA.

Given the problems associated with extending HIPAA and absent broad privacy legislation, what would be most effective in reducing or eliminating regulatory disruption and arbitrage in health-care data protection? In this admittedly imperfect world, this article suggests three strategies. First, HHS-OCR and the FTC should focus particular enforcement attention on the protection of HIPAA-zone data that are sources for big data. Second, ONC should use its existing regulatory powers to tighten up some aspects of the existing HIPAA privacy and security rules. Third, if politics continue to get in the way of comprehensive federal privacy legislation, Congress should at least pass narrower provisions aimed at some of the more obvious targets.

A. Increased Enforcement

Particularly with regard to big data brokers, both OCR and FTC need to remain vigilant and, through rigorous enforcement, pressure brokers to reform their practices to the benefit of consumers. There is little doubt that some HIPAA-zone data migrates into big data. Here, strong OCR enforcement of the existing data protection rules may deter some big data collection. For example, there should be heightened scrutiny of compliance with the requirements for PHI de-identification,[332] particularly with regard to the addressing of the potential for re-identification under HIPAA's "expert" (or statistical) method.[333] OCR should also dedicate particular enforcement attention to large caches of human subjects research data to ensure the highest levels of privacy and security for research subjects.[334]Additionally, OCR should extend its recent interest[335] regarding the

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332. *See, supra*, text accompanying notes 90-91.

333. *See generally How Do Experts Assess the Risk of Identification of Information?*, U.S. DEP'T HEALTH & HUM. SERVS., http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/#idrisk [https://perma.cc/C7VC-TQTZ] (providing risk assessment information regarding the risk of reidentification of various identifiers).

334. *See, e.g.*, Corrective Action Plan between the United States Department of Health and Human Services and the Feinstein Institute for Medical Research (Mar. 16, 2016) ($3.9m settlement with research institute that had exposed the PHI of 13,000 individuals), http://www.hhs.gov/sites/default/files/FIMR%20Resolution%20Agreement%20and%20Corrective%20Action%20Plan.pdf [https://perma.cc/HLE3-4D58].

335. Corrective Action Plan between the United States Department of Health and Human Services and Raleigh Orthopaedic Clinic, P.A. (Apr. 14, 2016) ($750,000 settlement), http://www.hhs.gov/sites/default/files/Raleigh%20Orthopaedic%20RA%20%26%20CAP%20%28508%29_0.pdf [https://perma.cc/NZB5-5TWJ]; North Memorial Health Care Resolution Agreement and Corrective Action Plan, ($1.55m settlement),

formation of business associate agreements (BAAs)[336] to scrutinizing the contemplated use of PHI in BAAs.[337] Meanwhile, the FTC should continue to address point-of-use discriminatory and other unfair practices with both its general powers under the FTC Act and its specific authority under the Fair Credit Reporting Act and other equal opportunity laws, as it promised in its *Tool for Inclusion or Exclusion* report.[338]

B. Amendments to the Privacy and Security Rules

Business Associates aside, ONC lacks authority to regulate data custodians who are not covered entities.[339] Notwithstanding this limitation, the agency could tighten up the protection of PHI or data that has been protected as PHI. As a result, the HIPAA Privacy Rule should be amended to require:

Any de-identified data derived from patient clinical information should be subject to a data use agreement prohibiting re-identification.

The Security Rule should be amended to require:

PHI data must be encrypted both in motion and at rest.

These amendments would lessen the risk of unlawful "exports" of PHI. They would also require mobile apps produced by covered entities or their business associates to adopt high levels of data protection for consumer-facing apps that collect, process, or transfer PHI.[340]

C. Targeted Federal Legislation

As already noted the probability for even targeted federal legislation being considered by Congress is low. However, political bodies are reactive and if there

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http://www.hhs.gov/sites/default/files/North%20Memorial%20RA%20and%20CAP%20March%202016%20%28508%29.pdf [https://perma.cc/85XQ-CN44].

336. *See* 45 C.F.R. § 160.103; 164.502(e), 164.504(e) (2016).

337. On a side note, providers should ensure that the BAAs they sign with big data providers do not allow data generated within the HIPAA zone to be exported for purposes not related to permitted uses. 45 C.F.R. § 164.501 (2016). On concerns about leakage from health-care systems as a result of such agreements, see Subhajit Basu, *Should the NHS share patient data with Google's DeepMind?* WIRED UK (May 16, 2016), http://www.wired.co.uk/article/nhs-deepmind-google-data-sharing [https://perma.cc/9BTE-CP4Q]; Ben Quinn, *Google Given Access to Healthcare Data of Up to 1.6 Million Patients*, GUARDIAN (May 4, 2016), https://www.theguardian.com/technology/2016/may/04/google-deepmind-access-healthcare-data-patients [https://perma.cc/E9YE-88DK].

338. *Big Data Report*, *supra* note 249.

339. See, *supra*, text accompanying note 85 *et seq*.

340. Non-HIPAA regulated apps would be subject to FTC ex post facto regulation if encryption was, for example, claimed but not implemented. *See* Press Release, Fed. Trade Comm'n, Fandango, Credit Karma Settle FTC Charges that They Deceived Consumers by Failing to Securely Transmit Sensitive Personal Information (Mar. 28, 2014), https://www.ftc.gov/news-events/press-releases/2014/03/fandango-credit-karma-settle-ftc-charges-they-deceived-consumers [https://perma.cc/82S3-6ZY5].

was to be some major breach or some other high profile abuse of health information in the mobile or big data space there might be the opportunity for targeted legislation.

Any such legislation would face a threshold, definitional issue. Data protected by HIPAA is defined both by data type (PHI) and by custodian type (covered entity). Exceptional treatment of health data will require a new definition that is custodian-agnostic. The EU GDPR contains a usable definition: "'data concerning health' means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status."[341] Examples of limited, targeted legislation include the following:

Any "data concerning health" collected by non-HIPAA covered entities must only be used for the limited purpose for which it was collected.

Consumer-facing sources must obtain consumers' affirmative express consent before collecting and sharing "data concerning health" with data brokers.[342]

Point-of-use prohibitions for discriminatory uses of "data concerning health" must be expanded.

Data custodians are prohibited from re-identifying or attempting to re-identify any individual who was the subject of protected health information that has been de-identified.[343]

All custodians of "data concerning health" must provide access to the data upon request from any identified or identifiable data subject and implement systems enabling correction or deletion of such data.

As is evident, these suggested reforms (even if all were passed into legislation) fall well-short of any more utopian calls for comprehensive data protection legislation. However, each proposal is true to the spirit of FIPPS and, even if adopted singly, each would reduce the current disruption and arbitrage in health care data protection.

CONCLUSION

At the root of the arguments advanced in this article is one unassailable fact: vast quantities of health-care data are now being exported to, or created outside of, HIPAA-protected spaces. The upshot is a dramatically uneven policy environment. The holders of vast amounts of health-care-like data increasingly benefit from low or no data protection. Existing "protections" are being applied to similar data not on the basis of any rational distinctions, but on the basis of an

341. Commission Regulation 2016/679, art. 4(15), 2016 O.J. (L 119) 1, 34.

342. The FTC proposal from 2014, discussed *supra* note 329.

343. Based on the Texas provision, discussed *supra* notes 263–265.

accident of creation or current, possibly transient, states. Health-care professionals, patients, pre-patients, and responsible data processors all suffer mightily from this uneven policy environment.

There is little doubt that increasingly our "medical selves" will exist outside of the traditional, HIPAA-regulated health-care domain. As regulatory disruption and arbitrage increase, this will create progressively exploitable confusion as health information moves in and out of differentially protected domains. There is now massive commercial value to be extracted from health-care data, leading data aggregators and processors to perform an end-run around health care's domain-specific protections by creating medical profiles (HIPAA proxies) of individuals in HIPAA-free space. This will only increase as the possibilities of the Internet of Things, robotics, autonomous vehicles, and technologies not yet imagined interact with our medical selves.

Unfortunately, as Fleischer recognized, "[i]n the [last] twenty-five years . . . the administrative state has increased substantially, and the amount of time lawyers devote to regulatory matters has grown apace."[344] As a result, "[t]he complexity of the modern administrative state provides more opportunities for regulatory arbitrage--another form of value creation for the client--than ever before."[345] Further, as Brad Smith, Microsoft's Chief Legal Officer, recently noted in the context of the collapse of U.S.-EU safe harbor, "privacy rights cannot endure if they change every time the data moves from one location to another. Individuals should not lose their fundamental rights simply because their personal information crosses a border."[346] Or, in this case, move from a hospital EHR to an iPhone.

Some policymakers now recognize (albeit belatedly) that the protection of health-care data is diminished when it is created in or migrates to the HIPAA-free zone; a place of considerably reduced, even zero data protection. There has also been some recognition that this new state results in regulatory turbulence, disruption, and, at least in the case of big data, regulatory arbitrage. It is less clear whether policymakers recognize the multi-faceted nature of the problem. Although a downstream, compliance-based data protection model such as HIPAA can deal with a relatively cohesive domain, it is ill-prepared for the variety of challenges that occur when data are created outside of the that domain. As a result, merely extending the domain protection is unlikely to work well. Further, the dangers associated with a HIPAA-free zone are not limited to disruption because of uneven data protection domains, but are exacerbated by the

344. Fleischer, *supra* note 64, at 237.

345. *Id.*

346. Brad Smith, *The Collapse of the US-EU Safe Harbor: Solving the New Privacy Rubik's Cube*, MICROSOFT (Oct. 20, 2015), http://blogs.microsoft.com/on-the-issues/2015/10/20/the-collapse-of-the-us-eu-safe-harbor-solving-the-new-privacy-rubiks-cube/ [https://perma.cc/74XE-ZYBZ].

chronic weaknesses of the non-HIPAA data protection models.

In 2009, the HITECH Act instructed HHS and FTC to "conduct a study, and submit a report . . . on privacy and security requirements for entities that are not covered entities or business associates."[347] This was to be followed by the HHS Secretary reporting to Congress on "the findings of the study . . . includ[ing] in such report recommendations on the privacy and security requirements described in such paragraph."[348] ONC's 2016 "Examining Oversight" purports to be that report,[349] even though HHS officials described it as "the first step in a conversation,"[350] and it failed to discuss big data and other existential threats to health-care privacy, or present meaningful recommendations. Yet the need for granular, workable proposals for legislation, particularly FIPPS-infused upstream protections, has never been greater.

In the meantime, the exceptional protection of health data is being depreciated. There are many reasons and forces conspiring to make this happen. Some are decisions that go back to the U.S. "original sin" of eschewing a comprehensive privacy law of general applicability. Some are instrumental, including the competing forces for data, be they commercial big-data brokers or the National Institutes of Health. Some are historical, such as the traditional ways U.S. data protection has been structured—sectoral and downstream, characteristics that tend to create regulatory turbulence, even arbitrage. Some are technological, as we come to terms with new generations of personal connected devices and the vast power of cloud-based data storage and analysis. Whether at root, this is an issue of health-care-privacy exceptionalism or of the general inadequacy of data protection in the United States is somewhat moot. Whatever the causes, exceptional health data protection must be preserved and protected by increased enforcement and new regulation designed to not only curtail contemporary regulatory disruption and arbitrage, but also to proactively address the inevitable technologically-enabled threats that will follow.

347. HITECH Act § 13424(b)(1), 42 U.S.C. § 17953 (2012).

348. HITECH Act § 13424(b)(2).

349. *Health Data Collected by Entities Not Regulated by HIPAA*, *supra* note 205, at 1 n.4.

350. Karen B. DeSalvo & Jocelyn Samuels, *Examining Oversight of the Privacy & Security of Health Data Collected by Entities Not Regulated by HIPAA*, HEALTH IT BUZZ BLOG,. (July 19, 2016), https://www.healthit.gov/buzz-blog/privacy-and-security-of-ehrs/examining-oversight-privacy-security-health-data-collected-entities-not-regulated-hipaa [https://perma.cc/4HDE-S7HE].

Suffrage for People with Intellectual Disabilities and Mental Illness: Observations on a Civic Controversy

Charles Kopel*

Abstract:

Most electoral democracies, including forty-three states in the United States, deny people the right to vote on the basis of intellectual disability or mental illness. Scholars in several fields have addressed these disenfranchisements, including legal scholars who analyze their validity under U.S. constitutional law and international-human-rights law, philosophers and political scientists who analyze their validity under democratic theory, and mental-health researchers who analyze their relationship to scientific categories. This Note reviews the current state of the debate across these fields and makes three contentions: (a) pragmatic political considerations have blurred the distinction between disenfranchisement provisions based on cognitive capacity and those based on personal status; (b) proposals that advocate voting by proxy trivialize the broad civic purpose of the franchise; and (c) the persistence of disenfranchisement on the basis of mental illness inevitably contributes to silencing socially disfavored views and lifestyles. Accordingly, the Note cautions reformers against advocating for capacity assessment or proxy voting, and emphasizes the importance of disassociating the idea of mental illness from voting capacity.

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INTRODUCTION

The majority of electoral democracies deny people the right to vote on the basis of intellectual disability or mental illness. A 2014 study of ninety-one democracies found that only sixteen maintain no suffrage restrictions for intellectual disability, while the seventy-five others maintain at least some restrictions.[1] Of the latter group, seventy-three states disenfranchise people by reference to certain statuses (e.g., retardation, legal incapacitation, guardianship, or detention in a psychiatric ward); and two states disenfranchise people using a more functional standard based on an individual's lack of capacity to understand the voting process, however they lack a defined procedure for ascertaining capacity.[2]

A 2016 study focusing on disenfranchisement of people with mental illness surveyed all 193 member states of the United Nations.[3] Its authors found that twenty-one states maintain no suffrage restrictions for mental illness, sixty-nine states disenfranchise all people "with any mental health problems . . . without any qualifier,"[4] nine states disenfranchise people detained under mental-health laws,[5] and fifty-six states authorize courts or magistrates to disenfranchise people for mental-health reasons.[6]

In the United States, where most voting qualifications are determined at the state level,[7] only eleven states maintain no suffrage restrictions on the basis of

1. Ludvig Beckman, *The Accuracy of Electoral Regulations: The Case of the Right to Vote by People with Cognitive Impairments*, 13 SOC. POL'Y & SOC'Y 221, 222–26 (2014). Beckman's study sample included democratic states with a population of at least one million people, identified by the author as "all major 'electoral democracies' in the world as of 2006." Guinea Bissau also meets the qualifications of population and democracy, but no data was available as to its suffrage restrictions. The sixteen nations without restrictions are Austria, Canada, Bolivia, Croatia, Ecuador, Finland, Ireland, Israel, Italy, Kenya, Mexico, the Netherlands, Norway, Slovenia, Sweden, and the United Kingdom.

2. *Id.* at 226.

3. Dinesh Bhugra et al., *Mental Illness and the Right to Vote: A Review of Legislation Across the World*, 28 INT'L REV. PSYCHIATRY 395 (2016).

4. *Id.* at 396.

5. *Id.* at 396–97 (noting that twelve other states disenfranchise all detained people, a group that presumably includes people detained for mental-health reasons but does not target them specifically).

6. *Id.* "Of the remaining, [the authors] had little or no information about the legal provisions with respect to right to vote for persons with mental illness in 24 Member States and legislative provisions were unclear in two Member States." *Id.* at 396.

7. Under U.S. law, states retain the power to regulate access to the franchise. Lassiter v. Northampton Cty. Bd. of Elections, 360 U.S. 45, 50–51 (1959) (upholding electoral literacy tests under the states' "broad powers to determine the conditions under which the right of suffrage may be exercised"). For more on *Lassiter* and its importance in the evolution of access to the franchise, see Part II.A below. Despite the states' general powers in this realm, the U.S. Constitution forbids

intellectual disability or mental illness.[8] Twenty-five states and the District of Columbia disenfranchise people found by a court to lack capacity to vote,[9] ten states and Puerto Rico disenfranchise any people "under guardianship,"[10] three states disenfranchise people considered *non compos mentis*,[11] and Montana disenfranchises people "adjudicated to be of unsound mind . . . unless the person has been restored to capacity as provided by law."[12]

Despite their ubiquity, suffrage restrictions based on intellectual disability and mental illness are controversial. This Note briefly sketches the current state of the controversy and advances three defined claims. Part I introduces the structure and terminology of the Note. Part II reviews criticisms of existing suffrage restrictions from the perspectives of U.S. law, international-human-rights law, and democratic theory. Part III criticizes the proposed shift to capacity-based restrictions, arguing that pragmatic political considerations have blurred the distinction between voting capacity and mental impairment status.

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disenfranchisement on the basis of "race, color, or previous condition of servitude," U.S. CONST. amend. XV, § 1, on the basis of sex, *id.* amend. XIX, or on the basis of age for citizens who are "eighteen years of age or older," *id.* amend. XXVI, § 1.

8. *VOTE. It's Your Right: A Guide to the Voting Rights of People with Mental Disabilities*, BAZELON CTR. FOR MENTAL HEALTH LAW ET AL., 13 (2016), http://www.bazelon.org/portals/0/voting/voting%20rights%20guide%202016.pdf [https://perma.cc/3MPQ-SGPG] [hereinafter BAZELON CTR.]. The eleven states with no restrictions are Colorado, Idaho, Illinois, Indiana, Kansas, Maine, Michigan, New Hampshire, North Carolina, Pennsylvania, and Vermont.

9. *Id.* The twenty-five states are Alaska, Arizona, Arkansas, California, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Kentucky, Maryland, Nevada, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Texas, Washington, West Virginia, Wisconsin, and Wyoming.

10. *Id.* at 12. Typically, people are placed under guardianship by court order for reasons incompetence or incapacity, but not specifically related to voting capacity. The ten states are Alabama, Louisiana, Massachusetts, Minnesota, Missouri, South Carolina, South Dakota, Tennessee, Utah, and Virginia. In some states, the restrictions have been interpreted to avoid any unconstitutional restrictions on the ability to vote. *Id.*

11. *Id.* at 13. The three states are Mississippi, Nebraska, and Rhode Island. The Rhode Island Constitution and the Mississippi statute both require a specific adjudication of *non compos mentis* status, but neither one defines the term. R.I. CONST. art. 2, § 1; MISS. CODE ANN. § 23-15-11 (2016). Nebraska law defines *non compos mentis* as "mentally incompetent." NEB. REV. STAT. § 32-312 (2016). While the Hawaii Constitution also prohibits individuals who are *non compos mentis* from voting, HAW. CONST. art. 2, § 2, the relevant statute requires a specific finding that the person is "incapacitated to the extent that the person lacks sufficient understanding or capacity to make or communicate responsible decisions concerning voting," HAW. REV. STAT. § 11-23(a) (2016).

12. MONT. CODE ANN. § 13-1-111(3) (2015). For a detailed chart of all the states' and territories' relevant constitutional and statutory language, see BAZELON CTR., *supra* note 8, at 28–52. For a historical overview of the evolution of U.S. state law on the voting rights of people with mental impairments, see Kay Schriner et al., *Democratic Dilemmas: Notes on the ADA and Voting Rights of People with Cognitive and Emotional Impairments*, 21 BERKELEY J. EMP. & LAB. L. 437 (2000); Benjamin O. Hoerner, Note, *Unfulfilled Promise: Voting Rights for People with Mental Disabilities and the Halving of HAVA's Potential*, 20 TEX. J. ON C.L. & C.R. 89, 107–16 (2015); Ryan Kelley, Note, *Toward an Unconditional Right to Vote for Persons with Mental Disabilities: Reconciling State Law with Constitutional Guarantees*, 30 B.C. THIRD WORLD L.J. 359, 370–80 (2010).

Part IV criticizes the proposition of proxy voting, arguing that it trivializes the broad purposes of voting. Finally, Part V analyzes the concept of mental illness, and advocates disassociating mental illness and voting capacity. I argue that disenfranchising people on the basis of mental illness per se necessarily contributes to silencing socially disfavored views and lifestyles.

In the academic literature on the legitimacy of suffrage restrictions, "cognitive impairment," "intellectual disability," and "intellectual impairment" are often used interchangeably.[13] This leads to considerable confusion, because U.S. law draws fine distinctions among these terms.[14] For the sake of clarity, this Note will refer to all of these conditions as "intellectual disabilities," and to the collective category of intellectual disabilities and mental illnesses as "mental impairments."[15] In particular contexts, however, it will be necessary to distinguish disability from illness, and "status-based restrictions" from "capacity-based" ones.

This Note will not specifically address the implicit barriers to voting faced by people with mental impairments, caused by a systemic deficit of awareness and accommodation.[16] Many other writers have addressed this form of disenfranchisement,[17] some arguing that it violates the fundamental suffrage right protected under both U.S. and international law.[18] This Note will also leave aside

13. *See, e.g.*, Ludvig Beckman, *Political Equality and the Disenfranchisement of People with Intellectual Impairments*, 6 SOC. POL'Y & SOC'Y 13 (2007) (using the terms "intellectual impairments," "cognitive impairments," and "intellectual disabilities" alternately, in apparent reference to the same conditions); Jason H. Karlawish et al., *Addressing the Ethical, Legal, and Social Issues Raised by Voting by Persons with Dementia*, 292 JAMA 1345 (2004) (using the terms "cognitive impairments" and "cognitive disabilities" alternately in apparent reference to the same conditions).

14. *See, e.g.*, Americans with Disabilities Act of 1990, 42 U.S.C. § 12102(1)(A) (2012) (defining "disability" as "a physical or mental impairment that substantially limits one or more major life activities of such individual").

15. *See* Civil Rights Div., *ADA Basics: Statutes and Regulations*, U.S. DEP'T OF JUSTICE, 5 (2006), https://www.ada.gov/pcatoolkit/chap1toolkit.pdf [https://perma.cc/W7MN-X32X] (listing both "mental retardation" and "mental illness" as examples of "mental impairments").

16. Some examples of possible accommodations include designing ballot technology that does not require fine-motor coordination and is not difficult to read, relaxing voting-booth time limits, and providing direct assistance by polling-place staff in filling out registration forms. *See* Pamela S. Karlan, *Framing the Voting Rights Claims of Cognitively Impaired Individuals*, 38 MCGEORGE L. REV. 917, 921–23 (2007) (elaborating on these possibilities and calling the implicit barriers to voting "[a] far greater source of effective exclusion" than the explicit barriers).

17. *See, e.g.*, Martha Nussbaum, *The Capabilities of People with Cognitive Disabilities*, 40 METAPHILOSOPHY 331 (2009); Lisa Schur et al., *Enabling Democracy: Disability and Voter Turnout*, 55 POL. RES. Q. 167 (2002).

18. For claims regarding U.S. law, see, for example, Hoerner, *supra* note 12; Kelley, *supra* note 12. For claims regarding international law, see, for example, János Fiala-Butora et al., *The Democratic Life of the Union: Toward Equal Voting Participation for Europeans with Disabilities*, 55 HARV. J. INT'L L. 71 (2014); Marcus Redley et al., *The Voting Rights of Adults with Intellectual Disabilities: Reflections on the Arguments, and Situation in Kenya and England and Wales*, 56 J. INTELL. DISABILITY RES. 1026 (2012).

the special issues raised by Alzheimer's disease and other forms of mental impairment associated with aging—e.g. voting in long-term care facilities and the possibility of disenfranchisement on the basis of advanced age—although that topic is undoubtedly important and others have addressed it as well.[19] All the legal and philosophical deliberations below apply with equal relevance to elderly people but do not treat them as a distinct category. Rather, the analysis that follows will focus squarely on the state of, and the theoretical legitimacy of, existing laws that explicitly restrict suffrage on the basis of mental impairment.

I. CRITICISMS OF MENTAL-IMPAIRMENT-BASED SUFFRAGE RESTRICTIONS

A. United States Law

United States courts have considered the legality, under federal constitutional and statutory law, of state disenfranchisement of people with mental impairments. This section will first sketch the historical and doctrinal background of this debate, and will then summarize two important twenty-first century judicial decisions. Finally, the section will review legal scholars' predictions as to how the U.S. Supreme Court would assess state provisions that disenfranchise people with mental impairments.

Intellectual disability has never been considered a suspect classification under the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution.[20] The Supreme Court announced this principle in *City of Cleburne v. Cleburne Living Center*, in a case challenging the constitutionality of the City of Cleburne's zoning policy. The City required Cleburne Living Center to obtain a special-use permit to operate a group home for people with intellectual disabilities in a residential neighborhood. Although the Court unanimously found an Equal Protection violation based on the particular facts under review,[21] a majority of the justices followed a rational-basis standard.[22] In Equal Protection Clause jurisprudence, legislative enactments and executive actions that classify among persons are subject to different levels of constitutional scrutiny depending on the nature of the classification. Classifications not deemed "suspect" are reviewed under the rational-basis standard—the lowest applicable standard—and are upheld as long as some set of facts exists which would provide a rational

19. *See, e.g.*, Paul S. Appelbaum et al., *The Capacity to Vote of Persons with Alzheimer's Disease*, 162 AM. J. PSYCHIATRY 2094 (2005); Symposium, *Facilitating Voting as People Age: Implications of Cognitive Impairment*, 38 MCGEORGE L. REV. 843 (2007); Hoerner, *supra* note 12, at 111.

20. City of Cleburne v. Cleburne Living Ctr., 473 U.S. 432, 442–47 (1985). The decision uses the term "mental retardation" to refer to intellectual disability. For the Equal Protection Clause, see U.S. CONST. amend. XIV, § 1 ("No State shall . . . deny to any person within its jurisdiction the equal protection of its laws.").

21. *Cleburne*, 473 U.S. at 447–56.

22. *Id.* at 448.

basis for the government's use of such a classification.[23]

The Court relied on four factors to determine that intellectual disability is not a suspect classification: (a) intellectual disability is a real, immutable difference, causing "a reduced ability to cope with and function in the everyday world," and states therefore have a legitimate interest in legal differentiation;[24] (b) evidence of legislative responses to the difficulties of people with intellectual disabilities disproves the contention that such people suffer from prejudice and need the assistance of the judiciary;[25] (c) evidence of legislative responses also suggests that this class has political power and does not require judicial interference to protect its interests;[26] and (d) it is difficult to distinguish this "large and amorphous class" of people from other disadvantaged groups—"the aging, the disabled, the mentally ill, and the infirm"—and the court did not want to undertake that complicated inquiry.[27] Therefore, legislation may separately classify people with intellectual disabilities as long as the particular classification is "rationally related to a legitimate governmental purpose."[28]

Some condemned that the Court's opinion labored to articulate a standard of review for a law that failed even rational-basis review, the most deferential of standards.[29] Furthermore, this particular brand of rational-basis review sounded far less deferential than that employed in other cases and more like "de facto heightened scrutiny."[30] Bornstein argues the Court wanted the law to fall, but chose its reasoning to account for: (a) widespread opposition of suburban communities to hosting group homes; (b) the Reagan Administration's scaling back of governmental accommodation to people with disabilities; and (c) Justice White's uniquely strong preference for rational-basis review.[31]

Three of the Court's four factors were widely criticized by Justice Marshall in his concurring opinion and by subsequent critics, for several reasons. First, in Equal Protection jurisprudence, the supposed immutability of intellectual

23. For a canonical statement of the rational-basis standard, see *United States v. Carolene Products Co.*, 304 U.S. 144, 153 (1938) ("Where the existence of a rational basis for legislation whose constitutionality is attacked depends upon facts beyond the sphere of judicial notice, such facts may properly be made the subject of judicial inquiry, and the constitutionality of a statute predicated upon the existence of a particular state of facts may be challenged by showing to the court that those facts have ceased to exist." (internal citations omitted)).

24. *Cleburne*, 473 U.S. at 442–43.

25. *Id.* at 443–45.

26. *Id.* at 445.

27. *Id.* at 445–46.

28. *Id.* at 446.

29. *See* Laura C. Bornstein, *Contextualizing* Cleburne, 41 GOLDEN GATE U. L. REV. 91, 99 & n.66 (2010) (citing several articles that made this observation).

30. John D. Wilson, Comment, Cleburne*: An Evolutionary Step in Equal Protection Analysis*, 46 MD. L. REV. 163, 188–89 (1986); *see also* Bornstein, *supra* note 29, at 99 & n.67 (citing several other articles that made this observation).

31. Bornstein, *supra* note 29, at 100–15.

disability would actually favor heightened scrutiny because people "should not be held responsible for traits over which they have no control," such as race or sex.[32] Moreover, prejudice has historically led legislators to misunderstand the relevance of immutable differences to the enjoyment of equal protection, as in the once-prevalent presumption that children with intellectual disabilities could not benefit from education.[33] Second, in considering legislative responses, the Court ignored a long history of exclusionary laws targeted at people with intellectual disabilities, such as eugenic-sterilization requirements, denial of education, and disenfranchisement.[34] Moreover, the Court's precedents on race and gender classifications have continued to apply higher levels of scrutiny despite the enactment of protective legislation for both categories.[35] Finally, the enactment of protective legislation does not suffice to establish that people with intellectual disabilities possess real political power.[36] For instance, in *Frontiero v. Richardson*, a 1973 gender-classification case, the Court found women lacked political power by noting their inadequate representation among elected officials.[37] The comparable lack of elected representatives with intellectual disabilities might therefore indicate that this group also lacks "political power" for Equal Protection purposes.[38]

Still, despite the lack of suspect-classification status for people with intellectual disabilities, a route to strict scrutiny remains open for mental-impairment-based suffrage restrictions because of the special nature of the right to vote. Even though this right is not explicitly mentioned in the U.S. Constitution, the Supreme Court recognizes it as "a fundamental matter in a free and democratic society . . . preservative of other basic civil and political rights[.]"[39] Thus, any state law abridging the right to vote on the basis of any

32. Wilson, *supra* note 30, at 176; *see also* Kay Schriner et al., *The Last Suffrage Movement: Voting Rights for Persons with Cognitive and Emotional Disabilities*, 27 PUBLIUS: J. FEDERALISM 75, 81 (1997).

33. Schriner et al., *supra* note 32, at 81; *see also Cleburne*, 473 U.S. at 462–63 (Marshall, J., concurring and dissenting) ("Retarded children were categorically excluded from public schools, based on the false stereotype that all were ineducable and on the purported need to protect nonretarded children from them.").

34. *Cleburne*, 473 U.S. at 461–65 (Marshall, J., concurring and dissenting); Bornstein, *supra* note 29, at 98; Schriner et al., *supra* note 32, at 82–83; Wilson, *supra* note 30, at 176–78.

35. Wilson, *supra* note 30, at 180–82.

36. Schriner et al., *supra* note 32, at 83 (pointing out that an important driving force behind such protective legislation is the sympathetic support of mental health professionals and others, which is not the same as autonomous political decision making on the part of the people with intellectual disabilities themselves).

37. Frontiero v. Richardson, 411 U.S. 677, 686 (1973).

38. *Id.*; *see also* Wilson, *supra* note 30, at 182–83.

39. Reynolds v. Sims, 377 U.S. 533, 561–62 (1964); *see also* Kramer v. Union Free Sch. Dist. No. 15, 395 U.S. 621, 626 (1969); Harper v. Va. State Bd. of Elections, 383 U.S. 663, 667 (1966); Yick Wo v. Hopkins, 118 U.S. 356, 370 (1886) ("Though not regarded strictly as a natural right, but as a privilege merely conceded by society, according to its will, under certain conditions,

classification—"suspect" or not—is subject to strict scrutiny under the Equal Protection and Due Process Clauses of the Fourteenth Amendment, and may only be upheld if necessary to achieve a compelling state interest.[40]

The extent of constitutional protection for this fundamental voting right was probed in the literacy-test controversies of the South. Following the ratification of the Fifteenth Amendment in 1870, which prohibited federal and state governments from disenfranchising on the basis of "race, color, or previous condition of servitude[,]"[41] every southern state enacted putatively colorblind measures to prevent black people from voting, including English literacy requirements for voters.[42] In *Lassiter v. Northampton County Board of Elections*, the Supreme Court upheld the constitutionality of North Carolina's English-literacy test, finding that "[t]he ability to read and write . . . has some relation to standards designed to promote intelligent use of the ballot. Literacy and illiteracy are neutral on race, creed, color, and sex, as reports around the world show."[43]

Congress responded to *Lassiter* in Section 4(e) of the Voting Rights Act of 1965, which prohibited states from using English-literacy tests to disqualify voters who had completed sixth grade in U.S.-accredited schools "in which the predominant classroom language was other than English," such as the schools of Puerto Rico.[44] In *Katzenbach v. Morgan*, the Supreme Court upheld Congress' decision to restrict state prerogatives in this way, finding that section 4(e) was "a proper exercise of the powers granted to Congress by § 5 of the Fourteenth Amendment[.]"[45]

This history of the U.S. experience with literacy tests provides helpful background for recent constitutional challenges to mental-impairment-based suffrage restrictions. When, in the twenty-first century, U.S. courts came face-to-

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nevertheless [voting] is regarded as a fundamental political right, because preservative of all rights.").

40. Dunn v. Blumstein, 405 U.S. 330 (1972) (finding durational residency requirements invalid under strict scrutiny, since such requirements were not necessary to promote the state's interest in preventing fraudulent voting and ensuring a knowledgeable electorate).

41. U.S. CONST. amend. XV, § 1.

42. ERIC FONER, GIVE ME LIBERTY: AN AMERICAN HISTORY 652 (4th ed. 2014).

43. Lassiter v. Northampton Cty. Bd. of Elections, 360 U.S. 45, 51 (1959).

44. Voting Rights Act of 1965, Pub. L. No. 89-110, § 4(e), 79 Stat. 439 (codified as amended at 52 U.S.C. § 10303(e) (2008)).

45. Katzenbach v. Morgan, 384 U.S. 641, 646 (1966). Section 5 of the Fourteenth Amendment grants Congress the "power to enforce, by appropriate legislation, the provisions of this article," including the Equal Protection Clause. U.S. CONST. amend. XIV § 5. The Court explained that under the Supremacy Clause, section 4(e) preempted New York's English-literacy law, and therefore made it unenforceable. Thus, even though the New York literacy requirement at issue was not itself found unconstitutional, "it is enough that we perceive a basis upon which Congress might predicate a judgment that [the law's application to the Puerto Rican community] constituted an invidious discrimination in violation of the Equal Protection Clause." *Katzenbach*, 384 U.S. at 656. The Voting Rights Act's literacy-test provision was deemed an appropriate legislative action to enforce the Equal Protection Clause of the Fourteenth Amendment. *Id.* at 658.

face with another breed of state laws premised upon preventing people from voting for reasons of intelligence, they were naturally skeptical. Whether or not states have a compelling interest in an intelligent electorate,[46] laws designed to protect that interest are likely to be driven by prejudice and are susceptible to discriminatory application against disfavored groups.[47] Two federal court decisions address this concern.

First, in *Doe v. Rowe*,[48] Maine's district court became the first to directly address mental-impairment-based state suffrage restrictions. Three women and an advocacy organization challenged a provision in Maine's constitution that withheld suffrage from the individual plaintiffs and all others "under guardianship for reasons of mental illness."[49] Both the plaintiffs and the State Attorney General agreed on strict scrutiny as the appropriate test, and both agreed that Maine had a compelling interest in ensuring that voters have capacity "to understand the nature and effect of the voting act" (seemingly echoing the statutory language of the State of Washington).[50] The court struck down this provision on its face as violative of the Equal Protection Clause. Since the disenfranchisement reached only people with mental illness and not those with other forms of mental incapacity, such as intellectual disability, the provision was not tailored to meet the State's asserted interest.[51]

The court also struck down the provision on two other grounds. First, it found the provision facially unconstitutional under the Fourteenth Amendment's Due Process Clause because individuals subject to guardianship proceedings for mental illness were not provided "uniformly adequate notice regarding the potential disenfranchising effect" of a guardianship placement.[52] Second, the

46. *See infra* page 275 (explaining the theory that states' interest in an intelligent electorate justifies the exclusion of certain unintelligent voters).

47. *See* Schriner et al., *supra* note 32, at 87–92. The subject of rationales for disenfranchisement will be taken up in greater detail below. *See infra* Part I.C.

48. Doe v. Rowe, 156 F. Supp. 2d 35 (D. Me. 2001).

49. ME. CONST. art. II, § 1 (1965).

50. *Rowe*, 156 F. Supp. 2d, at 51. For the Washington statute, see WASH. REV. CODE § 11.88.010(5) ("Imposition of a guardianship for an incapacitated person shall not result in the loss of the right to vote unless the court determines that the person is incompetent for purposes of rationally exercising the franchise in that the individual lacks the capacity to understand the nature and effect of voting such that she or he cannot make an individual choice.").

51. *Rowe*, 156 F. Supp. 2d at 56. In defense of the provision, Maine's Attorney General advanced a constitutional construction, broadly reading "mental illness" to include other forms of incapacity, but the court rejected that construction as archaic and regressive, resulting in the disenfranchisement of a great number of people who are sufficiently competent to vote. *Id.* at 53–56; *see also In re* The Guardianship of Erickson, 2012 Minn. Dist. LEXIS 193 (Minn. Dist. Ct. Oct. 4, 2012) (relying on *Rowe*'s constitutional holdings, the state court invalidated a provision of the Minnesota Constitution that states: "the following persons shall not be entitled or permitted to vote at any election in this state . . . a person under guardianship, or a person who is insane or not mentally competent," MINN. CONST. art. VII, § 1).

52. *Rowe*, 156 F. Supp. 2d, at 50–51. Here, too, the State attempted to save the provision by advancing a new construction under which an individual subject to guardianship proceedings

provision violated Title II of the Americans with Disabilities Act (ADA) and Section 504 of the Rehabilitation Act[53] because plaintiffs were qualified individuals with disabilities who were discriminated against by a public entity by reason of their disabilities.[54]

Six years later, the United States Court of Appeals for the Eighth Circuit considered a challenge to Article VIII, Section 2 of the Missouri Constitution,[55] which provides that "no person who has a guardian of his or her estate or person by reason of mental incapacity . . . shall be entitled to vote." This claim, too, was brought against the State by three individuals under guardianship and an advocacy group. The court rejected a facial Equal Protection challenge, finding that Missouri probate courts' power to preserve a ward's right to vote avoids imposition of a categorical ban on all people under guardianship.[56] Instead, the court found the Missouri provision did no more than impose a case-specific capacity standard. Additionally, the court rejected the plaintiff's ADA/Rehabilitation Act claim, also for lack of proof of categorical restriction.[57]

Though the jurisdiction of these two courts reaches just a small percentage of the U.S. populace, *Rowe* and *Carnahan* provide tools for other courts to overturn categorical suffrage bans, while upholding those bans subject to a particularized process of finding incapacity to vote.[58]

Some scholars have attempted to forecast how the Supreme Court might rule on this issue by reference to a conceptual analysis of its prior election-law jurisprudence.[59] Adam Winkler has discerned in this jurisprudence an adoption of what he calls the "instrumental power" view, according to which voting is a "societal tool for exerting political power . . . protected only to the extent that it

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retains a right to suffrage unless this right is specifically challenged by a petitioner and considered by a probate judge in the course of guardianship proceedings. The court agreed that such a construction would satisfy procedural due process, but found that it had not been properly adopted as law. Rather, the attorney general's construction constituted an invalid "amendment to substantive state law" and failed to save the constitutional provision. *Id.* at 49–50.

53. Americans with Disabilities Act, Pub. L. No. 101-336, tit. II, 104 Stat. 337 (1990) (codified at 42 U.S.C. § 12132 (2012)); Rehabilitation Act of 1973, Pub. L. No. 93-112, § 504, 87 Stat. 355, 394 (2012) (codified at 29 U.S.C. § 794 (2012)).

54. *Rowe*, 156 F. Supp. 2d, at 57–59. The state contested this finding by referring to its narrowing construction explained *supra* note 52. The court declined to consider the new construction in this context, clarifying that "there is no such thing as a facial challenge to the State's compliance with a federal statute." *Id.* at 59. Rather, the statutory claim concerns only previous and ongoing conduct. For more on the lasting impact of the *Rowe* decision, see the discussion of capacity-based suffrage restriction *infra* Part II.A.

55. Mo. Prot. & Advocacy Servs. v. Carnahan, 499 F.3d 803 (8th Cir. 2007).

56. *Id.* at 808–09.

57. *Id.* at 812.

58. *See* Hoerner, *supra* note 12, at 113–14 (identifying the categorical/particularized finding test as the only useful conclusion of *Rowe* and *Carnahan*).

59. Jennifer A. Bindel, Note, *Equal Protection Jurisprudence and the Voting Rights of Persons with Diminished Mental Capacities*, 65 N.Y.U. ANN. SURV. AM. L. 87, 111–14 (2009).

can be used as a means of pursuing informed political choices."[60] This view seems to justify suffrage restrictions targeting those less capable of independent, informed choice, seeing such restrictions as a less-than-"severe" burden: "Disenfranchisement will be allowed for those in the electorate insufficiently intelligent . . . ."[61] Correspondingly, the Supreme Court has shied away from conceiving of voting as an "expressive" act,[62] in which it "is considered a means of communicating various political ends and desires."[63] However, if a future Supreme Court is willing to reconceive of the franchise as an individual right to participate expressively in a public ritual of civil society, that Court would be more likely to treat mental-impairment-based restrictions as a "severe" burden worthy of strict scrutiny.[64]

B. International Human Rights Law

As noted above, democracies across the world disenfranchise people on the basis of mental impairments. This phenomenon has received attention in the corpus of international human rights law. Generally speaking, just as the electoral regulations of individual U.S. states must comply with the U.S. Constitution and federal statutes, the electoral regulations of independent nations must comply with applicable international law. The following section will (a) address the United Nations' conventional response to the problem of voters with mental impairments; (b) review the relevant case law of judicial and quasi-judicial international tribunals; and (c) summarize a recent proposal for a new legal test for assessing the validity, under international human rights law, of various nations' disenfranchising provisions.

Article 29(a) of the United Nations Convention on the Rights of Persons with Disabilities (CRPD) requires states parties to "[e]nsure that persons with disabilities can effectively and fully participate in political and public life on an equal basis with others . . . including the right and opportunity for persons with disabilities to vote and be elected."[65] The Convention has 172 parties, and 15 additional states (including the United States) have signed the Convention but not yet ratified it.[66] Additionally, the Optional Protocol, allowing individual recourse

60. Adam Winkler, Note, *Expressive Voting*, 68 N.Y.U. L. REV. 330, 330–31 (1993).

61. *Id.* at 343.

62. *Id.* at 338 (noting "the failure of the Court's guiding conception of the right to vote to capture certain expressive values inherent in voting.").

63. *Id.* at 365.

64. *See* Bindel, *supra* note 59, at 114–21 (advocating strict-scrutiny review of mental-impairment-based suffrage restrictions on the basis of an expressive view of voting, in reliance upon the ideas of Winkler and other theorists).

65. Convention on the Rights of Persons with Disabilities art. 29(a), Mar. 30, 2007, 2515 U.N.T.S. 3.

66. *Convention on the Rights of Persons with Disabilities*, UNITED NATIONS TREATY COLLECTION 1, https://treaties.un.org/doc/Publication/MTDSG/Volume%20I/Chapter%20IV/IV-

to the Committee on the Rights of Persons with Disabilities (CRPD Committee) for allegations of Convention violations,[67] has ninety-two parties.[68] France,[69] Malta,[70] Romania,[71] and Singapore[72] entered Reservations and Declarations regarding the applicability of Article 29 to existing electoral regulations and to potential safeguards against manipulation of voters with mental impairments. However, the vast majority of states parties remain fully bound to the requirements of Article 29, and its plain meaning prohibits any law disenfranchising people on the basis of any disability.[73]

Article 29(a) has become the subject of international litigation in recent years. In *Kiss v. Hungary*, the European Court of Human Rights (ECtHR) considered the claim of a Hungarian national against his government after his diagnosis of manic depression and guardianship placement resulted in automatic loss of his right to vote.[74] Relying on both the European Convention on Human Rights' general guarantee of the right to vote and Article 29 of the CRPD,[75] the

15.en.pdf [https://perma.cc/WSR2-N2PR].

67. Optional Protocol to the Convention on the Rights of Persons with Disabilities art. 1.1, Mar. 30, 2007, U.N. Doc. A/61/611 ("A State Party to the present Protocol ("State Party") recognizes the competence of the Committee . . . to receive and consider communications from or on behalf of individuals or groups of individuals subject to its jurisdiction who claim to be victims of a violation by that State Party of the provisions of the convention."); *id.* at art. 6 ("If the Committee receives reliable information indicating grave or systematic violations . . . the Committee shall invite that State Party to cooperate in the examination of the information and to this end submit observations. . . . The State Party concerned shall, within six months of receiving the findings, comments, and recommendations transmitted by the Committee, submit its observations to the Committee.").

68. *Optional Protocol to the Convention on the Rights of Persons with Disabilities*, UNITED NATIONS TREATY COLLECTION 1, https://treaties.un.org/doc/Publication/MTDSG/Volume%20I/Chapter%20IV/IV-15-a.en.pdf [https://perma.cc/3Q7Y-ARUD] (showing that the United States is not a party to the Optional Protocol).

69. *Convention on the Rights of Persons with Disabilities*, *supra* note 66, at 7.

70. *Id.* at 8.

71. *Id.* at 14.

72. *Id.* at 9.

73. *See, e.g.*, Redley et al., *supra* note 18, at 1027 ("States with laws declaring people legally incapacitated because of a disability . . . violate Article 29"); *see also* Eur. Comm'n for Democracy Through Law (Venice Comm'n), *Revised Interpretive Declaration to the Code of Good Practice in Electoral Matters on the Participation of People with Disabilities in Elections*, COUNSEL OF EUR. CDL-AD (2011)045 ("People with disabilities may not be discriminated against in [suffrage matters], in conformity with Article 29 of the Convention of the United Nations on the Rights of Persons with Disabilities . . . ."). Some authors have undertaken to assess individual states' compliance with established CRPD law in this matter. *See, e.g.*, Redley et al., *supra* note 18 (examining the situation in Kenya, England, and Wales); Jonathon Savery, Comment, *Voting Rights and Intellectual Disability in Australia: An Illegal and Unjustified Denial of Rights*, 37 SYDNEY L. REV. 287 (2015) (examining the situation in Australia).

74. Alajos Kiss v. Hungary, App. No. 38832/06, Eur. Ct. H.R. ¶ 22 (2010), http://hudoc.echr.coe.int/eng#{"itemid":["001-98800"]} [https://perma.cc/A2FP-JBFV].

75. The ECtHR routinely refers to the CRPD in informing its own standards under the European Convention. *See* Fiala-Butora et al., *supra* note 18, at 83 & n.69.

Court rejected Hungary's practice of automatic disenfranchisement but explicitly allowed for disenfranchisement based upon individualized consideration of voter capacity.[76]

In line with this decision and with a pre-CRPD Human Rights Committee General Comment,[77] the European Commission for Democracy through Law (Venice Commission), a constitutional law advisory body of the Council of Europe, released an Interpretive Declaration allowing disenfranchisement on the basis of "individual decision of a court of law [finding] proven mental disability."[78] After a firestorm of criticism and a worldwide NGO campaign led by the UK-based Mental Disability Advocacy Centre,[79] the Venice Commission reversed course, announcing that "universal suffrage is a fundamental principle of the European Electoral Heritage. People with disabilities may not be discriminated against in this regard, in conformity with Article 29 of the Convention of the United Nations on the Rights of Persons with Disabilities[.]"[80] Subsequently, the Human Rights Commissioner for the Council of Europe, the U.N. Human Rights Council, and the U.N. Human Rights Committee have all affirmed this absolutist interpretation of Article 29.[81]

In 2013, the CRPD Committee considered an Optional Protocol complaint against Hungary in which, again, six individuals were automatically barred from voting as a consequence of being placed under guardianship.[82] In its defense, Hungary noted that it had amended its electoral legislation to bring it into compliance with the *Kiss* ruling,[83] but the Committee nevertheless found Hungary in violation of Article 29 and declared an obligation for Hungary to remedy the individuals' injury and take preventative steps against future

76. *Alajos Kiss*, App. No. 38832/06, Eur. Ct. H.R. ¶ 42. In *Gajcsi v. Hungary*, the ECtHR considered a set of facts "virtually identical to those of the *Alajos Kiss* judgment" and reached the same result. Gajcsi v. Hungary, App. No. 62924/10, Eur. Ct. H.R. ¶ 11 (2014), http://hudoc.echr.coe.int/eng#{"itemid":["001-146411"]} [https://perma.cc/26J3-7N6H].

77. Human Rights Comm., CCPR General Comment No. 25, ¶ 4, U.N. Doc. CCPR/C/21/Rev.1/Add.7 (July 12, 1996) ("[E]stablished mental incapacity may be a ground for denying a person the right to vote or to hold office.").

78. Venice Comm'n, *Interpretive Declaration the Code of Good Practice in Electoral Matters on the Participation of People with Disabilities in Elections*, COUNSEL OF EUR. CDL-AD (2010)036.

79. *See* Oliver Lewis, *Two Years and Seven Minutes Ago*, MENTAL DISABILITY ADVOC. CTR.: OLIVER TALKS (June 18, 2013), http://www.mdac.info/en/olivertalks/2013/06/18/two-years-and-seven-minutes-ago [https://perma.cc/XY2W-PYWB]; *see also* Redley et al., *supra* note 18, at 1029–30.

80. Eur. Comm'n for Democracy through Law (Venice Comm'n), *supra* note 73, § II, ¶ 2.

81. For a more detailed account of these developments, see Redley et al., *supra* note 18, at 1030.

82. Comm. on the Rights of Persons with Disabilities, Views of the Committee on the Rights of Persons with Disabilities Under Article 5 of the Optional Protocol to the Convention on the Rights of Persons with Disabilities (Tenth Session), ¶ 2, U.N. Doc. CRPD/C/10/D/4/2011 (Oct. 16, 2013).

83. *Id.* ¶¶ 4.1–4.7.

violations.[84] In response to Hungary's defense, the Committee noted: (a) legislative change notwithstanding, the six individuals had, in actuality, been automatically barred from voting; and (b) even the new legislation violated Article 29, as it provided for disenfranchisement on the basis of individualized determination of incapacity, while Article 29 bars all disability-based disenfranchisement.[85] The CRPD Committee thus rejected the ECtHR's interpretation of Article 29 in *Kiss*. The Committee has reinforced its absolutist interpretation of Article 29 in several "Concluding Observations" on reports of its states parties, urging elimination of all mental-impairment-based suffrage restrictions.[86]

In 2014, three Harvard Law School researchers published an international human rights law analysis of disabilities-related suffrage restrictions.[87] After recounting the judicial and quasi-judicial developments described above, the authors proposed an test to determine when states may, consistent with international law, restrict the exercise of human rights: "[E]ach abridgement must be prescribed by law and objectively justified on one or more specified grounds. Thus, the restriction must pursue an acceptable aim and must be necessary to achieve that objective without unduly restricting the right in question."[88] Disenfranchisement of people with disabilities, the authors argue, satisfies neither of these prongs.

First, the aim of protecting the integrity of the electorate from incompetent voters, although approved by *Kiss*,[89] is rendered illegitimate by the overarching purpose of the CRPD, which is to affirm the autonomy and equal legal capacity of persons with disabilities.[90] Second, even accepting *Kiss*'s conclusion that

84. *Id.* ¶ 10.

85. *Id.* ¶ 9.3.

86. For a partial listing and overview of these Concluding Observations, see Savery, *supra* note 73, at 292–94 & n.43.

87. Fiala-Butora et al., *supra* note 18.

88. *Id.* at 90. As precedent for this test, the authors refer to the International Covenant on Economic, Social and Cultural Rights; the Charter of Fundamental Rights of the European Union; the Convention on the Rights of the Child; the International Covenant on Civil and Political Rights; and the European Convention on Human Rights. *See id.* & nn. 109–10. This test's "acceptable aim" sounds similar to the U.S. strict-scrutiny test's "compelling interest," and "necessary to achieve that objective without unduly restricting the right in question" sounds like strict scrutiny's "narrowly tailored to achieve" the interest. *See supra* notes 39–40 and accompanying text (describing the strict-scrutiny test).

89. Alajos Kiss v. Hungary, App. No. 38832/06, Eur. Ct. H.R. ¶ 38 (2010), http://hudoc.echr.coe.int/eng#{"itemid":["001-98800"]} [https://perma.cc/A2FP-JBFV].

90. Fiala-Butora et al., *supra* note 18, at 91 ("[This] is exactly what the CRPD aims to overcome, and therefore it is decidedly unclear whether the ECtHR's justification would prevail under an analysis grounded in the CRPD"). For additional substantiation of this claim regarding the purpose of the CRPD, see, for example, Convention on the Rights of Persons with Disabilities, *supra* note 65, at pmbl.(e) ("Recognizing the importance for persons with disabilities of their individual autonomy and independence, including the freedom to make their own choices . . . ."); *id.* at art. 12.2 ("States Parties shall recognize that persons with disabilities enjoy legal capacity on

protecting the integrity of the electorate is a legitimate aim, measures pursuing this aim must not unduly restrict individual suffrage rights.[91] For this second prong, the authors employ ECtHR's "proportionality" analysis as follows:[92] The number of individuals who are incapable of voting, or of doing so in a rational manner, is miniscule compared to the number of capable voters who cast votes in error or based on irrational considerations. "Thus, any gains to the legitimacy of a state's electoral system associated with disability-based restrictions . . . are marginal at best."[93]

States may respond that, though they cannot identify all irrational voters, they can identify those incapable of voting rationally.[94] Still, any system for assessing capacity, even if not based on a categorical exclusion, will inevitably impact some capable voters because no system is perfectly accurate.[95] Some overexclusion is permissible under international law, as in age and residency requirements for voting.[96] However, while age and residency are not "suspect classifications" under international law, disability is, and therefore is precluded as a basis for discrimination under both the CRPD and the jurisprudence of the ECtHR.[97] In addition, allowing individualized capacity assessments would be an ill-advised stance for international human rights law, because "international bodies are simply not in a good position to police assessment procedures."[98] Clear rules are preferable, and because a categorical disenfranchisement of all mentally impaired people is clearly prohibited under international law, eliminating all disability-related disenfranchisement is the only reasonable

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an equal basis with others in all aspects of life.").

91. *See supra* note 88 and accompanying text (describing the "unduly restricts" test).

92. Fiala-Butora et al., *supra* note 18, at 92 n.118. The authors do not elaborate on the principles of this ECtHR doctrine, but refer in a footnote to Aharon Barak, *Proportionality and Principled Balancing*, 4 L. & ETHICS OF HUM. RTS. 3, 6 (2010).

93. Fiala-Butora et al., *supra* note 18, at 92–93 (using Hungary as an example, the authors present statistics placing the population of incapable voters at less than 0.15 percent of the electorate, and the population of capable voters who, in practice, vote in error or irrationally, at more than 3 percent).

94. *Id.* at 93–94.

95. *Id.* at 94. For this point, the authors cite Sally Balch Hurme & Paul S. Appelbaum, *Defining and Assessing Capacity to Vote: The Effect of Mental Impairment on the Rights of Voters*, 38 MCGEORGE L. REV. 931, 962 (2007) ("There is no scientifically determinable point on that spectrum at which we can say the person manifests sufficient capacity for the task.").

96. Fiala-Butora et al., *supra* note 18, at 94. These requirements, too, attempt to address voting capacity but do so by excluding a broad sector of the population.

97. *Id.* For their claim that age and residency are not "suspect classifications," the authors note the absence of these categories from the list of prohibited bases of discrimination in ECHR art. 14. The term "suspect classification" appears to be borrowed from U.S. jurisprudence, although the authors do not make this association explicit. As noted above, mental disability is not currently considered a suspect classification in U.S. constitutional law. *See supra* note 20 and accompanying text. For anti-disability discrimination's preclusion under the CRPD and ECtHR jurisprudence, see *supra* Part I.B.

98. Fiala-Butora et al., *supra* note 18, at 95–96.

option.[99]

Finally, the Harvard researchers' proportionality analysis requires states to consider "a less restrictive alternative."[100] Education and facilitation can effectively lower the rate of participation of voters incapable of voting rationally by helping more voters make rational decisions. Therefore, European states must undertake inclusive measures rather than resort to exclusion.[101]

C. Democratic Theory: Normative Rationales and Criticisms

In addition to the different streams of legal analysis addressed above, the political-science literature on the subject of mental-impairment-based suffrage restrictions features a lively normative debate. This literature advances, and disputes, several rationales for disenfranchising people on the basis of mental impairments. The rationales can be helpfully grouped into two categories: (1) enfranchising people with mental impairments is inherently problematic; and (2) voters with mental impairments can be easily manipulated to vote in a manner that endangers the electoral process. The following section will review each of these rationales and the various criticisms lodged against them by political scientists and philosophers.

1. Argument That Enfranchising Mentally Impaired Individuals Is Inherently Problematic

One popular position, elaborated in the following paragraphs, argues that membership in democratic society, or the demos, depends upon the capacity to make rational judgments. According to this view, the idea of democracy rejects the legitimacy of autocratic or oligarchic political power, in which all members of society are subject to the judgment of only a small number of them. Voting in a democratic system, by contrast, allows all members of the demos to collectively exercise power through their own independent judgment. To the extent that certain classes of individuals are incapable of independent judgment, then, any power they exercise is democratically illegitimate. Therefore, such people, though they are subject to the will of the demos, cannot themselves be included within it.

John Stuart Mill expressed this idea in 1861: "No one but those in whom an *à priori* theory has silenced common sense, will maintain, that power over others, over the whole community, should be imparted to people who have not acquired the commonest and most essential requisites . . . for pursuing intelligently their

99. *Id.* at 96.

100. *Id.* at 96 & n.145; *see also* Alajos Kiss v. Hungary, App. No. 38832/06, Eur. Ct. H.R. ¶ 33 (2010), http://hudoc.echr.coe.int/eng#{"itemid":["001-98800"]} [https://perma.cc/A2FP-JBFV].

101. Fiala-Butora et al., *supra* note 18, at 96.

own interests."[102] And Robert A. Dahl, a political scientist and theorist of political pluralism, wrote in 1989:

> That we cannot get around the principle of competence in deciding on the inclusiveness of the demos is decisively demonstrated by the exclusion of children . . . .[103] There are also the troublesome cases for which experience, even when joined with compassion, points to no clear solution. . . . *The demos must include all adult members of the association except transients and persons proved to be mentally defective.*[104]

Upon this theoretical basis, states may choose to utilize the electoral law to protect the legitimacy of the democratic process.[105] And states have indeed invoked this rationale in legal contexts. When challenged in court, Maine and Hungary referred to this argument, and neither court rejected it.[106] In another telling judicial pronouncement, a Minnesota state judge framed participation of incompetent voters as an actual injury suffered by the rest of the population,

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102. JOHN STUART MILL, CONSIDERATIONS ON REPRESENTATIVE GOVERNMENT (1861), *reprinted in* 19 THE COLLECTED WORKS OF JOHN STUART MILL 371, 470 (John M. Robson ed., 1976).

103. For more on the question of enfranchising minors, see CLAUDIO LÓPEZ-GUERRA, DEMOCRACY AND DISENFRANCHISEMENT: THE MORALITY OF ELECTORAL EXCLUSIONS 61 (2014); Linda Barclay, *Cognitive Impairment and the Right to Vote: A Strategic Approach*, 30 J. APPLIED PHIL. 146 (2013); Joanne C. Lau, *Two Arguments for Child Enfranchisement*, 60 POL. STUD. 860 (2012); Nicholas John Munn, *Capacity Testing the Youth: A Proposal for Broader Enfranchisement*, 15 J. YOUTH STUD. 1048 (2012). The problem of suffrage for minors is certainly related to the problem of suffrage for people with mental impairments, but, because this Note leaves the issue of minors aside for another day.

104. ROBERT A. DAHL, DEMOCRACY AND ITS CRITICS 126–29 (1989). For a more recent articulation of the illegitimacy of a democratic process that enfranchises people with mental impairments, see Karlan, *supra* note 16, at 918 ("And yet, there's something discomfiting about the idea that voters may be casting their ballots randomly or arbitrarily, without real comprehension of the issues or of the candidates' positions. The idea that voting reflects the citizenry's free and informed choices is central to the legitimacy of our political system.").

105. For more on the role of this rationale in the development of electoral law vis-à-vis people with mental impairments, see, for example, Hurme & Appelbaum, *supra* note 95, at 964.

106. *See* Doe v. Rowe, 156 F. Supp. 2d 35, 51 (D. Me. 2001) ("[T]he parties agree that Maine has a compelling state interest in ensuring that 'those who cast a vote have the mental capacity to make their own decision by being able to understand the nature and effect of the voting act itself.' The only question left for the Court to resolve is whether Maine's restriction is narrowly tailored to meet this compelling interest.") (internal citation omitted); Alajos Kiss v. Hungary, App. No. 38832/06, Eur. Ct. H.R. ¶ 38 (2010), http://hudoc.echr.coe.int/eng#{"itemid":["001-98800"]} [https://perma.cc/A2FP-JBFV] ("[Hungary] submitted that the measure complained of pursued the legitimate aim of ensuring that only citizens capable of assessing the consequences of their decisions and making conscious and judicious decisions should participate in public affairs. The applicant accepted this view and the Court sees no reason to hold otherwise."). The Committee on the Rights of Persons with Disabilities, however, rejected Hungary's defense as per se illegitimate because it is prohibited by international law. *See* Comm. on the Rights of Persons with Disabilities, supra note 82, ¶ 9.6.

declaring that voter-capacity assessment was the court "owes [to] the general electorate."[107]

Others frame this problem differently, and with decidedly lower stakes: Even if the participation of people with mental impairments does not undermine the legitimacy of the democratic process, society has a reasonable utilitarian interest in an intelligent electorate. To avoid "sub-optimal political outcomes," the majority of voters choose to enact constitutions or legislation excluding the minority whose judgment is devoid of rationality and untrained by a sophisticated education.[108] In the terminology of classical republicanism, ideal results follow when the "civic duty" of voting is preconditioned upon the "civic virtue of . . . capacity for critical understanding and rational choice."[109] Moreover, when people lacking civic virtue cast votes, they may negate the effect, vote-by-vote, of votes cast by individuals possessing civic virtue.[110]

Yet another formulation focuses on the "social contract" aspect of democracy. Individuals enter into the social contract by voting, an act that expresses their consent to be governed by people chosen through the electoral system. Because the chosen leaders have power to regulate and tax private property, an individual's consent to the social contract brings direct financial consequences. Thus, the social contract created by voting is also a commercial contract. Just as mental capacity is a fundamental element of any commercial contract—due to "the public policy of protecting an incapacitated person from assuming contractual duties to which she was not capable of assenting"—so must it be for the contract of voting.[111]

Recent scholarship has challenged the "inherent problem" rationales on several grounds. First, some note that there is simply insufficient evidence to show that enfranchising people with mental impairments hurts the quality of elections.[112] In fact, the available evidence cuts against this claim from two directions. As far as mental illness is concerned, multiple studies have shown that the voting behavior of psychiatric inpatients closely mirrors the votes of the

107. *In re* Guardianship of Erickson, 2012 Minn. Dist. LEXIS 193, *30 n.5 (Minn. Dist. Ct. Oct. 4, 2012).

108. Redley et al., *supra* note 18, at 1027; *see also* Schriner et al., *supra* note 32, at 87–92 (analyzing the "intelligent electorate" rationale's potential as a "compelling" state interest); Bindel, *supra* note 59, at 121 (conducting the same analysis).

109. James. T. McHugh, *Idiots and Insane Persons: Electoral Exclusion and Democratic Values Within the Ohio Constitution*, 76 ALB. L. REV. 2189, 2209 (2012).

110. *Id.*

111. *Id.* at 2214–15 (construing E. ALLAN FARNSWORTH, CONTRACTS 3–7 (4th ed. 2004)). For a historical presentation of this rationale, see Kay Schriner, *The Competence Line in American Suffrage Law: A Political Analysis*, 22 DISABILITY STUD. Q. 61, *8 (2002), http://dsq-sds.org/article/view/345/438 [https://perma.cc/U3N2-YARU] ("Just as they could not enter into civil contracts neither could they take part in the political contract.").

112. *See, e.g.*, Paul S. Appelbaum, *"I Vote. I Count": Mental Disability and the Right to Vote*, 51 PSYCHIATRIC SERVS. 849, 850 (2000); LÓPEZ-GUERRA, *supra* note 103, at 64–65.

patients' communities and socioeconomic strata.[113] At the same time, evidence shows that a significant percentage of presumptively rational voters make electoral decisions based on emotional, irrational factors and have little familiarity with the substantive policy issues at stake.[114] Political scientist Claudio López-Guerra has reasoned that defenders of disenfranchisement have to show that their logic "is so decisive—the risk [of people with mental impairments hurting the quality of electoral outcomes] would be too great—that it would be wrong to even give them a try. For indeed, the enfranchisement . . . can be undone if the results prove to be undesirable . . . [but they] cannot be shown to be so undesirable ex ante."[115]

Another version of the "inherent problem" rationale focuses on public perception. "Were the voting public to perceive that incompetent persons routinely cast ballots, the seriousness with which competent voters approach the process of selecting candidates and issues for their support might be diminished."[116] But, again, this fear is not substantiated by published evidence, and is in fact undermined—if not necessarily refuted—by the evidence that, despite the existing disenfranchisement of presumptively incompetent voters, presumptively competent voters often fail to approach the process with sufficient seriousness. Additionally, Linda Barclay has convincingly argued that this perception concern simply reflects society's discriminatory attitudes and should therefore not be entertained. "If we see the value of the vote being trashed only in the case where people with cognitive impairments are voting [despite a lack of evidence to that effect], then I would suggest that we should admit our prejudices and focus our energies on tackling those."[117]

Second, some argue that rational capacity is morally unrelated to the fundamental right to vote. Robert Goodin and others have proposed an "affected interests" model for suffrage, arguing that all individuals whose interests are at stake in a democratic polity's governmental decisions must be considered members of the demos entrusted with choosing the polity's leaders.[118] This

113. *See, e.g.*, George Howard & Robert Anthony, *The Right to Vote and Voting Patterns of Hospitalized Psychiatric Patients*, 49 PSYCHIATRIC Q. 124 (1977); Morris M. Klein & Saul A. Grossman, *Voting Competence and Mental Illness*, 127 AM. J. PSYCHIATRY 1562 (1971); Alfred N. Wellner & Lawrence S. Gaines, *Patients' Right to Vote*, 21 HOSP. & COMMUNITY PSYCHIATRY 163 (1970).

114. *See, e.g.*, Redley et al., *supra* note 18, at 1027–28; Schriner et al., *supra* note 32, at 89 & n.65; Bindel, *supra* note 59, at 115–16 & nn.169–73; *see also supra* notes 94–101 and accompanying text (applying this argument in a "proportionality" analysis to demonstrate the illegality of mental impairment-based suffrage restrictions under international human rights law).

115. LÓPEZ-GUERRA, *supra* note 103, at 65.

116. Hurme & Appelbaum, *supra* note 95, at 964; *see also* Barclay, *supra* note 103, at 157 ("[I]t might be argued that symbolic damage is done to value of voting and of democracy itself if we allow people without capacity to vote . . . .").

117. Barclay, *supra* note 103, at 157.

118. Robert E. Goodin, *Enfranchising All Affected Interests, and its Alternatives*, 35 PHIL. &

principle necessarily includes people with mental impairments. Whether or not they can express their interests rationally, and whether or not expression of their interests will hurt the quality of elections, "[i]t is not as if those interests are less deserving of consideration."[119, 120]

Goodin's argument explicitly includes enfranchisement for non-human animals whose interests are affected by government,[121] and Linda Barclay sees this point as a fatal flaw of Goodin's proposition. The comparison to animals is deeply insulting to people with disabilities, and is opposed by disability-rights advocates who see such an alignment as hurting the political viability of their cause.[122]

Third, focusing on the utility, or legitimacy, of participation of people with mental impairments in government ignores another important facet of suffrage. Voting is not only about electing leaders; voting is also a politically expressive act, a means of connecting the voter to the community, and an essential public ritual of democracy.[123] Mental health professionals, as well, have emphasized the therapeutic potential of voting as a form of social inclusion for people with various forms of mental impairment.[124]

Another important criticism of the "inherent problem" rationales focuses on the disconnect between the objectives of disenfranchisement and the actual legal provisions.[125] Many of the cognitive and mental statuses targeted by disenfranchising provisions around the world and in the United States are

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PUB. AFF. 40 (2007); *see also* Barclay, *supra* note 103, at 148 & n.11.

119. Robert E. Goodin, *Enfranchising the Earth, and its Alternatives*, 44 POL. STUD. 835, 841 (1996).

120. LÓPEZ-GUERRA, *supra* note 103, at 71–72 & n.25. This argument differs from the democratic legitimacy argument advanced by Mill and Dahl, *supra* notes 102 & 104 and accompanying text, in that it focuses upon the importance of rational thought for a person's ability to protect her own affected interests, rather than on the importance of rational thought for a person's right to exercise political power over other members of society.

121. Goodin's argument also necessarily includes enfranchisement for children and non-citizens. These subjects are beyond the scope of this article. For more on the question of enfranchising children, see *supra* note 103. For more on the question of non-citizen suffrage, see Jamin B. Raskin, *Legal Aliens, Local Citizens: The Historical, Constitutional and Theoretical Meanings of Alien Suffrage*, 141 U. PA. L. REV. 1391 (1993).

122. Barclay, *supra* note 103, at 150.

123. Winkler, *supra* note 60 (noting that, as a matter of U.S. law, the Supreme Court has not endorsed the expressive view of the franchise); *see also*, Bindel, *supra* note 59, at 111–20 (explicitly applying Winkler's "expressive" voting theory to the mental impairment-based suffrage restriction context).

124. Michael Nash, *Voting as a Means of Social Inclusion for People with a Mental Illness*, 9 J. PSYCHIATRIC & MENTAL HEALTH NURSING 697 (2002); *see also* Bindel, *supra* note 59, at 120 & nn.193–94.

125. *See, e.g.*, Beckman, *supra* note 1, at 221 ("A basic problem with legal rules excluding people from the vote on the basis of cognitive status is that they are unlikely to achieve their goals.").

extremely vague and archaic.[126] Disenfranchisement of "idiots" or people with "unsound mind", or even of more contemporary statuses such as guardianship and intellectual disability, inevitably reaches large numbers of people who are fully capable of rational decision-making.[127]

Furthermore, the broader the classification targeted, the more likely it is that suffrage restrictions will be enforced arbitrarily against disfavored populations, as were the U.S. literacy tests addressed *supra* Part I.A.[128] Mental-status-based restrictions not only originate from stigmatization of people with mental impairments, but they help perpetuate such prejudiced and unscientific attitudes by enshrining these attitudes in the law.[129] As a result, scholars and courts have started to advocate shifting the focus of disenfranchising provisions from status to some more objective measure of voting capacity. This development, and the debate surrounding it, will be taken up in greater detail below.[130]

2. Manipulation of Voters with Mental Impairments

Many scholars have addressed the concern that people with mental impairments are especially susceptible to the influence and manipulation of their guardians, caregivers, and family members. Enfranchisement of people with mental impairment thus allows other people in their lives to quietly appropriate extra votes and obtain outsized political influence for themselves.[131]

Ludvig Beckman contends that this fear of vote misappropriation stems from the canon of democratic theory.[132] As explained above,[133] Mill, Dahl, and other political theorists saw capacity for independent, rational decision-making as the basis of democratic legitimacy. In Beckman's elaboration, independence is

126. For provisions around the world, see Bhugra et al., *supra* note 3, at 396 ("Varying and stigmatizing terminology is used in legislation to describe persons with mental health problems, e.g. insanity, weakness of mind, unsound mind, lunatic . . . ."). For provisions in the United States, see BAZELON CTR., *supra* note 8, at 13 ("Seven states have laws that use outmoded and stigmatizing terms such as 'idiots,' 'insane persons,' and 'of unsound mind' to describe who is barred from voting based on competence concerns. Such laws are rarely enforced because they are virtually impossible to understand and apply." (internal footnote omitted)).

127. *See* Appelbaum, *supra* note 112, at 849–50; Beckman, *supra* note 1, at 221; Hurme & Appelbaum, *supra* note 95; Schriner et al., *supra* note 32, at 93.

128. Appelbaum, *supra* note 112, at 849–50; Beckman, *supra* note 1, at 222.

129. Schriner et al., *supra* note 32, at 85–86, 95 ("Much progress has been made in recent decades in demythologizing mental illness and mental retardation, in recognizing and accommodating the rights of persons with disabilities, and in providing support and assistance to such persons as necessary. Abolishing legal barriers to voting by such persons would be a logical and appropriate extension of necessary rights protections, and an extension consistent with modern efforts to bring persons with disabilities into the mainstream of society.").

130. *See infra* Part II.

131. *See, e.g.*, Karlawish et al., *supra* note 13; McHugh, *supra* note 109, at 2194; Schriner et al., *supra* note 32, at 92; Hoerner, *supra* note 12, at 122.

132. Beckman, *supra* note 13, at 15–18.

133. *See supra* Part I.C.

essential because it ensures an equal distribution of political influence among the electorate. The extent to which individual voters possess an outsized influence undermines the legitimacy of the electoral outcome. It is easy to see, then, how people whose opinion formation is more dependent on others pose a serious threat to democracy. Even in the absence of outright voter fraud, people with mental impairments often live with and depend heavily upon caregivers, and these circumstances may easily lead them to substitute the caregiver's interests and political preferences for their own. The result is that certain individuals receive extra political influence, undermining the equal distribution of power essential to democratic legitimacy.[134] Upon this theoretical basis, states may choose to utilize the electoral law to "protect the integrity of the electoral process" by excluding those whose suffrage rights endanger the democratic endeavor.[135]

However, recent scholarship has questioned this rationale as well. First, Beckman argued that the traditional bases of democratic theory itself undermined the "integrity" claim.[136] Building on the works of earlier thinkers, he argued that one of the primary responsibilities of democratic society is to promote the "fair value of the political rights of its members."[137] To the extent that some members face obstacles in exercising their basic rights, democratic government must seek to provide them the means necessary to do so. If someone's "difficulties in making independent political judgments . . . [are] to be accounted for by reference to the absence of some opportunity that others should reasonably provide," society is called upon to provide those opportunities.[138] In other words, rather than disenfranchising people with mental impairments, the state should make an effort to socially include them and foster independent judgment, as well as to educate caregivers on the importance of cultivating their wards' independent judgment.[139]

Others have pointed out that the concern for the integrity of the vote, like the concern over the quality of electoral outcomes, is not borne out by any empirical evidence of manipulation.[140] Moreover, the problem of integrity, also like the outcome quality problem, is not actually particular to people with mental impairments. "[I]nfluencing a voter's intentions . . . is part of the culture of

134. Beckman, *supra* note 13, at 16.

135. For more on the role of this rationale in the development of electoral law vis-à-vis people with mental impairments, see, for example, Hurme & Appelbaum, *supra* note 95, at 964; Hoerner, *supra* note 12, at 108–19.

136. Beckman, *supra* note 13, at 18–20.

137. *Id.* at 18.

138. *Id.* at 19.

139. *Id.* at 19–20. In arguing for accommodation over disenfranchisement, Beckman borrows explicitly from "the language of American law," requiring a solution "necessary to further the interest in preventing manipulation." *Id.* at 19.

140. Fiala-Butora et al., *supra* note 18, at 86–89; Redley et al., *supra* note 18, at 1028.

politics, and is not something that can easily, or even should be, legislated against."[141] Citizens regularly seek to persuade each other regarding electoral politics through op-eds, social media, and ordinary conversation. No one would contend that these practices undermine the integrity of elections by providing outsized political power to the persuading party. Far from hindering the exercise of independent judgment, persuasion actually facilitates the development of such judgment. The difference between this sort of influence and a guardian's influence over her ward is one of degree, not kind.[142]

II. CAPACITY-BASED RESTRICTIONS VERSES STATUS-BASED RESTRICTIONS

One way to cure the vagueness and discriminatory potential of status-based suffrage restrictions is to legislate a functional standard. Under such a standard, disenfranchisement is triggered not by belonging to a certain category of individuals, but by failing to meet an objective test of capacity. People who successfully demonstrate capacity are presumptively competent to vote, while those who do not may be excluded for all the reasons that democratic societies wish to exclude incompetent people from the franchise.[143]

The various proposed capacity-assessment models have sought to balance a state's interests in the quality and integrity of its electorate with each individual's right to participate in the democratic process.[144] Moreover, these models strive to render an objective measure of capacity to understand the voting process, unlike assessments of literacy or education level, which inherently favor privileged classes and have historically been utilized to target poor people and disfavored racial groups.[145]

The following part will address the issue of capacity assessment. Part II.A

141. Redley et al., *supra* note 18, at 1028.

142. *See also* Nicholas John Munn, *Against the Political Exclusion of the Incapable*, 33 J. APPLIED PHIL. (forthcoming 2016) (manuscript at 9) (on file with the author) ("We neither ask nor care whether someone is voting through well considered deliberation, or as their religious leadership tells them to, as their political ideology requires, or simply as someone they admire has claimed to be voting. Discriminating against the incapable for doing what the devout, the ideologically compelled, and the unconfident do freely would not be defensible.").

143. *See supra* Part I.C.

144. Hoerner, *supra* note 12, at 125.

145. *See* Barclay, *supra* note 103, at 152 ("[S]urely one reason why education or literacy requirements for the right to vote are no longer countenanced is because historically they were often a thinly veiled excuse for racial discrimination or discrimination against the poor. For that reason educational levels and literacy levels are no longer considered relevant for possessing the capacity to vote. . . . Perhaps cognizant of the threat of discrimination, the few concrete proposals for capacity testing people with cognitive impairments that have been proposed do not set the bar high. . . . This kind of capacity testing is not designed to test whether a person casts her vote in a 'rational' or 'informed' manner (whatever is meant by those terms), but merely whether she understands the nature and purpose of voting."). For an explanation of the historical significance of literacy tests in the United States, see *supra* Part I.A.

reviews the existing capacity assessment model proposals, and Part II.B will argue that the failure of these proposals to become law stems from pragmatic political considerations.

A. Proposed Assesment Models

First, in response to the rising momentum of the disability-rights movement in the 1970s, the American Bar Association's (ABA) Commission on Mental and Physical Disability Law undertook an ambitious project to propose state-law reforms. In 1982, this project, christened the Developmental Disabilities State Legislative Project, advocated for the repeal of existing status-based disenfranchisement provisions, finding them to be likely unconstitutional.[146] For states that wished to exclude incompetent voters from the electorate, the Project recommended replacing the existing provisions with a universal, objective test, under which "[a]ny person who is able to provide the information, whether orally, in writing, through an interpreter or interpretive device or otherwise, which is reasonably required of all persons seeking to register to vote, shall be considered a qualified voter of this state and shall be registered to vote[.]"[147]

However, critics viewed this standard as insufficient and simplistic. After all, basic information such as name, address, and age could potentially be memorized by someone lacking the capacity to rationally choose between candidates or ballot measures.[148] Voters suffering from Alzheimer's disease or other progressive cognitive impairments may have no trouble remembering this sort of information but a great deal of trouble making rational political decisions.[149] Simply put, "the ability to provide one's name and address does not speak directly to the task that a voter will undertake in the voting booth."[150]

Two propositions for a more relevant assessment model emerged from the McGeorge School of Law's 2007 symposium on *Facilitating Voting as People Age: Implications of Cognitive Impairment*.[151] The symposium's resolution, endorsed by the ABA's Commission on Mental and Physical Disability Law and its House of Delegates,[152] urged states to affirmatively codify a status-blind presumption of capacity to vote, in deference to principles of democracy: "To promote the democratic process to the fullest extent possible, no governmental entity should exclude any otherwise qualified persons from voting on the basis of medical diagnosis, disability status, or type of residence. A person's capacity to

146. Bindel, *supra* note 59, at 124–25.

147. BRUCE DENNIS SALES ET AL., DISABLED PERSONS AND THE LAW: STATE LEGISLATIVE ISSUES 111 (1982).

148. Bindel, *supra* note 59, at 128.

149. *Id.*

150. *Id.* (quoting Karlawish et al., *supra* note 13, at 1346).

151. Symposium, *supra* note 19.

152. Bindel, *supra* note 59, at 129.

vote should be presumed regardless of guardianship status."[153] Exclusion on the basis of capacity was allowed only when accompanied by due process protections, including individualized determination by a court of competent jurisdiction and a "clear and convincing" evidentiary standard.[154]

The symposium endorsed a functional capacity definition (for those states that elect to retain a capacity standard), allowing exclusion only for people lacking the ability to "communicate, with or without accommodations, a specific desire to participate in the voting process."[155] Although this, too, is a low bar, expression of a desire to vote conveys a degree of understanding of the process and is arguably more relevant to the democratic endeavor than provision of name and address. California has recently adopted this standard. Although its state constitution allows "disqualification of electors while mentally incompetent,"[156] its statutory election code now presumes every voter to be competent unless, during conservatorship proceedings, the court finds lack of capacity using the symposium's substantive and evidentiary standards.[157]

However, two symposium participants refused to take the resolution's capacity standard at face value. According to Sally Burch Hurme and Paul Appelbaum, if the sole criterion for voting is the ability to respond "affirmatively to a query as to whether the person wants to vote . . . no meaningful capacity requirement would have been established."[158] A person with dementia who has little comprehension of political issues may very well respond affirmatively without understanding the question.[159] Rather than reject the resolution, though, Hurme and Appelbaum interpreted it in accordance with a more rigorous assessment model, first promoted by Appelbaum and two colleagues in *The American Journal of Psychiatry* in 2005.[160]

This model, the "Competence Assessment Tool for Voting" (CAT-V) is founded upon the competence definition enunciated in the Washington state statute and the *Rowe* ruling: ability to understand "the nature and effect of voting such that she or he [can] make an individual choice."[161] Hurme and Appelbaum explain that understanding nature and effect is more meaningful than expression of a desire to vote, and yet is also a significantly lower bar than the usual four-

153. *Recommendations of the Symposium*, 38 MCGEORGE L. REV. 861, 862–63 (2007).

154. *Id.* at 863.

155. *Id.*

156. CAL. CONST. art. II, § 4.

157. CAL. ELEC. CODE § 2208(a) (Deering 2016).

158. Hurme & Appelbaum, *supra* note 95, at 966 n.209.

159. *Id.*

160. *Id.* at 967 n.210. For the *American Journal of Psychiatry* article, see Appelbaum et al., *supra* note 19.

161. WASH. REV. CODE § 11.88.010(5) (2017); *see also* Hurme & Appelbaum, *supra* note 95, at 964–74; *supra* notes 48–64 and accompanying text (describing *Doe v. Rowe*, 156 F. Supp. 2d 35 (D. Me. 2001)).

part capacity standard for medical decision making.[162] This lower bar is amply justified by the special nature of the right to vote and the miniscule likelihood that enfranchisement of some incompetent voters will actually harm the quality of elections. In other words, the concern of over-enfranchisement calls for a meaningful, functional capacity standard, but the more powerful concern of under-enfranchisement dictates that this standard be easily met.[163]

Hurme and Appelbaum read this definition into the "specific desire to participate in the voting process" standard endorsed by the symposium Recommendations. "To have a specific desire to participate in a process implies knowledge of the nature and purpose of the process, as well as an intentional choice to participate."[164] If the voter does not understand the relationship between her vote and the election of a president, mayor, or other elected official, her desire to vote does not translate into a genuine desire to participate in this *specific* process.[165]

CAT-V "operationalizes" the *Doe*/Washington standard into a fixed system of questions and scoring. First, the would-be voter is asked a question about the nature of voting: "Imagine that two candidates are running for Governor of [subject's state], and that today is Election Day . . . What will the people of [subject's state] do today to pick the next Governor?"[166] Completely correct responses (e.g., "They will go to the polls and vote") receive two points, ambiguous responses (e.g., "That's why we have Election Day") receive one point, and incorrect responses (e.g., "There's nothing you can do; the TV guy decides") receive zero.[167] Next, the voter's understanding of the effect of voting is assessed: "When the election for governor is over, how will it be decided who the winner is?"[168] Again, correct responses (e.g., "The votes will be counted and the person with more votes will be the winner") receive two points, ambiguous responses (e.g., "By the numbers") receive one, and incorrect responses (e.g., "It all depends which sign they were born under") receive zero.[169]

The subject's capacity to choose between candidates is tested by providing the subject with a hypothetical about two candidates and their opposing platforms. The subject is asked to choose between two candidates. Clear indication of a choice receives two points, an ambiguous response (e.g., "I think I

162. Hurme & Appelbaum, *supra* note 95, at 965. The authors identify the four parts of the medical standard as "substantial abilities to understand, appreciate, reason, and choose." For a broader presentation of the law of capacity determinations and the place of voting capacity within that field, see *id.* at 962–66.

163. *Id.*

164. *Id.* at 966 n.209.

165. *Id.*

166. *Id.* at 967.

167. *Id.*

168. *Id.* at 968.

169. *Id.*

might go for the guy who doesn't like taxes, but I'm not sure because schools are important too") receives one, and total lack of a choice (e.g., "I don't know") receives zero.[170]

Hurme and Appelbaum did not take the position that any particular score from 0 to 6 represents minimum capacity for voting. Instead, they caution against drawing a firm capacity line among the possible scores and suggest that different decision-makers may use CAT-V data differently.[171]

The initial *American Journal of Psychiatry* study assessed thirty-three people with Alzheimer's disease.[172] Only four subjects (12%) failed to indicate a choice, but a greater number failed to understand the nature (fifteen subjects, or 45%) and/or effect (ten subjects, or 30%) of voting.[173] CAT-V performance correlated strongly with the severity of the subject's dementia, while expression of desire to vote—the alternative interpretation of the symposium's resolution—was not a good predictor of CAT-V performance.[174]

Subsequently, CAT-V has continued to attract interest among scientific researchers, who have tested its application to aging people with and without dementia,[175] as well as to psychiatric outpatients with serious mental illness.[176] Most of these studies supplemented the basic *Doe*/Washington criteria with additional questions to assess subjects' *appreciation* of the effect of voting and their *reasoning* underlying electoral choice.[177] Some researchers found that capacity to vote, as measured by CAT-V, does not correlate strongly with common measures of cognitive function,[178] lending scientific support to the

170. *Id.* at 968–69.

171. *Id.* at 973 ("So long as a CAT-V score in itself is not the ultimate determinant of whether a person can vote, but merely triggers a referral of the question to a neutral decision-maker . . . a screening instrument would appear to play a helpful role."); *id* at 971 ("To the extent that there is disagreement over a person's capacity to vote, the argument will turn on the interpretation of a common set of data . . . .").

172. Appelbaum et al., *supra* note 19, at 2096.

173. *Id.*

174. *Id.* at 2096–97.

175. *See* Luis Javier Irastorza et al., *Capacity to Vote in Persons with Dementia and the Elderly*, 2011 INT'L J. ALZHEIMER'S DISEASE 1 (2011), https://www.hindawi.com/journals/ijad/2011/941041 [https://perma.cc/3RW6-DG82]; Pietro Tiraboschi et al., *Evaluating Voting Competence in Persons with Alzheimer's Disease,* 2011 INT'L J. ALZHEIMER'S DISEASE 1 (2011), https://www.hindawi.com/journals/ijad/2011/983895 [https://perma.cc/CT5E-NJCF].

176. *See* Adiel Doron et al., *Voting Rights for Psychiatric Patients: Compromise of the Integrity of Elections, or Empowerment and Integration into the Community?*, 51 IS. J. PSYCHIATRY & RELATED SCIS. 169 (2014) (studying psychiatric inpatients); Raymond Raad et al., *The Capacity to Vote of Persons with Serious Mental Illness*, 60 PSYCHIATRIC SERVS. 624 (2009) (studying psychiatric patients residing in the community).

177. *See* Appelbaum et al., *supra* note 19, at 2095; Irastorza et al., *supra* note 175, at *2; Raad et al., *supra* note 176, at 625; Tiraboschi et al., *supra* note 175, at *2. *But see* Doron et al., *supra* note 176, at 172 (limiting the CAT-V component of study to assessment of understanding of nature and effect of voting).

178. *See* Raad et al., *supra* note 176, at 628 ("[I]t may be appropriate to assume that as a group,

contention that status-based disenfranchisement provisions are too broad.[179] In the same vein, all the studies that considered CAT-V recommended its usage, either for people with moderate Alzheimer's disease or for people with legal guardians.[180]

Demonstrating awareness of public policy concerns, some researchers noted that CAT-V studies of people without Alzheimer's disease or mental illness could help establish a capacity cutoff. Rather than arbitrarily choosing an intermediate CAT-V score as the cutoff, legislators can base their judgment on the range of scores attained by presumptively competent voters.[181] Nonetheless, the CAT-V procedure has apparently not been adopted into electoral law.[182]

Undoubtedly, a major reason for the staying power of status-based disenfranchisement is "the simple belief that the [capacity-based] standards that have been produced thus far . . . have been fundamentally too relaxed."[183] Assessments of ability to answer basic questions about the working of an election have not placated concerns over the quality and integrity of the vote. For this reason, Benjamin O. Hoerner has proposed the following hybrid standard: A state may legislate categorical disenfranchisement of all people under guardianship, but provide notice during guardianship proceedings of the ward's right to seek retention of suffrage via assessment of his or her voting capacity. The ward would have to undergo a court-administered capacity assessment designed to

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persons with serious mental illness do not manifest a substantial incidence of incapacity to vote."); Tiraboschi et al. *supra* note 175, at *5 ("[G]lobal measures of cognitive functioning . . . do not appear to be strong predictors of the capacity to vote."). *But see* Doron et al., *supra* note 176, at 174 ("Contrary to Raad et al., who did not find a significant correlation between CAT-V scores and cognition, we found a positive correlation between cognition and capacity to vote. In addition, patients with legal guardians performed worse than those without guardians." (footnote omitted)).

179. For this contention, see *supra* notes 125–130 and accompanying text.

180. Some researchers found that people with mild Alzheimer's disease can be presumed competent and those with severe Alzheimer's disease can be presumed incompetent, but that people with moderate Alzheimer's disease cannot be presumed one way or the other and could be assessed using CAT-V. *See* Appelbaum et al., *supra* note 19, at 2098–99; *see also* Irastorza et al., *supra* note 175, at *5 (recommending that CAT-V's choice assessment be made stronger by adding more information to the hypothetical choice question); Tiraboschi et al., *supra* note 175, at *5. Others recommended CAT-V usage for people whose capacity to vote is questioned (a helpful proxy for identifying people with questionable decision-making capacity). *See* Doron et al., *supra* note 176, at 174 (advocating CAT-V screening for individuals with a legal guardian); Raad et al., *supra* note 176, at 628.

181. Appelbaum et al., *supra* note 19, at 2098 (noting it could be helpful to have CAT-V studies of non-demented people for the purpose of establishing a cutoff); Raad et al., *supra* note 176, at 628 (urging CAT-V studies of people without mental illness, for the same purpose).

182. This author has not found any evidence of CAT-V's implementation into electoral law. Although no published sources state explicitly that CAT-V is not legally codified in any jurisdiction, some writers have suggested their own inability to find evidence of its implementation. *See* Beckman, *supra* note 1, at 229 (noting the CAT-V test "is not yet generally adopted"); Hoerner, *supra* note 12, at 127 (noting the CAT-V standards "have been largely ignored by both the [U.S.] federal government and the states").

183. Hoerner, *supra* note 12, at 127.

gauge his or her understanding of the voting process. Such a compromise would help placate electoral-integrity concerns by creating a hurdle for people under guardianship, but would also move away from over-exclusion and discrimination by providing notice and an opportunity to be enfranchised on capacity grounds.[184]

B. The Arbitrariness of Capacity Determinations

Alternatively, the failure of capacity-based standards to gain legislative traction may stem from a more essential problem. Drawing a legal voting-capacity line is "an exercise in policy, not science."[185] The best that assessment models could do is to illustrate a spectrum of capacity; translating this spectrum into distinct categories of competent and incompetent voters is a fundamentally arbitrary task. In contrast, statuses such as intellectual disability, mental illness, and guardianship are rooted in preexisting categories of law and science. Disenfranchisement of these well-defined "other" groups is more intuitive and more politically palatable than rearrangement of civil rights along the lines of newly constructed "capacity" categories.

Accordingly, status-based disenfranchisement remains on the books,[186] and, as will be shown below, even CAT-V, the gold standard for capacity assessment, fails to disregard status entirely. Moreover, as of the date of this writing, no electoral democracies have instituted universal cognitive capacity assessment as a prerequisite for voting.[187] The following section argues that, because political considerations favor focusing upon recognized statuses, scholars and legislators promoting the capacity assessment idea are unlikely to embrace objective assessment of all potential voters.

The ABA and McGeorge universal-capacity-screening proposals were shelved by Hurme and Appelbaum for their failure to sufficiently protect the electorate from incompetent voters,[188] and the more rigorous CAT-V standard has emerged as the favored capacity assessment mechanism in many subsequent analyses.[189] However, CAT-V assessment does not appear to have been seriously considered as a universal prerequisite for the franchise. Hurme and Appelbaum disapproved of such "indiscriminate screening" out of concern that it "may result

184. *Id.* at 127–29. Hoerner also notes that such a hybrid standard would meet the Due Process requirements announced in *Rowe* and *Carnahan*. *Id.* at 127–28.

185. Hurme & Appelbaum, *supra* note 95, at 962.

186. *See supra* Introduction.

187. For a survey of relevant electoral laws worldwide and in the United States, see *supra* Introduction.

188. *See supra* notes 158–165 and accompanying text (describing the concerns of Hurme & Appelbaum).

189. *See, e.g.*, Barclay, *supra* note 103, at 152; Beckman, *supra* note 1, at 229–30; Kelley, *supra* note 12, at 383.

in the disenfranchisement of the elderly in general."[190] The scientific studies of CAT-V considered only members of status groups (people with mental illness or Alzheimer's disease) and recommended CAT-V usage only for members of status groups (people with moderate Alzheimer's disease or under guardianship).[191] Some have recommended studying CAT-V performance in the general population, but only for the purpose of discerning a capacity cutoff line to be used in screening certain status groups.[192]

It may seem strange that the same scholars who advocate the relative desirability of capacity-based determinations would shy away from universal capacity screening out of fear that it would be taken too seriously and result in the disenfranchisement of people who are now permitted to vote. It may also seem strange that these scholars retain a discriminatory focus upon status groups by proposing to screen only members of such groups. Ludvig Beckman was troubled by this:

> The rationale for restricting the vote on the basis of capacity to vote is that people should not be disenfranchised simply because of their cognitive status. But the decision to test for capacity to vote is plausible only on the suspicion that people with a certain cognitive status may not be in possession of the capacity to vote. Hence, CAT-V testing is premised on the tenet that only people with some cognitive impairment should be tested. But once this is admitted, the problem of misclassification re-emerges . . . In the end, people denied the vote following a failed result on tests for capacity to vote are denied the vote also because . . . of their cognitive status.[193]

In international legal terms, singling out certain status groups for screening is likely prohibited under Article 12.2 of the CRPD, which declares that "persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life." As Oliver Lewis of the Mental Disability Advocacy Centre argued before the Venice Commission,

Given that it is only people with actual or perceived mental or cognitive disabilities who will be subjected to the [capacity assessment] in the first place, it does not matter whether the word "disabled" appears in the [assessment] or not. No matter how elegant the legal formulation, and no matter whether it is legislation or a judge which removes the franchise, these measures will still constitute unlawful discrimination.

If I were legal counsel to the Venice Commission I would be advising you

190. Hurme & Appelbaum, *supra* note 95, at 971.

191. *See supra* notes 175–180 and accompanying text (describing the recommendations).

192. *See id.*

193. Beckman, *supra* note 1, at 230.

that the only way for a "proper judgment" to be non-discriminatory is for the test to be administered to people with disabilities and all other potential voters. As far as I know this proposal is—unsurprisingly—not on the table.[194]

What, then, has the voting-rights debate gained from the pivot from status toward capacity? It seems that even the most celebrated capacity-based proposal is equally discriminatory, equally arbitrary, and equally illegal to the existing status-based provisions.[195] Linda Barclay has argued that the small benefits to be gained from conducting a capacity-screening test on every voter do not justify the immense monetary and social costs of the screening process.[196] She proceeded to argue that the same logic applies to capacity screening of suspect groups and, in its place, proposed elimination of all mental impairment-based suffrage restrictions.[197]

As illustrated above, pragmatic politics help to explain the capacity advocates' retention of status-based discrimination. The scholars who created and promoted CAT-V want their ideas to be acceptable to policymakers and voters. A universal screening scheme that rearranges the fundamentals of citizenship and potentially disenfranchises large numbers of people is bound to be an unpopular proposition. Just as some have proposed a compromise that combines capacity screening with preliminary categorical disenfranchisement of people under guardianship,[198] the CAT-V scheme apparently has a built-in compromise leaving alone the masses of presumptively rational voters. This may also be the import of

194. Oliver Lewis, Exec. Dir., Mental Disability Advocacy Ctr., The Promise of Democracy—Why the Venice Commission Should Adopt Universal Suffrage for People with Disabilities 3 (June 18, 2011), http://mdac.info/sites/mdac.info/files/The%20Promise%20of%20Democracy%20%E2%80%93%20Why%20the%20Venice%20Commission%20should%20adopt%20universal%20suffrage%20for%20people%20with%20disabilities.pdf [https://perma.cc/8LEU-FT58]. Linda Barclay contested Lewis's claim that capacity screening members of certain status groups is discriminatory, on several grounds: (a) Since capacity-screening seeks to hold people with mental impairments to the same competence standard as other people, rather than to a higher standard, they are not actually discriminated against in any appreciable way; (b) even if differential treatment—namely screening—itself constitutes discrimination, it is done on the basis of a morally relevant difference—namely capacity—and is therefore justifiable; (c) Lewis' notion of discrimination is detrimental to the disability-rights movement, because it holds the provision of special resources to people with disabilities—a form of differential treatment—to be per se discriminatory; and (d) Lewis' notion of discrimination is also detrimental to the universal enfranchisement cause in particular, because it requires acceptance of the much-less-popular contentions that children should be enfranchised without capacity screening, and people with mental impairments should not be subjected to capacity screening with regard to medical and financial decision making. Barclay, *supra* note 103, at 152–53.

195. For arguments that status-based disenfranchisement of people with mental impairments is discriminatory and arbitrary, see *supra* Part I.C. For authority stating that such disenfranchisement violates U.S. constitutional law, see discussion of the *Doe v. Rowe* case, *supra* Part I.A. For authority stating that such disenfranchisement violates international-human-rights law, see discussion of CRPD Article 29 and related case law, *supra* Part I.B.

196. Barclay, *supra* note 103, at 153–54.

197. *Id.* at 154–57.

198. *See supra* note 184 and accompanying text.

Beckman's contention that "the decision to test for capacity to vote is *plausible* only on the suspicion that people with a certain cognitive status may not be in possession of the capacity to vote."[199] The concern is political, rather than theoretical, plausibility.

The proponents of capacity assessment have therefore not succeeded in eliminating traditional barriers to suffrage. And even if the political concerns were overcome and universal capacity assessment were instituted, the upshot would be to preserve the exclusivity of the electorate by evolving traditional barriers to meet modern standards of law and justice—capacity rather than status. Meanwhile, another recent reform proposal has sought to radically expand the boundaries of the electorate, making it far more inclusive of people with mental impairments than it has ever been. This idea, popularized by philosopher Martha Nussbaum in 2009, is the subject of Part IV.[200]

III. VOTING BY PROXY

Nussbaum's analysis began with the contention that, with regard to "core political entitlements" such as the right to vote, "adequacy of capability requires equality of capability."[201] If voting rights are not possessed by all citizens of the demos on the basis of total equality—if, for instance, the vote of each black citizen is worth half the vote of each white citizen—the system is fundamentally unjust, despite the fact that all adult citizens have some right to vote. No arrangement short of equality is adequate.[202]

Nussbaum then applied this model to the question of suffrage for people with mental impairments. She conceptualized this question into three cases: In Case A, a person is cognitively capable of voting, but has difficulty doing so alone on account of some disability, such as social anxiety or limited literacy. To ensure equal rights for such a person, society must spend "the money required to facilitate that person's full inclusion in . . . voting."[203] In Case B, a person cannot vote even with facilitation, but can make an electoral choice and convey it to his or her guardian. To ensure equal rights, society must allow that person's guardian to cast a vote based on the person's expressed preference.[204] In Case C, "the person's disability is so profound that he or she is unable to perform the function in question, even to the extent of forming a view and communicating that view to a guardian."[205] Nussbaum argues that the person's guardian should be allowed to

199. *See* Beckman, *supra* note 1, at 230 (emphasis added).

200. Nussbaum, *supra* note 17.

201. *Id.* at 343.

202. *Id.* Nussbaum's analysis also concerns jury service, but this Note will focus on her contentions regarding voting.

203. *Id.* at 345.

204. *Id.* at 346.

205. *Id.* at 345.

cast a vote "on the person's behalf and in her interests, just as guardians currently represent people with cognitive disabilities in areas such as property rights and contract."[206] Arguably, this contention is the logical conclusion of the analogy between the rules of the "social contract" of voting and the rules of ordinary commercial contracts, invoked above to justify exclusion of people with mental impairments from the electorate.[207] According to Nussbaum, nothing short of voting by proxy ensures equal voting rights for every person with mental impairments.

As to the concern that guardians may usurp their wards' votes to vote twice for their own preferences, Nussbaum contends that this problem is equally applicable to any function of guardianship. Just as some bad guardians will insert their own interests into their wards' health and contract decisions, some will do so for voting as well. "Instead, we [should] design procedures to authorize guardianship that try to weed out the incompetent or the selfish."[208] After briefly musing on the slim chance of the Case C voting right being recognized in U.S. courts, Nussbaum closes with a recognition of the firestorm she would soon engender: "Let the debate begin."[209]

The proxy voting idea had been previously, if very briefly, considered in a 2004 *Journal of the American Medical Association* article.[210] The nine authors rejected the idea with an uncited assertion that:

> Unlike medical and financial decisions, the act of voting in a democratic polity is an incident of citizenship and an inalienable right. Citizenship creates certain obligations and opportunities that cannot be delegated, such submitting to a military draft or serving on a jury. Although a person has the prerogative to vote as another person recommends, the person cannot "assign" his or her right to vote to someone else.[211]

That these authors gave the proxy voting idea such short shrift lends credence to Nussbaum's assertion that she, by seriously considering the merits of the issue, was beginning a new debate. As predicted, her 2009 proposition received many vehement responses,[212] and the exchange has helped develop contemporary approaches to the problem of suffrage for people with severe

206. *Id.* at 347.

207. *See supra* note 111 and accompanying text.

208. Nussbaum, *supra* note 17, at 348.

209. *Id.* at 350.

210. Karlawish et al., *supra* note 13.

211. *Id.* at 1347.

212. These responses will be considered at great length below. Benajmin O. Hoerner has responded more ambivalently, calling Nussbaum's proposition "too large of a legislative leap" on the one hand and "a simple solution to a complex problem" on the other. Hoerner, *supra* note 12, at 123.

mental impairments. The remainder of this section will review two important responses to Nussbaum and offer one original response.

Claudio López-Guerra argues that right to vote should depend on interest "in the value of the franchise."[213] Appointing proxy voters for fully competent people would not satisfy their interest in the franchise because "they understand and value the . . . opportunity to contribute to the making of a more just society through the election of the right kind of representatives."[214] In contrast, people with severe mental impairments, who do not understand or value this opportunity, correspondingly do not have the requisite interest in the franchise to justify receiving any right to vote, through proxy or otherwise.[215]

In the international human rights law analysis considered in Part II.B.,[216] the three Harvard authors raise four objections to Nussbaum's proposition. First, they argue that proxy voting violates core human-rights norms of "autonomy, dignity, and respect for the individual—precisely, and ironically, the values [Nussbaum] seeks to honor."[217] More particularly, the prevalence of substituted decision-making models for people with disabilities was a major impetus for the adoption of the CRPD. Article 12 of the CRPD guarantees people with disabilities "legal capacity on an equal basis with others" and commits states parties to facilitate free exercise of this capacity—the so-called "supported decisionmaking" model.[218]

Second, voting by proxy does not promote the dignity of people with mental impairments. Far from engendering social inclusion, this scheme holds no therapeutic value for the person uninvolved in casting his or her own vote,[219] and is likely to perpetuate the societal stigma of people with mental impairments as flawed and incapable. And since Nussbaum's "Case C" voters are a small minority, proxy voting on their behalf is unlikely to have a significant impact on advancing their policy preferences.[220]

Third, the process of identifying the people whose voting rights should be assigned to proxies is likely to suffer from the same vagueness problems that plague mental-impairment-based suffrage restrictions. People unjustly included in this class will simply lose their right to vote and see it pass to fellow citizens.[221]

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213. LÓPEZ-GUERRA, *supra* note 103, at 73.

214. *Id.*

215. *Id.*

216. Fiala-Butora et al., *supra* note 18.

217. *Id.* at 99.

218. *Id.*

219. For more on voting as a means of social inclusion and therapy, see *supra* notes 123–124 and accompanying text.

220. Fiala-Butora et al., *supra* note 18, at 101.

221. *Id.* at 102.

Fourth, as Nussbaum herself noted, the potential for abusive vote usurpation is clear. Contrary to Nussbaum's assertion, though, voting by proxy presents a greater opportunity for the guardian to substitute her own interests than do medical and financial decisions. Voting, unlike those other contexts, is done in secret, thus shielding the guardian's decision and the process by which she reached it from outside oversight.[222] Finally, governments with an instrumentalist view of the value of voting "would have a strong incentive to subject increasingly more persons to proxy voting because they consider guardians better educated and more knowledgeable than voters with disabilities.[223] In this way, Nussbaum's proposition for greater inclusion can be utilized as a tool to further the disenfranchisement rationales explored above.[224]

But Nussbaum's proposal suffers from an essential flaw, in addition to the valid problems raised by López-Guerra and the international law scholars: The decision of which candidates and which referenda to support depends on much more than a calculation of personal interests. When citizens vote, they are called upon not only to protect their own economic and physiological welfare, but to advocate for their vision of the proper course of society in terms of war and peace, social policy, and the economy. To suggest that a guardian—no matter how familiar and caring she may be—can fairly express another person's political view trivializes both the nature (ideological, rather than mathematical) and the effect (upon all of society, not just the self) of voting. No personal-interests-based determination can fairly approximate someone else's vision for society at large. Instead, in the absence of a clear indication as to the ward's political preference, many guardians will inevitably substitute their own preferences.

Because Nussbaum's proposal would transform the purpose of voting from civic duty to economic self-interest, it must not be adopted into law. And because the potential for guardians to vote their own preferences would raise familiar fears of vote misappropriation,[225] this proposal is not likely to find widespread acceptance in any electoral democracy.

Both Nussbaum and the advocates of capacity assessment have sought to revolutionize the subject of voting capacity. The advocates of assessment take a more conservative approach, acknowledging that people need a minimum

222. *Id.* The impact upon the ward of an improper medical or financial decision is arguably greater than the impact of an improperly cast vote. Nonetheless, the Harvard authors do not address this differential of impact and instead focus squarely on the question of opportunity. From their perspective, "the situation is more serious in the case of voting," because there is a greater opportunity for abuse in this case than there is in the case of other guardian-made decisions. Fiala-Butora, *supra* note 18, at 102.

223. *Id.* at 103.

224. *Id.* For the rationales, see *supra* Part I.C.

225. *See supra* Part I.B.2 (describing the concern of vote misappropriation and reviewing critiques of this concern).

cognitive capacity to participate in the democratic process, but arguing that that capacity must be defined and assessed in an objective, scientifically precise way. Nussbaum, on the other hand, contends that voting capacity is transferable; all people have a right to participate in self-government, and when capacity to do so is lacking, it may simply be supplied by proxy. Parts II and III have reviewed these two ideas, arguing that both are flawed and unlikely to achieve political acceptance. Still, both ideas are correct in their insistence that voting regulations across the world exclude too many people who are ready and able to contribute to the democratic process.

Part IV will advance a new proposal for reforming legal conceptions of voting capacity: removal of mental illness as a factor for disenfranchisement. This idea is admittedly only a first step and not an attempt to perfect the rules of voting. Still, it will address a basic problem that permeates the existing law and scholarship on voting capacity. Treating mental illness as a marker of incapacity both misunderstands the nature of mental illness and makes the democratic process into an instrument of stigmatization.

IV. DISENFRANCHISEMENT ON THE BASIS OF MENTAL ILLNESS

The *Rowe* case sheds light on the absurdity of disenfranchisement provisions founded upon mental illness. Two of the plaintiffs in that case had been placed under guardianship on account of their bipolar disorder, and the third on account of intermittent explosive disorder, antisocial personality disorder, and mild organic brain syndrome.[226] That their mood, personality, and behavior disorders had little bearing on the plaintiffs' ability to understand and rationally participate in voting is amply clear from the record. Evidence showed that all three women fully understood the nature and effect of voting and were capable of making an informed choice; two of them had previously voted on their own initiative before learning that the Maine Constitution prohibited them from doing so.[227]

As mentioned above, multiple studies have shown that the voting behavior of psychiatric inpatients closely mirrors the votes of the patients' communities and socioeconomic strata.[228] Although these data do not prove that the psychiatric inpatient voters engaged in rational consideration of the options, the similarity of their voting pattern to those of other citizens "tend[s] to refute" the presumption that people with mental illnesses are, as a group, less competent to vote than other people.[229] As one 1970 study explained:

226. Doe v. Rowe, 156 F. Supp. 2d 35, 39–41 (D. Me. 2001).

227. *Id.*

228. *See supra* note 113.

229. Klein & Grossman, *supra* note 113, at 1565; *see also* Howard & Anthony, *supra* note 113, at 132 ("[T]his study seems to clearly support the premise that the hospitalized mental patient is competent to vote and is capable of doing so in an informed and thoughtful manner.").

> Disenfranchisement of mental patients is based on the assumption that mental illness is synonymous with mental incompetence and that such incompetence is all-pervasive and covers all phases of human activity . . . [The findings show that w]hile people may at times manifest dysfunction in one area of activity, they may still be competent in other areas.[230]

Nonetheless, electoral laws around the world and related scholarship continue to treat "mental illness" as a significant factor vis-à-vis voting capacity. Although no U.S. states still disenfranchise people for reasons of mental illness,[231] still, as noted above,[232] sixty nine U.N. member states disenfranchise all people "with any mental health problems . . . without any qualifier,"[233] nine member states disenfranchise people detained under mental health laws,[234] and fifty six member states authorize courts or magistrates to disenfranchise people for mental health reasons.[235]

Moreover, at least two of the recent published studies to apply the CAT-V assessment method focused upon mental illness, one assessing the CAT-V scores of "persons with serious mental illness" and one assessing the scores of "psychiatric patients."[236] These researchers, seeking subject populations with questionable voting capacity, draw no distinction between illnesses known to affect cognition and illnesses not known to do so. This phenomenon suggests that even mental-health scientists continue to view mental illness as an indicator of impaired voting capacity.[237]

This Part argues that considering mental illness when determining voting capacity turns electoral law into an instrument of stigmatization and disempowerment. Framing this point, however, requires some background on the definition of the term "mental illness." For half a century, psychologists, psychiatrists, and philosophers have disputed the proper definition of this term.[238]

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230. Klein & Grossman, *supra* note 113, at 1565.

231. *See* BAZELON CTR., *supra* note 8, at 28–52 (detailing the relevant electoral law in U.S. states and territories). Maine's constitution still disenfranchises people "under guardianship for reason of mental illness," the state no longer enforces the provision, in compliance with *Rowe*. *See supra* Part I.A.

232. *See supra* notes 3–6 and accompanying text.

233. Bhugra et al., *supra* note 3, at 396.

234. *Id.* at 396–97. Twelve other member states disenfranchise all detained people, a group that presumably includes people detained for mental-health reasons but does not target them specifically. *Id.*

235. *Id.* at 396.

236. *See supra* note 176.

237. For an illustration of the CAT-V researchers' focus on subjects with mental illness, see the studies described in *supra* page 295 and notes 177–78.

238. For two overviews of the history of this dispute, see, for example, Valérie Aucouturier & Steeves Demazeux, *The Concept of Mental Disorder*, *in* HEALTH, ILLNESS AND DISEASE: PHILOSOPHICAL ESSAYS 75 (Havi Carel & Rachel Cooper eds., 2014); Steeves Demazeux, *The*

The subject has been very contentious, and an exhaustive treatment of the dispute is beyond the scope of this Note. Instead, the following paragraphs will briefly introduce some of the most important events, positions, and currents of the dispute.

First, psychiatrist Thomas Szasz declared war on the field of psychiatry in 1960 by questioning the reality of the concept of mental illness. He wrote:

> The concept of illness, whether bodily or mental, implies *deviation from some clearly defined norm.* In the case of physical illness, the norm is the structural and functional integrity of the human body. . . . What is the norm deviation from which is regarded as mental illness? This question cannot be easily answered. But whatever this norm might be, we can be certain of only one thing: namely, that it is a norm that must be stated in terms of *psycho-social, ethical,* and *legal* concepts. For example, notions such as "excessive repression" or "acting out an unconscious impulse" illustrate the use of psychological concepts for judging (so-called) mental health and illness. The idea that chronic hostility, vengefulness, or divorce are indicative of mental illness would be illustrations of the use of ethical norms (that is, the desirability of love, kindness, and a stable marriage relationship). Finally, the widespread psychiatric opinion that only a mentally ill person would commit homicide illustrates the use of a legal concept as a norm of mental health.[239]

Szasz's claim that the concept of mental illness draws upon values external to medicine has become emblematic of the anti-psychiatry movement, and it inspired attempts by others in the field to more precisely define, and defend, the term.[240] Another catalyzing event in this debate was the American Psychiatric Association's 1973 decision to remove homosexuality from its Diagnostic and Statistical Manual of Mental Disorders (DSM), which it made in response to a shift in popular attitudes toward homosexuality.[241]

Throughout the 1970s, mental health researchers sought to identify objective

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Function Debate and the Concept of Mental Disorder, *in* CLASSIFICATION, DISEASE, AND EVIDENCE: NEW ESSAYS IN THE PHILOSOPHY OF MEDICINE 63 (Philippe Huneman et al. eds., 2015).

239. Thomas S. Szasz, *The Myth of Mental Illness*, 15 AM. PSYCHOLOGIST 113, 114 (1960); *see also* THOMAS S. SZASZ, THE MYTH OF MENTAL ILLNESS (revised ed., 1974) (expounding further upon the position announced in his 1960 article).

240. Aucouturier & Demazeux, *supra* note 238, at 83–84; Demazeux, *supra* note 238, at 65.

241. Aucouturier & Demazeux, *supra* note 238, at 84–85; *see also* Neel Burton, *When Homosexuality Stopped Being a Mental Disorder*, PSYCHOL. TODAY (Sept. 18, 2015), https://www.psychologytoday.com/blog/hide-and-seek/201509/when-homosexuality-stopped-being-mental-disorder [https://perma.cc/Z225-DFGG] ("The evolution of the status of homosexuality in the classifications of mental disorders highlights that concepts of mental disorder can be rapidly evolving social constructs that change as society changes.").

criteria for the concept of mental illness. Robert Spitzer and Jean Endicott emphasized suffering and distress, while Donald Klein insisted on the necessity of "actual dysfunction."[242] In a series of influential articles in the 1990s, Jerome Wakefield advocated a middle position: mental illness is characterized by "harmful dysfunction": "dysfunction" refers to a person's objective mental abnormality, but the abnormality is only considered "harmful" on the basis of subjective sociocultural values. In Wakefield's view, then, the concept of mental illness includes both an objective scientific element and a subjective value-laden one.[243]

This Note takes no position in this debate. However, it is very significant that recent literature reviewing the debate highlights the continuing prevalence of the idea, including among psychiatrists themselves, that "psycho-social, ethical, and legal values play a role in the classification of mental illnesses. Indeed, some writers now consider it a matter of "consensus" that mental illness is a value-laden concept.[244]

Accepting this "consensus" idea as true, even if just for the sake of argument, reveals a stunning problem in the use of mental illness as an indicator of voting incapacity. If diagnoses of mental illness inevitably incorporate elements of psychosocial, ethical, or legal disapproval, then disenfranchisement on the basis of mental illness reinforces that disapproval by excluding the voices of the marginalized group from the democratic process. This exclusion thereby inhibits the ability of people with mental illness to change social attitudes through the democratic process.

Government initiatives to reform psychiatric-care practices in Australia and the United States have noted the importance of political engagement by consumers/survivors of the psychiatric system to argue for change.[245] There is no

242. Aucouturier & Demazeux, *supra* note 238, at 86–88.

243. *See* Jerome C. Wakefield, *Disorder as Harmful Dysfunction: A Conceptual Critique of DSM-III-R's Definition of Mental Disorder*, 99 PSYCHOL. REV. 232 (1992); Jerome C. Wakefield, *Limits of Operationalization: A Critique of Spitzer and Endicott's (1978) Proposed Operational Criteria for Mental Disorder*, 102 J. ABNORMAL PSYCHOL. 160 (1993); Jerome C. Wakefield, *The Concept of Mental Disorder: On the Boundary Between Biological Facts and Social Values*, 47 AM. PSYCHOLOGIST 373 (1992).

244. *See, e.g.*, RACHEL COOPER, PHILOSOPHY OF SCIENCE AND PSYCHIATRY 42 (2007) (concluding that "there is a general consensus that diseases are necessarily harmful conditions"); *id.* at 33 (using "harmful" in the same sense as Wakefield to refer to social difficulty); Aucouturier & Demazeux, *supra* note 238, at 91 ("Nowadays, if any general consensus has been reached on the concept of mental disorder, it is clearly in the sense of a general recognition that it is a value-laden concept.").

245. *See, e.g.*, *A National Framework for Recovery-Oriented Mental Health Services: Guide for Practitioners and Providers*, AUSTL. HEALTH MINISTERS' ADVISORY COUNCIL at iii (2013), https://www.health.gov.au/internet/main/publishing.nsf/Content/67D17065514CF8E8CA257C1D0 0017A90/$File/recovgde.pdf [https://perma.cc/AMZ3-T7D7] ("There was a terrific response during the consultations and submissions. The framework has benefited greatly from the wisdom and unique experience of many people with mental health issues in their own lives or in the lives of

reason, then, that people with mental illness should not also use the democratic process to change conceptions of what is or is not an illness. Just as homosexuality was considered a mental illness by the APA until 1973 and is today considered a healthy, normal sexual orientation,[246] it is also plausible that some other tendency now thought of as symptomatic of mental illness will one day achieve acceptance and respectability. This Note ventures no guess as to which tendency may undergo such a transformation. Being accustomed to today's notions of normality and abnormality restricts our ability to imagine an alternative.

Nevertheless, the possibility that symptoms of mental illness may one day be seen as normal cautions against disenfranchisement on the basis of mental illness. Voting is the most basic means of exercising political power; disenfranchisement on the basis of mental illness inhibits the ability of people to change popular attitudes and gain societal acceptance. Therefore, even for those electoral regimes that retain cognitive capacity as a requirement, the status of being mentally ill must not be considered an indicator of incapacity.

CONCLUSION

Regarding suffrage rights for people with mental impairments, some scholars have approached the debate from the perspective of law, others have done so from the perspective of philosophy, and still others from the perspective of cognitive psychology. Each discipline employs its own specialized language, but they all share a common objective: finding a way to respect the dignity of all individuals while ensuring that electoral results are meaningful, legitimate expressions of democratic self-rule.

This Note has attempted to contribute to the discussion by criticizing two recent reform proposals and advancing a third. The capacity assessment idea, which seeks to shed the injustice of status-based disenfranchisement, is not likely to see political success because voters fear the consequences of radically redefining cognitive capacity. The proxy voting idea, which seeks to include as many voters as possible, must be rejected because of the damage it does to the notion of voting as a civic responsibility; moreover it is not likely to see political

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their loved ones. This is their framework. The consultations have made a lasting contribution to the national dialogue on recovery-oriented practice and this was in evidence during the National Mental Health Recovery Forum in June 2012, which was an important step in the framework's progress."); U.S. DEP'T OF HEALTH & HUMAN SERVS., MENTAL HEALTH: A REPORT OF THE SURGEON GENERAL 92 (Howard H. Goldman et al. eds., 1999) ("Through strong advocacy, consumer and family organizations have gained a voice in legislation and policy for mental health service delivery."); *see also* Nancy Tomes, *The Patient as a Policy Factor: A Historical Case Study of the Consumer/Survivor Movement in Mental Health*, 25 HEALTH AFF. 720, 720 (2006) ("Th[e] paper analyzes the history of the modern consumer/survivor movement and its impact on the policy-making climate in the mental health field.").

246. *See supra* note 241 and accompanying text (describing the 1973 change).

success because it raises fears of vote misappropriation. An appropriate alternative approach would be to fully dissociate mental illness from voting capacity. Such dissociation would allow all people who are capable of voting to do so, and would provide an avenue to increase the societal engagement of a group that is currently marginalized.